RULEMAKING ISSUE
(Affirmation)

June 30, 2004 SECY-04-0109

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: FINAL RULEMAKING TO ADD NEW SECTION 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS FOR NUCLEAR POWER REACTORS"

PURPOSE:

To obtain Commission approval to publish the final rule and the regulatory guidance implementing the final rule.

SUMMARY:

The final rule amends the NRC's regulations governing the domestic licensing of production and utilization facilities. Specifically, the rule adds to 10 CFR Part 50 a new § 50.69 that provides an alternative set of requirements for treatment of structures, systems, and components (SSCs). The alternative requirements use a risk-informed categorization process to determine the safety significance of the SSCs. These requirements can be voluntarily adopted by light-water reactor licensees and applicants.

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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, revises the scope of SSCs 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 basis functional requirements of the plant or the design basis accidents.

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 special treatment requirements. On October 29, 1999, the staff sent 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 in Part 50, referred to as § 50.69, to contain these alternative requirements. By an 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.

On September 30, 2002, the staff sent the Commission SECY-02-0176 containing the proposed § 50.69 rule package. The Commission approved issuance of proposed § 50.69 for public comment in an SRM dated March 28, 2003. Consistent with Commission direction, the staff subsequently published proposed § 50.69 for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511).

DISCUSSION:

The staff has developed § 50.69 as an alternative set of requirements whereby a licensee or applicant may voluntarily categorize its SSCs consistent with the requirements in § 50.69(c) and adjust treatment requirements per § 50.69(d) based upon the resulting significance. Under this approach, a licensee or applicant is allowed to remove the special treatment requirements listed in § 50.69(b) for SSCs that are determined to be of low individual safety significance. The regulatory requirements not removed by § 50.69(b) continue to apply, as well as the requirements specified in § 50.69. The rule contains requirements by which a licensee uses a risk-informed process to categorize SSCs, adjusts treatment requirements consistent with the

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

relative significance of the SSCs and manages the process over the lifetime of the plant. To implement the rule, 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 performed by an integrated decisionmaking process which uses both risk insights and traditional engineering insights. The safety functions include both the design basis functions (derived from the definition of "safety-related," which includes external events) and functions credited for severe accidents (including external events). The SSCs are required to be treated as necessary to maintain functionality and reliability. The treatment is a function of the category of the SSC. Finally, assessment activities are conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The rule contains requirements for obtaining prior NRC review and approval of the categorization process and for maintaining certain plant records and reports.

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

As discussed in more detail in the attached *Federal Register* notice (Attachment 1), the staff concludes that the final rule maintains safety through a combination of elements and that it is consistent with Commission guidance on risk-informed activities. The rule allows both the NRC staff and industry to better focus their attention and resources on regulatory issues of greater safety significance. This rule would reduce unnecessary regulatory burden by removing SSCs of low individual safety significance from the scope of certain special treatment requirements and would also identify more significant SSCs that receive enhanced attention. As a result, this rulemaking would aid in bringing the regulations in closer agreement with the risk-informed approaches to inspection and enforcement.

The staff notes that the rule does not contain criteria for determining whether a safety function is "significant," or whether a SSC has "low" safety significance. There are several factors that tend to minimize these weaknesses: (i) the existence of high-level requirements in the § 50.69 rule governing the categorization process, (ii) more detailed regulatory guidance on the categorization process and suggested criteria for assessing safety significance, which the majority of applicants are likely to use, (iii) the staff's intention to impose a license condition requiring continued use of the regulatory guidance for those applicants committing to using the regulatory guidance, and (iv) the weaknesses are confined to the application of special treatment, while the design basis for the plants remain unchanged by § 50.69 and must continued to be maintained. Nonetheless, the lack of such criteria could have the following effects: (i) for those plants that use an alternative to the regulatory guidance for the § 50.69 categorization process, NRC staff review may be more difficult to complete; (ii) NRC inspection may have greater variation as different plants have different working definitions of "high" and "low" safety significance, and (iii) defending challenges to the adequacy of the categorization process, and the adequacy of implementation may be more difficult. Although it may be possible to develop criteria for inclusion in the rule which would be utilized in determining "significant" safety functions, and "low" safety significance, there are significant technical issues which would have to be resolved requiring substantial additional time, resources, and interactions with stakeholders.

Stakeholder Feedback on the Proposed Rule

The Commission received 26 sets of comments comprising about 200 individual comments in response to the proposed rule and the specific areas of interest indicated in the *Federal Register* notice for the proposed rule. The comments reflected divergent views among the stakeholders on many aspects of the proposed rule and the specific areas of interest. The staff has reviewed each of the comments in detail in developing the final rule. The more significant comments are summarized in Section II of the attached *Federal Register* notice and all of the comments are discussed in more detail in the "Response to Public Comments on the Proposed Rule" (Attachment 4). Several of the key issues are highlighted below.

With respect to categorization, stakeholder comments ranged from those supporting more extensive probabilistic risk assessment (PRA) requirements to those stating that the PRA requirements specified in proposed § 50.69(c) were sufficient. For example, industry commenters stated that additional PRA requirements were not necessary because the other categorization requirements in § 50.69(c) addressed modes and events not addressed by the PRA. The comments from State organizations and public interest groups supported additional and more stringent PRA requirements. The staff concludes that the § 50.69 PRA requirements in the proposed rule are sufficient for this application, and has maintained those requirements in the final rule. The staff also concludes that the § 50.69 PRA requirements are consistent with the direction provided in the Commission's SRM dated December 18, 2003, such that a Level 2 internal and external initiating events, all-mode, peer-reviewed PRA is not necessary for implementation of this rule.

With respect to the treatment of RISC-3 SSCs (i.e., safety related, low safety significant SSCs), the divergent views of stakeholders revealed that the RISC-3 treatment requirements needed to be clarified and the supporting description in the Statements of Consideration (SOC) revised to focus on the meaning of the rule language. For example, some industry commenters asserted that general industrial practices would be sufficient to satisfy the requirements in § 50.69 for the treatment of RISC-3 SSCs. In this regard, industry commenters pointed to exercising valves and pumps as a means of satisfying the proposed rule language. It is the staff's view, based upon operational experience and research, that exercising is not sufficient to provide confidence in the design basis capability of pumps and valves. Therefore, exercising pumps and valves would not provide reasonable confidence in the capability of those components to perform their design basis safety functions in accordance with the reliability values assumed in the categorization process. As a result, the staff clarified the rule to specify that the treatment of RISC-3 SSCs must be consistent with the categorization process, and has revised the SOC to indicate that exercising a pump or valve alone is insufficient to satisfy the treatment requirements of the rule. Some comments suggested that licensees might not implement sufficient processes to determine that RISC-3 SSCs are capable of performing their safety-related functions under design basis environmental and seismic conditions. As a result, the staff clarified the rule to specify that the treatment processes for RISC-3 SSCs, including determination of design basis capability, must be documented, and revised the SOC to indicate that the requirements for RISC-3 SSCs to be capable of performing their safety-related functions under design basis conditions continue to apply. Several stakeholders also indicated that the proposed rule did not address potential common-cause failures of RISC-3 SSCs. Since SSCs are categorized as RISC-3 primarily on their low individual safety significance, the failure of several RISC-3 SSCs can have a significant impact on the response of a nuclear power plant to design basis events and the risk associated with those design basis events. To emphasize the importance of avoiding common-cause failures of RISC-3 SSCs, the staff clarified the requirements for the corrective action process for RISC-3 SSCs by adding a requirement that, for significant conditions adverse to quality, the cause of the condition must be determined and action taken to preclude repetition. This requirement was proposed by the Nuclear Energy Institute (NEI) and uses language that is similar to 10 CFR Part 50, Appendix B, Criterion XVI. As such, this should be a well-understood requirement that minimizes the potential for common-cause failures.

Comments from public interest groups and State organizations generally stressed the need for the NRC to review and approve RISC-3 treatment processes in advance of the implementation of § 50.69 to confirm that appropriate treatment will be applied to RISC-3 SSCs for the performance of their safety-related functions. On the other hand, industry commenters did not consider prior review and approval of RISC-3 treatment to be necessary in light of the low individual safety significance of RISC-3 SSCs, other requirements that help maintain safety, and the availability of inspection and enforcement by the NRC. The staff believes that licensees should be allowed to establish treatment processes for RISC-3 SSCs without NRC review prior to implementation of those processes, given the low individual safety significance of RISC-3 SSCs and the high-level treatment requirements in § 50.69. To provide additional assurance, the staff intends to conduct sample inspections at nuclear power plants implementing § 50.69 to address programmatic issues related to the categorization and treatment processes. Public comments on the proposed rule indicated general support for providing regulatory oversight of the implementation of processes established under § 50.69 through the NRC's inspection and enforcement process.

Some stakeholders commented that operating experience argues against removal of special treatment requirements and that regulatory attention should be increased for all safety-related equipment. To emphasize the importance of applying operating experience in maintaining plant safety, the staff revised the rule to clarify that § 50.69(e)(1) requires the feedback of plant operational experience in addition to the requirements to feed back performance data, plant changes, operational changes, and industry experience. This plant operational information may be obtained from the corrective action program and processes, as well as other sources.

Implementation Guidance for § 50.69

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 rule, the NRC staff reviewed drafts of this document. 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 (RG). The final draft revision of NEI 00-04 (Attachment 6), submitted on April 14, 2004, forms the basis for the NRC Regulatory Guide (Attachment 5). The NRC staff's review of NEI 00-04 revealed several areas where the staff finds it necessary to identify exceptions to, and/or clarify, the NEI guidance or to include further guidance to supplement the document as it is currently written. These areas are discussed in RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in

Nuclear Power Plants According to Their Safety Significance." These remaining few technical interpretation/implementation issues of the guidance are best resolved by testing the guide against actual applications. Therefore, this RG is being issued for trial use.

ACRS and CRGR Review

The draft final rule was reviewed by the Advisory Committee on Reactor Safeguards (ACRS) on June 2, 2004. The Committee To Review Generic Requirements (CRGR) reviewed the final rule and elected to waive a briefing on the final rule. Neither the ACRS nor the CRGR object to issuance of the final rule.

Implementation

Section 50.69 requires licensees or applicants, who voluntarily elect to implement § 50.69, to submit information concerning the categorization process for prior NRC review and approval. For licensees, this review and approval will be in the form of a § 50.90 license amendment. The NRC staff expects that licensees and applicants will follow RG 1.201. As part of the NRC approval of a license amendment, the NRC staff intends to impose a license condition upon which the categorization process approval is based to control categorization process changes. The license condition will require the licensee to notify the NRC in advance of implementing changes with respect to specific aspects of the categorization process. With experience in the application of § 50.69, the NRC might modify the rule to specify generic criteria for the control of changes to the categorization process during implementation of the rule.

The NRC staff will update, as appropriate, the current inspection procedures under the NRC Reactor Oversight Process to incorporate inspection guidance for monitoring the implementation of 10 CFR 50.69 at nuclear power plants. The staff intends to conduct sample inspections of plants implementing 10 CFR 50.69 in a manner that is sensitive to conditions that could significantly increase risk. These sample inspections are intended to gather information that will enable the staff to assess whether modifications are needed to the ongoing baseline inspection program. The sample inspections will focus on the implementation of the categorization process approved as part of the NRC review of the 10 CFR 50.69 license amendment request. The sample inspections will also evaluate the treatment processes established under 10 CFR 50.69 with primary attention directed to programmatic and common-cause issues, including those associated with known degradation mechanisms. Inspector training will be conducted to support rule implementation.

The final rule excludes applicants for standard design certifications from the group of entities who may take advantage of the provisions of § 50.69. In considering whether to extend the applicability of § 50.69 to design certifications, the staff identified a number of difficult issues which would have to be resolved to support such an extension. For example, it is unclear whether the dynamic process of recategorizing SSCs under § 50.69 would be consistent with the special change restrictions in § 52.63(a), thereby requiring the inclusion of a special change provision in the individual design certification rule. Inasmuch as the proposed rule did not include a provision that would have allowed design certification applicants to use § 50.69, the NRC has not had the benefit of the views of the industry and the public on these issues. Moreover, the industry has not expressed any interest in submitting a design certification using the principles of § 50.69. Accordingly, the staff recommends that the final rule not address the issue of applying § 50.69 to new design certifications; issues associated with the application of § 50.69 to design certification rulemaking can be addressed on a case-by-case basis as necessary. In the future, the Commission could initiate rulemaking to extend § 50.69 to new design certifications after the staff has had some experience in this area.

Contents of the Final Rulemaking Package

This rulemaking package includes the *Federal Register* final rule document, which includes the final rule language and SOC (Attachment 1), the regulatory analysis (Attachment 2), an environmental assessment (Attachment 3), the staff's response to the public comments on the proposed rule (Attachment 4), Regulatory Guide 1.201 (Attachment 5), and the NEI categorization guidance document, NEI 00-04 (Attachment 6).

RESOURCES:

The resources to complete the final rule and associated guidance (for NRR: 0.3 FTE in FY 2004) are included in the budget for FY 2004. These resources are for the staff's effort to develop guidance for the review of licensee amendment submittals and to develop guidance for the inspection of plants implementing § 50.69. This estimate does not contain the resources for inspector training and the actual inspection of § 50.69 implementation since we do not currently know how many plants will implement § 50.69 and when implementation will occur.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking for publication in the *Federal Register* (Attachment 1) with an effective date 30 days after the date of issuance.

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

3. Note:

    a. That the final rule (Attachment 1) will be published in the *Federal Register*:

    b. That a final regulatory analysis has been prepared for this rulemaking.

    c. That a final environmental assessment has been prepared for this rulemaking.

    d. 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.

    e. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 and has confirmed this determination with the Office of Management and Budget.

f. Copies of the final rule will be distributed to all affected Commission licensees. The document 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), and the Public Document Room and on the NRC rulemaking Web site.

g. That a press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the Federal Register.

h. The appropriate congressional committees will be informed.

i. The NRC will publish separately the implementation guidance for this rulemaking in the form of RG 1.201.

COORDINATION:

The Office of 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 ACRS and CRGR have no objection to issuing this final rule. The Office of the Chief Information Officer has reviewed the final rule information technology and information management implications and concurs in it.

/RA/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Response to Public Comments on the Proposed Rule
5. Regulatory Guide 1.201
6. Final draft of NEI 00-04

[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: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending 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 amendment revises 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 amendment permits 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 issuing a regulatory guide (RG) to implement the rule.

EFFECTIVE DATE: [insert date 30 days after publication in Federal Register]

ADDRESSES: The final rule and related documents are available on NRC's rulemaking website at http://ruleforum.llnl.gov. For information about the interactive rulemaking website contact Ms. Carol Gallagher, (301) 415-5905 (email: CAG@nrc.gov).

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Reed, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone (301) 415-1462; e-mail: tar@nrc.gov.

SUPPLEMENTARY INFORMATION

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I. Background

I.1 History and General 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 and 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 are defined as “safety-related,” and these SSCs are the subject of many regulatory requirements designed to ensure that they are of high quality and high reliability, and have the 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 (GDC) of Appendix A to 10 CFR Part 50, is not explicitly defined.

These prescriptive requirements as to how licensees are 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 SSCs 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 non-probabilistic 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 is appropriate from a regulatory perspective. 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" 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 NRC staff developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis." 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.

RG 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.

I.2 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 NRC 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 (BPV), or seismic requirements, continued to impose substantial burdens. As a result, the replacement of a low safety significant component needed to 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 to 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 Part 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 discussion on this exemption request is provided in Section IV.2).

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 basis functional requirements 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, which are designed to maintain consistency between actual performance and the performance credited in the assessment process that determines their significance. As a result, both the NRC and industry should be able to better focus their resources on regulatory issues of greater safety significance.

The Commission directed the NRC 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 Register* on 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, now identified as § 50.69, to contain these alternative requirements.

The Commission received more than 200 comments in response to the ANPR. The NRC staff sent the Commission SECY-00-0194, “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 of SECY-02-0176, “Proposed Rulemaking to Add New Section 10 CFR 50.69, ‘Risk-Informed Categorization and Treatment of Structures, Systems, and Components’,” dated September 30, 2002 (ADAMS accession number ML022630007).

The concept developed for this rule, discussed at length in the ANPR, applies 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 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 NRC staff prepared a proposed rule package and provided it to the Commission in SECY-02-0176. The Commission approved issuance of proposed 10 CFR 50.69 for public comment in a SRM dated March 28, 2003. The proposed 10 CFR 50.69 rule was published for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511). The Commission received 26 sets of comments in response to the proposed rule. The comments are discussed in Section II below.

1.3 Rule Overview.

Section 50.69 represents an alternative set of requirements whereby a licensee or applicant may voluntarily undertake categorization of its SSCs consistent with the requirements in § 50.69(c), remove the special treatment requirements listed in § 50.69(b) for SSCs that are determined to be of low individual safety significance, and implement alternative treatment requirements in § 50.69(d). The regulatory requirements not removed by § 50.69(b) continue to apply as well as the requirements specified in § 50.69. The rule contains requirements by which a licensee categorizes SSCs using a risk-informed process, adjusts treatment requirements consistent with the relative significance of the SSC, and manages 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 performed by an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions 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 for the SSCs is required to be applied as necessary to maintain functionality and reliability, and is a function of the category into which the SSC is categorized. Finally, assessment activities are conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The rule contains requirements for obtaining prior NRC review and approval of the categorization process and for maintaining certain plant records and reports. For a more detailed discussion of the rule requirements refer to Sections III and V of this rule.

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 on an individual basis, this approach should allow an acceptable, though reduced, level of assurance that these SSCs will satisfy functional requirements. However, continued maintenance of the health and safety of the public will depend on effective implementation of § 50.69 by the licensee or applicant applying the rule at its nuclear power plant.

II. Public Comments

II.1.0 Comments on Proposed Rule.

The Commission published proposed § 50.69 for public comment on May 16, 2003 (68 FR 26511). Twenty-six sets of comments were received (comments are available at http://ruleforum.llnl.gov/cgi-bin/rulemake?source=SSC_PRULE&st=prule). The Commission requested feedback on several specific issues in Section VI of the proposed rule notice. A summary of the public feedback concerning these issues, as well as a discussion of the more significant comments, follows. A detailed discussion of the issues raised by all comments is contained in a separate document (see Section IX, Availability of Documents).

II.1.1 Consideration of More Detailed Language for § 50.69(d)(2) regarding RISC-3 SSC Treatment Requirements.

