RULEMAKING ISSUE
NOTATION VOTE

September 30, 2002 SECY-02-0176

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING TO ADD NEW SECTION 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS" (WITS 199900061)

PURPOSE:

To obtain Commission approval to publish the proposed rule and the draft regulatory guidance implementing the proposed rule for public comment.

SUMMARY:

The staff has prepared a proposed rulemaking to add a new section to 10 CFR Part 50 to provide an alternative set of requirements for treatment of structures, systems and components (SSCs), using a risk-informed categorization process to determine safety significance of the SSCs. These requirements can be voluntarily adopted by light-water reactor licensees and applicants. The proposed rule is based upon extensive interactions with stakeholders (including consideration of public comments on draft rule language made available on the NRC rulemaking web site), experience with pilot plants, and guidance development activities.

The staff has prepared a proposed rule package and draft implementing guidance. The paper summarizes the development of the proposed rule and the contents of the rule package. In addition, the paper discusses issues that arose during this rulemaking and some of the key

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stakeholder concerns with the rule and how it would be implemented. The staff recommends that the Commission approve publication of the proposed rule and draft implementation guidance in the *Federal Register* for public comment.

BACKGROUND:

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50--'Domestic Licensing of Production and Utilization Facilities'," dated December 23, 1998, the staff recommended the development of risk-informed approaches to the application of special treatment requirements.[1] This initiative, referred to as Option 2, addresses the implementation of changes to the scope of structures, systems and components that need special treatment, while still providing assurance that the SSCs will perform their design basis functions. Option 2 does not include changes to the requirements pertaining to the design of the plant or the design basis accidents. These technical risk-informed changes are addressed under Option 3 of SECY-98-300.

The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999. In that SRM, the Commission directed the staff to evaluate strategies to risk-inform the scope of the commercial nuclear reactor regulations that impose unique requirements identified in this discussion as "special treatment requirements." On October 29, 1999, the staff sent to the Commission SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," to obtain approval for a rulemaking plan and issuance of an advance notice of proposed rulemaking (ANPR). In its rulemaking plan, the staff proposed to create a new section within Part 50, referred to as § 50.69, to contain these alternative requirements. By SRM dated January 31, 2000, the Commission approved the rulemaking plan and publication of the ANPR. The ANPR was published in the *Federal Register* on March 3, 2000 (65 FR 11488) and the 75-day comment period ended on May 17, 2000.

The Commission received more than 200 comments in response to the ANPR. On September 7, 2000, the staff sent the Commission SECY-00-0194, "Risk-Informing Special Treatment Requirements," which provided the staff's preliminary views on the ANPR comments. With respect to treatment requirements, the staff stated that conceptually, licensees will be required to maintain the functional requirements of the low safety-significant, safety-related (RISC-3) SSCs. The staff further said that it expected to establish minimal requirements in the rule for this purpose. The requirements would involve measures and activities such as procurement control, monitoring and corrective action.

DISCUSSION:

The staff has developed a proposed rule that would permit power reactor licensees and license applicants to implement a voluntary alternative regulatory framework with respect to special treatment. Under this framework, licensees (or applicants), using a risk-informed process to categorize SSCs according to their safety significance, can remove SSCs of low safety

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[1]Special treatment requirements are current requirements imposed on SSCs that go beyond industry-established requirements for equipment classified as commercial grade that provide additional confidence that equipment is capable of meeting its functional requirements under design basis conditions. These additional special treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.

significance from the scope of certain identified special treatment requirements. For SSCs of safety significance, existing requirements are retained, and the rule would add requirements that ensure SSC performance remains consistent with that relied upon in the categorization process for beyond design basis conditions.

As discussed in more detail in the attached proposed rule, the staff has concluded that the proposed rule would maintain safety through a combination of elements, and that it is consistent with Commission guidance on risk-informed activities. The rule would reduce unnecessary regulatory burden by removing SSCs of low safety significance from the scope of certain special treatment requirements as well as identifying SSCs of greater significance which should receive potentially enhanced attention. As a result, both the NRC staff and industry should be able to better focus their attention and resources on regulatory issues of greater safety significance. With respect to efficiency and effectiveness, this rulemaking would aid in bringing the regulations in closer agreement with the risk-informed approaches to inspection and enforcement. The staff concludes that public confidence would be maintained through the opportunity for public comment on the rulemaking and guidance; by staff review of the probabilistic risk assessment (PRA) and categorization approach through the use of the license amendment process for plant-specific implementation, and by focusing licensee resources on SSCs of greatest safety significance.

Proposed Rule

The proposed rule would establish a risk-informed process by which a licensee (or applicant) would categorize SSCs, adjust treatment requirements consistent with the relative significance of each SSC, and manage the process over the lifetime of the plant. This proposed rule is a voluntary alternative to existing requirements. First, a licensee would employ a risk-informed categorization process to determine the safety significance of SSCs and to place the SSCs into one of four risk-informed safety class (RISC) categories. The determination of safety significance would be performed through an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions would include both the design basis functions (derived from the “safety-related” definition, which includes external events), as well as functions credited for severe accidents (including external events). The categorization process would also require the licensee to determine that any resultant potential increase in risk is small. Treatment requirements for the SSCs would then be applied dependent on the RISC category into which the SSC is categorized. Finally, a licensee would conduct assessment activities to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The proposed rule also contains requirements for obtaining NRC approval as well as related supporting requirements.

It is important to note that this rulemaking effort, while intended to make the scope of special treatment requirements imposed on SSCs risk-informed, is not intended to allow licensees to eliminate SSC functional requirements, or to remove equipment that is required by the deterministic design basis from the facility. Changes to the design of the facility must continue to meet the current requirements governing design change, most notably § 50.59.

Stakeholder Feedback on Draft Rule Language

On November 29, 2001, the staff published a first draft of rule language on the NRC rulemaking web site, along with a brief explanation of the intent of the rule and its guidance. The NRC received comments on this draft from the Nuclear Energy Institute (NEI), licensees, and individuals. The comments led the staff to revise the draft rule language. A second version of the draft rule was made available on April 5, 2002. Additional comments were received in response to this posting. A final version of the draft rule was posted on the web site on August 2, 2002. Comments that resulted in substantive changes in rule language are addressed in the statement of considerations for the proposed rule (Attachment 1). The staff has responded to many other comments through the discussions in the statement of considerations that explain the basis for, and the means of complying with, the proposed rule.

Contents of the Proposed Rulemaking Package

This rulemaking package includes the proposed *Federal Register* notice for the proposed rule, which includes the proposed rule language and statement of considerations (Attachment 1), the regulatory analysis (Attachment 2), an environmental assessment (Attachment 3), and the staff's final recommendations regarding the ANPR comments (Attachment 4). The package also contains the Draft Regulatory Guide, DG-1121 (Attachment 5), and the NEI categorization guidance document, NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline" (Attachment 6), which are further discussed below.

Finally, the rule amends information collection requirements that must be submitted to the Office of Management and Budget no later than the date the proposed rule is forwarded to the *Federal Register* for publication. The staff has prepared its supporting statement for this rulemaking, which will be finalized upon Commission approval to publish the proposed rule.

ISSUES OF INTEREST

This rulemaking is the first instance[2] in which the NRC would establish, by rule, specific requirements concerning the conduct of a PRA in support of a particular regulatory action. Thus, during the development of the rulemaking, issues arose concerning what attributes of the PRA are important for this application (e.g., the scope, level of detail, and technical quality expected, and updating requirements), and specific technical issues (such as how to address initiating events, modes or SSCs that are not modeled in the PRA). In lieu of putting all of these details into an appendix to the rule (as initially envisioned in SECY-99-256), the staff recommends more general rule requirements, supported by detailed implementation guidance, based upon ANPR comments (see Attachment 4). Further, a focused staff review and approval of the categorization process will be conducted.

The NRC staff plans to complete a regulatory guide (RG) that would endorse NEI 00-04 with clarifications and exceptions as necessary. At the present time, there are a number of issues that need further discussion and development before the staff can complete such a document. For purposes of the proposed rule, the staff has prepared a draft guide, DG-1121, "Guidelines for Categorizing Structures, Systems and Components in Nuclear Power Plants According to their Safety Significance" (Attachment 5), which identifies these areas. The NRC staff has also provided these comments to NEI so that NEI 00-04 can be revised accordingly. In a few specific areas, the staff recommends that the industry develop guidance to assist licensees in implementing the rule, which could then be endorsed in the final RG. The proposed *Federal Register* notice containing the proposed rule includes a request for stakeholder input on these

[2]The staff notes that § 52.47(v) requires submittal of a design-specific PRA in connection with an application for a design certification rule (DCR), but includes no additional details on its requirements or on how the PRA is to be used in decisionmaking with respect to the issuance of a DCR.

documents, so that the implementation guidance is ready to be issued when the final rule is sent to the Commission.

As reported in the Option 2 status reports, an area that received considerable attention during preparation of the proposed rule was the development of the alternative treatment requirements for the low safety-significant, safety-related (RISC-3) SSCs. During the development of this rulemaking (as well as during the review of the South Texas exemptions request, which concerned similar issues), there was considerable debate among internal and external stakeholders, as to the extent of treatment requirements that the NRC needs to specify for RISC-3 SSCs in order to have sufficient confidence that such SSCs remain capable of performing design basis functions. As discussed in SECY-00-0194, the proposed rule includes high-level requirements that are structured to address the key elements of SSC functionality, while giving licensees significant flexibility regarding the means of implementation.

Some staff[3] feel that absent more specific and detailed RISC-3 treatment requirements, licensees may implement practices that allow RISC-3 SSC degradation, potentially increasing the probability of common cause failures. For example, absent specific requirements, licensees might conclude that it is acceptable to allow RISC-3 SSCs to run to failure. These concerns were heightened with the proposed removal of portions of § 50.55a (the regulation that imposes the requirements of the American Society of Mechanical Engineers (ASME) Code on safety-related SSCs) as requirements for RISC-3 SSCs. In its selection of the proposed rule requirements, and in the presentation in the statement of considerations, the staff has addressed these issues with clear requirements for continued functionality. The staff also concludes that the enhancements made to the categorization process that have developed over time (see DG-1121 for details) also support removal of treatment details for RISC-3 SSCs. The proposed rule specifies the minimum attributes for the treatment processes (to be in place at the facility), but allows flexibility in application provided that functional performance is maintained. The staff had decided not to develop implementation guidance on treatment for RISC-3 SSCs, or to review in advance the programs that a licensee or applicant would have in place. Rather, the proposed rule places the responsibility on the licensee (or applicant) to implement those elements of the treatment processes that are necessary (for the particular SSCs and activity) to maintain the safety-related functions under design basis conditions.

In its draft rule language for proposed § 50.69, the staff considered including more detailed requirements for RISC-3 SSCs in § 50.69(d)(2). For the reasons discussed above, and on the basis of stakeholder comments on the draft rule language, the staff concludes that this level of specificity is beyond what is necessary to provide reasonable confidence in RISC-3 design basis capability in light of the robust categorization requirements incorporated into the proposed § 50.69. The staff recognizes that some stakeholders may wish to provide further input on these former provisions of draft § 50.69, and has included a section in the *Federal Register* notice that invites public comments on the previously considered rule language. This would enable the Commission to fully consider stakeholder feedback on this issue when formulating the final rule.

As a result of the more performance-based approach for RISC-3 treatment, the staff concludes that the RISC-3 requirements are more closely aligned with the reactor oversight process in its

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[3]Note that on September 26, 2002, three members of the staff filed Differing Professional Views (DPVs) on this proposed rulemaking. The staff concerns described in this paper, and other concerns, are raised by these DPVs. The DPVs will be addressed in accordance with agency practice.

approach to inspection and enforcement. Because there are few details about how a licensee or applicant should implement its processes to maintain functionality of SSC, should NRC have concerns about particular licensee practices, NRC would need to establish a basis for enforcement that the licensee's approach is not providing reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions, rather than because a specific treatment requirement was not met. The *Federal Register* notice invites public comments on inspection and enforcement considerations.

Some stakeholders raised concerns about the proposed rule provisions that require a § 50.90 license amendment before implementation of the remainder of the proposed rule. The staff has concluded that use of the license amendment process is appropriate for this application because the approvals would change the authority granted to licensees under their operating licenses, and the determinations about suitability of the PRA for the application will involve substantial staff judgment and discretion.

Another aspect of the proposed rule that concerns some stakeholders is the requirement in § 50.69(c)(1)(iv) that licensees provide reasonable confidence that increases in core damage frequency (CDF) and large early release frequency (LERF) due to implementation of § 50.69 would be small. The previous drafts of the rule language for § 50.69 had a stronger link between RISC-3 treatment and the potential for this treatment to change RISC-3 reliability, requiring licensees to characterize the effects of revised treatment on RISC-3 reliability. Some external stakeholders believe that it is not possible to comply with this requirement because of the difficulty in quantifying the impact that revised treatment might have on RISC-3 SSC reliability. Conversely, some staff believed that there should be even a stronger link, such as requiring that a licensee monitor performance against the categorization assumptions. Because many of the SSCs involved are in standby systems, and the treatment changes include a range of activities, the staff concluded that "monitoring" RISC-3 SSCs against specific values of reliability or unavailability would not be effective and furthermore is not necessary given the low safety significance of these SSCs. Thus, the proposed rule would require that the licensee consider the reliability of the RISC-3 SSCs used in their evaluations of the impact on risk and have an acceptable basis to support the evaluations to show that no greater than a small change in risk may occur due to implementation of § 50.69. It should be noted that § 50.69 requires inspection, test and surveillance processes to be conducted to provide information that SSCs are still capable of performing their safety-related functions. The proposed rule also includes a feedback requirement for the licensee to use such performance information to determine if adverse changes in performance are occurring and to take appropriate action.

RESOURCES:

The resources needed to complete the proposed rulemaking and guidance (4 FTE for FY 2003 and 3 FTE for FY 2004) are included in the current budget. Plant-specific implementation will be achieved through individual licensing actions. Inspection of licensee implementation will be performed through the normal inspection process. As discussed above, the staff is still considering whether any different inspection efforts on performance of SSCs or audits of the categorization process would be appropriate. The staff does not expect to need additional resources to complete this effort beyond current budgets.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

The staff met with the Advisory Committee on Reactor Safeguards (ACRS) concerning the rulemaking approach and implementation guidance, on a number of occasions, most recently on September 13, 2002. In a memorandum dated September 18, 2002, the Committee agreed with the staff's proposal to issue the proposed rule and draft regulatory guide for public comment.

The Committee to Review Generic Requirements has deferred its review of the rule until the final rule stage.

RECOMMENDATIONS:

That the Commission:

1. *Approve* the notice of proposed rulemaking for publication (Attachment 1).

2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).3.

    Note:

    1. The proposed rule will be published in the *Federal Register* with a 75-day public comment period.

    2. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

    3. Copies of the *Federal Register* Notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties upon request. Copies of the documents are also available in the NRC's Agencywide Document Access and Management System (ADAMS), the Public Document Room and on the NRC rulemaking web site.

    4. A public announcement will be issued.

    5. The appropriate Congressional committees will be informed.

6. The supporting statement concerning changes in information collection requirements will be sent to the Office of Management and Budget.

7. Unless otherwise directed, the staff plans to end preparation of the quarterly status report on this rulemaking (WITS 200000111).

/RA/

William D. Travers
Executive Director
for Operations

Attachments:
1. *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Disposition of ANPR Comments
5. Draft Regulatory Guide (DG-1121)
6. NEI 00-04, Rev. C, dated June 28, 2002

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG42

Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to provide an alternative approach for establishing the requirements for treatment of structures, systems and components (SSCs) for nuclear power reactors using a risk-informed method of categorizing SSCs according to their safety significance. The proposed amendment would revise requirements with respect to "special treatment," that is, those requirements that provide increased assurance (beyond normal industrial practices) that SSCs perform their design basis functions. This proposed amendment would permit licensees (and applicants for licenses) to remove SSCs of low safety significance from the scope of certain identified special treatment requirements and revise requirements for SSCs of greater safety significance.

In addition to the rulemaking and its associated analyses, the Commission is also proposing a draft regulatory guide to implement the rule.

DATE: Submit comments by [insert date 75 days after publication in the *Federal Register.]* Comments received after this date will be considered if it is practical to do so, but the commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington

DC 20555-0001. ATTN: Rulemakings and Adjudications Staff. Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m., Federal workdays.

You may also provide comments via the NRC's interactive rulemaking website through the NRC's home page (http://ruleforum.llnl.gov). This site provides the capability to upload comments as files (any format) if your web browser supports that function. For information about the interactive rulemaking website, contact Ms. Carol Gallagher, (301) 415-5905; e-mail cag@nrc.gov.

Copies of comments received may be examined at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Reed, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone (301) 415-1465; e-mail: tar@nrc.gov or Ms. Eileen McKenna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: (301) 415-2189 email: emm@nrc.gov,

SUPPLEMENTARY INFORMATION

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I. Background

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing reasonable assurance of adequate protection to public health and safety.

The current body of NRC regulations and their implementation are largely based on a "deterministic" approach.

This deterministic approach establishes requirements for engineering margin, quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist (e.g., equipment failures and human errors) and establishes a specific set of design basis events (DBEs). The deterministic approach contains implied elements of probability (qualitative risk considerations), from the selection of accidents to be analyzed (e.g., reactor vessel rupture is considered too improbable to be included) to the system level requirements for emergency core cooling (e.g., safety train redundancy and protection against single failure). The deterministic approach then requires that the licensed facility include safety systems capable of preventing and/or mitigating the consequences of those DBEs to protect public health and safety. Those SSCs necessary to defend against the DBEs were defined as "safety-related," and these SSCs were the subject of many regulatory requirements designed to ensure that they were of high quality, high reliability, and had capability to perform during postulated design basis conditions. Typically, the regulations establish the scope of SSCs that receive special treatment using one of three different terms: "safety-related, " "important to safety," or "basic component." The terms "safety-related " and "basic component" are defined in the regulations, while "important to safety" (used principally in the general design criteria of Appendix A to 10 CFR Part 50) is not explicitly defined.

These prescriptive requirements as to how licensees were to treat SSCs, especially those that are defined as "safety-related," are referred to in the rulemaking as "special treatment requirements." These requirements were developed to provide greater assurance that these SSCs would perform their functions under particular conditions (e.g., seismic events, or harsh environments), with high quality and reliability, for as long as they are part of the plant. These include particular examination techniques, testing strategies, documentation requirements, personnel qualification requirements, independent oversight, etc. In many instances, these "special treatment" requirements were developed as a means to gain assurance when more direct measures, e.g., testing under design basis conditions or routine operation, could not show that SSCs were functionally capable.

Special treatment requirements are imposed on nuclear reactor applicants and licensees through numerous regulations that have been issued since the 1960's. These requirements specify different scopes of equipment for different special treatment requirements depending on the specific regulatory concern, but are derived from consideration of the deterministic DBEs.

Treatment for an SSC, as a general term and as it will be used in this rulemaking, refers to activities, processes, and/or controls that are performed or used in the design, installation, maintenance, and operation of structures, systems, or components as a means of (1) specifying and procuring SSCs that satisfy performance requirements; (2) verifying over time that performance is maintained; (3) controlling activities that could impact performance; and (4) providing assessment and feedback of results to adjust activities as needed to meet desired outcomes. Treatment includes, but is not limited to, quality assurance, testing, inspection, condition monitoring, assessment, evaluation, and resolution of deviations. The distinction between "treatment" and "special treatment" is the degree of NRC specification as to what must be implemented for particular SSCs or for particular conditions.

Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. Defense-in-depth is a philosophy used by the NRC to provide redundancy as well as the philosophy of a multiple-barrier approach against fission product releases. The defense-in-depth philosophy ensures that safety will not be wholly dependent on any single element of the design, construction, maintenance, or operation of a nuclear facility. The net effect of incorporating defense-in-depth into design, construction, maintenance, and operation is that the facility or system in question tends to be more tolerant of failures and external challenges.

A probabilistic approach to regulation enhances and extends the traditional deterministic approach by allowing consideration of a broader set of potential challenges to safety, providing a logical means for prioritizing these challenges based on safety significance, and allowing consideration of a broader set of resources to defend against these challenges. Until the accident at Three Mile Island (TMI), the NRC only used probabilistic criteria in specialized areas, such as for certain man-made hazards and for natural hazards (with respect to initiating event frequency). The major investigations of the TMI accident recommended that probabilistic risk assessment (PRA) techniques be used more widely to augment traditional nonprobabilistic methods of analyzing plant safety.

In contrast to the deterministic approach, PRAs address credible initiating events by assessing the event frequency. Mitigating system reliability is then assessed, including the potential for common cause failures. The probabilistic treatment goes beyond the single failure requirements used in the deterministic approach. The probabilistic approach to regulation is therefore considered an extension and enhancement of traditional regulation by considering risk in a more coherent and complete manner.

The primary need for improving the implementation of defense-in-depth in a risk-informed regulatory system is guidance to determine how many measures are appropriate and how good these should be. Instead of merely relying on bottom-line risk estimates, defense-in-depth is invoked as a strategy to ensure public safety given there exists both unquantified and unquantifiable uncertainty in engineering analyses (both deterministic and risk assessments).

Risk insights can make the elements of defense-in-depth clearer by quantifying them to the extent practicable. Although the uncertainties associated with the importance of some elements of defense may be substantial, the fact that these elements and uncertainties have been quantified can aid in determining how much defense makes regulatory sense. Decisions on the adequacy of, or the necessity for, elements of defense should reflect risk insights gained through identification of the individual performance of each defense system in relation to overall performance.

The Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA) on August 16,1995 (60 FR 42622). In the policy statement, the Commission stated that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that supports the NRC's traditional defense-in-depth philosophy. The policy statement also stated that in making regulatory judgments, the Commission's safety goals for nuclear power reactors and subsidiary numerical objectives (on core damage frequency and containment performance) should be used with appropriate consideration of uncertainties.

To implement this Commission policy, the staff developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1. 174. This RG provided guidance on an acceptable approach to risk-informed decision-making consistent with the Commission's policy, including a set of key principles. These principles include:

(1) Be consistent with the defense-in-depth philosophy;

(2) Maintain sufficient safety margins

(3) Any changes allowed must result in only a small increase in core damage frequency or risk, consistent with the intent of the Commission's Safety Goal Policy Statement; and

(4) incorporate monitoring and performance measurement strategies.

Regulatory Guide 1.174 states that consistency with the defense-in-depth philosophy will be preserved by ensuring that:

(1) a reasonable balance is preserved among prevention of accidents, prevention of barrier failure, and mitigation of consequences;

(2) an over-reliance on programmatic activities to compensate for weaknesses in equipment or device design is avoided;

(3) system redundancy, independence, and diversity are preserved commensurate with the expected frequency, consequences of challenges to the system, and uncertainties (e.g., no risk outliers);

(4) defenses against potential common cause failures are preserved, and the potential for the introduction of new common cause failure mechanisms is assessed;

(5) the independence of barriers is not degraded; and

(6) defenses against human errors are preserved.

II. Rule Initiation

In addition to RG 1.174, the NRC also issued other regulatory guides on risk-informed approaches for specific types of applications. These included RG 1.175, Risk-informed Inservice Testing, RG 1.176, Graded Quality Assurance, RG 1.177, Risk-informed Technical Specifications, and RG 1.178, Risk-informed Inservice Inspection. In this respect, the Commission has been successful in developing and implementing a regulatory means for considering risk insights into the current regulatory framework. One such risk-informed application, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company (STPNOC) requested that the NRC approve a revised Operations Quality Assurance Program (OQAP) that incorporated the methodology for grading quality assurance (QA) based on PRA insights. The STP graded QA proposal was an extension of the existing regulatory framework. Specifically, the STP approach continued to use the traditional safety-related categorization, but allowed for gradation of safety significance within the “safety-related ” categorization (consistent with 10 CFR Part 50 Appendix B) through use of a risk-informed process. Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP on November 6, 1997. Subsequent to NRC’s approval, STPNOC identified implementation difficulties associated with the graded QA program. Despite the reduced QA requirement applied for a large number of SSCs in which the licensee judged to be of low safety significance, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, or seismic continue to impose substantial burdens. As a result, the replacement such a low safety significant component needs to also satisfy other special requirements during a procurement process. These requirements prevented STPNOC from realizing the full potential reduction in unnecessary regulatory burden for SSCs judged to have little or no safety importance. In an effort to achieve the full benefit of the graded QA program (and in fact go beyond the staff’s previous approval of graded QA), STPNOC submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including 10 CFR 50 Appendix B) for SSCs categorized as low safety significant or as non-risk significant. STPNOC’s exemption was ultimately approved by the staff in August 2001 (further discussed in section IV.4).

The experience with graded QA was a principal factor in the NRC’s determination that rule changes would be necessary to proceed with some activities to risk-inform requirements. The Commission also believes that the development of PRA technology and decision-making tools for using risk information together with deterministic information supported rulemaking activities to allow the NRC to refocus certain regulatory requirements using this type of information.

Under Option 2 of SECY-98-300, “Options for Risk-Informed Revisions to 10 CFR Part 50 - ‘Domestic Licensing of Production and Utilization Facilities,’ ” dated December 23, 1998, the NRC staff recommended that risk-informed approaches to the application of special treatment requirements be developed as one application of risk-informed regulatory changes. Option 2 (also referred to as RIP50 Option 2) addresses the implementation of changes to the scope of SSCs needing special treatment while still providing assurance that the SSCs will perform their design functions. Changes to the requirements pertaining to the design of the plant or the design basis accidents are not included in Option 2. These technical risk-informed changes are addressed under Option 3 of SECY-98-300. The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999.

The stated purpose of the “Option 2" rulemaking was to develop an alternative regulatory framework that enables licensees, using a risk-informed process for categorizing SSCs according to their safety significance (i.e., a decision that considers both traditional deterministic insights and risk insights), to reduce unnecessary regulatory burden for SSCs of low safety significance by removing these SSCs from the scope of special treatment requirements. As part of this process, those SSCs found to be of risk-significance would be brought under a greater degree of regulatory control through the requirements being added to the rule designed to maintain consistency between actual performance and the performance considered in the assessment process that determines their significance. As a result, both the NRC staff and industry should be able to better focus their resources on regulatory issues of greater safety significance.

The Commission directed the staff to evaluate strategies to make the scope of the nuclear power reactor regulations that impose special treatment risk-informed. SECY-99-256, “Rulemaking Plan for Risk-Informing Special Treatment Requirements,” dated October 29, 1999, was sent to the Commission to obtain approval for a rulemaking plan and issuance of an Advance Notice of Proposed Rulemaking (ANPR). By SRM dated January 31, 2000, the Commission approved publication of the ANPR and approved the rulemaking plan. The ANPR was published in the Federal Registeron March 3, 2000 (65 FR 11488) for a 75-day comment period, which ended on May 17, 2000. In the rulemaking plan, the NRC proposed to create a new section within Part 50, referred to as § 50.69, to contain these alternative requirements.

The Commission received more than 200 comments In response to the ANPR,. The staff sent the Commission SECY-00-194 “Risk-Informing Special Treatment Requirements”, dated September 7, 2000, which provided the staff’s preliminary views on the ANPR comments and additional thoughts on the preliminary regulatory framework for implementing a rule to revise the scope of special treatment requirements for SSCs. The comments from the ANPR are further discussed in Section IV.1.0 below.

The concept developed for this proposed rule, discussed at length in the ANPR, was to apply treatment requirements based upon the safety-significance of SSCs, determined through consideration of both risk insights and deterministic information. Thus, the risk-informed approach discussed in this proposed rule for establishing an alternative scope of SSCs subject to special treatment requirements uses both risk and traditional deterministic methods in a blended “risk-informed” approach. The Commission finds the risk-informed approach outlined in RG 1.174 is appropriate for use in this rulemaking.

It is important to note that this rulemaking effort, while intended to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed, is not intended to allow for the elimination of SSC functional requirements, or to allow equipment that is required by the deterministic design basis to be removed from the facility (i.e., changes to the design of the facility must continue to meet the current requirements governing design change, most notably § 50.59). Instead, this rulemaking should enable licensees and the staff to focus their resources on SSCs that make a significant contribution to plant safety by restructuring the regulations to allow an alternative risk-informed approach to special treatment. Conversely, for SSCs that do not significantly contribute to plant safety, this approach should allow an acceptable, though reduced, level of assurance that these SSCs will satisfy functional requirements.

III. Proposed Regulations.

The Commission is proposing to establish § 50.69 as an alternative set of requirements whereby a licensee may undertake categorization of its SSCs using risk insights and adjust treatment requirements based upon their resulting significance. Under this approach, a licensee would be allowed to reduce special treatment requirements for SSCs that are determined to be of low safety significance and would enhance requirements for treatment of other SSCs that are found to be safety significant. The proposed requirements would establish a process by which a licensee would categorize SSCs using a risk-informed process, adjust treatment requirements consistent with the relative significance of the SSC, and manage the process over the lifetime of the plant. To implement these requirements, a risk-informed categorization process would be employed to determine the safety significance of SSCs and place the SSCs into one of four risk-informed safety class (RISC) categories. It is important that this categorization process be robust to enable the Commission to remove requirements for SSCs determined to be of low safety significance. The determination of safety significance would be performed by an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions would include both the design basis functions (derived from the "safety-related" definition, which includes external events), as well as functions credited for severe accidents (including external events). Treatment requirements for the SSCs are applied as necessary to maintain functionality and reliability, and are a function of the category into which the SSC is categorized. Finally, assessment activities would be conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The proposed rule also contains requirements for obtaining NRC approval of the categorization process and for maintaining plant records and reports.

III.1.0 Categorization of SSCs.

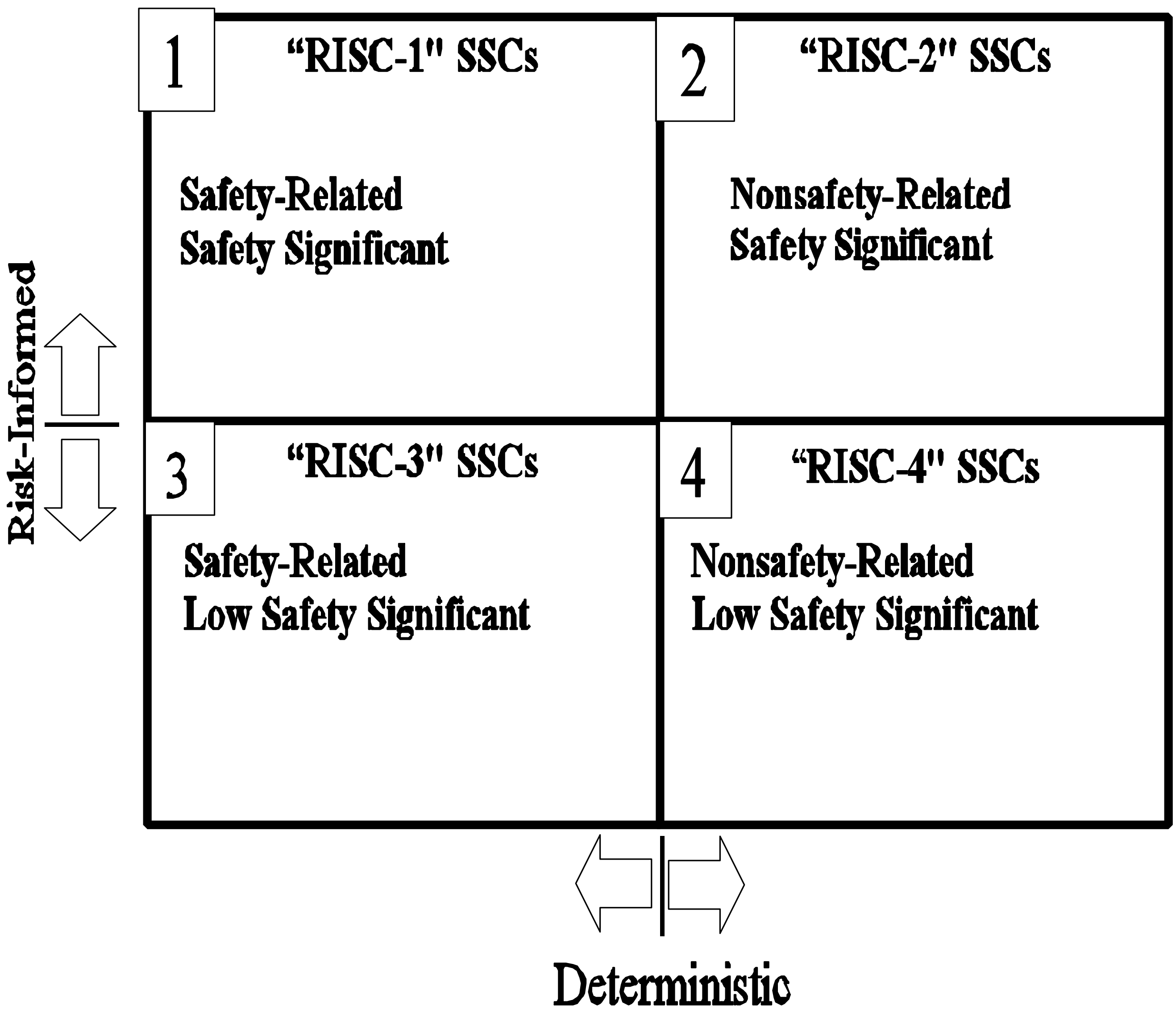
Section 50.69 would define four RISC categories into which SSCs are categorized. Four categories were chosen because it is the simplest approach for transitioning between the previous SSC classification scheme and the new scheme used in the proposed § 50.69. The depiction in Figure 1 provides a conceptual understanding of the new RISC categories. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new risk-informed categorization. In the traditional deterministic approach, SSCs were generally categorized as either "safety-related" (as defined in §50.2) or nonsafety-related. This division is shown by the vertical line in the figure. Risk insights, including consideration of severe accidents, can be used to identify SSCs as being either safety-significant or low safety-significant (shown by the horizontal line). Hence, the application of a risk-informed categorization results in SSCs being grouped into one of four categories as represented by the four boxes in Figure 1.

Box 1 of Figure 1 depicts safety-related SSCs that a risk-informed categorization process determines are significant contributors to plant safety. These SSCs are termed RISC-1 SSCs. RISC-2 SSCs are nonsafety-related, and the risk-informed categorization determines them to be significant contributors to plant safety. The third category are those SSCs that are safety-related SSCs and that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-3 SSCs. Finally, there are SSCs that are nonsafety-related and that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-4 SSCs.

Section 50.69 would define the terminology "safety-significant function" as functions whose loss or degradation could have a significant adverse effect on defense-in-depth, safety margins or risk. This definition was chosen to be consistent with the concepts described in RG 1.174. The proposed rule would impose greater treatment requirements on SSCs that perform safety-significant functions (RISC-1 and RISC-2 SSCs) in order to ensure that defense-in-depth and safety margins are maintained. The proposed rule also requires that the change in risk associated with implementation of proposed § 50.69 be small.

III.2.0 Methodology for Categorization.

The cornerstone of proposed § 50.69 is the establishment of a robust, risk-informed categorization process that provides high confidence that the safety significance of SSCs is correctly determined considering all relevant information. As such, all the categorization



requirements incorporated into proposed § 50.69 are to achieve this objective. Essentially the process is structured to ensure that all relevant information pertaining to SSC safety significance is considered by a panel that has the expertise and capabilities for making a sound decision regarding the SSC's categorization, and that information is considered in a manner that ensures the Commission's criteria for risk-informed applications are satisfied (i.e., that defense-in-depth is maintained, safety margins are maintained, any risk change is small, and a monitoring and performance assessment strategy is used). This process enables SSCs to be placed in the correct RISC category such that the appropriate treatment requirements will be applied commensurate with their safety significance. A safety-significant SSC is an SSC that performs a safety-significant function. The proposed rule would require that SSC safety significance be determined using quantitative information from an up-to-date PRA reasonably representing the current plant configuration, which as a minimum covers internal events at full power, and other available risk analyses and traditional engineering information to supplement the quantitative PRA results.

Section 50.69 contains requirements to ensure that the PRA is adequate for this application. The proposed rule would require that as part of the categorization process defense-in-depth is considered, and that the revised treatment applied to RISC-3 SSCs be considered for its potential impact on risk. As an example, the Commission's position is that the containment and its systems are important in the preservation of the defense-in-depth philosophy (in terms of both large early and large late releases). As part of meeting the defense-in-depth principle, a licensee must demonstrate that the function of the containment as a barrier (including fission product retention and removal) is not significantly degraded when SSCs that support the functions are moved to RISC-3. Thus, the rule contains requirements for the IDP to consider defense-in-depth as part of the categorization process.

The risk insights and other traditional information are required to be evaluated by an Integrated Decision-Making Panel (IDP) comprised of expert, plant-knowledgeable members whose expertise includes PRA, safety analysis, plant operation, design engineering, and system engineering. Because the IDP makes the final determination about the safety significance of an SSC, it is important that the membership include a variety of expertise about the plant, how it is operated, and the safety analyses (both deterministic and probabilistic), so that all pertinent information is considered. Hence the available deterministic and probabilistic information pertaining to SSC safety significance is considered in the decision process. The information considered must reflect the as-built and as-operated plant, so that the decisions are based upon correct information, leading to proper categorization. Where applicable, the information is to come from a PRA that is adequate for this application (i.e., categorization of SSC safety significance). From this perspective, the IDP decision process can be viewed as an extension of the previous process for determining SSC safety classification (i.e., safety-related or nonsafety-related), in that it is making use of relevant risk information which was either not considered, or not available when the SSCs were initially classified. The IDP makes the final determination of the safety significance of SSCs using a process that takes all this information into consideration, in a structured, documented manner. The structure provides consistency to decisions that may be made over a period of time, and the documentation gives both the licensee and the NRC the ability to understand the basis for the categorization decision, should questions arise at a later date.

The proposed rule contains general requirements for consideration of SSCs, modes of operation or initating events not modeled in the PRA. As a result, the implementing guidance plays a significant role in effective implementation, and bolsters the need for NRC review and approval of the categorization process before implementation. As noted in the ANPR, the Commission could include more requirements in the rule itself, rather than only being in the guidance. Public comment is requested on the merits of placing the additional detail shown in the guidance (and discussed in Section V.4 of the Statement of Considerations (SOC) in the rule itself.

Implementation of the categorization process relies heavily on the skills, knowledge, and experience of the people that implement the process, in particular on the qualifications of IDP members. Therefore, the Commission concludes that requirements are necessary for the composition of the panel to be experienced personnel who possess diverse knowledge and insights in plant design and operation and who are capable in the use of deterministic knowledge and risk insights in making SSC classifications.

The PRA used to provide the risk information to the categorization process is required to be subjected to a peer review. The peer review focuses on the PRA completeness and technical adequacy for determining importance of particular SSCs, including consideration of the scope, level of detail, and technical quality of the PRA model, the assumptions made in the development of the results, and the uncertainties that impact the analysis. This provides assurance that for IDP decisions that utilize PRA information that the results of the categorization process provide a valid representation of the risk importance of SSCs.

Before implementation of § 50.69, the NRC will approve, through a license amendment, the categorization process because of the importance of the PRA and categorization process to successful implementation of the proposed rule. This review will determine whether the licensee's application satisfies the § 50.69 requirements, and consider the adequacy of the PRA, focusing on the results of the peer review and the actions taken by the licensee to address any peer review findings. The Commission has determined that a focused NRC staff review of the PRA is necessary because there are key assumptions and modeling parameters that can have a significant enough impact on the results such that NRC review of their adequacy for this application is considered necessary to verify that the overall categorization process will yield acceptable decisions.

Section 50.69(c)(iv) would require that a licensee or applicant provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential changes in core damage frequency (CDF) and large early release frequency (LERF) resulting from the implementation of § 50.69 are small. That is, plants with total baseline CDF of 10^{-4} per year or less would be permitted CDF increases of up to 10^{-5} per year, and plants with total baseline CDF greater than 10^{-4} per year would be permitted CDF increases of up to 10^{-6} per year. Plants with total baseline LERFs of 10^{-5} per year or less would be permitted LERF increases of up to 10^{-6} per year, and plants with total baseline LERFs greater than 10^{-5} per year would be permitted LERF increases of up to 10^{-7} per year. However, if there is an indication that the baseline CDF or LERF may be considerably higher than these values, the focus of the licensee should be on finding ways to reduce risk and the licensee may be required to present arguments as to why steps should not be taken to reduce risk in order to consider the reduction in special treatment requirements. This is consistent with the guidance in Section 2.2.4 of RG 1.174. It should be noted that this allowed increase shall be applied to the overall categorization process, even for those licensees that will implement § 50.69 in a phased manner. Thus, the allowable potential increase in risk must be determined in a cumulative way for all the SSCs being recategorized.

Section 50.69 contains requirements for maintaining the design basis of the facility. These requirements, considered in conjunction with the requirements to maintain the potential change in risk as small (as discussed above), ensure that safety margins are maintained. The performance of candidate RISC-3 SSCs should not be significantly degraded by the removal of special treatment. This is because the licensee is required to implement processes that provide reasonable confidence that SSCs remain functional, that is, remain capable of performing their function with a reliability that is not significantly degraded to such an extent that there will be a significant number of failures that can lead to unacceptable increases in CDF or LERF.

The proposed rule would require applicants and licensees to perform evaluations to assess the potential impact on risk from changes to treatment. For SSCs modeled in the PRA, this would likely be accomplished by sensitivity studies to assess the impact of changes in SSC failure probabilities or reliabilities that might occur due to the revised treatment. For example, a licensee would be expected to increase the failure rates of RISC-3 SSCs by appropriate factors to understand the potential effect of applying reduced treatment to these SSCs (e.g., reduced maintenance, testing, inspection, and quality assurance). For other SSCs, other types evaluations would be used to provide the basis for concluding that the potential increase in risk would be small. A licensee will need to submit its basis to support that the evaluations are bounding estimates of the potential change in risk and that programs already in existence or implemented for proposed §50.69 can provide sufficient information that any potential risk change remains small over the lifetime of the plant. A licensee is required to consider potential effects of common-cause interaction susceptibility and potential impacts from known degradation mechanisms. To meet this requirement, licensees need to maintain an understanding of common-cause effects and degradation mechanisms and their potential impact on RISC-3 SSCs and of the programmatic activities that provide defenses against common cause failures (CCFs) and failures resulting from degradation; and to factor this knowledge into the treatment applied to the RISC-3 SSCs.

The proposed rule focuses on common-cause effects because significant increases in common-cause failures could invalidate the evaluations, such as sensitivity studies, performed to show a small change due to implementation of § 50.69. With respect to known degradation mechanisms, this is an acknowledgment that certain treatment requirements have evolved over time to deal with such mechanisms (e.g., use of particular inspection techniques or frequencies), and that when contemplating changes to treatment, the lessons from this experience are to be taken into account.

For SSCs categorized by means other than PRA models, the licensee would need to provide a basis to conclude that the small increase in risk requirement would still be met in light of potential changes in treatment. All of these requirements are included in § 50.69 so that a licensee has a basis for concluding that the evaluations performed to show a small change in risk remain valid.

In addition, the rule would require that implementation be done for an entire system or structure and not for selected components within a system or structure. This required scope ensures that all safety functions associated with a system or structure are properly identified and evaluated when determining the safety significance of individual components within a system or structure and that the entire set of components that comprise a system or structure are considered and addressed.

III.3.0 Treatment Requirements.

Treatment requirements are applied to SSCs commensurate with SSC safety significance and as a function of the RISC category into which the SSCs are categorized.

III.3.1 RISC-1 and RISC-2 Treatment.

For SSCs determined by the IDP to be safety-significant (i.e., RISC-1 and RISC-2 SSCs), §50.69 would maintain the current regulatory requirements (i.e., it does not remove any requirements from these SSCs) for special treatment. These current requirements are adequate for addressing design basis performance of these SSCs. Additional requirements are being added to these SSCs to ensure that their performance remains consistent with the assumed performance in the categorization process (including the PRA) for beyond design basis conditions. For example, in developing the PRA model, a licensee will make assumptions regarding the availability, capability, and reliability of RISC-1 and RISC-2 SSCs in performing specific functions under various plant conditions. These functions may be beyond the design basis for individual

SSCs. Further, the conditions under which those functions are assumed to be performed may exceed the design-basis conditions for the applicable SSCs. In the proposed rule, a licensee would be required to ensure that the treatment applied to RISC-1 and RISC-2 SSCs is consistent with the performance credited in the categorization process. This includes credit with respect to prevention and mitigation of severe accidents. In some cases, licensees might need to enhance the treatment applied to RISC-1 or RISC-2 SSCs to support the credit taken in the categorization process, or conversely adjust the categorization assumptions to reflect actual treatment practices. In addition, requirements exist for monitoring and adjustment of treatment processes (or categorization decisions) as needed based upon performance.

III.3.2 RISC-3 Treatment.

For RISC-3 SSCs, § 50.69 would impose requirements which are intended to maintain their design basis capability. Although individually RISC-3 SSCs are not significant contributors to plant safety, they do perform functions necessary to respond to certain design basis events of the facility. Thus, collectively, RISC-3 SSCs can be safety-significant and it is important to maintain their design basis functional capability. Maintenance of RISC-3 design basis functionality is important to ensuring that defense-in-depth and safety margins are maintained. As a result, § 50.69(d)(2) would require licensees or applicants to have processes in place that provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout the service life. The proposed rule contains high-level requirements for the treatment of RISC-3 SSCs with respect to design control; procurement; maintenance, inspection, test, and surveillance; and corrective action. These alternative treatment requirements for RISC-3 SSCs represent a relaxation of those special treatment requirements that are removed for RISC-3 SSCs by the proposed rule. For example, the alternative treatment requirements for RISC-3 SSCs in proposed § 50.69 are less detailed than provided in the special treatment requirements, and allow significantly more flexibility by licensees in treating RISC-3 SSCs. The Commission is allowing greater flexibility and a lower level of assurance to be provided for RISC-3 SSCs in recognition of their low safety significance, and this recognition includes a consideration for the potential change in reliability that might occur when treatment is reduced from what had previously been required by the special treatment requirements.

The Commission is proposing to specify four processes that must be controlled and accomplished for RISC-3 SSCs: Design Control; Procurement; Maintenance, Inspection, Testing, and Surveillance; and Corrective Action. The high level RISC-3 requirements are structured to address the various key elements of SSC functionality by focusing in these areas. When SSCs are replaced, RISC-3 SSCs must remain capable of performing design basis functions. Hence, the high level requirements focus on maintaining this capability through design control and procurement requirements. During the operating life of a RISC-3 SSC, a sufficient level of confidence is necessary that the SSC continues to be able to perform its design basis function; hence, the inclusion of high level requirements for maintenance, inspection, test, and surveillance. Finally, when data is collected, it must be fed back into the categorization and treatment processes, and when important deficiencies are found, they must be corrected; hence, requirements are also provided in these areas.

In devising these requirements, the Commission has focused upon those critical aspects of the various processes that must exist to provide assurance of performance. Thus, in the design area, for instance, the design conditions under which equipment is expected to perform, such as environmental conditions or seismic conditions, are still to be met. As another example, in the procurement area, procured items are to satisfy their design requirements. These steps provide the basis for concluding that a newly designed and procured replacement item will be capable of meeting its design requirements, even though the special treatment requirements that previously existed are no longer being required.

In implementing the processes required by the proposed rule, licensees will need to obtain data or information sufficient to make a technical judgement that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions. These requirements are necessary because they require the licensee to obtain the data necessary to continue to conclude that RISC-3 SSCs remain capable of performing design basis functions, and to enable the licensee to take actions to restore equipment performance consistent with corrective action requirements included in the proposed rule.

Effective implementation of the treatment requirements provides reasonable confidence in the capability of RISC-3 SSCs to perform their safety function under normal and design basis conditions. This level of confidence is both less than that associated with RISC-1 SSCs, which are subject to all special treatment requirements, and consistent with their low safety significance.

It is noted that changes that affect any non-treatment aspects of an SSC (e.g., changes to the SSC design basis functional requirements) are still required to be evaluated in accordance with other regulatory requirements such as § 50.59. Section 50.69(d)(2)(i), which focuses upon design control, is intended to draw a distinction between treatment (managed through § 50.69) and design changes (managed through other processes such as § 50.59). As has been previously noted, this rulemaking is only risk-informing the scope of special treatment requirements. The process and requirements established in § 50.69 do not extend to making changes to the design basis of SSCs.

III.3.3 RISC-4 Treatment

Section § 50.69 would not impose treatment requirements on RISC-4 SSCs. Instead RISC-4 SSCs are simply removed from the scope of any applicable special treatment requirements. This is justified in view of their low significance considering both safety-related and risk information. Any changes (beyond changes to special treatment requirements) must be made per existing design change control requirements including § 50.59 as applicable.

III.4.0 Removal of RISC-3 and RISC-4 SSCs from the Scope of Special Treatment Requirements.

RISC-3 and RISC-4 SSCs, through the application of § 50.69, are removed from the scope of specific special treatment requirements listed in proposed § 50.69. These requirements were initially identified in the ANPR based upon a set of criteria as to whether the regulation imposed requirements relating to quality assurance, qualification, documentation, testing, etc., that were intended to add assurance to performance of SSCs.

The special treatment requirements were originally imposed to provide a very high level of assurance that safety-related SSCs would perform when called upon with high reliability. As previously noted, the requirements include extensive quality assurance requirements, qualification testing requirements, as well as inservice inspection and testing requirements. These requirements can be quite demanding and expensive, as indicated in the data provided in the regulatory analysis on procurement costs. For those SSCs that this new categorization identifies as most safety-significant (RISC-1 and RISC-2), the existing special treatment requirements are being maintained because the Commission still desires a high level of assurance. However, the Commission concluded that for the less significant SSCs, it was no longer necessary to have the same high level of assurance that they would perform as specified. This is because some increased likelihood of failure can be tolerated without significantly impacting safety. Thus, the Commission decided to remove the RISC-3 and RISC-4 SSCs from those detailed, specific requirements that provided the very high level of assurance. However, the functional requirements for these SSCs remain. As an example, a RISC-3 component must still be designed to withstand any harsh environment it would experience under a design basis event, but the NRC will not require that this capability be demonstrated by a qualification test. Further, the performance (and treatment) of these RISC-3 SSCs remain under regulatory control, but in a different way. Instead of the special treatment requirements, the Commission has set forth more general requirements by which a licensee is to maintain functionality. These requirements give the licensee more latitude in applying its treatment processes to achieve performance objectives. The more general requirements that the Commission is specifying for the RISC-3 SSCs include steps to procure SSCs suitable for the conditions under which they are to perform, to conduct performance and/or condition monitoring and to take corrective action, as a means of maintaining functionality. As discussed elsewhere in this notice, the Commission concludes that the requirements in §50.69 maintain adequate protection of public health and safety. Hence, implementation of §50.69 should result in a better focus for both the licensee and the regulator on issues that pertain to plant safety, and is consistent with the Commission's policy statement for the use of PRA.

In some cases, the Commission concluded that the RISC-3 and RISC-4 SSCs could be totally removed from the scope of specific special treatment requirements while in other cases the Commission concluded that only partial removal was appropriate. The reduced assurance for the RISC-3 SSC would be provided by the alternative requirements being added by this proposed rule. Finally, there was a set of requirements initially identified as special treatment for which the Commission is not proposing to remove RISC-3 and RISC-4 SSCs from their scopes. These requirements are discussed at the end of this section (III.4.9).

III.4.1 Reporting requirements under 10 CFR Part 21 and §50.55(e)

Section 206 of the Energy Reorganization Act of 1974 (ERA) requires the directors and responsible officers of nuclear power plant licensees and firms supplying "components of any facility or activity...licensed or other wise regulated by the Commission” to “immediately report” to the Commission if they have information that "such facility, activity, or basic components supplied to such facility or activity either fails to comply with the AEA, or Commission rule, regulation, order or license "relating to substantial safety hazards," or contains a "defect which could create a substantial safety hazard...." *Id*., paragraph (a). Congress adopted Section 206 to ensure that individuals, and responsible directors and officers of licensees and firms supplying important components to nuclear power plants notify the NRC in a timely fashion of potentially significant safety problems or non-compliance with NRC requirements. The NRC then may assess the reported information and take any necessary regulatory action in a timely fashion to protect public health and safety or common defense and security. Congress did not include definitions for the terms, "components," "basic components," or "substantial safety hazard," in Section 206, but instead directed the Commission to promulgate regulations defining these terms.

The Commission's regulations implementing Section 206 are set forth in 10 CFR Part 21 and 10 CFR 50.55(e) for license holders and construction permit holders, respectively. The definitions of "basic component," "defect," and "substantial safety hazard" in Part 21 were established by the Commission based upon the premise that the deterministic regulatory paradigm embedded in the Commission's regulations would continue to be the appropriate basis for determining the safety significance of an SSC, and therefore the extent of the reporting obligation under Section 206. This is most evident in the 10 CFR 21.3 definition of "basic component," which is very similar to the definition of "safety-related" SSCs in 10 CFR 50.2 (originally embodied in 10 CFR 50.49). Part 21 also recognizes that Congress did not intend that every potential noncompliance or "defect" in a component raises such significant safety issues that the NRC must be informed of every identified or potential noncompliance or defect. Instead, Congress limited the Section 206 reporting requirement to those instances of noncompliance and defects which represent a "substantial safety hazard." Thus, Part 21 limits the reporting requirement to instances of noncompliance and defects representing "substantial safety hazard," which Part 21 defines as:

> a loss of safety function to the extent there is a major reduction in the degree of protection afforded to public health and safety for any facility or activity licensed, other than for export, pursuant to parts 30, 40, 50, 60, 61, 63, 70, 71, or 72 of this chapter.

10 CFR 21.3. Finally, Part 21 establishes that a licensee or vendor should "immediately report" potential noncompliance or defects to the NRC in a telephonic "notification," *see* 10 CFR 21.3 within two (2) days of receipt of information identifying a noncompliance or defect in a basic component, *see* 10 CFR 21.21(d). In addition, Part 21 requires that vendors/suppliers of basic components must make notifications to purchasers or licensees of a reportable noncompliance or defect within five (5) working days of completion of evaluations for determining whether noncompliance or defect constitutes a substantial safety hazard, see 10 CFR 21.21(b). Thus, Part 21 establishes a reporting scheme for immediate reporting of the most safety-significant noncompliances and defects, as contemplated by Section 206 of the ERA.

Section 50.69 would substitute a risk-informed approach for regulating nuclear power plant SSCs for the current deterministic approach. Therefore, it is necessary from the standpoint of regulatory coherence to determine: (1) what categories of SSCs (*i.e*., RISC-1, RISC-2, RISC-3 and RISC-4) should be subject to Part 21 and 50.55(e) reporting under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to ensure proper reporting of substantial safety hazards; and (2) the appropriate reporting obligations of licensees and vendors under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to impose the intended reporting obligations on these entities under proposed § 50.69.

III.4.1.1 RISC-1, RISC-2, RISC-3, and RISC-4 SSCs.

After consideration of the underlying purposes of Section 206 and the risk-informed approach embodied in § 50.69 (which blends both deterministic and risk information), the Commission believes that RISC-1 SSCs should be subject to the reporting requirements in Part 21 and § 50.55(e) because of their high safety significance. The NRC should be informed of any potential defects or noncompliance with respect to RISC-1 SSCs, so that it may evaluate the significance of the defects or noncompliance and take appropriate action. The fact that properly-categorized RISC-1 SSCs in all likelihood fall within the Commission's definition of "basic components" and are currently subject to Part 21 and § 50.55(e) provides confirmation that the Commission's determination is prudent.

Similarly, the Commission believes that SSCs which are categorized as RISC-4 should continue to be beyond the scope of, and not be subject to, Part 21 and §50.55(e). SSCs properly categorized as RISC-4 have little or no risk significance, and it is highly unlikely that any significant regulatory action would be taken by the NRC based upon information on defects or instances of noncompliance in RISC-4 SSCs. Inasmuch as no regulatory purpose would be served by reporting for RISC-4 SSCs, the Commission proposes that RISC-4 SSCs should not be subject to Part 21 or § 50.55(e). Again, the fact that SSCs properly categorized as RISC-4 do not otherwise fall within the definition of "basic component" and, therefore, are not subject to Part 21 and § 50.55(e), provides some confirmation of the prudence of the Commission's determination.

Thus, the most problematic issue from the standpoint of regulatory coherence, is determining the appropriate scope of reporting for RISC-2 and RISC-3 SSCs. For the reasons discussed below, the Commission proposes that neither RISC-2 nor RISC-3 SSCs be subject to Part 21 and § 50.55(e) reporting requirements.

The Commission begins by considering the regulatory objective of Part 21 and § 50.55(e) reporting under Section 206, and believes that there are two parallel regulatory purposes inherent in these reporting schemes. The first objective is to ensure that the NRC is immediately informed of a potentially significant noncompliance or defect in supplied components (in the broad sense of "basic components" as defined in § 21.3), so that the NRC may make a determination as to whether such a safety hazard requires that immediate NRC regulatory action at one or more nuclear power plants be taken to ensure adequate protection to public health and safety or common defense and security. The second is to ensure that nuclear power plant licensees are immediately informed of a potentially significant noncompliance or defect in supplied components. Such reporting allows a licensee using such components to immediately evaluate the noncompliance or defect to determine if a safety hazard exists at the plant, and take timely corrective action as necessary. In both cases, the regulatory objective is limited to components which have the highest significance with respect to ensuring adequate protection to public health and safety and common defense and security, and whose failure or lack of proper functioning could create an imminent safety hazard such that *immediate* evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection. In the context of a construction permit, the safety hazard is two-fold: first, that a non-compliance or defect could be incorporated into construction where it could never be detected; and second, that a noncompliance or defect would, upon initial operation and without prior indications of failure, create a substantial safety hazard.

The Commission believes that the regulatory objectives embodied in Part 21 and Section 50.55(e) reporting remain the same regardless of whether the nuclear power plant is operating under the existing, deterministic regulatory system or the proposed alternative, risk-informed system embodied in § 50.69. In both cases, the reporting scheme should focus on immediate reporting to the NRC and licensee of potentially significant noncompliances and defects that could create a safety hazard requiring immediate evaluation and corrective action to ensure continuing adequate protection. Accordingly, in determining whether RISC-2 and RISC-3 SSCs should be subject to Part 21 reporting, the Commission assessed whether failure or malfunction of these SSCs could reasonably lead to a safety hazard such that *immediate* evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection.

For RISC-2 SSCs, the Commission does not believe their failure or malfunction could reasonably lead to a safety hazard such that immediate licensee and NRC evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection. Although a RISC-2 SSC may be of significance for particular sequences and conditions, for the reasons discussed below, the Commission believes that no RISC-2 SSC, in and of itself, is of such significance that its failure or lack of function would necessitate immediate notification and action by licensees and the NRC.

The categorization process embodied in § 50.69 determines the relative significance of SSCs, with those in RISC-1 and RISC-2 being more significant than those in RISC-3 or RISC-4. This does not mean that any RISC-2 SSC would rise to the level of necessitating immediate action if defects were identified.

Those SSCs that are viewed as being of sufficient safety significance to require Part 21 reporting are RISC-1 SSCs. It is the capability provided by these RISC-1 SSCs for purposes of satisfying safety-related functional requirements that also leads to RISC-1 SSCs as being safety-significant, as these are key functions in prevention and mitigation of severe accidents. Thus, RISC-1 SSCs are generally significant for a range of events and conditions and as the primary means of accident prevention and mitigation, the Commission wants to continue to achieve the high level of quality, reliability, preservation of margins, and assurance of performance of current regulatory requirements.

By contrast, RISC-2 SSCs are less important than RISC-1 SSCs because they do not play a role in prevention and mitigation of design basis events (i.e., the SSCs that maintain integrity of fission product barriers, that provide or support the primary success paths for shutdown, or that prevent or mitigate accidents that could lead to potential offsite exposures). They are not part of the reactor protection system or engineered safety features that perform critical safety functions such as reactivity control, inventory control and heat removal. When viewed from a deterministic standpoint, RISC-2 SSC are not considered to rise to the level of a potential substantial safety hazard. From the risk-informed perspective, SSCs may end up classified as RISC-2 for a number of reasons. It might be because they: (i) contribute to plant risk by initiating transients that could lead to severe accidents (if multiple failures of other mitigating SSCs were to occur), or (ii) they can reduce risk by providing backup mitigation to RISC-1 SSCs in response to an event. The Commission recognizes that, on its face, noncompliance by or defects in RISC-2 SSCs, which could increase risk, such as by more frequent initiation of a transient, may appear to constitute a "substantial safety hazard." However, upon closer examination, the Commission believes otherwise. The risk significance of such "transient initiating" RISC-2 SSCs depends upon their frequency of initiation, with resultant consequences depending upon the failure of multiple other components of varying types in different systems. Further, their risk significance, as identified by the categorization process, is a result of the reliability (failure rates) currently being achieved for these SSC being treated as commercial-grade components, which includes the possibility of noncompliances and defects. Since requirements on RISC-2 SSCs are not being reduced, there is no reason to believe that their performance would degrade as a result of implementation of § 50.69. In fact, by better understanding of their safety significance, and through the added requirements in this rule for RISC-2 SSCs for consistency between the categorization assumptions and how they are treated, performance should only be enhanced. As discussed in Sections III.3 and III.5 of this SOC, the Commission is proposing that additional regulatory controls be imposed on RISC-2 SSCs to prevent their performance from degrading. In addition, the Commission is proposing that licensees evaluate treatment being applied for consistency with key categorization assumptions, monitor the performance of these SSCs, take corrective actions, and report when a loss of a safety-significant function occurs. The requirements of the maintenance rule (§ 50.65 (a) through (a)(3)) also continue to apply to these SSCs. Thus, there are requirements for corrective action by the licensee if noncompliances involving these SSCs are identified. The Commission concludes that these requirements are sufficient because no RISC-2 SSC is so significant as to necessitate immediate Commission (or licensee) action.

For RISC-2 SSCs that provide backup mitigation to RISC-1 SSCs, the Commission also finds it prudent and desirable from a risk-informed standpoint to provide an enhanced level of assurance that RISC-2 SSCs can perform their safety-significant functions, but the failure or malfunction of such RISC-2 SSCs also does not raise a concern about imminent safety hazards. Moreover, over the last several years, the current fleet of power reactors have been subjected to a number of risk studies, including WASH-1400 (Reactor Safety Study), and other generic and plant-specific reviews. While some safety improvements have been identified as a result of these reviews, none has been of such significance as to require immediate action. This essentially means that no SSCs that would be categorized as RISC-2 SSC would rise to the level of significance that their failure or lack of functionality would constitute a substantial safety hazard requiring immediate regulatory action. For example, in the case of two key risk scenarios, Station Blackout and Anticipated Transient without Scram, the Commission imposed regulatory requirements to reduce risk from these events; however, the rules were promulgated as cost-beneficial safety improvements. The equipment used for station blackout or anticipated transients without scram would generally fall within the RISC-2 category. The Commission believes its conclusion about the relative significance of RISC-2 SSC is also supported by plant-specific risk studies, such as the IPE and IPEEE[1], conducted to identify (and correct) any plant-specific vulnerabilities to severe accident risk. NRC's review of the responses to the licensee submittals has not identified any situations requiring immediate action for protection of public health and safety.   In addition, as part of license renewal reviews, the NRC reviews severe accident mitigation alternatives, to identify and evaluate plant design changes with the potential for improving severe accident safety performance. In the license renewals completed to date, only a few candidate SAMAs were found to be cost-beneficial (and none were considered necessary to provide adequate protection of public health and safety).

In sum, the Commission believes that in light of risk assessments and actions that have already been implemented, there would be no SSCs categorized under 50.69 as RISC-2 whose failure would represent a significant and substantial safety concern such that immediate notification and action is required. Accordingly, the results of these risk assessments provide additional confidence to the Commission that Part 21 requirements need not be imposed on RISC-2 SSCs.

The Commission believes that the multiple simultaneous failures of either RISC-2 or RISC-3 components, in the same or in different systems, is not a concern such that Part 21 reporting is necessary. Even for components of the same type, it is not likely that the installed components are identical in terms of their specific characteristics or operating and maintenance history such that a defect would lead to simultaneous failure of multiple components at the same time. For both RISC

[1] In Generic letter 88-20, dated November 23, 1988, licensees were requested to perform individual plant examinations to identify plant-specific vulnerabilities to severe accidents that might exist in their facilities and report the results to the Commission. As part of their review and report, licensees were asked to determine any cost-beneficial improvements to reduce risk. In supplement 4 to the generic letter dated June 28, 1991, this request was extended to include external events (earthquakes, fires, floods). The NRC staff reviewed the plant-specific responses and prepared a staff evaluation report on each submittal. Further, the set of results were presented in NUREG-1560, IPE Program: Perspectives on Reactor Safety and Plant Performance. A similar report on IPEEE results was issued as NUREG-1742. In addition, as discussed in SECY-00-0062, the staff has conducted IPE followup activities with owners groups and licensees to confirm that identified improvements have been implemented and if any other actions were warranted.

categories, there are requirements to collect data about performance of the SSCs, to review the data to determine if adverse performance is occurring and to take appropriate action (e.g., correct failures and adjust treatment processes). Thus, it would be expected that degradation or problems affecting a component type would be detected and dealt with before multiple failures becomes likely. For many RISC-2 SSCs, failures tend to be self-revealing (as it is initiation of a transient as a result of failure of many RISC-2 SSC that makes them significant). For RISC-3 SSCs, requirements exist for design and procurement for any replacement components to meet their design conditions, thus making it unlikely that unsuitable components would be installed. Further, for the RISC-3 SSCs, evaluations will be performed, assuming significantly increased failure rates for large number of components occurring simultaneously to show that there is no more than a small (potential) change in risk. Therefore, the Commission believes appropriate regulatory attention has been given to the potential for multiple simultaneous failures.

The Commission also considered the question as to whether notification of component defects should be required from the perspective of other potentially-affected licensees. The set of SSCs that are RISC-2 would vary from site to site, because it depends upon specifics of plant design and operation, particularly for the balance-of-plant which typically differs more from plant to plant than does the nuclear steam supply part. Further, the suppliers of these components would then also vary. Therefore, the specific type of notifications under Part 21, for the purposes of NRC assessment of generic implications of component defects and to assure notification of licensees with the same components in service, would not fulfill a useful regulatory function. The Commission notes that although Part 21 and § 50.55(e) (component defect) reporting will not be required for RISC-2 SSCs, proposed § 50.69(g) contains enhanced reporting requirements applicable to loss of system function attributable to, *inter alia*, failure or lack of function of RISC-2 SSCs. This is discussed in greater detail in III.5 of this SOC.

The Commission does not believe that any changes to Part 21 are necessary to accomplish the Commission's proposal, and that this proposal is consistent with the statutory requirements in Section 206 of the ERA. Section 206 does not contain any definition of "substantial safety hazard," but contains a direction to the Commission to define this term by regulation. Nothing in the legislative history suggests that Congress had in mind a fixed and unchanging concept of "substantial safety hazard," or that the term was limited to deterministic regulatory principles. Hence, the Commission has broad discretion and authority to determine the appropriate scope of reporting under Section 206. The Commission believes that the current definition of "substantial safety hazard" in 10 CFR 21.3 is broadly written to permit the Commission to determine that a RISC-2 SSC does not represent a "substantial safety hazard" as defined in § 21.3 in the context of a risk-informed regulatory approach.

Therefore, because of the more supporting role that the RISC-2 SSCs play with respect to ensuring critical safety functions, a noncompliance or defect in a RISC-2 SSC would not result in a safety hazard such that immediate licensee and NRC evaluation of the situation and implementation of necessary corrective action is necessary to ensure adequate protection. Thus, the Commission believes that a noncompliance or defect in a RISC-2 SSC does not constitute a substantial safety hazard for which reporting is necessary under Part 21. Accordingly, the Commission proposes that reporting requirements to comply with Section 206 of the ERA are not necessary for RISC-2 SSCs and that the scope of Part 21 and § 50.55(e) reporting requirements should exclude RISC-2 SSCs.

The Commission also proposes that RISC-3 SSCs should not be subject to Part 21 and § 50.55(e) reporting. A failure of a properly-categorized RISC-3 SSC should result in, at most, only a small change in risk, and should not result in a major degradation of essential safety-related equipment (see NUREG-0302, Rev. 1)[2]. As discussed above, the body of regulatory requirements

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[2]NUREG-0302, Remarks Presented (Questions and Answers Discussed) At Public Regional Meetings to Discuss Regulations (10 CFR Part 21) for Reporting of Defects and Noncompliances. Copies of NUREGs may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington DC 20013-7082. Copies are also

(the retained requirements and the requirements contained in this proposed rule) are sufficient such that simultaneous failures in multiple systems (as would be necessary to lead to a substantial safety hazard involving RISC-3 SSCs) would not occur. Thus, there is little regulatory need for the NRC to be informed of instances of noncompliance and defects with RISC-3 SSCs. This is consistent with the NRC's current position that a "substantial safety hazard" involves a major degradation of essential safety-related equipment (see NUREG-0302). Accordingly, the Commission proposes that RISC-3 SSCs should not be subject to reporting requirements of Part 21 and § 50.55(e).

In sum, the Commission proposes that Part 21 reporting requirements should extend only to SSCs classified as RISC-1 SSCs, since these SSCs are those that are important in ensuring public health and safety and minimizing risk. RISC-2 SSCs should not be subject to reporting because play a lesser role than RISC-1 SSC in protection of public health and safety and no regulatory purpose would be served by Part 21 reporting (as discussed above). RISC-3 and RISC-4 SSCs have little or no risk significance and no regulatory purpose would be served by subjecting RISC-3 and RISC-4 SSCS to Part 21 and § 50.55(e).

The Commission does not believe that any changes to Part 21 or § 50.55(e) are necessary to accomplish the Commission's proposals with respect to RISC-2 and RISC-3 SSCs, and that this proposal is consistent with the statutory requirements in Section 206 of the ERA. As discussed above, Section 206 does not contain any definition of "substantial safety hazard,"

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available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying for a fee at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Public File Area O1-F21, Rockville, MD.

but contains a direction to the Commission to define this term by regulation. Nothing in the legislative history suggests that Congress had in mind a fixed and unchanging concept of "substantial safety hazard," or that the term was limited to deterministic regulatory principles. Hence, the Commission has broad discretion and authority to determine the appropriate scope of reporting under Section 206. The Commission believes that the current definition of "substantial safety hazard" in 10 CFR 21.3 is broadly written to permit the Commission to interpret it as applying, in the context of a risk-informed regulatory approach, only to RISC-1 SSCs. As discussed earlier, § 50.69 embodies a risk-informed regulatory paradigm which is different in key respects from the Commission's historical deterministic approach, and applies the risk-informed approach to classifying a nuclear power plant's SSCs according to the SSC's risk significance. SSCs that are classified as RISC-1 are those that represent the most important SSCs from both a risk and deterministic standpoint: they perform the key functions of preventing, controlling and mitigating accidents and controlling risk. Failure of RISC-1 SSCs represent, from a risk-informed regulatory perspective, the most important and significant safety concerns - i.e., a "substantial safety hazard." Therefore, the Commission believes that, in the context of the risk-informed regulatory approach embodied in § 50.69, it is reasonable for the Commission to interpret "substantial safety hazard" as applying to RISC-1 SSCs and that reporting under Section 206 may be limited to RISC-1 SSCs.

The Commission considered two alternative approaches for limiting the reporting requirements in Part 21 and § 50.55(e) to RISC-1 SSCs: (i) interpreting "basic component" to encompass a risk-informed view of what SSCs the term encompasses, and (ii) including a second definition of "basic component" in § 21.3, which would apply only to those portions of a plant which have been categorized in accordance with § 50.69, and would be defined as an SSC categorized as RISC-1 under § 50.69. The Commission does not believe that the Part 21 definition of "basic component" may easily be read as simultaneously permitting both a deterministic concept of basic component and risk-informed concept, inasmuch as the Part 21 definition was drawn from, and was intended to be consistent with the definition of "safety-related SSC" in 10 CFR 50.2. The § 50.2 definition of "safety-related SSC" refers to the ability of the SSC to remain functional during "design basis events." The term, "design basis events" in Commission practice has referred to the deterministic approach of defining the events and conditions (*e.g*., shutdown, normal operation, accident) for which an SSC is expected to function (or not fail). Identification of design basis events is inherently different conceptually when compared to a risk-informed approach, which attempts to identify all possible outcomes (or a reasonable surrogate) and assign a probability to each outcome and consequence before integrating the probability of the total set of outcomes. The Commission rejected the second approach of adopting an alternative definition of "basic component," because a change to the definition in § 21.3 could be misunderstood as a change to the reporting requirements for licensees who choose not to comply with § 50.69.

III.4.1.2 Reporting Obligations of Vendors for RISC-3 SSCs.

The reporting requirements of Section 206 apply to individuals, directors and responsible officers of a firm constructing, owning, operating or supplying the basic components of any NRC-licensed facility or activity. Nuclear power plant licensees and nuclear power plant construction permit holders are subject to reporting under Section 206, and Part 21 and § 50.55(e) will continue to provide for such reporting by those entities. Section 206 also imposes a reporting obligation on "vendors," i.e., firms who supply basic components to nuclear power plant licensees and construction permit holders. The Commission does not intend to change the reporting obligations under Part 21 or § 50.55(e) for licensees, construction permit holders, or vendors with respect to RISC-1 SSCs, and the Commission does not intend to require reporting under Part 21 and § 50.55(e) for RISC-2, RISC-3 or RISC-4 SSCs.

Thus, a vendor who supplied a safety-related component to a licensee that was subsequently classified by the licensee as RISC-3 would no longer be legally obligated to comply with Part 21 or § 50.55(e) reporting requirements. However, as a practical matter that vendor would likely continue to comply with Part 21 or § 50.55(e). Vendors are informed of their Part 21 or § 50.55(e) obligations as part of the contract supplying the basic component to the licensee/construction permit holder. Vendors supplying basic components that have been categorized as RISC-3 as of the time of contract ratification would know that they have no Part 21 or § 50.55(e) obligations. However, vendors that provide (or in the past provided) safety-related SSCs would not know, absent communication from the licensee or construction permit holder implementing § 50.69, whether the SSCs which they provided under contract as safety-related are now categorized as RISC-3, thereby removing the vendor's reporting obligation under either Part 21 or § 50.55(e). Failing to inform a vendor that a safety-related SSC which it provided is no longer subject to Part 21 or 50.55(e) reporting because of its reclassification as a RISC-3 SSC could result in unnecessary reporting to the licensee and the NRC. It may also result in unnecessary expenditure of resources by the vendor in determining whether a problem with a supplied SSC rises to the level of a reportable defect or noncompliance under the existing provisions of Part 21 and § 50.55(e).

To address the potential for unnecessary reporting under proposed § 50.69, the Commission considered including a new requirement in either proposed § 50.69, or Part 21 and § 50.55(e). The new provision would require the licensee or construction permit holder to inform a vendor that a safety-related SSC which it provided has been categorized as RISC-3. After consideration, the Commission believes that it is unlikely that such a provision would result in any great reduction in the potential scope of reporting by vendors. The NRC does not receive many Part 21 reports, so the overall reporting burden to be reduced may be insubstantial. Furthermore, the Commission believes that the proposal could cause confusion, inasmuch as a vendor may supply many identical components to a licensee/holder, with some of the items intended for use in SSCs categorized as RISC-3, and other items intended in non- safety-related applications. A vendor would have some difficulty in determining whether the problem with the supplied SSC potentially affects the SSC recategorized as RISC-3 (as opposed to the supplied SSC used in nonsafety-related applications). The Commission also believes there may be some value in notification of the NRC when defects are identified, as they may reveal issues about the quality processes, or implications for basic components at other facilities. Finally, the NRC notes that the vendor has already been compensated by the licensee for the burden associated with Part 21 and 50.55(e) as part of the initial procurement process. For these reasons, the Commission does not propose to adopt a provision in § 50.69, Part 21 or § 50.55(e) requiring a licensee or construction permit holder to inform a vendor of safety-related SSCs that its SSCs have been categorized as RISC-3.

III.4.1.3 Criminal Liability under Section 223.b. of the AEA

As discussed earlier, Section 206 of the AEA authorizes the imposition of civil penalties for a licensee's and vendor's failure to report instances of noncompliance or defects in "basic components" that create a "substantial safety hazard." However, in addition to the civil penalties authorized by Section 206, criminal penalties may be imposed under Section 223.b. of the AEA on an individual director, officer or employee of a firm that supplies components to a nuclear power plant, that knowingly and willfully violate rules or regulations that results (or could have resulted) in a "significant impairment of a basic component...." Licensees, applicants and vendors should note the difference in the definition of "basic component" in Part 21, versus the definition set forth in Section 223.b:

> For the purposes of this subsection, the term "basic component" means a facility structure, system, component or part thereof necessary to assure--

> (1) the integrity of the reactor coolant pressure boundary,
>
> (2) the capability to shut-down the facility and maintain it in a safe shut-down condition, or
>
> (3) the capability to prevent or mitigate the consequences of accidents which could result in an unplanned offsite release of quantities of fission products in excess of the limits established by the Commission.

Id. The U.S. Department of Justice is responsible for prosecutorial decisions involving violations of Section 223.b.

III.4.1.4 Posting Requirements

Both AEA section 223.b and ERA section 206 require posting of their statutory requirements at the premises of all licensed facilities. This is implemented through 10 CFR Parts 19 and 21.

As a result of implementation of § 50.69, rights and responsibilities of licensee workers will be slightly different. For instance, SSCs categorized as RISC-3 would no longer be subject to Part 21. However, RISC-1 SSCs (and "safety-related" SSCs not yet categorized per § 50.69), still are subject to the Part 21 requirements. No additional responsibilities for identification or notification are involved. The supporting information such as procedures to be made available to workers would need to reflect the reduction in scope of requirements. For the reasons already mentioned, the Commission concludes that there would be no impact on vendors with respect to posting requirements in that these changes in categorization would be "transparent" to them as suppliers.

III.4.2 Section 50.49 Environmental Qualification of Electrical Equipment.

The general requirement that certain SSCs be designed to be compatible with environmental conditions associated with postulated accidents is contained in GDC-4. Section 50.49 was written to provide specific programmatic requirements for a qualification program and documentation for electrical equipment, and thus, is a special treatment requirement.

The regulation at § 50.49(b), imposes requirements on licensees to have an environmental qualification program that meets the requirements contained therein. It defines the scope of electrical equipment important to safety that must be included under the environmental qualification program. Further, this regulation specifies methods to be used for qualification of the equipment for identified environmental conditions and documentation requirements.

RISC-3 and RISC-4 SSCs would be removed from the scope of the requirements of § 50.49 through § 50.69(b)(2)(ii). As discussed above in section III.4.0, for SSCs categorized as RISC-3 or RISC-4, the Commission has concluded that for low safety-significant SSCs, additional assurance, such as that provided by the detailed provisions in section § 50.49 for testing, documentation files and application of margins, are not necessary. The requirements from GDC-4 as they relate to RISC-3 and RISC-4 SSCs, and the design basis requirements for these SSCs, including the environmental conditions such as temperature and pressure, remain in effect. Thus, these SSCs must continue to remain capable of performing their safety-related functions under design basis environmental conditions.

III.4.3 Section 50.55a(f), (g), and (h) Codes and Standards.

Section 50.69(b)(2)(iv), would remove RISC-3 SSCs from the scope of certain provisions of § 50.55a, relating to Codes and Standards. The provisions being removed are those that relate to “treatment” aspects, such as inspection and testing, but not those pertaining to design requirements established in § 50.55a. Each of the subsections being removed is discussed in the paragraphs below.

The regulation at section 50.55a(f) incorporates by reference provisions of the ASME

Code as endorsed by NRC that contains inservice testing requirements. These are special treatment requirements. Through this proposed rulemaking, RISC-3 SSCs would be removed from the scope of these requirements, and instead would be subject to the requirements in § 50.69(d)(2)(iii). For the reasons discussed in section III.4.0, the Commission has determined that for low safety-significant SSCs, it is not necessary to impose the specific detailed provisions of the Code, as endorsed by NRC, and these requirements can be replaced by the more "high-level" alternative treatment requirements, which allow greater flexibility to licensees in implementation.

Section 50.55a(g) incorporates by reference provisions of the ASME Code as endorsed by NRC that contains the inservice inspection, and repair and replacement requirements for ASME Class 2 and Class 3 SSCs. The Commission will not remove the repair and replacement provisions of the ASME BPV Code required by § 50.55a(g) for ASME Class 1 SSCs, even if they were categorized as RISC-3, because those SSCs constitute principal fission product barriers as part of the reactor coolant system or containment. For Class 2 and 3 SSCs that are shown to be of low safety-significance if categorized as RISC-3, the additional assurance from the specific provisions of the ASME Code is not considered necessary.

Section 50.55a(h) incorporates by reference the requirements in either Institute of Electrical and Electronics Engineers (IEEE) 279, "Criteria for Protection Systems for Nuclear Power Generating Stations," or IEEE 603-1991 "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." Within these IEEE standards are special treatment requirements. Specifically, sections 4.3 and 4.4 of IEEE 279 and sections 5.3 and 5.4 of IEEE 603-1991 contain quality and environmental qualification requirements. RISC-3 SSCs are being removed from the scope of this special treatment requirement consistent with the Commission decision already discussed.

III.4.4 Section 50.65 Monitoring the Effectiveness of Maintenance.

The Commission is proposing to remove RISC-3 and RISC-4 SSCs from the scope of the requirements of § 50.65 (except for paragraph (a)(4)). The basis for this includes section III.4.0 and the following discussion.

Section 50.65, referred to as the maintenance rule, imposes requirements for licensees to monitor the effectiveness of maintenance activities for safety-significant plant equipment to minimize the likelihood of failures and events caused by the lack of effective maintenance. Specifically, § 50.65 requires the performance of SSCs defined in § 50.65(b) to be monitored against licensee established goals, in a manner sufficient to provide confidence that the SSCs are capable of fulfilling their intended functions. The rule further requires that where performance does not match the goals, appropriate corrective action shall be taken. Included within the scope of § 50.65(b) are SSCs that are relied upon to remain functional during design basis events or in emergency operating procedures, and nonsafety-related SSCs whose failure could result in the failure of a safety function or cause a reactor scram or activation of a safety-related system.

Sections 50.65(a)(1), (a)(2), and (a)(3) impose documentation and action requirements; thus, they are special treatment requirements. Upon implementation of § 50.69, a licensee would not be required to apply maintenance rule monitoring, goal setting, corrective action, alternate demonstration, or periodic evaluation treatments required by §§ 50.65(a)(1), (a)(2), and (a)(3) to RISC-3 and RISC-4 SSCs. The proposed rule does include in § 50.69(e)(3) provisions for a licensee to use performance information to feedback into its processes to adjust treatment (or categorization) when results so indicate. However, this requirement does not require the specific monitoring and goal setting as required in § 50.65, in consideration of the lesser safety-significance of these SSCs.

RISC-1 and RISC-2 SSCs that are currently within the scope of § 50.65(b) would remain subject to existing maintenance rule requirements. Any RISC-1 or RISC-2 function not currently within the scope of § 50.65(b) would be added to the scope of the maintenance rule (as a result of the requirement in § 50.69(e)(2) that requires monitoring, evaluation and appropriate action for these SSCs).

The proposed removal of RISC-3 and 4 SSCs from the scope of requirements does not include § 50.65(a)(4), which contains requirements to assess and manage the increase in risk that may result from proposed maintenance activities. The requirements in § 50.65(a)(4) remain in effect. It is noted that § 50.65(a)(4) already includes provisions by which a licensee can limit the scope of the assessment required to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety. Thus, there is no need to revise the requirements to permit a licensee to apply requirements commensurate with safety-significance.

III.4.5   Sections 50.72 and 50.73 Reporting Requirements.

This proposed rule would remove the requirements in §§ 50.72 and 50.73 for RISC-3 and RISC-4 SSCs. The basis for this removal follows.

Sections 50.72 and 50.73 contain requirements for licensees to report events involving certain SSCs. These reporting requirements are special treatment requirements . NRC requires event reports in part so that it can followup on corrective action for these circumstances. Through this rulemaking, the Commission proposes to remove RISC-3 and RISC-4 SSCs from the scope of these requirements. The low safety-significance of these SSCs does not warrant the burden associated with reporting events or conditions only affecting such SSCs, for the reasons already discussed.   In particular, under NRC's risk-informed inspection process, NRC followup of corrective action will be focused upon safety-significant situations.

III.4.6 10 CFR Part 50 Appendix B Quality Assurance Requirements

This proposed rule would remove RISC-3 SSC from the scope of requirements in

Appendix B to 10 CFR Part 50. These requirements are currently not applicable to RISC-4 SSCs so there is no change for these SSCs. Appendix B contains requirements for a quality assurance program meeting specified attributes. While many of the general attributes are still appropriate for RISC-3 SSCs (and in some instances are included within the high-level requirements in § 50.69(d)(2)), it was considered simpler to remove RISC-3 SSCs from the scope of the existing requirements in Appendix B (with its attendant set of guidance and implementing documents), and to add back the minimum set of requirements viewed as necessary for RISC-3 SSCs, rather than to subdivide the existing Appendix B requirements for this purpose.

The intent of Appendix B to10 CFR Part 50, and the complementary regulations is to provide quality assurance requirements for the design, construction, and operation of nuclear power plants. The quality assurance requirements of Appendix B are to provide adequate confidence that an SSC will perform satisfactorily in service; these requirements were developed to apply to safety-related SSCs. In the implementation of Appendix B, a licensee is bound to detailed and prescriptive quality requirements to apply to activities affecting those SSCs. As such, these requirements meet the Commission's definition of special treatment requirements. These requirements are removed from application to RISC-3 and RISC-4 SSCs because their low safety-significance does not warrant the level of quality requirements that currently exist with Appendix B.

III.4.7 10 CFR Part 50, Appendix J Containment Leakage Testing.

The proposed rule would remove a subset of RISC-3 and RISC-4 SSCs from the scope of the requirements in Appendix J to Part 50 that pertain to containment leakage testing. Specifically, RISC-3 and RISC-4 SSCs that meet specified criteria would be removed from the scope of the requirements for Type B and Type C testing. The basis for the removal is described below.

One of the conditions of all operating licenses for water-cooled power reactors as specified in § 50.54(o) is that primary reactor containments shall meet the containment leakage test requirements set forth in Appendix J to 10 CFR 50. These test requirements provide for preoperational and periodic verification by tests of the leak-tight integrity of the primary reactor containment, and systems and components which penetrate containment of water-cooled power reactors, and establish the acceptance criteria for these tests. As such, these tests are special treatment requirements. The purposes of the tests are to assure that (a) leakage through the primary reactor containment , or through systems and components penetrating primary containment shall not exceed allowable leakage rate values as specified in the technical specifications and (b) periodic surveillance of reactor containment penetrations and isolation valves is performed so that proper maintenance and repairs are made during the service life of the containment, and systems and components penetrating primary containment. Appendix J includes two Options, Option A and Option B. Option A includes prescriptive requirements while Option B identifies performance-based requirements and criteria for preoperational and subsequent periodic leakage-rate testing. A licensee may choose either option for meeting the requirement of Appendix J.

The discussion contained in Appendix J to 10 CFR 50 can be divided into two categories. Parts of Appendix J contain testing requirements. Other parts contain information, such as definitions or clarifications, necessary to explain the testing requirements. A review of Appendix J did not identify any technical requirements other than those describing the methods of the required testing. Therefore, Appendix J was considered to be, in its entirety, a special treatment requirement.

The NRC believes that risk-informing this appendix may lead to less testing and therefore would reduce unnecessary regulatory burden on the licensees. Although the 1995 revision to Appendix J was characterized as risk-informed, the changes were not as extensive as those expected in the risk-informed Part 50 effort. The revision primarily decreased testing frequencies, whereas risk-informing the scope of SSCs that are subject to Appendix J testing would remove some components from testing (i.e., to the extent that defense-in-depth is maintained in accordance with the risk-informed evaluation process).

The proposed rule would exclude certain identified containment isolation valves from Type C testing. For RISC-3 components, which includes containment isolation valves, leak testing is not required. The reliability strategy is to monitor and restore component functions once they are identified through the corrective action program or the periodic feedback process. Similarly, requirements for Type B testing of certain penetrations would not be required. The relief from testing is limited to components meeting specified criteria such that acceptable results for large early release and defense-in-depth are maintained.

III.4.7.1 Types of Tests Required by Appendix J.

Appendix J testing is divided into three types: Type A, Type B, and Type C. Type A tests are intended to measure the primary reactor containment overall integrated leakage rate after the containment has been completed and is ready for operation, and at periodic intervals thereafter. Type B tests are intended to detect local leaks and to measure leakage across each pressure-containing or leakage-limiting boundary. Primary reactor containment penetrations required to be Type B tested are identified in Appendix J. Type C tests are intended to measure containment isolation valve leakage rates. The containment isolation valves required to be Type

C tested are identified in Appendix J.

III.4.7.2 Reduction in Scope for Appendix J Testing.

Type A Testing: The Commission concludes that Type A testing should continue to be required as described in Appendix J.

Type B Testing: The Commission concludes that Type B testing should continue to be required for air lock door seals, including door operating mechanism penetrations which are part of the containment pressure boundary and doors with resilient seals or gaskets except for seal-welded doors. Type B testing is not necessary for other penetrations that are determined to be of low safety significance and that meet one or both of the following criteria:

1. Penetrations pressurized with the pressure being continuously monitored.
2. Penetrations less than 1 inch in equivalent diameter.

Type C Testing: The Commission concludes that Type C testing is not necessary for valves that are determined to be of low safety significance and that meet one or more of the following criteria:

1. The valve is required to be open under accident conditions to prevent or mitigate core damage events.
2. The valve is normally closed and in a physically closed, water filled system.
3. The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and that is not connected to the reactor coolant pressure boundary.
4. The valve size is 1-inch nominal pipe size or less.

III.4.7.3 Basis for Reduction of Scope

The first criterion for Type B testing deals with penetrations that are pressurized with the pressures in the penetrations being continuously monitored by licensees. The pressurization itself establishes a leak tight barrier, for such penetrations. The monitoring of the pressures in the penetrations, in conjunction with the proposed requirements for RISC 3 SSCs (including taking corrective action when an SSC fails) provide sufficient assurance, without the need for Type B testing, to ensure that these penetrations are functional.

The second criterion for reducing the scope of Type B testing (i.e., penetrations less than 1 inch in equivalent diameter) is essentially the same as the fifth criterion for reducing the scope of Type C testing (i.e., valve size is 1-inch or less). By definition penetrations of this size do not contribute to large early release.

The Commission finds that the criteria for reducing the scope of the Type C testing requirements are reasonable in that, even without Type C testing, the probability of significant leakage during an accident (that is, leakage to the extent that public health and safety is affected) is small. This is true even though some of the valves that satisfy these criteria may be fairly large.

Appendix J to 10 CFR Part 50 deals only with leakage rate testing of the primary reactor containment and its penetrations. It assumes that containment isolation valves are in their safe position. No failure is assumed that would cause the containment isolation valves to be open when they are supposed to be closed. The valve would be open if needed to transmit fluid into or out of containment to mitigate an accident or closed if not needed for this purpose. For purposes of this evaluation, if a valve is open, it is assumed to be capable of being closed. Testing to ensure the capability of containment isolation valves to reach their safe position is not within the scope of Appendix J, and as such is not within the scope of this evaluation. Therefore, the valves addressed by this evaluation are considered to be closed, but may be leaking. The increase in risk due to this proposed revision affecting Appendix J is negligible.

Past studies (e.g., NUREG-1150, “Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants; Final Summary Report,” dated December 1990) show that the overall reactor accident risks are not sensitive to variations in containment leakage rate. This is because reactor accident risk is dominated by accident scenarios in which the containment either fails or is bypassed. These very low probability scenarios dominate predicted accident risks due to their high consequences.

The Commission examined in more detail the effect of containment leakage on risk as part of the Appendix J to 10 CFR Part 50, Option B, rulemaking. The results of these studies are applicable to this evaluation. NUREG-1493, “Performance-Based Containment Leak-Test Program,” dated September 1995, calculated the containment leakage necessary to cause a significant increase in risk and found that the leakage rate must typically be approximately 100 times the Technical Specification leak rate, L_a. It is improbable that even the leakage of multiple valves in the categories under consideration would exceed this amount. Operating experience shows that most measured leaks are much less than 100 times L_a. A more direct estimate of the increase in risk for the proposed revision to Appendix J can be obtained from the Electric Power Research Institute (EPRI) report TR-104285, “Risk Impact Assessment of Revised Containment Leak Rate Testing Intervals,” dated August 1994. This report examined the change in the baseline risk (as determined by a plant’s IPE risk assessment) due to extending the leakage rate test intervals. For the pressurized water reactor (PWR) large dry containment examined in the EPRI report, for example, the percent increase in baseline risk from extending the Type C test interval from 2 years to 10 years was less than 0.1 percent. While this result was for a test interval of 10 years vs. the current proposal to do no more Type C testing of the subject valves for the life of a plant, the analysis may reasonably apply to this situation because it contains several conservative assumptions which offset the 10-year time interval. These assumptions include the following:

1. The study used leakage rate data from operating plants. Any leakage over the plant’s administrative leakage limit was considered a leakage failure. An administrative limit is a utility’s internal limit and does not imply violation of any Appendix J limits. Therefore, the probability of a leakage failure is overestimated.

2. Failure of one valve to meet the administrative limit does not imply that the penetration would leak because containment penetrations typically have redundant isolation valves. While one valve may leak, the other may remain leak-tight. The study assumed that failure of one valve in a series failed the penetration; however, the probability of failure was that for a single valve.

3. The analysis assumed possible leakage of all valves subject to Type C testing, not just those subject to the proposed revision.

According to this analysis, the proposed revision would not have a significant effect on risk. The NUREG-1493 analysis shows that the amount of leakage necessary to significantly increase risk is two orders of magnitude greater than a typical Technical Specification leakage rate limit. Therefore, the risk to the public will not significantly increase due to the proposed relief from the requirements of Appendix J to 10 CFR Part 50.

III.4.8 Appendix A to 10 CFR Part 100 (and Appendix S to 10 CFR Part 50 (Seismic Requirements))

The proposed rule would remove RISC-3 and RISC-4 SSCs from the requirement in Appendix A to Part 100 to demonstrate that SSCs are designed to withstand the safe shutdown earthquake (SSE) by qualification testing or specific engineering methods. GDC 2 requires that SSCs "important to safety" be capable of withstanding the effects of natural phenomena such as earthquakes. The requirements of 10 CFR Part 100 pertain to reactor site criteria and its Appendix A addresses seismic and geologic siting criteria used by the Commission to evaluate suitability of plant design bases in consideration of these characteristics. Sections VI(a)(1) and (2) of Appendix A to 10 CFR Part 100 address the engineering design for the SSE and

Operating Basis Earthquake (OBE), respectively. The rule change would exclude RISC-3 and RISC-4 SSCs from the scope of the requirements of sections VI.(a)(1) and (2) of Appendix A to 10 CFR Part 100, only to the extent that the rule requires testing and specific types of analyses to demonstrate that safety-related SSCs are designed to withstand the SSE and OBE. It is only these aspects of Appendix A to 10 CFR Part 100 that are considered special treatment. As discussed in Section III.4.0, because of the low safety significance of the RISC-3 and RISC-4 SSCs, the additional assurance provided by qualification testing (or engineering analyses) is not considered necessary.

For current operating reactors, Appendix A to Part 100 is applicable. For new plant applications, the seismic design requirements are set forth in Appendix S to Part 50. The NRC has determined that Appendix S does not need to be included in the proposed § 50.69 because the wording of the requirements with respect to "qualification" by testing or specific types of analysis is not present in this rule. Therefore, a rule change would not be necessary to permit a licensee to implement means other than qualification testing or the specified methods to demonstrate SSC capability.

III.4.9 Requirements Not Removed by § 50.69(b)(1).

In the following paragraphs, the Commission discusses certain rules that were considered as candidates for removal as requirements for RISC-3 and RISC-4 SSCs during development of this rulemaking. These rules were identified as candidate rules in SECY-99-256. They are not part of this rulemaking for the reasons presented.

III.4.9.1 Section 50.34 Contents of applications.

Section 50.34 identifies the required information that applicants must provide in preliminary and final safety analysis reports. Since § 50.69 contains the documentation requirements for licensees and applicants who choose to implement § 50.69, and these requirements do not conflict with § 50.34, it is not necessary to revise § 50.34 to implement § 50.69.

III.4.9.2 Section 50.36 Technical specifications.

Section 50.36 establishes operability, surveillance, limiting conditions for operation and other requirements on certain SSCs. To the extent that this rule specified testing and related requirements, it was considered as a candidate for being "special treatment". However, the Commission concluded that it was not appropriate to revise § 50.36 for several reasons. First, risk-informed criteria have already been established in §50.36 for determining which SSCs should have TS requirements. Improved standard TS have already resulted in relocation of requirements for less important SSCs to other documents. Further, other improvement efforts are underway that could be implemented by individual licensees to make their plant-specific requirements more risk-informed. Thus, no changes to this rule (or its implementation) are necessary as part of § 50.69 to make the TS risk-informed or to accommodate the revised requirements of this proposed rule.

III.4.9.3 Section 50.44 Combustible Gas Control

Certain provisions within § 50.44 were identified as containing special treatment requirements in that they specified conformance with Appendix B for particular design features, specified requirements for qualification, and related statements. The Commission notes that a separate rulemaking is underway to "rebaseline" the requirements in § 50.44 using risk insights (see August 2, 2002; 67 FR 50374). Therefore, the NRC believes that there is no need to include those sections of (existing) § 50.44 as being removed for RISC-3 SSC. If portions of § 50.44 that were identified as special treatment requirements are retained, and/or relocated to other rules (and they are not necessary for RISC-3 SSCs), then there may be a need to reference these rules within § 50.69(b)(1) when § 50.69 is issued as a final rule.

III.4.9.4 Section 50.48 (Appendix R and GDC 3) Fire Protection.

Initially, fire protection requirements were considered to be within the scope of this rulemaking effort. There are augmented quality provisions applied to fire protection systems and these augmented quality provisions are considered special treatment requirements. However, these provisions are not contained in the rules themselves. The Commission has approved development of a proposed rulemaking to allow licensees to voluntarily adopt National Fire Protection Association (NFPA)-805 requirements in lieu of other fire protection requirements. NFPA-805 would permit a licensee to implement a risk-informed fire protection program as a voluntary alternative to compliance with § 50.48 and 10 CFR Part 50, Appendix R. Accordingly, changes to these regulations were not included in the scope of the § 50.69 rulemaking.

III.4.9.5 Section 50.59 Changes, Tests and Experiments.

The Commission does not believe that a § 50.59 evaluation need be performed when a licensee implements § 50.69 by changing the special treatment requirement for RISC-3 and RISC-4 SSCs. Accordingly, § 50.69 (f)(iii) contains language that removes the requirement for a § 50.59 evaluation of the changes in special treatment as part of implementation. The process of adjusting treatment for RISC-3 and RISC-4 SSCs does not need to be subject to § 50.59 because the rulemaking already provides the decision process for recategorization and determination of revision to requirements resulting from the categorization. Thus, subjecting the implementation steps as they relate to changes to treatment from what was described in the final safety analysis report (FSAR), to determine if NRC approval is needed of those changes, is an unnecessary step. Since it is only in the area of treatment for RISC-3 and RISC-4 SSCs that might be viewed as involving a reduction in requirements, these are the only aspects for which this rule provision would have any effect. As required by § 50.69(f)(ii), the licensee/applicant will be required to update the FSAR appropriately to reflect incorporation of its treatment processes into the FSAR.

However, it is important to recognize that changes that affect any non-treatment aspects of an SSC (e.g., changes to the SSC design basis functional requirements) are required to be evaluated in accordance with the requirements of § 50.59. Section 50.69(d)(2)(i), which focuses upon design control, is intended to draw a distinction between treatment (managed through § 50.69) and design changes (managed through other processes such as § 50.59). As previously noted, this rulemaking is only risk-informing the scope of special treatment requirements. The process and requirements established in § 50.69 do not extend to making changes to the design basis of SSCs.

III.4.9.6 Appendix A to 10 CFR 50 Part 50 General Design Criteria (GDC)

The NRC has concluded that the GDC of Appendix A to 10 CFR Part 50 do not need to be revised because they specify design requirements and do not specify special treatment requirements. Because this rulemaking is not revising the design basis of the facility, the GDC should remain intact and are not within the scope of § 50.69. This subject is discussed in more detail in the NRC's action on the South Texas exemption request, in which their request for exemption from certain GDCs was denied as being unnecessary to accomplish what was proposed (see section IV.4.0)

III.4.9.7 10 CFR Part 52 Early Site Permits, Standard Design Certifications and Combined Operating Licenses

Part 52 contains, by cross-reference, regulations from other parts of Chapter 10 of the Code of Federal Regulations, most notably Part 50. Therefore, it was initially considered for inclusion in the rulemaking effort. However, with the proposed "applicability" paragraph (§ 50.69(b)) extending to applicants for a facility license or design certification under Part 52, the Commission presently sees no need for revisions to Part 52 itself.

III.4.9.8 10 CFR Part 54 License Renewal

In SECY-99-256, 10 CFR Part 54, which provides license renewal requirements, was identified as a candidate regulation for removal from scope of applicability to low significance SSCs. The aging management requirements could be viewed as being special treatment requirements in that they provide assurance that SSCs will continue to meet their licensing basis requirements during the renewed license period. Section 54.4 explicitly defines the scope of the license renewal rule using the traditional deterministic approach. Part 54 imposes aging management requirements in § 54.21 on the scope of SSCs meeting § 54.4.

In SECY-00-0194, the NRC staff provided its preliminary view that RISC-3 SSCs should not be removed from the scope of Part 54, and that licensees can renew their licensees in accordance with Part 54 by demonstrating that the § 50.69 treatment provides adequate aging management in accordance with § 54.21. The NRC staff suggested that no changes are necessary to Part 54 to implement § 50.69 either prior to renewing a licensing or after license renewal.

The goal of the license renewal program is to establish a stable, predictable, and efficient license renewal process. The Commission believes that a revision of Part 54 at this time could have a significant effect on the stability and consistency of the processes established for preparation of license renewal applications, and for NRC staff review. Further, as discussed below, the Commission believes that the requirements in Part 54 are compatible with the § 50.69 approach, including use of risk information in establishing treatment (aging management) requirements. Refer to section V.3.0 for additional discussion regarding the implementation of § 50.69 for a facility that has already received a renewed license. Thus, Part 54 requires no changes at this time. However, in the future, the Commission will consider whether revisions to the scope of Part 54 are appropriate.

The use of risk in establishing the scoping criteria within Part 54 was addressed by the Commission on May 8,1995 (60 FR 2461), when amending Part 54. In the 1995 amendment, the Commission stated that the current licensing basis for current operating plants is largely based on deterministic engineering criteria. Consequently, there was considerable logic in establishing license renewal scoping criteria that recognized the deterministic nature of a plant's licensing basis. Without the necessary regulatory requirements and appropriate controls for plant-specific PRAs, the Commission concluded that it was inappropriate to establish a license renewal scoping criterion that relied on plant-specific probabilistic analyses. Therefore, the Commission concluded further that within the construct of the final rule, PRA techniques were of very limited use for license renewal scoping. (60 FR 22468).

The 1995 amendment to Part 54 excluded active components to "reflect a greater reliance on existing licensee programs that manage the detrimental effects of aging on functionality, including those activities implemented to meet the requirements of the maintenance rule," (60 FR 22471). Although § 50.69 would remove RISC-3 components from the scope of the maintenance rule requirements in § 50.65(a)(1), (a)(2), and (a)(3), a licensee is required under the proposed § 50.69(d)(2) to provide confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions when challenged. The SOC for Part 54 also indicated the Commission's recognition that risk insights could be used in evaluating the robustness of an aging management program (60 FR 22468). The NRC staff has received and accepted one proposal (Arkansas Unit 1) for a risk-informed program for small-bore piping which demonstrates that risk arguments can be used to a degree.

III.4.9.9 Other Requirements.

In the ANPR and related documents, the staff and stakeholders suggested a number of other regulatory requirements that might be candidates for inclusion in § 50.69. These included § 50.12(exemptions), § 50.54(a), (p), and (q) (plan change control), and § 50.71(e) (FSAR updates). As the rulemaking progressed, the Commission concluded that these requirements did not need to be changed to allow a licensee to adopt § 50.69 as it is being proposed.

III.5.0 Evaluation and Feedback, Corrective Action and Reporting Requirements.

The validity of the categorization process relies on ensuring that the performance and condition of SSCs continues to be maintained consistent with applicable assumptions. Changes in the level of treatment applied to an SSC might result in changes in the reliability of the SSCs which are used in the categorization process. Additionally, plant changes, changes to operational practices, and industry operational experience may impact the categorization assumptions. Consequently, the proposed rule contains requirements for updating the categorization and treatment processes when conditions warrant to assure that continued SSC performance is consistent with the categorization process and results.

Specifically the proposed rule would require licensees to review in a timely manner but no longer than every 36 months, the changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization. In addition, licensees would be required to obtain sufficient information on SSC performance to verify that the categorization process and its results remain valid. For RISC-1 SSCs, much of this information may be obtained from present programs for inspection, testing, surveillance, and maintenance. However for RISC-2 SSCs and for RISC-1 SSCs credited for beyond design basis accidents, licensees would need to ensure that sufficient information is obtained. For RISC-3 SSCs, there is a relaxation of requirements for obtaining information when compared to the applicable special treatment requirements; however sufficient information would need to be obtained, and rule requirements are being proposed to consider performance data, see if adverse changes in performance might occur, and to make necessary adjustments such that desired performance is achieved so that the evaluations conducted to meet § 50.69(c)(1)(iv) remain valid. The feedback and adjustment process is crucial to ensuring that the SSC performance is maintained consistent with the categorization process and its results.

Taking timely corrective action is an essential element for maintaining the validity of the categorization and treatment processes used to implement proposed § 50.69. For safety-significant SSCs, all current requirements would continue to apply and, as a consequence, Appendix B corrective action requirements would be applied to RISC-1 SSCs to ensure that conditions adverse to quality are corrected. For both RISC-1 and RISC-2 SSCs, requirements would be included in § 50.69(e)(2) for monitoring and for taking action when SSC performance degrades.

When a licensee or applicant determines that a RISC-3 SSC does not meet its established acceptance criteria for performance of design basis functions, the proposed rule would require that a licensee perform timely corrective action (§ 50.69(d)(2)(iv)). Further, as part of the feedback process, review of operational data may reveal inappropriate assumptions for reliability or performance and a licensee would need to re-visit the findings made in the categorization process or modify the treatment for the applicable SSCs (§ 50.69(e)(3)). These provisions would then restore the facility to the conditions that were considered in the categorization, and would also restore the capability of SSCs to perform their functions.

Finally, the proposed rule would require reports of events or conditions that would have prevented RISC-1 and RISC-2 SSCs from being able to perform their safety-significant functions. A new reporting requirement would be added in § 50.69(g) for events or conditions that would prevent RISC-2 SSCs from performing their safety-significant functions (if not otherwise reportable). Since the categorization process has determined that RISC-2 SSCs are of safety significance, NRC is interested in reports about circumstances where the safety-significant function would have been prevented because of events or conditions. This reporting will enable NRC to be aware of situations impacting those functions found to be significant under § 50.69, such that NRC can take any actions deemed appropriate.

Properly implemented, these requirements would ensure that validity of the categorization process and results are maintained throughout the operational life of the plant.

III.6.0 Implementation Process Requirements.

The proposed rule would also contain requirements specifying how a licensee (or applicant) would be able to use the alternative requirements in lieu of the existing requirements. The rule would specify applicability requirements as well as requirements on the Commission approval process for implementation.

The Commission is making the provisions of § 50.69 available to both applicants for licenses or design certification rules and to holders of facility licenses for light-water reactors. The proposed rule would be limited to light-water reactors because it was developed to risk-inform the scope of special treatment requirements which are applied to light-water reactors. Consequently, the technical aspects of the rule (e.g., providing reasonable confidence that risk increases (e.g.,changes in CDF and LERF are small) including the implementation guidance, are specific to light-water reactor designs.

Proposed § 50.69 would rely on robust categorization to provide high confidence that the safety significance of SSCs is correctly determined. To ensure a robust categorization is employed, proposed § 50.69 would require the categorization process to be reviewed and approved prior to implementation of § 50.69 either by following the license amendment process of § 50.90 or as part of the license application review. While detailed regulatory guidance has been developed to provide guidance for implementing categorization consistent with the proposed rule requirements, the Commission concluded that a prior review and approval was still necessary to enable the NRC staff to review the scope and quality of the plant-specific PRA taking into account peer review results. The NRC staff would also review other evaluations and approaches to be used such as margins-type analyses. Additionally, this review would examine any aspects of the proposed categorization guidance that are not consistent with the staff's regulatory guidance for implementing § 50.69. Thus, the proposed rule would require that a licensee who wishes to implement § 50.69 submit an application for license amendment to the NRC containing information about the categorization process and about the peer review process employed. An applicant would submit this information as part of its license application. The Commission will approve, by license amendment, a request to allow a licensee to implement § 50.69 if it is satisfied that the categorization process to be used meets the requirements in § 50.69. Commission action on an applicant's request would be part of the Commission decision on the license application.

The Commission is proposing that the approval to implement for a licensee be by license amendment. As discussed above, prior NRC review and approval of the licensee's proposed PRA, basis for sensitivity studies and evaluations, and results of PRA review process is required. This review will involve substantial professional judgment on the part of NRC reviewers, inasmuch as the rule does not contain objective, non-discretionary criteria for assessing the adequacy of the PRA process, PRA review results and sensitivity studies. Consistent with the Commission's decision in *Cleveland Electric Illuminating Co.* (Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315 (1996), the proposed rule requires NRC approval to be provided by issuance of a license amendment. In a July 10, 2002, letter to the Director of NRR, the Nuclear Energy Institute (NEI) submitted a paper, "License Amendments: Analysis of Statutory and Legal Requirements" (NEI Analysis). In this analysis, NEI contends that approval of a licensee's/applicant's request to implement § 50.69 need not be accomplished by a license amendment. NEI essentially argues that the proposed rule does not increase the licensee's operating authority, but merely provides a “different means of complying with the existing regulations...” Id., p.8. The Commission disagrees with this position, inasmuch as proposed § 50.69 would permit the licensee/applicant, once having obtained approval from the NRC, to depart from compliance with the “special treatment” requirements set forth in those regulations delineated in § 50.69. NEI also argues that the NRC’s review and approval of the SSC categorization process under proposed § 50.69 is analogous to the review and approval process in *Perry*, which the Commission determined did not require a license amendment. Unlike the Perry case, where the license already provided for the possibility of material withdrawal schedule changes and the governing American Society for Testing and Materials (ASTM) standard set forth objective, non-discretionary criteria for changes to the withdrawal schedule, § 50.69 does not contain such criteria for assessing the adequacy of the PRA process, PRA review results, and the sensitivity studies. Hence, the NRC’s approval of a request to implement § 50.69 will involve substantial professional judgment and discretion. In sum, the Commission does not agree with NEI’s assertion that the NRC’s approval of a request to implement § 50.69 may be made without a license amendment in accordance with the *Perry* decision.

The Commission does not believe it necessary to perform a prior review of the treatment processes to be implemented for RISC-3 SSCs in lieu of the special treatment requirements. Instead, the NRC has developed proposed § 50.69 to contain requirements that ensure the categorization is robust to provide high confidence that SSC safety significance is correctly determined; sufficient requirements on RISC-3 SSCs to provide a level of assurance that these SSCs remain capable of performing their design basis functions commensurate with their low safety significance; and requirements for obtaining sufficient information concerning the performance of these SSCs to enable corrective actions to be taken before RISC-3 SSC reliability degrades beyond the values used in the evaluations conducted to satisfy § 50.69(c)(1)(iv). The

NRC concludes that compliance with these requirements, in conjunction with inspection of § 50.69 licensees is a sufficient level of regulatory oversight for these SSCs.

The Commission recognizes that this proposed rule may have implications with respect to our reactor oversight process including the inspection program, significance determination process, and our enforcement approach. In its final decision on this rulemaking, the Commission proposes to document its conclusions as to whether new or revised inspection or enforcement guidance is necessary. Public comment on this issue is requested as part of comments on this proposed rule.

The Commission included requirements in the proposed rule for documenting categorization decisions to facilitate NRC oversight of a licensee's or applicant's implementation of the alternative requirements. The proposed rule would also include provisions to have the FSAR and other documents updated to reflect the revised requirements and progress in implementation. These requirements will allow the NRC and other stakeholders to remain knowledgeable about how that licensee is implementing its regulatory obligations as it transitions from past requirements to the revised requirements in § 50.69. As part of these provisions, the Commission has concluded that requiring evaluations under § 50.59 (for changes to the facility or procedures as described in the FSAR) or under § 50.54(a) (for changes to the quality assurance plan) is not necessary for those changes directly related to implementation of § 50.69. For implementation of treatment processes for low safety-significant SSC, in accordance with the rule requirements contained in § 50.69, the Commission concludes that requiring further review as to whether NRC approval might be required for such changes is unnecessary burden. If a licensee is satisfying the rule requirements, as applied to RISC-3 SSC, the Commission could not postulate circumstances under which NRC approval of such changes would be required. Thus, a licensee would be permitted to make changes concerning treatment requirements that might be contained in these documents. The Commission is limiting this relief to changes directly related to implementation (with respect to treatment processes). Changes that affect any non-treatment aspects of an SSC (e.g., changes to the SSC design basis functional requirements) are still required to be evaluated in accordance with other regulatory requirements such as § 50.59. This rulemaking is only risk-informing the scope of special treatment requirements. The process and requirements established in § 50.69 do not extend to making changes to the design basis of SSCs.

III.7.0 Adequate Protection.

The Commission believes that reasonable assurance of adequate protection of public health and safety will be provided by applying the following principles in the development and implementation of proposed § 50.69:

(1) The net increase in plant risk is small;

(2) Defense-in-depth is maintained;

(3) Safety margins are maintained; and

(4) Monitoring and performance assessment strategies are used.

As described previously, these principles were established in RG 1.174, which provided guidance on an acceptable approach to risk-informed decision-making consistent with the 1995 Commission policy on the use of PRA. Proposed § 50.69 was developed to incorporate these principles, both to ensure consistency with Commission policy, and to ensure that the proposed rule maintains adequate protection of public health and safety.

The following discusses how proposed § 50.69 meets the four criteria, and as a result, maintains adequate protection of public health and safety.

III.7.1 Net Increase in Risk is Small.

Proposed § 50.69 requires the use of a robust, risk-informed categorization process that ensures that all relevant information concerning the safety significance of an SSC is considered by a competent and knowledgeable panel who makes the final determination of the safety significance of SSCs. The review and approval of the categorization process ensures that it meets the requirements of § 50.69(c) and that as a result, the correct SSC safety significance is determined with high confidence. Correctly determining safety significance of an SSC provides confidence that special treatment requirements are only removed from SSCs with low safety significance, and that these requirements continue to be satisfied for SSCs of safety significance. The proposed rule requires that the potential net increase in risk from implementation of proposed § 50.69 be assessed, and that this risk change is small. These requirements to provide reasonable confidence that the net change in risk is small as part of the categorization decision, in conjunction with the proposed rule requirements for maintaining design basis functions and the processes noted below for feedback and adjustment over time, all contribute to preventing risk from increasing beyond the ranges that the Commission has determined to be appropriate. As a result, these requirements are a contributing element for maintaining adequate protection of public health and safety.

III.7.2 Defense-in-Depth is Maintained.

Section 50.69 would require that the defense-in-depth philosophy be maintained as part of the categorization requirements of paragraph (c)(1) and as a result, defense-in-depth is considered explicitly in the categorization process. Thus, SSCs that are important to defense- in-depth, as outlined in the implementation guidance, will be categorized as safety-significant (and will retain their treatment requirements). For safety-significant SSCs (i.e., RISC-1 and RISC-2 SSCs), all current special treatment requirements would remain (i.e., the proposed rule does not remove any of these requirements) to provide high confidence that they can perform design basis functions, and additionally requires sufficient treatment be applied to support the credit taken for these SSCs for beyond design basis events. For RISC-3 SSCs, proposed § 50.69 would impose high level treatment requirements that when effectively implemented, maintain the capability of RISC-3 SSCs to perform their design basis functions. Thus, the complement of SSCs installed at the facility that provide the defense-in-depth will continue to be available. The proposed rule does not change the design basis of the facility, which was established based upon defense-in-depth considerations. Accordingly, the Commission believes that the proposed rule maintains defense-in-depth.

III.7.3. Safety Margins are Maintained.

Proposed § 50.69 maintains sufficient safety margins by a combination of -- (1) maintaining all existing functional and treatment requirements on RISC-1 and RISC-2 SSCs and additionally ensuring that any credit for these SSCs for beyond design basis conditions is valid and maintained; (2) maintaining the design basis of the facility for all SSCs, including RISC-3 SSCs as described above; and (3) requiring a licensee to have reasonable confidence that the overall increase in risk that may result due to implementation of proposed § 50.69 is small. Maintaining current requirements on RISC-1 and RISC-2 SSCs, and ensuring that credit taken for these SSCs in the PRA for beyond design basis events is maintained, provides assurance that the safety-significant SSCs continue to perform as assumed in the categorization process. Maintaining the design basis ensures that SSCs continue to be designed to criteria that ensure the SSCs perform their design basis functions, and therefore are nominally capable of performing their design basis functions. Because the only requirements that are relaxed are those related to treatment, existing safety margins for SSCs arising from the design technical and functional requirements would remain. The proposed rule also requires (through monitoring requirements) that the SSCs must be maintained such that they continue to be capable of performing their design basis functions. The reduction in treatment applied to RISC-3 SSCs may result in an increase in RISC-3 failure rates (i.e., a reduction in RISC-3 reliability). To address how this relates to safety margin, proposed § 50.69 would require that there be reasonable confidence that any potential increases in CDF and LERF be small from assumed changes in reliability resulting from the treatment changes permitted by the proposed rule. As a result, individual SSCs continue to be capable of performing their design basis functions, as well as to perform any beyond design basis functions consistent with the categorization process and results. Therefore, the Commission concludes that the proposed rule preserves sufficient safety margins.

III.7.4 Monitoring and Performance Assessment Strategies are Used.

Proposed § 50.69(e) would contain requirements that ensure that the risk-informed categorization and treatment processes are maintained, and reflect operational practices, the facility configuration, and SSC performance. In addition, proposed § 50.69(g) would contain requirements that reports are made to NRC of conditions preventing SSCs from performing their safety-significant functions. Together, these requirements maintain the validity of the risk-informed categorization and treatment processes such that the above criteria will continue to be satisfied over the life of the facility.

III.7.5 Summary and Conclusions.

Proposed § 50.69 would contain requirements that ensure that the net risk increase from implementation of its requirements is small, that defense-in-depth is maintained, that safety margins are maintained, and that monitoring and performance measurement strategies are used. Together, these requirements result in a proposed § 50.69 that is consistent with Commission policy on the use of PRA, and that maintains adequate protection of public health and safety.

IV. Public Input to the Proposed Rule

IV.1.0 Advance Notice of Proposed Rulemaking (ANPR) Comments.

The Commission published an ANPR (March 3, 2000; 65 FR 11488) to solicit public input on the direction and scope of this rulemaking. A number of comments were received. The NRC staff provided its preliminary responses to the issues raised by the commenters in

SECY-00-194, dated September 7, 2000. The Commission has considered these issues in developing the proposed rule. More detailed discussion of the comments and the Commission's preliminary positions are contained in a separate document (see Section X, Availability of Documents). A summary of some of the more substantive issues follows.

IV.1.1 Need for Prior NRC Review and PRA "Quality."

As originally envisioned in the ANPR, with development of a detailed Appendix T to contain the categorization process requirements, implementation of § 50.69 could be undertaken without a prior NRC review and approval. As the rulemaking, guidance development, and pilot reviews progressed, it became apparent that some degree of NRC review would be necessary to determine that the PRA was technically adequate to support its use in the categorization process. While the completion of documents such as the ASME Standard for Probabilistic Risk Assessments for Nuclear Power Plant Applications and completion of peer reviews can lead to improved PRAs, there is still some lack of definitive guidance on preparation of PRAs that would allow use of PRA results in the manner anticipated without some degree of NRC review of the PRA itself. Concerns were also raised that excessive detail in the rule might be problematic and require exemptions. Thus, the approach that has been developed is for a rule with the minimum elements of the categorization process defined in the rule, a requirement for NRC review and approval of the categorization process (including PRA peer review information) to be used, and detailed implementation guidance (in the form of a regulatory guide).

IV.1.2 Treatment Attributes.

Many of the ANPR comments focused on what treatment requirements should be established for various RISC categories of SSC. For example, there were comments that the requirements should not be "added-on" to existing requirements, but should reflect the significance of the SSCs. The Statement of Considerations of this rulemaking provides details about the decisions the Commission has made concerning the appropriate treatment requirements to include for the various categories of SSCs.

IV.1.3 Selective Implementation.

The Commission received a number of comments on selective implementation, both during the ANPR process and later. The Commission concludes that selective implementation of § 50.69 should be allowed to permit a licensee/applicant to depart from compliance with a limited set of the special treatment rules delineated in § 50.69(b)(1). This topic is discussed further in section V.5.1. Because of the existing requirements that would remain in place, a licensee could choose not to revise requirements for all of the rules within the scope of § 50.69(b). However, there is no selective implementation for the overall requirements in § 50.69. Thus for example, a licensee could not elect to adopt paragraph (b)(1) and not (d)(2). The other question was whether selective implementation with respect to the scope of SSCs to be categorized should be allowed. The Commission has determined that selective implementation on a system basis should be allowed, but not for components within a system. The rule includes specific language about this limitation. This required scope ensures that all safety functions associated with a system or structure are properly identified and evaluated when determining the safety significance of individual components within a system or structure and that the entire set of components that comprise a system or structure are considered and addressed. As further discussed in section III.2, the implementation, including the categorization process must address an entire system or structure, not selected components within a system.

With respect to the question about categorizing only some systems, because the process of categorization of individual components within the systems can be time-consuming, categorization will occur over a period of time. In theory, certain systems might not be categorized at all. Initially there was some reservation that a licensee might only choose to categorize in systems where they anticipated relief from requirements (i.e., with a large set of RISC-3 SSCs) and would not categorize a system that would have RISC-2 SSCs. The Commission notes that requirements remain for RISC-3 SSCs until they are recategorized, and both sets of requirements are intended to maintain the design basis functions of RISC-3 SSCs. However, in categorizing any SSC, the categorization process may result in making assumptions about other SSCs in the plant (through the PRA modeling and in the IDP). In other words, for some SSCs to be of low safety significance, it is necessary for other SSCs to be safety-significant. For example, a RISC-2 SSC may be credited in the categorization process and subsequently another SSC becomes RISC-3 (low safety-significant). If a licensee wants to selectively implement § 50.69 just for the system in which a particular RISC-3 SSC resides, then the licensee would also have to assure that the credit for the RISC-2 SSC is maintained also. To ensure that the categorization process is valid, such assumptions and credit must be retained over time, as determined by the PRA update process. Because the NRC will be reviewing the categorization process before implementation, NRC can determine if the categorization process is compatible with this approach.

IV.2.0 Draft Rule Comments.

On November 29, 2001 (66 FR 59546), the NRC staff released draft rule language for proposed § 50.69, in response to guidance from the Commission dated August 2, 2001. The draft rule language was released to stakeholders as a means of obtaining early input from stakeholders about the rulemaking and how it would be implemented. The NRC staff received ten sets of comments from stakeholders in response to the FR notice. The NRC staff revised the draft rule and re-issued the revised language on April 5, 2002, taking into account the issues raised by the stakeholders. A third draft of the rule was made publicly available on August 2, 2002. Some revisions to the rule resulted from the input provided by the stakeholders and others were taken into account in the development of the SOC. The remaining discussion identifies the significant comments which resulted in changes to the draft rule.

Many of the comments received related to the way in which the high-level treatment requirements for RISC-3 SSCs were organized and worded. Based upon these comments, the NRC reduced the number of separate subsections (from 8 to 4), and simplified the wording by removing duplication of phrases. Suggested simplifications that were accepted were the deletion of details of the types of maintenance (corrective, predictive), and deletion of the words "design inputs." Some stakeholders, such as the NEI, stated that the requirements were overly prescriptive and were not consistent with the concept of removing SSCs from the scope of NRC special treatment requirements. The issue about level of detail is the topic that drew the most comment during the draft rule language process. At the same time, comments and input from other stakeholders (including the Advisory Committee on Reactor Safeguards (ACRS), were resulting in strengthening of the categorization process such that any individual SSC categorized as RISC-3 is of very low safety significance. Specific consideration was also added in the rule requirements to deal with potential common-cause failures. Based upon this evolution, concerns about prescriptiveness as stated in these comments led the Commission to simplify the requirements on treatment for RISC-3 SSCs. The specific requirements that were part of the draft rule (as most recently released) but which no longer appear in the proposed rule are included in Section VI below, to allow all stakeholders to express their views about this matter.

Another part of the draft rule that drew comment was the requirement for monitoring of RISC-3 SSCs. Some of the comments indicated that this was not necessary for low safety-significant SSCs, and was inconsistent with the removal of maintenance rule monitoring (by removing § 50.65(a)(1) through (3) as requirements). In the proposed rule, the Commission has clarified that the type of monitoring of availability and failures under the maintenance rule is not necessary and that the type of monitoring appropriate for RISC-3 SSCs is the performance monitoring specified in § 50.69(d)(2)(iii) and the feedback specified in § 50.69(e)(3).

Other comments proposed that the scope of rules being removed should be expanded to include the requirements in § 50.55a (ASME code requirements), and Appendix A to Part 100. Rule language was added to accomplish this by listing specific subsections of § 50.55a and

Appendix A to Part 100 in the list of requirements removed, and through other changes to the rule designed to maintain the necessary reliability of SSCs. The ASME provided comments on the draft rule language stating that the risk-informed Code Cases and Standards developed by ASME should not be directly referenced in the rule, but that there should be a framework developed to ensure that the Code Cases are used, and that partial use does not occur. The proposed rule permits, but does not require, use of the Code Cases for purposes of meeting rule requirements. The Commission notes that these Code Cases cover both categorization and treatment requirements in the areas of inservice inspection, inservice testing, and repair/replacement. The Commission expects licensees will utilize the ASME Code Cases as part of their implementation of § 50.69.

Another commenter stated that the rule should be made applicable to applicants as well as license holders, and NRC agreed that this was appropriate and made revisions to the rule language to accommodate this. Another commenter stated that the wording of the requirement to “assure risk is small from changes to treatment” set an impossible standard, and that the rule wording should be revised to allow use of sensitivity studies to provide confidence that the risk is small. The NRC agreed with this comment and revised the rule wording in the manner suggested that the licensee provide reasonable confidence that the increase in risk is small through performance of appropriate evaluations, such as sensitivity studies for SSCs modeled in the PRA.

A commenter thought it was unnecessary to require that a schedule or scope of systems to be categorized be part of the submittal. It was noted that implementation of the rule would of necessity occur over time, and that existing requirements would remain in effect until SSCs were categorized. Thus, the commenter felt that a licensee should not be held to any particular schedule for implementation. The NRC’s intent in requesting a schedule and scope was for informational purposes to know what requirements would be in effect, but agrees that a firm commitment to a schedule is not required. This part of the rule was removed, and instead there is a requirement to update the FSAR, in accordance with § 50.71(e), to reflect implementation as it occurs for particular systems.

IV.3.0 Pilot plants.

To aid in the development of the proposed rule and associated implementation guidance, several plants volunteered to conduct pilot activities with the objective of exercising the proposed NEI implementation guidance and using the feedback and lessons-learned to improve both the implementation guidance and the governing regulatory framework. The pilot effort was supported by three of the industry owners groups who identified pilots for their reactor types and participated by piloting sample systems using the draft NEI implementation guidance. Supporting the pilot effort were the Westinghouse Owners Group with lead plants Wolf Creek and Surry, the BWR Owners Group with lead plant Quad Cities, and the CE Owners Group with lead plant Palo Verde. The B&W Owners Group did not participate, but did follow the pilot activities.

The NRC staff's participation and principal point of interaction in the pilot effort was primarily in observation of the deliberations of the integrated decision-making panel (IDP). By observing the IDP, the NRC staff was able to view the culmination of the categorization effort and gain good insights regarding both the robustness of the categorization process in general, and the IDP decision-making process specifically. Following each of the pilot IDPs, the staff developed and issued a trip report containing the staff's observations.

The following points set forth the principal lessons learned and key feedback from the NRC staff's observations of the pilot activities.

! Potential treatment changes and their potential effects need to be understood by the IDP as part of the deliberations on categorization.

! The pilots showed the importance of documentation of the IDP decisions and the basis. The rule contains a requirement for the categorization basis to be documented (and records retained) in § 50.69(f).

- The pilots experienced difficulty in explicit consideration about safety margins, especially in view of the fact that functionality must be retained. In the first draft rule language posted, requirements were included for the IDP to consider safety margins in its deliberations. Based upon the pilot experience, NRC adjusted its approach to margins to include this in the section of the rule that requires consideration of effects of changes in treatment and the use of evaluations as the means of providing reasonable confidence safety margins are maintained.
- The need for a number of improvements to the implementation guidance in NEI 00-04 were noted, for instance, improvement in a defense-in-depth matrix presented therein, and the need for more specific guidance on making decisions where quantitative information is not available. These lessons-learned were factored into the revised version of NEI 00-04.
- During the pilot activity, pressure boundary ("passive") functions were also categorized using the draft version of an ASME Code Case on categorization available at that time. A separate categorization process was used for these passive functions because it was recognized by pilot participants that the approach for these SSCs must be somewhat different than for "active" functions because of such considerations as spatial interaction. Specifically, if a pressure boundary SSC failed, the resulting high-energy release or flooding might impact other equipment in physical proximity, so the process needed to account for those effects in addition to the significance of the SSC that initially failed. Improvements to the ASME Code Case for categorization of piping (and related components) were identified and fed back into the code development process.
- The pilot experiences also revealed the intricacies of the relationship between "functions" (which play a role in decisions on safety significance) and

"components" (importance measures are associated with components and treatment is also generally applied on a component basis). Because a particular component may support more than one function, the categorization of the component needs to correspond with the most significant function and means must be provided for a licensee to "map" the components to the functions they support.

- At each pilot, the NRC noted that the IDP needed to include consideration of long term containment heat removal in characterizing SSCs. The NRC considers retention of long term containment heat removal capability important to defense-in-depth for light water reactors.
- Finally, a number of lessons were learned about how to conduct the IDP process, such as training needs, materials to be provided to the panel, etc. As a result of this feedback, NEI revised NEI 00-04 and developed draft revision C of the implementation guidance (discussed in section VII).

IV.4.0 South Texas Exemption as Proof of Concept.

A major element of the rulemaking plan described in SECY-99-256 was the review of the South Texas Project Nuclear Operating Company (STPNOC) exemption request. The review of the STPNOC exemption request was viewed as a proof-of-concept prototype for this rulemaking rather than a pilot because it preceded development of draft rule language or related implementation guidance.

By letter dated July 13, 1999, STPNOC requested approval of exemption requests to enable implementation of processes for categorizing the safety significance of SSCs and treatment of those SSCs consistent with its categorization process. The STPNOC process included many similar elements to that described in this rulemaking, but with some differences. Their process identified SSCs as being either high, medium, low or not risk-significant. The scope of the exemptions requested included only those safety-related SSCs that have been categorized as low safety-significant or as nonrisk significant using STPNOC's categorization process. The licensee indicated that the categorization and treatment processes would be implemented over the remaining licensed period of the facility. Thus, the basis for the exemptions granted was the staff's approval of the licensee's categorization process and alternative treatment elements, rather than a comprehensive review of the final categorization and treatment of each SSC (review of the process rather than the results is also the approach planned under the rulemaking). As a result of discussions with the NRC staff on a number of topics, STPNOC submitted a revised exemption request on August 31, 2000.

On November 15, 2000, the NRC staff issued a draft safety evaluation (SE), based on the revised exemption requests. Following the licensee's response to the draft SE, the staff prepared SECY-01-0103 dated June 12, 2001, to inform the Commission of the staff's finding regarding the STPNOC exemption review. The staff approved the STPNOC exemption requests by letter dated August 3, 2001 (ADAMS accession number ML011990368).

The NRC has applied lessons learned from the review of the STPNOC exemption request in developing proposed § 50.69 and the description of intended implementation of the rule in this SOC. For example, in the STPNOC review, the NRC staff reviewed the categorization process proposed by the licensee in detail. With respect to proposed § 50.69, the NRC continues to require a robust categorization with a detailed staff review.

The proposed rule specifies the requirement that the licensee provide reasonable confidence in functionality and further specifies some high-level requirements for SSC treatment. Under proposed § 50.69, the NRC does not plan to review each licensee's plan for SSC treatment in detail.   Licensees will have to establish appropriate performance-based SSC treatment processes to maintain the validity of the categorization process and its results. The proposed rule would require that licensees adjust the categorization or treatment processes, as appropriate, in response to the SSC performance information obtained as part of the treatment process.

V. Section by Section Analysis

V.1.0 Section 50.8 Information Collection.

This proposed rule includes a revision to § 50.8(b). This section pertains to approval by the Office of Management and Budget (OMB) of information collection requirements associated with particular NRC requirements. Since the new § 50.69 includes information collection requirements, a conforming change to § 50.8(b) is necessary to list § 50.69 as one of these rules. See also Section XIV of the SOC for discussion about information collection requirements of § 50.69.

V.2.0 Section 50.69(a) Definitions.

Section 50.69(a) provides the definition for the four RISC categories and the definition of the term "safety-significant function." As discussed in section II of the SOC, RISC-1 SSCs are those SSCs that are safety-related (as defined in § 50.2) and that are found to be safety-significant (using the risk-informed categorization process being established by this rule). RISC-2 SSCs are SSCs that do not meet the safety-related definition, but which are safety-significant. RISC-3 SSCs are safety-related but are low safety-significant. Finally, RISC-4 SSCs are not safety-related and are low safety-significant. The NRC selected the terms "safety-significant" and "low safety-significant" as the best representations of their meaning. Every component (if categorized) is either safety-significant or low safety-significant. The "low" category could include those SSCs that have no safety significance, as well as some SSCs that individually are not safety-significant, but collectively can have a significant impact on plant safety (and hence the need for maintaining the design basis capability of these SSCs). Similarly, within the category of "safety-significant," some SSCs are of more importance than others; so it did not appear appropriate to call them all "high safety-significant." The RISC definitions of paragraph (a) are used in subsequent paragraphs of § 50.69 where the treatment requirements are applied to SSCs as a function of RISC category.

The definitions provided in paragraph (a) are written in terms of SSCs that perform functions. In the categorization process, it is the various functions performed by systems that are assessed to determine their safety significance. For those functions of significance, the structures and components that support that function are then designated as being of that RISC category. Then, the treatment requirements are specified for the SSCs that perform those functions. Where an SSC performs functions that fall in more than one category, the treatment requirements derive from the more safety-significant function (i.e., if a component has both a RISC-1 and a RISC-3 function, it is treated as RISC-1).

The rule also contains a definition of "safety-significant" function. NRC selected the term "safety-significant" instead of "risk-significant" because the categorization process employed in § 50.69 considers both probabilistic and deterministic information in the decision process. Thus, it is more accurate to represent the outcome as a determination of overall safety significance, including risk significance, and not just "risk-significant."

Those functions that are not determined to be safety-significant are considered to be low safety-significant. The determination as to which functions are safety-significant is done by following the categorization process outlined in paragraph (c), as implemented following the guidance in DG-1121, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance."

V.3.0 Section 50.69(b) Applicability.

Section (b) of § 50.69 provides that § 50.69 may be voluntarily implemented by:

Holders of §50.21(b) or §50.22 light water reactor (LWR) operating licenses; holders of Part 54 renewed LWR licenses; a person seeking a design certification under Part 52 of this chapter; or applicants for a LWR license under §50.22 or under Part 52.