As discussed in the proposed rule, the Commission believed that detailed rule language for the treatment of RISC-3 SSCs (i.e., safety-related SSCs that are categorized as low safety significant) was not necessary to provide reasonable confidence in RISC-3 design basis capability and, as a consequence, constructed proposed § 50.69 to contain high-level (i.e., less detailed) RISC-3 treatment requirements. However, the Commission recognized that some stakeholders could disagree with this approach and invited comment on this issue. For the most part, industry commenters asserted that there was no need for more detailed treatment requirements for RISC-3 SSCs in the rule. The state commenters and public interest groups considered the proposed rule language to be inadequate to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions. In reviewing the public comments, the Commission found significant divergence in the interpretation of the proposed rule language by industry commenters from the Commission's expectations as described in the Statement of Considerations - preamble - (SOC) for the proposed rule. As a result, in the final rule the Commission has clarified § 50.69(d)(2) and simplified the SOC discussion to focus on the meaning of the rule language (more details concerning these changes can be found in Section II.1.6). These changes to the rule and SOC should address many of the concerns raised by the state commenters and public interest groups.

II.1.2 PRA Requirements.

The Commission requested stakeholder comment on whether the NRC should amend the requirements in § 50.69(c) to require a level 2 internal and external initiating events, all-mode, peer-reviewed PRA that must be submitted to, and reviewed by, the NRC. Stakeholder comments ranged from those supporting such PRA requirements to those who conclude that the proposed PRA requirements in § 50.69(c) are sufficient. The industry commenters stated that additional PRA requirements were not necessary because the other categorization requirements in § 50.69(c) addressed other modes and events not addressed by the PRA and as a result, all sources of risk were addressed. The states and public interest groups supported increased PRA requirements. The Commission concludes that the § 50.69 PRA requirements in the proposed rule are sufficient for this application. The supporting guidance for the rule has been structured such that licensees will gain more benefit when PRA methods are used (beyond the minimum PRA requirements in § 50.69(c)), and where non-PRA methods are used, the requirements and associated implementation guidance account for this situation by requiring a process that tends to conservatively categorize SSCs into RISC-1 and RISC-2 (i.e., no special treatment requirements are removed). There are several other features to the regulatory framework that also contribute to ensuring sound PRA is used such as requiring aspects of the categorization process to be reviewed and approved before implementation, requiring the PRA to be peer reviewed, Integrated Decision-Making Panel (IDP) requirements, provisions for addressing all modes and events regardless of whether in the PRA, feedback and update requirements, and supporting standards. (Also see the Commission's SRM on PRA quality dated December 18, 2003, ADAMS Accession No. ML033520457.)

II.1.3 Review and Approval of RISC-3 Treatment.

The Commission requested stakeholder comment on whether the NRC should review and approve the RISC-3 treatment processes being developed by the licensee or applicant before implementation in addition to reviewing the categorization process. Public interest groups and comments from state organizations generally stressed the need for the NRC to review and approve RISC-3 treatment processes in advance of implementation to confirm appropriate treatment will be applied to RISC-3 SSCs given that these SSCs are safety-related.

On the other hand, industry commenters did not consider prior review and approval of RISC-3 treatment to be necessary in light of the low safety significance of individual RISC-3 SSCs, other requirements that help maintain safety, and the availability of inspection and enforcement by the NRC. The NRC agrees that the individual low safety significance of RISC-3 SSCs supports allowing licensees to establish treatment processes for RISC-3 SSCs without prior NRC review. This conclusion is based on the rule containing:

(1) Robust categorization and PRA requirements;

(2) Requirements to show that implementation risk is small;

(3) Feedback requirements of paragraph (e) to help maintain the validity of the categorization process; and

(4) The high-level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability.

In addition, a provision has been added to the final rule to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. To provide additional assurance, the NRC intends to conduct sample inspections at nuclear power plants implementing § 50.69 to address programmatic issues related to the categorization and treatment processes (see below).

II.1.4 Inspection and Enforcement.

The Commission requested stakeholder comment on whether or not changes are needed in the NRC's reactor oversight process including the inspection program and enforcement to enable NRC to exercise the appropriate degree of regulatory oversight of these aspects of facility operation regarding § 50.69. The public comments on the proposed rule indicated general support for providing regulatory oversight of the implementation of processes established under § 50.69 through the NRC's inspection and enforcement process. Some stakeholders considered the current inspection and enforcement process to be sufficient without adjustment. Other stakeholders recommended that the NRC consider additional training and guidance to inspectors to support implementation of § 50.69. Some stakeholders provided specific and constructive suggestions regarding the inspection and enforcement process under § 50.69 including aspects of treatment processes to be inspected, and the application of enforcement discretion. Based on its consideration of this issue, the Commission plans to conduct inspections of § 50.69 implementation. These inspections will be performed on a sampling basis (in terms of the number of plants inspected) and will depend on the number of licensees who decide to implement § 50.69. These sample inspections are intended to gather information that will enable the NRC to assess whether modifications are needed to the ongoing baseline inspection program. The principal focus of the inspection will be on the safety significant aspects of § 50.69 implementation such as categorization and treatment of RISC-1 and RISC-2 SSCs, but the inspection will also consider the implementation of RISC-3 treatment processes focusing on programmatic and common cause issues, which could undermine the categorization process and its results.

II.1.5 Operating Experience.

The Commission requested stakeholder feedback regarding the role that relevant operational experience could play in reducing the uncertainty associated with the effects of treatment on performance and specifically sought public comment as to what information might be available and how it could be used to support implementation of this rulemaking. Some stakeholders commented that relevant operating experience argues against the removal of special treatment requirements and that regulatory attention should be increased for this equipment. Other stakeholders suggested that there is a large amount of data that demonstrates that commercial and safety-related SSCs have comparable failure rates with the implication that special treatment requirements can be removed with little impact. The specific study referenced by those stakeholders was not submitted for formal NRC review. The Commission concludes that a single unreviewed study does not provide a sufficient basis to make broad conclusions regarding the performance of SSCs subject to commercial and industrial practices for fabrication, installation, and maintenance. Other stakeholders commented that there are already opportunities for industry to share experience data with existing industry and regulatory programs implying that a new program is not necessary. In some instances, however, those referenced programs will be eliminated for RISC-3 SSCs under § 50.69. To emphasize the importance of applying operating experience in maintaining plant safety, the final rule has been revised to clarify that § 50.69(e)(1) requires the feedback of plant operational experience in addition to the requirements to feed back performance data, plant changes, operational changes, and industry experience. This plant operational information may be obtained from the corrective action program and processes, as well as other sources.

II.1.6 Other Substantive Issues.

In addition to the issues addressed in Section II.1.5, stakeholders provided substantive comments that caused the NRC to re-examine the § 50.69 framework and make changes. Those issues and comments are discussed below. Additionally, there were several issues that involved a significant number of stakeholder comments, and even though the Commission decided not to revise its approach, those issues and comments are also discussed in this section.

II.1.6.1 SOC Guidance.

Numerous comments were received from the industry regarding the nature of the information in the proposed rule's SOC supporting both § 50.69(d)(2) and § 50.69(c). Several industry commenters stated that the discussion in the SOC was inconsistent with the rule requirements. For example, some commenters suggested that, contrary to the SOC discussion, the treatment requirements for RISC-3 SSCs in § 50.69(d)(2) would allow exercising of pumps and valves as a means of providing reasonable confidence in the design basis capability of those components. Another commenter claimed that, contrary to the SOC discussion, § 50.69 would allow the leakage tests required by 10 CFR Part 50, Appendix J, for containment isolation valves to be eliminated without considering the capability of those valves to close under design basis conditions. Other commenters asserted that the corrective action process alone would be sufficient to satisfy the high-level requirements for feedback and monitoring of RISC-3 SSCs in § 50.69. These industry comments raised concerns regarding the interpretation of the rule language. Therefore, the Commission clarified the rule requirements and simplified the SOC to focus on the meaning of the rule language (see Sections II.1.6.2 through II.1.6.3, Section V.5.2, and the responses to comments d-32 and e-4 in Table 3 of "Response to Comments on Proposed § 50.69" as referenced in Section IX of this document).

II.1.6.2 RISC-3 Treatment Requirements

Numerous stakeholder comments were received concerning the § 50.69(d)(2) requirements for RISC-3 SSCs. Some public stakeholders provided their view that the RISC-3 treatment requirements were inadequate in light of previous industry experience (e.g., regarding the use of substandard parts) and that more detailed RISC-3 requirements were needed to address common cause failures, significant degradation, and in general to avoid an increase in risk to the health and safety of the public. Industry stakeholders tended to view the RISC-3 requirements as too prescriptive and beyond what is necessary to maintain reasonable confidence of RISC-3 SSC design basis capability. Some of the industry comments revealed that the rule requirements might not be implemented consistent with the Commission's expectations discussed in the SOC. Therefore, the Commission clarified the rule and SOC as discussed in the following sections.

II.1.6.2.1 Fracture Toughness.

In the SOC for the proposed rule, the Commission noted that design requirements for fracture toughness would continue to apply for replacement ASME components categorized as RISC-3 SSCs. One industry commenter asserted that fracture toughness is not a design issue while other commenters argued in general that the SOC discussion exceeded the rule requirements. The Commission emphasizes that the intent of § 50.69 is to remove special treatment requirements while maintaining design requirements for RISC-3 SSCs. The Commission considers fracture toughness to be an important design consideration. Fracture toughness is a property of the material that prevents premature failure of an SSC at abrupt geometry changes, or at small undetected flaws. Adequate fracture toughness of SSCs is necessary to prevent common cause failures due to design basis events, such as earthquakes. To ensure that this design consideration continues to be applicable to § 50.69 licensees, § 50.69(b)(1)(v) was clarified to exclude fracture toughness from the scope of § 50.55a repair and replacement requirements which are removed for RISC-3 SSCs.

II.1.6.2.2 Consistency with the Categorization Process.

Several industry comments indicated that licensees might not consider the impact of changes in treatment on RISC-3 SSCs as part of the categorization process. For example, one industry commenter asserted that sensitivity studies eliminate the need to specifically consider SSC reliability changes that might occur due to treatment changes. Another industry commenter stated that cross-system common cause interactions are rarely modeled in PRAs. Similarly, another industry commenter indicated that degradation mechanisms resulting from treatment processes are typically not considered in PRAs. The treatment practices for plant SSCs must support the capability credited in the categorization process for there to be reasonable confidence that any increase in risk remains small. Therefore, § 50.69(d)(2) was clarified to explicitly require the treatment of RISC-3 SSCs to be consistent with the categorization process.

II.1.6.2.3 Voluntary Consensus Standards.

In the SOC for the proposed rule, the Commission discussed the use of voluntary consensus standards as one effective means to establish treatment requirements for RISC-3 SSCs. In its comments, the ASME did not recommend adding a provision on voluntary consensus standards in the rule itself because it considered the SOC to provide adequate guidance for RISC-3 treatment. However, several industry commenters suggested that licensees might only apply general industrial practices when implementing treatment requirements for RISC-3 SSCs. For example, some industry commenters believed that exercising a pump or valve would provide sufficient assurance under § 50.69 of the capability of the pump or valve to perform its design basis safety functions. Although exercising a pump or valve might be consistent with general industrial practices, operating experience has demonstrated that exercising a pump or valve is not sufficient to provide confidence in its design basis capability. For example, the Commission modified § 50.55a to require licensees implementing the ASME *Code for Operation and Maintenance of Nuclear Power Plants* to periodically verify the design basis capability of motor-operated valves to perform their safety functions in light of the recognized inadequacies in stroke-time testing (somewhat more informative than exercising) to assess the operational readiness of those valves. The NRC issued Regulatory Issue Summary 00-03 (March 15, 2000), “Resolution of Generic Safety Issue 158, Performance of Safety-Related Power-Operated Valves Under Design Basis Conditions,” to discuss the importance of this issue relative to safety-related air-operated and other power-operated valves. Further, the ASME developed comprehensive pump testing provisions to provide more appropriate testing under significant flow conditions in light of the weakness of the previous Code testing under minimal loading conditions. In SECY-00-0194, the NRC noted that a wide variation existed in industrial practices. Therefore, certain industrial practices may not be sufficient to satisfy the treatment requirements for RISC-3 SSCs in § 50.69. To address these concerns, the Commission clarified the rule requirements to indicate that the treatment of RISC-3 SSCs must be consistent with the categorization process. One way to achieve this consistency could be the application of consensus standards. However, licensees or applicants must recognize that the application of such standards must meet § 50.69(d)(2) requirements to be acceptable. The determination of consistency between treatment and categorization also includes consideration of applicable operational experience, which may be found from such sources as NRC information notices, bulletins, and generic letters; and vendor recommendations.

II.1.6.2.4 Design Control Process.

In the SOC for the proposed rule, the Commission listed several attributes to be considered as part of the design control process for RISC-3 SSCs in satisfying the high-level treatment requirements in § 50.69. One industry commenter suggested that a focused list of design control attributes be substituted in § 50.69 for the proposed rule language. This list would include selection of suitable materials; verification of design adequacy, and control of design changes. With the removal of guidance from the SOC and the wide range of interpretations of the proposed rule language, the Commission accepted this comment and revised § 50.69(d)(2)(i) to indicate specific attributes for design control for RISC-3 SSCs including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes. In addition to the list of specific design control attributes suggested by the commenter, § 50.69(d)(2)(i) includes control of installation and post-installation testing under design control requirements because public comments revealed that licensees did not intend to implement the guidance for treatment (related to installation) that was provided in the proposed rule SOC. The specification of the design control attributes (including those related to installation) in the rule supports the overall requirement in § 50.69(d)(2) that the licensee or applicant develop and implement treatment processes that provide reasonable confidence in the design basis capability of RISC-3 SSCs.

II.1.6.2.5 Design Basis Conditions.

Under § 50.69, RISC-3 SSCs will be exempt from special treatment requirements for qualification methods for environmental conditions and effects and seismic conditions. Nevertheless, RISC-3 SSCs continue to be required to be capable of performing their safety-related functions under applicable environmental conditions and effects and seismic conditions. Based on industry comments on the proposed rule, some licensees appeared to interpret the proposed rule language as not requiring evaluation of environmental and seismic capability of RISC-3 SSCs. For example, one industry commenter stated that § 50.69 exempts RISC-3 electrical equipment from aging issues and that the rule would not require the establishment of design life for RISC-3 electrical equipment. Contrary to the public comment, a licensee implementing § 50.69 must consider operating life (aging) and combinations of operating life parameters (synergistic effects) in the design of RISC-3 electrical equipment. This is particularly important if the equipment contains materials which are known to be susceptible to significant degradation due to thermal, radiation, and/or wear (cyclic) aging including any known synergistic effects that could impair the ability of the equipment to meet its design basis function. Therefore, to ensure that SSCs meet applicable design requirements, the Commission clarified § 50.69(d)(2) to indicate that the licensee or applicant must develop and implement documented processes to control the design of RISC-3 SSCs.

II.1.6.2.6 Corrective Action.

Some public commenters raised concerns regarding the lack of requirements for the consideration of common-cause issues for RISC-3 SSCs. An industry commenter also noted this omission in the proposed rule and provided proposed rule language to resolve this issue. Therefore, the Commission decided to revise § 50.69(d)(2)(iv) to require that, for significant conditions adverse to quality associated with RISC-3 SSCs, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action is taken to preclude repetition. This requirement was proposed by the Nuclear Energy Institute and uses language that is similar to 10 CFR Part 50 Appendix B Criterion XVI. As such, this should be a well-understood requirement that minimizes the potential for common cause failures.

II.1.6.2.7 Seismic Experience Data.

Several industry commenters stated that the SOC for the proposed rule might create additional burden on plants licensed before implementation of Appendix A to 10 CFR Part 100. In establishing § 50.69, the Commission did not intend to alter the seismic design requirements for RISC-3 SSCs. Industry commenters also raised concerns regarding the SOC discussion on use of seismic experience data. In meeting § 50.69, the licensee or applicant must have adequate technical bases to conclude that RISC-3 SSCs will perform their safety-related functions under seismic design basis conditions, which includes the number and magnitude of earthquake events specified for the SSC design. Some commenters implied that it would be acceptable to use "experience data" alone to have reasonable confidence that an SSC is capable of functioning during an earthquake even if there is no actual "experience data" for the SSC. While the use of experience data is not prohibited by the rule, it may be difficult for a licensee or applicant to show that experience data alone will satisfy the applicable design requirements of 10 CFR Part 100 (which § 50.69 leaves intact). The Commission clarified the SOC with respect to the use of seismic experience data and to indicate that § 50.69 will not change the seismic design basis for Unresolved Safety Issue (USI) A-46[1] plants or impose additional seismic requirements for those plants.

II.1.6.3 Feedback.

Several industry commenters requested adjustments to the feedback requirements in § 50.69(e)(1) to provide more efficient implementation of the rule. Upon consideration of those comments, the Commission revised § 50.69(e)(1) to replace the maximum time interval for updating the categorization and treatment processes from 36 months to two refueling outages, and to indicate that the licensee or applicant may adjust either its categorization process or its treatment processes in satisfying the feedback requirement.

II.1.6.4 Section 50.46a/Appendix B Requirements for High Point Vents.

A comment was submitted that the NRC should undertake a review of the recently

[1] In December 1980 the NRC designated “Seismic Qualification of Equipment in Operating Plants” as an unresolved safety issue. For more information refer to GL 87-02.

revised § 50.44 to determine whether the new rule contains special treatment requirements that should be within the scope of § 50.69. The Commission agreed with this comment. The Commission noted in the proposed rule (Section III.4.9.3) that there may be a need to scope into § 50.69 certain provisions of the old § 50.44 dependent on the outcome of the effort to risk inform the § 50.44 requirements. The revised § 50.44 has no special treatment requirements. However, when § 50.44 was revised, a portion of the old § 50.44 regarding application of Appendix B requirements to high point vents was moved to § 50.46a. This particular requirement was not risk-informed as part of the § 50.44 effort and was instead simply relocated. Because application of Appendix B is a special treatment requirement, the Appendix B portion of § 50.46a(b) has been included within the scope of § 50.69 by the inclusion of § 50.69(b)(1)(ii).

II.1.6.5 Basis for RISC-3 SSC Reliability Used in § 50.69(c)(1)(iv) Evaluation.

A number of comments were received regarding the technical basis for the RISC-3 SSC reliability (failure rates) to be used in the risk sensitivity study performed to meet § 50.69(c)(1)(iv) requirements to demonstrate reasonable confidence that any potential risk increase from implementation of the rule is small. Some commenters suggested that licensees or applicants that voluntarily implement the rule should be required to characterize and reasonably bound the specific effects of eliminating treatment on SSC reliability under design basis and severe accident conditions. Other commenters suggested that there is evidence that reductions in treatment (using industry practices) has no impact on SSC reliability.