For current licensees, implementation will be through a license amendment as set forth in § 50.90. Until the request is approved, a licensee would continue to follow existing requirements. Upon approval of the categorization process (and review of the supporting PRA), the licensee can begin implementation by performing categorization of SSCs and revising treatment requirements accordingly.

Applicants would be permitted to implement the treatment requirements, although the process involved for them would likely be different, depending upon the stage at which they seek approval. An applicant would have to categorize its SSCs into the four RISC categories, which would first require the applicant to design the facility to meet the Part 50 requirements including classifying SSCs according to the safety-related definition of Part 50. The applicant could then use the provisions of § 50.69 (upon NRC approval) to categorize SSCs into the four RISC categories, and this in turn would enable the applicant to initially procure these SSCs to meet the applicable § 50.69 requirements.

For Part 54 license holders, implementation is the same as that for a holder of an operating license under Part 50, that is, to apply for an amendment to the (renewed) license. In the development of § 50.69, questions have been received regarding what would be the impact to licensees that implement the proposed § 50.69 and then apply to renew their license. Because Part 54 includes scoping criteria that bring safety-related components within its scope, these components could not be exempted without amending Part 54 to allow for their exclusion. However, there are still options available to applicants for renewal that have implemented § 50.69 first. Because § 50.69 includes alternative treatment requirements for RISC-3 components, an applicant may be able to provide an evaluation that justifies why these alternative treatment criteria (§ 50.69(d)(2)) provide a sufficient demonstration that aging management of the components will be achieved during the renewal period to ensure the functionality of the structure, system, or component. In addition, in the 1995 amendment to Part 54, the Commission recognized that risk insights could be used in evaluating the robustness of an aging management program. The NRC staff has already received and accepted one proposal (Arkansas Unit 1) for a risk-informed program for small-bore piping which demonstrates that risk arguments can be used to a degree.

For the case where a licensee renewed its license first and then implemented § 50.69, a licensee might revise some aging management programs for RISC-3 SSCs, consistent with the requirements of § 50.69. The Commission considers that there should be little or no impediment for doing so because the categorization process that allows for the reduction in the special treatment requirements for RISC-3 components is expected to provide an appropriate level of safety for the respective structures, systems and components.

Adopting the proposed § 50.69 requirements for an applicant that has not obtained a § 50.21(b) or § 50.22 operating license (e.g. for a construction permit holder), is not as straightforward, and requires that the applicant first design the facility to meet the current Part 50 requirements. Specifically, to use the proposed § 50.69 requirements requires that SSCs first be classified into the traditional safety-related and nonsafety-related classifications. This establishes the design basis for the facility, which as previously stated, the proposed § 50.69 is not changing. Once the SSC categorization has been done consistent with the safety-related definition in § 50.2, then proposed § 50.69 can be used to re-categorize SSCs into RISC-1, RISC-2, RISC-3, and RISC-4, and the alternative treatment requirements of proposed § 50.69 implemented. A new applicant who chooses to adopt these proposed § 50.69 requirements, must seek approval of the categorization process as part of its license application, and following NRC approval, would be able to procure RISC-3 SSCs to proposed § 50.69 requirements before initial plant operation. An applicant who references a certified design and wishes to implement § 50.69 would include the specified information as part of its application for a license. This does not mean that an applicant would actually construct the facility per all Part 50, and 100 requirements first, before applying § 50.69. Instead, the facility needs to be designed per these requirements, but following approval of application of § 50.69, RISC-3 SSCs could be procured per the requirements of § 50.69(d).

The rule provisions were devised to provide means for licensees and applicants for light water reactors to implement § 50.69. In view of some of the specific provisions of the rule, for example, “safety-related” definition and use of CDF/LERF metrics, the Commission is making this rule only applicable to light-water reactor designs.

An applicant for a design certification could request to implement § 50.69 with respect to categorizing SSCs. Because the rule requirements in § 50.69 include elements of procurement and installation, as well as inservice activities, implementation of the rule by a holder of a manufacturing license or by a design certification applicant would have implications for the eventual operator of the facility. The entity that actually constructs and operates the facility would also have to implement § 50.69 to maintain consistency with the categorization process and feedback requirements. Otherwise, the operator would be required to meet other Part 50 requirements, such as Appendix B or § 50.55a, which may not be compatible with the facility as manufactured by the manufacturing licensee. However, applicability of this proposed rule is not excluded for manufacturing licenses or design certificate applicants.

V.3.1 Section 50.69(b)(1) Removal of RISC-3 and RISC-4 SSCs From the Scope of Treatment Requirements.

Section 50.69 (b)(1) of the proposed rule lists the specific special treatment requirements from whose scope the RISC-3 and RISC-4 SSCs are being removed through the application of § 50.69. In this paragraph, each of the rule requirements (or portions thereof) that are being removed by this rulemaking are listed in a separate item, numbered from § 50.69(b)(1)(i) through (ix). The basis for removal of each of these requirements was discussed earlier. These requirements are being removed due to the low safety significance of RISC-3 and RISC-4 SSCs as determined by an approved risk-informed categorization process meeting the requirements of § 50.69(c). The special treatment requirements for RISC-3 SSCs are replaced with the high level requirements in § 50.69(d)(2), which when effectively implemented by licensees to provide a sufficient level of confidence that RISC-3 SSCs continue to be capable of performing their safety-related functions under design basis conditions. Note that special treatment requirements are not removed from any SSCs until a licensee (or applicant) has categorized those SSCs using the requirements of § 50.69(c) to provide the documented basis for the decision that they are of low safety significance.

V.3.2 Section 50.69 (b)(2) Application Process.

Proposed § 50.69(b)(2) would require a licensee who voluntarily seeks to implement § 50.69 to submit an application for a license amendment pursuant to § 50.90 that contains the following information:

(i) A description of the categorization process that meets the requirements of § 50.69(c).

(ii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific PRA, margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for the categorization of SSCs.

(iii) Results of the PRA review process to be conducted to meet § 50.69(c)(1)(i).

(iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy § 50.69(c)(1)(iv). The evaluations shall include the effects of common cause interaction susceptibility, and the potential impacts from known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions).

Regarding the categorization process description, the NRC expects that most licensees and applicants will commit to draft regulatory guide DG-1121 which endorses NEI 00-04, with some conditions and exceptions. If a licensee or applicant wishes to use a different approach, the submittal would need to provide sufficient description of how the categorization would be conducted. As part of the submittal, a licensee or applicant is to describe the measures they have taken to assure that the plant-specific PRA, as well as other methods used, are adequate for application to proposed § 50.69. The measures described would include such items as any peer reviews performed, any actions taken to address peer review findings that are important to categorization, and any efforts to compare the plant-specific PRA to the ASME PRA standard. The NRC has developed reviewer guidance applicable to these submittals and this is described below in section VII.2. The licensee/applicant would also describe what measures they have used for the methods other than a PRA to determine their adequacy for this application.

Further, the licensee (or applicant) would be required to include information about the evaluations they intend to conduct to provide reasonable confidence that the increase in risk would be small. This would include any sensitivity studies for RISC-3 SSCs, including the basis for whatever change in reliability being assumed for these analyses. A licensee would need to provide sufficient information for the NRC describing the sensitivity studies and other evaluations, and the basis for their acceptability as appropriately representing the potential increase in risk from implementation of the revised requirements in this proposed rule.

As discussed elsewhere, the RISC-3 SSCs have low safety significance under § 50.69. The Commission expects licensees and applicants to implement effective treatment processes to maintain RISC-3 functionality that comply with § 50.69(d). Those processes do not need to be described to the NRC as part of the proposed § 50.69 submittal under § 50.69(b)(2).

V.3.3 Approval for Licensees.

Section 50.69(b)(3) would further provide that the Commission will approve a licensee's implementation of this section by license amendment upon its determination that the proposed process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs satisfies the requirements of § 50.69(c).

The NRC will review the description of the categorization process set forth in the application to confirm that it contains the elements required by the rule. Further, the NRC will review the information provided about the plant-specific PRA, including the peer review process to which it was subjected, and methods other than a PRA relied upon in the categorization process.

The NRC intends to use review guidance (discussed in more detail in section VII) for this purpose. The NRC will approve the licensee's use of § 50.69 by issuing a license amendment.

V.3.4 Process for Applicants.

Section 50.69(b)(4) would require that an applicant for a license (or for a design certification) that chooses to implement proposed § 50.69 must submit the information listed in § 50.69(b)(2) as part of its application for a license. As previously discussed, the rule is structured to transition from the "safety-related" classification (and related treatment requirements) to a safety-significant classification. Thus, an applicant would first need to design the facility to meet applicable Part 50 design requirements, and then apply the requirements of § 50.69. The above-cited information must be submitted in addition to other technical information necessary to meet § 50.34. The NRC will provide its approval of implementation of § 50.69, if it concludes that the rule requirements would be met, as part of its action on the application for a license or the design certification rule. As noted in section V.3.0, an applicant referencing a certified design that implemented § 50.69 would need to adopt the remaining provisions of § 50.69 or apply the other requirements in Part 50 to its processes.

V.4.0 Section 50.69(c) Categorization Process Requirements.

Section 50.69(c) would establish the requirements for the risk-informed categorization process including requirements for the supporting PRA. Licensees or applicants who wish to adopt the requirements of § 50.69 will need to make a submittal (per § 50.69(b)(2) or § 50.69(b)(4)) that discusses how their proposed categorization process, supporting PRA, and evaluations meet the paragraph (c) requirements. As described above in section III.2.0, these requirements are intended to ensure that the risk-informed § 50.69 categorization process determines the safety significance of SSCs with a high level of confidence. The introductory paragraph states that SSCs must be categorized as RISC-1, 2, 3, or 4 by a process that detemines whether the SSC performs one or more safety-significant functions and identifies those functions.

V.4.1 Section 50.69(c)(1)(i) Results and Insights from a Plant-Specific Probabilistic Risk Assessment.

Section 50.69(c)(1)(i) contains the requirements for the PRA itself, and how it is to be used in the categorization process. The PRA must have sufficient capability and quality to support the categorization of the SSCs. How this is to be accomplished is discussed in section V.4.1.1. The PRA and associated sensitivity studies are used primarily in the categorization of the SSCs as to their safety significance as discussed in section V.4.1.2, and the PRA is also used to perform evaluations to assess the potential risk impact of the proposed change in treatment of the RISC-3 SSCs as discussed in section V.4.4.

V.4.1.1 Scope, Capability, and Quality of the PRA to Support the Categorization Process.

As required in paragraph (c)(1)(ii), initiating events from sources both internal and external to the plant, and for all modes of operation, which would include low power and shutdown modes, must be considered when performing the categorization of SSCs. It is recognized that few licensees have fully developed PRA models that cover such a scope. However, as a minimum, the PRA to be used to support categorization under § 50.69(c)(1) must model internal initiating events occurring at full power operations. The PRA will have to be able to calculate both core damage frequency and large early release frequency in order to meet the requirement in § 50.69(c)(iv). The PRA must reasonably represent the current configuration and operating practices at the plant to meet § 50.69(c)(1)(ii). The PRA model should be of sufficient technical quality and level of detail to support the categorization process. This means that it represents a coherent, integrated model, and have sufficient detail to support the initial categorization of SSCs into the safety-significant, and low safety-significant categories.

The quality and scope of the plant-specific PRA will be assessed by the NRC taking into account appropriate standards and peer review results. The NRC has also prepared a draft regulatory guide (DG-1122) on determining the technical adequacy of PRA results for risk-informed activities. As one step in the assurance of technical quality, the PRA must have been subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC. Thus, the NRC staff would use the NEI Peer Review Process as modified in the NRC's approval, or the ASME/ANS Peer Review Process, as modified in the NRC's approval. As discussed in section VII, NRC has developed review guidelines for considering the sufficiency of a PRA that was subjected to the NEI peer review process, as it would be used in implementation of § 50.69. The submittal requirements listed in § 50.69(b)(2) include a requirement to provide information about the quality of the PRA analysis and about the peer review results.

V.4.1.2 Risk Categorization Process Based on PRA Information.

For SSCs modeled in the PRA, the categorization process relies on the use of importance measures as a screening method to assign the preliminary safety significance of SSCs. (Other methodologies such as success path identification methodologies can also be used, however, this discussion will focus on the use of importance measures because these are the most commonly used tools to identify safety significance of SSCs, for example, in the implementation of § 50.65.) In addition to being a useful tool to help prioritize NRC staff and licensee resources, use of importance measures can provide a systematic means to identify improvements to current plant practices. The determination of the safety significance of SSCs by importance measures is also important because it can identify potential risk outliers and therefore, changes that exacerbate these outliers can be avoided; and it can facilitate IDP deliberations of SSCs that are not modeled in the PRA, for example, events from the ranked list can be used as surrogates for those SSCs that are not modeled or are only implicitly modeled in the PRA.

For SSCs modeled in the PRA, SSC importance must be determined based on both CDF and LERF. Importance measures should be chosen so that results can provide the IDP with information on the relative contribution of an SSC to total risk. Examples of importance measures that can accomplish this are the Fussell-Vesely (F-V) importance and the Risk Reduction Worth (RRW) importance. Importance measures should also be used to provide the IDP with information on the margin available should an SSC fail to function. The Risk Achievement Worth (RAW) importance and the Birnbaum importance are example measures that are suitable for this purpose.

In choosing screening criteria to be used with the PRA importance measures, it should be noted that importance measures do not directly relate to changes in the absolute value of risk. Therefore, the final criteria for categorizing SSCs into the safety-significant and the low safety-significant categories must be based on an assessment of the potential overall impact of SSC categorization and a comparison of this potential impact to the acceptance criteria for changes in CDF and LERF. However, typically in the initial screening stages, an SSC with F-V < 0.005 based on CDF and LERF, and RAW < 2 based on CDF and LERF can be considered as potentially low safety-significant. IDP consideration of §§ 50.69(c)(1)(ii), (c)(1)(iii), and (c)(1)(iv) should be carried out to confirm the low safety significance of these SSCs.

In determining the importance of SSCs, consideration should be given to the potential for the multiple failure modes for the SSC. PRA basic events represent specific failure events and failure modes of SSCs. The calculation of SSC importance should take into account the combined effects of all associated basic PRA events (such as failure to start and failure to run), including indirect contributions through associated common cause failure (CCF) event probabilities.

Another concern that arises because importance measures are typically evaluated on the basis of individual events is that single-event importance measures have the potential to dismiss all elements of a system or group, despite the system or group having a high importance when taken as a whole. (Conversely, there may be grounds for screening out groups of SSCs, owing to the unimportance of the systems of which they are elements.) One approach around this problem is to first determine the importance of system functions performed by the selected plant systems. If necessary, each component in a system is then evaluated to identify the system function(s) supported by that component. SSCs may be initially assigned the same category as the most limiting system function they support. System operating configuration, reliability history, recovery time available, and other factors can then be considered when evaluating the effect on categorization from an SSC's redundancy or diversity. The primary consideration in the process is whether the failure of an SSC will fail or severely degrade the safety function. If the answer is no, then a licensee may factor into the categorization the SSC's redundancy, as long as the SSC's reliability assumed in the categorization process and that of its redundant counterpart(s) have been taken into account.

When the PRA used in the importance analyses includes models for external initiating events and/or plant operating modes other than full power, caution should be used when considering the results of the importance calculations. The PRA models for external initiating events (e.g., events initiated by fires or earthquakes), and for low power and shutdown plant operating modes may be more conservative and have a greater degree of uncertainty than for internal initiating events. Use of conservative models can influence the calculation of importance measures by moving more SSCs into the low safety significance category. Therefore, when PRA models for external event initiators and for the low power and shutdown modes of operation are available, the importance measures should be evaluated for each analysis separately, and the results of the analyses should be provided to the IDP.

As part of the demonstration of PRA adequacy, the sensitivity of SSC importance to uncertainties in the parameter values for component availability/reliability, human error probabilities, and CCF probabilities should be evaluated. Results of these sensitivity analyses should be provided to the IDP. In IDP deliberations on the sensitivity study results, the following should be considered:

(1) The change in event importance when the parameter value is varied over its uncertainty range for the event probability can in some cases provide SSC categorization results that are different. Therefore, in considering the sensitivity of component categorization to uncertainties in the parameter values, the IDP should ensure that SSC categorization is not affected by data uncertainties.

(2) PRAs typically model recovery actions, especially for dominant accident sequences. Estimating the success probability for the recovery actions involves a certain degree of subjectivity. The concerns in this case stem from situations where very high success probabilities are assigned to a sequence, resulting in related components being ranked as low risk contributors. Furthermore, it is not desirable for the categorization of SSCs to be impacted by recovery actions that sometimes are only modeled for the dominant scenarios. Sensitivity analyses should be used to show how the SSC categorization would change if recovery actions were removed. The IDP should ensure that the categorization is not unduly impacted by the modeling of recovery actions.

(3) CCFs are modeled in PRAs to account for dependent failures of redundant components within a system. CCF probabilities can impact PRA results by enhancing or obscuring the importance of components. A component may be ranked as a high risk contributor mainly because of its contribution to CCFs, or a component may be ranked as a low risk contributor mainly because it has negligible or no contribution to CCFs. The IDP should ensure that the categorization is not unduly impacted by the modeling of CCFs. The IDP should also be aware that removing or relaxing requirements may increase the CCF contribution, thereby changing the risk impact of an SSC.

V.4.2 Section 50.69(c)(1)(ii) Integrated Assessment of SSC Function Importance.

Section 50.69(c)(1)(ii) contains requirements for an integrated, systematic process to address events including those not modeled in the PRA, including both design basis and severe accident functions. For various reasons, many SSCs in the plant will not be modeled explicitly in the PRA. Therefore, the categorization process must determine the safety significance of these SSCs by other means, as discussed below. Because importance measures are not available for use as screening, other criteria or considerations must be used by the IDP to determine the significance. To provide the necessary structure, the Commission is setting forth guidance on how these deliberations should be conducted; this information will also be included in the regulatory guidance for this proposed rule. These considerations were selected based upon NRC experience about what functions are important to prevention of core damage or large early release.

The proposed rule would also include requirements that all aspects of the processes used to categorize SSC must reasonably reflect the current plant configuration, operating practices and applicable operating experience. The terminology of "reasonably reflect" was selected to allow for appropriate PRA modeling and also to make clear that the PRA and processes do not need to be instantaneously revised when a plant change occurs (see also requirements in § 50.69(e)(1) on PRA updating).

V.4.2.1 Initiating Events and Plant Operating Modes not Modeled in the PRA.

When initiating events with frequencies of greater than 10^{-6} per year are not modeled in the PRA, or when the low power and shutdown plant operating modes are not modeled in the PRA, other means are needed to determine the safety significance to meet § 50.69(c)(1). The proposed implementation guidance contains information about how this can be accomplished by the IDP assessments. The licensee should demonstrate that the relaxation of regulatory requirements will not unacceptably degrade plant response capability and will not introduce risk vulnerabilities for the unmodeled initiating events or plant operating modes. For these unmodeled events, the IDP assessment should consider whether an SSC has an impact on the plant's capability to:

(1) Prevent or mitigate accident conditions,

(2) Reach and/or maintain safe shutdown conditions,

(3) Preserve the reactor coolant system pressure boundary integrity,

(4) Maintain containment integrity, or

(5) Allow monitoring of post-accident conditions.

In determining the importance of SSCs for each of these functions, the following factors should be considered:

- Safety function being satisfied by SSC operation
- Level of redundancy existing at the plant to fulfill the SSC's function
- Ability to recover from a failure of the SSC
- Performance history of the SSC
- Use of the SSC in the Emergency Operating Procedures or Severe Accident Management Guidelines

The licensee or applicant (through the IDP) must document the basis for the assignment of an SSC as RISC-3 based on the above considerations. Insights and results from risk assessment and risk management methodologies (for example the fire and external events screening methodologies, the seismic margins analyses, or the shutdown safety management models) may be used to help form this basis.

V.4.2.2 SSCs not Modeled in the PRA.

In addition to being safety-significant in terms of their contribution to CDF or LERF, SSCs can also be safety-significant in terms of other risk metrics or conditions. Therefore, for SSCs not modeled explicitly in the PRA, the IDP should verify low safety significance based on traditional engineering analyses and insights, operational experience, and information from licensing basis documents and design basis accident analyses. The IDP should assess the safety significance of these SSCs by determining if:

(1) Failure of the SSC will significantly increase the frequency of an initiating event, including those initiating events originally screened out in the PRA.

(2) Failure of the SSC will compromise the integrity of the reactor coolant pressure boundary. It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

(3) Failure of the SSC will fail a safety-significant function, including SSCs that are assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems, and instrumentation and control systems). For example, it is expected for PWRs that a sufficiently robust categorization process would categorize high energy ASME Section III Class 2 piping of the main steam and feedwater systems as RISC-1.

(4) The SSC supports important operator actions required to mitigate an accident, including the operator actions taken credit for in the PRA.

(5) Failure of the SSC will result in failure of safety-significant SSCs (e.g., through spatial interactions or through functional reliance on another SSC).

(6) Failure of the SSC will impact the plant's capability to reach and/or maintain safe shutdown conditions.

(7) The SSC is one of a redundant set that can be justifiably identified as a common cause failure group.

(8) The SSC is a part of a system that acts as a barrier to fission product release during severe accidents. It is expected that a sufficiently robust categorization process would result in fission product barriers (e.g., the containment shell or liner) being categorized as RISC-1.

(9) The SSC is depended upon in the Emergency Operating Procedures or the Severe Accident Management Guidelines.

(10) Failure of the SSC will result in unintentional releases of radioactive material in excess of 10 CFR Part 100 guidelines even in the absence of severe accident conditions.

(11) The SSC is relied upon to control or to mitigate the consequences of transients and accidents.

If any of these conditions is true, the IDP should use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation should include identifying the functions being supported by SSC operation, the relationship between the SSC's failure modes and the functions being supported, the SSC failure modes for which the failure rate may increase, and the SSC failure modes for which detection could become or are more difficult. The IDP can then justify low safety significance of the SSC by demonstrating the following:

! The categorization is consistent with the defense-in-depth philosophy (per section V.4.3 below).

! Operating experience indicates that degradation mechanisms (e.g., for piping flow accelerated corrosion or microbiologically-induced corrosion), for passive and active SSCs are not present, relaxing the requirements will have minimal impact on the failure rate increase, and degradation in the ability of the SSC to perform its safety function can be detected in a timely fashion

! Relaxing the requirements will have a minimal impact on the expected onsite occupational or offsite doses from transients and accidents that do not contribute to CDF or LERF.

V.4.3 Section 50.69(c)(1)(iii) Maintaining Defense-in-Depth Philosophy.

Section 50.69(c)(1)(iii) requires that the categorization process maintain the defense-in-depth philosophy. To satisfy this requirement, when categorizing SSCs as low safety- significant, the IDP must demonstrate that the defense-in-depth philosophy is maintained. Defense-in-depth is considered adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure the risk acceptance guidelines discussed below in section V.4.4 are met, and that:

- Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release
- System redundancy, independence, and diversity is preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters
- There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design, and
- Potential for common cause failures is taken into account

The Commission's position is that the containment and its systems are important in the preservation of the defense-in-depth philosophy (in terms of both large early and large late releases). Therefore, as part of meeting the defense-in-depth principle, a licensee should demonstrate that the function of the containment as a barrier (including fission product retention and removal) is not significantly degraded when SSCs that support the functions are moved to RISC-3 (e.g., containment isolation or containment heat removal systems). The concepts used to address defense-in-depth for functions required to prevent core damage may also be useful in addressing issues related to those SSCs that are required to preserve long-term containment integrity. One way to do this would be to show that these SSCs are not relied on to prevent late containment failure during core damage accidents. An alternative method would be to demonstrate that a potential decrease in reliability of RISC-3 SSCs that support the containment function does not have significant impact on the estimate of late containment failure probability. In essence, what the NRC expects is for a plant-specific understanding of the effects of containment systems on large late releases and an understanding of the credit given to these systems in maintaining the conditional probability for these releases. A licensee or applicant can qualitatively argue that an SSC is not relied upon to prevent large late containment failure and is thus low safety-significant from this standpoint. If an SSC plays a role in supporting the containment function in terms of large late releases, and if the licensee wants to categorize these SSCs as low safety-significant (for example, because of available redundant systems or trains or because failure is dominated by factors not related to the SSC), NRC would find acceptable the use of sensitivity studies to show that the effects on (i.e., change in) the late containment failure probability is small (i.e., less than a 10 percent increase from the base value) and that factors such as common cause failures or other dependencies are not important.   Where a licensee categorizes containment isolation valves or penetrations as RISC-3, the licensee will need to address the impact of the proposed change in treatment on a case-by-case basis to ensure that the defense-in-depth principle continues to be satisfied.

V.4.4 Section 50.69(c)(1)(iv) Include evaluations to provide reasonable confidence that sufficient safety margins are maintained and that any potential increases in CDF and LERF resulting from changes in treatment permitted by implementation of § 50.69(b)(1) and § 50.69(d)(2) are small.

Section 50.69(c)(1)(iv) specifies that the categorization process include evaluations to provide reasonable confidence that as a result of implementation of revised treatment permitted for RISC-3 SSC, sufficient safety margins are maintained and any potential increases in CDF and LERF are small. Safety margins can be maintained if the licensee maintains the functionality of the SSCs following implementation of the revised requirements and if periodic maintenance, inspection, tests, and surveillance activities are adequate to prevent, detect and correct significant SSC performance and reliability degradation. Later sections of this SOC provide discussion on the proposed treatment processes the licensee will implement to provide reasonable confidence that RISC-3 SSCs remain capable of performing their safety functions under design basis conditions. The requirements of the rule to show that sufficient safety margins are maintained and that potential increases in risk are small are discussed below.

As part of their submittal, a licensee (or applicant) is to describe the evaluations to be conducted for purposes of meeting the requirement that there would be no more than a small (potential) increase in risk. For SSCs included in the PRA, the Commission expects that sensitivity studies (evaluations) would be done to provide a basis for concluding that even if reliability of these SSC should degrade because of the changes in treatment, the potential risk increase would be small. Satisfying the rule requirement that the risk increase is small presumes that the increase in failure rates assumed in the PRA sensitivity study bounds any reasonable estimate of the increase that may be expected as a result of the proposed changes in treatment.

The categorization process encompasses both active and passive functions of SSCs. Paragraph 50.69(b)(2)(iv) includes the requirement that the change-in-risk evaluations performed to satisfy § 50.69(c)(1)(iv) must include potential impacts from known degradation mechanisms on both active and passive functions. It is necessary for a licensee to consider the impact that a change in treatment (as a result of removal of special treatment requirements) might have on the ability of the SSC to perform its design basis function and on reliability of SSCs. The purpose is to provide an understanding of the new treatment requirements and their effects on RISC-3 SSCs due to removal of special treatment requirements. This will help form the basis for the change-in-risk evaluations and will support developing a technical basis for concluding that SSC performance is consistent with the categorization process and its results and with those evaluations performed to show that there is a no more than a small increase in risk associated with implementation of § 50.69. The basis supporting the evaluations that examine potential SSC reliability changes due to treatment changes may be either qualitative or quantitative.

One mechanism that could lead to large increases in CDF/LERF is extensive, across system common cause failures. However, for such extensive CCFs to occur would require that the mechanisms that lead to failure, in the absence of special treatment, were sufficiently rapidly developing or are not self-revealing that there would be few opportunities for early detection and corrective action. Thus, when deciding how much to assume that SSC reliability might change, the applicant or licensee is expected to consider potential effects of common-cause interaction susceptibility, including cross-system interactions and potential impacts from known degradation mechanisms.

Those aspects of treatment that are necessary to prevent SSC degradation or failure from known degradation mechanisms, to the extent that the results of the evaluations are invalidated, must be retained. Identifying those aspects will involve an understanding of what the degradation mechanisms are and what elements of treatment are sufficient to prevent the degradation. As an example of how this would be implemented, the known existence of certain degradation mechanisms affecting pressure boundary SSC integrity might support retaining the current requirements on inspections or examinations or use of the risk-informed ASME Code Cases, as accepted by the NRC regulatory process. An alternative might be to relax certain elements of treatment, but retain those that were assessed to be the most effective in negating the degradation mechanisms. As another example, changing levels of treatment on several similar components that might be sensitive to CCF potential would require consideration as to whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective in sufficiently minimizing CCF potential such that the evaluations remain bounding.

The treatment for all RISC-3 SSCs may not need to be the same. As an example, motor operated valves (MOVs) operating in a severe environment (e.g., in the steam tunnel) would be more susceptible to failure because of grease degradation if they were not regularly maintained and tested. However, not all MOVs, even if they have the same design and are identical in other respects, will be exposed to the same environment. Therefore the other MOVs may not be as susceptible to failure as those in the steam tunnel and less frequent maintenance and testing would be acceptable. While it may be simpler to increase the unreliability or unavailability of all the RISC-3 SSCs by a certain bounding factor to demonstrate that the change in risk is small and acceptable, the above example suggests that it may also be appropriate to use different factors for different groups of SSCs depending on the impact of reducing treatment on those SSCs.

Section 50.69(c)(1)(iv) requires that the increase in the overall plant CDF and LERF resulting from potential decreases in the reliability of RISC-3 SSCs as a result of the changes in treatment be small. The rule further requires the licensee (or applicant) to describe the evaluations to be performed to meet this requirement. The Commission regards “small” changes for plants with total baseline CDF of 10^{-4} per year or less to be CDF increases of up to 10^{-5} per year, and plants with total baseline CDF greater than 10^{-4} per year to be CDF increases of up to 10^{-6} per year. However, if there is an indication that the CDF may be considerably higher than 10^{-4} per year, the focus of the licensee should be on finding ways to decrease rather than increase CDF and the licensee may be required to present arguments as to why steps should not be taken to reduce CDF in order for the reduction in special treatment requirements to be considered. For plants with total baseline LERFs of 10^{-5} per year or less, small LERF increases are considered to be up to 10^{-6} per year, and for plants with total baseline LERFs greater than 10^{-5} per year, LERF increases of up to 10^{-7} per year. Similarly, if there is an indication that the LERF may be considerably higher than 10^{-5} per year, the focus of the licensee should be on finding ways to decrease rather than increase LERF and the licensee may be required to present arguments as to why steps should not be taken to reduce LERF in order for the reduction in special treatment requirements to be considered. This is consistent with the guidance in Section 2.2.4 of RG 1.174. It should be noted that this allowed increase shall be applied to the overall categorization process, even for those licensees that will implement §50.69 in a phased manner.

The licensee can choose a factor for the increase on unreliability such that the corrective action and feedback processes discussed in §§ 50.69(d)(2) and 50.69(e)(3) would provide sufficient data to substantiate that the increased unreliability used in the evaluations is not exceeded.

If a PRA model does not exist for the external initiating events or the low power and shutdown operating modes, justification should be provided, on the basis of bounding analyses or qualitative considerations, that the effect on risk (from the unmodeled events or modes of operation) is not significant and that the total effect on risk from modeled and unmodeled events and modes of operation is small, consistent with Section 2.2.4 of RG 1.174.

V.4.5 Section 50.69(c)(1)(v) System or Structure level review.

Section 50.69(c)(1)(v) specifies that the categorization be done at the system or structure level, not for selected components within a system. A licensee or applicant is allowed to implement § 50.69 for a subset of the plant systems and structures (ie., partial implementation) and to phase in implemention over a period of time. However, the implementation, including the categorization process, must address entire systems or structures; not selected components within a system or structure.

V.4.6 Section 50.69(c)(2) Use of Integrated Decision-Making Panel (IDP).

Section 50.69(c)(2) sets forth the requirements for using an IDP to make the determination of safety significance, and for the composition of the IDP. The fundamental requirement for the categorization process (as stated in § 50.69 (c)(1)(ii)) is that it include use of an integrated systematic process. The determination of safety significance of SSCs is to be performed as part of an integrated decision-making process, which uses both risk insights and traditional engineering insights. In categorizing SSCs as low safety-significant, it should be demonstrated that the defense-in-depth philosophy is maintained, that sufficient safety margin is maintained, and that increases in risk (if any) are small. To account for each of these factors and to account for risk insights not found in the plant-specific PRA, § 50.69(c)(2) requires that the final categorization of each SSC be performed using an integrated decision-making panel (IDP). A structured and systematic process using documented criteria shall be used to guide the decision-making process. Categorization is an iterative process based on expert judgment to integrate the qualitative and quantitative elements that impact SSC safety significance. The insights and varied experience of IDP members are relied on to ensure that the final result reflects a comprehensive and justifiable judgment.

The panel must be composed of experienced personnel who possess diverse knowledge and insights in plant design and operation and who are capable in the use of deterministic knowledge and risk insights in making SSC classifications. The NRC places significant reliance on the capability of a licensee to implement a robust categorization process that relies heavily on the skills, knowledge, and experience of the people that implement the process, in particular on the qualification of members of the IDP. The IDP should be composed of a group of at least five experts who collectively have expertise in plant operation, design (mechanical and electrical) engineering, system engineering, safety analysis, and probabilistic risk assessment. At least three members of the IDP should have a minimum of five years experience at the plant, and there should be at least one member of the IDP who has worked on the modeling and updating of the plant-specific PRA for a minimum of three years.

The IDP should be trained in the specific technical aspects and requirements related to the categorization process. Training should address at a minimum the purpose of the categorization; present treatment requirements for SSCs including requirements for design basis events; PRA fundamentals; details of the plant-specific PRA including the modeling, scope, and assumptions, the interpretation of risk importance measures, and the role of sensitivity studies and the change-in-risk-evaluations; and the defense-in-depth philosophy and requirements to maintain this philosophy.

The licensee or applicant (through the IDP) shall document its decision criteria for categorizing SSCs as safety-significant or low safety-significant pursuant to § 50.69(f)(1). Decisions of the IDP should be arrived at by consensus. Differing opinions should be documented and resolved, if possible. If a resolution cannot be achieved concerning the safety significance of an SSC, then the SSC should be classified as safety-significant. SSC categorization shall be revisited by the licensee or applicant (through the IDP) when the PRA is updated or when the other criteria used by the IDP are affected by changes in plant operational data or changes in plant design or plant procedures. Requirements for PRA updating are contained in § 50.69(e)(1).

V.5.0 Section 50.69(d) Requirements for Structures, Systems, and Components.

After SSCs are categorized as either RISC-1, RISC-2, RISC-3, or RISC-4, then the § 50.69(d) requirements, which provide the treatment requirements applicable to each RISC category, are applied. Until a structure or system is categorized using this process, the existing requirements on SSCs in that structure or system are retained. Section 50.69(d) contains two sub-items. The first contains the requirements being imposed on RISC-1 and RISC-2 SSCs. The second section contains the "high-level" requirements that are being added for RISC-3 SSCs to provide necessary confidence that design basis capability will be retained for these SSCs. (The list of existing special treatment requirements that are being removed through this rulemaking for RISC-3 and RISC-4 SSCs is contained in § 50.69(b)(1)).

V.5.1 Section 50.69(d)(1) RISC-1 and RISC-2 Treatment.

Section 50.69 (d)(1) requires that a licensee or applicant ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance. To meet this, a licensee should first evaluate the treatment being applied in light of the credit being taken in the categorization process, with appropriate adjustment of treatment or categorization to achieve consistency as necessary. For SSCs categorized as RISC-1 or RISC-2, all existing applicable requirements continue to apply. This includes any applicable special treatment requirements. The rule language notes that this evaluation is to focus upon those key assumptions in the PRA that relate to performance of particular SSCs. For example, if a relief valve was being credited with capability to relieve water (as opposed to its design condition of steam), such an evaluation would look at whether the component has been designed or otherwise determined to be able to perform as assumed. Other examples might be for the failure rates used in the PRA model. As a general matter, for those SSCs modeled in the PRA, conformance with industry standards on PRAs would also result in such evaluation steps being accomplished in order to help assure the PRA represents the facility.

If a § 50.69 licensee chooses to categorize a selective set of SSCs as RISC-3, and the categorization of SSCs as RISC-3 is based on credit taken for the performance of other plant SSCs (that would be RISC-1 or RISC-2, whether or not these SSCs are within the selective implementation set), then the licensee must ensure that consistency of performance with what was credited in the categorization. (As discussed in section V.4.5, selective implementation of components within a system is not permitted). This applies to credit taken in: 1) PRA models, inputs and assumptions; 2) screening and margin analyses; and 3) IDP deliberations. This implies that the licensee must ensure that the credited (RISC-2) SSCs perform their functions per § 50.69(d)(1), and the performance of these SSCs must be monitored per § 50.69(e)(2).

V.5.2   Section 50.69(d)(2) RISC-3 Treatment.

Section 50.69(d)(2) contains, as an overall requirement for the treatment of RISC-3 SSCs, that licensees shall have processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action, for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout their service life. In other words, the Commission expects licensees to have sufficient treatment controls in place to have reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions if they were called upon to perform those functions. Licensees may decide to apply current practices at their facilities or may establish new practices for the treatment of RISC-3 SSCs, provided the requirements of § 50.69 are satisfied.

During its review of the South Texas exemption request, the NRC staff identified several instances where the licensee's interpretation of the extent to which treatment could be relaxed for low-risk safety-related SSCs was not consistent with the staff's expectations under Option 2 of the NRC's risk-informed rulemaking initiative (i.e., that design basis functions be maintained). To ensure more consistent implementation of § 50.69, the SOC discusses some of these areas for the implementation of proposed § 50.69 about how the treatment processes for low-risk safety-related SSCs should be conducted. The Commission is also giving examples of what it considers good practice to achieve confidence of functionality. The Commission does not believe that it is necessary to include these "expectations" as specific requirements because there may be other means of achieving the specified outcome and failure to implement a particular expectation would not, by itself, be a regulatory concern. The Commission's intent is to place on the licensee the responsibility to determine the necessary treatment to maintain functionality without the Commission having to establish prescriptive requirements.

The categorization process assumes that the functionality of SSCs in performing their safety functions will be retained, although the treatment applied to RISC-3 SSCs may be reduced under proposed § 50.69. Further, the categorization process may include specific reliability assumptions for plant SSCs in performing their intended functions. Therefore, when establishing the performance-based treatment process for RISC-3 SSCs, the licensee should take these assumptions into account to support the evaluations of small increase in risk resulting from implementation of the changes in treatment . It is important to obtain sufficient information on

SSC performance to allow the results of the categorization process to remain valid. The Commission considers the risk-informed, performance-based ASME Code Cases (as endorsed in § 50.55a) to be one acceptable method of establishing treatment processes that are consistent with the categorization process.

Proposed § 50.69 identifies four processes that must be controlled and accomplished for RISC-3 SSCs: Design Control; Procurement; Maintenance, Inspection, Testing, and Surveillance; and Corrective Action. The high level RISC-3 requirements are structured to address the various key elements of SSC functionality by focusing in several areas. When SSCs are replaced, RISC-3 SSCs must remain capable of performing design basis functions; hence, the high level requirements focus on maintaining this capability through design control and procurement requirements. During the operating life of a RISC-3 SSC, a sufficient level of confidence is necessary that the SSC continues to be able to perform its design basis functions; hence, the inclusion of high level requirements for maintenance, inspection, test, and surveillance. Finally, when data is collected, it must be fed back into the categorization and treatment processes, and when important deficiencies are found, they must be corrected; hence, requirements are also provided in these areas.

The Commission notes that use of voluntary consensus standards is an effective means of establishing treatment requirements to achieve functionality. As an example, ASME risk-informed Code Cases have been developed with the purpose of determining appropriate treatment requirements for low safety-significant SSCs in their specific functional areas. Further, the Commission expects that related standards (such as ASME Code Cases N-658 and N-660 on SSC categorization and treatment for purposes of repair and replacement) be used in conjunction with each other as intended by the accredited standards writing body. Where suitable standards do not exist or available standards are not sufficient, the Commission expects the licensee to establish sufficient controls to provide reasonable confidence in the functionality of RISC-3

SSCs, based upon such factors as operating experience and vendor recommendations. However, the Commission also notes that use of a voluntary consensus standard in and of itself might not be sufficient to maintain functionality for particular SSCs under certain service conditions, and that the licensee might need to supplement its processes to achieve the desired results.

The proposed rule would require the treatment processes for RISC-3 SSCs be implemented to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions. That is to say, the pertinent requirements identified in § 50.69 for each process must be satisfied for RISC-3 SSCs unless the requirements are clearly not applicable or are not necessary in the particular circumstance to achieve functionality of the SSC. As an example, a licensee might determine that it is more efficient and effective to replace a particular component before the end of its design life rather than conducting maintenance to repair the component. Further, a licensee might determine that some maintenance activities are within the skill of the craft (such as replacing missing bolts on motor-operated valve switch compartments), such that detailed work orders would not be necessary. On the other hand, an activity to procure a replacement component with active functions that is not the same as the one being replaced would necessitate use of most of the specified processes, with a greater need for documentation and independent review to achieve the expected result.

As part of the high level requirement that RISC-3 SSCs be capable of performing their safety-related functions under design basis conditions, the Commission emphasizes that implementation of the processes must provide reasonable confidence of the future capability of the SSC (i.e., not just confidence that the SSC works at a certain point in time but rather provides confidence that the component will work when called upon). The level of confidence can be less than was provided by the special treatment requirements listed in § 50.69(b)(1). As an example, exercising of a valve or simply starting a pump does not provide reasonable confidence in design basis capability, will not detect service-induced aging or degradation that could prevent the component from performing its design basis functions in the future, and is insufficient by itself to satisfy the intent of the rule.

Licensees implementing § 50.69 are responsible for implementing the treatment requirements for RISC-3 SSCs in an effective manner to maintain their capability to perform the safety functions under design basis conditions. Licensees should address the potential impact on the functionality of RISC-3 SSCs as a result of the changes to testing programs, such that the categorization process assumptions and results remain valid. To provide a basis to conclude that the potential increase in risk would be small, a licensee is required to conduct evaluations that assume failure rates that might occur as a result of the revisions to treatment. These evaluations would need to consider, for instance, any planned alteration in a licensee's program for diagnostic testing of motor-operated valves. If a likely result of a contemplated change in treatment is an increase in failure rate, outside the bounds of the evaluations, that change in treatment would not be acceptable under proposed § 50.69 because the criterion in § 50.69(c)(i)(iv) about providing reasonable confidence of a small increase in risk would not be met.

V.5.2.1 Section 50.69(d)(2)(i) Design Control Process.

Section 50.69(d)(2)(i) specifies that the functional requirements and bases for RISC-3 SSCs be maintained and controlled. The functional requirements and bases continue to apply unless they are specifically changed in accordance with the appropriate regulatory change control process (e.g., § 50.59). The rule further states that RISC-3 SSCs must be capable of performing their safety-related functions under design basis conditions including (any applicable) design requirements for environmental conditions (temperature, pressure, humidity, chemical effects, radiation, and submergence), effects (aging and synergisms), and seismic conditions (design load combinations of normal and accident conditions with earthquake motions).

It is recognized that the level of confidence in the design basis capability of RISC-3 SSCs may be less than the confidence provided in the capability of RISC-1 SSCs to perform their safety functions. The proposed treatment requirements for the control of the design of RISC-3 SSCs are included, in part, to provide a basis for the assumption in the categorization process that these SSCs will continue to be capable of performing their safety-related functions under design basis conditions throughout their service life. The implementation of an effective design control process is crucial to the maintenance of the functionality of safety-related SSCs because many SSCs cannot be monitored or tested to demonstrate design basis capability or to identify potential degradation as part of normal plant operations. For instance, if the SSC were modified or replaced, the design control processes are important means by which the required capability is installed and maintained over the life of the component. Further, because it is not possible to test or monitor some SSCs under the conditions that they might experience in service, other means, such as control of design and procurement of SSCs, and condition monitoring, are used such that the SSCs are capable of performing their functions. The proposed rule would require that licensees have a design control process that maintains and applies design requirements to ensure that RISC-3 SSCs will be capable of performing their safety-related functions under design basis conditions. To meet this performance objective, the licensee's design control process would be expected to specify appropriate quality standards; select suitable materials, parts, and equipment; control design interfaces; coordinate participation of design organizations; verify design adequacy; and control design changes. The manner in which the design control requirements for RISC-3 SSCs are accomplished would be the responsibility of the licensees adopting § 50.69. The proposed rule would allow flexibility for licensees to focus their resources on the SSCs that are most safety-significant while implementing an effective design control process for RISC-3 SSCs. For example, licensees might provide design control for RISC-3 SSCs through application of (1) the process established under Criterion III of 10 CFR 50, Appendix B; (2) an augmented quality assurance program such as might have been established in response to regulatory guidance issued in conjunction with § 50.62 (for SSCs used to comply with anticipated transients without a plant scram; or (3) a plant-specific process currently in place or established to satisfy the treatment requirements of § 50.69.

The design control process under § 50.69 is intended to provide assurance that the proposed rule is satisfying the principle that the design requirements of RISC-3 SSCs would not be changed under § 50.69. For example, the design provisions of Section III of the ASME *Boiler and Pressure Vessel Code* (BPV Code) required by §50.55a(c), (d), and (e) for RISC-3 SSCs are not affected by the proposed rule. Another example is a requirement for fracture toughness of particular materials that is part of a licensee's design requirements; such a requirement would continue to apply when repair or replacement of affected components is undertaken. Licensees would continue to be required by § 50.59 to evaluate proposed modifications to design requirements for safety-related SSCs, including those categorized as RISC-3.

For RISC-3 SSCs, the proposed rule would remove the requirements for a program for environmental qualification of electric equipment specified in § 50.49, "Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants." However, the proposed rule would not eliminate the requirements in 10 CFR 50, Appendix A, "General Design Criteria for Nuclear Power Plants," that electric equipment important to safety be capable of performing their intended functions under the applicable environmental conditions. For example, Criterion 4 of 10 CFR 50, Appendix A, "General Design Criteria for Nuclear Power Plants," requires that SSCs important to safety be designed to accommodate the effects of and to be compatible with the environmental conditions associated with normal operation, maintenance, testing, and postulated accidents. In accordance with § 50.69(d)(2), the licensee is required to design, procure, install, maintain, and monitor electric equipment important to safety such that they are capable of performing their intended functions under the environmental conditions listed in § 50.69(d)(2)(i) throughout their service life. Further, if RISC-3 electrical equipment is relied on to perform its safety-related function beyond its design life, licensees should have a basis justifying the continued capability of the equipment under adverse environmental conditions.

RISC-3 and RISC-4 SSCs would continue to be required to function under design basis seismic conditions, but would not be required to be qualified by testing or specific engineering methods in accordance with the requirements stated in 10 CFR Part 100, Appendix A. A licensee who adopts the proposed rule would no longer be required to meet certain requirements in Appendix A to Part 100, Sections VI(a)(1) and VI(a)(2), to the extent that those requirements have been interpreted as mandating qualification testing and specific engineering methods to demonstrate that RISC-3 SSCs are designed to withstand the Safe Shutdown Earthquake and Operating Basis Earthquake. The proposed rule does not remove the design requirements related to the capability of RISC-3 SSCs to remain functional considering Safe Shutdown Earthquake and Operating Basis Earthquake seismic loads, including applicable concurrent loads. These continue to be part of the design basis requirements or procurement requirement for replacement SSCs. The proposed rule would not change the design input earthquake loads (magnitude of the loads and number of events) or the required load combinations used in the design of RISC-3 SSCs. For example, for the replacement of an existing safety-related SSC that is subsequently categorized as RISC-3, the same seismic design loads and load combinations would still apply. The proposed rule would permit licensees to select a technically defensible method to show that RISC-3 SSCs will remain functional when subject to design earthquake loads. The level of confidence for the design basis capability of RISC-3 SSCs, including seismic capability, may be less than the confidence in the design basis capability of RISC-1 SSCs. The use of earthquake experience data has been mentioned as a potential method to demonstrate SSCs will remain functional during earthquakes. However, it would be difficult to rely on earthquake experience alone to demonstrate functionality of SSCs if the design basis includes multiple earthquake events or combinations of loadings unless these specific conditions were enveloped by the experience data. Additionally, if the SSC is required to function during or after the earthquake, the experience data would need to contain explicit information that the SSC actually functioned during or after the design basis earthquake events as required by the SSC design basis. The successful performance of an SSC after the earthquake event does not demonstrate it would have functioned during the event. Qualification testing of an SSC would be necessary if no suitable alternative method is available for showing that the SSC will perform its design basis function during an earthquake.

Licensees are responsible for proper installation and post-installation testing of RISC-3 SSCs as part of design control and other treatment processes to provide reasonable confidence in the capability of SSCs to perform their functions. The Commission also expects licensees to control special processes associated with installation, such as welding, to provide reasonable confidence in the design basis capability of RISC-3 SSCs. Licensees would be expected to perform sufficient post-installation testing to verify that the installed SSC is operating within expected parameters and is capable of performing its safety functions under design basis conditions. In performing post-installation testing, licensees may apply engineering analyses to extrapolate the test data to demonstrate design basis capability.

V.5.2.2 Section 50.69(d)(2)(ii) Procurement Process.

Section 50.69(d)(2)(ii) specifies that procured RISC-3 SSCs satisfy their design requirements. In order to obtain components that meet the requirements, the licensee would be expected specify the technical requirements (including applicable design basis environmental and seismic conditions) for items to be procured. Further, the Commission expects licensees to use established methods (e.g., vendor documentation, equivalency evaluation, technical evaluation, technical analysis, or testing) to develop a technical basis for the determination that the procured item can perform its safety-related function under design basis conditions, including applicable design basis environmental conditions (temperature, pressure, humidity, chemical effects, radiation, and submergence), and effects (aging and synergisms), and seismic conditions (design load combinations of normal and accident conditions with earthquake motions). In addition to appropriately specifying in the procurement the desired component, the licensee/applicant would also be expected to conduct activities upon receipt to confirm that the received component is what was ordered.

The proposed rule would allow more flexibility in the implementation of the procurement process for RISC-3 SSCs than currently provided by 10 CFR 50, Appendix B. Nevertheless, licensees will continue to be responsible for implementing an effective procurement process for RISC-3 SSCs. Differences constituting a design change are expected to be documented and addressed under the licensee's design control process. As an example of one acceptable procurement process, a licensee might use an approach similar to that described below:

Vendor Documentation - Vendor documentation could be used when the performance characteristics for the SSC, as specified in vendor documentation (e.g., catalog information, certificate of conformance), satisfy the SSC's design requirements. If the vendor documentation does not contain this level of detail, the design requirements could be provided in the procurement specifications. The vendor's acceptance of the stated design specifications provides sufficient confidence that the RISC-3 SSC would be capable of performing its safety-related functions under design basis conditions.

Equivalency Evaluation - An equivalency evaluation could be used when it is sufficient to determine that the procured SSC is equivalent to the SSC being replaced (e.g., a like-for-like replacement).

Engineering Evaluation - For minor differences, a technical evaluation could be performed to compare the differences between the procured SSC and the design requirements of the SSC being replaced and determines that differences in areas such as material, size, shape, stressors, aging mechanisms, and functional capabilities would not adversely affect the ability to perform the safety-related functions of the SSC under design basis conditions.

Engineering Analysis - In cases involving substantial differences between the procured SSC and the design requirements of the SSC being replaced, a technical analysis could be conducted to determine that the procured SSC can perform its safety-related function under design basis conditions. The technical analysis would be based on one or more engineering methods that include, as necessary, calculations, analyses and evaluations by multiple disciplines, test data, or operating experience to support functionality of the SSC over its expected life.

Testing - Testing under simulated design basis conditions could be performed on the SSC.

V.5.2.3 Section 50.69(d)(2)(iii) Maintenance, Inspection, Test, and Surveillance Process.

Section 50.69(d)(2)(iii) specifies that periodic maintenance, inspections, tests, and surveillance activities be established and conducted, and their results evaluated using prescribed acceptance criteria to determine that the RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions until their next scheduled activity.

To meet this requirement, licensees are expected to establish the scope, frequency, and detail of predictive, preventive, and corrective maintenance activities (including post-maintenance testing) to support the determination that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions throughout their service life. For a RISC-3 SSC in service beyond its design life, the Commission expects licensees to have a basis to determine that the SSC will remain capable of performing its safety-related function. Following maintenance activities that affect the capability of an SSC to perform its safety-related function, licensees would be expected to perform post-maintenance testing to verify that the SSC is performing within expected parameters and is capable of performing its safety function under design basis conditions. Licensees may apply engineering analyses to extrapolate the test data to demonstrate design basis capability as part of post-maintenance testing. The Commission expects licensees to identify the preventive maintenance needed to preserve the capability of

RISC-3 SSCs to perform their safety-related functions under applicable design basis environmental and seismic conditions for their expected service life.

In order to have reasonable confidence that SSCs can perform their functions, licensees must implement effective processes for inspection, testing, and surveillance of RISC-3 SSCs; they may apply their own individual approaches such that the requirements of § 50.69 are satisfied. As an example, the provisions for risk-informed inspection and testing in applicable ASME Code Cases would constitute one effective approach in satisfying the § 50.69 requirements. To prevent the occurrence of common-cause problems that might invalidate the categorization process assumptions and results, effective implementation would include a determination of the functionality of safety-related SSCs checked using measuring and test equipment that was later found to be in error or defective.

With respect to RISC-3 pumps and valves, the Commission expects licensees to implement periodic testing or inspection, and evaluation of performance data, sufficient to provide reasonable confidence that these pumps and valves will be capable of performing their safety function under design basis conditions. In order to determine that SSC will remain capable until the next scheduled activity, a licensees would have to obtain sufficient operational information or performance data to provide reasonable confidence that the RISC-3 pumps and valves will be capable of performing their safety function if called upon to function under operational or design basis conditions over the interval between periodic testing or inspections. Licensees may develop the type and frequency of the test or inspection for RISC-3 pumps and valves where sufficient to conclude that the pump or valve will perform its safety function. These tests or inspections may be less rigorous and less frequent than those performed on RISC-1 pumps and valves. For example, a licensee might establish more relaxed criteria for grouping of similar RISC-3 components, or might apply less stringent test acceptance criteria for RISC-3 pumps and valves, than specified for RISC-1 components. The licensee could apply staggered test intervals for the

RISC-3 components to provide confidence that the relaxed grouping or acceptance criteria had not resulted in SSC performance that is inconsistent with the categorization process or its assumptions. Licensees should note that performance data obtained for pumps and valves operating under normal conditions may not be capable of predicting their capability to perform safety functions under design basis conditions without additional evaluation or analysis. This does not mean that pumps and valves must be tested or inspected under design basis conditions. Methods exist for collecting performance data at conditions different than design basis conditions that can be used to reach conclusions regarding the design basis capability of components. Examples of such methods are described in Regulatory Guide 1.175, *An Approach for Plant-Specific, Risk-Informed Decision making: Inservice Testing*, and applicable risk-informed ASME Code Cases (e.g., OMN-1, OMN-4, OMN-7, OMN-12) as accepted by 10 CFR 50.55a.

V.5.2.4 Section 50.69(d)(2)(iv) Corrective Action Process.

Section 50.69(d)(2)(iv) specifies that conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions be identified, documented, and corrected in a timely manner. A licensee may obtain information from the inspection, test and surveillance activities discussed above, or from other sources, such as operating experience, that indicates that an SSC is not capable of performing its required functions and thus identifies that corrective action is needed.

In meeting proposed § 50.69, licensees may implement a corrective action process for RISC-3 SSCs that is different than the process established to satisfy 10 CFR Part 50, Appendix B. This more general requirement would allow a graded approach, as well as less stringent timeliness requirements. The Commission believes an effective corrective action process is crucial to maintaining the capability of RISC-3 SSCs to perform their safety-related functions because of the reduction in requirements for other processes for design control; procurement; and maintenance, inspection, test, and surveillance. For example, effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis.

V.6.0 Section 50.69 (e) Feedback and Process Adjustment.

Section 50.69(e)(1) requires the updating of the PRA. The PRA configuration control program must incorporate a feedback process to update the PRA model. The program must require that plant data, design, and procedure changes that affect the PRA models or input parameters be incorporated into the model. This update is to account for plant-specific operating experience as well as general industry experience. In particular, the proposed rule would require the licensee to review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization in a timely manner but no longer than every 36 months for RISC-1, RISC-2, RISC-3 and RISC-4 SSCs. Changes must be evaluated with respect to the impact on CDF and LERF. If the change would result in a significant increase in the CDF or LERF or might change the categorization of SSCs, the PRA must be updated in a timely manner; in this context it would clearly not be timely to wait to update the PRA if there would be a significant change in risk. Other changes are to be incorporated within 36 months. The results of the updated PRA and the associated risk categorizations based on the updated PRA information should be used as part of the feedback and corrective action process, and SSCs must be re-categorized as needed.

Section 50.69(e)(2) and (e)(3) contains the requirements for feeding back into the categorization process SSC performance information and data, and for adjusting the categorization and treatment processes as appropriate, with the goal that the validity of the categorization process and its results are maintained. Further, the proposed rule would require the licensee to monitor the performance of RISC-1 and RISC-2 SSCs and make adjustments as necessary to either the categorization or treatment processes. To meet this requirement, the

Commission expects licensees to monitor all functional failures (i.e., not just maintenance preventable unavailabilities and failures as is currently required by § 50.65) so that they can determine when adjustments are needed. Licensee monitoring programs will also need to include the monitoring of SSCs that support beyond design basis functions (if applicable) that are not necessarily included in the scope of an existing maintenance rule monitoring program. If the licensee chooses to categorize a selective set of SSCs as RISC-3, and the categorization of SSCs as RISC-3 is based on credit taken for the performance of other plant SSCs (whether or not these SSCs are within the selective implementation set), then the licensee must maintain the credited performance. This applies to credit taken in: 1) PRA models, inputs and assumptions; 2) screening and margin analyses; and 3) IDP deliberations. This implies that the licensee must ensure that the credited SSCs perform their functions per § 50.69(d)(1), and the performance of these SSCs must be monitored per § 50.69(e)(2).

For RISC-3 SSCs, the proposed rule would require the licensee to consider the performance data required by § 50.69(d)(2)(iii) to determine whether there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to meet § 50.69(c)(iv) and make adjustments as necessary to either the categorization or treatment processes, to maintain categorization process results valid. Section 50.69(d)2)(iii) requires periodic maintenance, testing and surveillance activities for RISC-3 SSCs. Based upon review of this information, if SSC reliability degrades to the point that the evaluations done to show that the potential risk was small are no longer bounding, action is necessary to either adjust the treatment (to improve reliability) or to perform the categorization process again (to determine if any changes in categorization of SSC are necessary).

V.7.0 Section 50.69(f) Program Documentation and Change Control and Records.

Section 50.69(f) contains administrative requirements for keeping information current, for handling planned changes to programs and processes and for records. Each subparagraph is discussed below.

Section 50.69(f)(1) states that the licensee or applicant shall document the basis for categorization of SSCs in accordance with this section before removing any requirements. The documentation is expected to address why a component was determined to be either safety-significant or low safety-significant based upon the requirements in § 50.69(c).

The Commission is not, except in this limited instance, specifying particular records to retain. Since the licensee is responsible for compliance with the requirements, subject to NRC oversight and inspection, the licensee (or applicant) would need to be able to show that they have established the processes required by the rules and conducted activities sufficient to provide reasonable confidence in functionality of SSCs under design basis conditions.

Section 50.69(f)(2) specifies that the licensee must update its FSAR to reflect which systems have been categorized using the provisions of § 50.69, and thus, may have revised treatment applied to the structures and components within that system. This provision is included to maintain clear information, at a minimum level of detail, about which requirements a licensee is satisfying; detailed information about particular SSCs is not required to be submitted. For an applicant, this updating would be expected to be either part of the original application or as a supplement to the FSAR under § 50.34. For licensees, the updating must be in accordance with the provisions of § 50.71(e) for licensees.

Once the NRC has completed its review of a licensee’s § 50.69 submittal as it relates to categorization, the licensee or applicant would be able to adjust its treatment processes provided that the rule requirements are met. NRC does not plan to perform a pre-implementation review of the revised treatment requirements under § 50.69(d). However, the Commission recognizes that existing information in the quality assurance (QA) plan or in the FSAR may need to be revised to reflect the changes to treatment that would be made as a result of implementation of § 50.69. Any revisions to these documents are to be submitted in accordance with the existing requirements of

§ 50.54(a)(2) and § 50.71(e) respectively. For instance, § 50.71(e) states that the FSAR is to contain the latest information developed and is to reflect information submitted to the Commission since the last update. The regulations further state in the cited sections how a licensee is to submit to the NRC revisions to the QA plan or to the FSAR. Information in these documents that would no longer be accurate upon implementation of § 50.69 must be updated. Details of the processes would be expected to be contained in plant procedures, procurement documents, surveillance records, etc.

Section 50.69(f)(3) specifies that for initial implementation of the rule, changes to the FSAR for implementation of this proposed rule need not include a supporting § 50.59 evaluation of changes directly related to implementation. Future changes to the treatment processes and procedures for § 50.69 implementation may be made, provided the requirements of the rule and § 50.59 continue to be met. While the licensee is to update its programs to reflect implementation of § 50.69, the Commission concluded that no additional review under § 50.59 is necessary for such changes, to these parts of the FSAR that might occur.

Section 50.69(f)(4) specifies that for initial implementation of the rule, changes to the quality assurance plan for implementation of this proposed rule need not include a supporting § 50.54(a) review of changes directly related to implementation. Future changes to the treatment processes and procedures for § 50.69 implementation may also be made, provided the requirements of the rule and § 50.54(a) continue to be met. While the licensee is to update its programs to reflect implementation of § 50.69, the Commission concluded that no additional review under § 50.54(a) is necessary for changes to these parts of the QA plan.

No specific change control process is being established for the categorization process outlined by § 50.69(c). Because the NRC is reviewing and approving a submittal containing the licensee or applicant's commitments for categorization, changes that would invalidate their submittal would also invalidate the approval. However, provided any revised process continues to conform with what was submitted or committed to (such as through a commitment to follow a particular RG), NRC review would not be needed of lower-tier changes (such as to implementing procedures) that might arise.

No explicit requirements are included in § 50.69 for the period for retention of records. The proposed rule would specify only a few specific types of records that must be prepared, e.g., those for the basis for categorization in § 50.69(f)(1). In accordance with § 50.71(c), these records are to be maintained until the Commission terminates the facility license.

V.8.0 Section 50.69(g) Reporting.

Section 50.69(g) provides a new reporting requirement applicable to events or conditions that would have prevented a RISC-1 or RISC-2 SSCs from performing a safety-significant function. Most events involving these SSCs will meet existing § 50.72 and § 50.73 reporting criteria. However, it is possible for events and conditions to arise that impact whether RISC-1 or RISC-2 SSCs would perform beyond design basis functions consistent with the assumptions made in the categorization process. This reporting requirement is intended to capture these situations. The reporting requirement is contained in § 50.69, rather than as a revision of § 50.73 so that its applicability only to those facilities that have implemented § 50.69 is clear. The existing reporting requirements in § 50.72 and § 50.73 would no longer apply to RISC-3 (and RISC-4) SSCs under the proposed rule.

VI. Additional potential requirements for public comment

The cornerstone of proposed § 50.69 is a robust, risk-informed categorization process that provides high confidence that the safety significance of SSCs is correctly determined considering all relevant information. The categorization requirements incorporated into the proposed rule achieve this objective. The Commission proposes to remove the RISC-3 and RISC-4 SSCs from the scope of the special treatment requirements delineated in § 50.69(b)(1), and instead require the licensee to comply with more general, high level requirements for maintaining functionality. The proposed rule would allow appropriate flexibility for implementation while continuing to provide reasonable confidence that the SSCs will remain functional. As discussed elsewhere in this notice, the Commission concludes that the requirements in proposed § 50.69 would maintain adequate protection of public health and safety. Previous drafts of this proposed rule posted to the NRC web site, contained more detailed requirements in § 50.69(d)(2) for RISC-3 SSCs. The Commission believes that this level of detail is beyond what is necessary to provide reasonable confidence in RISC-3 design basis capability in light of the robust categorization requirements incorporated into proposed § 50.69. However, the Commission recognizes that some stakeholders may disagree and invites public comment on this matter. To facilitate public comment, example language is provided below that identifies (in quotations and brackets) those requirements that were considered for inclusion in § 50.69 (as well as where they would have appeared in the rule).

> (2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout their service life. ["These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process."] The processes must meet the following requirements, as applicable:

(i)Design Control. Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled,[" including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes"]. RISC-3 SSCs must be ["have a documented basis to demonstrate that they are"] capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation, and submergence) and effects (i.e., aging and synergism); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions). ["Replacements for ASME Class 2 and Class 3 SSCs or parts must meet either: (1) the requirements of the ASME *Boiler & Pressure Vessel (BPV) Code*; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced."]

(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements. ["Upon receipt, the licensee shall verify that the item received is the item that was ordered."]

(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions until the next scheduled activity.

(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be identified, documented, and corrected in a timely manner. ["In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."]

The Commission is requesting comment as to whether any of these requirements (or other requirements) are necessary to provide reasonable confidence of SSC functionality commensurate with the safety significance of the RISC-3 SSC, i.e., whether the requirements on categorization are sufficiently robust that the level of detail contained in the proposed rule on treatment is appropriate.

VII. Other Topics

VII.1 Regulatory Guide and Implementation Guidance for § 50.69.

The Nuclear Energy Institute (NEI) submitted a proposed implementation guide for this rulemaking in the form of NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline". As part of the effort to develop the proposed rule, the NRC staff reviewed drafts of this document and in addition, NEI 00-04 was used in the pilot program discussed earlier. The objective of the staff's review was to determine the acceptability of the proposed implementing guidance with the intent that the NEI guidance could be endorsed in an NRC regulatory guide. The version of NEI 00-04, dated June 28, 2002, forms the basis for the draft regulatory guide.

The NRC staff's review of NEI 00-04 resulted in several areas where the staff would find it necessary to identify exceptions to NEI guidance or to include further guidance to supplement the document, as it is currently written. These areas are discussed in an attachment to the draft regulatory guide, DG-1121, "Guidelines for Categorizing Structures, Systems and Components in Nuclear Power Plants According to Their Safety Significance." Through this document, the Commission is also seeking public comment on the DG and the identified issues. Comments should be submitted as discussed under the ADDRESSES section. Availability of this document is noted in Section X.

VII.2 Review Guidance concerning PRA quality and peer review.

The NRC has prepared a draft regulatory guide DG-1122, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities.” This DG provides guidance the NRC position on voluntary consensus standards for PRA (in particular on the ASME standard for internal events PRAs) and industry PRA documents (e.g., NEI 00-02, “Probabilistic Risk Assessment Peer Review Process Guideline”). Further, this guide will be modified to address PRA standards on fire, external events, and low power and shutdown modes, as they become available. The NRC has also developed a draft supporting Standard Review Plan, SRP 19.1, to provide guidance to the staff on how to determine that a PRA providing results being used in a decision is technically adequate.

In a letter dated April 24, 2000, NEI requested the NRC staff review the suitability of the peer review process described in NEI 00-02 to address PRA quality issues for this application. NRC issued a request for additional information on September 19, 2000, to which NEI responded by letter dated January 18, 2001. By letter dated April 2, 2002 (ADAMS accession number ML020930632), the NRC staff sent to NEI, draft staff review guidance that was developed as a result of its review of NEI 00-02, for intended use for § 50.69 applications.

The staff review guidance is for a focused review of the plant-specific PRA based on a review of NEI 00-02 and NEI 00-04. In order to reach the conclusion that the PRA results support the proposed categorization, the review guidance is structured to lead the staff reviewer to either look for evidence that the impact of a given peer review issue on PRA results has been adequately addressed in the peer review report and, when necessary, has been identified for consideration by the IDP, or to request further information from the licensee.

VIII. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act, as amended, the Commission is issuing the proposed rule to add § 50.69 under one or more of sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties, as they apply to regulations in Part 50 are discussed in § 50.111.

IX. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement States Programs," approved by the Commission on June 20, 1997, and published in the Federal Register (62 FR 46517, September 3,1997), this rule is classified as compatibility "NRC." Compatibility is not required for Category "NRC" regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or the provisions of Title 10 of the Code of Federal Regulations, and although an Agreement State may not adopt program elements reserved to NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular State's administrative procedure laws, but does not confer regulatory authority on the State.

X. Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Rulemaking Website (Web). The NRC's interactive rulemaking Website is located at http://ruleforum.llnl.gov. These documents may be viewed and downloaded electronically via this Website.

NRC's Public Electronic Reading Room (PERR). The NRC's public electronic reading room is located at www.nrc.gov/reading-rm.html.

Document	PDR	Web	PERR
Comments on the ANPR	X	X	Available
Comments on the draft rule language	X	X	Available
ANPR Comment Resolution	X	X	ML022630030
Environmental Assessment	X	X	ML022630050
Regulatory Analysis	X	X	ML022630028
OMB Supporting Statement	X	X	ML022340449
Industry Implementation Guidance	X	X	ML021910534
Draft Regulatory Guide	X	X	ML022630041

XI. Plain Language

The Presidential memorandum dated June 1, 1998, entitled "Plain Language in Government Writing" directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). The NRC requests comments on the proposed rule specifically with respect to the clarity and reflectiveness of the language used. Comments should be sent to the address listed under the ADDRESSES caption of the preamble.

XII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this proposed rule, the NRC proposes to use the following Government-unique standard (Draft NRC Regulatory Guide DG-1121, August 2002). The Commission notes the development of voluntary consensus standards on PRAs, such as an ASME Standard on Probabilistic Risk Assessment for Nuclear Power Plant Applications. DG-1121 and DG-1122 (PRA Technical Adequacy) discuss how this standard could be used for the purpose of the internal events, full-power PRA. In addition, the Commission acknowledges development of risk-informed Code cases by the ASME on categorization of certain components, particularly with respect to pressure boundary considerations. DG-1121 explicitly notes such Code cases and that they could be proposed by a licensee or applicant as part of the means for satisfying the rule requirements. The government standards would allow use of these voluntary consensus standards, but would not require their use. The Commission does not believe that these other standards are sufficient to provide the overall construct for the alternative approach to categorization and treatment of SSCs that is the goal of this rulemaking. For example, the current standards do not address all types of components that might be recategorized, PRA requirements for all initiating events and modes of operation, nor other parts of the approach laid out such as determining the basis for the evaluations to show a small increase in risk. The NRC is not aware of any voluntary consensus standard that could be used instead of the proposed Government-unique standards. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain how the voluntary consensus standard is comparable and why it should be used instead of the proposed standard.

XIII. Finding of No Significant Environmental Impact: Environmental Assessment: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. However, the general public should note that the NRC is seeking public participation; availability of the environmental assessment is provided in Section X. Comments on any aspect of the environmental assessment may be submitted to the NRC as indicated under the ADDRESSES heading.

The NRC has sent a copy of the environmental assessment and this proposed rule to every State Liaison Officer and requested their comments on the environmental assessment.

XIV. Paperwork Reduction Act Statement

This proposed rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et se.). This rule has been submitted to the Office of Management and Budget for review and approval of the information collection requirements.

The burden to the public for these information collections is estimated to average 1640 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?
2. Is the estimate of burden accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be submitted?
4. How can the burden of the information collection be minimized, including the use of automated collection techniques?

Send comments on any aspect of these proposed information collections, including suggestions for reducing the burden, to the Records Management Branch (T-6 E6), U. S. Nuclear

Regulatory Commission, Washington DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011), Office of Management and Budget, Washington DC 20503.

Comments to OMB on the information collections or on the above issues should be submitted by (insert date 30 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given to comments received after this date.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XV. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requests public comment on the draft regulatory analysis. Availability of the regulatory analysis is provided in Section X. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

XVI. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XVII. Backfit analysis

The NRC has determined that the backfit rule does not apply to this proposed rule; therefore, a backfit analysis is not required for this proposed rule. As a voluntary alternative to existing requirements, these amendments do not impose more stringent safety requirements on 10 CFR Part 50 licensees or applicants and thus do not constitute a backfit pursuant to §50.109.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plant and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Part 50

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat.1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951, as amended by Pub. L. 102-486, sec. 2902, 106 Stat. 3123 (42 U.S.C. 5851). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a, and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Sections 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80, 50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. Section 50.8(b) is revised to read as follows:

§ 50.8 Information collection requirements: OMB approval.

(b) The approved information collection requirements contained in this part appear in §§ 50.30, 50.33, 50.33a, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.36b, 50.44, 50.46, 50.47, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.62, 50.63, 50.64, 50.65, 50.66, 50.68, 50.69, 50.71, 50.72, 50.74, 50.75, 50.80, 50.82, 50.90, 50.91, 50.120, and appendices A, B, E, G, H, I, J, K, M, N,O, Q, R, and S to this part.

3. Part 50 is amended by adding a new § 50.69 to read as follows:

§ 50.69 Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors

(a) *Definitions.*

“Risk-Informed Safety Class (RISC)-1 structures, systems, and components (SSCs)”

means safety-related SSCs that perform safety-significant functions.

"Risk-Informed Safety Class (RISC)-2 structures, systems and components (SSCs)" means nonsafety-related SSCs that perform safety-significant functions.

*"Risk-Informed Safety Class (RISC)-3 structures, systems and components (*SSCs)" means safety-related SSCs that perform low safety-significant functions.

"Risk-Informed Safety Class (RISC)-4 structures, systems and components (SSCs)" means nonsafety-related SSCs that perform low safety-significant functions.

"Safety-significant function" means a function whose degradation or loss could result in a significant adverse effect on defense-in-depth, safety margin, or risk.

(*b) Applicability and scope of risk-informed treatment of SSCs and submittal/approval process.*

(1) A holder of a license to operate a light water reactor (LWR) nuclear power plant under §§ 50.21(b) or 50.22, a holder of a renewed LWR license under Part 54 of this chapter; a person seeking a design certification under Part 52 of this chapter, or an applicant for a LWR license under § 50.22 or under Part 52, may voluntarily comply with the requirements in this section as an alternative to compliance with the following requirements for RISC-3 and RISC-4 SSCs:

(i) 10 CFR Part 21.

(ii) 10 CFR 50.49.

(iii) 10 CFR 50.55(e).

(iv) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement, requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g); and the electrical component quality and qualification requirements in section 4.3 and 4.4 of IEEE 279, and sections 5.3 and 5.4 of IEEE 603-1991, as incorporated by reference in 10 CFR 50.55a(h).

(v) 10 CFR 50.65, except for paragraph (a)(4).

(vi) 10 CFR 50.72.

(vii) 10 CFR 50.73.

(viii) Appendix B to 10 CFR Part 50.

(ix) The Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR Part 50, for penetrations and valves meeting the following criteria:

(A) Containment penetrations that are either 1-inch nominal size or less, or continuously pressurized.

(B) Containment isolation valves that meet one or more of the following criteria:

(*1*) The valve is required to be open under accident conditions to prevent or mitigate core damage events;

(*2*) The valve is normally closed and in a physically closed, water-filled system;

(*3*) The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and that is not connected to the reactor coolant pressure boundary; or

(*4*) The valve is 1-inch nominal size or less.

(x) Appendix A to Part 100, sections VI(a)(1) and VI(a)(2), to the extent that these regulations require qualification testing and specific engineering methods to demonstrate that SSCs are designed to withstand the Safe Shutdown Earthquake and Operating Basis Earthquake.

(2) A licensee voluntarily choosing to implement this section shall submit an application for license amendment pursuant to § 50.90 that contains the following information:

(i) A description of the process for categorization of RISC-1, RISC-2, RISC-3 and RISC-4 SSCs.

(ii) A description of the measures taken to assure that the quality and level of detail of the systematic processes that evaluate the plant for internal and external events during normal operation, low power, and shutdown (including the plant-specific probabilistic risk assessment

(PRA), margins-type approaches, or other systematic evaluation techniques used to evaluate severe accident vulnerabilities) are adequate for the categorization of SSCs.

(iii) Results of the PRA review process conducted to meet § 50.69 (c)(1)(i).

(iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy § 50.69(c)(1)(iv). The evaluations shall include the effects of common cause interaction susceptibility, and the potential impacts from known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions)

(3) The Commission will approve a licensee's implementation of this section upon its determination that the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs satisfies the requirements of § 50.69(c) by issuing a license amendment approving the licensee's use of this section.

(4) An applicant for a license voluntarily choosing to implement this section shall include the information in § 50.69 (b)(2) as part of application for a license. The Commission will approve an applicant's implementation of this section upon its determination that the process for categorization of RISC-1, RISC-2, RISC-3, and RISC-4 SSCs satisfies the requirements of § 50.69(c).

(c) *SSC Categorization Process.*

(1) SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 SSCs using a categorization process that determines whether an SSC performs one or more safety-significant functions and identifies those functions. The process must:

(i) Consider results and insights from the plant-specific PRA. This PRA must at a minimum model severe accident scenarios resulting from internal initiating events occurring at full power operation. The PRA must be of sufficient quality and level of detail to support the categorization process, and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC.

(ii) Determine SSC functional importance using an integrated, systematic process for addressing initiating events (internal and external), SSCs, and plant operating modes, including those not modeled in the plant-specific PRA. The functions to be identified and considered include design bases functions and functions credited for mitigation and prevention of severe accidents. All aspects of the integrated, systematic process used to characterize SSC importance must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operational experience.

(iii) Maintain the defense-in-depth philosophy.

(iv) Include evaluations that provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of § 50.69(b)(1) and § 50.69(d)(2) are small.

(v) Be performed for entire systems and structures, not for selected components within a system or structure.

(2) The SSCs must be categorized by an Integrated Decision-making Panel (IDP) staffed with expert, plant-knowledgeable members whose expertise includes, at a minimum, PRA, safety analysis, plant operation, design engineering, and system engineering.

(d) *Alternative treatment requirements*.

(1) *RISC-1 and RISC 2 SSCs*. The licensee or applicant shall ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization process assumptions by evaluating treatment being applied to these SSCs to ensure that it supports the key assumptions in the categorization process that relate to their assumed performance.

(2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to

perform their safety-related functions under design basis conditions throughout their service life. The processes must meet the following requirements, as applicable:

(i) *Design control.* Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled. RISC-3 SSCs must be capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation and submergence) and effects (i.e., aging and synergism); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions);

(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements;

(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions until the next scheduled activity; and

(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be identified, documented, and corrected in a timely manner.

(e) *Feedback and process adjustment*.

(1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs*. In a timely manner but no longer than every 36 months, the licensee shall review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization.

(2) *RISC-1 and RISC-2 SSCs*. The licensee shall monitor the performance of RISC-1 and RISC-2 SSCs. The licensee shall make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results are maintained valid.

(3) *RISC-3 SSCs*. The licensee shall consider data collected in § 50.69(d)(2)(iii) for RISC-3 SSCs to determine whether there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv). The licensee shall make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results are maintained valid.

(f) *Program documentation, change control and records.*

(1) The licensee or applicant shall document the basis for its categorization of any SSC under paragraph (c) of this section before removing any requirements under § 50.69(b)(1) for those SSCs.

(2) Following implementation of this section, licensees and applicants shall update their final safety analysis report (FSAR) to reflect which systems have been categorized in accordance with § 50.71(e).

(3) When a licensee first implements this section for a SSC, changes to the FSAR for the implementation of the changes in accordance with § 50.69(d) need not include a supporting § 50.59 evaluation of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of § 50.69(d), as described in the FSAR, may be made if the requirements of this section and § 50.59 continue to be met.

(4) When a licensee first implements this section for a SSC, changes to the quality assurance plan for the implementation of the changes in accordance with § 50.69(d) need not include a supporting § 50.54(a) review of the changes directly related to implementation. Thereafter, changes to the programs and procedures for implementation of § 50.69(d), as described in the quality assurance plan may be made if the requirements of this section and § 50.54(a) continue to be met.

(g) *Reporting*. The licensee shall submit a licensee event report under § 50.73(b) for any event or condition that would have prevented RISC-1 or RISC-2 SSCs from performing a safety-significant function.

Dated at Rockville, Maryland this __ day of ______ 2002

For the Nuclear Regulatory Commission.

Annette L Vietti-Cook,

Secretary of the Commission.

REGULATORY ANALYSIS

SUPPORTING

PROPOSED 10 CFR 50.69
“RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS AND COMPONENTS FOR NUCLEAR POWER REACTORS”

Table of Contents

Regulatory Analysis for Proposed Rule: §50.69

I. Statement of Problem and NRC Objectives

(a) History

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing a reasonable assurance of adequate protection to public health and safety. The current body of NRC regulations and their implementation are largely based on a “deterministic” approach. Requirements were devised on the basis of a defined and analyzed set of events as “design basis events.” This approach has employed the use of safety margins, operating experience, accident analysis, and qualitative assessments of risk, as defense-in-depth philosophy. One element of this defense-in-depth approach is the imposition of special treatment requirements on structures, systems, and components (SSCs) that are important to safety to provide a reasonable assurance that such SSCs will continue to function during the postulated design basis conditions. Special treatment requirements are imposed on nuclear reactor applicants and licensees through a number of regulations that have been promulgated since the 1960's. These requirements specify different levels of special treatment requirements for equipment depending on the specific regulatory concern.

As part of moving the Agency toward a more risk-informed regulatory body, in 1995, the Commission published a Policy Statement on the Use of Probabilistic Risk Assessment (PRA). To implement this Commission policy, the staff has developed guidance (Regulatory Guide (RG) 1.174, An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis, RG 1.175, Risk-informed Inservice Testing, RG 1.176, Graded Quality Assurance, RG 1.177, Risk-informed Technical Specifications, and RG 1.178, Risk-informed Inservice Inspection) on the use of risk information for reactor license amendments. In this respect, the Commission has been successful in developing and implementing a regulatory means for considering risk insights into the current regulatory framework. One such risk-informed application, the South Texas Project (STP) submittal on graded quality assurance, is particularly noteworthy.

In March 1996, STP Nuclear Operating Company (STPNOC) requested that the NRC approve a revised Operations Quality Assurance Program (OQAP) that incorporated the methodology for grading quality assurance (QA) based on PRA insights. The STP graded QA proposal was an extension of the existing regulatory framework. Specifically, the STP approach continued to use the traditional safety-related categorization, but allowed for gradation of safety significance within the “safety-related” categorization (consistent with 10 CFR Part 50 Appendix B) through use of a risk-informed process. Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP on November 6, 1997. Subsequent to NRC’s approval, STPNOC identified implementation difficulties associated with the graded QA program. Despite the reduced QA requirement applied for a large number of SSCs in which the licensee judged to be of low safety significance, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, or seismic continue to impose substantial burdens. As a result, the replacement such a low safety- significant component needs to also satisfy other special requirements during a procurement process. These requirements prevented STPNOC from realizing the full potential reduction in unnecessary regulatory burden for SSCs judged to have little or no safety importance. In an effort to achieve the full benefit of the graded QA program (and in fact go beyond the staff's previous approval of graded QA), STPNOC submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including 10 CFR 50 Appendix B) for SSCs categorized as low safety-significant or as non-risk-significant. STPNOC's exemption was ultimately approved by the staff in August 2001.

Under Option 2 of SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998, the staff recommended that risk-informed approaches to the application of special treatment requirements be developed. Option 2 (also referred to as RIP50 Option 2) addresses the implementation of changes to the scope of SSCs needing a revised special treatment while continue providing assurance that the SSCs will perform their designed and intended functions. Changes to the requirements pertaining to the design of the plant or the design basis accidents are not included in Option 2. Such technical risk-informed changes are being considered under Option 3 of SECY-98-300. The Commission subsequently approved the NRC staff's rulemaking plan and issuance of an Advanced Notice of Proposed Rulemaking (ANPR) as outlined in SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999. The ANPR was published in the Federal Register (65 FR 11488) on March 3, 2002.

In response to the ANPR, the Commission received more than 200 comments. The staff sent the Commission SECY-00-194 "Risk-Informing Special treatment Requirements," dated September 7, 2000, which provided preliminary view on the ANPR comments and more thoughts on preliminary regulatory framework for implementing Option 2.

(b) Objective for Proposed Rulemaking

As discussed above, the current scope of SSCs covered by the special treatment requirements governing commercial nuclear reactors is deterministically based and stems primarily from the evaluation of design basis events, as described in updated final safety analysis reports (UFSARs). This regulatory framework provides reasonable assurance of adequate protection (no undue risk) to the health and safety of the public. However, advances in technology, coupled with operating reactor experience, have suggested that an alternative approach, one that maintains safety while reducing unnecessary regulatory burden, is possible and the utilization of such an approach could increase regulatory effectiveness. The new approach embodied in the proposed rule uses a risk-informed process to evaluate the safety significance of SSCs and establish the appropriate level of special treatment requirements for SSCs. It is important to note that this proposed rule is intended only to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed. The proposed rule, however, does not allow SSC functional requirements to be eliminated, or to allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, by restructuring the regulations to allow an alternative risk-informed approach to special treatment, this rule would enable licensees and the staff to focus their resources on SSCs with significant contributions to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach would maintain SSC functionality, albeit at a reduced level of assurance.

II. Analysis Of Alternative Regulatory Strategies

A number of rulemaking strategies were considered for implementing Option 2. Those strategies considered most viable were evaluated in the rulemaking plan attached to SECY-99-256. The evaluation of those strategies has been updated based on additional information obtained since the issuance of SECY-99-256. The updated discussion is provided below. The staff continues to conclude that adding a new section to 10 CFR Part 50 is the appropriate approach for implementing Option 2 and hence this is the approach taken for the proposed rule. However, a significant change regarding the regulatory approach is being taken for the proposed rule in lieu of what was concluded in SECY-99-256. As discussed below and as a result of additional interactions with stakeholders, the staff no longer concludes that the best regulatory approach is to include an appendix that provides categorization requirements as part of the new 10 CFR Part 50 section.

Alternative regulatory approaches for implementing Option 2 were discussed in the ANPR. For example, the NRC discussed use of exemptions if only a limited number of plants were interested in this approach, as well as several variations for proceeding with rulemaking (e.g., including within each special treatment requirement any alternative requirements). The staff did not receive ANPR comments that disagreed with the staff's suggested approach to add a new section to Part 50. However, negative comments from stakeholders were received with regards to the use of a detailed appendix (i.e., Appendix T) to support a proposed new CFR section.

(a) No Action Alternative

This alternative is not responsive to the problem of making requirements more risk-informed as a means to focus staff and industry resources on safety-significant issues, while reducing unnecessary regulatory burden. Thus, this alternative was not chosen.

(b) Exemptions Alternative

One way to risk-inform special treatment requirements is to do it without a rulemaking, and instead to process exemptions per 10 CFR 50.12. Such an exemption request was reviewed for the South Texas Project as a "proof-of-concept" of the categorization and adjustment in special treatment concept. While other plant-specific exemptions could be processed, when there is sufficient industry interest, rulemaking is the most efficient means for implementing the type of generic changes encompassed by this effort. Rulemaking, when compared to the exemption process, also provides an opportunity for input from all stakeholders about the requirements that the staff is considering to promulgate for the contemplated risk-informed process. If only a small number of facilities are interested in risk-informing special treatment requirements, then review and approval of a limited number of exemptions under 10 CFR 50.12 would probably be more efficient. Based on the industry's response to the ANPR, and subsequent industry participation in the Option 2 regulatory effort to date, the NRC continues to conclude that there is sufficient industry interest in this initiative to warrant the staff continuing to expend its resources to develop the rule. Hence, at this time, the exemption approach is not the optimal approach.

(c) New 10 CFR 50.2 Definition Approach

This alternative rulemaking approach would entail the development and incorporation of a new definition into 10 CFR 50.2. This new definition (e.g., define a new term such as "safety-significant") would describe, for the purposes of the special treatment requirements within Part 50, which SSCs are safety-significant and, therefore, need to be within the scope of the special treatment requirements. To implement this approach, this new term would need to be incorporated into each special treatment rule, thereby enabling the scope of these special treatment rules to be revised per the new definition such that SSCs that are not "safety-significant" would no longer be subject to the special treatment provisions of the applicable rules. Licensees could voluntarily revise the scope of SSCs that are subject to special treatment requirements by implementing a risk-informed categorization process that determines which SSCs are safety-significant. To determine which SSCs are safety-significant, the Commission could issue a new Part 50 appendix or new section that contains the requirements governing the categorization of SSCs, or alternatively, a regulatory guide could be issued that contains the SSC categorization guidance.

A significant problem with this approach is that unless new requirements are placed into Part 50 to address the low safety significant SSCs (no longer subject to special treatment requirements) and ensure that their design basis functions are maintained (once special treatment is removed from these SSCs), the design basis functional capability could be lost. This is not consistent with the ground rules for Option 2. For this approach to work and meet the Option 2 objective of preserving the design basis, it would appear that these additional requirements (to maintain the design basis functions for low safety significant SSCs) would either need to be incorporated into each and every special treatment requirements section, or be incorporated into a separate section. In this later case this approach becomes very similar to the approach selected for the proposed rule. This rulemaking alternative appears to require duplicate changes to multiple rules, and it is less coherent when compared to an approach that combines all the relevant requirements into one section. There is also the potential to introduce confusion into the current special treatment requirements through the incorporation of the new language into each section. For these reasons, the NRC did not choose this alternative.

(d) Expand a §50.2 Definition or Define a Currently Used Part 50 Term

This alternative is a variation of the approach just described above, but instead of using new language (define a new term in §50.2), it would expand the definition of a currently defined term such as "safety-related," or it could define another term currently used (but not defined) in Part 50 such as "important to safety." This approach has one advantage over the "new definition" approach discussed above such that this approach uses the same terminology as already exists in each of the special treatment requirements. Therefore, it would not be necessary to change the language in any of the special treatment rules. However, a significant effort would be required to review all the regulations to ensure that inadvertent revisions to any non-special treatment rules will not occur and to make appropriate changes to preclude such occurrences. In a similar fashion to the "new term" approach, this consideration would also need to be supplemented with a new Part 50 appendix or section that contains the requirements governing the risk-informed categorization of SSCs. This approach has the problem of the previously described approach (new definition approach) in that a separate section would be required to contain the requirements needed to maintain the design basis of SSCs removed from the scope of special treatment requirements (in which case this approach becomes very similar to the approach selected for the proposed rule) or the requirements would need to be incorporated into each and every special treatment requirements section. This alternative would introduce unnecessary complications and confusion in the application of the terms at plants that choose to implement the new scope for a subset of the special treatment requirements covered in this effort, or for some systems and not others. Such a situation would result in the use of similar language with different meanings in the licensee's licensing basis documents and in the associated plant implementation documents. For these reasons, the NRC did not choose this alternative.

(e) New Section in Part 50 Approach (10 CFR 50.69)

This alternative rulemaking approach is the approach taken for the proposed rule, and entails the development of a new rule that would be added to Part 50. The proposed rule contains the categorization requirements (supported by a regulatory guide). Additionally, the proposed rule contains the new "treatment" requirements that apply to SSCs based on their associated risk-informed safety class (RISC) categorization.

The "new rule section" approach embodied in the proposed rule has the benefit of grouping and integrating all the risk-informed requirements into one rule. This contributes to regulatory clarity and makes it easier for both licensees and the staff to implement the regulation (as opposed to having risk-informed requirements incorporated into each regulation). Additionally, the "new section" rule approach enables the staff to identify in one place what the regulatory treatment requirements will be for each risk-informed safety class (RISC). RISC-1 and RISC-2 SSCs will continue to meet applicable special treatment requirements and will also have requirements that ensure initial categorization assumptions are valid, and updated consistent with the process feedback requirements in the rule. RISC-3 SSCs will have requirements that maintain their capability of performing their safety-related functions under design basis conditions. RISC-4 SSCs will be removed from any applicable special treatment requirements and have no additional requirements imposed by § 50.69 (recognizing that any technical/functional requirements continue to apply unless they are changed via the normal design change process including § 50.59). This approach of utilizing a separate section in Part 50 to contain the overall revised special treatment requirements has a significant advantage over any approaches that would attempt to identify specific special treatment requirements associated with individual SSC. Revising each specific special treatment rule would be more difficult and confusing because it would require changing the specific regulations that were intended only for "design basis" events to address RISC-2 and RISC-3 SSCs. In the case of RISC-2 SSCs, this would mean revising the current Part 50 regulations which have a design basis focus to address SSCs that are important for beyond design basis events. In the case of RISC-3 SSCs, this would mean revising the current Part 50 regulations with respect to the special treatment requirements. The potential for increased confusion is significant for such an approach. Further, since the proposed rule is a voluntary alternative to existing requirements, changing the individual sections could potentially be confusing for those licensees who elect not to implement the new alternative requirements. These considerations led to the decision to develop a separate section to contain the new requirements. As already noted, the stakeholder comments agreed with this portion of the suggested regulatory approach.

(f) Categorization Requirements

The NRC has considered two alternative approaches for incorporating the categorization requirements into the new regulatory framework: 1) a new appendix (i.e., Appendix T) that sets forth in significant detail, objective, nondiscretionary criteria governing the categorization that licensees could implement without prior NRC review, or 2) placing higher-level, less-detailed categorization requirements in the rule with the need for NRC to review and approve a submittal prior to implementation of § 50.69.

Incorporating the categorization requirements into an appendix, such that a no prior review approach could be pursued, would require the appendix to contain a sufficient level of detailed requirements such that the NRC would be able to determine, in an objective, non-discetionary manner involving no judgement, that a §50.69 licensee complies with the appendix categorization requirements and is therefore using a sufficiently robust categorization process and supporting PRA to determine the safety significance of SSCs with high confidence. This “appendix” regulatory approach was the approach the staff originally concluded was the best approach (see SECY-99-256 and the ANPR). This approach appears to have the following advantages:

- Provides a stable and predictable regulatory framework

- Reduces and potentially eliminates NRC and industry resources that would be expended on a submittal and associated review

- Simplifies inspection and enforcement

The disadvantages of the appendix approach were pointed out in the ANPR comments as follow:

- Incorporating detailed requirements into the regulations can, and has in the past (e.g., Appendix R), resulted in numerous exemption requests from licensees who wish to pursue alternative approaches. The review and approval of these exemption requests is very resource intensive.

- Incorporating detailed requirements into the regulations stifle new creative approaches (i.e., forces licensees to pursue exemption requests for alternatives which can be costly) and ultimately can cause licensees to not pursue these new creative approaches, which may be technically superior.

- It appears that there would be a need for the staff to review some aspects of the PRA to determine its acceptability for application to Option 2 under any circumstance. As such, a true “no-prior-review” type of approach simply does not appear to be feasible at this time. As a result, some level of prior review and approval appears to be needed, and this in turn removes much of the attractiveness of contemplated Appendix T “no prior review” approach.

As evidenced in the ANPR comments, stakeholders generally did not support the detailed appendix approach. Since this is a voluntary rulemaking initiative, and since it was clear that industry would not utilize the appendix approach, it was not appropriate, nor an efficient use of NRC resources, to continue to develop the appendix approach. Accordingly, the NRC elected to incorporate less detailed categorization requirements into the proposed rule, and to require licensees to provide a submittal for staff review and approve prior to implementation of §50.69.

(g) Conclusion Regarding Alternative Strategies

The NRC concludes that:

1. Contingent on continued industry interest, rulemaking is the most effective tool for implementing the type of generic changes encompassed by this effort. If industry does not continue to support this rulemaking, the review and approval of a limited number of exemptions under 10 CFR 50.12 would be a more efficient regulatory approach. Based on the industry's response to the ANPR, and industry participation in the Option 2 regulatory effort to date, the staff continues to believe that the industry supports this rulemaking initiative.

2. Adding a new section to Part 50 that contains the necessary requirements, but without a supporting appendix as initially suggested in the ANPR, is the best approach for rulemaking. The proposed rule reflects this decision.

III. Estimate and Evaluation of Values and Impacts

(a) Overview

The chief concern for the staff in moving forward with the proposed regulatory approach is ensuring that sufficient requirements have been incorporated into the new regulation to maintain adequate protection of public health and safety (please refer to section III of the statement of considerations supporting the proposed rule for a discussion of the technical basis for § 50.69). Once the staff has satisfied itself that the new regulation will maintain adequate protection, then the staff's next concern is whether the proposed regulatory approach is cost-beneficial. Since implementation of this rulemaking is voluntary, it is not in the staff's interest to continue developing a regulatory approach that would not be adopted by industry. Hence from this perspective, the NRC's interest in estimating the values and impacts of the proposed regulatory approach is to determine whether the approach is likely to prove cost-beneficial. If the approach should prove not to be cost-beneficial, then the NRC will not expend additional resources on development of the rulemaking since it would not be utilized by industry.

Available cost information has been utilized in this regulatory analysis. However, some of this analysis is qualitative with regard to the potential values and impacts of the rulemaking. It is currently not possible to develop a more quantitative regulatory analysis that has a reasonable level of certainty for this rulemaking. The staff requested cost and benefit information as part of the ANPR, but did not receive the requested information. However, the nuclear power industry, through the efforts of the Westinghouse Owners Group (WOG), was able to generate some cost and benefit information as a result of a detailed examination of the costs and benefits for implementing 50.69 based on its understanding of §50.69 (then in draft form). This information has been incorporated into the analysis. It should be recognized that the costs and benefits of implementing 50.69 will vary widely for licensees dependent on facility design, vintage, and licensing history. A further complicating factor is that §50.69 is really a "process approval." Licensees will not know the actual cost savings until they begin implementing the new process (categorizing SSCs, revising treatment, replacing SSCs) at their facilities. In this regard, the only facility that has developed real cost information is South Texas (whose exemption request was approved in August 2001). South Texas represents the bounding situation from the standpoint of having the greatest potential to realize the greatest cost savings from implementation of Option 2. It is a more recent facility, with a complex design (three train), large safety-related equipment list (i.e., list of equipment which receives special treatment), and a large number of applicable regulations. Some cost and benefit information was provided by Dominion from the Surry pilot activities. This information is incorporated into the following analysis. Additionally, based on the pilot efforts, the staff developed rough estimates of the costs (in terms of days and number of people involved) associated with categorizing SSCs on a system basis.

In addition facility design, vintage, and licensing history, the specific issues addressed below (as impacts) will also influence whether §50.69 is a cost beneficial endeavor for licensees.

III.(b) Impacts to Licensees

Licensees that wish to implement §50.69 will, at a minimum, incur the following impacts:

- PRA: The licensee will need to address PRA quality issues. At a minimum licensees will need to have a PRA that reflects the current plant configuration, is sufficiently complete for the intended application, meets some quality standard (either NEI 00-02 peer review guidance or an industry PRA standard), and is up-to-date. Depending on the state of the licensee's PRA, this activity could involve a significant commitment in resources. NRC notes that many licensees have already made investments in development of a PRA and having the PRA peer- reviewed for use in various applications, such as implementation of section 50.65(a)(4). Those licensees who choose to implement this risk-informed alternative would be likely to already have incurred many of these costs, and would be interested in additional opportunities for using the PRA. Another key factor is the NRC staff's requirements for submittal of PRA information and the resultant level of resources that § 50.69 licensees need to expend to provide the requested information (i.e., the effort to address the staff issues associated with NEI 00-02).

- Infrastructure for Categorization: The licensee will need to develop the infrastructure to support the risk-informed categorization of SSCs to determine safety significance. At a minimum, this involves the development of procedures governing the risk-informed SSC categorization process (e.g., for Palo Verde's pilot activities, procedure 70DP-0RA04 "Component Risk Significance Determination" was developed based on the NEI 00-04 guidance), establishment of the integrated decision-making panel (IDP), training of the IDP, and establishment of a supporting working group that provides the IDP with the relevant information to enable the IDP to make the categorization decisions.   Some of this infrastructure may already exist from previous categorization efforts to meet maintenance rule monitoring and for other purposes (e.g., risk-informed ISI applications may have categorized the passive components in the system). Training, based on the pilot experience, is estimated to take at least 1 day for the IDP members. This training would be to familiarize the IDP with the PRA and the IDP decision-making process.

- Performing the Categorization: The licensee will need to expend significant resources in evaluating the SSCs to determine safety significance, both for the working group to complete the initial work of developing and gathering the relevant information on SSC/function significance and for the IDP to convene and make the decision regarding SSC categorization. This will be an ongoing cost and it is a function of the number of systems the licensee decides to categorize. Based on the pilot experience, it is estimated that the working group (estimated to be three people at a minimum) would need to spend about two weeks developing and preparing the information for presentation to the IDP. It is estimated that the IDP (estimated to be 5 members plus the 3 working group presenters) would need to spend an average of 3 days per system reviewing the information and making the categorization decisions. For less-complicated systems, these numbers would be much less, while for more involved systems, the estimates increase. Also, it is expected that over time, the process would become much more efficient, and these costs probably can be reduced, particularly if efficiencies are identified for categorizing groups of components.

! Implementation of § 50.69 Revised Treatment: Following categorization, the licensee will incur impacts that result from revised treatment. These include changes to 1) plant procedures to implement the revised approach (e.g., changes to procedures governing procurement, receipt inspection, testing), 2) equipment specifications, 3) plant data bases, and 4) training of plant personnel to implement the revised approach.

! Monitoring: To implement § 50.69, licensees will incur impacts that result from ongoing monitoring. It is expected that current maintenance rule monitoring efforts (which must be expanded to address all functional failures) will largely be sufficient to address § 50.69's monitoring requirements for RISC-1 and RISC-2 SSCs (i.e., the practical reality is that licensees must monitor all failures for the maintenance rule, and then determine which are maintenance preventable, so this aspect of monitoring should be addressed by current programs). Additionally, a level of monitoring is needed for RISC-3 SSCs to ensure that the condition and performance of SSCs is consistent with categorization sensitivity studies, and that design basis functions are being maintained per § 50.69(d)(2).

! Updating: To implement § 50.69, licensees will incur impacts that result from the need to periodically update the PRA and categorization process to reflect the data collected from plant monitoring or from industry, and to reflect any changes to plant configuration that impact categorization. Licensees have already developed much of this infrastructure in order to comply with the PRA quality guidance being implemented in support of the maintenance rule.

! Submittal Review and Approval: Licensees will incur an impact resulting from the need for the NRC staff to review and approve a submittal prior to implementing § 50.69. This impact includes the licensee’s effort to develop a § 50.69 submittal, and the impact from the staff’s review of the submittal including the need to support any requests for additional information from the staff.

The Westinghouse Owners Group (WOG) estimates that the total cost for implementation of §50.69 at a single unit site is $2,400,000. For a dual-unit site, with identical plants, the costs are estimated at $3,300,000. These are the total costs for program development, implementation and maintenance, and these costs include both utility and contractor support. All of the above costs are included within the estimates. Additionally, these costs were estimated for the categorization of 12 systems, and were assumed to occur over a three year period.

III. (c) Impacts to the NRC

- The primary impact on the NRC is through the resources invested in conducting this rulemaking, including development of regulatory guidance (i.e., extensive interaction with NEI regarding the development of NEI 00-04).

- NRC would also expend resources to review and approve § 50.69 submittals. If licensees adopt the NEI 00-04 guidance as endorsed by the NRC RG, then review costs will be minimized (and this is the objective of this effort concerning the development of implementation guidance). This review effort will focus on the results of the PRA peer review, and the licensee's disposition of peer review findings. This impact is therefore a function of the number of licensees who choose to voluntarily implement § 50.69, the degree to which licensees adopt the RG (i.e., exceptions will require staff review), and the number of key peer review findings (i.e., the size of the submittal).

- There would also be additional resource impacts from adjusting inspection guidance or processes to take into account the existence of alternative requirements, and to perform an audit or inspection at some point in the future for some licensees following adoption of § 50.69 requirements.

III.(d) Impacts to Other Stakeholders

- The NRC has not identified any impacts upon other stakeholders. Public health and safety will be assured through either the existing or the revised requirements. Any costs of implementation will be borne by the licensees. The NRC does not expect licensees to implement § 50.69 unless they conclude it is cost-beneficial for their facility.

III. (e) Values of the Proposed Rulemaking for NRC, Industry, and Other Stakeholders

- The NRC concludes that this proposed regulatory approach can be accomplished while maintaining public health and safety. This rulemaking will allow licensees to remove RISC-3 and RISC-4 SSCs from the scope of special treatment requirements. This rulemaking will not allow SSCs to be removed from the facility, or for the design basis functional requirements of RISC-3 or RISC-4 SSCs to be changed or eliminated (i.e., for RISC-3 SSCs, design basis functional requirements are to be maintained, albeit at a reduced level of assurance, and in all cases, licensees must follow existing design change control requirements if they desire to change an SSC's design basis). Some SSCs are expected to be "scoped" into regulatory treatment (i.e., RISC-2 SSCs), and it is possible that these SSCs will receive enhanced attention thereby increasing the level of assurance that such previous "nonsafety-related" SSCs will perform as expected (i.e., as required by § 50.69(d)(1)). This element of the rulemaking may contribute to enhancing safety. Importantly, the regulatory approach will include a "performance-monitoring" element, such that if the reliability of equipment degrades substantially (to the extent that it is not reasonable to expect that the SSCs can meet functional requirements, or that the assumptions that supported the SSC categorization are no longer valid), or if operational experience indicates that an SSC may be more important to plant safety than previously thought, consideration can be given to revising the SSCs categorization and associated treatment (as required by § 50.69(e)).

- As an indication of the potential savings that could be achieved through a risk-informed special treatment approach, the following information was provided by the licensee for the South Texas Project (STP) during a presentation to the Advisory Committee on Reactor Safeguards in July 1999. The STP licensee estimated that full implementation of its exemption request (which involves relief from §50.49; §50.34 and 10 CFR Part 100; §50.65; 10 CFR Part 50 Appendix B; 10 CFR Part 50 Appendix J; and 10 CFR Part 21) would result in several million dollars in savings a year at STP Units 1 and 2. This estimate is judged to be an upper bound on the potential savings that can be realized by a given licensee based on STP's unique three-train design, which results in a larger number of SSCs whose special treatment requirements can be relaxed and based on a comparison with WOG estimates provided below. Part of the cost savings would arise if replacement components could be procured with less-prescriptive (and thus less expensive) quality and administrative impacts.

- Table 1 has some examples of procurement savings for STP that have resulted from approval of their exemption request (this information comes from a presentation at the Tenth Annual International Conference on Nuclear Engineering in Arlington Virginia, from April 14-18, 2002). As of April 2002, STP had saved an estimated $300,000 in labor and $60,000 in parts as a result of being able to modify the scopes and frequencies of preventative maintenance for SSCs categorized as low safety-significant or nonrisk-significant (i.e., the equivalent of RISC-3 for proposed § 50.69). In addition, STP noted that there are other less quantifiable benefits, such as reduced outage time (arising from not having to test certain isolation valves), and greater flexibility in maintenance (procedures and scheduling). In fact STP is modifying the scope and focus of post-maintenance testing to streamline the testing for low safety-significant SSCs while maintaining an adequate level of assurance.

Table 1: Some Examples of Procurement Savings for STP

Item	Safety-Related	Nonsafety-related
Spent Fuel Pool Heat Exchanger Outlet Valve flow guide	Quoted—safety-related/qualified price = $34000 (for two)	Identical commercial guides - = $842 (for two)

Generic Purchase of 1" vent and drain valves for lot of 100 valves	$2400/valve	$500/valve –total savings for 100 valves =$190,000
Flow switches used in 45 applications (18 safety-related and 27 nonsafety-related.	To buy all 45 switches safety-related costs $9000/switch	Nonsafety-related cost $1200/switch –changed out every 5 years – by purchasing all commercial and evaluating life savings on these switches = $900,000

! The WOG estimated that the total cost savings for implementation of §50.69 on a per unit basis per year is approximately $1,100,000. Based on the single unit costs ($2,400,000) and dual-unit costs ($3,300,000) the corresponding payback periods are approximately 2.2 year and 1.5 years respectively. Extending these savings to the entire fleet of Westinghouse plants (and assuming that all plants implement §50.69 and have an average licensed-life to 2020 and extended life to 2040), and calculating a net present value results in the cost savings shown in Table 2. These savings are significant, and when considered for the entire fleet of 48 Westinghouse plants could potentially exceed 500 million dollars.

Table 2: WOG Estimate of Cost Savings

Average WOG Plant	Single Unit Site Net Present Value	Dual Unit Site Net Present Value
Licensed Life (2020)	$6,800,000	$14,800,000
License Renewed (2040)	$11,200,000	$23,400,000

! Additional information was provided by Dominion (shown in Table 3) during a public meeting held on Feb 21, 2002. See the notes for the table for an explanation of the information provided.

Table 3: Procurement Cost Comparison: Safety-Related vs Dedicated vs Nonsafety-related SSCs For Surry

Item	Safety-Related	Dedicated	Nonsafety-related
Relief Valve 1 ½" X2"	$11,000	$4400	$3600
Operator (valve)	$30,000	$15,000	$9900
Gate Valve 3" SS	$7000	$800	$130
Butterfly Valve 36"	$36,000	$13000	$9500
Operator (large bore)	$70,000	$23,000	$18,000
Check valve	$3200	$1000	$320

Ball Valve 2"	$3500	$1000	$560
Gate Valve 6"	$15,000	$2600	$600
Butterfly valve 20"	$30,000	$7000	$5000

Notes:
1. These are estimated procurement savings from actual SSCs (taken from purchase orders) procured at Surry, an older, Westinghouse designed, 3-loop plant.
2. The information is meant to estimate the potential savings for procuring a similar component as either safety-related, dedicated (for safety-related application), or nonsafety-related.
3. This information does not contain the increased cost due to § 50.69 regulations. But this is estimated to be approximately $50–100 per component.
4. For valves procured as “ASME Section III” valves, it is estimated that the column 1 numbers would be a factor of 1.5 higher.
5. At Surry, the general practice is to “dedicate” safety-related equipment (this should be obvious from the substantial cost savings that are achieved)
6. Presumably the proposed rule would enable cost savings for procurement to be similar to column 3 (close to nonsafety-related SSCs) with some additional costs associated with application of § 50.69 requirements

III. (f) Decision Rationale

This regulatory analysis is largely a qualitative analysis of the potential costs and benefits associated with the proposed § 50.69. This is due to the uncertainties that currently exist regarding implementation, as well as the major factors that can affect the costs and benefits associated with implementation of the rule (facility design, vintage, and licensing history). However, the NRC utilized all available cost information to inform the regulatory analysis where the information was available. Because of the voluntary nature of this rule, the NRC is not attempting to justify implementation on the basis of cost information. With respect to values and impacts, the decision rationale that the NRC chose is whether there is reasonable expectation of a favorable value/impact from developing and implementing this rulemaking. Based on the available information, and noting the industry's continued interest in pursuing this rulemaking effort, it is the NRC's judgement that the values (including the cost savings and other benefits) described above outweigh the identified impacts. It is expected that better estimates of costs of implementation could be identified by the industry when they have had a chance to review the proposed rule, supporting SOC, and associated guidance in detail. Hence, through public input on the proposed rulemaking, the NRC staff should be able to improve the rigor of this supporting regulatory analysis, and may be able to improve the quantification of the costs and benefits to support the final rulemaking.

IV. Implementation

NRC is issuing a new rule section that defines the requirements and the process for transitioning from existing requirements to the new requirements. Implementation guidance will also be provided that discusses the categorization process requirements. The NRC is currently reviewing an industry-developed guidance document for categorization. If determined to be acceptable, the NRC could endorse the industry guidance document through a regulatory guide.

Proposed §50.69 requires licensees or applicants who wish to implement the requirements of §50.69 to make a submittal to the NRC for approval of the categorization process prior to implementation. NRC plans a focused review of the PRA that undergirds the significance determination as well as of the integrated decision-making process. NRC has prepared review guidance to assist the staff in reviewing this submittal to determine whether the PRA is adequate for this application. Under the rulemaking approach, a licensee who implements the alternative rule requirements would not provide to NRC the actual list of specific SSCs and their new category per 50.69 (i.e., RISC-1, RISC-2, RISC-3, RISC-4), nor would the licensee provide NRC with a description of the revised treatment applied to RISC-3 SSCs. Rather, NRC will review the categorization process before implementation begins (i.e., process approval), and following this approach, the licensee would proceed to categorize SSCs and to implement treatment processes that satisfy the rule requirements over time. Until SSCs are categorized per §50.69 (i.e., categorized as RISC-1, RISC-2, RISC-3, or RISC-4 such that the treatment requirements associated with each category in §50.69(d) can be applied), existing requirements remain in effect. NRC oversight of implementation would be through the routine inspection process.

Given the NRC's expectations that implementation guidance will be issued in conjunction with the final rule, the staff expects that the final rule can be made effective immediately.

V. Conclusion

The risk-informed approach embodied in this proposed rule for establishing an alternative scope of SSCs subject to special treatment requirements is a regulatory approach that maintains safety and is consistent with the NRC's efforts to risk-inform its regulatory activities. The risk-informed approach will be consistent with the defense-in-depth philosophy, will provide reasonable assurance that necessary safety functions will be performed, will ensure that increases in core damage frequency or risk are small and consistent with the safety goal policy statement, and will ensure that a performance measurement strategy is employed. The overall value/impact of the rulemaking has been examined from a qualitative standpoint, and NRC concludes that the expected benefits outweigh the expected costs. As already noted, the decision to implement this regulation is voluntary. NRC expects that as part of the public comment process on the rule, further cost information may become available on the values and impacts that can be factored into the final rulemaking.

UNITED STATES NUCLEAR REGULATORY COMMISSION

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of a new regulation to 10 CFR Part 50. The proposed rule change would add a new section, § 50.69, which would contain voluntary alternative requirements to certain existing requirements in 10 CFR Parts 21, 50 and Appendix A to Part 100.

ENVIRONMENTAL ASSESSMENT

Identification of the Proposed Action:

The proposed action would permit power reactor licensees and applicants for licenses to implement a voluntary alternative regulatory framework with respect to "special treatment" i.e., those requirements beyond normal industrial practices that are imposed to provide added confidence that equipment is capable of meeting its functional requirements under design basis conditions. These treatment requirements include additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, quality assurance, and the like. Under this framework, licensees (or applicants), using a risk-informed process for categorizing structures, systems, and components (SSC) according to their safety significance, can remove SSCs of low safety significance from the scope of certain specified special treatment requirements. For SSCs of safety significance, existing requirements are retained, and the rule adds requirements that ensure SSC performance remains consistent with that assumed in the categorization process for beyond design basis conditions. The proposed rule requirements establish a process by which a licensee would categorize SSCs using a risk-informed process, adjust treatment requirements consistent with the relative significance of the SSC, and manage the process over the lifetime of the plant. To implement these requirements, a risk-informed categorization process is employed to determine the safety significance of SSCs and place the SSCs into one of four risk-informed safety class (RISC) categories. The determination of safety significance is to be performed by an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions are to include both the design basis functions, as well as functions credited for severe accidents (including external events). Treatment requirements for the SSCs are applied as necessary to maintain functionality and reliability, and are a function of the category into which the SSC is categorized. Finally, assessment activities are to be conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The proposed rule also contains requirements for obtaining NRC approval of the categorization process and for maintaining plant records and reports.

The requirements that are being removed for SSCs categorized as low safety-significant (i.e., RISC-3 and RISC-4 SSCs) are those that involve special treatment (see list below from proposed § 50.69(b)). Only the treatment requirements are being revised; functional requirements for these SSC will remain and the licensee would be required to apply sufficient treatment to maintain functionality of these SSCs. RISC-3 and RISC-4 SSCs would be removed from the scope of the following special treatment requirements listed in proposed § 50.69:

(i) 10 CFR Part 21

(ii) 10 CFR 50.49

(iii) 10 CFR 50.55(e)

(iv) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement, requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g); and the electrical component quality and qualification requirements in section 4.3 and 4.4 of IEEE 279, and sections 5.3 and 5.4 of IEEE 603-1991, as incorporated by reference in 10 CFR 50.55a(h)

(v) 10 CFR 50.65, except for paragraph (a)(4)

(vi) 10 CFR 50.72

(vii) 10 CFR 50.73

(viii) Appendix B to 10 CFR Part 50

(ix) The Type B and Type C leakage testing requirements in both Options A and B of Appendix J to 10 CFR Part 50, for penetrations and valves meeting the following criteria:

(A) Containment penetrations that are either 1-inch nominal size or less, or continuously pressurized.

(B) Containment isolation valves that meet one or more of the following criteria:

(*1*) The valve is required to be open under accident conditions to prevent or mitigate core damage events;

(*2*) The valve is normally closed and in a physically closed, water-filled system;

(*3*) The valve is in a physically closed system whose piping pressure rating exceeds the containment design pressure rating and that is not connected to the reactor coolant pressure boundary; or

(*4*) The valve is 1-inch nominal size or less.

(x) Appendix A to Part 100, sections VI(a)(1) and VI(a)(2), to the extent that these regulations require qualification testing and specific engineering methods to demonstrate that SSCs are designed to withstand the Safe Shutdown Earthquake and Operating Basis Earthquake.

The Need for the Proposed Action:

The proposed action is needed to implement the Commission's Policy Statement on the Use of Probabilistic Risk Assessment (PRA) on August 16,1995 (60 FR 42622), to increase the use of risk insights in all regulatory matters. This specific action pertains to special treatment requirements.

The current body of NRC regulations and their implementation are largely based on a "deterministic" approach. Requirements were devised on the basis of a defined and analyzed set of events as "design basis events." This approach has employed the use of safety margins, operating experience, accident analysis, and qualitative assessments of risk, as defense-in-depth philosophy. One element of this defense-in-depth approach is the imposition of special treatment requirements on structures, systems, and components (SSCs) that are important to safety to provide a reasonable assurance that such SSCs will continue to function during the postulated design basis conditions. Special treatment requirements are imposed on nuclear reactor applicants and licensees through a number of regulations that have been promulgated since the 1960's. These requirements specify different levels of special treatment requirements for equipment depending on the specific regulatory of concern. This regulatory framework provides reasonable assurance of adequate protection (no undue risk) to the health and safety of the public but in some cases also results in unnecessary regulatory burden.

The current scope of SSCs covered by the special treatment requirements governing commercial nuclear reactors is deterministically based and stems primarily from the evaluation of design basis events. However, advances in technology, coupled with operating reactor experience, have suggested that an alternative approach, one that maintains safety while reducing unnecessary regulatory burden, is possible and the utilization of such approach could increase regulatory effectiveness. The new approach embodied in the proposed rule uses a risk-informed process to evaluate the safety significance of SSC and establish the appropriate level of special treatment requirements of SSC. It is important to note that this proposed rule is intended only to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed. The proposed rule, however, does not allow SSC functional requirements to be eliminated, or to allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, by restructuring the regulations to allow an alternative risk-informed approach to special treatment, this rule would enable licensees and the staff to focus their resources on SSCs with significant contributions to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach would maintain SSC functionality, albeit at a reduced level of assurance.

Specifically, proposed § 50.69 implements the Commission decision regarding the application of risk-informed approaches to the regulations documented in a June 8, 1999, staff requirements memorandum (SRM) associated with SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - 'Domestic Licensing of Production and Utilization Facilities,' " dated December 23, 1998. Consistent with the rulemaking plan described in SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999, the Commission is proposing to establish § 50.69 as an alternative set of requirements whereby a licensee may undertake categorization of its SSCs using risk insights and adjust treatment requirements based upon their resulting significance.

Environmental Impacts of the Proposed Action:

This environmental assessment focuses on those aspects of proposed § 50.69 where requirements are either reduced or eliminated, and where there is a resultant potential for an environmental impact.

The NRC has concluded that there will be no significant radiological environmental impacts associated with implementation of the proposed rule requirements for the following reasons:

(1) Proposed § 50.69 maintains the design basis of the facility. For RISC-3 SSCs that have special treatment requirements removed, proposed § 50.69 incorporates alternative treatment requirements in paragraph (d)(2) that maintain reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout their service life. As a result, all the SSCs associated with limiting the releases of offsite radiological effluents will continue to be able to perform their functions, and as a result there would be no significant radiological effluent impact.

(2) The process and requirements established in § 50.69 do not extend to making changes to the design basis of SSCs and this includes removal of SSCs from the facility. Any changes that affect any non-treatment aspects of an SSC (e.g., changes to the SSC design basis functional requirements) are still required to be evaluated in accordance with other regulatory requirements such as § 50.59.

(3) The proposed rule is only enabling the special treatment requirements to be risk-informed. These requirements relate to the level of assurance that SSCs will perform their design basis functions, but all the associated SSCs are required to continue to function. Removal of special treatment requirements for low safety-significant SSCs may potentially result in changes to SSC reliability. Accordingly, the proposed rule has provisions in § 50.69(c)(1)(iv) which require that there be "reasonable confidence that for SSCs

categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from implementation of § 50.69(b)(1) and § 50.69(d)(2) are small." This implementation of this requirement ensures that reliability is maintained such that the risk associated with implementation of proposed § 50.69 is small. This provides further assurance that SSCs important to limiting offsite radiological releases perform their functions, and that there will be no significant radiological environmental impacts associated with implementation of the proposed rule requirements.

(4) The standards and requirements applicable to radiological releases and effluents are not affected by this rulemaking and continue to apply to the SSCs affected by this rulemaking. The SSCs for which special treatment requirements are removed are located entirely within the restricted area (as defined in Part 20). Therefore implementation of the proposed rule requirements would not result in off-site impacts due to normal operation.

(5) The proposed rule contains feedback and process adjustment requirements in paragraph (e) that cause adjustments to be made, as necessary, to either the categorization or treatment processes to provide continued support for the assumptions of the categorization process and its results. These requirements, in conjunction with the corrective action requirements in § 50.69(d) for RISC-3 SSCs, ensure that SSCs associated with limiting the releases of offsite radiological effluents will continue to be able to perform their functions.

The NRC has concluded that as a result of this proposed action there will be a beneficial impact on occupational exposure. Removal of special treatment requirements for RISC-3 and RISC-4 SSCs results in a reduction of activities associated with quality assurance, environmental qualification, monitoring, testing, and inspection. In many cases, the low safety-significant SSCs (for which the aforementioned activities are being reduced or eliminated) are located within radiological areas, and as a result, there would be a reduction in occupational exposures. The magnitude of this benefit has not been quantified, and will vary dependent on the extent (i.e., how many systems) to which a licensee implements proposed §50.69, the facility design, and vintage and licensing history of the facility (which determines how many special treatment requirements apply).

The proposed action will not significantly increase the probability or consequences of accidents, nor result in changes being made in the types of any effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure. The basis for this conclusion is that the proposed rule requirements maintain the facility design basis, provide reasonable confidence that any change in risk associated with implementation is small, do not allow that SSCs be removed from the facility (unless the appropriate and applicable change control requirements are satisfied), and do not otherwise impact station operation (i.e., no changes to the types of radiological and nonradiological effluents or quantity of effluents). Therefore, there are no significant radiological environmental impacts associated with the proposed action.

With regard to potential nonradiological impacts, implementation of the proposed rule requirements has no other impact on the facility than to revise the treatment applied to SSCs, and specifically will not involve any historic sites. It does not affect nonradiological plant effluents and has no other environmental impact. Therefore, there are no significant nonradiological environmental impacts associated with the proposed action.

Accordingly, the NRC staff concludes that there are no significant environmental impacts associated with the proposed action.

Alternatives to the Proposed Action:

As an alternative to the rulemakings described above, the NRC staff considered not taking the proposed action (i.e., the “no-action” alternative). Not adopting a risk-informed special treatment would result in no change in current environmental impacts. However, such an action is not consistent with the Commission’s Policy Statement on the Use of Probabilistic Risk Assessment (PRA) published in 1995 which stated that the use of PRA technology should be increased in all regulatory matters to the extent supported by the state of the art in PRA methods and data, and in a manner that supports the NRC’s traditional defense-in-depth philosophy, nor is it consistent with the Commission’s direction provided in SRMs associated with SECY-98-300 and SECY-99-256 which :

(1) directed the staff to evaluate strategies to make the scope of the nuclear power reactor regulations that impose special treatment risk-informed (SRM for SECY-98-300),

(2) and approved publication of the ANPR and the rulemaking plan for developing a proposed rule for risk-informing special treatment requirements (SRM for SECY-99-256).

Alternative Use of Resources:

This action does not involve the use of any resources not previously considered by the NRC in its past environmental statements for issuance of operating licenses for power reactors.

Agencies and Persons Consulted:

In accordance with its stated policy, the NRC staff will send a copy of the proposed rule to designated liaison officials for each state. Comments received will be considered as part of the rulemaking. No other agencies were consulted.

FINDING OF NO SIGNIFICANT IMPACT

On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Documents may be examined and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Library component of the NRC web site http://www.nrc.gov (Electronic Reading Room).

Dated at Rockville, Maryland, this th day of , 2002.

FOR THE NUCLEAR REGULATORY COMMISSION

Christopher I. Grimes, Program Director
Policy and Rulemaking Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

TABLE 1 - APPROACH

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-1	Public health risk is dominated by severe accidents (reactor core damage) with containment bypassed or breached. Normal operation of nuclear power plants or accidents at nuclear power plants without severe core damage have little or no impact on public health risk. From a technical standpoint, complying with the set of existing design basis accidents does not address public health risk except to say that, as far as we know, the plants have enough equipment, if used properly, to avoid and mitigate severe accidents. We need a set of regulations that directly addresses public health risk. We need to use Probabilistic Risk Assessments that are specific for each nuclear unit to identify the equipment and procedures that are most important to public health risk (i.e., the equipment and procedures most important to severe accidents (reactor core damage) with containment bypassed or breached) and then identify the "special treatment" requirements that will help avoid and mitigate such accidents.	Results of Probabilistic Risk Assessments (PRAs) confirm that the risk from the operation of nuclear power plants is low, and meets the quantitative health objectives established in the Commission's Safety Goal Policy Statement. The comment seems to suggest a rulemaking approach that is different from that outlined in the ANPR. The current effort to risk-inform special treatment requirements will maintain safety while reducing unnecessary burden in areas not important to risk. This process involves extensive use of plant-specific PRAs and other risk assessments, and focuses efforts on SSCs most important to core damage and large release frequencies, as suggested in the comment. Further, the treatment requirements being added in the rule are intended to maintain their capability and reliability so that accidents can be avoided and mitigated. Although the process will not directly address public risk in terms of health effects, consideration of core damage and large release frequencies are adequate surrogates.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-2	It is impossible to maintain overall safety provided by the existing Part 50 if you don't know what level of safety Part 50 provides. There is not a nuclear electric generating unit in the United States that knows the level of public health risk (prompt fatality rate and latent cancer fatality rate) represented by the unit when the unit is considered as a whole much less the part provided by the existing Part 50.	This comment is not directly relevant to the rulemaking approach outlined in the ANPR. Overall plant safety is maintained by adhering to the requirements of Part 50. Regulatory principles such as defense-in-depth and margin of safety have been utilized successfully to ensure that nuclear power does not impose undue risk to the health and safety of the public. As the industry has matured, gained operating experience, and as PRA technology has improved; we have used this information to better inform regulatory and safety decisions. The effort to risk-inform the special treatment requirements is one example of how we are using risk information to reevaluate requirements.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-3	Option 2 should include the risk-informing of: 10 CFR 50.2, 50.12, 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, 50.73, Appendix A (GDCs 1, 2, 3, 4, 18, 37, 40, 42, 43, 45, 46, 53, 54, and 61), Appendix B, Appendix J, Appendix R, Appendix S, 10 CFR Parts 21, 52, 54, and Part 100, Appendix A.VI. Option 2 should include three phases. The first phase should include 10 CFR 50.44, 50.49, 50.54(a), 50.55, 50.55a, 50.65, Appendix A, Appendix B, Appendix J, Appendix S, Part 54, and Appendix A to Part 100; and conforming changes to 10 CFR 50.2 and 10 CFR 50.34. The second phase should include administrative requirements and include 10 CFR 50.34, 50.54, 50.59, 50.71, 50.72, 50.73, Part 52, Part 21 and a complete review of reporting requirements to reduce duplicative reports, data, and reporting functions. Technical specifications (the last phase) should be a separate activity in parallel to Option 2 and should risk-inform the SSC scope of Technical Specifications; address the current duplicative requirements in §50.36 and §50.65(a)(4), and assess the inclusion of administrative requirements.	The NRC has considered all the rules proposed by this comment. A discussion of the rules included and those not included in this rulemaking, as well as NRC's reasons, are provided in Section III.4.0 of the statement of considerations. The rules from the commenter's list that are part of the rulemaking are §§50.49, 50.55a, 50.65, 50.72, 50.73, Appendix B, Appendix J, Part 21 and Appendix A to Part 100. The Commission disagrees with the phased approach proposed in this comment because no advantages have been identified any advantages for proceeding with a phased approach. A single rulemaking can be completed in the same time frame as the proposed first phase. Therefore, a single rulemaking would be a more efficient use of our resources than two separate rulemakings. The NRC does agree that revisions to §50.36 should be accomplished under a separate rulemaking as part of the initiatives currently under development for §50.36, as discussed in Section III.4.0 of the statement of considerations.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-4	The new rule should be based on performance-based and risk-informed requirements that are linked to each regulation. One commenter proposed rule language for a new 10 CFR 50.69, Appendix T, and conforming changes to 10 CFR 50.2 and 50.54(a).	The NRC agrees that the new rule should be risk-informed, and in fact the proposed rule includes a risk-informed categorization process to categorize SSCs with respect to their significance to safety. The NRC is using performance-based techniques, such as performance and condition monitoring and licensee corrective action programs, as much as possible, to preserve attributes of regulatory interest. The rule language offered by the commenter was considered in the development of §50.69.
1-5	Any changes in requirements, new, or alternative requirements resulting from this rulemaking effort should be subject to the requirements in 10 CFR 50.109 (the backfit rule) in order for the Commission to fully understand the effects of the proposed changes. The well-established benefits that flow from a rigorous application of the backfit rule should not be avoided by characterizing the changes as voluntary.	We disagree that the backfit rule should be applied to this rulemaking effort. This is a voluntary regulatory approach, and as such, new requirements are not being imposed on licensees. Applying the concept of backfitting appears to be inappropriate, inasmuch as the development of a new, alternative, regulatory approach does not implicate the policies underlying the Backfit Rule, viz. upsetting of settled expectations by a regulated entity. However, the Commission has prepared a regulatory analysis that is designed to ensure that any regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.
1-6	Once a licensee adopts the risk-informed rules, any new requirements that the NRC believes should be added should be subject to the requirements in §50.109 (the backfit rule).	The NRC agrees with this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-7	For proposed reductions in requirements, the Committee to Review Generic Requirements (CRGR) charter requires the staff to (1) explain how public health and safety would be adequately protected and (2) justify the reduction in requirements by showing a substantial enough cost savings.	A discussion of the technical basis for proposed §50.69 (including whether adequate protection is maintained) is provided in the statement of considerations accompanying the proposed rule. A regulatory analysis examining costs and benefits associated with the proposed rule has been performed and is referenced in the statement of considerations supporting the proposed rule. The CRGR's review is an internal NRC process and confers no rights upon any external stakeholder.
1-8	The risk-informed rules resulting from this rulemaking should be optional. The safety and economic benefits of implementing risk-informed special treatment requirements will vary from plant to plant, depending upon a multitude of factors. For some plants, there may be little or no safety or economic benefit from risk-informing their special treatment requirements, and the costs may be relatively high and would not be justified on a cost-benefit analysis.	The NRC agrees with the reasons expressed by the commenter that the risk-informed rules should be optional and the proposed rule is structured accordingly.
1-9	Licensees should be given significant flexibility in the development of a schedule to implement Option 2. The process of categorizing SSCs is long. To require full and complete implementation of all systems within a short time frame is impractical. A licensee must be permitted to develop a schedule for evaluating the safety significance of its systems in a phased and selective manner. It is expected because of system interdependencies and the need to improve efficiencies that a licensee would eventually categorize all systems.	The NRC agrees that flexibility should be allowed in the development of a schedule for licensees to implement §50.69, since existing requirements remain in effect until a licensee performs the implementation of the alternative requirements. However, a licensee is to keep the staff apprised of its progress in implementation of §50.69 through FSAR updates.

TABLE 2 - SCREENING

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
2-1	GDCs in Appendix A to Part 50 are proposed to be included in the scope of applicability for the §50.69 rulemaking. This should preclude the need for exemptions. The basis for making the change to the scope of GDCs is the safety-significance categorization process.	All the GDCs were removed from the scope of §50.69. It is the NRC's conclusion that these GDCs contain design requirements and are not special treatment requirements. Since this proposed rule is not changing the design basis, the GDCs are not within its scope.
2-2	10 CFR 50.54(a), 50.54(p), and 50.54(q) impose limitations on changing controls and should be included in Option 2. As such, a licensee is prevented from making improvements to its programs because of the manner in which the regulations are crafted, "reduction in commitment" or the rigid and implacable interpretation in regard to the term "reduction in effectiveness."	Section 50.54(a) is not included within the scope of proposed §50.69 for the following reasons. The NRC has adopted a direct final rule addressing "reductions in commitments" under §50.54(a)(3). The result of this relaxation to date has been a significant reduction in the number of licensee submittals requesting NRC review under this regulation. The revised regulation provides for exceptions based on precedents when the bases of NRC approval applies to the licensee's facility. Therefore, the number of submittals under this regulation is expected to continue to decline. The NRC does not plan to address the change control requirements for security plans and emergency plans located in §50.54(p) and §50.54(q) respectively, because Part 73 and §50.47 are not within the list of regulations that we are considering in the current rulemaking efforts. They do not contain special treatment requirements as it has been defined by the Commission for this rulemaking.

TABLE 3 - CATEGORIZATION METHODOLOGY

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-1	It should be recognized that plants may be able to categorize some systems without exercising the categorization process.	Although in some cases exercising the categorization process may be very simple, the intent is for systems to be categorized in accordance with the defined categorization process. The NRC believes that exercising the categorization process is important in order to assure that all important considerations are addressed and to identify safety significant beyond design basis attributes.
3-2	The rule should not identify the consensus PRA standards (e.g., ASME and ANS) as the only acceptable methodologies for performing PRAs. Furthermore, a licensee should not be required to justify its PRA merely because it does not conform with these consensus standards. Acceptable methodologies for performing PRAs include: (1) the criteria in Generic Letter 88-20, (2) the criteria in Section 2.2.3 of Regulatory Guide 1.174, (3) the Industry PRA Certification and Peer Review Program, and (4) the PRA process described in the ANPR.	The NRC agrees that there may be other acceptable approaches for assuring PRA quality besides demonstrating conformance to the consensus ASME/ANS PRA standard documents. As such, the proposed rule does not specifically refer to the ASME/ANS PRA standard documents. The guidance endorsed by the NRC for implementation of §50.69 (e.g., NEI 00-04) refers to both the Industry's PRA Peer Review Process Guidelines for ensuring PRA quality and the ASME PRA standard.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-3	Different types of PRAs (e.g., Fire, Seismic, Internal Events) have different degrees of conservatism and uncertainty. In addressing PRA quality and completeness concerns, it is very important to ensure that no bias is introduced when comparing quantified Core Damage Frequencies (or other figures of merit) between the different types of PRAs for individual plants.	The NRC agrees that different levels of conservatism and uncertainties associated with internal event, fire, and seismic risk analyses, could mask insights from these risk assessments if the core damage frequencies from these studies are merely added together. To avoid this concern, the NRC-endorsed guidance for implementation of §50.69 (e.g., NEI 00-04) specifies that the process for identifying safety significant SSCs should consider SSC importances for the different initiators individually as well as cumulatively.
3-4	Risk profiles associated with any plant outage are highly dependent on the schedule and activities conducted in the individual outage. Attempts to determine importance measures are only as valid as the assumption of a generic outage schedule. This should be addressed in the rulemaking process.	The NRC agrees that the risk profiles associated with a plant outage are dependent on the schedule and activities conducted during that particular outage, and will vary from outage to outage depending on work scope. Although risk insights determined on the basis of a generic outage schedule will not reflect all possible plant configurations, licensees will continue to be required to assess and manage any increase in risk that may result from maintenance activities, in accordance with §50.65(a)(4). In addition, if an unanalyzed plant configuration becomes important (in terms of frequency and safety significance) it is expected that the licensee's process will include the configuration in an update of the categorization process. Thus, acceptable risk levels will continue to be maintained.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-5	The proposed Appendix T is unduly detailed and prescriptive. Detailed and prescriptive rules will reduce the flexibility of licensees implementing them and may therefore discourage licensees from adopting them. Detailed and prescriptive rules will also make it harder to take advantage of and potentially discourage advances in technology. The rule should include only policy-level criteria and should allow different approaches for compliance with the rule. Details of an acceptable risk-ranking process should be included in a guidance document, not a rule. Furthermore, the production of the guidance document should be a living process and future changes as a result of operating experience should be easy to make. An approach that utilizes an endorsed guidance document for implementation does not necessitate prior NRC review. This has been demonstrated by the implementation of the maintenance rule.	The NRC agrees. Proposed §50.69 does not utilize a “no prior review” type approach, and therefore does not contain detailed, objective criteria that would obviate the need for NRC review and approval. Hence Appendix T has been eliminated from the approach.
3-6	The proposed Appendix T is unduly burdensome. Commenters provided specific examples of areas where they believed that Appendix T was unduly burdensome.	The proposed rule does not include Appendix T. The proposed rule utilizes a prior review and approval type of approach.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-7	The rulemaking approach should minimize the number of risk significance levels to the extent practical. Creating more risk significant levels would likely lead to more levels of treatment. More risk significance levels and sub-levels will make the categorization process over-complicated. This will result in increased implementation difficulties for both licensees and the NRC.	We agree with this comment, for the reasons stated. The four quadrant approach for risk-informed categorization provides a simple framework for differentiating between the safety classification (safety-related versus non-safety-related) and safety significance of an SSC. Under this approach, both safety-related and nonsafety-related SSCs are classified as either “safety-significant” or “low safety-significant.”