The NRC recognizes that the reliability of RISC-3 SSCs could potentially decrease (RISC-3 SSC failure rates increase) due to the reduction in treatment applied to these SSCs as a result of § 50.69 implementation. This is the reason why the Commission requires in the rule that the licensee demonstrate with reasonable confidence that any potential risk increase due to implementation of the rule will be small. However, the NRC also recognizes that it is difficult *a priori* to relate specific changes in treatment directly to specific changes in SSC reliability.

The rule has been constructed to account for this difficulty. First, the categorization process that a licensee uses must comply with the rule's requirements. Second, this categorization process will be reviewed and approved by the NRC before implementation. These steps are to have high confidence that SSCs are appropriately categorized so that RISC-3 SSCs are of low individual safety significance. Third, licensees are required to provide reasonable confidence that any risk increase due to implementation is acceptably small and this assessment must be supported by a supporting technical justification that discusses why the assessment adequately addresses the potential reliability changes for RISC-3 SSCs. This basis may include reliance on the capability of the licensee's data collection, feedback, and corrective action processes, which are also addressed by requirements of the rule. Finally, the rule has been revised to clarify the linkage between treatment and categorization and specifically to ensure that the treatment process is consistent with the categorization process, including the risk sensitivity study (i.e., maintain that any risk increase due to reduced treatment is acceptably small). Therefore, the rule is structured to contain:

(1) robust categorization and PRA requirements;

(2) requirements to show that implementation risk is small;

(3) a new provision to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process;

(4) feedback requirements of § 50.69(e) to maintain the validity of the categorization process; and,

(5) the high-level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability.

Thus, the Commission finds that the rule, as revised, has the appropriate provisions for addressing the concerns regarding the basis for RISC-3 SSC reliability used in the risk sensitivity study to be performed to meet the § 50.69(c)(1)(iv) requirement to demonstrate with reasonable confidence that any potential risk increase from implementation of the rule is small.

II.1.6.6 RISC-1 and RISC-2 Treatment Requirements and Crediting SSCs.

A number of industry stakeholders commented on the treatment requirements applicable to RISC-1 and RISC-2 SSCs in § 50.69(d)(1). These stakeholders commented that this requirement obligated a licensee implementing § 50.69 to evaluate treatment applied to all safety significant SSCs to ensure adequacy of treatment and cited this as an added burden that is neither necessary nor appropriate because RISC-1 SSCs are already subjected to full regulatory requirements. They also commented that it appeared that this requirements was extending special treatment requirements (such as Appendix B) to RISC-2 SSCs. In fact there was a general consensus of comments that any additional treatment requirements for RISC-1 and RISC-2 SSCs should be removed from the SOC or that the SOC be clarified to address the specific beyond design basis scope of additional regulatory controls. First, the Commission notes that § 50.69(d)(1) does not require licensees or applicants to evaluate the application of special treatment requirements to RISC-1 SSCs. These requirements are to maintain the design basis functional requirements with a high level of assurance. The special treatment requirements remain intact and unchanged, and hence there is no reason that an evaluation of the application of special treatment requirements should be required. Secondly, the Commission notes that it is not the intent of § 50.69(d)(1) to simply extend special treatment requirements such as Appendix B to RISC-1 and RISC-2 beyond design basis functions. Instead, the focus of § 50.69(d)(1) is on the PRA credited performance of RISC-1 and RISC 2 SSCs for beyond design basis conditions, and specifically for ensuring that there is a valid technical basis for the credit taken in the PRA (i.e., there must be a valid technical basis for the failure rate/probability of the SSC performing the function). The basis for this credit should already be established and documented in the PRA supporting documentation, so this should not be an additional burden for licensees to capture and implement. If an existing technical basis does not exist or is insufficient to support the credit taken in the PRA, then § 50.69(d)(1) would require that a technical basis be developed for the credit taken; potentially including the creation of a treatment program for the SSC that validates the capability credited.

Regarding the issue of “credited” SSCs, several commenters stated that the SOC implied an enormous program would be required if a licensee decides to selectively implement § 50.69 for a set of systems. It was commented that this enormous program would result due to the application of §§ 50.69(d)(1) and 50.69(e)(2) to maintain credited performance within the PRA and thereby enable the selected set of SSCs to be categorized as low safety significant. As the Commission has already noted, § 50.69(d)(1) obligates licensees to have a basis to support the performance of RISC-1 and RISC-2 SSCs credited in the PRA used in the categorization process, including the performance credited for beyond design basis conditions. This is an important aspect of the rule. The categorization process will result in a number of safety-related SSCs being determined to be of low safety significance (i.e., RISC-3) and subject to reduced treatment. This determination of low safety significance will implicitly take credit for the performance capability of other SSCs in the PRA, some or all of which may not be included in the scope of the licensee’s categorization process (due to the allowance for licensees to selectively implement the rule and to phase that implementation over time). To maintain the validity of the categorization process, and more importantly to maintain any potential risk increase as small, it is necessary to maintain the “credited” SSCs per § 50.69, and this means the application of §§ 50.69(d)(1) and 50.69(e)(2) requirements as suggested by the comment.

II.1.6.7 Adequate Protection Comments.

The NRC received several comments indicating that the proposed regulation would not maintain adequate protection of public health and safety. The Commission disagrees with these comments based in part on the requirements identified in the proposed rule. However, the public comments on proposed § 50.69 revealed divergent interpretations of these requirements for the treatment of RISC-3 SSCs in § 50.69. As a result, the Commission found it necessary to clarify § 50.69 requirements with respect to RISC-3 treatment requirements and with respect to the feedback requirements in § 50.69(e). These clarifications are discussed previously in this rulemaking.

II.1.6.8 License Amendment.

It was commented that the requirement to prepare, submit, and then receive approval of a license amendment to implement § 50.69 is a disincentive to its use. It was commented that, in light of the desire to move to a more performance-based regulatory regime, voluntary implementation of § 50.69 should be developed by licensees using the requirements in the rule and any attendant regulatory guidance, with routine NRC inspection serving to verify acceptable compliance. The Commission has decided not to revise § 50.69 in response to this comment. The Commission continues to conclude that (as discussed in Section III.6.0 of this rule) the review of the license amendment submittal will involve substantial engineering 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 final rule requires NRC approval to be provided by issuance of a license amendment.

III. Final Rule

The Commission is establishing § 50.69 as an alternative set of requirements whereby a licensee or applicant may undertake categorization of its SSCs consistent with the requirements in § 50.69(c) and adjust treatment requirements per § 50.69(d) based upon the resulting significance. Under this approach, a licensee or applicant is allowed to remove the special treatment requirements listed in § 50.69(b) for SSCs that are determined to be of low safety significance while potentially enhancing requirements for treatment of other SSCs that are found to be safety significant. The requirements establish a process by which a licensee categorizes SSCs using a risk-informed process, adjusts treatment requirements consistent with the relative significance of the SSC, and manages 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 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 is performed by an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions 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 are conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The 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 defines 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 § 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 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, depicted by box 2 in Figure 1, are nonsafety-related SSCs that the risk-informed categorization determines 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 individual contributors to plant safety. These SSCs are termed RISC-3 SSCs and are depicted by box 3 in Figure 1. 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 and are depicted by box 4 in Figure 1.

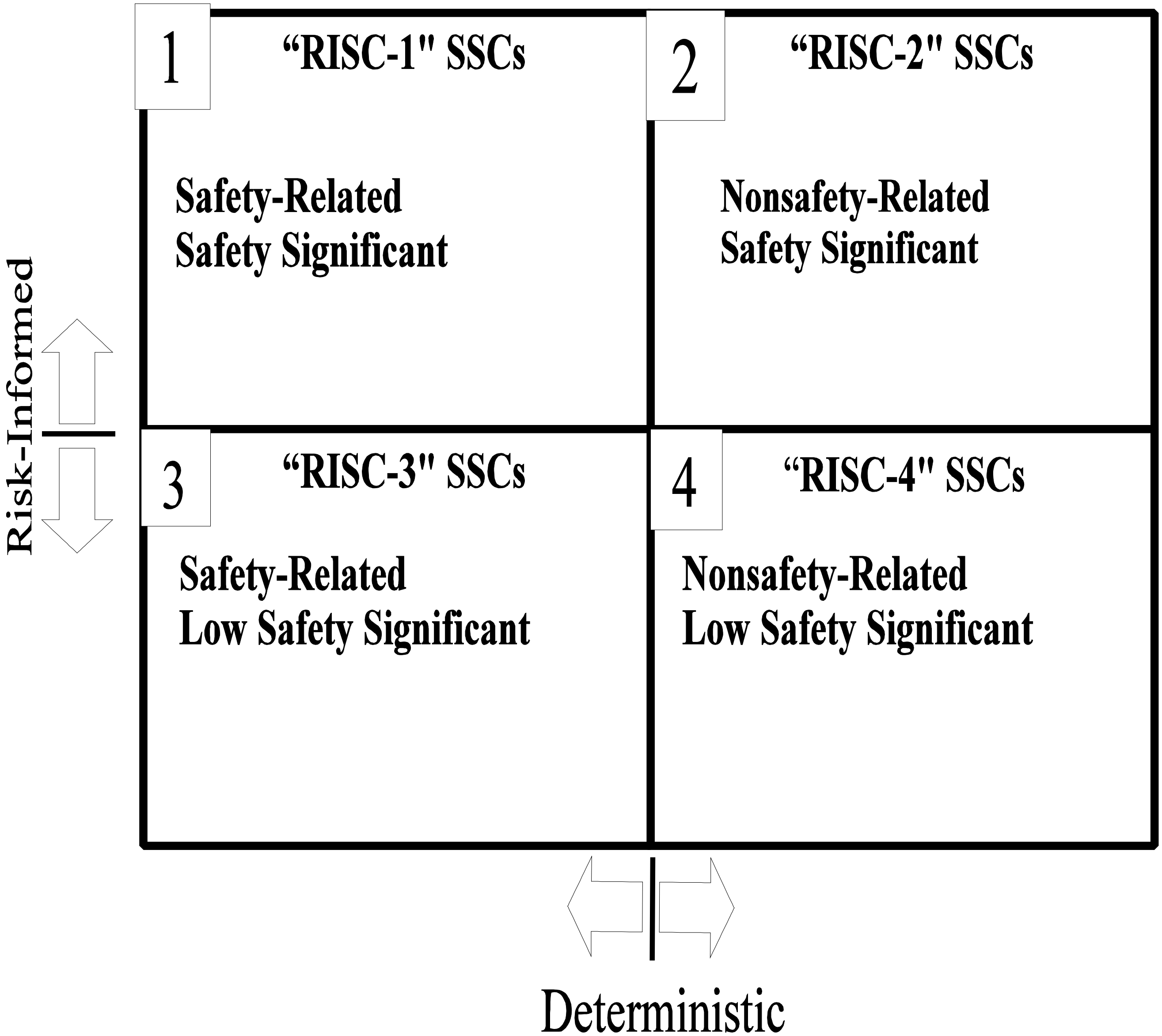

Figure 1

Section 50.69 defines 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 rule maintains more treatment requirements on SSCs that perform safety significant functions (RISC-1 and RISC-2 SSCs) than on SSCs that perform low safety significant functions to ensure that defense-in-depth and safety margins are maintained. The rule also requires that the licensee or applicant provide reasonable confidence that the change in risk associated with implementation of § 50.69 will be small.

III.2.0 Methodology for Categorization.

The cornerstone of § 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 § 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 (referred to as either an expert panel or an integrated decision-making panel (IDP)) that has the expertise and capabilities for making a sound decision regarding the SSC's categorization, and that the assembled information is considered in a manner that ensures the Commission's criteria for risk-informed applications are satisfied (i.e., defense-in-depth is maintained, reasonable confidence that safety margins are maintained, reasonable confidence that any risk increase is small, and a monitoring and performance assessment strategy is used). This process enables SSCs to be placed in the correct RISC category so that the appropriate treatment requirements will be applied commensurate with the SSC's safety significance. A safety significant SSC is an SSC that performs a safety significant function as defined in § 50.69. The rule requires that SSC safety significance be determined using quantitative information from a PRA that reasonably represents the as-built, as-operated, current plant configuration, and which at a minimum covers internal events at full power. The categorization process must address both internal events and external events for all modes of operation and can use other available risk analyses and traditional engineering information to supplement the quantitative PRA results to address modes and events not within the scope of the PRA.

Section 50.69(c)(1)(i) ensures that the PRA is adequate for this application. Section 50.69(c)(1)(iii) requires that defense-in-depth is maintained as part of the categorization process. Section 50.69(c)(1)(iv) requires 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 defense-in-depth (in terms of both large early and large late releases). As part of maintaining defense-in-depth, 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.

Section 50.69(c)(2) requires the risk insights and other traditional information to be evaluated by the IDP and this panel must be 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, the Commission concludes that the requirements in § 50.69(c)(2) 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 to categorize SSCs.

As mentioned previously, the § 50.69 categorization process requires that available deterministic and probabilistic information pertaining to SSC safety significance be considered in the decision process. The information considered must reasonably 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 that was 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 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.

Section 50.69(c)(1)(ii) contains general requirements for consideration of SSCs, modes of operation, and initiating 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.

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's completeness and technical adequacy for determining the 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 confidence that for IDP decisions that use PRA information, the results of the categorization process provide a valid representation of the risk importance of SSCs.

Before a licensee may implement § 50.69, the NRC must approve the categorization process through a license amendment. This is necessary because of the importance of the PRA and categorization process to successful implementation of the rule. This review and approval of the categorization process is a one-time, process approval (i.e., the approval is not restricted to a set of systems or structures, and can be applied to any system or structure in the plant and the licensee is not required to come back to the NRC for review of the categorization process provided that licensee remains within the scope of the NRC's safety evaluation). The NRC's review of the § 50.69 submittal will determine whether § 50.69 requirements are satisfied 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 review of the PRA is necessary because there are key assumptions and modeling parameters that can have a significant impact on the results so 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)(1)(iv) requires reasonable confidence that the increase in the overall plant core damage frequency (CDF) and large early release frequency (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. As presented in RG 1.174, the NRC considers small changes to be relative and to depend on the current plant CDF and LERF (hence we also refer to "acceptably small" changes in other portions of this notice since small can be different for different plants with different baseline levels of risk). For plants with total baseline CDF of 10^{-4} per year or less, small means CDF increases of up to 10^{-5} per year and for plants with total baseline CDF greater than 10^{-4} per year, small means 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 for the reduction in special treatment requirements to be considered. For plants with total baseline LERF 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 LERF greater than 10^{-5} per year, small LERF increases are considered to be up to 10^{-7} per year. However, if there is an indication that the baseline CDF or LERF may be considerably higher than 10^{-4} or 10^{-5}, respectively, the licensee either must find ways to reduce risk and present the arguments to the NRC staff before implementation of § 50.69, otherwise it is likely that the NRC will deny the § 50.69 application. 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. This means that the allowable potential increase in risk must be determined in a cumulative way for all SSCs being categorized under § 50.69.

Section 50.69 is structured to maintain the design basis functional requirements of the facility. These requirements (that maintain design basis functional requirements) when considered in conjunction with the requirements to provide reasonable confidence that the potential change in risk is small (as previously discussed), also provide reasonable confidence that safety margins are maintained. Specifically, licensees are required to implement processes that provide reasonable confidence that RISC-3 SSCs remain capable of performing their design basis functions and these SSCs must remain capable of performing their design basis function with a reliability that is not significantly degraded to provide reasonable confidence that any increases in CDF or LERF will be acceptably small.

Section 50.69(c)(1)(iv) requires applicants and licensees to perform evaluations to assess the potential impact on risk from changes to treatment. Further, § 50.69(d)(2) requires that the treatment applied to RISC-3 SSCs be consistent with the categorization process. For SSCs modeled in the PRA, the licensee or applicant might conduct a risk sensitivity study that assesses the impact of changes in SSC failure probabilities or reliabilities that might occur due to the revised treatment. For example, a licensee could increase the failure rates of RISC-3 SSCs by appropriate factors to provide insights into the potential changes in risk that might result from reduced treatment (e.g., reduced maintenance, testing, inspection, and quality assurance). For other SSCs, other types of evaluations would be used to provide the basis for concluding that the potential increase in risk would be small. Under § 50.69(b)(2)(iv), a licensee will need to submit its basis supporting the evaluations that estimate the potential change in risk. A licensee is required by § 50.69(b)(2)(iv) to consider potential effects of common-cause interaction susceptibility and potential impacts from known degradation mechanisms.

The rule focuses on common-cause effects because significant increases in common-cause failures could invalidate the evaluations performed to show that any potential change in risk due to implementation of § 50.69 would be small. With respect to known degradation mechanisms, this is an acknowledgment that certain treatment requirements have evolved over time to deal with these 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 needs to provide a basis to conclude that any potential increase in risk that might result from reduced treatment would be small. These requirements are included in § 50.69 so that a licensee has a basis for concluding that the evaluations performed to provide reasonable confidence that only a acceptably small change in risk will result remain valid.

In addition, the rule requires that implementation be performed 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.

The final rule applies treatment requirements to SSCs commensurate with their safety significance.

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 maintains 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. Additionally, § 50.69(d)(1) requires that sufficient treatment be applied to support the credit taken for these SSCs for beyond design basis events. For example, in developing the PRA model, a licensee must determine 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 to be performed may exceed the design basis conditions for the applicable SSCs. Section 50.69(d)(1) requires the treatment applied to RISC-1 and RISC-2 SSCs to be 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 credit for performance of the SSC in the categorization process to reflect actual treatment practices and/or documented performance capability. In addition, § 50.69(e) requires monitoring and adjustment of treatment processes or categorization decisions as needed based upon operational experience.

III.3.2 RISC-3 Treatment.

Section 50.69(d)(2) imposes requirements that are intended to maintain RISC-3 SSC 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 as such, it is important to maintain their design basis functional capability. Maintenance of RISC-3 design basis functionality is important to ensure that defense-in-depth and safety margins are maintained. As a result, § 50.69(d)(2) requires licensees or applicants to have documented 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 their service life.

The rule contains high-level requirements for the treatment of RISC-3 SSCs with respect to design control; procurement; maintenance, inspection, testing, 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 rule. For example, the alternative treatment requirements for RISC-3 SSCs in § 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 individual 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 specifying 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 on these areas.

In devising these requirements, the Commission has focused upon those critical aspects of the various processes that must exist to provide reasonable confidence of performance. Thus, in the design area, for instance, the design conditions under which equipment is expected to perform (e.g., 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 basis functional requirements, even though the special treatment requirements that previously existed are no longer being required.

In implementing the processes required by the 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 their design basis functions and to enable the licensee to take actions to restore equipment performance consistent with corrective action requirements included in the rule.

Effective implementation of the treatment requirements provides reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related 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 individual 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 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 functional requirements of SSCs.

III.3.3 RISC-4 Treatment.

Section § 50.69 does not impose any new treatment requirements on RISC-4 SSCs. Instead, RISC-4 SSCs are simply removed from the scope of any applicable special treatment requirements identified in § 50.69(b)(1). This is justified in view of their low significance considering both safety-related and risk information. Requirements applicable to RISC-4 SSCs not removed by § 50.69(b)(1) continue to apply. 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.

Through the application of § 50.69, RISC-3 and RISC-4 SSCs are removed from the scope of the specific special treatment requirements listed in § 50.69(b)(1). The special treatment requirements were originally imposed to provide a 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 and 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. The Commission concluded that, in light of the low individual safety significance of RISC-3 SSCs, it is unnecessary to have the same high level of assurance that they would perform as designed. This is because some increased likelihood of their individual failure can be tolerated without significant impact to safety. Thus, the Commission decided to remove the RISC-3 and RISC-4 SSCs from those detailed, specific requirements that provided the 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 maintain the design basis functional capability of the RISC-3 SSCs. 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 the SOC of this rule, the Commission concludes that the requirements in § 50.69 will maintain adequate protection of public health and safety if effectively implemented by licensees. 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 removed from the scope of specific special treatment requirements, while in other cases the Commission concluded that only partial removal was appropriate. Finally, there was a set of requirements initially identified as special treatment for which the Commission is not removing RISC-3 and RISC-4 SSCs from their scopes. These requirements are discussed in Section III.4.10.

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 otherwise 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 noncompliance 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 issue regulations defining these terms.

The Commission's regulations implementing Section 206 appear in 10 CFR Part 21 and § 50.55(e) for license holders and construction permit holders, respectively. The Commission established definitions of "basic component," "defect," and "substantial safety hazard" in Part 21 on 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 § 21.3 definition of "basic component," which is similar to the definition of "safety-related" SSCs in § 50.2 (originally embodied in § 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 that 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.

Finally, Part 21 establishes that a licensee or vendor should "immediately report" potential noncompliance or defects to the NRC in a telephonic "notification" (*see* § 21.3) within two (2) days of receipt of information identifying a noncompliance or defect in a basic component (*see* § 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 deviation within five (5) working days of completion of evaluations for determining whether noncompliance or deviation constitutes a substantial safety hazard (see § 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 substitutes 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 § 50.69 and whether changes to Part 21 and/or § 50.55(e) are necessary to ensure proper reporting of substantial safety hazards caused by these SSCs; and (2) the appropriate reporting obligations of licensees and vendors under § 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 § 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 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. 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 so reporting them serves no regulatory purpose. 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 following reasons, 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 if such a safety hazard requires that immediate NRC regulatory action be taken at one or more nuclear power plants 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. This reporting allows a licensee using these 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 that 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 so 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:

(1) that a noncompliance or defect could be incorporated into construction where it could never be detected; and,

(2) 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 § 50.55(e) reporting remain the same regardless of whether the nuclear power plant is operating under the existing, deterministic regulatory system or the 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 substantial 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 so 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 so 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.

RISC-1 SSCs are viewed as being of sufficient safety significance to require Part 21 reporting. 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 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 assure the integrity of the reactor coolant boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the applicable exposure guidelines set forth in § 50.34(a)(1) or §100.11). For example, 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 SSCs 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. The classification might occur because: (1) they contribute to plant risk by initiating transients that could lead to severe accidents (if multiple failures of other mitigating SSCs were to occur); or (2) they can reduce risk by providing backup mitigation to RISC-1 SSCs in response to an event.

The Commission recognizes that 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 SSCs treated as commercial-grade components, which includes the possibility of noncompliances and defects. Because 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 to achieve consistency between their categorization and treatment, performance should, at a minimum, be maintained and in some cases, enhanced. As discussed in Sections III.3 and III.5 of this rule, the Commission is imposing additional regulatory controls on RISC-2 SSCs to prevent their performance from degrading. In addition, the Commission is requiring: 1) that licensees evaluate treatment being applied for consistency with the performance credited in the categorization; 2) monitoring of the performance of these SSCs; 3) corrective actions; and 4) reporting when a loss of a safety significant function occurs. 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 to preclude the need for Part 21 reporting, 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 these RISC-2 SSCs 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 NUREG-1150, 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 categorized as RISC-2 would rise to the level of significance that their failure or lack of functionality would constitute a substantial safety hazard requiring immediate NRC 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 issued as cost-beneficial safety improvements. The Commission believes its conclusion about the relative significance of RISC-2 SSCs is also supported by plant-specific risk studies, such as the Individual Plant Examination (IPE) and Individual Plant Examination of External Events (IPEEE)[2], conducted to identify (and correct) any plant-specific vulnerabilities to severe accident risk. NRC's review of 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 (SAMAs), 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 have been found to be cost-beneficial (and none were considered necessary to provide adequate protection of public health and safety).

In light of risk assessments and actions that have already been implemented, the Commission believes there would be no SSCs categorized under § 50.69 as RISC-2 whose failure would represent a significant and substantial safety hazard so that immediate notification under Part 21 and NRC regulatory 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 also considered if notification of component defects should be required

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[2] 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 (e.g., 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 follow-up activities with owners groups and licensees to confirm that identified improvements have been implemented and if any other actions were warranted.

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 the 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 portion. Further, the suppliers of these components would 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, § 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 Section III.5.

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 substantial safety hazard such that immediate licensee and NRC evaluation of the situation and implementation of 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 concludes 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 exclude RISC-2 SSCs.

The Commission also concludes that RISC-3 SSCs should not be subject to Part 21 and § 50.55(e) reporting. A failure of a properly-categorized RISC-3 SSCs 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, Rev. 1)[3]. As previously discussed, the body of regulatory requirements (i.e., the retained requirements and the requirements contained in this rule) are sufficient, if effectively implemented, so that simultaneous failures in multiple systems (as would be necessary to lead to a substantial safety hazard involving RISC-3 SSCs) would not occur. Further, the broad applicability of information from a single RISC-3 SSC that would be provided under Part 21 and § 50.55(e) reporting would be questionable because of the significant changes in treatment (including design) for RISC-3 SSCs allowed under § 50.69. Accordingly, the Commission concludes that RISC-3 SSCs should not be subject to reporting requirements of Part 21 and § 50.55(e).

The Commission concludes that Part 21 reporting requirements extend only to RISC-1 SSCs because they are important in ensuring public health and safety. RISC-2 SSCs are not subject to reporting because they play a lesser role than RISC-1 SSCs in protection of public health and safety and with the significant changes in treatment allowed under § 50.69, no regulatory purpose would be served by Part 21 reporting (as previously discussed). Individually, 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 its conclusions with respect to RISC-2 and RISC-3 SSCs. The Commission believes this 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

[3]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 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.

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 § 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. Section 50.69 embodies a risk-informed regulatory paradigm that 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 only 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:

(1) Interpreting “basic component” to encompass a risk-informed view of what SSCs the term encompasses; and,

(2) Including a second definition of “basic component” in § 21.3, which would apply only to those portions of a plant that 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 § 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, and 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 who are subject to reporting under Section 206, 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 at 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 that they provided under contract as safety-related are now categorized as RISC-3, thereby removing the vendor's reporting obligation under Part 21 or § 50.55(e). Failing to inform a vendor that a safety-related SSC that 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 § 50.69, the Commission considered including a new requirement in either § 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 that it provided has been categorized as RISC-3. After consideration, the Commission believes that it is unlikely that this 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 nonsafety-related applications. A vendor would have some difficulty in determining whether the problem with the supplied SSC potentially affects the SSC categorized 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 is not adopting 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 ERA 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 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 shutdown the facility and maintain it in a safe shutdown condition; or

(3) The capability to prevent or mitigate the consequences of accidents that could result in an unplanned offsite release of quantities of fission products in excess of the limits established by the Commission.

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 would 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) 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.

Section 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 are removed from the scope of the requirements of § 50.49 by § 50.69(b)(2)(ii). 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 § 50.49 for testing, documentation files and application of margins, are not necessary (for the reasons stated in Section III.4.0). The requirements in 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) removes 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.

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 rulemaking, RISC-3 SSCs are removed from the scope of these requirements and instead are 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 contain 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 Code required by § 50.55a(g) for ASME Class 1 SSCs, even if they are 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 Class 3 SSCs that are shown to be of low safety significance and categorized as RISC-3, the additional assurance obtained from the specific provisions of the ASME Code is not considered necessary. However, the Commission has not removed the requirements for fracture toughness specified for ASME Class 2 and Class 3 SSCs because fracture toughness is a significant design parameter for the material used to construct the SSC. Fracture toughness is a property of the material that prevents premature failure of an SSC at abrupt geometry changes, or at small undetected flaws. Adequate fracture toughness of SSCs is necessary to prevent common cause failures due to design basis events, such as earthquakes.

Section 50.55a(h) incorporates by reference the requirements in either 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.

III.4.4 Section 50.65 Monitoring the Effectiveness of Maintenance.

The Commission is removing RISC-3 and RISC-4 SSCs from the scope of the requirements of § 50.65 (except for paragraph (a)(4)). The basis for this removal is provided in Section III.4.0 and the following discussion.

Section 50.65, 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 either be monitored against licensee established goals in a manner sufficient to provide confidence that the SSCs are capable of fulfilling their intended functions, or demonstrated to be effectively controlled through the performance of appropriate preventative maintenance. 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 action requirements; thus, they are special treatment requirements. Upon implementation of § 50.69, a licensee is not 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 rule includes provisions for a licensee to use performance information to feedback into its processes to adjust treatment (or categorization) when results so indicate in

§ 50.69(e)(3). However, this requirement does not require the specific monitoring and goal setting as required in § 50.65, in consideration of the lower safety significance of these SSCs.

RISC-1 and RISC-2 SSCs that are currently within the scope of § 50.65(b) remain subject to existing maintenance rule requirements. Furthermore, § 50.69(e)(2) requires additional monitoring, evaluation and appropriate action for these SSCs.

The removal of RISC-3 and RISC-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 maintenance activities. The requirements in § 50.65(a)(4) remain in effect. Section 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 SSC safety-significance.

III.4.5 Sections 50.72 and 50.73 Reporting Requirements.

This rule removes the requirements in § 50.72 and § 50.73 for RISC-3 and RISC-4 SSCs. Sections 50.72 and 50.73 contain requirements for licensees to report events involving certain SSCs. These reporting requirements are special treatment requirements. The NRC requires event reports in part so that it can follow-up on corrective action for these circumstances. Through this rulemaking, the Commission is removing RISC-3 and RISC-4 SSCs from the scope of these requirements. The broad applicability of information obtained under § 50.72 and § 50.73 for RISC-3 SSCs would be questionable because of the significant changes in treatment allowed under § 50.69 (see the similar discussion for Part 21 in Section III.4.1.1). Therefore, the Commission does not consider the burden associated with reporting events or conditions only affecting these SSCs to be warranted.

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

This rule removes RISC-3 and RISC-4 SSCs from the scope of requirements in

Appendix B to 10 CFR Part 50. 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 more appropriate 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 specify 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 to 10 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 be applied 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 individual 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.

Section 50.69(b)(1)(x) removes a subset of RISC-3 and RISC-4 SSCs from the scope of the requirements in Appendix J to 10 CFR Part 50 that pertain to containment leakage testing. Specifically, RISC-3 and RISC-4 SSCs that meet specified criteria in § 50.69(b)(1)(x) are removed from the scope of the requirements for Type B and Type C testing. It is important to note that this removes only the Appendix J leakage testing requirements from these SSCs. These SSCs must still be capable of performing their design basis functions (i.e., to close or isolate containment). The basis for the removal of the Appendix J leakage testing requirements follows.

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 Part 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 that 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:

(1) 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

(2) 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 requirements of Appendix J.

The discussion contained in Appendix J to 10 CFR Part 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.

Although the 1995 revision to Appendix J was characterized as risk-informed, the changes were not as extensive as those expected by inclusion of Appendix J within the scope of § 50.69. The 1995 revision to Appendix J primarily decreased testing frequencies, whereas risk-informing the scope of SSCs that are subject to Appendix J testing removes some components from testing (i.e., to the extent that defense-in-depth is maintained in accordance with the risk-informed categorization process).

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 (CIV) 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 is not changing the Type A testing requirements of Appendix J.

Type B Testing: The Commission is not changing the Type B testing requirements for air lock door seals, including door operating mechanism penetrations that are part of the containment pressure boundary and doors with resilient seals or gaskets, except for seal-welded doors. However, the Commission concludes that 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 are 1 inch nominal size or less.

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 is not connected to the reactor coolant pressure boundary.
4. The valve size is 1-inch nominal pipe size or less.

The Commission has made a determination that the size specified in § 50.69(b)(x) and identified above is acceptable. At this time, the NRC has not determined that a larger size is acceptable for application to § 50.69, nor has the NRC received a such a proposal. At this time, for the Commission to entertain a larger penetration/CIV size, and subsequently revise the rule language to reflect any such review (assuming that such as size is acceptable) would likely cause the NRC to re-notice § 50.69 for stakeholder comment. Licensees and applicants are free to pursue exemptions (to § 50.69(b)(x)) to this criteria if they conclude a larger penetration opening can be justified for their containment design. If such a proposal is ultimately reviewed and accepted, and can be applied generically, the NRC will consider a revision to § 50.69 to reflect the new criteria.

III.4.7.3 Basis for Reduction of Scope.

The first category of penetrations which are excluded from Type B testing are penetrations that are pressurized with the pressures in the penetrations being continuously monitored by licensees. This monitoring would detect significant leakage from the penetrations. The monitoring of the pressures in the penetrations, in conjunction with the requirements for

RISC-3 SSCs (including taking corrective action when an SSC fails), provide reasonable confidence, without the need for Type B testing to ensure that these penetrations are functional.

The second category of penetrations excluded from Type B testing are penetrations that are 1 inch nominal size or less. These penetrations do not contribute to large early releases. Accordingly, the failure of such penetrations does not contribute in a significant way to safety or increased risk. The Commission concludes that such penetrations will not be subject to Type B testing.

Regarding Type C containment leakage testing, the Commission finds that for the four categories of containment isolation valves identified in § 50.69(b)(1)(x), the removal of Type C testing requirements is reasonable because even without Type C testing, the probability of significant leakage during an accident (i.e., leakage to the extent that public health and safety is affected) is small.

Appendix J to 10 CFR Part 50 deals only with leakage rate testing of the primary reactor containment and its penetrations. It assumes that CIVs are in their safe position. No failure is assumed that causes the CIVs 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, it is assumed that an open valve is capable of being closed. The licensee or applicant implementing § 50.69 must apply treatment to RISC-3 CIVs that provides reasonable confidence that those valves are capable of performing their safety-related function to close under design basis conditions. Testing to ensure the capability of CIVs 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 these SSCs being removed from the scope of Appendix J requirements is negligible.

The acceptability of the removal of Appendix J leakage testing for the RISC-3 CIVs is based on the assumption that those valves are capable of achieving the full seated position by means of the actuator. Therefore, even though a RISC-3 CIV might be exempt from Appendix J leakage testing, the RISC-3 CIV must meet the treatment requirements in § 50.69(d) to provide reasonable confidence that the CIV can perform its safety function (e.g., to close) under design basis conditions. Because it is likely that most CIVs will be categorized as RISC-3, the licensee or applicant must evaluate the proposed change in the treatment of RISC-3 CIVs to ensure that defense-in-depth is maintained by providing reasonable confidence that the RISC-3 CIVs are capable of performing their safety-related functions under design basis conditions. Although the licensee or applicant is allowed flexibility in addressing this issue, the rule requires that the licensee or applicant have reasonable confidence in the capability of RISC-3 CIVs to perform their safety functions to maintain defense-in-depth as discussed in RG 1.174.

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 the effect of containment leakage on risk in more detail 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 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 that 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 valve may remain leak-tight. The study assumed that failure of one valve in a series failed the penetration. Therefore, the probability of a penetration leak is overestimated.
3. The analysis assumed possible leakage of all valves subject to Type C testing, not just those subject to the relief per § 50.69.

According to this analysis, the removal of SSCs from the scope of Appendix J requirements does 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 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)).

Section 50.69(b)(1)(xi) removes RISC-3 and RISC-4 SSCs from the requirement in Appendix A to 10 CFR 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 Appendix A addresses seismic and geologic siting criteria used by the Commission to evaluate the suitability of plant design bases considering 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. Section 50.69 excludes 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 requirements. As discussed in Section III.4.0 of this rulemaking, because of the low individual safety significance of the RISC-3 and RISC-4 SSCs, the additional assurance provided by qualification testing (or specific methods of analysis) is not considered necessary.

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

III.4.9 Section 50.46a(b) Appendix B Requirements for Reactor Coolant System Vents.

The Commission established new requirements for combustible gas control in § 50.44 using risk insights and issued the revised rule on September 16, 2003 (68 FR 54123). As part of the § 50.44 rulemaking, portions of the old § 50.44 were relocated to more appropriate regulations. In particular, requirements formerly located in § 50.44 were relocated to § 50.46a(b) concerning the design of vents and associated controls, instruments, and power sources and the need for these components to conform to 10 CFR Part 50 Appendix B. This rule removes RISC-3 SSCs from the scope of Appendix B quality assurance requirements, as discussed in Section III.4.6. These same arguments apply to the requirements in § 50.46a(b) where Appendix B is being imposed on a specific set of components. As such, this rule removes the RISC-3 and RISC-4 SSCs from the scope of Appendix B requirements contained in § 50.46a(b). This applies only to the requirements relating to Appendix B in § 50.46a(b); the remaining requirements of § 50.46a remain unchanged.

III.4.10 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 stated.

III.4.10.1 Section 50.34 Contents of Applications.

Section 50.34 identifies the required information that applicants must provide in preliminary and final safety analysis reports. Because § 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.4.10.2 Section 50.36 Technical Specifications.

Section 50.36 establishes operability, surveillance, limiting conditions for operation and other requirements on certain SSCs. Because this rule specifies testing and related requirements, it was considered as a candidate special treatment rule. However, the Commission concluded that it was not appropriate to revise § 50.36 for several reasons.