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-8	In the quadrant approach there should be two subcategories for RISC-2 SSCs. The first, RISC-2(1), should include nonsafety-related SSCs that are currently identified as "important-to-safety" and are categorized as safety-significant. This subcategory should continue to be subject to the existing requirements. The second subcategory, RISC-2(2), should include nonsafety-related SSCs that are categorized safety-significant. This subcategory should be subject to: (1) A performance monitoring program that provides reasonable assurance that the safety functions identified in the risk-informed evaluation process will be satisfied; (2) Commercial level controls and specifications imposed by the licensee that provide reasonable assurance that the safety-significant functions identified by the risk-evaluation process are satisfied. Such programs shall include a change control provision that provides reasonable assurance that the safety-significant function(s) will be satisfied following a facility change that involved RISC-2(2) SSCs; and (3) A performance-based reporting program for deficiencies that result in a failure to satisfy a safety-significant function identified in the risk-informed evaluation process.	The NRC disagrees with the comment about subcategories, believing that one category for RISC-2 SSCs is sufficient. The proposed rule contains the necessary requirements (referred to in the comment), but does it in a simpler framework.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-9	The following insights on Integrated Decision making Panels (IDP) (Element 6 of Appendix T) were provided: The IDP membership should be maintained as consistent as possible. It is recommended that the use of alternate members be minimized, and that in general, the only alternate position permitted would be the Chairman position. The selection of the IDP chairman and IDP members should be the responsibility of a more-senior team that either offers oversight of the IDP, or serves as a sponsoring organization for the IDP The training of IDP members should be a combination of technical training prior to beginning the overall categorization process, and just-in-time training that addresses the specifics of the PRA insights for each particular system as it is addressed. IDP decision making should encourage the documentation of differing opinions when professional technical differences exist among IDP members that can not be resolved to each member's satisfaction.	The suggested insights were considered as part of the effort to develop guidance for implementing §50.69. The draft regulatory guide (DG-1121) (and the Nuclear Energy Institute (NEI) guidance on which it is based) includes statements about necessary training of members (on the overall categorization process and on PRA insights), and documentation of decision-making. The rule contains requirements about the constitution of the IDP.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-10	The importance and classification of an SSC can be determined using factors such as the Fussell-Vesely (F-V) importance and Risk Achievement Worth (RAW). In addition, the use of sensitivity studies (in place of baseline CDF and LERF changes) to bound the overall change in treatment and CDF/LERF should be allowed.	The NRC agrees with this comment. The use of importance measures such as Fussell-Vesely and Risk Achievement Worth will help identify SSCs which are potentially low safety-significant and are potential candidates for reduced treatment requirements. Low safety significance is validated by the IDP process which will considers factors such as defense-in-depth, and risk insights outside the scope of the PRA. Low safety significance must be confirmed by demonstrating that risk increases (if any) are small. This demonstration can be in the form of sensitivity studies to bound the overall change in CDF and LERF from changes in treatment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-11	The final rule should include a feedback mechanism for re-assessing SSC categorization based on operating experience to assure that the SSCs are properly categorized.	The NRC agrees with this comment. Feedback is necessary so that the licensee can monitor performance against expectations, and where these are not consistent, adjust treatment or categorization as needed. This maintains the validity of the categorization process that established the new treatment requirements. The proposed rule in paragraph (e) includes requirements for feedback and process adjustment based on operating experience, changes to the facility, changes to operating practices, and industry experience. Specifically, proposed §50.69(e)(1) applies to all SSCs and requires the licensee to review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization. The requirements in (e)(2) require the licensee to monitor the performance of RISC-1 and RISC-2 SSCs and make adjustments as necessary to either the categorization or treatment processes. The requirements in (e)(3) require the licensee to consider data collected in §50.69(d)(2)(iii) for RISC-3 SSCs to determine whether there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-12	The categorization process may identify other safety-related SSCs that are not categorized as safety-significant, and that are not directly and specifically referenced in the regulation or directly referenced in the safety analyses required by regulation. These SSCs may be categorized as RISC-4 on completion of a satisfactory 50.59 evaluation.	The NRC agrees that reclassification of SSCs from safety-related to nonsafety-related would be acceptable provided the licensee performs a satisfactory §50.59 evaluation and ensures that other documents which refer to such SSC are appropriately changed as necessary (e.g., technical specifications, orders, license conditions). The proposed rule does not address reclassification of SSCs from safety-related to nonsafety-related because such reclassification is not part of the risk-informed consideration of special treatment requirements.
3-13	Relative risk rankings of plant systems and components can change. An SSC categorized as RISC-3 or RISC-4 can later be categorized as RISC-1 or RISC-2, respectively, as a result of new information, a change in performance, or modifications to the plant. The rulemaking process should establish clear requirements for dealing with such situations.	The NRC agrees that changes in classification can occur. When this occurs, the rule requires SSCs whose categorization changes to be treated consistent with the treatment required for the revised RISC category (i.e., a change of SSC categorization from RISC-3 to RISC-1 requires that the component meet the RISC-1 treatment requirements). It is the licensee's responsibility to manage the process in a manner that avoids such situations.
3-14	ASME has developed risk-informed code cases for categorization, testing, and inspection. In addition, ASME is currently developing risk-informed code cases for other areas, including a code case on repair/replacement/modification activities. It would be more appropriate to reference those code cases instead of including detailed requirements in the rules.	The detailed requirements (on categorization) referred to in the comment (Appendix T) are no longer part of the proposed rule. The rule requirements on repair and replacement are not detailed. The proposed rule would permit the use of approved ASME risk-informed code cases for implementation of proposed §50.69.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-15	Since substantial effort has already been expended in the development and publishing of ASME Code Cases (as well as NRC Regulatory Guides), it would seem that the terminology that the industry has agreed to use should continue to be consistently utilized. The ASME Code Cases (and NRC Regulatory Guides) use terms High/Low Safety Significant Components vice Safety Significant Components/Low Safety Significant Components (as used in the ANPR).	The NRC disagrees with this comment. The terminology used in the ANPR as reflected in the proposed rule represents the Commission's views about the overall significance of the two categories for a broad range of SSCs. Terminologies used in specific code cases can be aligned with the categories as expressed in the rule.

TABLE 4 - PILOT PROGRAM

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-1	A higher degree of regulatory predictability and benefit must be established before piloting the proposed regulatory framework. This can be accomplished by development of an NRC-endorsed industry guideline.	This comment describes a situation in which an industry guideline is first endorsed by the NRC and then piloted. The NRC elected not to follow such an approach. Instead, as discussed in Section IV.3 of the SOC, pilot activities focused upon categorization of SSCs. The NEI 00-04 implementation guidelines reflect lessons-learned from this pilot program. The staff's review of drafts of the proposed guidelines was undertaken in parallel with the pilot program.
4-2	The purpose of the pilot program should be to verify that the requirements and associated guidance of the categorization process can be implemented by industry, to demonstrate the viability of risk categorization processes to establish alternative risk-informed special treatment requirements, and to test out special treatment requirements. The pilot program should also provide estimates of implementation costs and benefits from this effort.	These objectives are consistent with those described by the NRC in an October 19, 1999 letter regarding the pilot program from Samuel Collins to Ralph Beedle, and in SECY-99-256. However, the pilot activities focused primarily on the categorization process. The NRC staff's interaction with the pilots was to observe the IDP (the culmination of the categorization process) and provide feedback. This focus is consistent with the NRC's objective of developing a robust categorization process.
4-3	There is no need to specifically pilot each rule. Testing the guideline against a sample set of regulations and systems is sufficient for resolving implementation issues and providing the bases and confidence for generic implementation on the complete spectrum of Option 2 regulations.	The NRC agrees with this comment. The main purpose of the pilots as they were conducted was to test categorization.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-4	As with any unknown process, when you start the process it will be difficult to determine what schedules and resources must be applied to the process to come up with a "good" product. All that can be done is to initially define the best scope of work possible with well defined deliverables and schedules. As one proceeds with the pilot programs, continuous feedback must be used to adjust the process as one goes. It makes no technical sense to commit to schedules and requirements in advance.	The NRC agrees with this comment. We recognize the difficulties in planning activities that lack good precedent and experience. We also understand that schedules and scope of activities may require adjustment as experience is gained, and problems are identified and resolved.
4-5	The requirements on pilot plants are unnecessarily restrictive. The requirements that pilot plants must include a variety of plant systems is not necessary because South Texas Project has demonstrated the viability of the concepts underlying the risk-informed classification process.	The NRC agrees with this comment. In practice, a variety of systems were piloted by the different pilot plants as discussed in Section IV.3 of the SOC. The participants obtained NRC staff input concerning the systems which should piloted and this ensured that the staff was satisfied with the variety of systems that were ultimately piloted. The pilot program was implemented in a manner different than was initially envisioned in the extent of the pilots was limited to categorization of SSC, and not implementation of any revised special treatment. Thus, it was not necessary for pilot program participants to apply for exemptions from the current special treatment requirements.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-6	The STP exemption request should be completed prior to rulemaking. Potential pilot plants are closely watching the status of the STP exemption request. If the eventual outcome is that STP is not granted the exemption request, other potential pilot plants will likely consider the ability to categorize SSCs and adjust the special treatment requirements to be overly difficult and will not pursue this possibility.	The NRC agrees with this comment. The NRC staff's review of the STP exemption request was completed in August 2001, well before issuance of the proposed rule.
4-7	Pilot plants should not be forced to adopt the final rule because their methodologies would have been reviewed and found acceptable. Pilot plants will seek exemptions to NRC regulations to apply and pilot the special treatment requirements defined in Option 2. Some pilot plants may wish to deviate from the generic guidance because of differing designs and established licensee practices. This is both necessary and beneficial from a pilot project perspective. The varying approaches, approved by the NRC in the exemption process, will be assessed and evaluated by the NRC staff. As necessary and appropriate, a licensee might adjust its approach based on implementation insights and NRC input during the pilot project.	Because of the manner in which the pilot program was implemented, this comment is not applicable. No exemptions were requested for any pilot plants.

TABLE 5 - TREATMENT

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-1	The effort defined in the ANPR is based on an "add on" approach. The effort as described will retain all the existing special treatment requirements for design basis accidents and add more special treatment requirements for severe accidents. Such a process will not result in more effective and efficient regulations.	The NRC disagrees with this comment. Although, in some cases, additional treatment requirements may be added to some SSCs, it is not accurate to characterize the effort defined in the ANPR as an "add on" approach. It is true that for RISC-1 and RISC-2 SSCs, some additional requirements may be added as a result of the need to maintain the functional capability of SSCs consistent with the assumptions made in the categorization process. The proposed rule removes RISC-3 and RISC-4 SSCs from the scope of the special treatment requirements listed in §50.69. However, §50.69 does impose the minimum amount of regulatory treatment to maintain functional capability, albeit at a reduced level of confidence from that provided by the current special treatment requirements. The net result should provide a better focus for both NRC and industry resources.
5-2	Beyond design basis scenarios are included in the evaluation process for categorizing SSCs. However, this rulemaking should not require licensees to establish new design requirements for severe accidents. That task should be undertaken as part of Option 3 of SECY 98-300. To require licensees to establish new risk-informed design requirements for severe accidents and still require them to comply with the existing design requirements would be unfair.	The NRC agrees with this comment. The proposed rule only involves treatment of existing SSCs, and is not establishing new design requirements for severe accidents.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-3	Consideration of normal operation or the existing design basis accidents should be included in the proposed rulemaking only in clear areas (e.g., sabotage) where information from a Probabilistic Risk Assessment has not been applied.	The NRC disagrees with this comment. Under the proposed rule, safety-related SSCs must remain functional under design basis conditions, because the design basis for a plant remains unaffected by the 50.69 rule. The NRC is considering risk-informed changes to the existing design basis accidents under Option 3 of RIP50.
5-4	It is not clear what the Commission means by the last sentence in the proposed meaning for special treatment (i.e., "This definition does not encompass functional design requirements; that is, an SSC's functional design requirement is not considered a special treatment requirement.")	It is the NRC's position that regardless of the treatment imposed, SSCs must continue to be functional for the design basis events because the proposed rule does not change the design basis for any SSCs in the plant. The proposed rule is risk-informing the "assurance" requirements. The design basis functional requirements remain unchanged by the proposed rule. Hence, the proposed rule contains requirements intended to provide confidence that RISC-3 SSCs continue to perform their design basis functions at the conditions under which the intended functions are required to be performed.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-5	Existing special treatment requirements will continue to apply to RISC-1 SSCs. Any additional requirements considered for RISC-1 SSCs in order to satisfy PRA assumptions or beyond design basis events should be qualified to account for existing special treatment requirements and licensee programs being applied to these SSCs and the actual performance of the SSCs. An evaluation of the need for additional special treatment requirements for non-safety-related functions of RISC-1 SSCs should only be undertaken if a licensee: (1) takes credit in the PRA for a RISC-1 SSC functioning at a level that is better than the reliability/availability levels associated with existing operating experience; or (2) determines that a significant reduction in risk can be achieved through additional specific treatment requirements.	The NRC agrees that existing special treatment requirements will continue to apply to RISC-1 SSCs. Additional treatment requirements for RISC-1 SSCs are included in the proposed rule. These requirements do not preclude taking credit for existing requirements and programs. The NRC disagrees with the criteria in the comment for when an evaluation of the need for additional treatment is to be undertaken. We conclude that the licensee should ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization assumptions by evaluating treatment applied to these SSCs to ensure that it supports the key assumptions for performance. The NRC recognizes that in many cases, licensees may determine that no additional treatment is necessary.
5-6	The final rule should include a general performance-based standard for RISC-2 SSCs that would allow licensees to establish their own treatment programs or take credit for existing programs to maintain the reliability/availability of these SSCs as assumed in the PRA. This, when combined with the monitoring requirements of the maintenance rule and periodic PRA updates, should be sufficient to ensure the reliability/availability of the RISC-2 SSCs as assumed in the PRA.	The NRC agrees in principle to allowing flexibility in licensee implementation of performance monitoring methods. The proposed rule allows licensees to establish treatment programs or take credit for existing programs to maintain the reliability/availability of these SSCs as assumed in the PRA.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-7	The functional capability of RISC-3 SSCs should be maintained.	The NRC agrees with this comment and the proposed rule has been developed to include requirements that provide sufficient assurance that RISC-3 functional capability is maintained.
5-8	Because RISC-3 SSCs are by definition low safety-significant, no special treatment requirements, beyond normal commercial practices (as determined by the licensee), are warranted.	The NRC believes that an acceptable treatment program for RISC-3 SSCs must meet the minimum requirements specified in proposed §50.69(d)(2). We believe that some commercial programs do in fact satisfy these minimum requirements. However, we do not believe that all commercial programs satisfy these requirements, and therefore these requirements were included in proposed §50.69.
5-9	Monitoring of RISC-3 SSCs should only be required if a change in performance of the SSC could affect its safety classification.	NRC does not agree with this comment. The rule requires inspection, tests and surveillance for RISC-3 SSCs to obtain information about their capability to perform their functions in proposed §50.69(d)(2)(iii). The rule also requires the licensee to use this information to determine if the categorization, or the treatment being applied needs to be revised in proposed §50.69(e)(3).
5-10	RISC-4 SSCs should continue to be treated in accordance with normal commercial grade standards.	The NRC agrees with this comment. These SSCs are of low significance both from the “safety-related” and PRA perspectives, and thus there is no reason to alter the treatment requirements for these SSC (which is presently in accordance with commercial standards).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-11	A change-control process covering beyond design basis functions should be incorporated in the new 10 CFR 50.69.	The proposed rule contains feedback and process adjustment requirements such that the PRA and categorization process are to be reviewed and revised to account for plant design changes. Refer to the response to issue 3-11 for a detailed discussion of feedback requirements. Thus, if changes are made that affect beyond design basis functions, this would be reflected in the SSC categorization.
5-12	RISC-1 and RISC-3 SSCs should remain subject to the requirements of 10 CFR 50.59 for design basis functions.	The NRC agrees with this comment with respect to the application of §50.59 to RISC-1 and RISC-3 SSCs. Note that the current scope of applicability of §50.59 is more broad than the SSCs that will be categorized as RISC-1 and RISC-3.
5-13	RISC-3 SSCs should not be subject to 50.72 or 50.73 reporting requirements based on the assumption that these SSCs have minimal or no safety significance.	The NRC agrees with this comment. We have included §50.72 and §50.73 in the scope of §50.69(d)(2).
5-14	All commitments related to low safety-significant SSCs should be replaced by a single commitment that imposes commercial level (balance-of-plant) special treatment requirements (monitoring or controls) to provide reasonable assurance that the functions required by regulation or credit in the safety analyses required by regulations will be satisfied. Evaluation of individual SSCs with respect to commitments is not necessary or practical.	The NRC disagrees with this comment. Changes to treatment requirements for low safety-significant SSCs should only be made upon consideration of whether functionality under design basis conditions would be maintained with the planned change, not whether they are commitments.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-15	Part 21 should not be included in the Option 2 scope. Part 21 is a complex regulation with hard links to the Atomic Energy Act. As such, any change to the scope of Part 21 would be a complex and prolonged activity that may involve a change to the Atomic Energy Act.	NRC disagrees with this comment. The burden associated with Part 21 requirements is not appropriate for RISC-3 SSCs given their low safety significance. While it is true that Part 21 has hard links to the AEA, the NRC has included Part 21 within the scope of §50.69 and discusses why the requirements of the AEA are still satisfied in Section III.4.1 of the supporting statement of considerations. As a practical matter, vendors are still likely to report defects in RISC-3 SSCs per Part 21 for the reasons stated in Section III.4.1.2 of the supporting statement of considerations.
5-16	Part 21 does not currently apply to RISC-3 SSCs because a failure of these SSCs could not cause a substantial safety hazard. There also is no safety reason to impose risk-informed Part 21 requirements on SSCs that are not safety-significant.	We agree that when SSCs are correctly categorized with respect to their safety significance, deviations and failures to comply for RISC-3 SSCs are unlikely to create a substantial safety hazard and thus cause the notification requirements of Part 21 to be exceeded. A failure of a properly-categorized RISC-3 SSC should result in only a small change in risk, and should not result in a major degradation of essential safety-related equipment (see NUREG-0302). Thus, there is little regulatory need for the NRC to be informed of instances of noncompliance and defects with RISC-3 SSCs. This is consistent with the NRC's current position that a "substantial safety hazard" involves a major degradation of essential safety-related equipment (see NUREG-0302). Accordingly, the Commission proposes that RISC-3 SSCs should not be subject to reporting requirements of Part 21 and § 50.55(e).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-17	Part 21 does not currently apply to RISC-2 or RISC-4 SSCs because these SSCs are not basic components as defined in the Act or in Part 21. In addition, Part 21 requirements should not be imposed on RISC-2 SSCs because: (1) it would be unfair to vendors who have already sold the SSCs to incur the resulting costs, and (2) 50.72 and 50.73 are sufficient to alert the NRC to significant adverse conditions and failures in RISC-2 SSCs.	The NRC agrees that Part 21 should not be imposed on RISC-2 or RISC-4 SSCs, as discussed in greater detail in section III.4.1 of the SOC. As noted below, the 50.72 and 50.73 reporting requirements are being supplemented with a specific criterion for reporting concerning RISC-2 SSCs.
5-18	Making Part 21 risk-informed would not be inconsistent with Section 206 of the Energy Reorganization Act or Section 223.b of the Atomic Energy Act. The Commission has previously taken the position that Section 206 does not require Part 21 to apply to all safety-related SSCs and that the NRC has discretion to determine what kinds of SSCs should be considered "basic components," and this position has been accepted by the courts. See Natural Resources Defense Council v. NRC, 666 F.2d 595, 603 (D.C. Cir. 1981). Therefore, NRC is free to risk-inform the definition of "basic component" in Part 21. The definition of "basic component" in Section 223.b is restricted to that section, does not apply to Section 206, and does not require that the NRC use the same definition of "basic component" in Part 21.	The NRC agrees that implementing Part 21 in a risk-informed manner is not inconsistent with Section 206 of the Energy Reorganization Act. The NRC also agrees that the definition of basic component in Section 223.b of the Atomic Energy Act is restricted to that section. The U.S. Department of Justice has the authority and responsibility for criminal prosecutions under Section 223.b.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-19	A performance-based 10 CFR 50.73 type reporting requirement should be included in the new 50.69 for RISC-2 SSCs.	The NRC agrees that a reporting requirement for RISC-2 SSCs should be included in §50.69. Since these SSC are now viewed as safety-significant, the NRC, as part of its risk-informed oversight activities, wants to be informed about conditions impacting upon functionality of these SSC. This is included in the proposed rule.

TABLE 6 - SELECTIVE IMPLEMENTATION

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
6-1	The risk-informed rules resulting from this rulemaking should allow for selective implementation with respect to both rules and systems. Selective implementation of rules does not present any adverse impacts because if a licensee decides not to implement a risk-informed regulation, the licensee would be required to meet the existing deterministic regulation which provides adequate protection of the public health and safety. Therefore, although there may be benefits from full implementation of the risk-informed rules, licensees should be allowed to determine whether the benefits outweigh the costs. With respect to systems, some safety-related systems will obviously be safety-significant while other nonsafety-related systems will obviously be low safety- significant. There is no benefit to implementing the risk-informed rules for such systems. Implementation on a system basis should proceed with first priority on systems with components that are very likely to be categorized as RISC-2 or RISC-3, second priority for systems whose components have some potential for being categorized as RISC-2 or RISC-3, and no priority for systems whose components are highly likely to be categorized as RISC-1 or RISC-4.	The NRC agrees with this comment for the reasons noted. The proposed rule is constructed to allow implementation for select rules or select systems. As discussed in section IV.1.3 and V.5.0 of the SOC, selective implementation will necessitate that the categorization process assumptions continue to be valid, which involves satisfying certain requirements for evaluation and monitoring.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
6-2	The final rule should provide licensees with the option of categorizing the different functions of an SSC instead of forcing all functions of the same SSC to be categorized in the same RISC class.	The NRC agrees with this comment, as being a viable way to determine the appropriate classification of a particular SSC. We recognize that many licensees have used a “functional categorization” approach for the maintenance rule. The proposed rule allows this categorization approach. However, this can be a difficult and cumbersome process from the standpoint of record keeping.

TABLE 7 - IMPACT ON OTHER REGULATIONS

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
7-1	Maintaining a single NRC Form 3 posting (as required by 10 CFR Part 19) would not confuse licensee staff and contractors. Under either a risk-informed or deterministic regulatory regime, the NRC Form 3 intent remains the same.	Licensees and applicants who implement §50.69 should examine their posting practices (for required notices) to be sure that appropriate information is provided to employees.
7-2	A risk-informed Option for Part 54 should be developed. Since licensees in general rely upon existing special treatment requirements to satisfy Part 54, the scope of SSCs subject to Part 54 should not be broader than the scope of SSCs subject to special treatment. Risk informing Part 54 would likely result in a more efficient process for both licensees and NRC, since neither would be required to evaluate the impact of aging on SSCs that are not safety-significant.	The NRC disagrees that RISC-3 SSCs should be removed from the scope of Part 54 as part of this rulemaking. We believe that licensees that implement §50.69 can renew their licenses in accordance with Part 54 by demonstrating that the treatment applied in accordance with §50.69 provides adequate aging management under Part 54.21. Part 54 already allows consideration of risk in terms of the robustness of the aging management program, as discussed in Section III.4.9.8 of the SOC.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
7-3	The terms "operability" and "functionality" are not equivalent terms. A system can be “functional,” yet declared inoperable, e.g., because it has missed a required surveillance test or because a support system is not functional. In other words, a safety-related system can be declared inoperable even though the system is capable of providing its specified safety function. Although there is a difference in meaning between “functional” and “operable,” we do not believe that this difference has any importance with respect to the type of treatment to be afforded to RISC-3 SSCs. Such SSCs should be subject to commercial practices, which will be sufficient to ensure that they have sufficient availability and reliability to perform their safety-related functions. To the extent that such SSCs are also controlled by the technical specifications, they will also need to satisfy the operability requirements in the technical specifications, including passing all required surveillance tests (unless the licensee seeks and justifies a license amendment to remove such SSCs from the scope of the technical specifications).	The NRC agrees that the difference in meaning between “functional” and “operable” is not relevant to this rulemaking. The NRC’s position on treatment of RISC-3 SSCs sufficient to maintain functionality is covered by the responses to the issues in Section 5 of these tables and by the requirements in proposed §50.69. The NRC also agrees that to the extent that RISC-3 SSCs are controlled by technical specifications, they are required to satisfy the operability requirements in the technical specifications, including passing all required surveillance tests.

TABLE 8 - NEED FOR PRIOR NRC REVIEW

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-1	Performing a 50.59 evaluation (and, as necessary, obtaining NRC approval) for each change in a special treatment requirement in the UFSAR would be extremely burdensome and prohibitively costly for both licensees and the NRC. There are two options to dealing with 10 CFR 50.59. 10 CFR 50.59 could be made risk-informed to eliminate the need for individual 50.59 evaluations (and prior NRC approval) for each change in special treatment described in the UFSAR. Alternatively, the revised 50.59 could be interpreted as not requiring a full evaluation for revisions of the special treatment described in the UFSAR.	The NRC agrees that it would be unnecessarily burdensome to perform a §50.59 evaluation for each change in special treatment requirements resulting from the categorization. However, it is not necessary to change or reinterpret §50.59 to implement §50.69. Instead, the proposed §50.69 allows licensees to revise treatment without the need for a §50.59 evaluation to support the resulting FSAR changes. This rulemaking is being undertaken to establish the requirements for the revised treatment for the SSC. Performing §50.59 evaluations to determine if NRC review and approval of these changes would be unnecessary and redundant.
8-2	Ultimately, 10 CFR 50.59 should be risk-informed to allow licensees to make design changes that do not have risk-significance.	Risk-informing §50.59 is beyond the scope of the Option 2 regulatory effort.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-3	The industry fully supports and encourages the open dialogue that has been established by the NRC to provide public, licensee, and NRC staff participation. It is only through such open dialogue that a complete understanding of risk-informed regulatory improvements can be established. The existing process provides significant material for public review and provides sufficient opportunity for public input and participation on matters that have safety-significance. The public will have the opportunity to participate in developing the criteria for the classification process in the rulemaking. It is difficult to envision a higher degree of opportunity for public participation or access to information. Once the rule is approved, the public should have no special participation rights.	The proposed rule requires licensees to submit a license amendment to implement §50.69. The categorization process and supporting PRA information will be reviewed and approved by NRC. Under proposed §50.69, that review will entail considerable judgment and discretion on the part of the NRC, and the NRC approval effectively changes the authority afforded by the operating license. Accordingly, the NRC believes that such approvals must be implemented as a license amendment under the authority of *Cleveland Electric Illuminating Co.* (Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315 (1996).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-4	NRC review of a licensee's implementation of the final rule should be limited to certain process aspects of the categorization and treatment determination to ensure compliance with the final rule. A template submittal to notify the NRC of a licensee's intent to adopt the resulting risk-informed rules is being developed by NEI. This would include statements on PRA quality, the methodology used in the risk-evaluation process, the list of regulations being adopted, and a discussion of the extent to which the licensee's approach is consistent with an endorsed guideline. NRC review of the information provided in the template should be sufficient to ensure compliance. After implementation of the resulting rules, the inspection process should be sufficient to confirm reasonable assurance that public health and safety is maintained.	The NRC agrees with this comment as it related to treatment but disagrees with this comment as it relates to categorization. Because of the heavy reliance on a robust categorization process, the NRC believes that a thorough review of the categorization process (and in particular of the supporting PRA information) is necessary. The information that is required to be included in an application for implementation of §50.69 is in the proposed rule.
8-5	The objective to establish categorization and treatment criteria sufficient that if a licensee's program meets them there is no need for prior NRC review and approval of the plant-specific program is impossible to do in actual practice.	The NRC agrees with this comment. The NRC developed proposed §50.69 to utilize a "prior review and approval " type approach on categorization.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
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Division 1
Draft DG-1121
DRAFT REGULATORY GUIDE
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DRAFT REGULATORY GUIDE DG-1121

GUIDELINES FOR CATEGORIZING STRUCTURES, SYSTEMS, AND COMPONENTS IN NUCLEAR POWER PLANTS ACCORDING TO THEIR SAFETY SIGNIFICANCE

A. INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) has promulgated regulations to permit power reactor licensees and applicants for licences to implement an alternative regulatory framework with respect to "special treatment," where special treatment refers to those NRC requirements that provide increased assurance beyond normal industrial practices that structures, systems, and components (SSCs) perform their design basis functions. Under this framework, licensees using a risk-informed process for categorizing SSCs according to their safety significance can remove SSCs of low safety significance from the scope of certain identified special treatment requirements.

The genesis of this framework stems from Option 2 of SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50 - Domestic Licensing of Production and Utilization Facilities," dated December 23, 1998. In this SECY, the NRC staff recommended that risk-informed approaches to the application of special treatment requirements be developed to reduce unnecessary regulatory burden of SSCs of low safety significance by removing them from the scope of special treatment requirements. The Commission subsequently approved the NRC staff's rulemaking plan and issuance of an Advanced Notice of Proposed Rulemaking (ANPR) as outlined in SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999. The ANPR was published in the Federal Register (65 FR 11488) on March 3, 2000. In the rulemaking plan, the NRC proposed to create a new section within Part 50, referred to as section 50.69, to contain these alternative requirements.

This draft regulatory guide describes a method acceptable to the NRC staff for complying with the Commission's regulations with respect to the categorization of SSCs that are considered in risk-informing special treatment requirements. Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in the early stages of developing the regulatory positions. Draft regulatory guides have not received complete staff review, and they, therefore, do not represent official NRC staff positions at this time. However, if a licensee or its supplier elects to use or reference this guide, the licensee or supplier must comply with the provisions in the Regulatory Position of this guide.

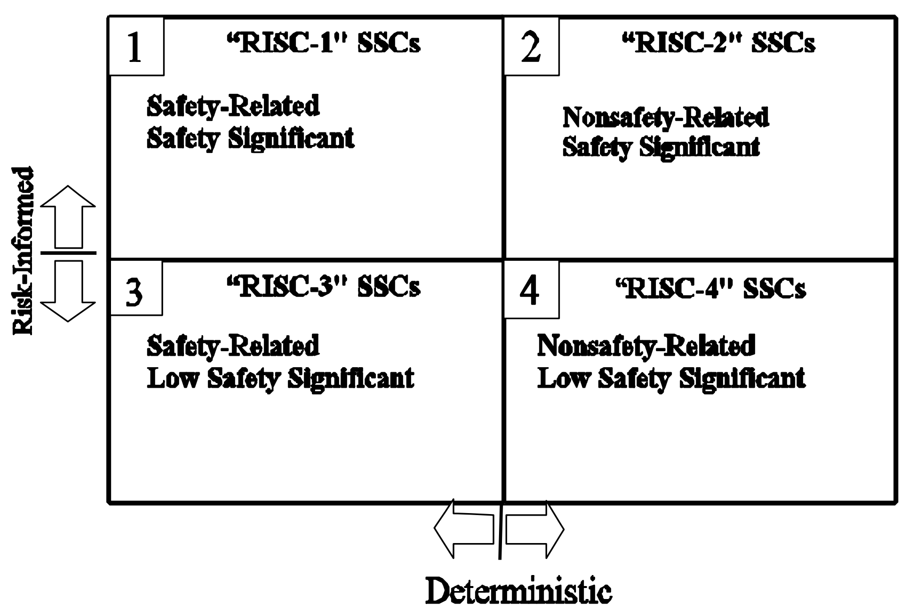
The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

This regulatory guide provides guidance for categorizing SSCs in accordance with their safety significance using the process described in Draft Revision C of Nuclear Energy Institute (NEI) 00-04, “10 CFR 50.69 SSC Categorization Guideline.” The categorization process determines the safety significance of SSCs and places them into one of four risk-informed safety class (RISC) categories. The safety significance of SSCs is determined by an integrated decision-making process, which incorporates both risk and traditional engineering insights. The safety functions of SSCs include both the design basis functions (deriving from the safety-related definition) and functions credited for severe accidents. Treatment requirements are then commensurately applied for the categorized SSCs to maintain their functionality and reliability.

Figure 1 provides a conceptual understanding of the new risk-informed SSC categorization scheme. The figure depicts the current safety-related versus nonsafety-related SSC categorization scheme with an overlay of the new safety-significance categorization. In the traditional deterministic approach, SSCs were generally categorized as either “safety-related” (as defined in 10 CFR 50.2) or nonsafety-related. This division is shown by the vertical line in the figure. Risk insights, including consideration of severe accidents, can be used to identify SSCs as being either safety-significant or low safety-significant (shown by the horizontal line). This results in SSCs being grouped into one of four categories as represented by the four boxes in Figure 1.

Figure 1. 10 CFR 50.69 RISC Categories



RISC-1 SSCs are safety-related SSCs that perform safety-significant functions. RISC-2 SSCs are nonsafety-related SSCs that perform safety-significant functions. RISC-3 SSCs are safety-related SSCs that perform low safety-significant functions. Finally, RISC-4 SSCs are nonsafety-related SSCs that perform low safety-significant functions.

The rule defines "safety-significant function" as functions whose loss or degradation could have a significant adverse effect on defense-in-depth, safety margins or risk. This definition was chosen to be consistent with the concepts described in RG 1.174. The term used is "safety-significant" instead of "risk-significant" because the categorization process employed in §50.69 considers both probabilistic and deterministic information in the decision process. Through the process described in the industry guidance document discussed below, as modified by the staff positions, the RISC category for SSCs is determined. Those functions that are not determined to be safety-significant are considered to be low safety-significant.

This draft regulatory guide contains specific instructions and cautions in the use of the categorization process. The guidance is limited to that presented in Section C of Draft Regulatory Guide 1121. This regulatory guide incorporates experience gained from a review of pilot programs, industry programs, and industry practices.

C. <u>REGULATORY POSITION</u>

This regulatory guide is being developed to provide guidance for determining whether an SSC performs safety-significant functions.

1. NRC Endorsement of Draft Revision C of NEI 00-04

Draft Revision C of NEI 00-04 "10 CFR 50.69 SSC Categorization Guidance," dated June 28, 2002, provides an approach that is acceptable to the NRC staff in meeting the categorization requirements in 10 CFR 50.69, subject to the following clarifications, enhancements, and conditions. [TBD upon resolution of the issues discussed in the attachment, either by appropriate revisions to NEI 00-04 or by inclusion of staff positions in the RG]

2. Use of Methods Other Than Draft Revision C of NEI 00-04

To meet the requirements of 10 CFR 50.69 for categorization of SSCs, licensees may use methods other than those set forth in Draft Revision C of NEI 00-04. The NRC will determine the acceptability of these other methods on a case-by-case basis.

3. Other Documents Referenced in Draft Revision C of NEI 00-04

Draft Revision C of NEI 00-04 references numerous other documents, but NRC's endorsement of Draft Revision C of NEI 00-04 is not an endorsement of these other referenced documents.

4. Use of Examples in Draft Revision C of NEI 00-04

Draft Revision C of NEI 00-04 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in Draft Revision C of NEI 00-04, the NRC's endorsement of Draft Revision C of NEI 00-04 is not a determination that the examples are applicable for all licensees. A licensee must ensure that an example is applicable to its particular circumstances before implementing the guidance as described in the example.

5. Limitations of Types of Analyses Used in Implementing Draft Revision C of NEI 00-04

In its 1995 Policy Statement on the use of probabilistic risk assessment (PRA), the Commission determined that the use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art PRA methods and data. Implementation of risk-informed regulation is possible because the development and use of a quantitative PRA requires a systematic and integrated evaluation. Development of a technically defensible quantitative PRA also requires sufficient and structured documentation to allow investigations of all aspects of the evaluation. To meet the requirements of 10 CFR 50.69 for categorization of SSCs, licensees must use risk evaluations and insights that cover the full spectrum of potential events (i.e., internal and external initiating events) and the range of plant operating modes (i.e., full power, low power, and shutdown operations). The NRC staff believes that current state-of-the-art PRA methods are available to quantitatively address the full spectrum of potential events and the full range of plant operating modes for this type of application and thus, it is desirable for licensees to use such broad-scope PRAs. However, Draft Revision C of NEI 00-04 allows the use of non-PRA type evaluations (e.g., FIVE, seismic margins analysis, NUMARC 91-06), when PRAs have not been performed. It should be recognized that the degree of relief that can be expected will be commensurate with the assurance provided by the evaluation.

6. Quality Attributes of Analyses Implementing Draft Revision C of NEI 00-04

Draft Revision C of NEI 00-04 states in Section 3.3 that the Option 2 categorization process is a Grade 3 application per the NEI 00-02 peer review process. Through NEI 00-02, as amended to incorporate NRC comments provided in the NRC letter to NEI, dated April 2, 2002, there is a mechanism for licensees to determine if their internal events PRA meets the attributes required for this application. An alternative to NEI 00-02 may be the ASME Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications, if and when endorsed by the NRC staff. The NRC endorsement of this ASME standard is currently under development as DG-1122. These documents cover internal events at full power only. Draft Revision C of NEI 00-04 does not address the application-specific quality/adequacy required of the external events PRA and non-PRA type analyses (e.g., FIVE, seismic margins analysis, NUMARC 91-06) and there is no industry guidance for determining the quality/adequacy attributes required for these types of analyses for this specific application. Industry standards are being prepared for external events (seismic, high winds, and other external events), fire, and low power and shutdown PRAs, although with the exception of the external events standard, they are not expected to be completed in the near future. Therefore, the NRC staff expects that the applicant will prepare arguments for why the method employed is adequate to perform the analysis required to support the categorization of SSCs. Until such time that these standards are available, these arguments supporting the quality and adequacy of the external events and non-PRA type analyses for each plant-specific submittal requesting to implement 10 CFR 50.69 will have to be evaluated on a case-by-case basis.

7. Uncertainty Considerations in Draft Revision C of NEI 00-04

The NRC staff notes that Draft Revision C of NEI 00-04 does not address modeling or data uncertainties explicitly. However, the sensitivity studies performed to support the categorization of SSCs using PRA models are intended to address the major sources of uncertainty identified (i.e., human error probabilities, common cause failure probabilities, and those items identified during the assessment of PRA adequacy). When assessing the potential increase in core damage frequency (CDF) and large early release frequency (LERF), uncertainties should be addressed as discussed in Section 2.2.5 of Regulatory Guide 1.174. The NRC staff also notes that there are potentially large differences in the levels of uncertainty in the modeling and data for the PRA models for the various types of events. This limits the ability of the licensee to perform the integral assessment proposed in Section 5.5 of Draft Revision C of NEI 00-04. It is for this reason that the NRC staff believes that it is appropriate to use the most conservative categorization over all the contributors taken individually.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC staff's plans for using this regulatory guide.

This draft guide has been released to encourage public participation in its development. Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods to be described in the active guide reflecting public comments will be used in the evaluation of licensee compliance with the requirements of 10 CFR 50.69 for the categorization of SSCs.

Value/Impact Statement

A separate Value/Impact Statement was not prepared for this draft regulatory guide. The Value/Impact Statement that was prepared as part of the Regulatory Analysis for the rulemaking is still applicable.

ATTACHMENT TO DRAFT REGULATORY GUIDE (DG)-1121

The following issues need to be resolved in order for the NRC staff to prepare positions on the acceptability of specific provisions in NEI 00-04. Section numbers refer to those of Draft Revision C of NEI 00-04, dated June 2002.

A. *Quality Attributes.* As discussed in Section C, Position 6 of the DG-1121, applicants for implementation of 10 CFR 50.69 will need to prepare arguments about the quality and adequacy of the methods to be used for external events and non-probabilistic risk assessment (PRA) analyses . To facilitate these reviews, the NRC staff recommends that the industry develop guidance as to the expected quality attributes of the external events PRA and non-PRA type analyses that are required for use in the Option 2 categorization process.

B. *Determination of Potential Risk Increase with non-PRA Methods*. In Draft Revision C of NEI 00-04, the final step in the allocation of SSCs into the different risk-informed safety classes (RISC) categories is to show that the reduction in treatment of low safety-significanct (LSS) structures, systems, and components (SSCs) will not result in a significant increase in risk. This is done by performing the risk sensitivity study, discussed in Section 8, based on increasing the failure probabilities of those SSCs for which treatment is proposed to be relaxed. This risk sensitivity study is a very important part of the categorization process. The choice of the factor to use in increasing the failure probabilities of LSS SSCs with reduced treatment must be based either on some reasonable expectation that it is bounding or that it is such that the change in unreliability that it represents will be detected and corrected by the monitoring, corrective action, and feedback processes. The NRC staff recommends that the industry develop a method to determine the appropriate factor to be used in the risk sensitivity study and provide the appropriate guidance for implementing the monitoring, feedback, and corrective action processes to ensure that potential performance degradations will not invalidate the factor used in the risk sensitivity study.

Further, when non-PRA methods are used, it is necessary for the licensee to demonstrate that the impact on core damage frequency (CDF) and large early release frequency (LERF) due to changes in treatment of LSS SSCs is acceptably small. The NRC staff recommends that the industry develop a method, or methods, to demonstrate that this is the case.

C. *Specific Comments on Draft Revision C of NEI 00-04*

1. Section 1.2

The fourth paragraph of this section states that the integrated decision-making process "...blends risk insights, new technical information and operational feedback..." The NRC staff interprets this phrase, and similar such phrases (e.g., Section 1.3 third guiding principle), as meaning that the integrated decision-making process must systematically consider the quantitative and qualitative information available regarding the various modes of plant operation and initiating events, including PRA, quantitative risk results and insights (e.g., CDF, LERF, and importance measures); deterministic, traditional engineering factors and insights (e.g., defense-in-depth, safety margins, containment integrity); and any other pertinent information (e.g., industry and plant-specific operational and performance experience, feedback, and corrective actions program) in the categorization of the SSCs.

2. Section 1.3

The second guiding principle states that deterministic or qualitative information should be used if no PRA information exists related to a particular hazard or operating mode. This principle is not to be interpreted to mean that deterministic or qualitative information should be used only when no PRA information exists. The NRC believes that the integrated decision-making process must systematically consider the quantitative and qualitative information available regarding the various modes of operation and initiating events, including: PRA, quantitative risk results and insights; deterministic, traditional engineering factors and insights; and any other pertinent information in the categorization of the SSCs.

The fifth guiding principle uses the term “original categorization.” The NRC staff interpretation of this phrase is that it is a reference to the original, default categorization of each SSC. The NRC concludes that the original categorization of safety-related SSCs is RISC-1, nonsafety-related important-to-safety SSCs is RISC-2, and other nonsafety-related SSCs is RISC-4 and that a risk-informed basis must be provided through an integrated decision-making process for any other risk category to be assigned to these SSCs.

The sixth guiding principle indicates that the attribute(s) that make a SSC safety-significant should be documented. While the NRC staff agrees that the safety-significant attribute(s) need to be documented, the licensee must also document the justification for SSCs determined to be LSS. In other words, documentation must be available and maintained by the licensee supporting the categorization of every SSC addressed by the licensee under 10 CFR 50.69.

3. Section 1.4

The third paragraph of this section states that the licensee can determine the appropriate set of equipment to recategorize under 10 CFR 50.69. The NRC staff agrees that categorization under 10 CFR 50.69 can be partially implemented by a licensee and the implementation can be phased in over a period of time. However, since the categorization process described in 10 CFR 50.69 and in NEI 00-04 is primarily based on system/structure functions, the categorization process must be implemented on a system/structure-basis; not selected components within a system. This is supported by the fact that system boundaries are to be defined under the “System Engineering Assessment” step of the categorization process outlined in Section 2.

4. Section 2

In this section and throughout NEI 00-04, reference is often made to a licensee’s “PRA.” This phrase is commonly used by industry when referring strictly to a licensee’s internal events Level I PRA. The NRC staff interprets the intent of this phrase in NEI 00-04, when not explicitly (or by context) limited to a specific analysis, to refer to the spectrum of analyses covering the range of initiating events (e.g., internal events and external events), analysis types (e.g., PRA, margins-type analyses, simplified risk analyses, and hazard screening assessments), and operating modes (i.e., full power and low power/shutdown).

Although it is clear from the text of Section 2, NEI should clarify the intent of Figure 2-1 that the “Detailed Engineering Review of HSS Components” is an optional task and is not an essential or required part of the risk-informed categorization process. (Note: NEI 00-04 uses the terms high safety-significant and low safety-significant; these correspond to the terms “safety-significant and low safety-significant” as used in the proposed rule).

5. Section 3.2

The NRC staff is currently preparing a Regulatory Guide (RG) and associated Standard Review Plan (SRP) chapter to address the issue of PRA quality. These documents will address the use of NEI 00-02, which when finalized, is expected to contain a licensee self-assessment process, that complements the peer review criteria with those of the American Society of Mechanical Engineers (ASME) PRA standard not addressed in NEI 00-02. The NRC staff expects the final version of NEI 00-04 to reference these documents as an appropriate way to ensure and document the acceptability of the underlying PRA for the purposes of categorization.

Reference is made to the development and use of industry consensus standards on PRA, which is assumed by the NRC staff to be a reference to the development of a standard that is currently underway for external events PRA. As this standard is still under development and has not been formally reviewed and endorsed by the NRC, the statements in NEI 00-04 are not to be taken to be an endorsement of this standard by the NRC.

The NRC staff notes that Draft Revision C of NEI 00-04 does not address modeling or data uncertainties explicitly. However, the sensitivity studies performed to support the categorization of SSCs using PRA models are intended to address the major sources of uncertainty identified (i.e., human error probabilities, common cause failure probabilities, and those items identified during the assessment of PRA adequacy). When assessing the potential increase in CDF and LERF, uncertainties should be addressed as discussed in Section 2.2.5 of Regulatory Guide 1.174. The NRC staff also notes that there are potentially large differences in the levels of uncertainty in the modeling and data for the PRA models for the various types of events. This limits the ability of the licensee to perform the integral assessment proposed in Section 5.5 of Draft Revision C of NEI 00-04. It is for this reason that the NRC staff believes that it is appropriate to use the most conservative categorization over all the contributors taken individually.

6. Section 3.3

NEI 00-04 states that the Option 2 categorization process is a Grade 3 application per the NEI 00-02 peer review process. This can be demonstrated for the internal events PRA, as described in NEI 00-02, as amended to incorporate NRC comments provided in the NRC letter to NEI dated April 2, 2002. Therefore, the licensee must provide sufficient justification for the adequacy of their PRA for this application and must address any technical elements that do not meet the required grade for this application (i.e., receive a grade of 1 or 2 on individual technical elements) and the significant peer review Facts and Observations (i.e., Categories A or B). Further, the NRC believes that a higher grade for PRA quality cannot be achieved by sensitivity studies, though sensitivity studies can be used to explore the impacts of modeling uncertainties on the categorization. The NRC staff notes that these sensitivity studies must also be evaluated in the “Component Safety Significance Assessment” step (Chapter 5) as the additional applicable sensitivity studies identified in the characterization of PRA adequacy in Tables 5-2, 5-3, 5-4, and 5-5.

In addition to demonstrating that the internal events PRA input to fire, seismic, and shutdown PRAs is technically acceptable, it is also necessary to demonstrate the technical acceptability of those elements dealing with the initiating event and specific mitigating features (e.g., initiating event frequencies, fire detection and suppression systems, etc.). Since no NRC-endorsed standards exist for these elements, the licensee must describe the licensee's approach and justify its acceptability for these elements.

NEI 00-04 does not identify the need for licensees to address the adequacy of any non-PRA types of analyses, such as a margins-type study, used in the categorization process. The licensees must explicitly address and document in their plant-specific submittal to the NRC, the adequacy of these non-PRA types of analyses and ensure that they appropriately reflect the as-built, as-operated plant and that any new information (e.g., new seismic hazard information, cable routing credited in fire analysis) does not invalidate their results.

7. Section 4

The NRC has not yet formally endorsed ASME Code Case N-658. The NRC staff review of the ASME Code Cases is expected to be completed prior to promulgating 10 CFR 50.69. The NRC staff notes that staff positions on the ASME Code Cases are provided in regulatory guides referenced in 10 CFR 50.55a. If and when endorsed by the NRC, the ASME risk-informed Code Cases on categorization and treatment will satisfy the applicable portions of the proposed 10 CFR 50.69. However, at this time, the licensee cannot assume that using this method will be acceptable to the NRC. NEI 00-04 does not provide a description of a methodology for categorization that addresses the passive pressure boundary (i.e., pressure retention capability) for the purpose of exempting SSCs from special treatment requirements in sufficient detail for the staff to endorse. Therefore, the endorsement of NEI 00-04 does not adopt any method to categorize the safety significance of the passive pressure boundary of SSCs. Until such a methodology is endorsed by the NRC, to support the categorization of SSCs, the licensee is required to describe in their plant-specific submittal requesting to implement 10 CFR 50.69, their methodology for addressing the passive pressure boundary of SSCs.

8. Section 5

The first decision block in Figure 5-1 refers to prevention or mitigation of core damage. To be consistent with the intent of the safety significance categorization process, this first decision block should be broader in scope and includes the prevention or mitigation of severe accidents. Further, the logic presented in Figure 5-1 presumes that a negative response to this first decision block means that the follow-on blocks do not need to be addressed. The NRC staff cannot be assured that this screening will eliminate SSCs that are only of low safety significance, especially as currently phrased. Even if a negative response results for this block, the rest of the logic must still be addressed. In essence, NRC would eliminate this initial screening of the system/structure.

In Figures 5-2 through 5-7, SSCs having a Risk Achievement Worth (RAW) greater than 2 or a Fussell-Vesely (FV) importance measure greater than 0.005 either on the basis of the base model or sensitivity studies are identified as "candidate safety significant." Further, throughout this section reference is made that if the external event is a small fraction of the internal events CDF, then safety significance of SSCs considered in the external events PRA can be considered to be LSS from that perspective. The NRC concludes that if a SSC is classified as safety-significant, it cannot be reclassified as LSS by an integral risk consideration. Though the integrated decision-making panel (IDP) may raise a candidate LSS SSC to safety-significant, the IDP cannot lower a safety-significant SSC to LSS. If a SSC is determined to be safety-significant by any of the analyses supporting the risk-informed categorization process, including the appropriate sensitivity studies, then the SSC is safety-significant.

Risk Achievement Worth (RAW) is an assessment of the safety significance (i.e., the margin it provides in preventing core damage) of an SSC, whether it be evaluated for a single SSC or a group of SSCs. The RAW value provides the factor that the CDF or LERF increases when the SSC enters a failed state or, for a group of SSCs, when a common cause failure (CCF) degradation mechanism manifests itself to the point that multiple SSCs are in a failed state. NEI 00-04 excludes the RAW of the CCF probability associated with a SSC from the importance measure calculations. The NRC believes it is appropriate to include the RAW of the CCF probability to assess the RAW associated with a component since the CCF contribution is a distinct contribution resulting from a specific failure mechanism not represented in the other basic events. The consequences of common cause events are of concern and as such, the risks from these types of events need to be fully assessed. NUREG/CR-5485, *Guidelines on Modeling Common-Cause Failures in Probabilistic Risk Assessment*, notes that more than 2,500 common cause events involving the majority of significant PRA SSCs are documented in the NRC common cause data base. If a CCF is modeled in the PRA, a plausible CCF mechanism has been identified that could cause the simultaneous failure of more than one nominally identical SSC. If there are no plausible mechanisms known (because of diversity or reliance on only passive functions) that could cause a simultaneous failure of more than one SSC, no CCF is modeled in the PRA. If a CCF is modeled in the PRA, the RAW associated with that CCF must be included in the safety-significance determination of the affected SSCs.

Section 5 discusses a number of sensitivity studies in Tables 5-2, 5-3, 5-4, and 5-5 where the unavailability of types of PRA events (e.g., human errors, CCFs, and maintenance unavailabilities) are simultaneously modified and the importance measures of the SSCs recalculated. These studies are performed to ensure that assumptions in these types of analyses are not masking SSC importance. The NRC finds the identified sensitivity studies reasonable and they are to be used in the categorization of SSCs. Therefore, if based on any of these sensitivity studies, an SSC is identified as being safety-significant, then this basis must be documented and the SSC must be considered safety-significant. SSCs must be categorized according to the highest safety significance determined, including these sensitivity study results and the results of any other pertinent considerations (e.g., defense-in-depth, shutdown risks, etc.).

9. Section 5.1

The NRC has not formally endorsed ASME Code Cases N-577 and N-578. The NRC staff review of the ASME Code Cases is expected to be completed prior to promulgating 10 CFR 50.69. The NRC staff notes that staff positions on the ASME Code Cases are provided in regulatory guides referenced in 10 CFR 50.55a. If and when endorsed by the NRC, the ASME risk-informed Code Cases on categorization and treatment will satisfy the applicable portions of the proposed 10 CFR 50.69. However, at this time, a licensee cannot assume that using the methods described in these code cases will be acceptable. The NRC has endorsed WCAP-14572 and EPRI TR-112657, which include guidance for the categorization of piping segments, but not individual SSCs, for the purpose of reducing the number of inservice inspections on piping welds. NEI 00-04 does not provide a description of a methodology for categorization that addresses the passive pressure boundary (i.e., pressure retention capability) for the purpose of exempting SSCs from special treatment requirements in sufficient detail for the staff to endorse. Therefore, the endorsement of NEI 00-04 does not adopt any method to categorize the safety significance of the passive pressure boundary of SSCs. Until such a methodology is endorsed by the NRC, to support the categorization of SSCs, the licensee is required to describe in their plant-specific submittal requesting to implement 10 CFR 50.69, their methodology for addressing the passive pressure boundary of SSCs.

NEI 00-04 defines relevant failure modes as "... those that are expected to be affected by the special treatment requirements being evaluated." As it cannot be determined precisely what specific failure modes might or might not be impacted due to the reduction in the applicable special treatment requirements for low safety-significant SSCs, the licensee must consider all the failure modes for the SSC identified in the PRA in making its Fussell-Vesely importance determination. This is consistent with the example provided in Table 5-1.

The intent and implications of the discussion of using the component failure mode or dominant failure mode in the identification of safety-significant attributes is ambiguous and open to multiple interpretations. The NRC staff expects NEI to clarify how the safety-significant attributes may be used by licensees within the scope of 10 CFR 50.69.

NEI 00-04 states that SSCs that have high failure probabilities are usually indicative of screening values. However, high failure probabilities can also be due to a number of other factors, including a lack of any testing of the SSC or an actually poor performing SSC. The NRC concludes that categorization results must not be overturned for SSCs simply because they have a high failure probability in the PRA, but rather, the licensee should first examine and determine the cause of the high value and then revise the model, as necessary.

10. Section 5.2

It is the NRC staff's interpretation of the discussion in the third paragraph of this section to mean that fire barriers would not be included within the scope of risk-informed treatment (i.e. would not be categorized) unless they are explicitly evaluated in the fire risk analyses.

11. Sections 5.2 and 5.3

NEI 00-04 recognizes in these sections that the vulnerability-type evaluation (e.g., FIVE) and margins-type analysis (e.g., seismic margins analysis) are somewhat limited in being able to support the identification of LSS SSCs. It is further stated that the approach for these types of analyses is conservative since SSCs are determined to be safety-significant essentially if they are identified in these analyses. For the FIVE analysis, SSCs are safety-significant if they participate in the scenario or are credited in the screening of the scenario. For the seismic margins analysis, SSCs are safety-significant if they are credited in the safe shutdown path. The licensees, as part of their submittal to the NRC requesting to implement 10 CFR 50.69, must demonstrate the adequacy of these types of analyses for this application and ensure that they will provide conservative results. If a licensee wants to gain the full benefit from the proposed 10 CFR 50.69 in reducing treatment of SSCs, the licensee should consider performing a fire and/or seismic PRA, which would provide greater ability to identify SSCs that could potentially be categorized as LSS.

12. Section 5.4

As the evaluation of other external events typically is a screening approach, NRC believes that a logic similar to Figure 5-4 might be more appropriate than the current Figure 5-6. Thus, if a SSC participates in an unscreened scenario or is credited in the screening of the scenario, then that SSC would be considered safety-significant.

13. Section 5.5

NUMARC 91-06 is stated in NEI 00-04 as an attempt to ensure that the plant has an appropriate complement of systems available at all times. The NRC staff is not sure that the use of NUMARC 91-06, as described in NEI 00-04 and as implemented through the plant-specific Outage Risk Management Guidelines, will provide conservative categorization results. Therefore, as part of the licensee's submittal requesting to implement 10 CFR 50.69, the licensee must demonstrate the adequacy of its approach to addressing shutdown risk for this application and ensure that the approach will provide conservative results. If this approach is used, any (not just the primary) SSCs identified in the plant-specific Outage Risk Management Guideline must be considered safety-significant. Further, if a licensee wants to gain the full benefit from the proposed 10 CFR 50.69 in reducing treatment of SSCs, the licensee should consider performing a shutdown PRA, which would provide greater ability to identify SSCs that could potentially be categorized as LSS.

14. Section 6.1

The NRC staff agrees that when an SSC is determined to be LSS, it is appropriate to confirm that adequate defense-in-depth is preserved. However, it is not clear how Figure 6-1 is to be interpreted in this process. The NRC staff interpretation is that the figure is intended to address defense-in-depth at the critical safety function level (i.e., the figure should be used for each critical safety function and the top line identifies what system(s) is(are) available in addition to the system of which the SSC is a part). The row is to be chosen commensurate with the highest frequency initiating event for which failure of the critical safety function would lead to core damage or a large release. Further, in a risk-informed framework, defense-in-depth must be applied to all potential initiating events. Consequently, the defense-in-depth evaluation must include all initiating events credible enough to be postulated in the PRA; not just design basis events. For example, initiating events such as loss of service water cooling system should be included. Further, the estimated plant-specific initiating event frequencies for all the initiating events must be compared to the ranges identified in Figure 6-1 and each plant-specific initiating event placed in the appropriate frequency range.

NEI 00-04 does not provide guidance on the use of the proposed defense-in-depth methodology in sufficient detail for the staff to review and endorse this method. For example, it is not clear if the methodology requires that all trains/systems credited in the defense-in-depth analysis (i.e., those considered in the header row) should be considered safety-significant or allow all of them to be LSS. Therefore, as part of a licensee's submittal requesting to implement 10 CFR 50.69, the licensee should provide the methodology for addressing defense-in-depth, which the staff will review to ensure that it properly reflects the intent of 10 CFR 50.69.

15. Section 6.2

The NRC concludes that the containment and its related systems are important in the preservation of the defense-in-depth philosophy in terms of both large early and large late releases. Therefore, as part of meeting the defense-in-depth principle, a licensee must demonstrate that the function of the containment as a barrier, including fission product retention and removal, is not significantly degraded when SSCs that support the functions are determined to be LSS. The concepts used to address defense-in-depth for functions required to prevent core damage may also be useful in addressing issues related to those SSCs that are required to preserve long-term containment integrity. One way to do this would be to show that these SSCs are not relied on to prevent late containment failure during core damage accidents. An alternative method would be to demonstrate that a potential decrease in reliability of low safety-significant SSCs that support the containment function does not have a significant impact on the estimated late containment failure probability. In essence, what the NRC staff expects is a plant-specific understanding of the effects of containment systems on large late releases and the credit given to these systems in maintaining the conditional probability for these releases. A licensee or applicant can qualitatively argue that an SSC is not relied upon to prevent large late containment failure and is thus low safety-significant from this standpoint. However, if an SSC plays a role in supporting the containment function in terms of large late releases and if the licensee wants to categorize these SSCs as LSS (e.g., because of available redundant systems or trains or because its failure is dominated by factors not related to the SSC), then sensitivity studies should be performed to show that the effects on (i.e., change in) the late containment failure probability is small (i.e., less than a 10 percent increase from the base value) and that the factors such as common cause failures or other dependencies are not important. Where a licensee categorizes containment isolation valves or penetrations as LSS, the licensee will need to address the impact of the proposed change in treatment on a case-by-case basis to ensure that the defense-in-depth principle continues to be satisfied.

The NRC believes that the first criteria listed for containment bypass needs to also include mitigation of an interfacing system loss-of-coolant accident as well as the initiation and isolation of these events.

16. Section 7.1

NEI 00-04 states that the safety significance of a system function is determined by the highest RAW or the highest FV of the SSCs in the flow path that are modeled in the PRA. The staff notes that the safety significance of functions derived from the proposed process requires a different definition than the safety significance of individual SSCs derived from the RAW and FV values. The safety-significance of an SSC derived from the RAW and the FV values reflect the increase in risk associated with a failure of that SSC and the fraction of the CDF or LERF to which the failure of the SSC contributes, respectively. An analogous system function safety significance would reflect the increase in risk associated with a failure of that system function and the fraction of risk to which the failure the system function contributes. Most system functions are, however, performed by two or more nominally independent trains and the failure of any one train will not lead to failure of the function. Failure of any individual SSC will, with few exceptions, only fail one train and not the system function. The RAW and the FV associated with the failure of all system trains will be higher, and in most cases much higher, than those associated with individual SSC failures. Consequently, the safety significance of functions derived from the PRA by this process is different and must be clearly differentiated from the safety significance of individual SSCs. An explanation of the difference should be included in the training provided to the IDP.

The staff notes that the safety significance of a CCF event that simultaneously fails nominally redundant trains in a system will generally provide a measure of system function safety significance consistent with SSC safety significance. Therefore, the RAW of CCF events must also be considered in this assessment.

Because of the potential confusion between a system safety function (e.g., high pressure injection from the high pressure injection system) and the train-level system safety function (e.g., high pressure injection from one high pressure injection train) there are a number of guidelines within the report that are ambiguous. For example, the discussion of the IDP process in this section includes several questions based on whether the failure of the SSC will fail a “function.” Until the NEI 00-04 guidance is further clarified, the definition of “function” that results in the highest safety significance assignment for an SSC must be used.

17. Section 7.2

The second bullet on page 37 states that if the SSC is of low safety significance based on the internal events, but potentially high (ie.., safety-significant) because of external events, then the integral assessment should be relied on. This is too strong a statement. The NRC concludes that though the IDP may raise a candidate LSS SSC to safety-significant, the IDP cannot lower a safety-significant SSC to LSS. If a SSC is determined to be safety-significant by any of the analyses supporting the risk-informed categorization process, including the appropriate sensitivity studies, then the SSC is safety-significant. Only through a thorough recategorization effort, which would involve going through the entire process and considerations at the same level of rigor and depth as the original categorization, can a SSC be recategorized lower than its initial categorization.

The third bullet states that “if the SSC was found to be safety significant based on sensitivity studies, this should be communicated to the IDP, along with the base and integral significance for each hazard”. The SSCs must be categorized according to the highest safety-significance determined in the categorization process, including these sensitivity studies and the results of any other pertinent considerations (e.g., defense-in-depth, shutdown risks, etc.).

The NRC staff notes that Figure 7-1 is overly simplistic and does not convey the proper level of detailed narrative expected in the documentation of categorization of SSCs. The NRC staff encourages the final version of NEI 00-04 to contain a more detailed and comprehensive example of the risk-informed SSC assessment worksheet.

18. Section 8

The final step in the allocation of SSCs into the different RISC categories is to show that the reduction in treatment of RISC-3 SSCs will not result in a significant increase in risk. This is done by performing the risk sensitivity study based on increasing the failure probabilities of those SSCs for which treatment is to be relaxed. This risk sensitivity study is a very important part of the categorization process. The choice of the factor to use to increase the failure probabilities of RISC-3 components must be based either on some reasonable expectation that it is bounding or that it is such that the change in unreliability it represents will be detected by the monitoring and corrective action program.

To develop a reasonable bounding estimate of the increase in failure probability, the licensee would need to assess the impact that a change in treatment as a result of removal of special treatment requirements might have on the reliability of SSCs. The result of this assessment would be a characterization of the potential impact, which could be qualitative or quantitative. This characterization would need to address the relationship between the elements of treatment being relaxed and their role in maintaining defenses against failure or degradation from known mechanisms. There must be a documented evaluation that provides the development of the quantitative increase in failure probability from the characterization of the impact of the change in treatment. If it is not possible to quantitatively develop a reasonable estimate of the change in reliability, a justified conservative value may be used. The estimate of the change in reliability or the conservative value is used to form the basis for the risk sensitivity study that is performed to show that there is no more than a small net increase in risk associated with implementation of 10 CFR 50.69.

The values in NEI 00-04 of two to five are discussed in the document as representing the nominal range between the mean and the 95th percentile values in typical distributions used to characterize current failure rates. The uncertainty in the current failure rates has been developed from the observation of the current population of components (almost all of which are subjected to special treatment requirements) and are developed to characterize the current population. The staff notes that there is no justification provided that selecting the "poor performers" of the current population to represent the failure rates will bound the reliability of components after exemption of special treatment requirements.

One mechanism that could lead to large increases in CDF/LERF is extensive, across system common cause failures (CCFs). However, for such extensive CCFs to occur would require that the mechanisms that lead to failure, in the absence of treatment, were sufficiently rapidly developing or not self-revealing, such that there would be few opportunities for early detection and corrective action. Thus, when characterizing the effects of reduced treatment on SSC reliability, the applicant or licensee must consider potential effects of common-cause interaction susceptibility, including cross-system interactions, and potential impacts from known degradation mechanisms.

It is expected that those aspects of treatment that are necessary to prevent SSC degradation or failure from known mechanisms to the extent that the results of the sensitivity studies are invalidated will be identified by the licensee and such aspects of treatment will be retained. This will require an understanding of what the degradation mechanisms are and what elements of treatment are sufficient to prevent the degradation. As an example of how this would be implemented, the known existence of certain degradation mechanisms affecting pressure boundary SSC integrity might support retaining the current requirements on inspections or examinations or use of the risk-informed ASME Code Cases, as accepted by the NRC regulatory process. An alternative might be to relax certain elements of treatment, but retain those that were assessed to be the most effective in negating the degradation mechanisms. As another example, changing levels of treatment on several similar components that might be sensitive to CCF potential would require consideration as to whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective in sufficiently minimizing CCF potential such that the sensitivity studies remain bounding.

In summary, if this approach is adopted, the determination of the appropriate factor (or factors) to use in the risk sensitivity study must be determined in concert with the consideration of planned changes in treatment. As part of this evaluation, the NRC expects licensees to: (a) demonstrate an understanding of common cause effects and degradation mechanisms and their potential impact on RISC-3 SSCs; (b) demonstrate an understanding of the programmatic activities that provide defenses against CCFs and failures resulting from degradation; and (c) to factor this knowledge into both the treatment applied to and the reliability assumptions made for the RISC-3 SSCs.

An alternative approach is to set the increase in unreliability at such a level that the increase would be detected through the corrective action and feedback processes. When this approach is used, the licensee must develop, document, and submit a quantitative evaluation based on the current unreliability of the SSCs, the number of SSCs, the frequency of the opportunities to identify failures, and the monitoring and corrective action program that will identify the minimum increase in failure rates that can be detected through monitoring and the corrective action program.

When non-PRA studies are used to address certain risk contributors (e.g., seismic initiators or fires) this approach is not directly applicable. In this case, it is necessary for the licensee to provide an argument as to why the impact on CDF and LERF from adopting the non-PRA approach is not significant.

19. Section 9

Under the sub-heading “Review of Safety Significant Functions”, it is stated “SSCs which have high failure probabilities (usually indicative of screening values) and meet the screening criteria solely on the basis of Fussell-Vesely importance may have been identified as candidate safety significant.” There is no action associated with this statement. The NRC finds that an acceptable approach to dealing with the issue of SSCs categorized as safety-significant solely on the basis of an artificially high failure probability is to first revise the model, if appropriate, to use the proper value and then to recategorize the SSC. Only through a thorough recategorization effort, which would involve going through the entire process and considerations at the same level of rigor and depth as the original categorization, can a SSC be recategorized lower than its initial categorization.

20. Section 9.2

Under the “Review Defense-In-Depth Implications” subsection, the NRC staff does not agree that low safety significance can be assigned if any one of the criteria listed is true. For the IDP qualitative evaluation to determine the impact of relaxing requirements on SSC reliability and performance, historical data must show that the failure mode is unlikely to occur and either the failure mode can be detected in a timely fashion or there is condition monitoring that provides a leading indicator. Further, the NRC staff interprets this evaluation and criteria to be applicable to both subsections, “Review of Risk Information” and “Review Defense-In-Depth Implications.” In addition to recommending staggered testing, inspection and/or calibration of equipment as strategies for reducing the potential for common cause failures and/or detection of failures, the licensee could take the strategy of not reducing treatment for those SSCs with the potential for common cause failures.

The IDP may want to use the following criteria to check whether the SSC is categorized appropriately, and for SSCs not explicitly modeled, by considering whether the SSC has an impact on the plant’s capability to:

(i) Prevent or mitigate accident conditions,

(ii) Reach and/or maintain safe shutdown conditions,

(iii) Preserve the reactor coolant system pressure boundary integrity,

(iv) Maintain containment integrity, or

(v) Allow monitoring of post-accident conditions.

21. Section 10.2

For licensees that perform the optional step, "Detailed Engineering Review of HSS Components," the same depth and rigor must be used in categorizing at the individual component level as was used for categorizing at the system functional level. Thus, if a SSC is determined by the categorization process to be safety-significant then it cannot be recategorized LSS without re-performing the entire categorization process at the component level. However, if the component is not determined to be safety-significant by the detailed component level categorization process, then the following factors must be considered in determining if the SSC can be categorized LSS in addition to the identified NEI 00-04 considerations:

- Safety function being satisfied by SSC operation
- Level of redundancy existing at the plant to fulfill the SSC's function
- Ability to recover from a failure of the SSC
- Performance history of the SSC
- Use of the SSC in the Emergency Operating Procedures or Severe Accident Management Guidelines

Further, the licensee or applicant, through the IDP, must document the basis for the classification of an SSC based on the above considerations, including the development of a SSC level categorization worksheet similar to that developed for the system-level results in Section 7.

For SSCs not modeled explicitly in the PRA, the IDP could use the following guidance to determine if low safety significance is appropriate based on traditional engineering analyses and insights, operational experience, and information from licensing basis documents and design basis accident analyses. The IDP could assess the safety significance of these SSCs by determining if:

(i) Failure of the SSC will significantly increase the frequency of an initiating event, including those initiating events originally screened out in the PRA.

(ii) Failure of the SSC will compromise the integrity of the reactor coolant pressure boundary. It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

(iii) Failure of the SSC will fail a safety-significant function, including SSCs that are assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems, and instrumentation and control systems). For example, it is expected for pressurized water reactors (PWRs) that a sufficiently robust categorization process would categorize high energy ASME Section III Class 2 piping of the main steam and feedwater systems as RISC-1.

(iv) The SSC supports important operator actions required to mitigate an accident, including the operator actions taken credit for in the PRA.

(v) Failure of the SSC will result in failure of safety-significant SSCs (e.g., through spatial interactions or through functional reliance on another SSC).

(vi) Failure of the SSC will impact the plant's capability to reach and/or maintain safe shutdown conditions.

(vii) The SSC is one of a redundant set that can be justifiably identified as a common cause failure group.

(viii) The SSC is a part of a system that acts as a barrier to fission product release during severe accidents. It is expected that a sufficiently robust categorization process would result in fission product barriers (e.g., the containment shell or liner) being categorized as safety significant.

(ix) The SSC is depended upon in the Emergency Operating Procedures or the Severe Accident Management Guidelines.

(x) Failure of the SSC will result in unintentional releases of radioactive material in excess of 10 CFR Part 100 guidelines even in the absence of severe accident conditions.

(xi) The SSC is relied upon to control or to mitigate the consequences of transients and accidents.

If none of the above eleven conditions is true, the IDP could use a qualitative evaluation process to determine the impact of relaxing requirements on SSC reliability and performance. This evaluation includes identifying the functions being supported by operation of the SSC, the relationship between the SSC's failure modes and the functions being supported, the SSC failure modes for which the failure rate may increase, and the SSC failure modes for which detection could become or are more difficult. The IDP could then justify low safety significance of the SSC by demonstrating the following:

(ii The reclassification is consistent with the defense-in-depth philosophy.

(ii Operating experience indicates that active degradation mechanisms (e.g., for piping flow accelerated corrosion or microbiologically-induced corrosion) for passive and active SSCs are not present, relaxing the treatment requirements will have minimal impact on SSC performance and reliability, and degradation in the ability of the SSC to perform its safety functions will be detected in a timely fashion

(ii Relaxing the requirements will have a minimal impact on the expected onsite occupational or offsite doses from transients and accidents that do not contribute to CDF or LERF.

The specific considerations that permit a LSS determination of an SSC in a safety-significant functional flow path must not be limited to just active failure modes, but must consider all potential failure modes for the subject SSC.

The NRC staff does not generically endorse the examples provided under the specific considerations that permit a LSS determination of an SSC in a safety-significant functional flow path. The specific conditions and criteria must be justified and documented for the specific SSCs under consideration. For example, a 1-inch diameter line off a small diameter pipe might create a large enough diversion path that would impair the system from meeting its safety-significant function. Thus, such a criteria would not be appropriate in determining that the SSC is LSS.

22. Sections 11.1 and 11.2

This section discusses the expansion of the licensee's design/configuration change control process to provide reasonable assurance that the safety-significant beyond design basis functions under 10 CFR 50.69 will be satisfied following a facility change. The NRC staff agrees with the need for the licensee's implementing 10 CFR 50.69 to expand their design/configuration change control process, as above, but also requires that this expansion include an evaluation to ensure that the categorized SSCs, considering both their design basis and beyond design basis functions, also are maintained within the assumptions of the categorization process (i.e., reliability of LSS SSCs is maintained within the potential reduction in reliability assumed in the risk sensitivity study of Section 8 of NEI 00-04 and the reliability of safety-significant SSCs is maintained in accordance with their reliability assumed in the analysis) and must encompass more than just the PRA, but also must address the deterministic, traditional engineering (e.g., defense-in-depth), non-PRA type analyses (e.g., seismic margins), and operating modes considerations (e.g., shutdown) of the SSC categorizations under 10 CFR 50.69.

23. Section 11.2

NEI 00-04 states that licensees will commit to updating their PRA based on the ASME PRA Standard. As stated in (draft) 10 CFR 50.69, in a timely manner but no longer than every 36 months, the licensee must review changes to the plant, operational practices, applicable industry operational experience, and as appropriate, update their PRA and SSC categorization.

NEI 00-04 states that changes to NRC commitments associated with any RISC SSC category should be controlled through NEI 99-04, Revision 1. Since this revision has not been reviewed by the NRC, the statements in NEI 00-04 are not to be taken to be an endorsement of this document by NRC. A licensee must, as part of its submittal requesting to implement 10 CFR 50.69, identify under what conditions they would notify the NRC of changes in RISC categorizations for SSCs and/or resulting treatment.

24. Section 11.4

The NRC concludes that the categorization process implemented via NEI 00-04 must include a provision that provides assurance that future changes in the SSC categorization caused by PRA model changes or other new information will continue to meet the risk acceptance guidelines in RG 1.174 based on a comparison between the new proposed risk-informed program and the original, deterministic special treatment requirements. Thus, the model used in the risk sensitivity study of Chapter 8 must be verified to be representative of the as-built, as-operated plant and the results of this study verified to be acceptable when compared to the RG 1.174 acceptance guidelines when the PRA model is changed or other new information is made available. This provision must be incorporated into the licensee's corrective action and/or feedback processes implemented to comply with 10 CFR 50.69.

NEI 00-04 states that a multi-disciplined station management review committee could take the place of the IDP to make the final determination on changes in SSC categorization after the completion of the categorization of all scheduled SSCs. The NRC staff does not agree with this allowance. Since the IDP is established to provide the full and balanced expertise in determining the final categorization of the SSCs that a licensee categorizes under 10 CFR 50.69, any proposed changes in SSC categories must also be reviewed and accepted by the IDP at the same level of rigor and depth applied to their initial categorization under 10 CFR 50.69.

25. Section 12

The documentation retention time suggested in NEI 00-04 is 5 years after completion of the categorization process or until the plant-specific PRA and, if necessary, SSC categorization is updated. Since this documentation provides the documentation of the methodology and results of the implementation of 10 CFR 50.69 in categorizing SSCs, may be phased in over many years, and may be re-initiated after some period of time after initially completing the process for some selected SSCs, the NRC concludes that this documentation must be retained for the life of the plant.

26. Section 13

The assessment of the impact of later SSC categorizations must encompass more than just the PRA results; this assessment must also address the potential impacts on the deterministic, traditional engineering (e.g., defense-in-depth), non-PRA type analyses (e.g., seismic margins), and operating modes considerations (e.g., shutdown) of prior SSC categorizations. Further, any proposed changes in prior SSC categorizations must be documented, provided to the IDP, and determined to be appropriate by the IDP before recategorizing the SSC. This is not intended to obviate the need for the licensee to properly implement their corrective action program.

NEI 00-04 identifies a number of reviews that are to be performed following revisions or updates to the PRA as part of a review of the SSC categorization. The NRC believes that the review of the updated PRA must include an independent review of the PRA update to ensure that it properly reflects the as-built, as-operated plant. In addition, the results of the risk sensitivity study of Chapter 8 must be confirmed to still be acceptable.

27. Appendix B

This appendix provides an outline/example of the information to be provided to the NRC for those licensees implementing 10 CFR 50.69. Based on the resolution of other comments presented above, some aspects of this outline may need to be further enhanced or expanded. Therefore, at this time, the NRC staff cannot endorse that this outline contains the requisite level of information to satisfy the requirements of 10 CFR 50.69. Licensee submittals will be evaluated on a plant-specific basis to ensure that they properly implement the categorization process requirements of 10 CFR 50.69.

NEI

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June 28, 2002

Mr. David B. Matthews
Director, Regulatory Improvement Programs
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Matthews:

Enclosed for NRC staff review is Draft Revision C to NEI 00-04, *10 CFR 50.69 SSC Categorization Guideline.* The document has been completely rewritten to reflect the NRC observations and comments provided in your February 8, 2002 letter, the NRC-industry interactions that have taken place since NEI 00-04, Rev. B was submitted in June 2001, and the lessons learned from the pilot plant SSC categorization activities.

The two most significant changes are:

- The document now focuses solely on SSC categorization, with treatment being addressed in a separate internal industry Option 2 Technical Basis Document, and
- The categorization process now identifies safety-significant functions and maps structures, systems and components (SSCs) to the safety-significant functions with a comparison against SSC risk significance derived from the PRA.

The guideline retains the integrated decision-making process for categorizing SSCs using a multi-disciplined integrated decision-making panel of experienced licensee designated personnel to oversee and categorize SSCs.

Enclosure 1 is the revised guideline. Enclosure 2 is summary of the major changes. We will send you a detailed summary of the industry's disposition of NRC comments on NEI 00-04, Rev. B early next week.

Y601
ADD: D Matthews
To e-RIDS

We look forward to discussing the revised guideline and the pilot project at our scheduled July 10, meeting. If you or your staff have any immediate questions, please contact Adrian Heymer (202)-739-8094, e-mail aph@nei.org or me.

Sincerely

Anthony R. Pietrangelo

Anthony R. Pietrangelo

Enclosures

NEI 00-04 (DRAFT - Revision C)

10 CFR 50.69 SSC Categorization Guideline

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June 2002

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ACKNOWLEDGMENTS

This report has been prepared by the NEI Risk Applications Task Force, the NEI Option 2 Task Force, and the NEI Risk-Informed Regulatory Working Group

NOTICE

TABLE OF CONTENTS

1 INTRODUCTION

This document provides detailed guidance on categorizing structures, systems and components for licensees that choose to adopt 10 CFR 50.69, *Scope of Structures, Systems and Components, Governed by Special Treatment Requirements*. A licensee wishing to implement §50.69 makes a submittal, consistent with the example described in Appendix B of this guideline, to the Director of Nuclear Reactor Regulation, NRC for review and approval. Licensees that commit to implementing §50.69 in accordance with this guideline should expect minimal NRC review.

This guidance is based on the principles of NRC Regulatory Guide 1.174, *An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis*, namely:

1. The initiative should result in changes that are consistent with defense-in-depth philosophy.
2. The initiative should result in changes that maintain sufficient safety margins.
3. Performance measurement strategies are used to monitor the change.
4. The implementation of the §50.69 initiative should not result in more than a minimal increase in risk.
5. The risk should be consistent with the Commission's safety goal policy statement.

There are two segments associated with the implementation of 10 CFR 50.69: the categorization of structures, systems and components; and the application of NRC special treatment requirements[1] consistent with the safety significance of the equipment categorized in the first step. This guidance deals the alternative categorization of structures, systems, and components per §50.69. The application of special treatment regulations and controls is a function of the SSC categorization. The existing special treatment provisions for RISC-1 and RISC-2 SSCs are maintained or enhanced to provide reasonable assurance that the safety-significant functions, identified in the §50.69 process will be satisfied. RISC-3 and RISC-4 SSCs are governed by the treatment requirements, described in 10 CFR 50.69.

1.1 BACKGROUND

The regulations for design and operation of US nuclear plants define a specific set of design bases events that the plants must be designed to withstand. This is known as a deterministic regulatory basis because there is little explicit consideration of the probability of occurrence of the design basis events. It is "determined" they will occur,

[1] Special treatment requirements are current NRC requirements imposed on structures, systems, and components that go beyond industry-established (industrial) controls and measures for equipment classified as commercial grade and are intended to provide reasonable assurance that the equipment is capable of meeting its design bases functional requirements under design basis conditions. These additional special treatment requirements include design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance requirements.

and the plant is designed and operated to prevent and mitigate such events. This deterministic regulatory basis was developed over thirty years ago, absent data from actual plant operation. It is based on the principal that the deterministic events would serve as a surrogate for the broad set of transients and accidents that could be realistically expected over the life of the plant.

Since the inception of the deterministic regulatory basis, over 2700 reactor years of operation have been accumulated in the US (over 10,000 reactor years worldwide), with a corresponding body of data relative to actual transients, accidents, and plant equipment performance. Such data is used in modeling accident sequences (including sequences not considered in the deterministic regulatory basis) to estimate the overall risk from plant operation. Further, each US plant has performed a probabilistic risk analysis (PRA), which uses these data. PRAs describe risk in terms of the frequency of reactor core damage and significant offsite release. Insights from PRAs reveal that certain plant equipment important to the deterministic regulatory basis is of little significance to safety. Conversely, certain plant equipment is important to safety but is not included in the deterministic regulatory basis.

Risk insights have been considered in the promulgation of new regulatory requirements (e.g., station blackout rule, anticipated transients without scram rule, maintenance rule). Also, the NRC has provided guidance in Regulatory Guide 1.174, on how to use risk-insights to change the licensing basis.

In 1999, the Commission approved a NRC staff recommendation to expand the scope of risk-informed regulatory reforms. The Commission directed the NRC staff to develop a series of rulemakings that would provide licensees with an alternative set of requirements in two areas: NRC technical requirements, and requirements that define the scope of structures, systems and components (SSCs) that are governed by NRC special treatment requirements.

1.2 REGULATORY INITIATIVE TO REFORM THE SCOPE OF EQUIPMENT AND ACTIVITIES SUBJECT TO NRC SPECIAL TREATMENT REQUIREMENTS

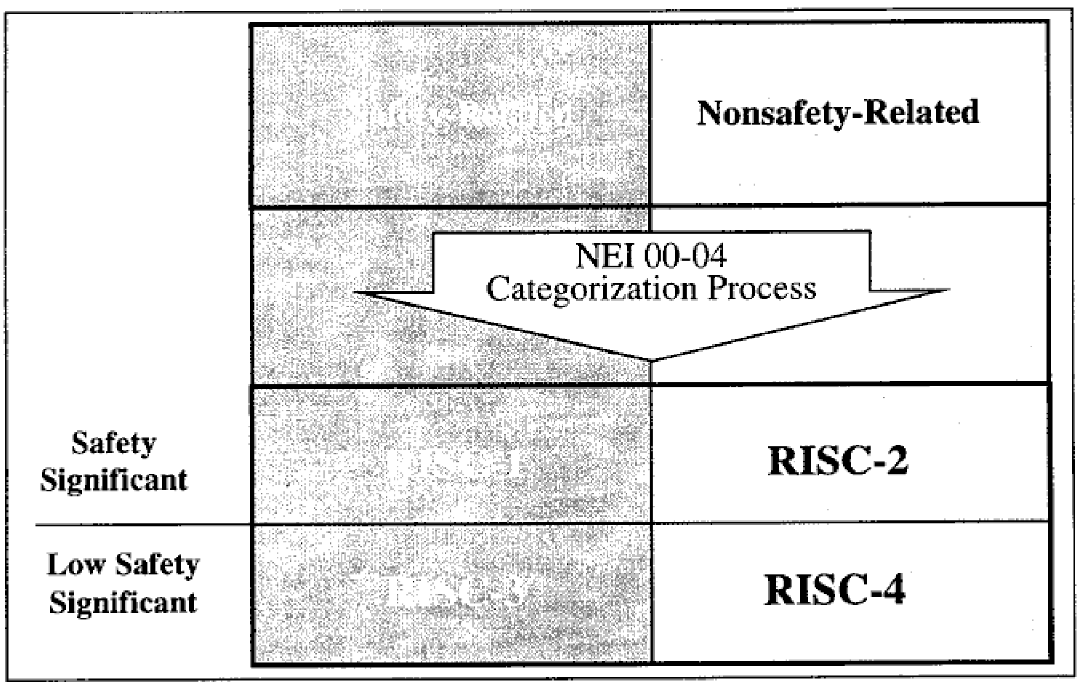
The objective of this regulatory initiative is to adjust the scope of equipment subject to special regulatory treatment (controls) to better focus licensee and NRC attention and resources on equipment that has safety significance. This guideline addresses the use of risk insights to define the scope of equipment that should be subject to NRC special treatment provisions as defined in §50.69.

Current NRC regulations define the plant equipment necessary to meet the deterministic regulatory basis as "safety-related." This equipment is subject to NRC special treatment regulations. Other plant equipment is categorized as "nonsafety-related", and is not subject to special treatment requirements. There is a set of nonsafety-related equipment that is subject to a select number of special treatment requirements or a subset of those requirements. This third set is often referred to as "important-to-safety." Generally, licensees apply augment quality controls (a subset of the criteria in Appendix B to Part 50) to these "important to safety" SSCs.

§50.69 does not replace the existing "safety-related" and "non safety-related" categorizations. Rather, §50.69 divides these categorizations into two subcategories based on high or low safety significance. The §50.69 categorization scheme is depicted in Figure 1-1, and detailed guidance is provided in Sections 2 through 10.

The §50.69 SSC categorization process is an integrated decision-making process. This process blends risk insights, new technical information and operational feedback through the involvement of a group of experienced licensee-designated professionals. This group, known as the Integrated Decision-Making Panel (IDP), is supported by additional working level groups of licensee-designated personnel, as determined by the licensee.

Figure 1-1
RISK INFORMED SAFETY CLASSIFICATIONS (RISC)



The §50.69 categorization process will identify some safety-related SSCs as being of low or no safety-significance and these will be recategorized as RISC-3 SSCs, while other safety-related SSCs will be identified as safety-significant, and be recategorized as RISC-1. Likewise, some nonsafety-related SSCs will be recategorized as safety-significant (RISC-2) and others will remain of low or no safety-significance, and be recategorized as

RISC-4 SSCs. For the purposes of implementing §50.69, "important to safety" SSCs enter into the categorization process as "non safety-related." Thus, safety-related SSCs can only be categorized as RISC-1 or RISC 3, and nonsafety-related SSCs, including the "important to safety" SSCs can only be categorized as RISC-2 or RISC-4.

Those SSCs that a licensee chooses not to evaluate using the §50.69 SSC categorization process remain as safety-related, nonsafety-related and "important to safety" SSCs.

1.3 GUIDING PRINCIPLES

The principles for categorizing SSCs have been assessed through pilot plant implementation and are:

- Use applicable risk assessment information.
- Deterministic or qualitative information should be used, if no PRA information exists related to a particular hazard or operating mode.
- The categorization process should employ a blended approach considering both quantitative PRA information and qualitative information.
- The Reg. Guide 1.174 principles of the risk-informed approach to regulations should be maintained.
- A SSC retains its original categorization if a basis for re-categorization cannot be developed.
- Attribute(s) that make a SSC safety-significant should be documented.

1.4 VOLUNTARY AND SELECTIVE IMPLEMENTATION

US nuclear generating plants have attained and maintained outstanding safety performance record. The existing NRC regulations together with the NRC's regulatory oversight and inspection processes clearly provide adequate protection of public health and safety. As a result, the decision to adjust and improve the scope of equipment that is subject to NRC special treatment requirements is a voluntary, licensee decision. Each licensee should make its determination to adopt the new rule based on the estimated benefit.

From a safety perspective, the benefits are associated with a better licensee and NRC focus of attention and resources on matters that are safety-significant. A risk-informed SSC categorization scheme should result in an increased awareness on that set of equipment and activities that could impact safety, and hence an overall improvement in safety.

From previous risk-informed activities, a licensee is already aware of the areas where the §50.69 categorization process would provide a benefit. As a result, a licensee can determine the appropriate set of equipment to recategorize under §50.69, and schedule the implementation over a period of time. The SSC categorization schedule should be sent to the NRC as part of the licensee's implementation submittal (see Appendix B).

2 OVERVIEW OF CATEGORIZATION PROCESS

The overall process used in categorizing SSCs for the purposes of changing the special treatment requirements under 10CFR50.69 is depicted in Figure 2-1. This process builds upon the insights and methods from many previous categorization efforts, including risk-informed IST and risk-informed ISI. It is intended to be a comprehensive, robust process that includes consideration of various contributors to plant risk and defense-in-depth.

The process includes eight primary steps:

- Assembly of Plant-Specific Inputs
- System Engineering Assessment
- Component Safety Significance Assessment
- Defense-In-Depth Assessment
- Preliminary Engineering Categorization of Functions
- Risk Sensitivity Study
- IDP Review and Approval
- SSC Categorization

Each of these steps is covered in more detail in subsequent section of this document. This section provides a brief overview of the elements of each step and the inter-relationships between steps.

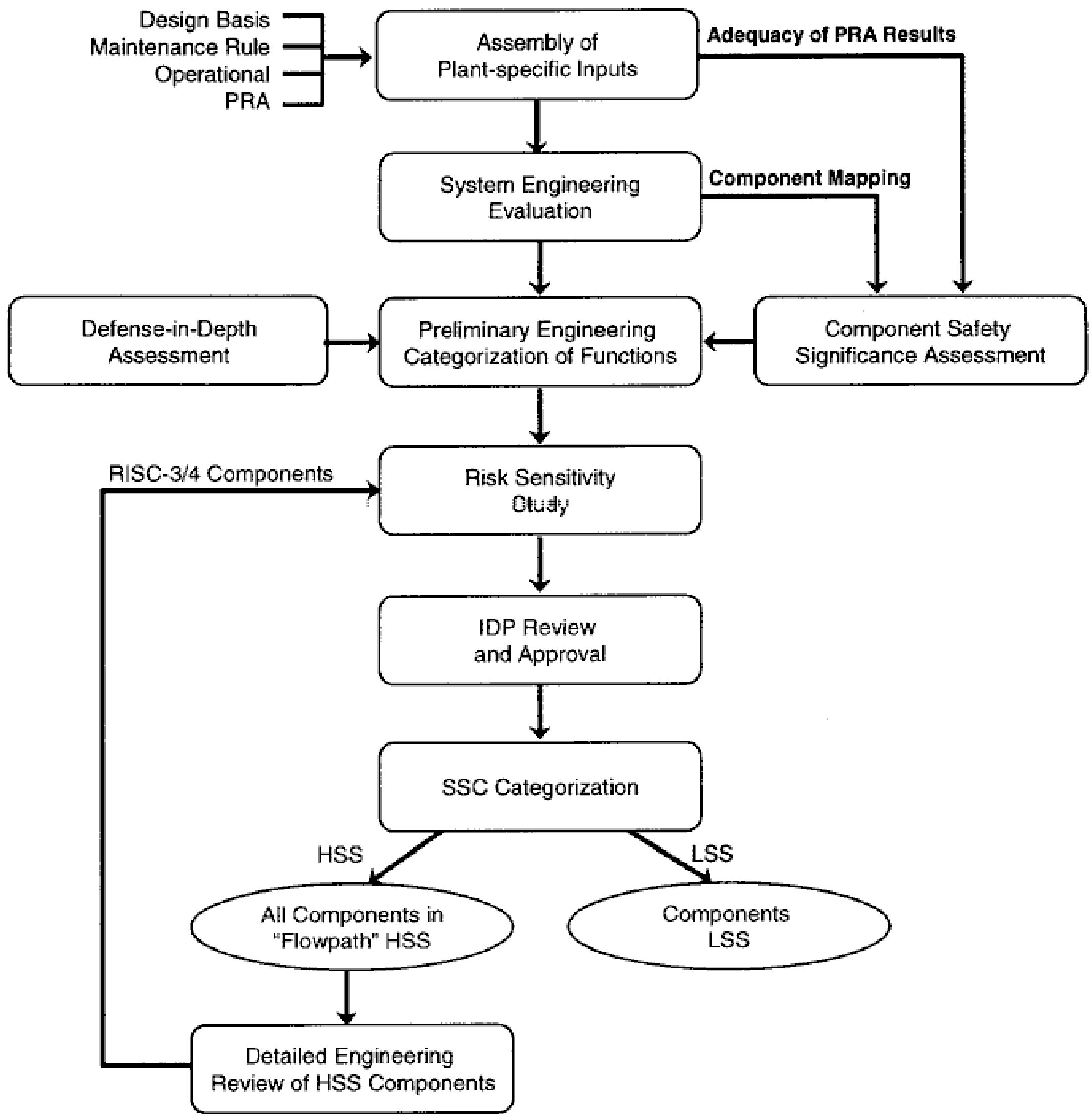
Assembly of Plant-Specific Inputs

This step involves the collection and assessment of the key inputs to the risk-informed categorization process. This includes design and licensing information, PRA analyses, and other relevant plant data sources. In addition, this step includes the critical evaluation of plant-specific PRA analyses to assure that they are adequate to support this application. More detail is provided on this step in Section 3.

System Engineering Assessment

This task involves the initial engineering evaluation of a selected system to support the categorization process. This includes the definition of the system boundary to be used and the components to be evaluated, the identification of system functions, and a coarse mapping of components to functions. The system functions are identified from a variety of sources including design/licensing basis analyses and PRA analyses. The mapping of components is performed to allow the correlation of PRA importance measures to system functions. More detail is provided on this step in Section 4.

Figure 2-1
RISK-INFORMED CATEGORIZATION PROCESS



Component Safety Significance Assessment

This step involves the use of the plant-specific PRA analyses to identify components that are to be considered safety significant. The process includes consideration of the component contribution to full power internal events risk, fire risk, seismic risk and other external hazard risks, as well as shutdown safety. More detail is provided on this step in Section 5.

Defense-In-Depth Assessment

This step involves the evaluation of the role of components in preserving defense-in-depth related to core damage, large early release and long term containment integrity. More detail is provided on this step in Section 6.

Preliminary Engineering Categorization of Functions

This step involves integrating the results of the two previous tasks to provide a preliminary categorization of the safety significance of system functions. This includes consideration of both the risk insights and defense-in-depth assessments. More detail is provided on this step in Section 7.

Risk Sensitivity Study

The preliminary categorization is used to identify the SSCs that may be low safety significant. A risk sensitivity study is performed to investigate the aggregate impact of potentially changing treatment of those low safety significant SSCs. More detail is provided on this step in Section 8.

IDP Review and Approval

The Integrated Decision-Making Panel (IDP) is a multi-disciplined team that reviews the information developed by the categorization team. The Integrated Decision-making Panel (IDP) uses the information and insights developed in the preliminary categorization process and combines that with other information from design bases and defense-in-depth to finalize the categorization of functions. More detail is provided on this step in Section 9.

SSC Categorization

When the IDP approves the categorization of system functions, then the initial coarse mapping of components to system function may be used to define the safety significant SSCs. Additionally, the licensee may elect to perform a more detailed evaluation of the system and components that have been categorized as safety-significant to identify those SSCs that can be categorized as low safety-significant because a failure of these SSCs would not inhibit a safety-significant function. In the event this more detailed review identifies any new low safety significant SSCs, the results of that re-categorization is reevaluated in the risk sensitivity study and provided to the IDP for final review and approval. More detail is provided on this step in Section 10.

3 ASSEMBLY OF PLANT-SPECIFIC INPUTS

The first step in the categorization process is the collection and assembly of plant-specific resources that can provide input to the determination of safety significance.

3.1 Documentation Resources

Like all risk-informed processes, the categorization process relies upon input from both standard design and licensing information, and risk analyses and insights.

The understanding of the risk insights for a specific plant are generally captured in the following analyses:

- Full Power Internal Events PRA,
- Fire PRA or FIVE Analysis,
- Seismic PRA or Seismic Margin Assessment,
- External Hazards PRA(s) or IPEEE Screening Assessment of External Hazards, and
- Shutdown PRA or Shutdown Safety Program developed per NUMARC 91-06.

Examples of resources that can provide information on the safety classification and design basis attributes of SSCs include:

- Master Equipment Lists (provides safety-related designation)
- UFSAR
- Design Basis Documents
- 10 CFR 50.2 Assessments
- 10 CFR 50.65 information

3.2 Use of PRA Information

An essential element of the SSC categorization process is a plant specific PRA model of the internal initiating events at full power operations. The PRA should be of a standard that satisfies the accepted standards for PRA technical adequacy, reflect the as-built and as-operated plant, and quantify core damage frequency (CDF) and large early release frequency (LERF) for power operations due to internal events. Assessments of other hazards and modes of plant operation should be reviewed to ensure that the results and/or insights are applicable to the as-built, as-operated plant. PRAs provide an integrated means to assess relative significance. In cases where applicable quantitative analyses are not available, the categorization process will generally identify more SSCs as safety significant than in cases where broader scope PRAs are available.

The PRA should be consistent with accepted practices, in terms of the scope and level of detail for the hazards evaluated. PRA adequacy can be assured through a peer review of the PRA, as described in NEI 00-02 (Ref. 9) as amended to incorporate NRC comments provided in NRC letter to NEI dated April 2, 2002 (Ref. 15). Following the guidance in NEI 00-02 help ensure appropriate scope, level of detail, and quality of the PRA. The

ASME PRA Standard (Ref. 17) provides a consensus process for defining the attributes of a PRA that are necessary to support an application like the categorization process. When available, the other industry consensus standards on PRA are also an acceptable means to assure acceptability of the PRA results. Where available, industry processes for using a combination of the peer review process and standards should be utilized to maximize the benefit of both processes.

The licensee should ensure that documentation exists for the review process, the qualification of the reviewers, the summarized review findings, and resolutions to these findings. Based on the PRA peer review process and on the findings from this process, the licensee should justify why the PRA is adequate for this application in terms of scope and quality. One product of the peer review process is a series of grades in a spectrum of technical areas. Areas with low grades (grades less than 3) should be reviewed and evaluated to assess whether changes in the PRA are necessary.

When a PRA is used to provide insights into the integrated decision-making panel, it is expected that the PRA will have been subject to quality measures. The following describes methods acceptable to ensure that the PRA is of sufficient quality to be used for regulatory decisions and meets the quality standards described in Reg. Guide 1.174, and includes measures such as:

- Use personnel qualified for the analysis.
- Use procedures that ensure control of documentation, including revisions, and provide for independent review, verification, or checking of calculations and information used in the analyses (an independent peer review program can be used as an important element in this process).
- Provide documentation and maintain records in accordance with licensee practices.
- Provide for an independent review of PRA completeness (an independent peer review program can be used for this purpose).
- Use procedures that ensure appropriate attention and corrective actions are taken if assumptions, analyses, or information used in previous decision-making is changed (e.g., licensee voluntary action) or determined to be in error.

Any existing PRA or analysis can be used to support the categorization process, provided it can be shown that the appropriate quality provisions have been met.

The non-PRA aspects of the categorization process should be subject to the normal licensee quality assurance practices, including the applicable provisions of the licensee's Appendix B quality program for safety-related SSCs.

3.3 Characterization of the Adequacy of PRA Results

Figure 3-1 depicts the approach to be employed in ensuring the adequacy of PRA information used in the categorization of SSCs. This process is consistent with the approach proposed by the industry for making use of industry peer reviews in demonstrating that the ASME PRA Standard has been met. It is anticipated that the Regulatory Guide under development on assessing the adequacy of PRAs will be similar to this approach also. This new regulatory guide will establish the common process for demonstrating that the results from a plant-specific PRA are adequate for the application being undertaken.

The primary PRA input into the categorization process is the internal events PRA. This PRA is expected to meet accepted attributes and characteristics and be subject to a peer review. The Industry PRA Peer Review Process (NEI 00-02) represents an acceptable approach to ensuring the adequacy of the base internal events PRA results. The NEI 00-02 peer review provides several outputs, which are useful in characterizing the PRA results. The first output is a set of element grades, ranging from 1 to 4, which provide a consensus assessment by the peer review team of the usability of the PRA in applications. In the terms of the NEI 00-02 grading scheme, the Option 2 categorization process is a Grade 3 application. Thus, elements receiving a grade of 3 or 4 are expected to be sufficient to support the categorization process. In cases where a Grade 3 or 4 was achieved through the use of a sensitivity study, the implications of the sensitivity on the categorization process must be assessed. Elements receiving a grade of 1 or 2 should be reviewed by the PRA team to determine whether the PRA needs to be revised to address the peer review findings or if additional sensitivity studies are called for as part of the categorization process.

The second important output of the NEI 00-02 peer review process are the Fact and Observations (F&Os) that document the strengths and weaknesses of specific aspects of the PRA. F&Os that identify weaknesses are classified with an importance ranging from A to D, where A is most important and D is generally editorial. All F&Os in categories A and B should be reviewed and dispositioned by either:

- Incorporating appropriate changes into the PRA model prior to use,
- Identifying appropriate sensitivity studies to address the issue identified, or
- Providing adequate justification for the original model, including the applicability of key assumptions to the categorization process.

Other PRA analyses, such as Fire PRAs, Seismic PRAs, and Shutdown PRAs, should be reviewed to ensure that (1) none of the internal event peer review findings invalidate the results and insights, (2) the study appropriately reflects the as-built, as-operated plant and (3) any new PRA information (e.g., RCP seal LOCA assumptions, physical phenomena, etc.) does not invalidate the results.

The results of the internal events peer review and the review of the other PRA analyses to be used should be summarized in a characterization of the adequacy of the PRA. This characterization should be provided to the IDP as a basis for the adequacy of the PRA information used in the categorization process and should be summarized in the submittal to the NRC. At a minimum, this characterization should include the following:

Internal Events PRA (Full Power PRA)

- A basis for why the internal events PRA reflects the as-built, as-operated plant.
- A high level summary of the results of the peer review of the internal events PRA including elements that received grades lower than 3.
- The disposition of any peer review fact and observations (F&Os) classified as A or B importance.
- Identification of and basis for any sensitivity analyses necessary to address identified elements and F&Os.
- Considerations identified by the NRC in their letter to NEI [Ref. 15].

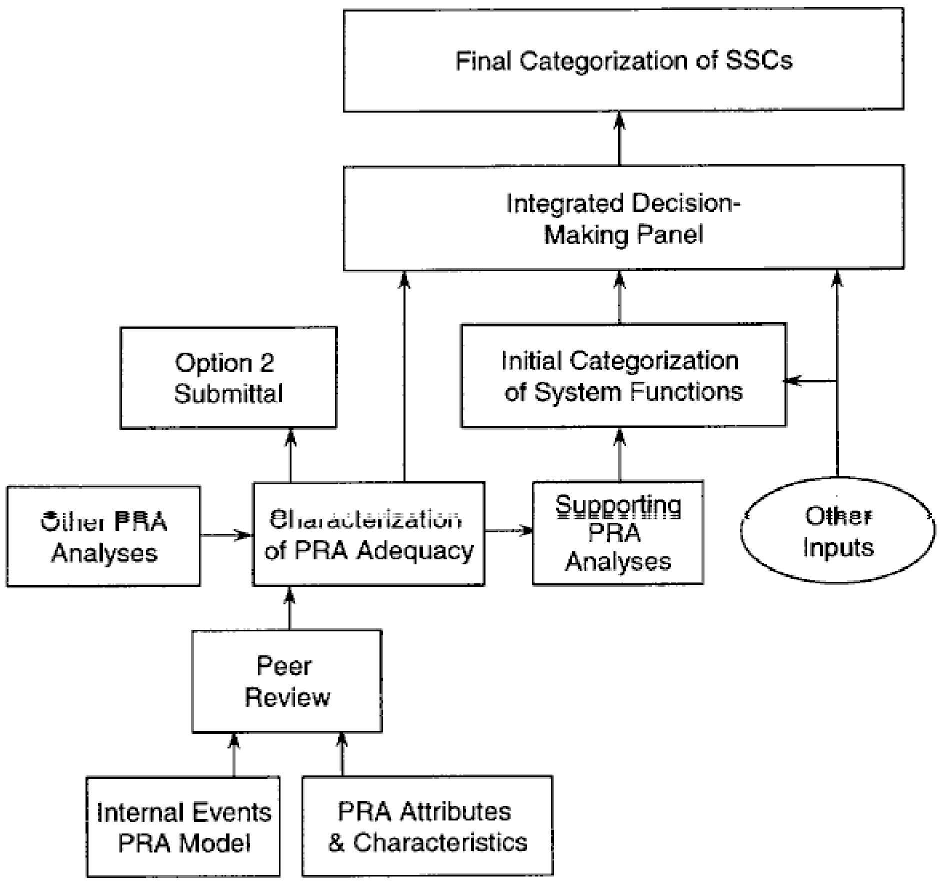
Other PRA Analyses

- A basis for why the other PRA analyses adequately reflect the as-built, as-operated plant.
- A disposition of the impact of elements grades or serious F&Os on the other PRA analyses.
- Identification of and basis for any sensitivity analyses necessary to address issues identified in the other PRAs.

The Integrated Decision-making Panel (IDP) should use this information, in combination with the results of the categorization analyses and other information, to recommend a categorization for each function/SSC. The process to be used to justify the adequacy of the PRA information is also summarized in the submittal to the NRC.

Figure 3-1

PROCESS FOR ASSURING PRA ADEQUACY FOR OPTION 2 CATEGORIZATION



4 SYSTEM ENGINEERING ASSESSMENT

The system engineering assessment involves the identification and development of the base information necessary to perform the risk-informed categorization. In general, it includes the following elements:

- System Selection and System Boundary Definition
- Identification of System Functions
- Coarse Mapping of Components to Functions

<u>System Selection and System Boundary Definition</u>

This step includes defining system boundaries where the system interfaces with other systems. The bases for the boundaries can be the equipment tag designators or some other means as documented by the licensee. All components and equipment of the chosen system should be included. However, care should be taken in extending beyond system boundaries to avoid the introduction of new systems and functions. For example, many systems require support from other systems such as electric power and cooling water. The system boundary should be defined such that any components from another system, only support the safety function of the primary system of interest. This may lead to the inclusion of some power breakers in the system boundary, but would probably exclude the MCC or bus.

<u>Identification of System Functions</u>

This step involves the identification of all system functions. A variety of sources are available for the identification of unique system functions including:

- Design Basis Safety Functions
- Maintenance Rule Functions
- Functions Modeled in the Plant-specific PRA
- Operational Functions

All design basis functions and beyond design basis functions identified in the PRA should be used. The system functions should be consistent with both the functions defined in the design basis documentation and the maintenance rule functions. While beyond design basis functions may be included in the maintenance rule functions, a review of the PRA should be conducted to assure that any function for the chosen system that is modeled in the PRA is represented. The system function should also be reviewed to assure that any special considerations for external events, plant startup / shutdown and refueling are also represented. Some functions may be further subdivided to allow discrimination between potentially safety significant and low safety significant functions associated with a flow path.

Coarse Mapping of Components to Functions

This step involves the initial breakdown of system components into the system functions they support. System components and equipment associated with each safety-significant function are identified and documented. There are several options to this implementation element:

1) Define the flow path associated with each function and then define the components associated with that function. In this case, the flow path definition must consider branch lines and interfaces with other flow paths to assure that the entire flow path is appropriately modeled and the boundaries clearly delineated.

2) If passive components have been categorized according to guidance for risk-informed ISI, the risk-informed segments are a good starting point. There would be additional benefit, if the SSC categorization for passive components using the ASME Code Case N-658, *Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities* (Ref. 16), is being implemented at the same time.

   In these cases, for each of the system functions from the previous step, the ISI segments associated with that function must be defined. That is, the flow path for each function is defined in terms of ISI segments. If the SSCs associated with an ISI segment have already been defined in the risk-informed ISI program, the only additional work is:
   a. Associate piece parts with a component that has already been categorized in the ISI program and,
   b. Create new equivalent ISI segments for portions of the system that may not have been in the scope of the RI ISI program.

   This is conservative because not every component in an ISI segment for each function is required to support that function.

Note that for either alternative, some functions (e.g., instrumentation to support the function, or isolation of the function) have no true flow path, but the components associated with these functions can be readily identified from system drawings once the system boundaries are identified.

Although this step involves the assignment of SSCs to a given flow path, this is not the primary focus of this step. In a later subsequent step, the categorization of the flow paths represented by each function will be presented to the IDP for review. The assignment of SSCs to the flow paths representing each of the functions is necessary at this step to ensure that every SSC with a tag identifier for the system being considered is represented in at least one of the functions. If SSCs are identified that are not assigned to at least one function, then new function(s) should be created for those SSCs.

5 COMPONENT SAFETY SIGNIFICANCE ASSESSMENT

The compilation of risk insights and identification of safety significant attributes builds upon the plant-specific resources. An overview of the safety significance process is shown in Figure 5-1.

The initial screening is performed at the system/structure level. If the system/structure is found to have a role in a particular portion of the plant's risk profile, then a component level evaluation can be performed.

Importance from Internal Events

The first question in the safety significance process involves the role the system/structure plays in the prevention and mitigation of severe accidents. If the system/structure is not involved in severe accident prevention or mitigation, then the screening process is terminated and the system functions is categorized as low safety significant.

If a system or structure is involved in the prevention or mitigation of severe accidents, then the first risk contributor evaluated is from the internal events PRA. The question of whether a system or structure is evaluated in the internal events PRA (or any of the analyses considered in this guideline) must be answered by considering not only whether it is explicitly modeled in the PRA (i.e., in the form of basic event(s)) but also whether it is implicitly evaluated in the model through operator actions, super components or another aggregated events sometimes used in PRAs. The term "evaluated" means:

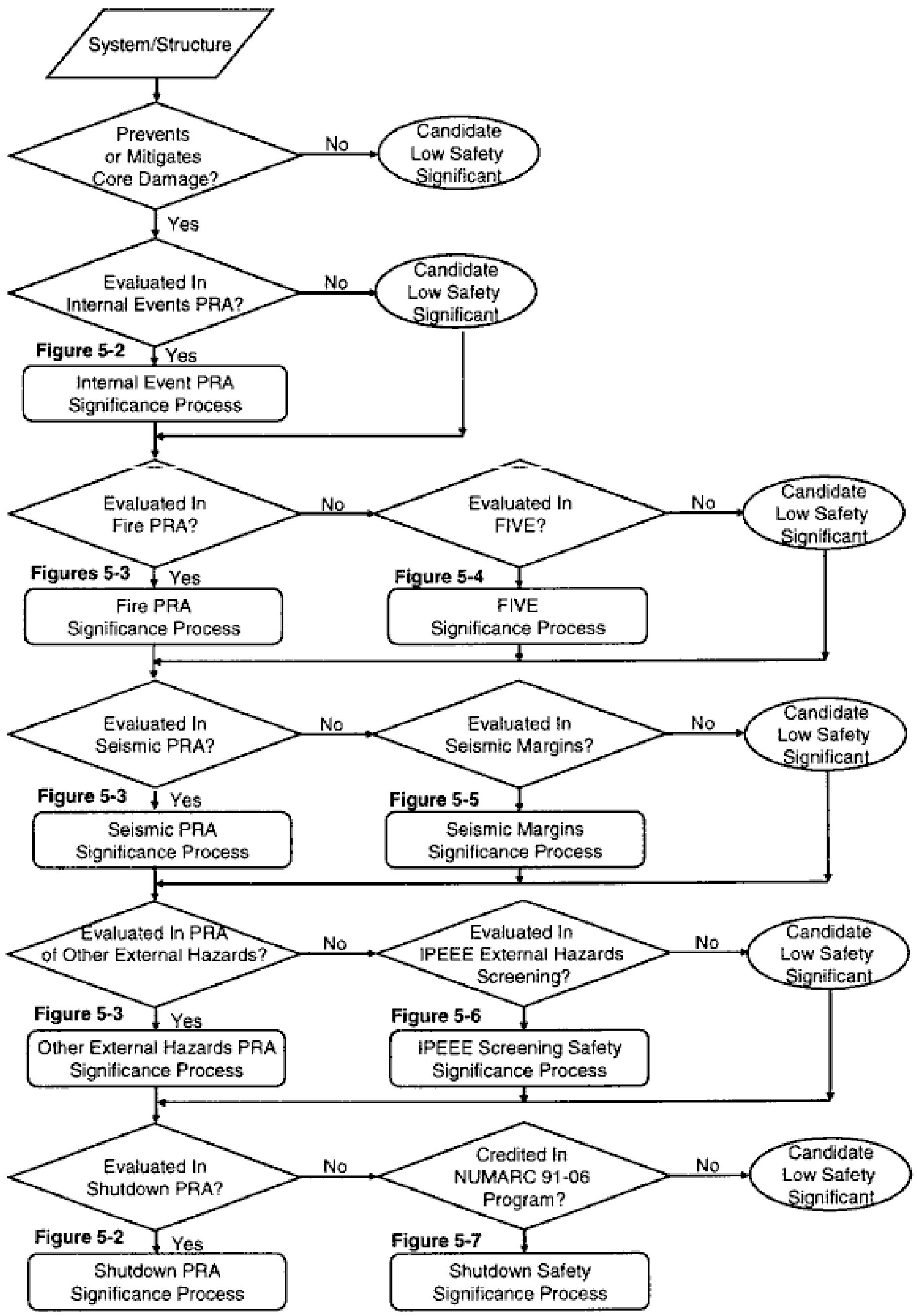
- Can it produce a potential initiating event?
- Is it credited for prevention of core damage or large early release?
- Is it necessary for another system or structure evaluated in the PRA to prevent an event or mitigate an event?

Some systems and structures are implicitly modeled in the PRA. It is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant specific PRA make these determinations. As outlined in Section 1, by focusing on the significance of system functions and then correlating those functions to specific components that support the function, it is possible to address even implicitly modeled components. If the system or structure is determined to be evaluated in the internal events PRA, then the internal event PRA significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.1.

If the system/structure is not evaluated in the internal events PRA, then the assessment of the safety categorization relative to internal events is performed and then reviewed and approved by the IDP to determine. In either case, the evaluation is continued with fire risk.

Figure 5-1

USE OF RISK ANALYSES FOR SSC CATEGORIZATION



Importance from Fire Events

If the plant has a fire PRA, then the next step of the screening process is to determine whether the system or structure is evaluated in the fire PRA. In making this determination specific attention should be given to structures and the role the play as fire barriers in the fire PRA. It is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant specific fire PRA make the determinations with respect to fire PRAs. If the system or structure is determined to be evaluated in the fire PRA, then the fire PRA significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.2.

If the plant does not have a fire PRA, a fire risk evaluation is required, such as the *EPRI Fire Induced Vulnerability Evaluation (FIVE).* Again, it is important that personnel that are knowledgeable in the scope, level of detail, and assumptions of the fire risk evaluation (FIVE) make these determinations. If the system or structure is determined to be evaluated in the FIVE analysis, then the FIVE significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.2.

If the system/structure is not involved in either a fire PRA or FIVE evaluations, then the assessment of the safety classification relative to fire risks is performed and then reviewed and approved by the IDP.

Importance from Seismic Events

If the plant has a seismic PRA, then the next step of the screening process is to determine whether the system or structure is evaluated in the seismic PRA. Often structures are explicitly modeled in seismic PRAs. Again, it is important that PRA personnel that are knowledgeable in the scope, level of detail, and assumptions of the plant specific seismic PRA make these determinations. If the system or structure is determined to be evaluated in the seismic PRA, then the seismic PRA significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.3.

If the plant does not have a seismic PRA, then a seismic risk evaluation, such as a seismic margin evaluation that was performed in response to the IPEEE should be performed. The seismic importance should be determined by personnel knowledgeable in the scope, level of detail, and assumptions of the seismic margins analysis. If the system or structure is included in the seismic margins analysis, then the seismic margins significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.3.

If the system/structure is not involved in either a seismic PRA or seismic margins evaluation, then the assessment of the safety classification relative to seismic risks is performed and then reviewed and approved by the IDP.

Importance from Other External Events

If the plant has a PRA, which evaluates other external hazards, then the next step of the screening process is to determine whether the system or structure is evaluated in the external hazards PRA. Often structures are explicitly modeled in external hazards PRAs. Personnel knowledgeable in the scope, level of detail, and assumptions of the external hazards PRA should make these determinations. If the system or structure is determined to be evaluated in the external hazards PRA, then the external hazards PRA significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.4.

If the plant does not have an external hazards PRA, then it is likely to have an external hazards screening evaluation that was performed to support the requirements of the IPEEE. Once again, personnel knowledgeable in the scope, level of detail, and assumptions of the external hazards analysis should make these determinations. If the system or structure is evaluated in the external hazards analysis, then the external hazards screening significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.4.

If the system/structure is not involved in either a external hazards PRA or external hazards screening evaluation, then the assessment of the safety classification relative to external hazards risks is performed and then reviewed and approved by the IDP.

Importance from Shutdown Events

If the plant has a shutdown PRA, then the next step of the screening process is to determine whether the system or structure is evaluated in the shutdown PRA. Personnel knowledgeable in the scope, level of detail, and assumptions of the shutdown PRA should make the determination. If the system or structure is evaluated in the shutdown PRA, then the shutdown PRA significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.5.

If the plant does not have a shutdown PRA, then it is likely to have a shutdown safety program developed to support implementation of NUMARC 91-06. Once again, personnel knowledgeable in the scope, level of detail, and assumptions of the NUMARC 91-06 program should make this determination. If the system or structure is determined to be credited in the NUMARC 91-06, then the shutdown safety significance process is used to determine whether it should be considered safety significant for this element of the plant risk profile. This process is discussed in Section 5.5.

If the system/structure is not involved in a shutdown PRA or NUMARC 91-06, then the assessment of the safety classification relative to shutdown risks is performed and then reviewed and approved by the IDP.

5.1 Internal Event Assessment

The significance of SSCs that are included in the internal events PRA is evaluated using Figure 5-2. Some PRA tools allow for the evaluation of importance measures, which include the role in initiating events. For those cases, the importance measures provide sufficient scope to perform the initial screening. In cases where the importance measures do not include initiating event importance, a qualitative process is used to address the initiating event role of the SSC. The mitigation importance of the SSC is assessed using the available importance measures.

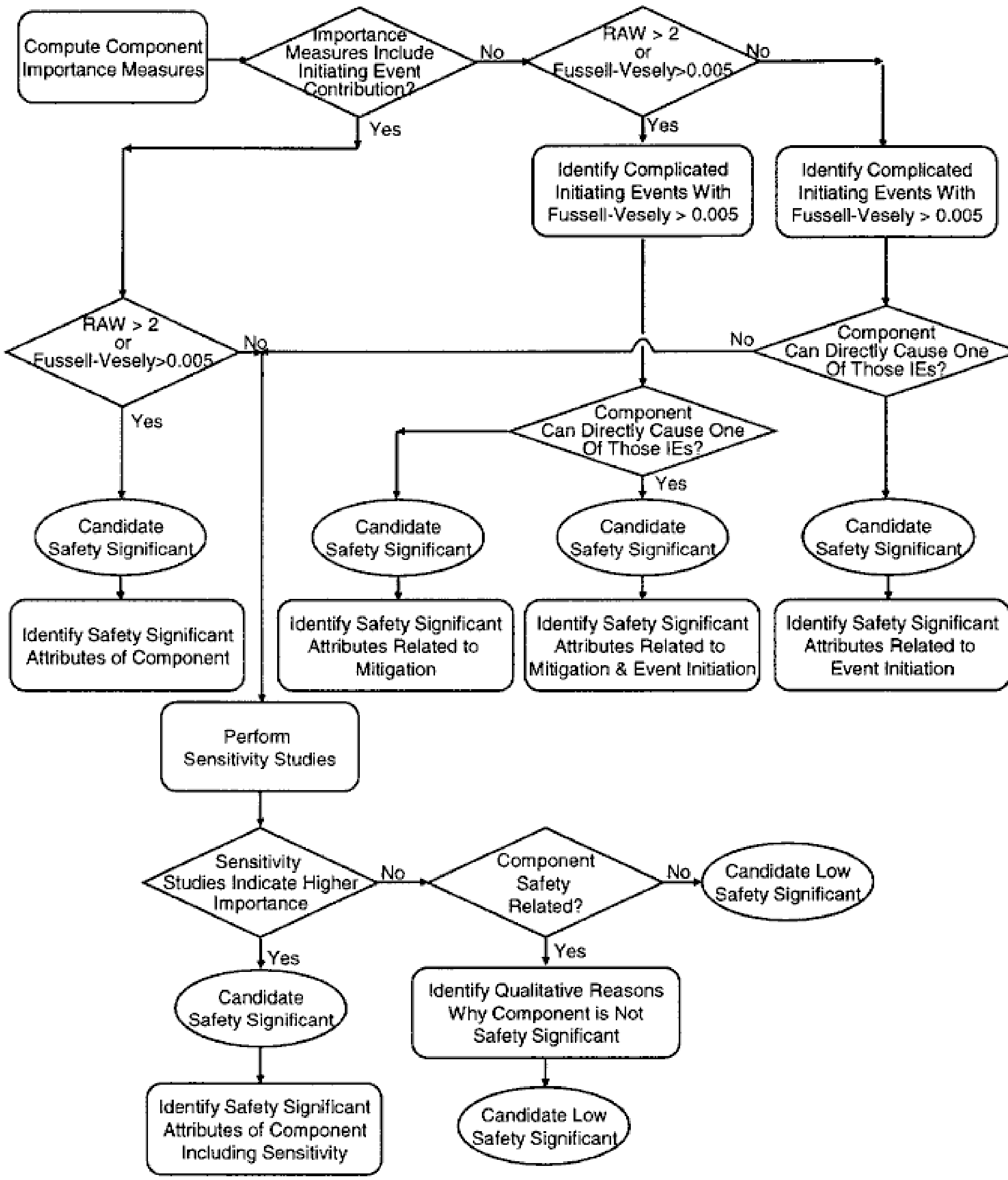
The qualitative process questions whether the SSC can directly cause a complicated initiating event that has a Fussell-Vesely importance greater than the criteria (0.005). If it does, then it is considered a candidate safety significant SSC and the attributes that could influence that role as an initiating event are to be identified. A complicated initiating event is considered an event that trips the plant and causes an impact on a key safety function. Examples of complicated initiating events include loss of all Feedwater (PWR/BWR), loss of condenser (BWRs), etc.

The assessment of importance for an SSC involves the identification of PRA basic events that represent the SSC. This can include events that explicitly model the performance of an SSC (e.g., pump X fails to start), events that implicitly model an SSC (e.g., some human actions, initiating events, etc.) or a combination of both types of events. Personnel familiar with the PRA will have to identify the events in the PRA that can be used to represent each SSC. In general, PRAs are not as capable of easily assessing the importance of passive components such as pipes and tanks. However, in some cases, focused calculations or sensitivity studies can be used [do we need examples]. For obtaining risk insights from the PRA for passive pressure boundary components, additional guidance is provided in ASME Code Case N-658, Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities. Guidance for categorization (and special treatment) for in-service inspection of passive pressure boundary piping components can be obtained from ASME Code Cases N-577 and N-578, along with Westinghouse Owners Group Topical Report WCAP-14572, Revision 1-NP-A and Electric Power Research Institute Report TR-112657 Rev.B-A, respectively.

The risk importance process utilizes two standard PRA importance measures, risk achievement worth (RAW) and Fussell-Vesely (F-V), as screening tools to identify candidate safety significant SSCs. Risk reduction worth (RRW) is also an acceptable measure in place of Fussell-Vesely. The Fussell-Vesely criteria can be readily converted to RRW criteria. The Fussell-Vesely importance of a component is considered to be the sum of the F-V importances for the relevant failure modes of the component, including common cause failure. The relevant failure modes of a component are those that are expected to be affected by the special treatment requirements being evaluated.

Figure 5-2

RISK IMPORTANCE ASSESSMENT PROCESS FOR COMPONENTS ADDRESSED IN INTERNAL EVENTS AT-POWER PRAs



If a component does not have a common cause event to be included in the computation of importances, then an assessment should be made as to whether a common cause event should be added to the model. The RAW importance of a component is considered the maximum of the RAW values computed for basic events involving the component. In the case of RAW, the common cause event is not considered in the assessment of component risk significance. The RAW for common cause events is an unrealistic parameter since it reflects the relative increase in CDF/LERF that would exist if a common cause failure condition existed for an entire year.

For example, a motor operated valve may have a number of basic events associated with it, each of which has a separate Fussell-Vesely importance. Likewise, the risk achievement worth of a component is the maximum value determined from the relevant failure modes (basic events):

The importance evaluation can be performed at the system level for the purposes of screening. The remainder of this section discusses the process at the component level, which is the lowest level of detail expected to be performed.

Table 5-1
EXAMPLE IMPORTANCE SUMMARY

COMPONENT FAILURE MODE	F-V	RAW
1) Valve 'A' Fails to Open	0.002	1.7
2) Valve 'A' Fails to Remain Closed	0.00002	1.1
3) Valve 'A' In Maintenance (Closed)	0.0035	1.7
4) Common Cause Failure of Valves 'A' & 'B' to Open	0.004	n/a
Component Importance	0.00952	1.7
Criteria	> 0.005	>2
Candidate Risk Significant?	**Yes**	

In the above example, Valve 'A' would be considered candidate safety significant due to the total Fussell-Vesely exceeding the criteria. The RAW criteria were not met. The component failure mode, which contributes significantly to the importance of Valve 'A', is failure to open (modes 1, 3 and 4). This failure mode is used in the identification of safety significant attributes. If an individual failure mode had not alone exceeded the screening criteria, then the dominant failure mode would be used in defining the attributes.

SSCs, which have high failure probabilities (usually indicative of screening values) and meet the screening criteria solely on the basis of Fussell-Vesely importance, should be identified as candidate safety significant, but the reasons for this categorization should be identified to the IDP. In many cases, special treatment should have little or no impact on such SSCs. If the IDP determines that this is the case, it may decide to categorize the SSC as low safety significant.

In cases where the internal events core damage frequency is dominated by flooding, it is appropriate to break the evaluation of importance measures into two steps. The first step uses importance measures computed using the entire internal events PRA. The second step uses importance measures computed without the dominant contributor included. This prevents "masking" of importance by the dominant contributor.

If the screening criteria are met for either importance measure, the SSC is considered a candidate safety significant component and the safety significant attributes are to be identified. If the risk importance measure criteria are not met, then it is not automatically low safety significant. It must be evaluated as part of several sensitivity studies, determined to be low safety significant for all risk contributors and must be reviewed by the IDP. If the importance measures computed by the PRA tool do not indicate that a component meets the Fussell-Vesely or RAW criteria, then sensitivity studies are used to determine whether other conditions might lead to the component becoming safety significant. The recommended sensitivity studies for internal events PRA are identified in Table 5-2.

Table 5-2
Sensitivity Studies For Internal Events PRA

Sensitivity Study
• Increase all human error basic events to their 95th percentile value • Decrease all human error basic events to their 5th percentile value • Increase all component common cause events to their 95th percentile value • Decrease all component common cause events to their 5th percentile value • Set all maintenance unavailability terms to 0.0 • Any applicable sensitivity studies identified in the characterization of PRA adequacy

The sensitivity studies on human error rates, common cause failures, and maintenance unavailabilities are performed to ensure that assumptions of the PRA are not masking the importance of an SSC. In cases where plant-specific uncertainty distributions are not readily available, other PRAs should be reviewed to identify appropriate parameter ranges. Experience with plant-specific PRAs has shown that the variations in distributions are relatively small, especially with respect the ratio of the mean and 95th percentile values in lognormal distributions (the most common distribution used in PRAs).

If the sensitivity studies identify that the component could be safety significant, then the safety significant attributes that yielded that conclusion should be identified.

If, following the sensitivity studies, the component is still found to be low safety significant and it is safety-related, it is a candidate for RISC-3. In this case the analyst is to define why that component is of low risk significance (e.g., doesn't perform an important function, excess redundancy, low frequency of challenge, etc.).

This risk importance process is performed for both CDF and LERF. In calculating the FV risk importance measure, it is recommended that a CDF (or LERF) truncation level of at least five orders of magnitude below the baseline CDF (or LERF) value be used for linked fault tree PRAs. For example, if the internal events, full power CDF baseline value is 1E-5 /yr, a truncation level of at least 1E-10 /yr is recommended. In addition, the truncation level used should support an overall CDF/LERF which has converged. For linked event tree PRAs, the unaccounted for frequencies should be sufficiently low as to provide confidence that the overall CDF/LERF and resulting importance measures are accurate. When the RAW risk importance measure is calculated by a full re-solution of the plant PRA model, then the truncation level does not significantly affect the RAW calculations. In this case, a default truncation value of 1E-9 /yr seems reasonable. However, if a pre-solved set of cutsets is used to calculate RAWs, the truncation level should be set to a sufficiently low value so that all SSCs with RAW>2 are identified (e.g., cutoff of 1E-10 /yr or lower). The truncation of the PRA model should be checked to ensure that the CDF and LERF values have converged and that the importance measures are stabilized.

5.2 Fire Assessment

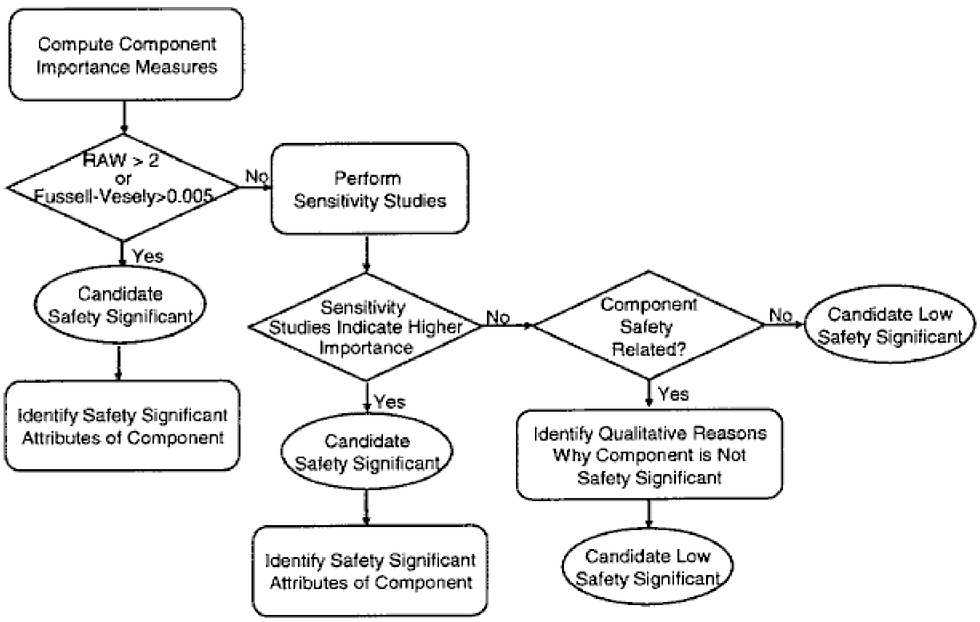
The fire safety significance process takes one of two forms. For plants with a fire PRA, the process is similar to that described for an internal events PRA. This process is shown on Figure 5-3, and is discussed below. Plants that relied upon a FIVE analysis to assess fire risks for the IPEEE should use the process shown in Figure 5-4.

The generalized safety significance process for plants with a fire PRA is the same as the process for an internal events PRA. The risk importance process is slightly modified to consider the fact that most fire PRAs do not have the ability to aggregate the mitigation importance of a component with the fire initiation contribution. For that reason, components are evaluated using standard importance measures for their mitigation capability only. Aside from that small change, the process is the same as the internal events PRA process.

Fire suppression systems that are evaluated using the fire risk analysis can be categorized using this process. However, in order to apply this categorization process to suppression systems, specific sensitivity studies may be required to identify their relative importance, consistent with Fussell-Vesely and RAW (guarantee success/failure). In general, fire barriers would not be considered, unless the fire risk analysis supports consideration of the impacts of failure of the barrier. In cases where the impact of fire barrier failure can be evaluated in the risk analysis, the categorization process is applicable. Once again, the use of sensitivity studies can be beneficial in identifying the role a barrier plays in maintaining risk levels.

Figure 5-3

RISK IMPORTANCE PROCESS FOR COMPONENTS ADDRESSED IN FIRE, SEISMIC & OTHER EXTERNAL HAZARD PRAs



If the fire PRA CDF is a small fraction of the internal events CDF (i.e., <1%), then safety significance of SSCs considered in the fire PRA can be considered low safety significant from a fire perspective.

If the sensitivity studies identify that the component could be safety significant, then the safety significant attributes which yielded that conclusion should be identified. If, following the sensitivity studies, the component is still found to be low safety significant and it is safety-related, the analyst is expected to define why that component is of low risk significance (e.g., doesn't perform an important function, excess redundancy, low frequency of challenge, etc.).

This risk importance process is performed for both CDF and LERF. Where LERF can not be quantitatively linked into the fire model, the insights from the internal events LERF model should be qualitatively coupled with the assessment of fire impacts on containment isolation to develop recommendations for the IDP on LERF contributors.