Currently, the NRC staff and the industry are developing risk-informed improvements to technical specifications. These improvements, or initiatives, are intended to maintain or improve safety while reducing unnecessary burden, and to bring technical specifications into congruence with the Commission's other risk-informed regulatory requirements, in particular risk management requirements of the Maintenance Rule in 10 CFR 50.65(a)(4). Eight initiatives for fundamental improvements to the Standard Technical Specifications (TS) have been proposed. Two of the initiatives have been approved and offered to licensees for adoption, and six are being developed by the industry and NRC staff. All of the initiatives involve, to some prescribed degree, assessing and managing plant risk using a configuration risk management program consistent with and in some cases exceeding the requirements of the Maintenance Rule in 10 CFR 50.65. The two approved initiatives involve: permitting the extension of up to one surveillance interval of an inadvertently missed surveillance; and, permitting plant mode transitions with inoperable equipment, anticipating the imminent return of the equipment to operability. The six initiatives under development involve: shutting down to hot shutdown rather than cold shutdown to repair equipment; permitting the temporary extension of allowed outage times; permitting the determination of surveillance frequencies through the use of an approved methodology; permitting time to restore equipment operability rather than immediately shutting down; providing extended time to restore support systems to operability; and, revising the scope of technical specifications to include only on risk significant systems, which would require rulemaking.

Improved standard TSs have already resulted in the relocation of requirements for less important SSCs to other documents. Given the ongoing regulatory efforts to risk-inform the TSs, it was not considered necessary to scope § 50.36 into § 50.69 as a special treatment requirement.

III.4.10.3 Section 50.44 Combustible Gas Control.

During the effort to identify candidate special treatment rules (refer to SECY-99-256), 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. For proposed § 50.69, the Commission elected not to identify § 50.44 as a special treatment rule, and instead decided to wait on the outcome of the effort to risk inform § 50.44. The Commission subsequently rebaselined the requirements in § 50.44 using risk insights and issued the revised rule on September 16, 2003 (68 FR 54123). As a result, the NRC concludes that there is no need to include § 50.44 within the scope of § 50.69. However, as part of the September 16, 2003, rulemaking, portions of the old § 50.44 were relocated to more appropriate regulations. In particular, requirements were relocated to § 50.46a(b) concerning the design of vents and associated controls, instruments, and power sources and the need for these components to conform to 10 CFR Part 50 Appendix B. Because this aspect of the relocated requirements is a special treatment requirement (and this same requirement was also identified in the old § 50.44 as being a special treatment requirement) it is now captured within the scope of § 50.69(b)(1) as discussed in Section III.4.9.

III.4.10.4 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 Commission's regulations and therefore a revision to the rules (i.e., to scope them into § 50.69) is not required to support a change (i.e., changes to these requirements can be made without a revision to the rules). Additionally, the Commission is considering a final rule that would allow licensees to voluntarily adopt National Fire Protection Association (NFPA)-805 requirements in lieu of other fire protection requirements. NFPA-805 sets forth requirements for establishing and implementing a risk-informed fire protection program. Inasmuch as the NRC is addressing fire protection in another rulemaking, fire protection requirements were not included in the scope of the § 50.69 rulemaking.

III.4.10.5 Section 50.59 Changes, Tests, and Experiments.

There is no change is being made to § 50.59 as a result of § 50.69, however, the Commission does not believe that a § 50.59 evaluation need be performed when a licensee implements § 50.69 and thereby changes the special treatment requirements applied to RISC-3 and RISC-4 SSCs. Accordingly, § 50.69(f) contains language that removes the requirement for licensees to perform § 50.59 evaluations for the changes in special treatment that stem from § 50.69 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 categorization and determination of revision to requirements resulting from the categorization. Because 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 applies. As required by § 50.69(f), the licensee or 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 may 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 non-treatment portion of the design basis of SSCs.

III.4.10.6 Appendix A to 10 CFR 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 non-treatment portion of 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.2.0).

III.4.10.7 10 CFR Part 52 Early Site Permits, Standard Design Certifications and Combined Operating Licenses.

Part 52 cross-references 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 this rulemaking effort. However, the "applicability" paragraph (§ 50.69(b)) makes clear that § 50.69 is available to applicants for, and holders of a facility license. Accordingly, there is no need to revise Part 52 to assure the availability of § 50.69. There are issues associated with Part 52 design certifications and these are currently excluded from the group of entities who may adopt the provisions of 50.69 as discussed in Section V.3.0.

III.4.10.8 10 CFR Part 54 License Renewal.

10 CFR Part 54, which sets forth the license renewal requirements for nuclear power reactors, was identified as a candidate special treatment requirement in SECY-99-256. The Part 54 aging management requirements are 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 licenses 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 before 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 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" (May 8, 1995; 60 FR 22471). Although § 50.69 removes 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 § 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 (May 8, 1995; 60 FR 22468).

III.4.10.9 Other Requirements.

In the ANPR and related documents, the NRC 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.

III.5.0 Feedback, Documentation, and Reporting Requirements.

The validity of the categorization process relies on ensuring that the performance and condition of SSCs continue 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 credited in the categorization process. Additionally, plant changes, changes to operational practices, and plant and industry operational experience may impact categorization process results. Consequently, the 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 rule requires licensees to review the changes to the plant, operational practices, applicable plant and industry operational experience, and, as appropriate, update the PRA and SSC categorization. The review must be performed in a timely manner but no longer than once every two refueling outages. In addition, licensees are 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 need to ensure that sufficient information is obtained. For RISC-3 SSCs, there is a relaxation of the requirements for obtaining information when compared to the applicable special treatment requirements. However, sufficient information still needs to be obtained. The rule requires considering performance data, determining if adverse changes in performance have occurred, and making the necessary adjustments so 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 § 50.69. For safety significant SSCs, all current requirements continue to apply and, as a consequence, Appendix B corrective action requirements are applied to the design basis aspects of RISC-1 SSCs to ensure that conditions adverse to quality are corrected. For both RISC-1 and RISC-2 SSCs, requirements are 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 rule requires that a licensee perform timely corrective action (§ 50.69(d)(2)(iv)). Further, as part of the feedback process, the review of operational data may reveal inappropriate credit 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 process and would also restore the capability of the SSCs to perform their functions.

Section 50.69(f) requires the licensee or applicant to document the basis for its categorization of SSCs before removing special treatment requirements. Section 50.69(f) also requires the licensee or applicant to update the final safety analysis report to reflect which systems have been categorized. Section 50.69(d)(2) also includes requirements for documenting the processes established for the treatment of RISC-3 SSCs.

Finally, § 50.69(g) requires reporting of events or conditions that prevented, or would have prevented, a RISC-1 or RISC-2 SSC from performing a safety significant function. Because the categorization process has determined that RISC-2 SSCs are of safety significance, NRC is interested in reports about circumstances where a safety significant function was, or 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, so that NRC can take any actions deemed appropriate.

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

III.6.0 Implementation Process Requirements.

The Commission is making the provisions of § 50.69 available to both applicants for licenses and to holders of facility licenses for light-water reactors. The rule is limited to light-water reactors because the Commission does not yet have substantial experience or information sufficient to develop risk-informed requirements applicable to non-light water reactors. Consequently, the technical aspects of the rule (e.g., providing reasonable confidence that risk increases are small), including the implementation guidance, are specific to light-water reactor designs.

Section 50.69 relies on a robust categorization process to provide reasonable confidence that the safety significance of SSCs is correctly determined. To ensure a robust categorization is employed, § 50.69 requires the categorization process to be reviewed and approved by the NRC before implementation of § 50.69 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 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 industry peer review results. The NRC staff will also review other evaluations and approaches that may be used, such as margins-type analyses, as well as examine any aspects of the proposed categorization process that are not consistent with the NRC's regulatory guidance for implementing § 50.69. Thus, the rule requires 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 industry peer review process employed. An applicant would submit this information as part of its license application. The NRC 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.

NEI submitted a paper, "License Amendments: Analysis of Statutory and Legal Requirements" (NEI Analysis) in a July 10, 2002, letter to the Director of the Office of Nuclear Reactor Regulation (NRR). 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 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 § 50.69 permits 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 § 50.69 is analogous to the review and approval process in *Cleveland Electric Illuminating Co.* (Perry Nuclear Power Plant, Unit 1), CLI-96-13, 44 NRC 315 (1996), 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 ASTM standard set forth objective, non-discretionary criteria for changes to the withdrawal schedule, § 50.69 does not contain these criteria for assessing the adequacy of the categorization process, PRA peer review results, and the basis for sensitivity studies. Hence, the NRC’s approval of a request to implement § 50.69 will involve substantial professional judgment and discretion. 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 is 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 § 50.69 to contain requirements that ensure the categorization process is sufficiently robust to provide reasonable 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 individual low safety significance; and requirements for obtaining information concerning the performance of these SSCs to help 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 included requirements in the rule for documenting categorization decisions to facilitate NRC oversight of a licensee's or applicant's implementation of the alternative requirements. The rule also includes 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 a 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 SSCs, in accordance with the rule requirements contained in § 50.69, the Commission concludes that requiring further review if NRC approval might be required for these changes is an unnecessary burden. Thus, a licensee is 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 non-treatment portion of the design basis.

III.7.0 Adequate Protection.

The Commission concludes that § 50.69 provides reasonable assurance of adequate protection of public health and safety because the principles listed below were used in the development of § 50.69 and because these principles will continue to be employed in the NRC's continuing regulatory oversight of § 50.69 implementation. Those principles are:

(a) Reasonable confidence that the net increase in plant risk is small;

(b) Defense-in-depth is maintained;

(c) Reasonable confidence that safety margins are maintained; and

(d) Monitoring and performance assessment strategies are used.

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. Section 50.69 was developed to incorporate these principles, both to ensure consistency with Commission policy, and to ensure that the rule maintains adequate protection of public health and safety.

The following discusses how § 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.

Section 50.69(c) 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 NRC review and approval of the licensee's 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 individual safety significance and that these requirements continue to be satisfied for SSCs of safety significance. The rule requires that the potential net increase in risk from implementation of § 50.69 be assessed and that reasonable confidence be provided that this risk change is small. These requirements to provide reasonable confidence that the net change in risk is acceptably small as part of the categorization decision, in conjunction with the 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 NRC has considered to be appropriate as discussed in the RG 1.174 acceptance guidelines. 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 (c)(1)(iii) requires that defense-in-depth be maintained as part of the categorization requirements of § 50.69(c)(1) and as a result, defense-in-depth is considered explicitly in the categorization process. Thus, SSCs that otherwise might be considered low safety significant, but are important to defense-in-depth as discussed in the implementation guidance, will be categorized as safety significant (and will remain subject to special treatment requirements). For safety significant SSCs (i.e., RISC-1 and RISC-2 SSCs), all current special treatment requirements remain (i.e., the rule does not remove any of these requirements) to provide high confidence that they can perform design basis functions. Additionally, § 50.69(d)(1) requires sufficient treatment be applied to support the credit taken for these SSCs for beyond design basis events. For RISC-3 SSCs, § 50.69 imposes 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 defense-in-depth will continue to be available and capable of performing the functions necessary to support defense-in-depth. The rule does not change the design basis functional requirements of the facility, which were established based upon defense-in-depth considerations. Accordingly, the Commission concludes that § 50.69 maintains defense-in-depth.

III.7.3. Safety Margins are Maintained.

Section 50.69(c)(1)(iv) requires that evaluations be performed that provide reasonable confidence that sufficient safety margins are maintained. This is provided by a combination of:

(1) Maintaining all existing functional and treatment requirements on RISC-1 and RISC-2 SSCs and additionally ensuring, through the application of sufficient treatment and feedback requirements, that any credit for these SSCs for beyond design basis conditions is valid and maintained;

(2) Maintaining the design basis functional requirements of the facility for all SSCs, including RISC-3 SSCs as described in Section III.7.2; and

(3) Requiring a licensee to have reasonable confidence that the overall increase in risk that may result due to implementation of § 50.69 is small.

Maintaining all current requirements on RISC-1 and RISC-2 SSCs and requiring sufficient treatment be applied to support the credit taken for these SSCs for beyond design basis events provides assurance that the safety significant SSCs continue to perform as credited in the categorization process. Maintaining design basis functional requirements for RISC-3 SSCs ensures that these SSCs continue to be designed to criteria that enable them to perform their design basis functions. The reduction in treatment applied to RISC-3 SSCs results in an increased level of uncertainty concerning the functionality of RISC-3 SSCs. This reduction in treatment may result in an increase in RISC-3 SSC failure rates (i.e., a reduction in RISC-3 SSC reliability). To address this possibility and its relationship to safety margin, § 50.69 requires that there be reasonable confidence that any potential increases in CDF and LERF that might stem from changes in RISC-3 SSC reliability due to reduced treatment permitted by § 50.69, be small. As discussed in Section III.7.4, the rule requires (through monitoring requirements) that the SSCs must be maintained so that they continue to be capable of performing their design basis functions. For these reasons, the Commission concludes that § 50.69 maintains sufficient safety margins.

III.7.4 Monitoring and Performance Assessment Strategies are Used.

Section 50.69(e) contains requirements that ensure that the risk-informed categorization and treatment processes are updated and maintained over time. Data that reflect operational practices, the facility configuration, plant and industry experience, and SSC performance are required to be fed back into the PRA and the categorization process on a periodic basis and when appropriate, adjustments to the categorization and/or treatment processes are required to maintain the validity of these processes. In addition, § 50.69(g) contains requirements that reports are made to NRC of conditions preventing RISC-1 and RISC-2 SSCs from performing their safety significant functions. Together, these requirements maintain the validity of the risk-informed categorization and treatment processes so that the above criteria will continue to be satisfied over the life of the facility.

III.7.5 Summary and Conclusions.

Section § 50.69 contains requirements that:

1. Provide reasonable confidence that any net risk increase from implementation of its requirements is small;

2. Maintain defense-in-depth;

3. Provide reasonable confidence that safety margins are maintained; and

4. Require the use of monitoring and performance assessment strategies.

Together, these requirements result in a rule that is consistent with the Commission's policy on the use of PRA and, more importantly, maintains adequate protection of public health and safety.

IV. Pilot Activities

IV.1.0 Pilot plants.

To aid in the development of the 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. There were two separate pilot efforts. The first pilot effort focused on the categorization guidance and IDP performance. This effort is discussed in Section IV.1.1 Categorization Pilot. The second pilot effort is ongoing and is focused on the § 50.69 submittal and its review. This pilot effort is discussed in Section IV.1.2 Submittal Pilot.

IV.1.1 Categorization Pilot.

The categorization 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 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 NRC staff developed and issued a trip report containing the its 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 documenting IDP decisions and the basis for them. 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. On the basis of the pilot experience, NRC adjusted its approach to safety 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 industry implementation guidance provided in NEI 00-04 were noted. For example, two areas for improvement were the 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 due to considerations such 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 (discussed in Section VI).

IV.1.2 Submittal Pilot.

The submittal pilot effort is a currently ongoing effort that focuses on the § 50.69 submittal and the NRC staff's review and approval of that submittal. This pilot effort is supported by the Westinghouse Owners Group with lead plants Wolf Creek and Surry. The objectives of this pilot effort are to:

- Enable the staff to develop reviewer guidance for review and approval of the § 50.69 submittal.
- To acquire experience with the use of RG 1.201 and use this experience to improve the guidance and address the technical interpretation/implementation issues identified in RG 1.201.
- Enable industry to develop (beyond RG 1.201/NEI 00-04) the specific information that will be required for a license amendment submittal that will be submitted for prior staff review and approval for implementing § 50.69.

The NRC staff will use the results of this pilot effort to improve RG 1.201 and to develop the reviewer guidance for § 50.69 submittals. Industry expects to use the results of the pilot to develop a template for a § 50.69 license amendment submittal.

IV.2.0 South Texas Exemption as Proof of Concept.

A major element of the rulemaking plan described in SECY-99-256 was the review of the 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 non-risk significant. The scope of the exemptions requested included only those safety-related SSCs that have been categorized as low safety significant or as non-risk 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 NRC 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 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)(ADAMS accession number ML003761558), 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 (ADAMS accession number ML011560317), 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 § 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 § 50.69, the NRC continues to require a robust categorization with a detailed staff review.

The rule specifies the requirement that the licensee provide reasonable confidence in functionality and further specifies some high-level requirements for SSC treatment. Under § 50.69, the NRC will not review and approve licensee's RISC-3 treatment programs. Licensees will have to establish appropriate performance-based SSC treatment processes to maintain the validity of the categorization process and its results. The rule requires 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 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. Because 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 XII 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.” RISC-1 SSCs are safety-related SSCs (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 determined to be safety significant. RISC-3 SSCs are safety-related SSCs that are determined to be low safety significant on an individual basis. Finally, RISC-4 SSCs are SSCs that are not safety-related and that are determined to be 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 have more safety significance 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, that includes the consideration of risk, as opposed to characterizing the outcome as purely "risk-significance."

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 RG 1.201, "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 50.69(b) may be voluntarily implemented by:

(1) A holder of a license to operate a light water reactor (LWR) nuclear power plant under this part;

(2) Holders of Part 54 renewed LWR licenses;

(3) An applicant for a construction permit or operating license under this part; and

(4) An applicant for a design approval, a combined license, or manufacturing license under Part 52 of this chapter.

For current licensees, implementation will be through a license amendment as set forth in § 50.90. This review and approval of the categorization process is a one-time process approval (i.e., the approval is not restricted to a set of systems or structures, and instead can be applied to any system or structure in the plant). The licensee is not required to come back to the NRC for review of the categorization process provided they remain within the scope of the NRC's safety evaluation. Until the request is approved, a licensee is free to develop (at their own risk) the § 50.69 processes and perform the § 50.69 categorization. However, they must continue to follow existing requirements until approval. Upon approval of the categorization process, the licensee can implement the results of the categorization process including the revised § 50.69 treatment 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. 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 believes 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.

In the development of § 50.69, questions were considered regarding the impact to licensees that implement § 50.69 and subsequently 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.

Adopting § 50.69 requirements for an applicant for a construction permit or operating license under this part requires that the applicant first design the facility to meet the current Part 50 requirements. Specifically, to use the § 50.69 requirements requires that SSCs first be classified into the traditional safety-related and nonsafety-related classifications. This establishes the design basis functional requirements for the facility, which as previously stated, § 50.69 is not changing. Once the SSC categorization has been done consistent with the safety-related definition in § 50.2, then § 50.69 can be used to categorize SSCs into RISC-1, RISC-2, RISC-3, and RISC-4 and the alternative treatment requirements of § 50.69 implemented. A new applicant who chooses to adopt the § 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 § 50.69 requirements before initial plant operation.

An applicant for a design approval, a combined license, or manufacturing license under Part 52 of this chapter may adopt § 50.69 requirements. An applicant for a design approval, or manufacturing license would follow a process very similar (from the standpoint of § 50.69) to that described above for an applicant for a construction permit or operating license under Part 50 (i.e., SSCs must first be classified into the traditional safety-related and nonsafety-related classifications which establishes the design basis functional requirements for the facility and then § 50.69 can be used to categorize SSCs into RISC-1, RISC-2, RISC-3, and RISC-4). Because § 50.69 includes elements of procurement and installation, as well as inservice activities, implementation of the rule by a holder of a manufacturing license or by a Part 52 applicant that references such a design would place restrictions on 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.

An applicant for a Part 52 combined license can apply § 50.69 to a referenced design certification that did not comply with § 50.69 provided the design is a LWR design that used the safety-related definition in § 50.2. An applicant who references a certified design and wishes to implement § 50.69 would include the specified information in § 50.69(b)(2) as part of its application for a license. This does not mean that an applicant would actually construct the facility per all Parts 50 and 100 requirements first, before applying § 50.69. Instead, the facility needs to be designed per these requirements, but following approval of the application request under § 50.69(b)(4), RISC-3 SSCs could be procured per the requirements of § 50.69(d).

The final rule excludes applicants for standard design certifications from the group of entities who may take advantage of the provisions of § 50.69. In considering whether to extend the applicability of § 50.69 to design certifications, the Commission identified a number of difficult issues which would have to be resolved to support such an extension. For example, it is unclear whether the dynamic process of recategorizing SSCs under § 50.69 would be inconsistent with the special change restrictions in § 52.63(a), thereby requiring the inclusion of a special change provision in the individual design certification rule. Inasmuch as the proposed rule did not include a provision that would have allowed design certification applicants to use § 50.69, the NRC has not had the benefit of the views of the industry and the public on these issues. Moreover, the industry has not expressed any interest in submitting a design certification using the principles of § 50.69. Accordingly, the final rule not address the issue of applying § 50.69 to new design certifications; issues associated with the application of § 50.69 to design certification rulemaking can be addressed on a case-by-case basis as necessary. In the future, the Commission could initiate rulemaking to extend § 50.69 to new design certifications after the NRC has had some experience in this area. For much the same reasons, the rule does not provide a process for changing an existing design certification rule to voluntarily comply with § 50.69. In addition, a rulemaking would be necessary to change an existing certified design (see Section VIII of Appendix A to 10 CFR Part 52), and it is unlikely that such a change would satisfy the requirements of § 52.63(a)(1). A request for a generic change to adopt § 50.69 would not meet the special backfit requirements of Section VIII. Therefore, the NRC would not review the request. Additionally, the NRC would not want to expend resources reviewing changes to designs that may not be referenced. However, applicants for COLs that reference a certified design could adopt § 50.69 and the rule provides for that approach.

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 applicable only to light-water reactor designs.

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) 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 regulatory requirement (or portions thereof) removed by this rulemaking is listed in a separate item, numbered from § 50.69(b)(1)(i) through (b)(1)(xi). The basis for removal of these requirements was discussed in Section III.4. 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, provide reasonable confidence that RISC-3 SSCs will 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 the NRC approves the categorization process and 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.

Section 50.69(b)(2) requires a licensee who voluntarily seeks to implement § 50.69 to submit an application for a license amendment under § 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 must 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 RG 1.201 which endorses NEI 00-04, with some conditions and exceptions. If a licensee or applicant wishes to use a different approach, the submittal must provide a 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 § 50.69. The measures described 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 that is described in Section VI. The licensee or applicant must 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 is required to include information about the evaluations they intend to conduct to provide reasonable confidence that the potential increase in risk would be small. This includes any risk sensitivity study for RISC-3 SSCs, including the basis for whatever change in reliability is being assumed for these analyses. A licensee must provide sufficient information to the NRC, describing the risk sensitivity study and other evaluations and the basis for their acceptability as appropriately representing the potential increase in risk from implementation of the requirements in this rule.

RISC-3 SSCs are defined as having low individual safety significance under § 50.69. Licensees and applicants must implement effective treatment processes to maintain RISC-3 SSC functionality as required by § 50.69(d)(2). Those processes do not need to be described to the NRC as part of the § 50.69 submittal as provided in § 50.69(b)(2).

V.3.3 Section 50.69 (b)(3) Approval for Licensees.

Section 50.69(b)(3) provides that the Commission will approve a licensee's implementation of this section by license amendment if it determines 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. The NRC will also 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 VI) for this purpose. The NRC will approve the licensee's use of § 50.69 by issuing a license amendment.

V.3.4 Section 50.69(b)(4) Process for Applicants.

Section 50.69(b)(4) requires that an applicant for a license, standard design approval, or manufacturing license that chooses to implement § 50.69 must submit the information listed in § 50.69(b)(2) as part of its application. 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. This 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 are met, as part of its action on the application.

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

Section 50.69(c) establishes 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) respectively) that discusses how their proposed categorization process, supporting PRA, and evaluations meet the § 50.69(c) requirements. As described in Section III.2.0, these requirements are intended to ensure that the risk-informed § 50.69 categorization process determines the appropriate safety significance of SSCs with high confidence. The introductory paragraph of § 50.69(c) states that SSCs must be categorized as RISC-1, RISC-2, RISC-3, or RISC-4 by a process that determines 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. Section V.4.1.1 discusses these requirements in more detail. 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 § 50.69(c)(1)(ii), initiating events from sources both internal and external to the plant and for all modes of operation, including 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 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 has sufficient detail to support the 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 prepared a regulatory guide (RG 1.200) 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 will rely on 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 both of which are (or will be) documented in RG 1.200. As discussed in Section VI, NRC has also developed review guidelines for considering the sufficiency of a PRA that was subjected to the NEI peer review process for this application in § 50.69. This guidance was developed based on an earlier draft version of NEI 00-04 and could be useful in ensuring the adequacy of the PRA for this application. The submittal requirements listed in § 50.69(b)(2) include a requirement to provide information about the quality of the PRA analysis and other supporting analyses and about the peer review results.

V.4.1.2 Risk Categorization Process Based on PRA Information.

For SSCs modeled in the PRA, the typical 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 methods to identify safety significance of SSCs using a PRA, for example, in the implementation of § 50.65). 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 is effectively determined (see § 50.69(c)(1)(iv)) based on both CDF and LERF. Importance measures should be chosen so that the IDP can be provided 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 guidelines 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. In addition, the appropriateness of the importance measures in specifically addressing SSC CCF contributions and associated screening criteria should be considered. 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 safety significance 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 determination of SSC safety significance should take into account the 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) events.

Because importance measures are typically evaluated on the basis of individual events, 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 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 credited 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 and used, the importance measures should be evaluated for each analysis separately and collectively, and the results of these evaluations 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. The following should be considered in IDP deliberations on the sensitivity study results:

(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. Because importance measures are not available for use as screening, other criteria or considerations must be used by the IDP to determine the significance. Guidance on how these deliberations should be conducted is included in the NRC regulatory guidance associated with this rule, and in the industry guidance .

Section 50.69 (c)(1)(ii) requires 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, "reasonably reflect," was selected to allow for appropriate PRA modeling and also to make clear that the PRA and categorization 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.4.3 Section 50.69(c)(1)(iii) Maintaining Defense-in-Depth.

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

! 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 defense-in-depth (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. Where a licensee categorizes containment isolation valves or penetrations as RISC-3, the licensee should address the impact of the change in treatment to ensure that defense-in-depth continues to be satisfied. Where the impact of changes in treatment does not support the reliability assumptions in the categorization process, the licensee should resolve this situation by adjustments to the categorization process assumptions or treatment of the component.

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 SSCs, 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 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 acceptably small are discussed below.

As part of their submittal, a licensee or applicant is to describe the evaluations to be conducted for purposes of providing reasonable confidence that there would be no more than an acceptably small (potential) increase in risk. For SSCs included in the PRA, the Commission expects a risk sensitivity study (evaluation) to be performed to provide a basis for concluding that if the reliability of these RISC-3 SSCs should collectively degrade because of the changes in treatment, the potential risk increase would be small. Satisfying the rule requirement that the risk increase is acceptably small presumes that the increase in failure rates credited in the PRA risk sensitivity study bounds any reasonable estimate of the increase that may be expected as a result of the changes in treatment; also considering the feedback and corrective action aspects of the rule.

The categorization process encompasses both active and passive functions of SSCs. Section 50.69(b)(2)(iv) includes the requirement that the change-in-risk evaluations performed to satisfy § 50.69(c)(1)(iv) must address potential impacts from known degradation mechanisms on both active and passive functions. The manner of addressing these potential impacts may be either qualitative or quantitative and may rely on the maintenance of current programs that address these degradation mechanisms (e.g., microbiologically-induced corrosion, flow-assisted corrosion) and/or may incorporate existing risk-informed approaches (e.g., risk-informed inservice inspection).

One mechanism that could lead to large increases in CDF/LERF is extensive, across system common cause failures. These CCFs could occur where the mechanisms that lead to failure, in the absence of special treatment, are 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; while also considering the feedback and corrective actions aspects of the rule.

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.

The treatment for all RISC-3 SSCs may not 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 acceptably small, this 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 reasonable confidence 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. As presented in RG 1.174, the NRC considers small changes to be relative and to depend on the current plant CDF and LERF (hence we also refer to “acceptably small” changes in other portions of this notice since small can be different for different plants with different baseline levels of risk). For plants with total baseline CDF of 10^{-4} per year or less, small means CDF increases of up to 10^{-5} per year and for plants with total baseline CDF greater than 10^{-4} per year, small means 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 for the reduction in special treatment requirements to be considered. For plants with total baseline LERF 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 LERF greater than 10^{-5} per year, small LERF increases are considered to be up to 10^{-7} per year. However, if there is an indication that the baseline CDF or LERF may be considerably higher than 10^{-4} or 10^{-5}, respectively, the licensee either must find ways to reduce risk and present the arguments to the staff before implementation of § 50.69, otherwise it is likely that the staff will reject the § 50.69 application. 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.

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 (i.e., partial implementation) and to phase in implementation over time. However, the implementation, including the categorization process, must address entire systems or structures; not selected components within a system or structure. Note that this requirement should be understood to exclude entire support systems (e.g., if system A is categorized as RISC-3, but is dependent on system B components which in turn have been categorized as RISC-1, then system A is understood not to include the system B components and is not to be categorized as RISC-1). 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.

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

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. By “integrated decision-making process,” the Commission means a process that integrates both risk insights and traditional engineering insights. In categorizing SSCs as low safety-significant, defense-in-depth must be maintained (per § 50.69(c)(1)(iii)) and there must be reasonable confidence that sufficient safety margin is maintained by showing that any increases in risk are small per § 50.69(c)(1)(iv). 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 must 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 qualifications of the members of the IDP. The IDP must be composed of a group of individuals 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 key 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 defense-in-depth.

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) Treatment Requirements for Structures, Systems, and Components.

Treatment requirements applicable to RISC-1, RISC-2, and RISC-3 SSCs are specified in § 50.69(d). Any regulatory requirements applicable to RISC-1, RISC-2, RISC-3, and RISC-4 SSCs not removed by § 50.69(b)(1) continue to apply.

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 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. This rule language means that the licensee or applicant must evaluate the treatment associated with 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 determined to be able to perform as assumed.

Because RISC-1 and RISC-2 SSCs are the safety significant SSCs and their performance as credited in the PRA is important to maintaining an acceptable level of plant risk, given that special treatment requirements are being removed from RISC-3 SSCs, it is a key and necessary part of § 50.69 to ensure these SSCs can perform as credited in the PRA. However, the requirements in § 50.69(d)(1) do not extend special treatment requirements to RISC-1 beyond design basis functions and to RISC-2 SSCs.

The performance conditions for beyond design basis capabilities of RISC-1 SSCs credited in the PRA are not subject to the requirements of 10 CFR Part 50, Appendix B. However, plant SSCs credited for beyond design basis capabilities must have a valid technical basis for the credit (i.e., the failure rate/probability of the SSC performing the beyond design basis function) given in the PRA. Further, the basis for this credit should already be established and documented in the PRA supporting documentation so this should not be an additional burden for licensees to capture and implement. If an existing technical basis does not exist or is insufficient to support the credit taken for beyond design basis capability (e.g., the supporting test program does not test the SSC at the beyond design basis conditions), the licensee or applicant is required by § 50.69(d)(1) to develop a technical basis for the credit taken in the PRA potentially including a treatment program for the SSC that validates the capability credited.

For SSCs categorized as RISC-1 or RISC-2, all existing applicable requirements continue to apply (i.e., no special treatment requirements are removed by § 50.69). This rule does not require licensees to evaluate the effectiveness of special treatment requirements for RISC-1 SSCs to ensure that they are capable of performing their design basis functions. The special treatment requirements in other NRC regulations address the design basis capability of RISC-1 SSCs.

The categorization process will result in a number of safety-related SSCs being determined to be of low safety significance (i.e., RISC-3) and subject to reduced treatment. This determination of low safety significance will implicitly take credit for the performance capability of other SSCs in the PRA, some, or all of which, may not be included in the scope of the licensee's categorization process (due to the allowance for licensees to selectively implement the rule and to phase that implementation over time). To maintain the validity of the categorization process, and more importantly to maintain any potential risk increase as small, it is necessary to maintain the “credited” SSCs per § 50.69, and this means the application of § 50.69(d)(1) and § 50.69(e)(2) requirements.

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

Section 50.69(d)(2) requires that the licensee or applicant develop and implement documented processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action of RISC-3 SSCs, to provide reasonable confidence in the capability of the RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout their service life. The licensee or applicant must control these processes using written (i.e., “documented”) procedures before implementation. These procedures may be less rigorous than those applied to SSCs subjected to 10 CFR Part 50, Appendix B, controls. However, the procedures must be sufficient to assure that RISC-3 SSCs will perform their safety-related functions at reliability levels consistent with the categorization process. The licensee or applicant must have written records of the implementation of the documented processes. For example, the licensee or applicant must have records showing that design requirements, such as earthquake and environmental design conditions, have been satisfied before the component is installed.

Section 50.69(d)(2) requires that the treatment of RISC-3 SSCs be consistent with the categorization process. This rule language means that, when establishing the treatment processes for RISC-3 SSCs, the licensee or applicant must take into account the assumptions in the categorization process regarding the design basis capability and reliability of RISC-3 SSCs to perform their safety-related functions throughout their service life. The evaluation by the licensee or applicant of the consistency of the treatment of RISC-3 SSCs with the categorization process may be qualitative so long as it provides reasonable confidence in the design basis capability of RISC-3 SSCs, based on plant-specific and industry-wide operational experience and vendor information. In establishing treatment processes for RISC-3 SSCs, the licensee or applicant will be responsible for addressing applicable vendor recommendations and operational experience to ensure that the treatment processes established for RISC-3 SSCs provide reasonable confidence in their design basis capability. For example, operational experience might be described in NRC information notices or identified in responses to NRC bulletins, generic letters, or other licensee commitment documents. The treatment applied to RISC-3 SSCs must also support the assumptions used in justifying the removal of requirements applicable to those SSCs. For example, where a licensee or applicant intends as part of implementing § 50.69 to eliminate leakage testing required in 10 CFR Part 50, Appendix J, for containment isolation valves, the treatment applied to those valves must support the assumption that they are capable of closing under design basis conditions.

Some public comments on the proposed rule suggested that a reference to general industrial practices would be sufficient to satisfy the requirements for the treatment for RISC-3 SSCs. However, as described in NUREG/CR-6752, “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,” significant variation exists in the application of industrial practices at nuclear power plants. Hence, a simple reference to these practices does not provide a basis to satisfy the rule’s requirements. To satisfy the requirement that the treatment of RISC-3 SSCs be consistent with the categorization process, the licensee or applicant must establish treatment processes that provide reasonable confidence that SSCs perform their safety-related functions consistent with reliability levels used in the categorization process. The licensee or applicant must either establish treatment processes that provide this level of reliability or use consensus standards that provide a proven level of reliability based on experience. In using consensus standards, the licensee or applicant must note that combining or omitting provisions of standards might result in ineffective implementation of § 50.69 by causing RISC-3 SSCs to be incapable of performing their design basis safety functions. The NRC considers the ASME code cases endorsed in § 50.55a and listed in RG 1.84, 1.147, and 1.192 to be one acceptable method of establishing treatment of RISC-3 SSCs, where applicable, in that those applicable endorsed code cases adjust treatment based on the safety significance of the components.

Under § 50.69, most special treatment requirements will be removed from RISC-3 SSCs, which will typically comprise a large percentage of safety-related SSCs in a nuclear power plant. These special treatment requirements will be replaced with the high-level treatment requirements in § 50.69(d)(2) that will allow significant reduction in the treatment applied to RISC-3 SSCs. This reduction in treatment can introduce common-cause concerns and weaken defenses against them. Therefore, the licensee or applicant will be responsible for effective implementation of the requirements of § 50.69 to avoid adverse impacts on the reliability and availability of multiple RISC-3 SSCs, which could reduce plant safety beyond the categorization process assumptions or results.

A licensee or applicant may not simply assume that a sensitivity study that increases the failure probability for all RISC-3 SSCs simultaneously, with no additional basis to support it, would necessarily bound the potential change in risk that could result due to implementation of § 50.69. There is a potential that risk due to implementation of § 50.69 could increase as a result of the reduction in treatment due to common-cause interactions or degradation, and this impact might not be uniform across the population of RISC-3 SSCs. For example, if a licensee were to simply eliminate maintenance, testing, or lubrication of pumps or valves, it could significantly impact performance of those specific components and the impact might exceed the cumulative impact of individually reducing the reliability of all RISC-3 SSCs by a few percent or less. Public comments on the proposed rule indicated that cross-system common-cause interactions and degradation mechanisms are typically addressed through the treatment processes applied to plant equipment, rather than being addressed in the categorization process. In satisfying the rule, the licensee or applicant must consider potential common-cause interactions and degradation mechanisms in establishing treatment processes for RISC-3 SSCs so there is a reasonable basis to support the assumptions made for the risk sensitivity study.