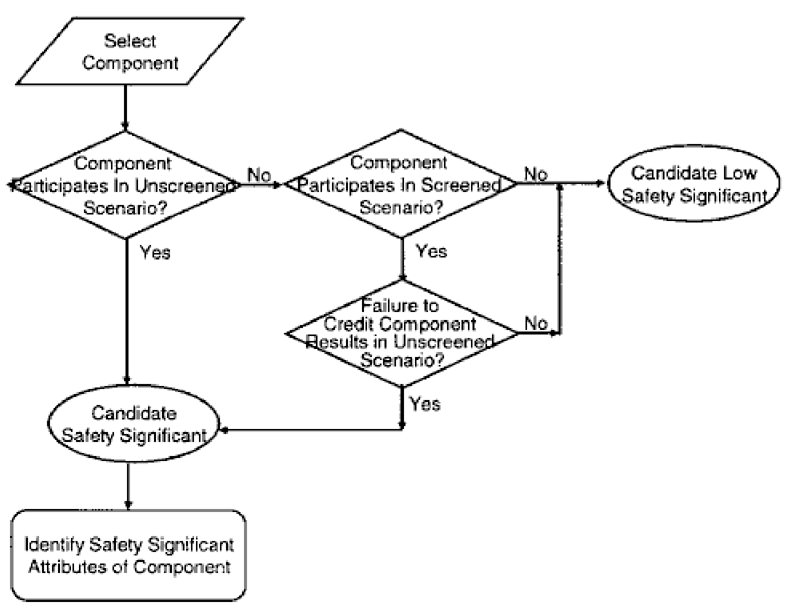
The recommended sensitivity studies for fire PRA are identified in Table 5-3.

Table 5-3
Sensitivity Studies For Fire PRA

Sensitivity Study
• Increase all human error basic events to their 95th percentile value
• Decrease all human error basic events to their 5th percentile value
• Increase all component common cause events to their 95th percentile value
• Decrease all component common cause events to their 5th percentile value
• Set all maintenance unavailability terms to 0.0
• All manual suppression =1.0
• Any applicable sensitivity studies identified in the characterization of PRA adequacy

The FIVE methodology is a screening approach to evaluating fire hazards. It does not generate numbers, which are true core damage values; rather, it simply assists in identifying potential fire susceptibilities and vulnerabilities. For this reason, it is somewhat limited in being able to support the identification of low safety significant components. The safety significance process for plants with FIVE evaluations is shown in Figure 5-4.

Figure 5-4
SAFETY SIGNIFICANCE PROCESS FOR SYSTEMS AND COMPONENTS ADDRESSED IN FIVE



In this process, after identifying the design basis and severe accident functions of the component, the results of the FIVE analysis are reviewed to determine if any SSCs can be identified as safety significant or low safety significant. If a component participates, either by initiating or in the mitigation of an unscreened fire scenario, it is considered safety significant. This is somewhat conservative since the FIVE process does not generate core damage frequency values. However, the option always exists for the licensee to extend their FIVE analysis to a fire PRA to remove any conservatisms.

If the component does not participate in an unscreened scenario, then its participation in screened scenarios is questioned. If it can be shown that the component either did not participate in any screened scenarios or, even if credit for the component was removed, the screened scenario would not become unscreened, then it is considered a candidate for the low safety significant category.

5.3 Seismic Assessment

The seismic safety significance process takes one of two forms. For plants with a seismic PRA, the process is similar to that described for a fire PRA. This process is shown on Figure 5-3 and discussed below. Plants that relied upon a seismic margins analysis to assess seismic risks for the IPEEE would use the modified process shown in Figure 5-5.

The generalized safety significance process for plants with a seismic PRA is the same as the process for a fire PRA. The risk importance process is slightly modified to consider the fact plant components can not initiate seismic events. Aside from that small change, the process is the same as the internal events PRA process.

However, if the seismic PRA CDF is a small fraction of the internal events CDF (i.e., <1%), then safety significance of SSCs considered in the seismic PRA can be considered low safety significant from a seismic perspective.

If the sensitivity studies identify that the component could be safety significant, then the safety significant attributes which yielded that conclusion should be identified. If, following the sensitivity studies, the analyst is expected to define why that component is of low risk significance (e.g., doesn't perform an important function, excess redundancy, low frequency of challenge, etc.).

This risk importance process is performed for both CDF and LERF. Where LERF can not be quantitatively linked into the seismic model, the insights from the internal events LERF model should be qualitatively coupled with the assessment of seismic impacts on containment to develop recommendations for the IDP on LERF contributors.

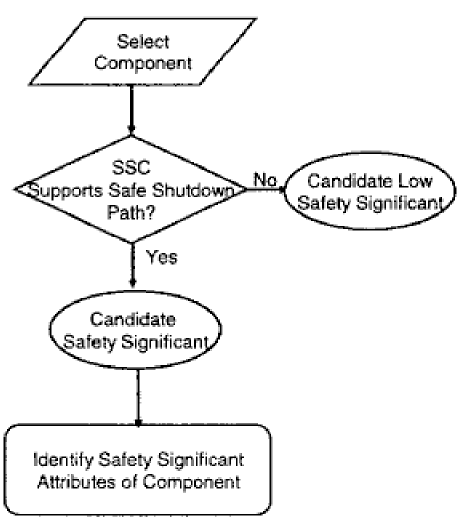
The recommended sensitivity studies for seismic PRA are identified in Table 5-4:

Table 5-4
Sensitivity Studies For Seismic PRA

Sensitivity Study
• Increase all human error basic events to their 95th percentile value • Decrease all human error basic events to their 5th percentile value • Increase all component common cause events to their 95th percentile value • Decrease all component common cause events to their 5th percentile value • Set all maintenance unavailability terms to 0.0 • Use correlated fragilities for all SSCs in an area • Any applicable sensitivity studies identified in the characterization of PRA adequacy

The seismic margins methodology is a screening approach to evaluating seismic hazards. It does not generate core damage values; rather, it simply assists in identifying potential seismic susceptibilities and vulnerabilities. For this reason, it is somewhat limited in being able to support the identification of low safety significant components. The safety significance process for plants with seismic margins evaluations is shown in Figure 5-5.

Figure 5-5
SAFETY SIGNIFICANCE PROCESS FOR
SYSTEMS AND COMPONENTS ADDRESSED IN SEISMIC MARGINS



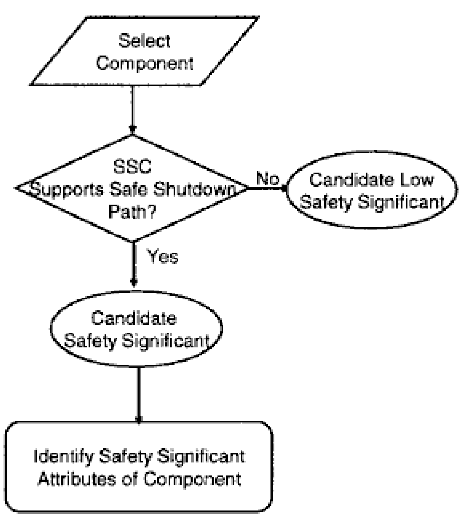
In this process, after identifying the design basis and severe accident functions of the component, the seismic margins analysis is reviewed to determine if the component is credited as part of the safe shutdown paths evaluated. If a component is credited, it is considered safety significant. This is conservative since the seismic margin process does not generate core damage frequency values. However, the option always exists for the licensee to perform a seismic PRA to remove any conservatisms.

If the component does not participate in the safe shutdown path, then it is considered a candidate low safety significant with respect to seismic risk.

5.4 Assessment of Other External Hazards

The significance process for other external hazards (i.e., excluding fire and seismic) also takes one of two forms. For plants with an external hazards PRA, the process is similar to that described for an internal events PRA. This process is shown on Figure 5-3 and discussed below. Plants that relied upon an external hazard screening to assess external hazards for the IPEEE would use the modified process shown in Figure 5-6.

Figure 5-6
OTHER EXTERNAL HAZARDS



The generalized safety significance process for plants with an external hazard PRA is the same as the process for an internal events PRA. As for seismic risk, the risk importance process is slightly modified to consider the fact plant components cannot initiate external events such a floods, tornadoes, and high winds. Aside from that small change, the process is the same as the internal events PRA process.

However, if the external hazards PRA CDF is a small fraction of the internal events CDF (i.e., <1%), then safety significance of SSCs considered in the external hazards PRA can be considered low safety significant from an external hazards perspective.

The recommended sensitivity studies for other external hazard PRAs are identified in Table 5-5.

Table 5-5
Sensitivity Studies For Other External Hazard PRA

Sensitivity Study
• Increase all human error basic events to their 95th percentile value
• Decrease all human error basic events to their 5th percentile value
• Increase all component common cause events to their 95th percentile value
• Decrease all component common cause events to their 5th percentile value
• Set all maintenance unavailability terms to 0.0
• Any applicable sensitivity studies identified in the characterization of PRA adequacy

If the sensitivity studies identify that the component could be safety significant, then the safety significant attributes which yielded that conclusion should be identified. If, following the sensitivity studies, the analyst is expected to define why that component is of low risk significance (e.g., doesn't perform an important function, excess redundancy, low frequency of challenge, etc.).

This risk importance process is performed for both CDF and LERF. Where LERF can not be quantitatively linked into the external hazard model, the insights from the internal events LERF model should be qualitatively coupled with the assessment of external hazard impacts on containment to develop recommendations for the IDP on LERF contributors.

The external hazard screening does not generate core damage values; rather it simply assists in identifying that the plant has no significant external hazard susceptibilities and vulnerabilities. For this reason, it is somewhat limited in being able to support the identification of low safety significant components. The safety significance process for plants with external hazard screening evaluations is shown in Figure 5-6.

In this process, after identifying the design basis and severe accident functions of the component, the external hazard analysis is reviewed to determine if the component is credited as part of the safety shutdown paths evaluated. If a component is credited, it is considered safety significant. This is conservative since the external hazard screening process does not generate core damage frequency values. However, the option always exists for the licensee to perform an external hazard PRA to remove any conservatisms.

The process of assessing whether an SSC is safety significant due to other external hazards is as follows:

1. Identify a safe shutdown path for each external event challenge (presumably the same as the seismic shutdown path).

2. The NEI 00-04 screening approach is then to:

   a) Review the SRP on the NUREG 1407 analysis to determine if the SSC is credited as part of the identified safe shutdown path.

      If a component is credited, it is considered safety significant.

   b) Ensure that the SSC is not relied upon to support or protect any of the SSCs supporting safe shutdowns functions given the challenges to the SSC resulting from the "other" external event. If a component is credited to be available under these conditions, it is considered safety significant, as are the SSCs which assure the functionality of those safety significant SSCs.

If the SSC passes these screens, then the answer to the question "SSC Supports Safe Shutdown Path?" can be "no."

If the component does not participate in the safe shutdown path, then it is considered a candidate low safety significant with respect to external hazards.

5.5 Shutdown Safety Assessment

The shutdown safety significance process also takes one of two forms. For plants with a shutdown PRA that is comparable to an at-power PRA (i.e., generates annual average CDF/LERF), the process is similar to that described for an internal events PRA. This process is shown on Figure 5-2. Plants that do not have a shutdown PRA would use the modified process shown in Figure 5-7 based on their NUMARC 91-06 program. Due to the similarities between shutdown and at-power PRAs, the generalized safety significance process for plants with a shutdown PRA is the same as the process for an internal events PRA.

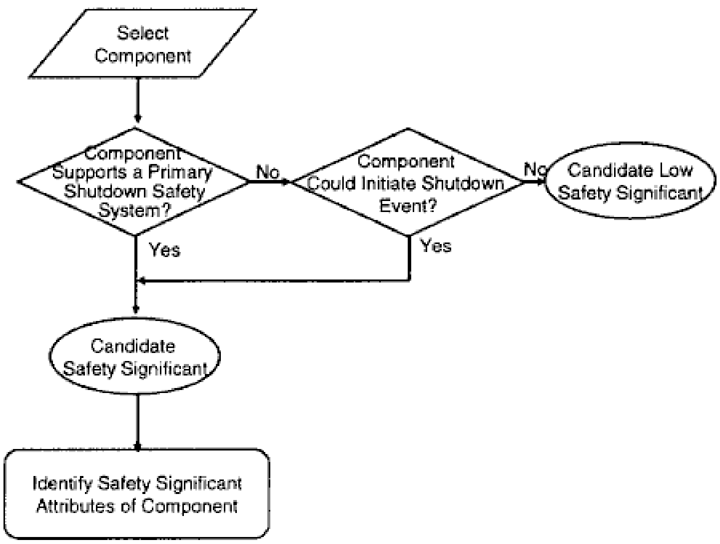
However, if the shutdown PRA CDF is a small fraction of the internal events CDF (i.e., <1%), then safety significance of SSCs considered in the shutdown PRA can be considered low safety significant from a shutdown perspective.

The same sensitivity studies identified in Table 5-2 should be used in the evaluation of shutdown risk significance.

Meeting the guidelines for shutdown safety identified in NUMARC 91-06 is not equivalent to a shutdown PRA and does not generate quantitative information comparable to core damage values. Rather, it simply attempts to ensure that the plant has an appropriate complement of systems available at all times. The safety significance process for plants without a shutdown PRA is shown in Figure 5-7.

Figure 5-7

SAFETY SIGNIFICANCE PROCESS FOR SYSTEMS AND COMPONENTS CREDITED IN NUMARC 91-06 PROGRAM



In this process a component can be identified as safety significant for shutdown conditions for one of two reasons:

- It could initiate a shutdown event (e.g., loss of shutdown cooling, drain down, etc.),
- It satisfies both of the following conditions:
    - It participates in a safety function whose failure can result in increasing CDF or LERF, and
    - The minimum requirements as defined by the plant outage risk management guidelines cannot be met for the safety function without the system, structure, or component. The Outage Risk Management Guidelines categorize the level of safety and specify the minimum acceptable number of systems for each safety function.

If the component does not participate in either of these manners, then it is considered a candidate as low safety significance with respect to shutdown safety.

In this assessment, a primary shutdown safety system refers to a system that has the following attributes:

- It has a technical basis for its ability to perform the function.
- It has substantial margin to fulfill the safety function.
- It does not require extensive manual manipulation to fulfill its safety function.

5.5 Integral Assessment

In order to provide an overall assessment of the risk significance of SSCs, an integrated computation is performed using the available importance measures. This integrated importance measure essentially weights the importance from each risk contributor (e.g., internal events, fire, seismic PRAs) by the fraction of the total core damage frequency contributed by that contributor. The following formulas define how such measures are to be computed for CDF. The same format can be used for LERF, if available.

Integrated Fussell-Vesely Importance

$$IFV_i = \frac{\sum_j \left(FV_{i,j} * CDF_j\right)}{\sum_j CDF_j}$$

Where,

IFV_i = Integrated Fussell-Vesely Importance of Component i over all CDF Contributors
$FVi_{,j}$ = Fussell-Vesely Importance of Component i for CDF Contributor j
CDF_j = CDF of Contributor j

Integrated Risk Achievement Worth Importance

$$IRAW_i = 1 + \frac{\sum_j \left(RAW_{i,j} - 1\right) * CDF_j}{\sum_j CDF_j}$$

Where,

$IRAW_i$ = Integrated Risk Achievement Worth of Component i over all CDF Contributors
$RAW_{i,j}$ = Risk Achievement Worth of Component i for CDF Contributor j
CDF_j = CDF of Contributor j

Once calculated, an assessment should be made of these integrated values against the screening criteria of Fussell-Vesely >0.005 and RAW > 2. In no case should the integrated importance become higher than the maximum of the individual measures. However, it is possible that the integral value could be significantly less than the highest contributor, if that contributor is small relative to the total CDF/LERF.

6 DEFENSE-IN-DEPTH ASSESSMENT

In cases where the component is safety-related and found to be of low safety significance, it is appropriate to confirm that defense in depth is preserved. This discussion should include consideration of the events mitigated, the functions performed, the other systems that support those functions and the complement of other plant capabilities that can be relied upon to prevent core damage and large, early release.

6.1 Core Damage Defense-in-Depth

The initial assessment should consider both the level of defense in depth in preventing core damage and to the frequency of the events being mitigated. Figure 6-1 is an example of such an assessment. This figure depicts the design basis events considered in the licensee's safety analysis report and considers the level of defense-in-depth available, based on the success criteria utilized in the PRA. This ensures that adequate defense-in-depth is available to mitigate design basis events. The defense-in-depth matrix is similar in form to the Significance Determination Process used in the Reactor Oversight Process and uses the same concepts of diverse and redundant trains and systems in evaluating the level of defense-in-depth.

For example, if a PWR found that SSCs in the condensate system could be categorized as low safety significant, this table could be used to qualitatively evaluate the safety significance. Since condensate is primarily relied upon as a secondary heat removal source following a reactor trip, the plant could confirm the low safety significance if three diverse trains or two redundant systems of heat removal are available. Many plants have three diverse trains of alternate feedwater makeup (e.g., turbine driven AFW, motor driven AFW and startup feedwater or diesel driven AFW) and many PWRs can utilize primary system bleed and feed as a means of heat removal. In these cases, the categorization of condensate components as a low safety significant could be confirmed. If less defense in depth is available, that information should be provided to the IDP for their consideration in the final categorization.

6.2 Containment Defense-in-Depth

Defense in depth should also be assessed for SSCs that play a role in preventing large, early releases. Level 2 PRAs have identified the several containment challenges that are important to LERF. These include containment bypass events such as ISLOCA (BWR and PWR) and SGTR (PWR), containment isolation failures (BWR and PWR), and early hydrogen burns (ice condensers and Mark III). Before making the final decision on whether a SSC is categorized as low safety significance, the IDP should be provided with information on containment performance using the following criteria:

Containment Bypass

- Can the SSC initiate or isolate an ISLOCA event?
- Can the SSC isolate a faulted steam generator following a steam generator tube rupture event?

Containment Isolation

- Does the SSC support containment isolation for containment penetrations that are:
    - >2" in diameter,
    - part of a system that is not considered closed as defined in GDC 57,
    - not normally closed or locked closed, and
    - not a part of a normally liquid filled system?

Early Hydrogen Burns

- Does the SSC support operation of hydrogen igniters in ice condenser and Mark III containments?

Long-term Containment Integrity

- Does the SSC perform a function that is not considered in CDF and LERF, but could be beneficial in preserving long-term containment integrity (i.e., containment temperature or pressure control)?

In cases where the answer to any of the above questions is "yes," the IDP should be informed that the SSC is potentially safety significant. If all of the above questions are answered "no," then low safety significance is confirmed.

In cases where SSCs are identified as safety significant, the safety significant attributes should be defined by the analyst familiar with the PRA. This involves identifying the performance aspects and failure modes of the SSC that contribute to it being safety significant. These attributes are to be provided to the IDP.

Figure 6-1

DEFENSE-IN-DEPTH MATRIX

Frequency	**Design Basis Event**	≥3 diverse trains OR 2 redundant systems	1 train + 1 system with redundancy	2 diverse trains	1 redundant automatic system
>1 per 1-10 yr	Reactor Trip Loss of Condenser				
1 per 10-10^2 yr	Loss of Offsite Power Total loss of Main FW Stuck open SRV (BWR) MSLB (outside cntmt) Loss of 1 SR AC Bus Loss of Instr/Cntrl Air			**POTENTIALLY SAFETY SIGNIFICANT**	
1 per 10^2-10^3yr	SGTR Stuck Open PORV/SV RCP Seal LOCA MFLB MSLB Inside Loss of 1 SR DC bus	**LOW SAFETY SIGNIFICANCE CONFIRMED**			
<1 per 10^3 yr	LOCAs Other Design Basis Accidents				

7 PRELIMINARY ENGINEERING CATEGORIZATION OF FUNCTIONS

7.1 Engineering Categorization

This step involves the assignment of a preliminary safety significance to each of the functions identified previously. The safety significant SSCs from the component safety significance assessment (Section 5) are mapped to the appropriate function for which they had a high safety significance. If any SSC function that supports a system function has high safety significance, from either the PRA-based component safety significance assessment (Section 5) or the defense-in-depth assessment (Section 6), then the system function is preliminarily assigned high safety significance. Once a system function has been identified as safety significant, then all components in the flow path (or system segment) supporting that system function are assigned a preliminary safety significant categorization. All other components were assigned a preliminary low safety significant categorization.

Due to the overlap of functions and components, a significant number of components support multiple functions. In this case, the SSC was assigned the highest risk significance for any function in which that SSC was used.

7.2 Summary of Results

The results of the compilation of risk information and safety significant attributes should be documented for the IDP's use. Figure 7-1 provides an example, conceptual layout of the information that is generated by this process and could be useful for the IDP. This format is for the purposes of identifying what could be communicated and is not required.

At a minimum, the IDP should be provided with the following information for each system function:

- System name
- The function(s) evaluated.
- The SSCs used as surrogates in the safety significance assessment.
- The results of the risk significance assessment for each hazard, and the integral assessment.
- Any applicable insights from sensitivity studies.
- The results of the defense-in-depth assessment.
- A summary of the basis for the categorization recommendation to the IDP.

The assessment of overall safety significance from the PRA involves consideration of the results of the categorization for each individual hazard and the integral assessment. The following guidelines are provided to assist in the communication of the categorization results to the IDP:

- If the SSC was found to be safety significant based on the internal events PRA without consideration of sensitivity studies, then it should be recommended to the IDP as safety significant.
- If the SSC was found to be of low safety significant based on the internal events PRA, but was found to be potentially safety significant based on the fire, seismic, other external hazards, or shutdown PRA assessments, then the integral assessment should be relied upon.
- If the SSC was found to be safety significant based on sensitivity studies, this should be communicated to the IDP, along with the base and integral significance for each hazard.

Figure 7-1

EXAMPLE RISK-INFORMED SSC ASSESSMENT WORKSHEET

System: ________________ Function: ________________________________

____

____

SSCs Considered in Safety Significance Assessment: ________________________

____

____

		Potentially Risk Significant	Potentially Non-Risk Significant	Not Assessed	Comments
Internal Events	CDF				
	LERF				
Fire	CDF				
	LERF				
Seismic	CDF				
	LERF				
External Hazards	CDF				
	LERF				
Low Power/ Shutdown	CDF				
	LERF				
Integral Assessment	CDF				
	LERF				

Insights From Sensitivity Studies:____

____

____

Defense-in-Depth Assessment:____

____

____

____

Recommended Categorization:

Safety Significant: _______ Low Safety Significant: _________

Basis for Categorization:____

____

____

____

8 RISK SENSITIVITY STUDY

The final step in the process of categorizing SSCs into risk-informed safety classifications involves the evaluation of the risk implications of changes in special treatment. In general, since one of the guiding principles of this process is that changes in treatment should not degrade performance for RISC-3 SSCs, and RISC-2 SSCs would be expected to maintain or improve in performance, it is anticipated that there would be little, if any, net increase in risk.

This risk sensitivity study is made using the available PRAs to evaluate the potential impact on CDF and LERF, based on a postulated change in reliability. This is useful because the importance measures used in the initial safety significance assessment were based on the individual SSCs considered. Changes in performance can influence not only the importance measures for the SSCs that have changes in performance, but also others. Thus, the aggregate impact of the changes should be evaluated to assess whether new risk insights are revealed. Risk sensitivity studies should be realistic.

For example, increasing the unreliability of all low safety significant SSCs by a factor of 2 to 5 could provide an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of all low safety significant SSCs. Such a degradation is extremely unlikely for an entire group of components. Utility corrective action programs would see a substantial rise in failure events and corrective actions would be taken long before the entire population experienced such a degradation. Individual components may see variations in performance on this order, but it is exceedingly unlikely that the performance of a large group of components would all shift in an unfavorable manner at the same time.

The risk sensitivity study should be performed by manipulating the unavailability terms for PRA basic events that correspond to component that were identified in the categorization process as having low safety significance because they do not support a safety significant safety function. The basic events for both random and common cause failure events should be increased for failure modes expected to be impacted by the changes in special treatment. A factor of 2 to 5 is appropriate as a sensitivity because it is representative of the change in reliability between a mean value and an upper bound (95th percentile) for typical equipment reliability distributions. For example, for a lognormal distribution the ratio of 95th percentile to mean value would be approximately 2.4 for an error factor of 3 and 3.5 for an error factor of 10.

This sensitivity study should be performed for each individual plant system as the categorization of its functions is provided to the IDP. A sensitivity study should be performed for the system, and a cumulative sensitivity for all the SSCs categorized using this process. This should provide the IDP with both the overall assessment of the potential risk implications and the relative contribution of each system.

Reducing the unreliability of safety significant SSCs by a similar factor may be called for, depending upon the specific changes in special treatment. The changes in CDF and

LERF computed in such sensitivity studies should be compared to the risk acceptance guidelines of Reg. Guide 1.174 as a measure of their acceptability. In addition, importance measures from these sensitivity studies can provide insight as to which SSCs and which failure modes are most significant.

It is noted that the recommended FV and RAW threshold values used in the screening may be changed by the PRA team following this sensitivity study. If the risk evaluation shows that the changes in CDF and LERF as a result of changes in special treatment requirements are not within the acceptance guidelines of the Regulatory Guide 1.174, then a lower FV threshold value may be needed (e.g., 0.001) for a re-evaluation of SSCs risk ranking. This may result in re-categorize some of the candidate low safety significant SSCs as safety significant SSCs.

The results of an initial sensitivity study should be provided to the IDP as an indication of the potential aggregate risk impacts. These sensitivity studies should be re-visited when the IDP has completed its final categorization to assure that the conclusions regarding the potential aggregate impact have not changed significantly. If the categorization of SSCs is done at different times, the sensitivity study should consider the potential cumulative impact of all SSCs categorized, not individual systems or components.

9 IDP REVIEW AND APPROVAL

The IDP uses the information and insights compiled in the initial categorization process and combines that with other information from design bases, defense-in-depth, and safety margins to finalize the categorization of functions/SSCs.

9.1 Panel Makeup & Training

The IDP is composed of knowledgeable plant personnel whose expertise represents the important process and functional elements of the plant organization, such as operations, design and engineering (e.g., systems, electrical, I&C including information technology, nuclear risk management), industry operating experience, and maintenance. The panel can call upon additional plant personnel or external consultants, as necessary, to assist in the resolution of issues.

The precise makeup of the panel is up to the licensee. Experience, plant knowledge, and availability to attend the majority, if not all meetings, are important elements in the selection of IDP permanent members. In general, there should be at least five experts designated as members of the IDP with joint expertise in the following fields:

- Plant Operations (SRO qualified),
- Design Engineering (including safety analyses),
- Systems Engineering,
- Licensing,
- Probabilistic Risk Assessment.

Members may be experts in more than one field; however, excessive reliance on any one member's judgment should be avoided.

The licensee should establish and document specific requirements for ensuing adequate expertise levels of IDP members, and ensure that expertise levels are maintained. Two key areas of expertise to be emphasized are experience at the specific plant being evaluated and experience with the plant specific PRA analyses relied upon in the categorization process.

The IDP should be aware of the limitations of the plant specific PRA and, where necessary, should receive training on the plant specific PRA, its assumptions, and limitations.

The IDP should be trained in the specific technical aspects and requirements related to the categorization process. Training should address:

- The purpose of the categorization,
- The risk-informed defense-in-depth philosophy and criteria to maintain this philosophy,
- PRA fundamentals,
- Details of the relied upon plant-specific PRA analyses, including the modeling scope and assumptions,
- The role of risk importance measures including the use of sensitivity studies, and
- The assessment of SSC failure modes and effects.

Each of these topics should be covered to the extent necessary to provide the IDP with a level of knowledge sufficient to evaluate and approve SSC categorization using both probabilistic and deterministic information.

IDP decision criteria for categorizing SSCs as safety significant or low safety significant should be documented. A consensus process should be used for decision-making. Differing opinions should be documented and resolved.

The IDP should perform their activities in accordance with a procedure for determining the safety-significance of a SSC, and for the review of safety-significant functions and attributes to ensure consistency in the decision making process. The integrated decision process should, where possible, apply objective decision criteria and minimize subjectivity. The decisions of the IDP, including the basis, should be documented and retained as quality records for the life of the facility.

The IDP should be described in a formal plant procedure that includes:

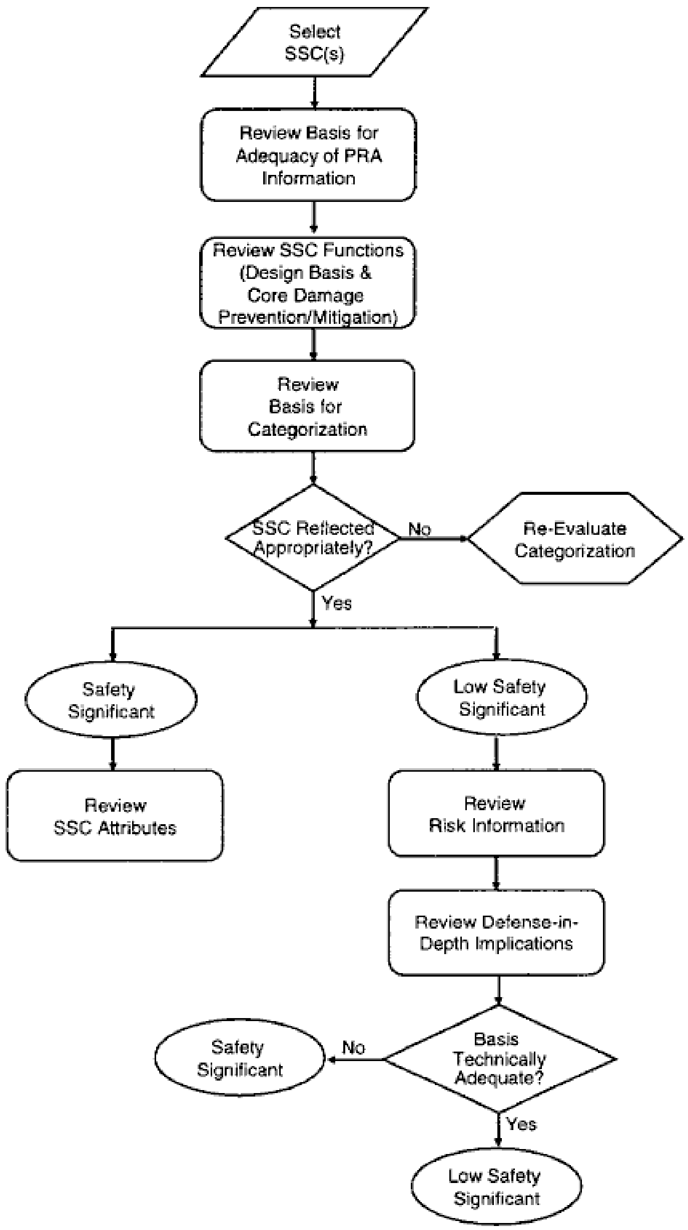
- The designated chairman, panel members, and panel alternates;
- Required training and qualifications for the chairman, members, and alternates;
- Requirements for a quorum, attendance records, agendas, and meeting minutes;
- The decision-making process;
- Documentation and resolution of differing opinions; and
- Implementation of feedback/corrective actions.

9.2 IDP Process

The preliminary categorization information generated as part of the categorization process, including consideration of the role each function in the plant-specific risk analyses and defense-in-depth, is provided to the IDP for review. The overall functional categorization process to be used by IDP is shown in Figure 9-1.

Figure 9-1

IDP PROCESS



The IDP reviews this preliminary categorization of system functions. In some cases, where the functional role of multiple SSCs is similar, those SSCs may be considered at the same time. For example, the suction and discharge isolation valves on a pump, may have similar functional impacts and could be considered together the pumping function of the system.

The initial steps of the IDP involve review of the primary technical bases for the initial categorization: the basis for adequacy of the PRA results, the system function(s) and the basis for their categorization. The appropriateness of the manner in which the SSC has been reflected should be judged based on the scope of functions considered and the manner in which the PRA analyses incorporate those functions. If the IDP determines that the function has not been appropriately reflected, then it is re-evaluated based on the insights from the IDP.

Review of Safety Significant Functions

For those functions/SSCs determined to be appropriately reflected in the categorization, the IDP should evaluate the key aspects of the recommended categorization. For RISC-1 and RISC-2 SSCs, if the IDP has determined that the SSC was appropriately reflected and it was categorized as RISC-1 or RISC-2, then the IDP cannot move that SSC to a less safety significant category. For RISC-1 SSCs, the IDP reviews the SSC attributes identified in the categorization process including the design basis attributes (for RISC-1), any important to safety attributes (for RISC-2) and any additional attributes that were identified as important to the core damage prevention and mitigation functions of the SSC.

SSCs, which have high failure probabilities (usually indicative of screening values) and meet the screening criteria solely on the basis of Fussell-Vesely importance, may have been identified as candidate safety significant.

Review of Low Safety-Significant Functions

The IDP's role for these functions is to perform a risk-informed assessment of the SSC categorization including consideration of the risk information, defense-in-depth and safety margins.

Review of Risk Information

For functions/SSCs that have not been identified as safety significant, the IDP should review the results to determine whether these functions/SSCs are not implicitly depended upon in the PRA. The IDP determines if:

- Failure of the associated SSC(s) will significantly increase the frequency of an initiating event, including those initiating events originally screened out of the PRA based on anticipated low frequency of occurrence.

- Failure of the associated SSC(s) will fail a safety function, including SSCs that are assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems, and instrumentation and control systems).

- The function/SSC is necessary for safety significant operator actions credited in the PRA, including instrumentation and other equipment called for in procedures.

- Failure of the function/SSC will result in failure of safety significant functions/SSCs in a manner that poses a risk impact (e.g., through spatial interactions).

If any of the above conditions are true, the IDP should use an evaluation to determine the impact of relaxing requirements on SSC reliability and performance.

Review Defense-In-Depth Implications

When categorizing a function/SSCs as low safety significant, the IDP should consider whether the defense-in-depth philosophy is maintained. Defense-in-depth is considered adequate if the overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure that no significant increase in risk should occur by the change in special treatment, and that:

- Reasonable balance is preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release (Section 7);

- System redundancy, independence, and diversity is preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters (Section 7);

- There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design; and

- Potential for common cause failures is taken into account in the risk analysis categorization.

If any of the above conditions are not true, the IDP should perform a qualitative evaluation to determine the impact of relaxing requirements on SSC reliability and performance. Low safety significance can still be assigned, if one or more of the following are true:

- Historical data show that these failure modes are unlikely to occur.
- Such failure modes can be detected in a timely fashion.
- Condition monitoring – leading indicators

Functions/SSCs identified as low safety significant in the categorization process, but having potential safety significance if common cause failure is assumed, should be reviewed by the IDP to determine appropriate strategies for reducing the potential for common cause failures and strategies for detection of failures. This could include recommending staggered testing, inspection and/or calibration of equipment.

Review Safety Margin Implications

The treatment of low safety significant SSCs maintains design basis functions. Therefore, the functional performance of these SSCs will be assured and safety margin will be unaffected. The potential reliability impacts of the treatment changes are assessed in the sensitivity study to assure that potential changes in CDF and LERF are not significant. Consequently, no specific assessment of safety margin is required by the IDP. However, the IDP should qualitatively review each function/SSC categorized as low safety significance (LSS) to ensure that no significant impacts on safety margin would be expected.

Review of LSS SSCs

The functions/SSCs initially categorized as LSS that include non-safety-related SSCs found in the categorization process to be of low safety significance. The IDP's role for these functions/SSCs is to ensure that the basis used in the categorization is technically adequate. For SSCs, which are important to safety, the IDP must consider if the risk information used in the categorization process provides an adequate basis for categorizing the SSC as RISC-4. In general, the risk analyses should address the SSC function(s) that caused it to be originally classified as important to safety in order for a RISC-4 categorization to be justified. If the IDP concludes that the categorization of the function/SSC as low safety significant is not justified, then the IDP can re-categorize the SSC to RISC-2. In doing so, however, the attributes of the SSC should be identified to ensure that any core damage prevention and mitigation attributes, that the IDP felt were significant, are included in future treatment.

10 SSC CATEGORIZATION

10.1 Coarse SSC Categorization

When the IDP approves the categorization of system functions, then the initial coarse mapping of components to system function may be used to define the safety significant SSCs. Thus, if a system function is found to be safety significant by the IDP, then all components in the flowpath could be considered safety significant (HSS). In some cases, components may support both safety significant and low safety significant system functions. In these cases, if the SSC is supports for <u>any</u> safety significant system function, then it should be considered safety significant. Likewise, if <u>all</u> system functions supported by the SSC are low safety significant, then the SSC can be considered low safety significant. For some systems, this may be adequate. In other cases, this approach may be found to be too conservative, so a more detailed categorization may be utilized.

10.2 Detailed SSC Categorization

The necessity of addressing each component, or each part of a component is determined by each licensee based on the anticipated benefit. A licensee may determine that it is sufficient only to perform system or subsystem analyses. In such cases, all the components within the boundaries of the subsystem or system would be governed by the same set of safety-significant functions. Each licensee has the option, based on the estimated benefit, of performing additional engineering and system analyses to identify specific component level or piece part functions and importance for the safety-significant SSCs.

There are two options:

1) Assignment of all SSCs in the flow path represented by the function to the RISC classification of that function. While this is a conservative assignment, it may best suit the cost-benefit assessment for Option 2 for a particular system. That is, the effort in going to the next step may not be commensurate with the benefits to be derived.

2) Assignment of SSCs in the flow path represented by the function based on the attributes of the function that the SSC satisfies. This applies primarily to categorizing selected SSCs on high safety significant functions as low safety significant. In this case, the potential failure of an SSC is assessed in light of the safety significant function attributes (e.g., allow flow, prevent flow, prevent fission product releases, etc.). The following criteria can be applied to this process:

   - The criterion for assignment of low safety significance for an SSC in a high safety significant flow path is that its failure would not preclude the fulfillment of the safety significant function. Specific considerations that would permit a low safety significance determination for an SSC in a safety significant functional flow path would include:

- There is no credible active failure mode for the SSC that would prevent a safety significant function from being fulfilled (e.g., a locked open or locked closed valve, a manually controlled valve, etc.),
- An active failure for the SSC would not prevent a safety significant function from being fulfilled (e.g., a vent or drain line not exceeding 1 inch in diameter, SSCs downstream of the first (second?) isolation valve from the active flow path of the function, etc.), and
- Instrumentation that would not prevent a safety significant function from being fulfilled (e.g., radiation monitors that do not have a direct diagnosis function, etc.).

IDP Review of RISC 3 and RISC-4 Components

For SSCs that retain the categorization of the function that they support, only minimal IDP review should be required; there should be no differences from the assessments considered in the initial IDP.

11 CHANGE CONTROL PROCESS

The regulatory change process (10 CFR 50.59) focuses on activities that are directly associated with the 10 CFR 50.2 design bases and that are described in the final safety analysis report.

In a risk-informed regulatory environment, management focus should be on activities and equipment that have safety significance, which may not necessarily comport with the aspects of the facility described in the final safety analyses report. For example, containment venting is not described in the final safety analysis reports for most BWRs, but may be a risk significant activity for some plants. As a result, Section 50.69 includes a risk-informed change control process for SSC categorization and treatment. Section 6 provides additional details on the change control processes for §50.69. It includes guidance for controlling changes to SSCs and activities that impact beyond design bases function.

11.1 Application of 10 CFR 50.59

10 CFR 50.59 continues to be applied to facility changes as specified in the rule. The first step is to screen the change to determine if the design function is adversely affected.

<u>Change Process For Safety-Significant Beyond Design Bases Functions</u>

The §50.59 process screening criteria focuses its change control activities on matters that could affect a design function as described in the USFAR. The §50.59 change control process does not fully evaluate changes that effect safety-significant beyond design bases functions. As a result, a licensee that adopts §50.69 should amend its configuration control process to include an additional provision that provides reasonable assurance that the safety-significant beyond design bases function(s) identified in the §50.69 categorization process will be satisfied following a facility change. This additional control provision is not part of the §50.59 process.

The design control (change) element in the configuration control program is not changed and continues to ensure that the design is controlled and maintained. The additional change control provision determination should be based on evaluations (quantitative or qualitative), or on a combined quantitative and qualitative evaluation of the change and how it impacts the beyond design bases function(s) identified in the §50.69 process. The information contained in the modification package, the risk-informed categorization process, and the design record file, provide the basis for the evaluation. Each proposed change package should be supported by engineering information, that may include but is not limited to, drawings, specifications, narrative description, design evaluations, installation and testing requirements, associated procedure changes (if any), revised analyses (if any) and similar information. This information demonstrates the safety and effectiveness of the change and is the mechanism for management approval of the implementation.

For changes that are associated with a safety-significant beyond design basis function(s), the following process is used:

- Perform an engineering evaluation to determine whether there is reasonable assurance that the safety-significant beyond design basis function will be satisfied following the change.
- If a determination is made that the beyond design bases function would be satisfied, the licensee implements the change, and updates the licensee documentation and, as necessary, licensing documentation such as the UFSAR in accordance with NRC requirements.
- If a determination is made that the beyond design basis function would not be satisfied following the change, the licensee has two options:

  (i) Amend the proposed change so that the beyond design basis function would be satisfied, or
  (ii) Evaluate the impact on the §50.69 SSC categorization and the plant specific PRA based on not satisfying the beyond design bases function. Reg. Guide 1.174 provides additional guidance on what may be an acceptable impact on the plant specific PRA and risk to the public.

If the proposed change would result in a change of RISC categorization, the NRC is notified of the change at the same time as a summary of the other §50.59 changes are provided to the NRC.

Design record files and the PRA are updated to reflect the implemented change. Changes to the UFSAR would be made in accordance with §50.71(e) and NEI 98-03, Rev. 1, Guidelines for Updating Final Safety Analysis Reports.

11.2 Changes to Commitments

Changes to NRC commitments associated with any RISC SSC category should be controlled through NEI 99-04, Rev 1 *(Under Review)*, Guidelines for Managing NRC Commitment Changes, which has been revised to reflect the impact of §50.69.

Changes To SSC Categorization Process

The risk-informed §50.69 SSC categorization process should be documented in a licensee controlled document. In a licensee's §50.69 NRC submittal, a commitment is made to update the PRA based on the ASME PRA Standard.

Changes to the categorization process should be controlled through the application of the NRC commitment management process, as described in the NRC endorsed NEI 99-04, Rev 1, Guidelines for Managing NRC Commitment Changes.

Changes in the PRA that result in changes in SSC categorization should be reported to the NRC at intervals consistent with the UFSAR updates.

11.3 Changes To The Plant Specific PRA

The plant specific PRA should be maintained and updated to assure that it reasonably reflects the as-built, as-operated plant is sufficient to support applications for which it being used.

A licensee's configuration control program should monitor changes in the design, operations, maintenance and industry-wide operating experience that could affect the plant and the PRA. The program should include monitoring of changes in PRA technology and industry experience that could change the results of the PRA model.

Changes to the plant specific PRA should be reviewed to determine if there is a potential for changing the §50.69 SSC categorization results. (See Reg. Guide 1.174)

11.4 Changes In SSC Categorization

The advancement of technology and the introduction of new information when combined with additional operational experience could impact SSC categorization. This facet is not new. Today, as new information becomes available, licensees may need to adjust safety-related SSC categorizations. Such SSC categorization changes are controlled through the 10 CFR 50.59 process. Similarly, if new information or insights from a PRA update indicate that a SSC is incorrectly categorized, the licensee would take similar actions as it does today.

The extent and scope of any SSC recategorization activities following the implementation of §50.69 may vary dependent upon the specific circumstances, licensing controls and original (safety-related/nonsafety-related) SSC categorization. Recategorization activities should be more demanding for SSCs that are being recategorized from RISC-3/4 SSCs to RISC-1/2 SSCs.

<u>Recategorization of a RISC3 SSC to RISC-1 SSC, or RISC-4 SSC to RISC-2</u>

Advances in technology now enable risk assessments to be performed more efficiently and effectively. These technology improvements provide the industry with a more effective and efficient capability to assess risk and the safety significance of equipment following changes to plant configurations.

Plant modifications, new technical information becomes available, and operating experience increases, introduce the potential for changing the plant specific PRA and the §50.69 SSC categorization results. For the plant specific PRA to be used as a valid assessment tool for regulatory activities, the PRA should be updated at periodic intervals, which could result in changes to SSC categorization.

Changes in CDF, LERF and SSC importance measures provide an indication on whether further evaluations are necessary to determine if there should be a change in SSC categorization. If further evaluations are necessary, the next step is to determine whether a safety-significant function or a design bases function is affected to the extent that the function would not be satisfied. If there is reasonable assurance that a safety-significant or design bases function can still be satisfied, no immediate action is necessary.

Changes in SSC categorization are not new or limited to plants that have performed §50.69 categorizations. Such changes occur in the deterministic regulatory regime, where licensees change SSC categorization and resolve operability and functional issues in a controlled manner using accepted licensing and work practices and procedures. The same processes that are used in the deterministic regulatory regime should be applied to control and manage changes in the §50.69 SSC categorizations, once an evaluation has confirmed that a RISC-3/4 SSC should be recategorized. The processes involved in these evaluations should include: in-situ dedication, additional engineering analyses and operability determinations. A licensee should follow established licensee procedures if a determination is made that a safety-significant function or design bases function would not be satisfied.

Recategorization of a RISC-1 SSC to RISC-3, or RISC-2 SSC to RISC-4

If new information suggests that a RISC-1 or RISC-2 SSC could be recategorized as a RISC-3/4 SSC, the licensee would follow the same process as described in this guideline for categorizing SSCs. If the §50.69 categorization has been completed for all scheduled SSCs a licensee has the option of using the multi-disciplined station management review committees in place of the IDP to make the final determination on changes in SSC categorization.

12 DOCUMENTATION AND APPROVAL

12.1 Documentation

The documentation on the §50.69 categorization process and the SSCs that have been subject to the categorization process should be stored in a readily retrievable form for use by the licensee and review by the NRC. For SSCs that are included in the new §50.69 categorization scheme by default, i.e., categorized as RISC-1 or RISC-4 SSCs, only a generic reference to the existing SSC categorization needs to be retained.

Documentation relating to the categorization process, including the assumptions and results, should be retained for at least five years after completion of the categorization process, or until the plant specific PRA and, if necessary, the SSC categorization is updated. The documentation should include:

- The plant specific PRA, including the assumptions;
- The comparison and assessment of the plant specific PRA against the PRA quality expectations for this type of application;
- Procedures and guidelines for categorizing the SSCs, including the SSC categorization decision criteria used by licensee staff or contractors in the categorization process;
- References to sources of information and data;
- Integrated Decision-making Panel meeting summaries;
- The results of the SSC categorization and the sensitivity analyses;
- Update of the design record files to documents specific SSC categorization attributes;
- A summary or reference to functional and performance monitoring programs required by §50.69;
- Descriptions and justifications of deviations from this guidance.

These records should be maintained consistent with the licensee's configuration control and documentation management practices. The licensee's design change process should be revised to reflect the availability of new information that should be reviewed as part of change process.

12.2 NRC Review and Approval

A licensee wishing to adopt §50.69 will make a submittal to the Commission requesting approval to implement §50.69 on a specific set of SSCs, as defined by the licensee. The submittal should define the set of regulations that are being adopted. However, it is expected that most licensees will choose to adopt all the regulations in §50.69 (d)(2) that are applicable to RISC-3 SSCs, yet only implement the specific elements on an as needed basis as equipment is changed, maintained and tested. Appendix B provides a submittal outline.

The licensee would notify the NRC of changes in the scope of SSCs or regulations that are being applied to §50.69. Changes in schedule need not be reported to the NRC.

12.3 FSAR Update

A Licensee that adopts §50.69 should update its UFSAR as follows:

- On receipt of NRC approval to proceed with implementing §50.69, the licensee should amend its quality program description included or referenced in the FSAR to include a summary of licensee's industrial program fro low safety-significant SSCs.
- On completion of categorizing the first set of SSCs or system, and on completion of subsequent systems.

These updates should be performed in accordance with NEI 98-03, Guidelines for Updating Final Safety Analysis Reports. The updates would be submitted as part of the regular UFSAR submittal as required by §50.71(e).

13 PERIODIC REVIEW

There are two separate and distinct periodic review elements associated with implementing §50.69: (a) impact from planned SSC categorizations, and (b) periodic reviews following the completion of the §50.69 categorizations.

In case (a), a planned and phased implementation of SSC categorization over several years could result in later SSC categorization activities impacting earlier SSC categorization schemes. As a penultimate step in developing the IDP recommendations on the SSC categorization, a review of the impact of the current categorization activity on previous categorizations should be performed. A determination needs to be made whether the importance measures in the previous categorizations have been changed as a result of these later categorization activities.

The assessment of the impact of later SSC categorizations on the PRA results and earlier categorizations is based on the absolute importance and the new safety-significance determination that are derived from revised SSC importance measure. The absolute importance is the product of the base CDF/LERF and the importance measure (RAW-1/Fussell-Vesely). Categorization reassessments of SSCs that have been previously categorized should be based on the following table:

Table 14-1
IMPACT OF LATER CATEGORIZATION ACTIVITIES

Existing Categorization	New CDF/LERF	New Significance Based on Importance	New Absolute Importance	New Categorization
Low	Higher	Safety-Significant	Higher	Safety-Significant
Low	Reduced/Same	Safety-Significant	Higher	Safety-Significant
Safety-Significant	Reduced/Same	Low	Lower	Low
Safety-Significant	Higher	Low	Lower	Low

In case (b), the periodic review of changes that could impact the SSC categorization following the completion of the 10 CFR 50.69 categorization activities, an evaluation is performed on the SSC categorization impact from changes in equipment performance or the introduction of new technical information. Plant changes that would impact the categorization of SSCs should be prioritized to ensure that the most significant changes are incorporated as soon as practical.

The first step is to determine whether an immediate evaluation is necessary based on the new information. An immediate evaluation and review should be performed if the new information is associated with a RISC-3 or RISC-4 SSC and would have prevented, or did prevent a safety-significant function from being satisfied. If the new information or deficiency would not have inhibited a safety-significant function, then the evaluation should be performed in a time frame that permits input into the licensee's general PRA update activities.

Following revisions or updates to the PRA a review of the SSC categorization should be performed. Such reviews should include:

- A review of the PRA
- A review of plant modifications since the last review
- A review of plant specific operating experience that could impact the SSC categorization,
- A senior management review of the results
- A review of the importance measures used for screening in the categorization process[2].

Additional guidance on PRA updates is provided in Section 5 of the ASME PRA Standard.

[2] If a review of the importance measures indicate that the SSC should be reclassified then both the relative and absolute values of the risk metrics should be considered by the IDP

14 REFERENCES

1. 10 CFR50.69, *Scope of Structures, Systems and Components, Governed by Special Treatment Requirements*
2. EPRI TR-105396, *PSA Applications Guide,*
3. Regulatory Guide 1.174, *An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis,*
4. NRC SECY 99-256, *Rulemaking Plan For Risk-Informing Special Treatment Requirements,*
5. NUMARC 93-01, Rev. 2 *Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*
6. NUMARC 91-06, *Guidelines for Industry Actions to Assess Shutdown Management*
7. NRC Regulatory Guides 1.175, 1.176, 1.177 and 1.178,
8. NRC Reg Guide on PRA Adequacy – Under development
9. Nuclear Energy Institute, "NEI 00-02, Revision 3, *Probabilistic Risk Assessment (PRA) Peer Review Process Guidance,*".
10. NEI 96-07, *Guidelines for 10 CFR 50.59 Safety Evaluations*
11. NEI 97-04, Revision 1, *Design Bases Program Guidelines*
12. NEI 98-03, *Guidelines for Updating Final Safety Analysis Reports*
13. NEI 99-04, *Rev. 1, Guidelines for Managing NRC Commitment Changes*
14. *NEI 00-02, Probabilistic Risk Assessment Peer Review Process Guideline*
15. *NRC letter to NEI dated April 2, 2002, NRC Staff Review Guidance for PRA Results used to support Option 2 Based on NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline, " supported by NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guideline."*
16. ASME Code Case, N658, *Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities*
17. ASME RA-s-2002, *Standard for Probabilistic Risk Assessments for Nuclear Power Plant Applications*

APPENDIX A

GLOSSARY OF SELECTED TERMS

Beyond design bases functions are those functional requirements that have been identified by a risk-informed evaluation process as being safety-significant yet are not encompassed by the original licensing basis for the facility

Common cause failure (CCF) - See ASME PRA Standard

Core damage - See ASME PRA Standard

Core damage frequency (CDF) - See ASME PRA Standard

Defense-in-depth is the application of deterministic design and operational features that compensate for events that have a high degree of uncertainty with significant consequences to public health and safety.

Design bases - See 10 CFR 50.2

Design functions – See NEI 96-07

Design bases functions - See NEI 97-04

Dependency - See ASME PRA Standard

Diverse – replication of an activity or structural, system, train or component requirement using a different design or method.

Evaluation is defined as an analysis (traditional or computer calculations), a review of test data, a qualitative engineering evaluation, or a review of operational experience, or any combination of these elements. (Industry UFSAR s)

Fussell-Vesely (FV) importance measure - See ASME PRA Standard

Large early release - See ASME PRA Standard

Large early release frequency (LERF) - See ASME PRA Standard

Probabilistic risk assessment (PRA) - See ASME PRA Standard

Redundant – duplication of a structure, system, train, or component to provide an alternative functional ability in the event of a failure of the original structure, system, train or component

Risk - See NUMARC 93-01, Rev 2

Risk achievement worth (RAW) importance measure - See ASME PRA Standard

Safety-related structures, systems and components - See 10 CFR 50.2

Safety-Significant structures, systems and components are those structures, systems and components that are significant contributors to safety as identified through a blended risk-informed process that combines PRA insights, operating experience and new technical information using expert panel evaluations.

Severe accident - an accident that usually involves extensive core damage and fission product release into the reactor vessel, containment, or the environment.

Train - See NUMARC 93-01, Rev 2

APPENDIX B

SUBMITTAL OUTLINE/EXAMPLE

OPTION 2
PROGRAM SUBMITTAL

Owner/Licensee Name

Subject Plant
Unit

NRC Docket Number

NOTE: *Items shown in italics reflect plant-specific information that needs to be provided in an actual Option 2 submittal.*

Option 2 Implementation Plan
Subject Plant
Unit

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INTRODUCTION

The objective of this submittal is to request adjustment to the scope of equipment subject to NRC special regulatory treatment (controls) per the regulatory process prescribed in 10 CFR 50.69, "Scope of Structures, Systems and Components, Governed by Special Treatment Requirements." The assessment and safety categorization of the structures, systems and components referenced in this submittal will be performed in accordance with NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline" and with Reg. Guide 1.XXX. *Licensee's name and unit number,* takes exception to NEI 00-04 and Reg. Guide1.XXX in the following areas:

- *Licensee lists the exceptions*

The technical basis for these exceptions and the basis for the alternative approach are provided in the Appendix to this submittal.

Background

The intent of the 10 CFR 50.69 regulatory initiative is to adjust the scope of equipment subject to special regulatory treatment (controls) to better focus licensee and NRC attention and resources on equipment that has safety significance. NEI 00-04 uses an integrated decision making process to define the scope of equipment that should be subject to NRC special treatment provisions.

The process identifies and categorizes the set of equipment that is safety-significant by blending risk insights, new technical information and operational feedback. A central task in the implementation of the §50.69 initiative is the use of groups of experienced licensee-designated professionals to make equipment categorization determinations. Treatment is then applied As prescribed in §50.69 consistent with the revised equipment safety categorizations.

SSC SCOPE & APPROACH

Scope of SSCs selected for §50.69 safety categorization assessment

The following systems are the scope of applicability for the implementation of §50.69 at *subject plant, unit,* under this submittal.

- *List the selected systems that are the subject of this approval request and that are being subject to the revised categorization process*

Schedule for Implementation

Provide schedule for implementing SSC categorization

The Director of NRR will be informed of changes to the SSC scope of applicability for §50.69 prior to implementing §50.69 on these systems, or in major changes in the schedule for implementation that result in an extension to the categorization activities, for the systems referenced above, in excess of 12 months.

Approach

The SSCs from the above systems will be placed in four categories as defined by 10 CFR 50.69 using the NRC endorsed NEI 00-04, except as described in the Appendix.

The categorization process uses an integrated decision-making process to determine SSC categorization by blending plant specific risk insights; operational feedback and experience (industrywide and plant specific); and new technical information.

Sensitivity studies will be performed in accordance with NEI 00-04, and the results assessed against the criteria defined in Regulatory Guide 1.174, *An Approach for Using Probabilistic Risk Assessment In Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis.* The impact of changes to SSC categorization and controls will be monitored through periodic PRA updates, as determined by industry consensus standards.

Consistent with Reg. Guide 1.XXX, this submittal, as a risk-informed application, meets the intent and principles of Regulatory Guide 1.174 as described below:

- <u>The Proposed Change Meets the Regulations</u> – The changes in special treatment are made under 10CFR50.69.

- <u>The Proposed Change Is Consistent With The Defense-In-Depth Philosophy</u> – The recategorization and treatment process provides reasonable assurance that safety functions are maintained. Therefore, defense-in-depth will not be impacted. As part of the categorization process, a review is performed which assesses the role the SSC plays in ensuring defense-in-depth.

- <u>The Proposed Change Maintains Sufficient Safety Margins</u> -- The recategorization and treatment process provides reasonable assurance that safety-significant functions are maintained. In addition, there will be reasonable confidence that the design bases will be maintained. Therefore, safety margins will not be impacted.

- <u>Any Increases in Core Damage Frequency or Risk Should Be Small and Consistent With the Intent of the Commission's Safety Goal Policy Statement</u> – They are-categorization and treatment process provides reasonable assurance that safety functions are maintained. Risk sensitivity studies will be used to demonstrate that no significant change in CDF and LERF.

- The Impact Of The Proposed Change Should Be Monitored Using Performance Measurement Strategies – Performance monitoring strategies will be employed as part of the treatment process.

Integrated Decision-Making Panel (IDP)

A licensee-designated integrated decision-making panel will make the determination on SSC categorization. The IDP will be responsible for oversight of the categorization process, review and approval of SSC categorization, and procedure and working practice development.

Procedures will be developed and approved in accordance with *plant name* procedures to control and document IDP activities and assure consistency in the decision-making process. The IDP panel members are:

- *List panel members, titles, and brief summary of plant/experience*
- *List of procedures*

Application of NRC Special Treatment Requirements

The revised SSC scope will be applied to the following special treatment requirements

- *List the selected NRC special treatment requirements or just reference §50.69.*

Change Control Provisions

The existing regulatory change control provisions prescribed in 10 CFR 50.59, "Changes, Tests and Experiments;" 10 CFR 50.54, "License Conditions;" 10 CFR 50.69; and as amplified in NEI 00-04 will be used to control changes to plant configuration, SSC categorization, and treatment requirements. These measures include a change control process for changes that could impact a beyond design basis function, as described in NEI 00-04. Changes to the PRA will be controlled through the application of NEI 99-04, Revision 1, "Guidelines for Managing NRC Commitment Changes."

CATEGORIZATION BASIS

The Subject Plant has performed a PRA that estimates core damage frequency and large early release frequency due to internally initiated events and internal flooding. Other important risk contributors, such as seismic risk, fire risk, other external event risks (high winds, tornadoes, etc.) during power operation, and risk during outage conditions have also been analyzed using methods that involve use of a PRA to quantify these risk impacts, or may involve simplified analyses or qualitative methods, or a combination of these methods.

The Subject Plant PRA is capable of quantifying core damage frequency (CDF) and large early release frequency (LERF) for power operations due to internal events and reflects the as-built and as-operated plant.

Plant-Specific Risk Information

The existing CDF and LERF values at the time of preparing this submittal are:

CDF – *Plant specific information*
LERF *Plant specific information*

Other plant specific PRA information should be described, such as:

- *The specific risk analyses to be utilized;*
- *The bases for determining that the analyses are both applicable and useful in categorization*

Characterization of PRA Quality

PRA input into the categorization process includes internal events PRA analyses and risk assessments encompassing external and shutdown events. The *Subject Plant's* PRA meets accepted attributes and characteristics as defined in Reg. Guide 1.XXX and has been subject to the Industry Peer Review Process for PRAs as described in NEI 00-02, "Probabilistic Risk Assessment (PRA) Peer Review Process Guidance".

The Subject Plant to provide the following information on the Internal Events PRA:

- *A basis for why the internal events PRA reflects the as-built, as-operated plant.*
- *A high level summary of the results of the PRA peer review of the internal events PRA, including elements that received grades lower than 3.*
- *The disposition of any peer review fact and observations (F&Os) classified as A or B importance.*
- *Provision of information identified in the NRC review of NEI 00-02, NRC letter to NEI dated April 2, 2002,* NRC Staff Review Guidance for PRA Results used to Support Option 2 Based upon NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," Supported by NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guideline."

The Subject Plant *provides the following additional information on other PRA Analyses, [If applicable]*

- *A basis for why the other licensee specific PRA analyses (e.g., external events and shutdown) adequately reflect the as-built, as-operated plant.*
- *A disposition of the impact of the significant peer review findings on the other PRA analyses.*
- *Identification of and basis for any sensitivity analyses necessary to address issues identified in the other PRAs.*

DOCUMENTATION UPDATE

The documentation on the § 50.69 categorization process and the list of SSCs that have been subject to the categorization process will be stored in a readily retrievable form for use by the *Subject Plant* and review by the NRC.

Documentation relating to the categorization process, including the assumptions and results, will be retained for at least five years after completion of the categorization process, or until the plant specific PRA and, if necessary, the SSC categorization is updated. These records will be maintained consistent with the *Subject Plant's* configuration control and document management procedure(s) XXXX. *The Subject* Plant's design change process will be revised to reflect the availability of new information that will be reviewed as part of change process.

REFERENCES

1. Reg. Guide 1.XXX, "Guidance for Categorizing Structures, Systems and Components under 10 CFR 50.69."
2. 10 CFR 50.69, "Scope of Structures, Systems and Components, Governed by Special Treatment Requirements"
3. ASME Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications
4. ASME Code Case N-658, *Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities*
5. NRC Regulatory Guide X.XXX PRA Technical Adequacy
6. Regulatory Guide 1.174, *An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis,*
7. NRC SECY 99-256, Rulemaking Plan For Risk-Informing Special Treatment Requirements,
8. NEI 00-04, Revision 0, "10 CFR 50.69 SSC Categorization Guideline."

9. NEI 99-04, Revision 1, "Guidelines for Managing NRC Commitment Changes."
10. Regulatory Guide 1.174, "An Approach for using Probabilistic Risk Assessment in Risk-Informed Decisions On Plant-Specific Changes to the Licensing Basis."
11. NEI 00-02, "Probabilistic Risk Assessment (PRA) Peer Review Process Guidance."
12. *NRC letter to NEI dated April 2, 2002,* NRC Staff Review Guidance for PRA Results used to Support Option 2 Based upon NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," Supported by NEI 00-02, "Probabilistic Risk Assessment Peer Review Process Guideline."
13. EPRI TR-105396, PSA Applications Guide,
14. NUMARC 93-01, Rev. 2 Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants
15. NUMARC 91-06, Guidelines for Industry Actions to Assess Shutdown Management

Appendix to *Licensee's Name and Plant* 10 CFR 50.69 Submittal

Basis and Alternative SSC Categorization Methodology for Exceptions to NEI 00-04 Categorization Process for 10 CFR 50.69

Enclosure 2

Summary of Changes Made to NEI 00-04, Rev B

1. Removed treatment sections

2. Updated Introduction and Background

3. Incorporated system function categorization process and added flowchart developed based on pilots.

4. Updated the change control process.

5. Modified description of PRA quality to address ASME PRA Standard and NRC Option 2 PRA Review Guidance

6. Changed guideline so that SSCs that do not have a role in CDF/LERF are considered low safety significant.

7. Added qualitative treatment of late containment failure as an input to IDP.

8. Added discussion of approach to treating changes in PRA model that potentially changes categorization

9. Added discussion on treatment of implicitly modeled SSCs. This is a major benefit of the revised approach that relies upon system functions as the initial basis for categorization.

10. Modified Figure 2.4-4 to clarify safety significance categorization and address NRC comment

11. Deleted references to monitoring as part of categorization

12. Added discussion of treatment of fire barriers and fire suppression systems to address NRC comment

13. Added guidance to document cases where IDP reviewed preliminary categorization and decided to re-categorize the SSC

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: David C. Fischer, Senior Mechanical Engineer ***/RA/***
Mechanical & Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW — RISK-INFORMED PART 50, OPTION 2

The purpose of this memorandum is to express my concern over a proposed rule aimed at risk-informing 10 CFR Part 50 (RIP-50) which is about to be issued for public comment. Since the mid-1980s, I have been actively involved with bringing risk insights into the regulatory process (e.g., risk-informing technical specifications, risk-informing inservice test requirements). I am a strong supporter of increased use of probabilistic risk assessments (PRAs) for regulatory activities in a manner that supports the Agency's Performance Goals. Since June 1999, I have been working on the RIP-50 Option 2 rule with the RIP-50 Option 2 Core Team. I was also actively involved with reviewing the related South Texas Project requests for exemptions from certain special treatment regulations and was a principal contributor to our safety evaluation which served as the basis for granting some of those exemptions. I take writing this memorandum to you very seriously and I do so only because I believe that the proposed rule, if ultimately issued in its current form and implemented, would not provide adequate protection of public health and safety.

Summary of Management's Current Approach for Option 2 Rulemaking

The current approach for risk-informing 10 CFR Part 50 relies on a "robust categorization process" to identify which safety-related components can be exempted from special treatment requirements (e.g., quality assurance, maintenance rule, inservice inspection, inservice testing, reporting). These components would, however, remain in the plant and would still be required to function under design-basis conditions.

The proposed rule identifies minimum high-level requirements for both the categorization and treatment processes. The staff has developed regulatory guidance related to the categorization process for Option 2. Licensees that choose to adopt 10 CFR 50.69 would be required to submit their categorization process to the NRC staff for review and approval prior to implementation. The proposed rule, as currently constructed, uses very high level treatment objectives to provide regulatory confidence that the safety-related components categorized as having low safety significance (RISC-3 components) will remain functional. The staff does not plan to develop regulatory guidance related to the treatment of RISC-3 SSCs. The licensee's treatment process will not be reviewed and approved by the staff prior to implementation. The proposed rule requires no information relative to the treatment of the RISC-3 SSCs.

The proposed rule relies on evaluations, such as sensitivity studies, to show that any potential change in core damage frequency (CDF) and large early release frequency (LERF) is small (i.e., potential change in risk that might result from any decrease in SSC capability/reliability as a result of reduced treatment being applied to RISC-3 SSCs). The proposed rule also requires that licensees provide the basis for the acceptability for these evaluations. For example, increasing the unreliability of all RISC-3 SSCs by a factor of 2 to 5 could, as stated in NEI-00-04, provide an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of all low safety-significant SSCs. The factor of 2 to 5 is assumed to be appropriate because it is representative of the change in reliability between a mean value and an upper bound (95^{th} percentile) for typical equipment reliability distributions.

The following is the proposed general high-level treatment objective to ensure the functionality of RISC-3 SSCs (there are other high-level requirements related to design control; procurement; inspection, maintenance, testing, and surveillance; and corrective action).

> "The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life."

Management asserts that the rule should only specify <u>what</u> the NRC's expectations are related to RISC-3 SSCs as opposed to specifying <u>how</u> those expectations are to be satisfied. Management's position is that, as a matter of policy, such high-level treatment requirements provide the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements is consistent with Commission expectations. Furthermore, management states that these high-level treatment requirements, if effectively implemented by licensees, will provide reasonable confidence in the functionality of the RISC-3 SSCs.

At South Texas Project, the proof-of-concept plant for the Option 2 rulemaking effort, approximately 75% of the safety-related pumps and valves were categorized as having low safety significance (analogous to RISC-3 SSCs under Option 2). Examples of equipment categorized as LSS at South Texas Project include:

- diesel generator air start valves;
- main steam isolation valves;
- all feedwater system valves (including flow control and isolation valves);
- spent fuel pool pumps and valves;
- most RHR system valves;
- all (but one) valve in the service water system;
- reactor head vent throttle and isolation valves;
- most chemical, volume, and control system valves;
- HPSI and LPSI flowpath motor-operated valves (MOVs);
- all component cooling water MOVs;
- containment spray pumps and valves;
- most containment isolation valves (including 9 ISLOCA valves)
- centrifugal charging pumps

As you can see, RISC-3 SSCs are not limited to vents and drains and other unimportant components as some often characterize them. Many are important components that need to function reliably in order to run the plant safely or mitigate the consequences of accidents.[1]

Differing View/Opinion

For the following reasons, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

- The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.
- The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.
- The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.