Section 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 rule includes requirements for individual treatment processes for RISC-3 SSCs in recognition of the different manner in which plant SSCs perform their safety functions. For example, the design control process required in § 50.69(d)(2)(i) needs to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design basis conditions throughout their service life. This is particularly important where the design basis capability of a RISC-3 SSC cannot be monitored for degradation during normal plant operations. The procurement process required in § 50.69(d)(2)(ii) must provide reasonable confidence that a proper replacement SSC (i.e., one that meets that SSC's design basis functional requirements) is obtained. The maintenance, inspection, test, and surveillance process required in § 50.69(d)(2)(iii) must provide sufficient performance data of RISC-3 SSCs to determine if the reduction in treatment has adversely affected their design basis capability and to provide reasonable confidence that the SSC can perform its safety function over the interval until the next scheduled activity. The corrective action process required in § 50.69(d)(2)(iv) must respond to SSC failures and provide reasonable confidence in avoiding future problems.

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 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. This rule language means that the design control process must be established so that functional requirements and bases for RISC-3 SSCs are satisfied unless they are specifically changed in accordance with the appropriate regulatory change control process (e.g., § 50.59). The implementation of an effective design control process is crucial to maintaining the functionality of safety-related SSCs because many SSCs cannot be monitored or tested to demonstrate design basis capability or to identify potential degradation.

The rule lists key attributes that must be addressed by the licensee or applicant in establishing an effective design control process. As part of design control and other treatment processes, the licensee or applicant is responsible for proper installation and post-installation testing of RISC-3 SSCs (including welding and other special processes) to provide reasonable confidence in the capability of these SSCs to perform their functions. The manner in which these requirements are accomplished for RISC-3 SSCs is the responsibility of the licensee or applicant adopting § 50.69.

The rule requires that RISC-3 SSCs be capable of performing their safety-related functions under design basis conditions including meeting design requirements for environmental conditions (e.g., temperature, pressure, humidity, chemical effects, radiation, and submergence) and effects (e.g., aging and synergisms), and seismic conditions (e.g., design load combinations of normal and accident conditions with earthquake motions). Section 50.69(b)(1) removes the requirements for a program on environmental qualification of electric equipment specified in § 50.49, "Environmental qualification of electric equipment important to safety for nuclear power plants." However, § 50.69(b)(1) does 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, GDC-4 of 10 CFR 50, Appendix A, requires that SSCs important to safety be designed to accommodate the effects of, and to be compatible with, the environmental conditions and effects associated with normal operation, maintenance, testing, and postulated accidents. To satisfy the provisions of GDC-4 of 10 CFR Part 50, Appendix A, the licensee or applicant must address environmental conditions such as temperature, pressure, humidity, chemical effects, radiation, and submergence; and environmental effects such as aging and synergisms. In accordance with § 50.69(d)(2), the licensee or applicant must design electric equipment important to safety so they are capable of performing their intended functions under applicable environmental conditions and effects throughout their service life. The requirements of § 50.69(d)(2) also mandate that, if RISC-3 electrical equipment is relied on to perform its safety-related function beyond its design life, the licensee or applicant has a basis for the continued capability of the equipment under adverse environmental conditions and effects.

Under § 50.69, RISC-3 SSCs would continue to be required to function under design basis seismic conditions (such as design load combinations of normal and accident conditions with earthquake motions), 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 or applicant who adopts the 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 Earthquakes. The 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. The rule does 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 rule would permit the licensee or applicant to select a technically defensible method to show that RISC-3 SSCs will remain functional when subject to design earthquake loads. Several public comments on the proposed rule supported the use of earthquake experience data as a method to demonstrate SSCs will remain functional during earthquakes. If the licensee or applicant chooses to use only earthquake experience data to demonstrate that the SSC will perform its safety-related function, with no further engineering evaluation, then the earthquake experience data must envelope the SSC design basis, including the number of earthquake events and the design load combinations. 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. Implementation of § 50.69 does not change the seismic design basis for USI A-46 facilities and, therefore, does not impose additional requirements on these facilities.

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

Section 50.69(d)(2)(ii) specifies that procured RISC-3 SSCs must satisfy their design requirements. This rule language means that the licensee or applicant will have 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). Under § 50.69(d)(2)(ii), the licensee or applicant might determine that a procurement specification provides reasonable confidence in the design basis capability of a RISC-3 SSC to perform its safety-related function over the service life.

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 must 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. With respect to maintenance activities for RISC-3 SSCs, this rule language means that the scope, frequency, and detail of predictive, preventive, and corrective maintenance activities (including post-maintenance testing) must be established by the licensee or applicant implementing the rule 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 licensee or applicant must have a basis to provide reasonable confidence that the SSC will remain capable of performing its safety-related function.

The special treatment requirements in §§ 50.55a and 50.65 for inspection, testing, and surveillance have been removed for RISC-3 SSCs. In lieu of those requirements, the licensee or applicant must implement effective processes for inspection, testing, and surveillance of RISC-3 SSCs so that the requirements of § 50.69 are satisfied in providing reasonable confidence that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions throughout their service life. The licensee or applicant may apply industrial practices for the treatment of RISC-3 SSCs if those practices maintain the capability of the RISC-3 SSCs to perform their design-basis safety functions. For example, a licensee or applicant might determine that specific maintenance activities are within the skill of the craft (sometimes referred to as tool-pouch maintenance) so that detailed work orders would not be necessary. On the other hand, procurement of a component to replace a dissimilar RISC-3 component would require more documentation and independent review to provide reasonable confidence that the procured RISC-3 component is capable of performing its safety-related functions under design-basis conditions throughout its service life.

With respect to RISC-3 pumps and valves, the rule language in § 50.69(d)(2)(iii) means that the licensee or applicant must 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-related functions under design basis conditions. To determine that the pump or valve will remain capable of performing its safety-related function until the next scheduled activity, the licensee or applicant will need 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-related functions if called upon to function under operational or design basis conditions over the interval between periodic testing or inspections. In addition, the operational information and performance data must be sufficient to satisfy the requirements of § 50.69(d)(2)(iii) for use in identifying the need for corrective action under § 50.69(d)(2)(iv) and in providing information for feedback to the categorization and treatment processes under § 50.69(e)(3).

In some cases, a licensee or applicant implementing § 50.69 might apply more rigorous test methods than previously applied to satisfy the ASME Code inservice testing provisions because § 50.69 does not specify restrictive time limits on test intervals that were provided in the ASME Code. As a result, § 50.69 allows significant flexibility by the licensee or applicant in verifying the design basis capability of their safety-related SSCs categorized as RISC-3. However, the licensee or applicant needs to consider the lessons learned over the last 20 years regarding SSC performance in establishing the treatment processes for RISC-3 SSCs. Contrary to suggestions in some public comments on the proposed rule, operating experience and research does not support an assumption that exercising a valve or pump will provide reasonable confidence in its design-basis capability in that such exercising will not detect service-induced aging or degradation that could prevent the component from performing its design basis functions in the future, and therefore is insufficient by itself to satisfy § 50.69(d)(2)(iii). The licensee or applicant may develop the type and frequency of tests or inspections for RISC-3 pumps and valves provided they are sufficient to conclude that the pump or valve will perform its safety-related function throughout the service life. The provisions for risk-informed inspection and testing in applicable ASME code cases (as incorporated in § 50.55a) would constitute one effective approach for satisfying the § 50.69 requirements.

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

Section 50.69(d)(2)(iv) requires that conditions that 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, the rule requires that measures be taken to assure that the cause of the condition is determined and corrective action taken to preclude repetition. Significant conditions adverse to quality could involve common-cause concerns for multiple RISC-3 SSCs or concerns related to the validity of the categorization process or its results. For example, if measuring and test equipment is found to be in error or defective, the licensee or applicant will be responsible for determining the functionality of safety-related SSCs checked using that equipment to prevent the occurrence of common-cause problems that might invalidate the categorization process assumptions and results. 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. Contrary to some public comments on the proposed rule, the corrective action process alone is insufficient to monitor the effects of reduced treatment on RISC-3 SSCs, and therefore the Commission has incorporated feedback requirements into § 50.69.

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

Section 50.69(e)(1) requires the licensee or applicant to review changes to the plant, operational practices, applicable plant and industry operational experience and, as appropriate, update the PRA and SSC categorization and treatment processes, in a timely manner, but no longer than every two refueling outages for RISC-1, RISC-2, RISC-3, and RISC-4 SSCs. The date the NRC grants the license amendment to implement 10 CFR 50.69 begins the updating interval and provides a recognizable date for the periodic updating of the categorization and treatment processes. Depending on the timing of license amendment issuance (for example, just before a refueling outage), the licensee or applicant might have minimal plant changes, operational practices, or operational experience to review in updating the categorization and treatment processes in the early phases of implementing the rule. If plant changes, operational practices, or operational experience would result in a significant adverse impact on plant safety or public health and safety, the licensee or applicant must update the categorization or treatment processes in a timely manner without waiting for the two refueling outage schedule. The information collected under § 50.69(e)(2) and (e)(3) would be among the information used to determine the need for updating the categorization or treatment processes in a timely manner required under § 50.69(e)(1). The plant and industry operational experience referred to in § 50.69(e)(1) includes the data collected under § 50.69(e)(3) for RISC-3 SSCs. In addition to the periodic updating of the quantitative reliability information, the feedback of plant operational experience is intended to include qualitative information on the performance of plant SSCs obtained through the corrective action program and processes as well as from applicable vendor recommendations and operational experience. For example, lessons learned from operational experience might be described in NRC information notices or implemented in response to NRC bulletins or generic letters. The evaluation of the categorization process includes verifying the continued validity of the risk sensitivity study and the associated SSC performance assumptions.

Section 50.69(e)(2) requires the licensee or applicant to monitor the performance of RISC-1 and RISC-2 SSCs and make adjustments as necessary to either the categorization (i.e., by moving other RISC-3 or RISC-4 SSCs back into RISC-1 or RISC-2 until the change in risk is acceptably small) or treatment processes so the categorization process and results are maintained valid. To meet this requirement, the licensee or applicant must monitor all unavailabilities and functional failures so they can determine when adjustments to the categorization or treatment processes are needed. The licensee or applicant will also need to monitor SSCs that are credited in the PRA for performing beyond design basis functions (if applicable) that are not necessarily included in the scope of an existing maintenance rule program.

The categorization process will result in a number of safety-related SSCs being determined to be of low safety significance (i.e., RISC-3) and subject to reduced treatment. This determination of low safety significance will implicitly take credit for the performance capability of other SSCs in the PRA, some, or all of which, may not be included in the scope of the licensee's categorization process (due to the allowance for licensees to selectively implement the rule and to phase that implementation over time). To maintain the validity of the categorization process, and more importantly to maintain any potential risk increase as small, it is necessary to maintain the "credited" SSCs per § 50.69.

In § 50.69(e)(3) the rule requires the licensee or applicant to consider the performance 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 meet § 50.69(c)(iv) and to make adjustments as necessary to either the categorization or treatment processes so the categorization process and results are maintained valid. Based on the review of this information, if SSC reliability degrades so as not to support the categorization process assumptions, the licensee or applicant must adjust the treatment to improve SSC reliability or make appropriate changes to the categorization of SSCs.

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, handling planned changes to programs and processes, and records. Each requirement 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 must 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 also notes that § 50.69(d)(2) requires the processes applied to RISC-3 SSCs to be documented, but § 50.69 does not specify particular records in that regard. The documentation must 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. Systems that are categorized by § 50.69 will have their treatment revised consistent with the RISC category into which the SSC is categorized and the associated treatment requirements of § 50.69(d). This provision is included to maintain clear information, at a minimum level of detail, about which requirements a licensee is satisfying. However, detailed information about particular SSCs is not required to be submitted to the NRC. 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(b). For licensees, the updating must be in accordance with the provisions of § 50.71(e).

Once the NRC has completed its review of a § 50.69 application, the licensee can adjust its treatment processes provided that the requirements of § 50.69 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 are made as a result of implementation of § 50.69. Any revisions to these documents are to be submitted to NRC in accordance with the existing requirements of § 50.54(a)(2) and § 50.71(e), respectively.

Section 50.69(f)(3) specifies that for initial implementation of the rule, changes to the FSAR for implementation of this 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 directly related to implementation of this rule need not be considered a reduction in commitment for the purposes of § 50.54(a). 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 NRC staff 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). At this time, the NRC is unable to determine generic criteria for the control of changes to the categorization process during its implementation that could be included in § 50.69. As a result, the NRC will review and approve a license amendment submittal containing the licensee or applicant's categorization process and intends to impose a license condition upon which the categorization process approval is based to control categorization process changes. The license condition will require the licensee to notify the NRC in advance of implementing changes with respect to specific aspects of the categorization process. With experience in the application of § 50.69, the NRC might modify the rule to specify generic criteria for the control of changes to the categorization process during implementation of the rule.

No explicit requirements are included in § 50.69 for the period for retention of records. The rule specifies 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 prevented, or would have prevented, a RISC-1 or RISC-2 SSC 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 performance capability credited 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 are removed for RISC-3 (and RISC-4) SSCs under § 50.69(b)(vii) and (viii).

V.9.0 Inspection of 10 CFR 50.69 Implementation.

The NRC will review and update, as appropriate, the current inspection procedures under the NRC Reactor Oversight Process to incorporate inspection guidance for monitoring the implementation of § 50.69 at nuclear power plants. The NRC intends to conduct sample inspections of plants implementing § 50.69 in a manner that is sensitive to conditions that could significantly increase risk. These sample inspections are intended to gather information that will enable the NRC to assess whether modifications are needed to the ongoing baseline inspection program. The sample inspections will focus on the implementation of the categorization process approved as part of the NRC review of the § 50.69 license amendment request. The sample inspections will also evaluate the treatment processes established under § 50.69 with primary attention directed to programmatic and common-cause issues; including those associated with known degradation mechanisms. The inspections might help provide operating experience information on RISC-3 SSCs that can also be provided to other licensees.

VI. Guidance

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

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 rule, the NRC staff reviewed drafts of this document and in addition, NEI 00-04 was used in the pilot programs 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 final revision of NEI 00-04 was submitted on April 14, 2004, and forms the basis for the NRC RG “Guidelines for Categorizing Structures, Systems and Components in Nuclear Power Plants According to Their Safety Significance.” Availability of this document is noted in Section IX.

The NRC staff’s review of NEI 00-04 resulted in several areas where the staff finds it necessary to identify clarifications, limitations, and conditions to the NEI guidance or to include further guidance to supplement the document, as it is currently written. These clarifications, limitations, and conditions, and the reasons therefore, are set forth in Section C.8 of RG 1.201. These issues are best resolved by testing the guide against actual applications. Therefore, this RG is being issued for trial use. This RG does not establish any final staff positions, and may be revised in response to experience with its use. As such, this trial regulatory guide does not establish a staff position for purposes of the Backfit Rule, 10 CFR 50.109, and any changes to this RG prior to staff adoption in final form will not be considered to be backfits as defined in 10 CFR 50.109(a)(1). This will ensure that the lessons learned from regulatory review of pilot and follow-on applications are adequately addressed in this document and that the guidance is sufficient to enhance regulatory stability in the review, approval, and implementation in the use of PRAs and their results in the risk informed categorization process required by 10 CFR 50.69. These areas are discussed in RG 1.201 at Section C.1 through 7.

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

RG 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities," provides guidance on the NRC position on voluntary consensus standards for PRA (in particular on the ASME standard for internal events PRAs) and associated 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 if a PRA providing results being used in a decision is technically acceptable.

In a letter dated April 24, 2000, NEI requested that 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 draft 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. To reach the conclusion that the PRA results support the proposed categorization, the review guidance is structured to lead the staff reviewer to 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.

VII. Criminal Penalties

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

VIII. 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.

IX. 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**
Response to Public Comments	X	X	ML041040190
Environmental Assessment	X	X	ML041040236
Regulatory Analysis	X	X	ML041000474
Industry Implementation Guidance	X	X	ML041120253
Regulatory Guide	X	X	ML041340087

X. 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 rule, the NRC is using the following Government-unique standard (RG 1.201, June 2004). 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. RG 1.201 and RG 1.200 (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. RG 1.201 explicitly notes these 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 allow use of these voluntary consensus standards, but do 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 categorized, nor do standards currently exist for addressing the PRA requirements for all initiating events and modes of operation. Additionally, there are no voluntary consensus standards that can address other parts of the approach laid out such as determining the basis for the evaluations to show an acceptably small increase in risk. The NRC is not aware of any voluntary consensus standard that could be used instead of the Government-unique standards.

XI. 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 is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. As set forth in the final environmental assessment, this action will not have a significant environmental impact principally because it is structured to maintain the design basis functional requirements for the SSCs in the facility, because the rule contains feedback and process adjustment requirements to maintain the validity of the categorization process over time, and because the standards and requirements applicable to radiological releases and effluents are not affected by this rulemaking.

The NRC requested public comments on any aspect of the environmental assessment. No public comments were received. The NRC requested the views of the States on the environmental assessment for this rule. No State comments were received. Availability of the final environmental assessment is provided in Section IX.

XII. Paperwork Reduction Act Statement

This rule contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et se.). These requirements were approved by the OMB, approval number 3150-0011.

The burden to the public for these information collections is estimated to average 1032 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. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), 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.

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.

XIII. Regulatory Analysis

The Commission has prepared a regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. Availability of the regulatory analysis is provided in Section IX.

XIV. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commission certifies that this rule does not have a significant economic impact on a substantial number of small entities. This 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).

XV. Backfit Analysis

The NRC has determined that the Backfit Rule does not apply to this rule; therefore, a backfit analysis is not required for this rule. As a voluntary alternative to existing requirements, the final rule does not impose different or new requirements on 10 CFR Part 50 licensees or applicants and thus does not constitute a backfit pursuant to § 50.109.

XVI. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 50

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants 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. 552 and 553, the NRC is adopting 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, 937, 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, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat.1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); See 1704, 112 Stat. 2750 (44 U.S.C. 3504 note)..

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. (42 U.S.C. 5841). Sections 50.10 also issued under secs. 101, 185, 68 Stat. 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 Sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 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. In § 50.8 paragraph (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, 50.70, 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. A new § 50.69 is added under center heading “Issuance, Limitations, and Conditions of Licenses and Construction Permits” 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 this part; a holder of a renewed LWR license under Part 54 of this chapter; an applicant for a construction permit or operating license under this part; or an applicant for a design approval, a combined license, or manufacturing license under Part 52 of this chapter; 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) The portion of 10 CFR 50.46a(b) that imposes requirements to conform to Appendix B to 10 CFR Part 50.

(iii) 10 CFR 50.49.

(iv) 10 CFR 50.55(e).