<u>The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.</u>

The categorization process uses long-term average unavailabilities and failure probabilities that are based on steady state assumptions. Other than common cause failures among selected basic events, dependencies among basic events, such as might be introduced by changes to the treatment applied to these SSCs, are generally not modeled. As a result, the importance of certain components or groups of components may not be appropriately categorized. In addition, the treatment portion of the proposed rule is so generally worded and subject to mis-interpretation that licensees could easily establish treatment processes that are ineffective at ensuring that RISC-3 SSCs would be capable of reliably performing their design-basis functions. As a result, licensees that implemented treatment programs, that they believe comply with the proposed rule, could fail to detect degradation that could result in multiple component failures during a single design-basis event.

The proposed rule no longer requires licensees to “characterize the effects of the treatment to be applied to RISC-3 SSCs on SSC capability and performance characteristics under design basis and severe accident conditions.” As such, neither the licensee nor the NRC will be able to make a quantitative assessment of the change in risk associated with the proposed treatment changes. Rather, the proposed rule relies on evaluations (e.g., sensitivity studies) performed by the licensee that assume a certain change in SSC reliability to obtain a sense of what the potential change in risk might be. There is no requirement that the evaluations produce a bounding assessment of the potential change in risk associated with the change in treatment that will be applied to RISC-3 SSCs. While the rule does require “a description of, and basis for acceptability of the evaluations,” there is no standard and very little guidance on what would constitute an acceptable basis (particularly in the areas of fire, seismic, high winds, and other external events). Changes to treatment practices (such as not performing maintenance on a vendor-recommended schedule) could have a significant impact on SSC reliability such that the evaluations (e.g., sensitivity studies) would not be valid. There is no technical basis for assuming that the factor of 2 to 5 will bound the potential change in reliability or failure rates associated with changes to the treatment of RISC-3 components. There needs to be a process that either ensures that what we are allowing by 50.69 is safe (e.g., by doing either a best estimate or bounding sensitivity studies) or the process should monitor SSC capability/reliability sufficiently to ensure that the unavailabilities are adequately maintained (i.e., ensure that unavailabilities and reliabilities do not exceed the values assumed in the sensitivity studies). In other words, a sensitivity study where the unreliability of all RISC-3 SSCs are increased by a factor of 2 to 5 is only valid if 1) there is data to support the assertion that reduced treatment will not have a significant affect on availability and reliability of these components, or 2) measures are taken to ensure that the failure rate distributions of these SSCs do not shift unexpectedly as a result of the reduced treatment (i.e., by monitoring and corrective action).[2]

Total elimination of regulatory special treatment requirements and reliance on high-level treatment objectives and the licensee's commercial practices would likely result in significant degradation to safety-related equipment that is not directly involved with power production (e.g., standby safety systems) as a result of reduced maintenance, QA, testing, and inspection. Even if the licensee initially established effective maintenance, QA, inspection, testing and surveillance processes for the treatment of these components, economic pressures at some utilities could ultimately result in marginally acceptable or ineffective programs. This degradation would also likely go undetected as a result of being exempt from maintenance rule monitoring, Appendix B, inservice inspection, inservice testing, and regulatory oversight. The potentially widespread degradation of these safety-related components might only manifest itself during a design-basis event. This would be an unacceptable situation (and one which has not been explicitly evaluated by the staff in terms of changes to CDF and LERF).[3]

The proposed rule also no longer requires timely monitoring and adjustment of the categorization or treatment processes to ensure that sensitivity study assumptions remain valid (e.g., provide prompt adjustment of the treatment being applied to the RISC-3 SSC if the monitoring and corrective action programs suggest that the reduced treatment is having an adverse effect of SSC functionality) and thereby ensure acceptable levels of safety are maintained. The proposed rule also no longer requires that significant conditions adverse to quality be evaluated for their applicability to other components (as such, common-cause failures could go uncorrected).

Requiring the use of the ASME risk-informed Code Cases (or an equivalently effective approach developed by the licensee) could be used to provide reasonable confidence that any substantive shift in RISC-3 SSC capability/reliability would be detected and corrected in a timely manner. This approach was presented to the Risk-Informed Licensing Panel (RILP) and Executive Team (ET), but was rejected because it was viewed as a "how" as opposed to a "what."

<u>The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.</u>

In 2001 and in direct support of the 10 CFR 50.69 rulemaking effort, the Division of Engineering contracted the Idaho National Engineering and Environmental Laboratory to compare the special treatment requirements applied to safety-related components at nuclear power plants to commercial practices applied to non-nuclear components. That study concluded, in part, that commercial practices varied widely and that commercial standards by themselves are not adequate to provide reasonable confidence of functionality. Measures such as using a combination of detailed engineering specifications, plant processes and procedures, and multilevel QA programs that provide for less rigor than required for the full 10 CFR 50, Appendix B, but augmented commercial requirements might be one way to establish reasonable confidence of functionality. The study also concluded that plant processes will have a significant effect on providing reasonable confidence of component functionality, and that the adequacy of the commercial standards and reduced plant processes would have to be evaluated on a plant-by-plant basis. Thus, the construct and content of the proposed rule are not consistent with the conclusions of this study.

Based on the South Texas Project exemption request review (RIP-50 Option 2, proof-of-concept review) such high-level objectives were proven to be ineffective in conveying the staff's expectations relative to the treatment of these SSCs. During the South Texas Project exemption review, the staff and the licensee had extensive discussions and negotiations on each treatment process. For example, with high-level objectives as are currently included in the proposed rule, the licensee stated that bumping a pump or exercising a motor-operated valve would provide them with confidence that the pump or valve would be capable of performing their safety-related functions under design-basis conditions.[4] These approaches were found by the staff to be inadequate in providing reasonable confidence of the components' ability to function under design-basis conditions. The high-level objectives were adjusted based on these discussions and are reflected in the licensee's FSAR (Section 13.7.3) which are subject to specific regulatory controls. Language was included in the STP FSAR to preclude ineffective implementation of their high-level treatment objectives.

The Division of Engineering used the INEEL report (NUREG/CR-6752) and the lessons learned from the South Texas Project exemption request review to identify a minimal set of treatment requirements to be included in the 10 CFR 50.69 rule. Over about a two year period, NRR management (via direction from various management teams and partially in response to stakeholder input on draft versions of the rule) whittled away at this minimal set of treatment requirements (e.g., by voting on alternatives with varying level of detail, by using boundary conditions to define the appropriate content of the rule, by deciding that the proposed rule should only contain high-level treatment requirements that specify <u>what</u> the NRC's expectations are related to RISC-3 SSCs as opposed to specifying <u>how</u> those expectations are to be satisfied, by arguing that the proposed rule is a categorization rule). The process used to develop the proposed rule did not focus on safety and certainly was not efficient and effective. Nevertheless, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC external website version). Then, during the concurrence process, senior management made significant technical and policy adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Alternative Treatment Requirements* portion of the proposed rule for RISC-3 SSCs is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is <u>not</u> in the proposed rule.]

(2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life. **These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process.** The processes must also meet the following requirements, as applicable:

(i) *Design Control*. Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled**, including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes**. RISC-3 SSCs must **have a documented basis to demonstrate that they are** <u>be</u> capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation, and submergence) and effects (i.e.,aging and synergisms); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions). **Replacements for ASME Class 2 and Class 3 SSCs or parts must meet either: (1) the requirements of the ASME *Boiler & Pressure Vessel (BPV) Code*; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced.**

(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements. **Upon receipt, the licensee shall verify that the item received is the item that was ordered.**

(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design-basis conditions until the next scheduled activity.

(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design-basis conditions must be identified, documented, and corrected in a timely manner. **In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.**

Management's position is that, as a matter of policy, such high-level treatment requirements [i.e., without the bold language] provides the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements [i.e., without the bold language] is consistent with Commission expectations and that including the bolded language would be inconsistent with the Commission's expectation. However, it is not clear why this language has been deleted from the proposed rule when the accompanying Statements of Consideration clearly states that licensees will be expected to do these things.

The text which was deleted from the proposed rule is necessary to provide reasonable regulatory confidence that the RISC-3 SSCs will remain functional. For example, deleting the requirement that licensees comply with voluntary consensus standards removes the technical basis for asserting that the proposed rule will provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. Ad hoc treatment of RISC-3 SSCs by licensees fails to take advantage of the technical expertise of industry standard setting groups, is inconsistent with the National Technology Transfer and Advancement Act of 1995, Public Law 104-113), and could result in inadequate or ineffective treatment of RISC-3 SSCs. In many cases, these consensus standards already explicitly address how to treat low safety significant components. Further, deletion of the requirement to consider vendor recommendations and industry operating experience could result in use of outdated technical information, repetition of poor practices of the past, and common-cause problems that would affect multiple SSC functionality. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations in support of the proposed rule clearly states (on page 75) that "the proposed rule permits, but does not require, use of the Code Cases for purposes of meeting rule requirements," and "the Commission expects licensees will utilize the ASME Code Cases as part of their implementation of §50.69." However, nothing in the rule would prompt licensees to utilize the Code Cases and there will be no regulatory guidance to steer licensees in this direction. If the Commission's expectation is that licensees use the Code Cases then the deleted language (i.e., these processes must meet voluntary consensus standards which are generally accepted in industrial practice) should be included in the rule.

As a second example, documented procedures and guidelines are needed for RISC-3 treatment processes and assessments of their effectiveness to provide reasonable confidence in the functionality of RISC-3 SSCs for initial implementation and follow-up activities. Allowing treatment processes to be undocumented will fail to provide reasonable confidence that activities related to RISC-3 SSCs will be implemented adequately. Absence of a requirement to control assessments of the effectiveness of the licensee's treatment processes will result in the inability to rely on the licensee's internal processes to manage and audit the treatment processes.

As a final example, the requirement that measures be taken to assure that the cause of significant conditions adverse to quality be determined and corrective action taken to preclude repetition is also necessary to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. The licensee's treatment processes must guard against widespread common cause failures. Experience indicates the changes to treatment (e.g., maintenance, test, and inspection practices) can have a significant and widespread effect on component capability and reliability and could invalidate the safety analysis performed to justify the changes. The proposed rule only requires specific failed SSC to be repaired. The proposed rule does not contain a requirement for potential common-cause problems to be evaluated and corrected. Common-cause problems that extend across system boundaries can invalidate the categorization process and result in inadequate protection of public health and safety. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations clearly states that "effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis".

Reliance on the very high-level treatment objectives, as contained in the proposed rule, will not provide reasonable confidence that the RISC-3 SSCs will remain functional. As learned from the RIP-50 Option 2 proof-of-concept exemption request review, high-level requirements alone are inadequate to provide reasonable confidence that licensees will implement sufficient treatment such that RISC-3 SSCs will perform their safety function under design-basis conditions. Moreover, reliance on very high-level treatment objectives will not ensure that degradation that could significantly affect the ability of groups of RISC-3 SSCs to perform their safety function reliably will be detected and corrected in a timely manner.

<u>The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.</u>

The proposed rule should describe (i.e., require) a treatment process that will provide reasonable confidence in the functionality of the RISC-3 SSCs. As currently constructed, the proposed rule relies too heavily on the categorization process. It is overly risk-based and fails to embrace one of the key safety principles identified in RG 1.174, that is, "The impact of the proposed change should be monitored using performance measurement strategies." RG 1.174 clearly states that "[t]he staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that supports the change to the LB." The proposed Option 2 rule should propose monitoring that is consistent with this guidance or there should be a technical basis for why such monitoring is no longer considered necessary.

As stated earlier, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC website version). Then, during the concurrence process, senior management made significant adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Feedback and Process Adjustment* portion of the proposed rule is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is not in the proposed rule.]

Feedback and process adjustment.

(1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs*. In a timely manner and no longer than every 36 months, the licensee shall review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization.

(2) *RISC-1 and RISC-2 SSCs*. The licensee shall monitor the performance of RISC-1 and RISC-2 SSCs and **in a timely manner and no later than every 36 months, perform an evaluation to assess whether the performance is consistent with the performance credited in the categorization process. Based upon that evaluation, the licensee shall** make adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

(3) *RISC-3 SSCs*. The licensee shall consider **performance** data collected in § 50.69(d)(2)(iii) for RISC-3 SSCs to determine **if the performance is consistent with performance credited in the categorization process, and** whether there are any adverse changes in performance **are due to changes in treatment applied to that SSC. In a timely manner and no later than every 36 months, the licensee shall make** such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv) and shall adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

My concern with the *Feedback and process adjustment* portion of the proposed rule is twofold. First, it does not require that the categorization process assumptions and treatment applied to RISC-3 SSCs be maintained consistent (as is required for the RISC-1 and RISC-2 SSCs). Second, it does not require timely adjustment to the treatment, or categorization process, if RISC-3 performance degrades significantly.

Recognizing that data does not currently exist to predict the effect of reduced treatment on RISC-3 SSC availability and reliability, it is particularly important to establish a process that maintains the treatment applied to the RISC-3 SSCs consistent with the categorization process assumptions. The overall process should require timely evaluation of performance problems that occur with RISC-3 SSCs, particularly problems that could pose a common cause concern, and require prompt adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. In this way, the change in risk can be maintained acceptably small while data is obtained on the effects of reduced treatment on RISC-3 availability and reliability. This linkage between categorization and treatment needs to be unambiguously clear in the rule. The categorization portion of the proposed rule at (c)(1)(iv) currently states:

> Provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of § 50.69(b)(1) and § 50.69(d)(2) are small [where § 50.69(b)(1) lists the rules that RISC-3 SSCs are being exempted from and § 50.69(d)(2) lists the alternate treatment requirements for RISC-3 SSCs].

This requirement does not clearly require that the categorization process assumptions and treatment applied to RISC-3 SSCs be <u>maintained</u> consistent. The proposed rule requirement above also does not require <u>timely</u> adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. As a result, this portion of the proposed rule does not provide reasonable confidence that risk associated with the reduced treatment will be maintained acceptably small and does not provide adequate feedback to ensure RISC-3 functionality.

In addition to the above safety concerns, I have the following process concerns with the proposed rule and the way it was developed.

<u>The proposed rule is inconsistent with the Commission's PRA Policy Statement and with the Commission-approved description of Option 2.</u>

The Commission's PRA Policy Statement states that "use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art in PRA methods and data." There is insufficient data regarding the effect of reduced treatment on RISC-3 reliability to assess the change in CDF and LERF associated with the proposed rule. While sensitivity studies can be used to assess the potential change in CDF and LERF, the rule needs to require that any assumptions made in those sensitivity studies remain valid. This provision of the draft rule (published on the NRC's website) was deleted without any official public comment from stakeholders. SECY-99-256 indicates that "RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance." As mentioned above, the proposed rule does not provide reasonable confidence that the RISC-3 SSCs will remain functional.

<u>The proposed rule is not responsive to public comments received from ASME and exceeds some suggestions provided by NEI.</u>

In its letter dated June 17, 2002, ASME agreed with the provision in the draft versions of the rule to exempt licensees that implement 50.69 from the requirements of 50.55a provided a framework is developed to ensure that the ASME's risk-informed Code Cases and Codes & Standards are used. In its letter dated May 15, 2002, NEI did not object to requirements regarding use of national codes and standards, specific design control aspects, and procurement receipt verification. At a public meeting on June 18, 2002, NEI stated that it did not have a problem with requiring that applicable voluntary consensus standards be used. The provision of the draft rule (published on the NRC's website) which would require that the treatment processes meet voluntary consensus standards, as well as other provisions in the draft rule, were deleted without any official public comment from stakeholders.

The established process for developing the proposed rule was not followed.

Significant technical and policy changes were made to the proposed rule package during the concurrence process without consulting with the technical staff, without providing a technical basis, without discussing the changes with the teams that were involved with developing the rule (e.g., RIP-50 Core Team, Risk Management Team, Risk-Informed Licensing Panel), and without receipt of official public comments. As a result of hastily making these changes to the proposed rule, there are significant inconsistencies between the proposed rule and associated Statement of Considerations. Staff expectations and requirements described in the Statement of Considerations are often not supported by language in the proposed rule.

For example, the Statement of Considerations states (page 80) that "Licensees will have to establish appropriate performance-based SSC treatment processes to maintain the validity of the categorization process and its assumptions." Page 101 of the Statement of Considerations discusses "developing and maintaining a technical basis for concluding that SSC performance is consistent with the categorization assumptions and with those evaluations performed to show that there is no more than a small increase in risk associated with implementation of § 50.69." The Statement of Considerations also states (page 101) that "changing levels of treatment on several similar components that might be sensitive to CCF potential would require consideration as to whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective in sufficiently minimizing CCF potential such that the sensitivity studies remain bounding." Similarly, the Statement of Considerations (page 108) indicates that "the categorization process may include specific reliability assumptions for plant SSCs in performing their intended functions. Therefore, when establishing the performance-based treatment process for RISC-3 SSCs, the licensee must take these assumptions into account. It is important to obtain sufficient information on SSC performance to allow the assumptions and results of the categorization process to remain valid." However, the development and maintenance of this linkage between the categorization and treatment processes is not required by the proposed rule and cannot be reasonably be read into the rule.

In addition, the Statement of Considerations identifies expectations related to the categorization process that are not supported by language in the proposed rule. For example (page 96):

- It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

- It is expected for PWRs that a sufficiently robust categorization process would categorize high energy ASME Section III Class 2 piping of the main steam and feedwater systems as RISC-1.

- It is expected that a sufficiently robust categorization process would result in fission product barriers (e.g., the containment shell or liner) being categorized as RISC-1.

The Statement of Considerations also identifies expectations related to the treatment process that are not supported by language in the proposed rule. For example:

- The Commission expects that related standards (such as ASME Code Cases N-658 and N-660 on SSC categorization and treatment for purposes of repair and replacement) be used in conjunction with each other as intended by the accredited standards writing body (page 109).

- The licensee's design control process would be expected to specify appropriate quality standards; select suitable materials, parts, and equipment; control design interfaces; coordinate participation of design organizations; verify design adequacy; and control design changes (page 112).

- The Commission also expects licensees to control special processes associated with installation, such as welding, to provide reasonable confidence in the design-basis capability of RISC-3 SSCs (page 114).

- For a RISC-3 SSC in service beyond its design life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety-related function (page 117).

These types of expectation should be reasonably linked to specific language in the proposed rule. Furthermore, I believe that turning these expectations into requirements of the rule would not be inconsistent with the Commission's expectations as articulated in the Staff Requirements Memoranda (SRMs) in response to SECY-98-300, SECY-99-256, and SECY-00-0194 (SRMs dated 6/8/99, 1/31/00, and 11/9/00, respectively).

As a final note, the strategy of publishing *Additional potential requirements for public comment* (Section VI of the Statement of Considerations) containing the treatment portion of the August 2, 2002, NRC website version of the rule for public comment, in addition to the less prescriptive proposed rule language, will probably not yield any fruitful responses and should be abandoned.

Conclusion

The proposed rule, as it is currently constructed, does not provide reasonable confidence that the change in risk associated with implementation of the rule will be maintained acceptably small. The proposed rule, as it is currently constructed, also does not provide sufficient regulatory assurance that RISC-3 SSCs (most of the safety-related equipment at the plant) will function reliability. The proposed rule simply requires that licensee establish processes to ensure that the RISC-3 SSCs will perform their safety functions under design-basis conditions. Finally, because of the construct of the current Reactor Oversight Process, the NRC won't periodically check to see if the licensee treatment processes for this "low-risk" equipment are effective. Consequently, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

Recommendations

The proposed rule should describe a process that considers the potential effects of reduced treatment on SSC reliability and availability both in categorizing components and in assessing the potential change in risk associated with implementing the rule. The proposed rule should describe a process (i.e., monitoring, corrective action, and feedback) that ensures PRA assumptions are maintained or that adjusts the treatment being applied to the RISC-3 SSCs as appropriate.

In order to demonstrate that the potential changes in CDF and LERF from the reduced treatment being applied to RISC-3 SSCs are small, the licensee should either 1) determine the effects of reduced treatment to be applied to RISC-3 SSCs on their unavailability and reliability, 2) perform a bounding analysis, or 3) perform sensitivity studies that reasonably assess potential changes that could occur and then monitor RISC-3 performance against the assumptions made in the sensitivity studies. Whichever option is chosen, the licensee should have a technical basis for any assumptions made or the licensee should establish a process that ensures that the assumptions are not inadvertently invalidated.

The proposed rule should make use the ASME's Risk-Informed Code Cases, as endorsed by the NRC staff, or an approach developed by the licensee that provides an equivalent level of effectiveness, as an acceptable method for meeting the high-level objectives of the rule (i.e, maintaining the ability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions). These Code Cases were developed by technical experts as part of a national consensus process. They will address all the major areas in the Code (e.g., ISI, IST, repair and replacement). The Risk-Informed Code Cases define appropriate, generally performance-based test and inspection strategies specifically for low safety significant components. Use of the ASME risk-informed Code Cases would provide reasonable confidence that RISC-3 SSCs would remain functional and would result in a more consistent approach towards the treatment of the RISC-3 SSCs. Such monitoring, if adequately coupled to the licensee's corrective action program, could also be used as a technical basis for asserting that sensitivity studies adequately bound potential increases in CDF and LERF associated with reduced treatment.

Referencing the ASME Code Cases, as endorsed by the NRC staff, will demonstrate that the Agency has a preeminent concern for maintaining public health and safety and will, at the same time, significantly reduce unnecessary regulatory burden (e.g., consistent with procurement of RISC-3 SSCs to commercial standards). It will also preclude any appearance, to the public or the Congress, of coziness with the regulated nuclear industry by working through the ASME and a national consensus process. Use of the ASME Code Cases, as endorsed by the NRC Staff, would also be consistent with the National Technology Transfer and Advancement Act of 1995.

Rather than relinquish specific regulatory controls for over approximately 75% of the safety-related equipment all at one time (and without having specified our expectations regarding how to meet the high-level objectives identified in the proposed rule), I believe it would be more prudent to significantly reduce the regulatory treatment to be applied to the RISC-3 SSCs by referencing the ASME risk-informed Code Cases as endorsed by the NRC. This would allow licensees to gain experience with the reduced maintenance, testing, inspection, and surveillance strategies and allow both licensees and the NRC to get a better understanding of the effect of reduced treatment on component availability and reliability. As experience is gained applying 10 CFR 50.69, the staff can always revisit whether certain categorization or treatment requirements in the rule are necessary.

The aforementioned concerns and recommendations can be ameliorated, in large part, by issuing the August 2, 2002, NRC website version of the rule (as published on the NRC external website) as the proposed rule.

cc: D. Terao
E. Imbro
W. Dean
R. Barrett

ADAMS ACCESSION NUMBER: ML022690452

Endnotes:

1. Some NRC staff and managers have recently argued that the categorization process proposed under Option 2 is more robust than that which was approved during the South Texas Project exemption review and would result in far fewer, and less safety significant, components being categorized as having low safety significance. However, the proposed rule neither defines nor requires a robust PRA. The categorization requirements in the proposed rule are also written at a very high level and do not ensure that only very insignificant components get categorized as RISC-3. The examples of robustness that have been mentioned are contained in draft regulatory guide DG-1121, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance."

2. While a study conducted by the South Texas Project licensee asserted that non-safety-related failure rates were not appreciably greater than corresponding safety-related failure rates for similar component types, the study was flawed for the following reasons.

- Failure data in NPRDS and MRRI is generally obtained during normal plant operating conditions and may not provide an indication of how the equipment will function under accident conditions.

- There was generally more safety-related equipment experience reported in the databases (because of reporting requirements) than for corresponding types of non-safety-related equipment. The reporting of non-safety-related failure data into NPRDS was voluntary and licensee dependent. As acknowledged in the report, there is incomplete data reporting in NPRDS and MRRI raw data for all component engineering and failure records. As a result, the non-safety-related failure frequencies will tend to be underestimated.

- Counting functional or operational failures over calender hours of plant operation does not give a reasonable estimate of a component's availability/unavailability or a component's reliability if called upon to function under design basis conditions.

- Detailed calculation of demand-based and run-time based failure "rates" similar to those applied in the probabilistic risk assessment (PRA) was not possible within the NPRDS database, because detailed failure mode and demand exposure (or success) data was not included therein. For both demand and run failure rate calculations, most component success or total "exposure" data (i.e., total demands and total run time) values in the MRRI database are estimated, not actually recorded like failure events. The estimates for the demand-based and run-time based failure "rates" assume that safety-related and non-safety-related components have similar demand profiles and run-time profiles. The basis for this assumption needs to be explained.

- Only functional or operational failures were considered in the analysis. There was no indication that other component records were evaluated to determine whether deficiencies identified in them would have prevented the component from functioning under design-basis-accident conditions.

- Only NPRDS safety class S (safety-related equipment) and safety class N (non-safety-related equipment) data was considered in the analysis. Safety class Z (other) was omitted from the analysis.

3. A more meaningful sensitivity study (than varying the unavailabilities of all RISC-3 SSCs by a factor of 2 to 5) might be to significantly reduce, or set to 1, the unavailabilities of selected RISC-3 SSCs to see the potential effect on CDF and LERF. It is noteworthy that modeling of common cause failures typically would <u>not</u> go across system boundaries. Inasmuch as, reducing the treatment applied to a group of components can both introduce common cause failure mechanisms (e.g., test or maintenance errors) and eliminate the defensive strategies against proximate causes (e.g., design controls, use of qualified equipment, testing and preventive maintenance programs, procedural review, personnel training, quality control) it is particularly important to either understand (i.e., up front) the effects of reduced treatment on common cause failure mechanisms or monitor for potentially more widespread common cause concerns. While increasing the failure rates by a factor of 2 to 5 also increases the common-cause failure contribution to the overall system unavailability by a factor of 2 to 5, it generally does not address inter-system common cause concerns and it is not mathematically correct in that parametric multipliers are neither known nor estimated.

4. The Commission previously concluded in NRC Generic Letter 89-10, “Safety-Related Motor-Operated Valve Testing and Surveillance,” dated June 28, 1989, and again in the Supplementary Information in support of the September 22, 1999, revision to 10 CFR 50.55a (64 FR 51370) that the quarterly stroke-time testing requirements for MOVs in the Code are not sufficient to provide assurance of MOV operability under design-basis conditions. Therefore, elimination of a licensee’s commitment to conduct periodic diagnostic testing (on an interval as long as once every 10 years based on valve performance) in conjunction with more frequent exercise testing [i.e., once a year or every refueling outage (whichever is longer)], in lieu of the quarterly stroke-time testing, would be unsafe.

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: John R. Fair, Senior Mechanical Engineer ***/RA/***
Mechanical and Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW CONCERNING THE PROPOSED 10 CFR 50.69 RULEMAKING

The purpose of this memorandum is to document my differing professional view concerning the proposed rulemaking to add new section 10 CFR 50.69, “Risk Informed Categorization and Treatment of Structures, Systems, and Components.” My specific concern is that the treatment requirements specified for RISC-3 SSCs are not sufficient to provide reasonable assurance of adequate protection of public health and safety.

The staff in NRR has spent over two years developing the 50.69 rule language. This effort included numerous internal staff meetings, review by internal oversight groups, and public meetings with external stakeholders. This effort resulted in the July, 31, 2002, version of the rule published on the NRC web site (posted on August 2). The July 31 version of the rule represented the balance of categorization and treatment requirements necessary to achieve a staff consensus to go forward with the proposed rulemaking. The Division of Regulatory Improvement Programs significantly altered the July 31 version of the rule without any input from the technical reviewers that were involved in the development of the rule for the past two years. Critical portions of the treatment process were eliminated based on the nebulous assertion that the rule language contained too much detail. The accompanying statement of considerations (SOC) indicates that the Commission expects licensees and applicants to satisfy many of the treatment provisions that were eliminated from the July 31 rule language. The current rule language is not consistent with many of the SOC expectations. As discussed in the ensuing paragraphs, portions of the July 31 rule language were eliminated without a valid technical justification.

The following language was deleted from the general treatment requirements for RISC-3 SSCs specified in the July 31 version of 50.69(d)(2):

> *These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process.*

Section III.3.2 of the SOC contains the statement: “Thus, collectively, RISC-3 SSCs can be safety significant and it is important to maintain their design basis functional capability.” It is important to recognize that, although on an individual basis RISC-3 SSCs may have low risk significance, collectively RISC-3 SSCs are safety significant. The failure of even a small number of these RISC-3 SSCs could lead to serious safety consequences. Therefore, in order for the staff to conclude that 50.69 provides reasonable assurance of adequate protection of public health and safety, the staff must conclude that the RISC-3 treatment requirements provide an adequate framework for assuring that RISC-3 SSCs maintain their design basis functionality. As stated in Section V.4.4 of the SOC, “It is necessary for a licensee to consider the impact that a change in treatment (as a result of removal of special treatment requirements) might have on the ability of the SSC to perform its design basis function and on the reliability of SSCs.” The SOC further concedes that this assessment may be either quantitative or qualitative. This is a weakness in the categorization process. A key cornerstone of the robust categorization process, the sensitivity study, may hinge on individual judgement. Safety-related SSCs are assumed to be highly reliable. A change in unavailability by a factor of 2 to 5, such as recommended in the NEI categorization guidelines (NEI 00-04) for the sensitivity study, still requires that the SSCs remain highly reliable. Monitoring normal operational SSC performance will not provide reliability estimates of SSC performance during design basis events. In order to have reasonable confidence that high reliability of SSCs is achieved for all design basis conditions, the RISC-3 treatment processes must meet standards that are generally accepted in industrial practice along with applicable vendor recommendations, and must be accomplished using controlled procedures. It is difficult to understand why these general requirements were considered too detailed for the rule language. Consensus standards and vendor recommendations are developed considering past performance of SSCs. The consensus standards and vendor recommendations contain essential criteria that is necessary to provide confidence in the functionality of SSCs. If licensees and applicants don’t use available consensus standards and don’t even follow vendor recommendations, the staff will not have a basis to assess reliability assumptions used in the categorization process.

The following bracketed language was deleted from the design control requirements specified in the July 31 version of 50.69(d)(2)(i):

> *Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled [“including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes”]. RISC-3 SSCs must be [“have a documented basis to demonstrate that they are”] capable of performing their safety-related functions...*

Post-installation testing is an essential step in establishing the functionality of newly installed SSCs. Section V.5.2.1 of the SOC contains the statement: “Licensees would be expected to perform sufficient post-installation testing to verify that the installed SSC is operating within expected parameters and is capable of performing its safety functions under design-basis conditions.” It is not clear why the requirement for post-installation testing was deleted from the rule language if licensees are expected to perform post-installation testing.

The current rule language does not require licensees and applicants to have any documentation to show that design requirements have been met. This is a significant deficiency in the current rule language. Without documentation, there is no assurance that

SSCs meet their design requirements and, consequently, no assurance that design basis functionality has been maintained. Maintaining documentation to show that design requirements have been met is a relatively simple common sense requirement. It is not clear why this requirement was considered overly prescriptive and removed from the rule language.

The following additional language was removed from the design control provisions specified in the July 31 version of 50.69(d)(2)(i):

> *"Replacements for ASME Class 2 and Class 3 SSCs and parts must meet either: (1) the requirements of the ASME Boiler & Pressure Vessel (BPV) Code; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced."*

Proposed 50.69(b)(1)(iv) allows licensees to replace ASME SSCs with non-ASME SSCs. This constitutes a change in the design of these components since the ASME Code contains design requirements. As a consequence, it is necessary to establish some criteria for the design of these SSCs. Section III.3.2 of the SOC contains the statement, "For the specific case of repair and replacement of ASME Class 2 and Class 3 SSCs, the Commission concludes that it would be acceptable to allow these SSCs to meet a voluntary consensus standard that is generally accepted in industrial practice..." However, the current rule language does not require these SSCs to meet any standard. The July 31 rule language is necessary to achieve the stated objective in the SOC. Section V.5.2.1 of the SOC also contains the statement, "Another example is a requirement for fracture toughness of particular materials that is part of a licensee's design requirements; such a requirement would continue to apply when repair and replacement of affected components is undertaken." However, the fracture toughness requirements are specified in the ASME Code. If a licensee does not use the ASME Code for replacement SSCs, then fracture toughness requirements will be lost. That is the reason the fracture toughness was addressed in the July 31 rule language. If SSCs do not possess adequate fracture toughness, then multiple brittle failures could occur when the SSCs are challenged by a design basis event such as an earthquake.

The following language was removed from the procurement provisions specified in the July 31 version of 50.69(d)(2)(ii):

> *"Upon receipt, the licensee shall verify that the item received is the item that was ordered."*

The purpose of the rule language is to assure that licensees and applicants maintain some control over procured items. Lack of procurement control could result in the installation of SSCs that are not capable of performing their design basis function. Section V.5.2.2 of the SOC contains the statement: "In addition to appropriately specifying the procurement of the desired component, the licensee/applicant would also be expected to conduct activities upon receipt to confirm that the received component is what was ordered." It is not clear why the requirement was considered too prescriptive for the rule language if the Commission expects of licensees and applicants to confirm that a received item is what was ordered.

The following language was removed from the corrective action provisions specified in the July 31 version of 50.69(d)(2)(iv):

> *"In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."*

Without this requirement a licensee or applicant would only have to fix a deficiency without having to determine whether the deficiency has any generic implications. This could lead to the failure to detect multiple SSCs that are not functional due to a generic deficiency. Section V.5.2.4 of the SOC contains the statement: "For example, effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis." The current rule language in not consistent with that statement. It is not clear why this provision was removed from the rule language.

In summary, the provisions of the July 31 rule language that were deleted contained high level requirements the technical staff considered necessary to provide reasonable confidence in the functionality of RISC-3 SSCs. The requirements in the current rule language are not sufficient for the staff to conclude that 50.69 provides reasonable assurance of adequate protection of public health and safety.

cc: R. Barrett
E. Imbro

ADAMS ACCESSION NUMBER: ML022690398

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: Thomas G. Scarbrough ***/RA/***
Mechanical and Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW REGARDING PROPOSED 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS FOR NUCLEAR POWER REACTORS"

For many years, NRC staff members in the NRR Division of Engineering (DE) have been reviewing and approving the application of risk insights in licensee programs at nuclear power plants through risk-informed inspection and testing programs. I have participated in these activities, including review of the application of risk insights in motor-operated valve (MOV) testing programs and assisting in the development of guidelines for the implementation of risk-informed testing programs at nuclear plants. Recently, I participated as a principal DE reviewer for the request by the South Texas Project for exemption from multiple special treatment requirements through the application of risk insights. Throughout this time, I and other members of the DE staff have supported the application of risk insights in NRC activities, and encouraged the implementation of risk-informed inspection and testing programs by nuclear plant licensees.

Over the last two years, I have participated as a principal DE reviewer for Option 2 of the NRC staff initiative to incorporate risk insights into the regulations. In this assignment, I have applied knowledge obtained from my experience during NRC activities to evaluate licensee programs to verify the design-basis capability of safety-related MOVs, review and acceptance of risk-informed and deterministic inservice testing programs established and implemented at nuclear plants, and participation in ASME code and standard activities including development of provisions for risk-informed component testing programs. Although the goal of the Option 2 effort is strongly supported by all internal and external stakeholders, significant differences exist regarding the interpretation of the Commission's directives for the Option 2 effort, the safety function of plant structures, systems, and components (SSCs) ranked as having low safety significance by the categorization process, and the implementation of high-level treatment requirements for low safety significant SSCs.

The NRC staff expended considerable resources to prepare proposed 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," to satisfy the directives in the Commission papers describing the Option 2 effort. For example, the staff provided an opportunity for advance public comment on drafts of the rule language per Commission direction. The staff also conducted several public meetings to discuss draft rule language and to consider comments submitted by stakeholders.

On July 31, 2002, the staff prepared a draft rule for Commission review that specified high-level requirements to provide sufficient regulatory treatment for plant SSCs consistent with the Commission papers describing the Option 2 effort. However, the 50.69 rulemaking package was significantly modified during the concurrence process. Based on my experience in component engineering and lessons learned from the Option 2 proof-of-concept effort, I consider the rulemaking package for proposed 10 CFR 50.69 submitted for Commission approval to be insufficient to maintain adequate protection of the public health and safety during operation of nuclear power plants implementing the rule. Therefore, I am submitting this Differing Professional View (DPV) regarding the rulemaking package for proposed 10 CFR 50.69.

As discussed in detail in the attachment to this memorandum, it is my opinion that the rulemaking package for proposed 10 CFR 50.69:

- does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs;

- is inconsistent with the Commission's Probabilistic Risk Assessment (PRA) Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation;

- does not provide a balanced discussion in the accompanying Commission paper of this first-of-a-kind regulation that will eliminate most special treatment requirements for most safety-related SSCs in operating and future nuclear power plants;

- provides a Statement of Considerations that is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements; and

- fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

If 10 CFR 50.69 is issued as proposed, I believe that treatment programs at some nuclear plants that implement the rule will be insufficient to maintain the reliability of SSCs to perform their safety functions assumed in the categorization process. These insufficient treatment programs can result in the unavailability of multiple SSCs to perform their safety functions under design-basis conditions. The unavailability of multiple SSCs to perform their safety functions might not be identified prior to a plant event, and increase the severity of the event or interfere with the licensee's ability to mitigate the event. If unacceptable SSC performance is identified, the absence of documentation allowed by the rule will increase the difficulty for regulatory and licensee staff to determine the extent of functionality concerns to other plant SSCs and the significance of the issue related to public health and safety.

I will be pleased to discuss my safety concerns with the proposed 50.69 rulemaking package.

Attachment: As stated

SAFETY CONCERNS WITH PROPOSED 50.69 RULEMAKING PACKAGE

1. The proposed 50.69 rule does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs.

Proposed 50.69 Rule

The proposed 50.69 rule (as of September 25, 2002) provides a voluntary approach for nuclear power plant licensees to categorize SSCs according to their safety significance and then to establish treatment processes for the SSCs based on their risk category. The proposed rule identifies safety-related SSCs of high safety significance as RISC-1, nonsafety-related SSCs of high safety significance as RISC-2, safety-related SSCs of low safety significance as RISC-3, and nonsafety-related SSCs of low safety significance as RISC-4. The proposed rule would provide for review and approval of the categorization process for each licensee that submitted a license amendment request to implement 10 CFR 50.69. The NRC staff plans to review and endorse guidelines prepared by the Nuclear Energy Institute (NEI) for the categorization of SSCs. The staff also plans to conduct inspections of the categorization process established by licensees implementing the rule.

In implementing 10 CFR 50.69, the licensee would establish treatment processes for individual SSCs based on their safety significance categorization. For RISC-1 and 2 SSCs, the licensee will be required to maintain current regulatory requirements and to adjust treatment to be consistent with credit assumed for those SSCs in the categorization process. For RISC-3 SSCs, the proposed rule would specify high-level treatment requirements, and eliminate most special treatment requirements, including the quality assurance requirements in Appendix B to 10 CFR 50; the inservice inspection and testing requirements for most SSCs within the scope of 10 CFR 50.55a; equipment qualification requirements in 10 CFR 50.49; most maintenance requirements in 10 CFR 50.65; reporting requirements in 10 CFR 50.72 and 73; and seismic qualification testing requirements in 10 CFR Part 100. For RISC-4 SSCs, the proposed rule would eliminate a similar list of special treatment requirements, where applicable, and not specify any high-level treatment requirements.

In lieu of the eliminated special treatment requirements for RISC-3 SSCs, the proposed 50.69 rule contains the following treatment requirements:

> The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life. The processes must meet the following requirements, as applicable:

(i) *Design control.* Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled. RISC-3 SSCs must be capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation and submergence) and effects (i.e., aging and synergism); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions);
(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements;
(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design-basis conditions until the next scheduled activity; and
(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design-basis conditions must be identified, documented, and corrected in a timely manner.

The NRC staff does not plan to prepare implementation guidance for the RISC-3 treatment requirements in 10 CFR 50.69 (other than that provided in the Statement of Considerations) to replace the guidance in regulatory guides, standard review plans, bulletins, generic letters, regulatory information summaries, and information notices applicable to the eliminated special treatment requirements. Further, the staff does not plan to conduct any inspections of the implementation of the treatment processes established by licensees implementing the rule to evaluate the effectiveness of those processes.

RISC-3 SSC Importance

The categorization process will identify SSCs that perform safety-related functions that have a low safety significance on an individual basis. The robust nature of nuclear power plant design results in redundant and diverse means to satisfy most safety functions. Consequently, the individual importance of any particular safety-related SSC will typically be small, and most safety-related SSCs will be ranked as having low safety significance at a nuclear plant. Experience with risk-informed programs has revealed that typically 50 to 80 percent of safety-related SSCs are ranked as low safety significant at nuclear plants. For example, in the proof-of-concept effort, the licensee categorized about 75% of its safety-related SSCs as low safety significant, including main steam isolation valves (MSIVs); all feedwater system valves (including control and isolation valves); valves in the diesel generator air start system; spent fuel pool pumps and valves; most residual heat removal (RHR) system valves; all (but one) valves in the service water system; reactor head vent throttle and isolation valves; most chemical, volume, and control system valves; high pressure safety injection (HPSI) and low pressure safety injection (LPSI) flowpath MOVs; all component cooling water MOVs; containment spray pumps and valves; and most containment isolation valves (including 9 intersystem LOCA valves).

The Statement of Considerations for the proposed rule asserts that the categorization process has been improved since the South Texas review such that only safety-related SSCs with low or negligible significance will be categorized as RISC-3. However, there are no requirements in the proposed rule that would indicate such a significant change in the categorization process. Further, the Statement of Considerations does not discuss the differences between the previous categorization approach accepted in the South Texas review and a more robust categorization process asserted to be required by the proposed rule.

The categorization process can provide a reliable ranking of safety-related SSCs based on their individual safety importance. However, the categorization process does not eliminate the safety functions required to be performed by SSCs categorized as being of low safety significance. The proposed rule improperly relies on a categorization process that is asserted to rank only safety-related SSCs of low or negligible significance as RISC-3 without adequate consideration of the treatment requirements necessary to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions.

Common-Cause Interactions

Assuming a proper safety significance ranking of SSCs at a nuclear power plant, the safety impact of eliminating treatment requirements and regulatory guidance for most safety-related SSCs depends primarily on the potential for multiple SSCs failing to perform their safety functions when called upon during an accident. The complexity of the categorization process does not allow common-cause interactions among SSCs across system boundaries to be evaluated on a quantitative basis except for a few limited instances (such as specific circuit breakers). NUREG/CR-5485, "Guidelines on Modeling Common-Cause Failures in Probabilistic Risk Assessment," discusses the challenges of modeling common cause failure events in nuclear power plants and provides a set of guidelines to help PRA analysts in this effort. The proposed rule requires that licensees submit information related to their consideration of common-cause interactions as part of their categorization process. However, common-cause interactions also need to be addressed as part of the establishment and implementation of treatment programs. For example, NUREG/CR-5485 indicates that defense strategies for common-cause failures typically include design control; use of qualified equipment; testing and preventive maintenance programs; procedure review; personnel training; quality control; barriers; diversity (functional, staff, equipment); and staggered testing and maintenance. The proposed rule does not provide confidence that defense strategies for common-cause failures will be established as part of the treatment processes for RISC-3 SSCs.

Commercial Practices

In NUREG/CR-6752 (January 2002), "A Comparative Analysis of Special Treatment Requirements for Systems, Structures, and Components (SSCs) of Nuclear Power Plants with Commercial Requirements of Non-Nuclear Power Plants," the Idaho National Engineering and Environmental Laboratory (INEEL) found that normal commercial and industrial practices at nuclear power plants not only vary widely between plants, but apply to a wide range of activities regarding the functionality of balance-of-plant SSCs. A criticism raised regarding the INEEL study is that the use of varying amounts of practices and treatment for commercial SSCs is not relevant because there are no regulatory requirements for that equipment. Once the NRC imposes a regulatory requirement, the criticism asserts that licensee practices will be changed accordingly. The assumption that licensees will change their commercial treatment to satisfy regulatory requirements in 10 CFR 50.69 is only valid if the regulatory requirements are sufficiently clear to ensure that licensees understand that the treatment must be consistent with the categorization process assumptions. Further, licensees might have widely varying levels of expertise in determining which specific commercial practice needs to be applied to low-risk safety-related SSCs that would be treated under commercial practice according to 10 CFR 50.69. For example, the INEEL study found that licensees base the amount of treatment applied to balance-of-plant SSCs on their relationship to power generation. Therefore, a licensee might apply specific controls for design, installation, and monitoring of a balance-of-plant SSC that directly supports the generation of electric power, but allow a balance-of-plant SSC that does not directly support power generation to degrade with repairs performed when the SSC is found to not be functional. RISC-3 SSCs associated with the response to plant events (such as containment isolation valves) that do not directly support power generation might be treated as standby equipment with minimal attention under current commercial practices. The results of the INEEL study are consistent with an NRC inspection effort of licensee quality assurance activities applied to nonsafety-related equipment documented in a memorandum dated December 7, 1984, by P. McKee. Further, the conclusions in NUREG/CR-6752 were reinforced by the NRC staff's findings during the review of the South Texas exemption request where the licensee initially planned to apply commercial practices (such as MOV stroke-time testing) to low-risk safety-related SSCs without adequate consideration of the ability to provide reasonable confidence in the functionality of those SSCs. A study referenced by the South Texas licensee in support of its reliance on commercial practice based on an assertion that the reliability of nonsafety-related SSCs exceeded that of safety-related SSCs was found to have several weaknesses, including relying on reported failures over a 25-year time period for nonsafety-related equipment that have minimal testing and reporting requirements. As a result, reliance in the proposed 50.69 rule on general industrial and commercial practices without a clear understanding of the treatment requirements is insufficient to provide confidence in the functionality of RISC-3 SSCs.

<u>Specific Inadequacies in Proposed 50.69 Rule</u>

a. Consensus Standards, Vendor Recommendations, and Operational Experience

Based on the importance of RISC-3 SSCs on a multiple SSC basis, lessons learned from the proof-of-concept effort, and NRC studies of balance-of-plant practices in the nuclear industry, the proposed rule's allowance for each licensee to develop unique methods based on their individual levels of expertise in SSCs, including design, construction, installation, operation, repair, and replacement, does not provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions under design-basis conditions. To resolve this safety concern, the DE staff recommended that the proposed rule include a requirement that the RISC-3 treatment processes meet voluntary consensus standards and to address applicable vendor recommendations and operational experience. Such a requirement was supported by the American Society of Mechanical Engineers (ASME) in its comments submitted on June 17, 2002, that exemption of the inservice inspection and testing requirements in 10 CFR 50.55a for RISC-3 SSCs would be acceptable provided a framework is developed to ensure that risk-informed ASME Code Cases and Codes & Standards are used. In its comments submitted on May 15, 2002, NEI supported a similar requirement to apply applicable codes and standards. At a public meeting between NRC, ASME, and NEI representatives on June 18, 2002, the participants did not object to a requirement for licensees to use applicable voluntary consensus standards in implementing the proposed rule.

In addition to requiring use of applicable voluntary consensus standards, a requirement to consider applicable vendor recommendations and operating experience is necessary in light of the history of SSC functionality problems where such recommendations and experience were not addressed. For example, NRC Information Notice 95-31, “Motor-Operated Valve Failure Caused by Stem Protector Pipe Interference,” reported multiple MOV operational problems resulting from licensee-fabricated valve stem protector pipes. Also, NRC Information Notice 97-32, “Defective Worm Shaft Clutch Gears in Limitorque Motor-Operated Valve Actuators,” discussed the failure of a non-safety related MOV as a result of improper refurbishment using parts from a supplier other than the original equipment manufacturer. Similarly, a requirement to consider operating experience is necessary to provide confidence that common-cause problems that might affect multiple SSC functionality are addressed. For example, in the proof-of-concept effort, the licensee initially proposed that it would eliminate all regulatory commitments related to RISC-3 SSCs based on only risk categorization without consideration of operating experience that might have a potential impact on SSC functionality. Similarly, the proof-of-concept licensee initially indicated that RISC-3 electrical equipment exceeding their environmental design life would be assumed to remain functional simply because of their risk categorization.

b. Consistency of Treatment with Categorization

The categorization process assumes a specific reliability for RISC-3 SSCs. In sensitivity studies, a licensee implementing 10 CFR 50.69 would reduce the RISC-3 SSC reliability based on its assumptions for the impact of the reduced treatment. Factors of 3 to 4 for reduced RISC-3 SSC reliability have been discussed in conducting those sensitivity studies. These reductions in RISC-3 SSC reliability continue to assume a very high reliability for the functionality of RISC-3 SSCs. For example, a typical MOV reliability assumption of 99.9% assumed in the categorization process might be adjusted to 99.6% in the sensitivity study evaluating the impact of elimination of special treatment requirements. Although changes in design control associated with paperwork might be considered to result in such small changes in the probability of SSC failure, changes in maintenance (such as not performing preventive maintenance on a vendor-recommended schedule) can have a significant impact on SSC reliability such that the categorization process would not be valid. The proposed rule should require that the treatment processes be consistent with the assumptions credited in the categorization process.

c. Design Requirements

An Option 2 directive specifies that the design of the plant not be changed as part of this rulemaking effort. The NRC staff has interpreted this directive to mean that the design functional requirements and bases for safety-related SSCs are not directly affected by the proposed rule. For example, in the proof-of-concept effort, the staff accepted the proposal by the licensee that RISC-3 SSCs designed to ASME Code provisions could be replaced with SSCs designed to less restrictive codes and standards. However, the licensee also indicated that it planned to apply portions of multiple codes and standards in designing RISC-3 SSCs. The staff considered such hybrid designs of safety-related SSCs to have potential adverse safety implications if installed in a nuclear plant without a history of their performance. To prevent this safety problem from occurring with the implementation of 10 CFR 50.69, the proposed rule should require that licensees follow all of the provisions of the code or standard selected for the design of RISC-3 SSCs. A similar concern relates to the design aspect of fracture toughness of ASME Class 2 and 3 SSCs and parts categorized as RISC-3. The proposed rule should specify this design requirement because lessons learned from the proof-of-concept effort indicate that licensees might not recognize this aspect of design for replacement SSCs.

d. Design Control Aspects

In the proof-of-concept effort, the licensee did not request exemption for Criterion III, Design Control, of 10 CFR 50, Appendix B, to help support its exemption from other special treatment requirements. In light of the importance of adequate design control, the NRC staff identified the most important aspects of design control described in Criterion III that would continue to allow licensees to have flexibility in implementing 10 CFR 50.69. The staff considered the selection of suitable materials, methods, and standards; verification of design adequacy; and control of design changes as the aspects of design control necessary to provide reasonable confidence in RISC-3 SSC functionality. In its May 15 letter, NEI also suggested rule language specifying design control requirements for selection of suitable materials, verify design adequacy, and control changes to the design. The staff had included the control of installation and post-installation testing under design control to allow the elimination of a separate rule requirement for an installation process. The proposed rule specifies no requirements for the control of installation, including installation activities such as welding or post-installation testing. The proposed rule should include specific aspects of design control for selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes.

e. Corrective Action

The proposed rule does not specify that corrective action will include evaluation of performance problems with RISC-3 SSCs for generic implications and resolution. Common-cause problems can invalidate the conclusion that treatment reductions for RISC-3 SSCs will not result in a safety concern. For example, improper performance of a RISC-3 SSC resulting from use of inaccurate measuring and test equipment can have widespread generic implications for the functionality of other RISC-3 SSCs. The importance of an adequate corrective action process was recognized in the proof-of-concept effort where the licensee did not request exemption from Criterion XVI, “Corrective Action,” of 10 CFR 50, Appendix B, so as to support its exemption requests. The proposed rule should include a corrective action requirement that the cause of the functionality problems be determined and action taken to address generic implications.

f. Process Control and Assessment

The proposed rule will rely on licensee initiative for providing reasonable confidence in the functionality of RISC-3 SSCs. The proposed rule provides almost no documentation requirements for RISC-3 SSCs. For example, licensees will not be required to maintain any documentation associated with design, procurement, installation, testing, or maintenance associated with RISC-3 SSCs. Licensees will not be required to prepare any written procedures for activities associated with RISC-3 SSCs or maintain any records of those activities. Licensees will not required to perform any audits of the treatment processes to provide confidence that the processes are meeting expectations. Allowing treatment processes for RISC-3 SSCs to be undocumented fails to provide reasonable confidence that activities related to RISC-3 SSCs will be implemented adequately. For example, some licensees in the past reportedly considered complete disassembly and reassembly of MOVs to be within the skill of the craft which lead to numerous performance problems. The lack of requirements for licensee assessments of the effectiveness of the treatment processes will result in the inability to rely on a licensee's internal processes to oversee its treatment processes. Further, absence of documentation will prevent the NRC from conducting an evaluation of plant safety in the event of the loss of control of SSC functionality by a licensee without significant resource expenditures by the licensee and NRC staff. The proposed rule should require that implementation of the treatment processes and assessment of their effectiveness be controlled and accomplished through documented procedures and guidelines.

g. Control of Procured SSCs

The proposed rule contains no requirements for the control of procured items upon receipt. Improper control and inspection of procured RISC-3 SSCs can result in multiple SSCs being incapable of performing their safety functions if called upon during an accident. The categorization process, and its conclusion that adequate protection of the public health and safety will be maintained, are not valid if multiple SSCs are incapable of performing their safety functions. NEI did not object to the procurement requirement for receipt verification. The proposed rule should include a requirement that, upon receipt, the licensee shall verify that the item received is the item ordered.

h. Feedback

The proposed rule does not require that the performance of RISC- 3 SSCs be evaluated in a timely manner to provide confidence that their performance is consistent with the categorization process assumptions. The proposed rule only requires that RISC-3 performance data be considered to determine whether any performance changes are due to treatment changes, and to make necessary adjustments. The proposed rule does not require that the categorization process assumptions for reliability be assessed either before or during implementation on a timely basis. The proposed rule should require sufficient feedback to provide confidence that the treatment reductions have not invalidated the categorization process and the finding that implementation of the rule continues to maintain adequate protection of the public health and safety.

2. The proposed rule package is inconsistent with the Commission's PRA Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation.

The Commission's PRA Policy Statement states that "use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art in PRA methods and data." The actual effect of reduced treatment on the reliability of RISC-3 SSCs cannot be determined in advance of implementation of the rule. However, the proposed rule fails to recognize this fact. The proposed rule should provide confidence that assumptions made in the categorization process of the potential effects of treatment reductions are reasonable; that means are in place to monitor SSC performance and to provide sufficient treatment controls where performance monitoring is not sufficient; and that corrective action will be taken and feedback will implemented as necessary to maintain the validity of the categorization process and its conclusion that the impact on plant safety from the implementation of 10 CFR 50.69 will be small.

Under Option 2 of the NRC initiative to risk-inform the regulations discussed in SECY-98-300, 99-256, and 00-0194, RISC-3 SSCs need to receive sufficient regulatory treatment such that these SSCs will continue to meet their functional requirements, albeit with a reduced level of assurance. The rulemaking plan provided an example of the hydrogen recombiners and the challenge in specifying adequate treatment requirements in the rule. The proposed rule does not recognize the safety significance of RISC-3 SSCs on a multiple SSC basis, and fails to provide sufficient regulatory treatment for RISC-3 SSCs. The Statement of Considerations for the proposed rule claims that the categorization process has been modified to ensure that SSCs with only negligible safety significance will be categorized as RISC-3. However, no requirements are specified in the proposed rule or described in the Statement of Considerations that would support such a claim.

The Commission's White Paper indicates that risk-informed, performance-based approaches use risk insights, engineering analysis and judgement including the principle of defense-in-depth and the incorporation of safety margins and performance history. The Statement of Considerations indicates that the proposed rule relies on a "cornerstone" of a robust categorization process. With an assumption that the categorization process has been enhanced, the proposed rule is now characterized as a "categorization rule" or, in other words, a risk-based rule. In the White Paper, the Commission states that it does not endorse an approach that is "risk-based" because of heavier reliance on risk assessment results than is currently practicable for reactors due to uncertainties in PRA such as completeness.

The proposed rule should provide sufficient requirements such that the categorization and treatment processes meet the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations while remaining consistent with the Commission's PRA Policy Statement and White Paper.

3. The rulemaking package does not provide a balanced discussion of this first-of-a-kind regulation that will eliminate most special treatment requirements for most of the safety-related SSCs in operating and future nuclear power plants.

The preparation of the proposed 50.69 rule represents the most significant NRC regulatory action related to the treatment of safety-related equipment at nuclear power plants in many years. The proof-of-concept effort and smaller scale risk-informed treatment programs reveal that most of the safety-related SSCs in nuclear plants will be categorized as RISC-3. The impact of the proposed replacement of the current regulations, regulatory guides, and standard review plan for most safety-related SSCs with a few high-level treatment requirements cannot be determined in advance. As illustrated by the lessons learned from the proof-of-concept effort, incorrect interpretation of high-level treatment requirements by licensees might lead to multiple SSCs being incapable of performing their safety functions. With minimal design and procurement control, general inspection and testing provisions, limited corrective action, and almost no documentation, the implementation of 10 CFR 50.69 will significantly reduce the ability of licensees and regulatory staff to verify the functionality of low-risk safety-related SSCs.

The Commission paper provided with the proposed rule does not discuss the potential safety issues that might result if the categorization or treatment processes fail to meet expectations. While the NRC staff will review the categorization process prior to implementation of 10 CFR 50.69, licensees will implement the treatment processes without staff review. If unacceptable performance is identified for multiple RISC-3 SSCs in the future, it could be difficult to determine the impact of those performance issues on the remaining SSCs, plant safety, and public health and safety, with reduced documentation and records. If a licensee implemented an ineffective treatment process, the inability of multiple RISC-3 SSCs to perform their safety functions might not be identified in advance, and might only be discovered during an accident.

Overall, the potential benefits of focused attention on high-risk SSCs and reduced costs might outweigh the disadvantages of reduced confidence in the capability of low-risk SSCs to perform their safety functions. The Commission paper should provide a balanced discussion of these issues.

4. The Statement of Considerations is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements.

The Statement of Considerations for the proposed rule includes numerous instances where NRC expectations are indicated. Many of these expectations were specified as requirements in the July 31 draft of the proposed rule. As discussed above, the requirements were included in the July 31 draft rule as a result of component engineering experience and lessons learned from plant-specific and generic review of licensee treatment programs. A discussion of expectations in the Statement of Considerations that are not connected with requirements in the rule does not provide confidence that licensees will follow the expectations rather than their own interpretation of the general requirements in the rule. Further, the Statement of Considerations is typically used for historical reference and not for daily interpretation of regulatory requirements during nuclear plant operations. Rather than relying on discussion in the Statement of Considerations, the proposed rule should specify the requirements necessary to provide reasonable confidence in the functionality of RISC-3 SSCs, and a regulatory guidance document should describe acceptable methods of implementing the requirements as appropriate.

The Statement of Considerations was originally prepared to support the July 31 draft of the proposed 50.69 rule. Following the significant changes to the draft rule during the management concurrence process, the Statement of Considerations was hurriedly modified in an effort to reflect the proposed rule. As a consequence, the Statement of Considerations contains inaccurate and misleading statements regarding the requirements in the proposed rule. Examples include:

> Section III.1.0, “Categorization of SSCs,” states that RISC-3 SSCs are not significant contributors to plant safety. This statement is accurate for individual RISC-3 SSCs. However, inadequate performance of multiple RISC-3 SSCs can have a significant impact on plant safety.

Section III.2.0, “Categorization Requirements,” of the Statement of Considerations states that the proposed rule will require that the revised treatment applied to RISC-3 SSCs be considered for its potential impact on risk. However, the proposed rule only specifies that the licensee have reasonable confidence that the change in risk is small.

Section III.3.2, “RISC-3 Treatment,” states that the Commission concludes that it would be acceptable to allow ASME Class 2 and 3 SSCs categorized as RISC-3 to meet a voluntary consensus standard. This statement is misleading by implying that the proposed rule contains requirements for the approaches that would be acceptable in lieu of the current ASME Code requirements in 10 CFR 50.55a. Further, Section III.3.2 states that “effective implementation” of the treatment requirements provides reasonable confidence of the capability of RISC-3 SSCs, but the Statement of Considerations does not discuss its reliance on effective implementation of the rule to maintain adequate protection of the public health and safety.

Section III.4.0, “Removal of RISC-3 and RISC-4 SSCs from the Scope of Special Treatment Requirements,” states that it is no longer necessary to have the same high level of assurance that less significant SSCs would perform as specified. However, the sensitivity studies required by the proposed rule may increase the failure rate for RISC-3 SSCs by only a factor of 3 to 4 (for example, a typical MOV might have its reliability reduced from 99.9% to 99.6%). Thus, the categorization process continues to assume a high reliability for RISC-3 SSCs.

Section III.4.3, “§50.55a(f), (g), and (h) Codes and Standards,” states that the proposed rule would not remove provisions pertaining to design requirements established in §50.55a. However, as discussed above, the proposed rule has removed several design requirements.

Section III.5.0, “Evaluation and Feedback, Corrective Action and Reporting Requirements,” states that the proposed rule contains requirements for updating the categorization and treatment processes when conditions warrant to assure that continued SSC performance is consistent with the categorization assumptions. The proposed rule does not contain such requirements for RISC-3 SSCs, but rather only a requirement to consider RISC-3 performance data to determine whether any adverse performance changes are due to treatment, and to make necessary adjustments. Section III.5.0 also states that feedback and adjustment is crucial to ensuring that SSC performance is maintained consistent with the assumptions of the categorization process and its results. However, the proposed rule only requires that changes in performance of RISC-3 SSCs be considered in whether to make changes to the categorization or treatment processes without a timeliness provision. Section III.5.0 also states that taking timely corrective action is an essential element for maintaining the validity of the categorization and treatment processes, but the proposed rule does not contain requirements for evaluations of performance problems with RISC-3 SSCs on a generic basis in a timely manner.

Section III.7.1, “Net Change in Risk is Small,” under Section III.7.0, “Adequate Protection,” states that the proposed rule requires that the potential net risk change from implementation of its requirements be assessed, and these requirements will ensure that the net risk change is small. However, the proposed rule only requires reasonable confidence that the net change in risk is small.

Section III.7.2, “Defense-in-Depth is Maintained,” asserts that defense-in-depth will be maintained simply because the proposed rule requires that defense-in-depth be considered in the categorization process, and relies on the consideration of the defense-in-depth in the facility design basis without addressing the removal of treatment (such as for most containment isolation valves).

Section III.7.3, “Safety Margins are Maintained,” states that the proposed rule preserves safety margins. However, the proposed rule only requires reasonable confidence that safety margins are maintained. Section III.7.3 asserts that, because only treatment requirements are relaxed, existing safety margins arising from design technical and functional requirements would remain, but does not address the significant impact that treatment can have on SSC performance and, therefore, safety margins. This section also asserts that the proposed rule will place a limit on how much the reliability of RISC-3 SSCs can change, although such a requirement is not in the proposed rule.

Section III.7.4, “Monitoring and Performance Measurement Strategies are Used,” asserts that the proposed rule contains requirements that reports are made to NRC of conditions preventing SSCs from performing their safety-significant functions. The proposed rule does not require generic aspects of corrective action to be addressed, nor does it require safety significant impacts of multiple RISC-3 SSC problems to be reported.

Section IV.2.0, “Draft Rule Comments,” asserts that the categorization process has been strengthened such that any individual SSC categorized as RISC-3 is of very low safety significance. No technical basis for this assertion is provided.

Section IV.4.0, “South Texas Exemption as Proof of Concept,” states that the NRC has applied the lessons learned from the review of the South Texas exemption request in developing the proposed rule. However, as discussed above, the proposed rule has not applied lessons learned from the proof-of-concept effort. Further, the Statement of Considerations does not include lessons learned from the proof-of-concept effort for the need to specify that 10 CFR 50.69 would not affect the commitment change process approved by the NRC.

Section V.5.2.1, “§50.69(d)(2)(i) Design Control Process,” states that a design requirement exists for fracture toughness, but the proposed rule does not indicate that this design requirement for repair and replacement of SSCs is retained. Section V.5.2.1 also states that licensees are responsible for proper installation and post-installation testing of RISC-3 SSCs, including welding and other special processes, as part of design control and other treatment processes. The proposed rule does not contain such requirements.

Section V.5.2.2, “§50.69(d)(2)(ii) Procurement Process,” states that the licensee would be expected to conduct activities upon receipt to confirm that the received component is what was ordered. The proposed rule does not contain such a requirement.

Section V.5.2.3, “§50.69(d)(2)(iii) Maintenance, Inspection, Test, and Surveillance Process,” states that, for a RISC-3 SSC in service beyond its service life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety function. However, the proposed rule does not contain requirements for documentation of technical bases for RISC-3 SSC functionality, other than as part of the corrective action process. Section V.5.2.3 also states that, as discussed under design control, licensees are responsible for proper installation (including welding) and post-installation testing of RISC-3 SSCs during the maintenance process. As noted, the proposed rule does not contain such requirements.

Section V.5.2.4, “§50.69(d)(2)(iv) Corrective Action Process,” asserts that effective implementation of the corrective action process would include timely response to information that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis. However, the proposed rule does not require generic corrective action for RISC-3 SSCs.

Section VI, “Additional potential requirements for public comment,” lists changes to the July 31 draft rule that was posted on the NRC website. The Statement of Considerations does not provide a technical bases for those significant changes.

5. The proposed 50.69 rule fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

The NRC staff prepared a draft version of the 50.69 rule (dated July 31, 2002) based on the experience and technical expertise of staff members, lessons learned from plant-specific and generic evaluations of risk-informed programs and commercial practices at nuclear plants, and stakeholder input provided in public comment letters from ASME and NEI on an earlier version of the draft rule (dated April 3, 2002). The staff also held several public meetings and workshops, including most recently on June 18, 2002, to discuss the draft rule language. Following the completion of the staff’s activities to develop a proposed rule that was technically valid, significant changes were made to the proposed rule during the concurrence process without sufficient technical basis.

Various reasons have been indicated for the significant changes made to the July 31 draft rule. None of the reasons is adequate to support the changes. Examples of those reasons are discussed below:

a. The July 31 draft rule was said to be too detailed to meet Commission expectations. However, the July 31 draft of the proposed rule fully met the Commission’s directives for a technically valid rule that provides minimal but sufficient treatment requirements for low-risk safety-related SSCs while applying state-of-the-art PRA methods. Following successful experience with the implementation of the rule as described in the July 31 draft, the NRC could evaluate whether further reductions in treatment for RISC-3 SSCs could be accomplished. Issuance of a less detailed but inadequate rule would result in safety problems as a result of licensees implementing ineffective treatment programs.

b. The July 31 draft rule was said to contain requirements specifying how to implement the overall functionality requirement for RISC-3 SSCs. As part of the preparation of the draft rule, the staff focused on specifying what are the treatment requirements for RISC-3 SSCs. One arguable exception to this focused effort was the requirement for licensees to use of applicable voluntary consensus codes and standards in their treatment processes for RISC-3 SSCs. This particular treatment requirement (whether termed a "what" or a "how" requirement) was based on safety concerns resulting from plant-specific and generic evaluations that licensees might have limited expertise and understanding of design, procurement, installation, maintenance, testing, and replacement of particular safety-related SSCs.

c. The categorization process was said to be improved such that only SSCs of negligible importance will be ranked as RISC-3. Improvements in the categorization process such that less significant SSCs are categorized as RISC-3 are commendable and may allow further reductions in treatment requirements. However, the proposed rule does not require that the categorization process only rank SSCs of negligible importance as RISC-3. During the proof-of-concept effort, the robust nature of the South Texas categorization process was said to result in mostly "vents and drains" being categorized as low risk, but the process was found to also categorize MSIVs and other equipment that together perform important safety functions as low risk.

d. Proposed 10 CFR 50.69 is said to be a "categorization rule" such that only general treatment requirements for RISC-3 SSCs are necessary. The removal of treatment requirements based on the assertion that proposed 10 CFR 50.69 is a categorization or risk-based rule is inconsistent with the Commission's White Paper discussing risk-informed approaches.

e. The technical staff is told to simply trust licensees and PRAs. The staff has been reviewing and approving the application of risk insights in licensee and regulatory programs for many years. The staff trusts licensees to follow the regulatory requirements and the categorization process to rank SSCs according to the relative safety significance. The NRC needs to ensure that regulatory requirements are clear with sufficient specificity such that licensees will implement effective treatment programs that maintain the validity of the categorization process and, thereby, adequate protection of the public health and safety.

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