(v) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement (with the exception of fracture toughness), 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).

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

(vii) 10 CFR 50.72.

(viii) 10 CFR 50.73.

(ix) Appendix B to 10 CFR Part 50.

(x) 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 is not connected to the reactor coolant pressure boundary; or

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

(xi) 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 under § 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 must 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 if it determines 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 choosing to implement this section shall include the information in § 50.69(b)(2) as part of application. The Commission will approve an applicant's implementation of this section if it determines 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 if 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 defense-in-depth.

(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 (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 documented processes to control the design; procurement; inspection, maintenance, testing, and

surveillance; and corrective action 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 treatment of RISC-3 SSCs must be consistent with 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 capable of performing their safety-related functions including meeting 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 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. For significant conditions adverse to quality, measures must be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.

(e) *Feedback and process adjustment*.

(1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs*. The licensee shall review changes to

the plant, operational practices, applicable plant and industry operational experience, and, as appropriate, update the PRA and SSC categorization and treatment processes. The licensee shall perform this review in a timely manner but no longer than once every two refueling outages.

(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 if 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 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 prevented, or would have prevented, a RISC-1 or RISC-2 SSC from performing a safety significant function.

Dated at Rockville, Maryland this ___ day of ____ 2004.

For the Nuclear Regulatory Commission.

Annette L Vietti-Cook,
Secretary of the Commission.

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

REGULATORY ANALYSIS

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Regulatory Analysis for §50.69

I. Statement of Problem and NRC Objectives

(a) History

The Nuclear Regulatory Commission (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. 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 of 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 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 a voluntary, 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 Register* on 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 of SECY-02-0176 "Proposed Rulemaking to Add New Section 10 CFR 50.69, 'Risk-Informed Categorization and Treatment of Structures, Systems, and Components' " dated September 30, 2002 (ADAMS accession number ML022630007).

The staff prepared a proposed rule package and provided it to the Commission in SECY-02-176 dated September 30, 2002. The Commission approved issuance of proposed 10 CFR 50.69 for public comment in an SRM dated March 28, 2003. Consistent with Commission direction, the staff subsequently published proposed 10 CFR 50.69 for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511). The Commission received 26 sets of comments comprising more than 250 individual comments in response to the proposed rule. The comments are discussed in section II of the final rule *Federal Register* notice.

(b) Objective for 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 continues to maintain reasonable assurance of public health and safety and common defense and security, while reducing unnecessary regulatory burden, is possible and the utilization of such an approach could increase regulatory effectiveness. The new approach embodied in the 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 rule is a voluntary rule (it is not being imposed on licensees) that is intended only to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed. The 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 enables licensees who elect to implement its provisions, and the NRC, to focus its resources on SSCs with significant contributions to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach maintains SSC functionality, albeit at a reduced level of assurance.

II. Analysis Of Alternative Regulatory Strategies

A number of rulemaking strategies were considered for risk-informing the special treatment requirements. 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 NRC continues to conclude that adding a new section to 10 CFR Part 50 is the appropriate approach for risk-informing the special treatment requirements and hence this is the approach taken for the rule. However, a significant change regarding the regulatory approach is being taken for the rule in lieu of what was concluded in SECY-99-256. As discussed below (in section II.f) and as a result of additional interactions with stakeholders, the NRC no longer concludes that the best regulatory approach is to include an appendix to 10 CFR Part 50 that provides categorization requirements as part of the regulatory approach.

Alternative regulatory approaches for risk-informing special treatment requirements were discussed in the ANPR (attached to SECY-99-256). 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 NRC did not receive ANPR comments that disagreed with the NRC'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 (refer to section II.f for a summary of these ANPR comments).

(a) No Action or Exemption Alternative

This alternative describes what would occur without the rule. 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 approach was followed for STPNOC who filed an exemption request (from numerous special treatment requirements) which was then subsequently reviewed and approved by the NRC. This exemption review for STPNOC was 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 NRC 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 this rulemaking effort to date, the NRC continues to conclude that there is sufficient industry interest in this initiative to warrant the NRC continuing to expend its resources to develop the rule. For these reasons, the NRC did not choose this alternative.

(b) 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 this rulemaking. For this approach to work and meet the rulemaking 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 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. Relative to the preferred rule change, this alternative is disadvantaged because the changes to NRC regulations are more extensive, and thus the NRC rulemaking effort should be more time consuming and costly than the recommended alternative. In addition, as a vehicle to risk-inform the regulations, it is likely to be less effective than the recommended rule change because it would be more confusing and less coherent to licensees. For these reasons, the NRC did not choose this alternative.

(c) 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 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.

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

This alternative rulemaking approach is the approach taken for the rule, and entails the development of a new rule that would be added to Part 50 that licensees could voluntarily adopt. The rule contains the categorization requirements (supported by a regulatory guide). Additionally, the 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 10 CFR 50.69 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 NRC to identify in one place what the regulatory treatment requirements will be for each risk-informed safety class (RISC)[1]. RISC-1 and RISC-2 SSCs will continue to meet applicable special treatment requirements and will also have requirements that ensure that key categorization assumptions that relate to credited performance in beyond design basis scenarios are technically valid, and updated consistent with the process feedback requirements in the rule. RISC-3 SSCs will have requirements that maintain with reasonable confidence the 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 revised special treatment requirements is a significantly more coherent regulatory approach than any of the previously described approaches. Revising each specific special treatment rule, as suggested by the other alternatives, would be more difficult and confusing because it involves changing each specific regulation, and in addition each of these specific special treatment requirements would need to be modified to address RISC-2 and RISC-3 SSCs. Given that these requirements were structured for "design basis" events, this would be a difficult task. 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, and replacing these requirements with similar, but less extensive treatment requirements. The potential for increased confusion is significant for such an approach. Further, since 10 CFR 50.69 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.

(e) Categorization Requirements

The NRC considered two alternative approaches for incorporating the categorization requirements into the new regulatory framework: 1) adopting a rule (i.e., a new appendix) that sets forth in significant detail, objective, nondiscretionary criteria governing the categorization that licensees could implement without prior NRC review and approval 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-discretionary manner involving no substantial professional judgement on the part of NRC staff reviewers, that a § 50.69 licensee complies with the appendix categorization requirements. This “appendix”

[1]Safety-related SSCs that a risk-informed categorization process determines are significant contributors to plant safety are termed RISC-1 SSCs. Nonsafety-related SSCs that the risk-informed categorization determines to be significant contributors to plant safety are termed RISC-2 SSCs. Safety-related SSCs that a risk-informed categorization process determines are not significant contributors are termed RISC-3 SSCs. Finally, nonsafety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety are termed RISC-4 SSCs.

regulatory approach was the approach the NRC 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 NRC to review some aspects of the PRA to determine its acceptability for application to § 50.69 under any circumstance. As such, a true “no-prior-review” type of approach simply does not appear to be technically 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. In response to the proposed rule, two comments were provided on this issue. Both comments were from industry owners groups, and both did not support putting more detailed categorization requirements back into the regulatory framework. 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 rule, and to require licensees to provide a license amendment submittal for NRC review and approve prior to implementation of § 50.69. This approach (regarding the incorporation of more high level categorization requirements into the rule versus a detailed appendix) is supported by industry based on the comments on the proposed rule.

(f) Conclusion Regarding Alternative Strategies

The NRC concludes that:

1. Rulemaking is the most effective tool for implementing the type of generic changes encompassed by this effort. This conclusion is based on the industry’s continued support for the rulemaking as evidenced with their ongoing development of implementation guidance, their

continued participation in pilot activities, and the fact that no major impediments to wide industry use were identified in the proposed rule comments.

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 final rule reflects this decision.

III. Estimate and Evaluation of Values and Impacts

(a) Overview

The NRC's chief concern in moving forward with this 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 rule for a discussion of the technical basis for § 50.69). Once the NRC has satisfied itself that the new regulation will maintain adequate protection, then the NRC's next concern is whether the regulatory approach is cost-beneficial. Since implementation of this rulemaking is voluntary, it is not in the NRC'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 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 not possible to develop a more quantitative regulatory analysis that has a reasonable level of certainty for this rulemaking. The NRC 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 this regulatory analysis. No additional information involving costs and benefits for implementing § 50.69 was received in response to the proposed rule request for comment, and as a consequence, there has been no adjustments made to the previous estimates for costs and benefits that were provided in the draft regulatory analysis that supported proposed § 50.69.

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. As a result, 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, cost benefit situation since the facility has the greatest potential to realize the greatest cost savings from risk-informing special treatment requirements. South Texas 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. However, some cost benefit information was provided by Dominion from their Surry pilot activities. This information is incorporated into this regulatory analysis.

Additionally, based on the § 50.69 categorization 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 to 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.

(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 a quality standard (RG 1.200), 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'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 NRC's 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 Inservice Inspection (ISI) applications may have categorized the passive components in the system). Training, based on the pilot experience, is estimated to take at least one 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 additional monitoring activities. It is expected that current maintenance rule monitoring efforts will address a significant portion of the § 50.69 monitoring requirements for RISC-1 and RISC-2 SSCs. However, monitoring activities must be expanded to consider all SSC performance issues (in addition to maintenance related issues) and include RISC-2 SSCs that may fall outside the scope of the maintenance rule in order to meet § 50.69 monitoring requirements. From a practical standpoint, licensees typically evaluate all failures for maintenance rule impact, therefore expanding the monitoring scope to consider failures other than those that are maintenance related can be readily 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 (every other refueling outage) 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 this estimate. Additionally, these costs were estimated for the categorization of 12 systems, and were assumed to occur over a three year period.

(c) Impacts to the NRC

! NRC would expend resources to review and approve § 50.69 submittals. If licensees adopt the NEI 00-04 guidance as endorsed by the RG 1.201, 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 NRC review), and the number of key peer review findings (i.e., the size of the submittal). An estimate of this impact is that the staff will receive four (one per year) § 50.69 submittals and expend 400 staff-hours on each submittal for a total of 1600 hours of staff review time. This estimate could vary substantially is significantly more licensees implement § 50.69 that the estimate.

! There would also be additional resource impacts for 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. The initial effort to develop the inspection guidance is estimated to take 4-5 person weeks.

(d) Impacts to Other Stakeholders

! The NRC has not identified any impacts upon other stakeholders. 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.

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

! The NRC concludes that this 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 performance 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 addresses the same set of special treatment requirements specifically involving 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 § 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 adopting § 50.69 on a per unit basis per year is approximately $1,100,000. Based on the single unit costs ($2,400,000 incurred over three years) and dual-unit costs ($3,300,000 incurred over three years) 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[2]	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, § 50.69 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

(f) Decision Rationale

This regulatory analysis is largely a qualitative analysis of the potential costs and benefits associated with § 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

[2] This refers to licensee's effort to qualify commercial equipment for safety-related applications. Refer to 10 CFR Part 21 for more information.

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. Therefore, with respect to costs, efficiencies will be realized by incurring a one-time rulemaking cost in lieu of expending many of the repetitive costs of individual exemption requests. Relative to benefits, rulemaking is also preferable because it will add greater clarity and certainty to risk-informing the SSCs which in turn is likely to encourage more licensees to participate than would be the case if they had to rely on the vagaries of successfully receiving an exemption. 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 was 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. However, no comments were provided on the regulatory analysis through the public input on the proposed 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. The NRC plans to endorse the industry guidance document through a regulatory guide.

Section 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 or shortly thereafter, the NRC expects that the final rule can be made effective immediately upon publication (or within a reasonably short period of time such as 30 days) in the Federal Register.

V. Conclusion

The risk-informed approach embodied in this 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 1) is consistent with the defense-in-depth philosophy, 2) provides reasonable assurance that necessary safety functions will be performed, 3) provides reasonable confidence that any increases in core damage frequency or large early release frequency (and therefore risk) are small, 4) is consistent with the safety goal policy statement, and 5) utilizes a performance measurement strategy. 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.

UNITED STATES NUCLEAR REGULATORY COMMISSION

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

The U.S. Nuclear Regulatory Commission (NRC) is issuing a new regulation to 10 CFR Part 50. The rule change adds a new section, § 50.69, which contains voluntary alternative requirements to certain existing requirements in 10 CFR Parts 21, 50 and Appendix A to Part 100.

ENVIRONMENTAL ASSESSMENT

Identification of the Action:

The action permits 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 SSCs 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 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 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 § 50.69(b)). Only the treatment requirements are being revised; functional requirements for these SSC will remain and the licensee are required to apply sufficient treatment to maintain functionality of these SSCs. RISC-3 and RISC-4 SSCs are removed from the scope of the following special treatment requirements listed in § 50.69:

(i) 10 CFR Part 21

(ii) The portion of 10 CFR 50.46a(b) that imposes requirements to conform to Appendix B to 10 CFR Part 50

(iii) 10 CFR 50.49

(iv) 10 CFR 50.55(e)

(v) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement (with the exception of fracture toughness) 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)

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

(vii) 10 CFR 50.72

(viii) 10 CFR 50.73

(ix) Appendix B to 10 CFR Part 50

(x) 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.

(xi) 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 Action:

The 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 rule uses a risk-informed process to evaluate the safety significance of SSCs and establish the appropriate level of special treatment requirements of SSCs. It is important to note that this rule is intended only to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed. The 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 enables licensees and the staff to focus their resources on SSCs that are significant contributors to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach maintains SSC functionality, albeit at a reduced level of assurance.

The staff prepared a proposed rule package and provided it to the Commission in SECY-02-176. The Commission approved issuance of proposed 10 CFR 50.69 for public comment in a staff requirements memorandum (SRM) dated March 28, 2003. Consistent with Commission direction, the staff subsequently published proposed 10 CFR 50.69 for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511). The Commission received 26 sets of comments in response to the proposed rule. The comments are discussed in section II of the final rule *Federal Register* notice.

<u>Environmental Impacts of the Action:</u>

This environmental assessment focuses on those aspects of § 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 rule requirements for the following reasons:

(1) Section 50.69 maintains the design basis functional requirements of the facility. For RISC-3 SSCs that have special treatment requirements removed, § 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 functional requirements 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 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 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 provides reasonable confidence that reliability is maintained such that the risk associated with implementation of § 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 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 rule requirements would not result in off-site impacts due to normal operation.

(5) The 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 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 1) the extent (i.e., how many systems) to which a licensee implements § 50.69, 2) the facility design, and 3) the vintage and licensing history of the facility (which determines how many special treatment requirements apply).

The 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 rule requirements: 1) maintain the facility design basis functional requirements, 2) provide reasonable confidence that any change in risk associated with implementation is small, 3) do not allow that SSCs be removed from the facility (unless the appropriate and applicable change control requirements are satisfied), and 4) 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 action.

With regard to potential nonradiological impacts, implementation of the 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 action.

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

Alternatives to the Action:

As an alternative to the rulemakings described above, the NRC staff considered not taking the 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 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, SECY-99-256, and SECY-02-0176 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) 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),

(3) directed the staff to issue proposed § 50.69 for public comment.

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:

The NRC staff developed the final rule and this environmental assessment. In accordance with its stated policy, the NRC staff provided a copy of the final rule to designated liaison officials for each state. No other agencies were consulted. The NRC staff previously provided a copy of this environmental assessment to the state liaison officials as part of the issuance of the proposed rule for public comment and no comments on the environmental assessment were received.

FINDING OF NO SIGNIFICANT IMPACT

On the basis of the environmental assessment, the NRC concludes that the 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 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 Agencywide Documents Access and Management System (ADAMS) Public Library component of the NRC web site http://www.nrc.gov (Electronic Reading Room).

Dated at Rockville, Maryland, this th day of , 2004.

FOR THE NUCLEAR REGULATORY COMMISSION

Catherine Haney, Program Director
Policy and Rulemaking Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Responses to Public Comments on the Proposed Rule

TABLE 1 - 50.69 Paragraph (b) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-1	The NRC must establish standards for full scope internal and external, level 2 probabilistic risk assessments (PRAs) and verify that PRAs meet or exceed these standards prior to their use in 50.69. See comments, b-10, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. The NRC has concluded that the PRA requirements in the rule in conjunction with the implementation guidance as endorsed in Regulatory Guide (RG) 1.201 ensures a robust categorization is implemented. Licensees are encouraged to utilize broader scope PRAs and can expect to gain more relief from special treatment requirements (STRs) when broader scope and more detailed PRA techniques are used. However, the categorization requirements and associated guidance ensure that a conservative categorization occurs when non-PRA methods are used (i.e., no relief allowed for structures, systems, and components (SSCs) relied upon in the non-PRA approaches, which effectively limits the scope of SSCs subject to relief). It is for these reasons (i.e., that the requirements are robust, and that the process is conservative where non-PRA methods are used) that the NRC has not revised the PRA requirements for the final rule. No revisions to the final rule have been made as a result of this comment.
b-2	The only acceptable reasons for excluding rule sections from the scope of § 50.69 should be that the risk-informed process is insufficient for the particular application, or that its conclusions have been determined to be overly conservative. See comments b-3, b-15	The NRC disagrees with this comment. The NRC believes the criteria identified and discussed in Attachment 3 to SECY-99-256 to determine which STRs were to fall within the scope of § 50.69 are appropriate for determining the scope of applicability of § 50.69 as explained in Section III.4 of the Statements of Consideration (SOC). SOC Section III.4.9 discusses the rules that were initially considered for inclusion but which are not within the scope of the final rule. While the NRC agrees that including some of the rule which were excluded might result in a less complex set of regulations, the NRC concludes that including these rules makes the § 50.69 a much more difficult rulemaking that would take much longer to complete. As a result, the NRC has decided to scope in the set of regulations identified in the rule in order to complete the rulemaking in a more reasonable time period, and if necessary, revisit the rules, which were not scoped into § 50.69, in the future. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-3	RISC-3 SSCs should not require Technical specification (TS) testing and reporting and as such, § 50.36 should be added back into the list of applicable regulations. See comments b-2, b-15	The NRC disagrees with this comment. For the reasons stated in Section III.4.9.2 of the SOC (i.e., basically that other risk-informed efforts are addressing § 50.36), there is no need at this time to include 50.36 within the scope of 50.69. No revisions to the final rule have been made as a result of this comment.
b-4	The requirement to prepare, submit, and then receive approval of a license amendment in order to implement § 50.69 is seen as a particular disincentive to use of § 50.69. Implementation should be developed by licensees, using rule requirements and associated guidance, and with NRC inspections to verify compliance. In light of the desire to move to a more performance-based regulatory regime, voluntary implementation of § 50.69 should be developed by licensees using the requirements in the rule and any attendant regulatory guidance, with routine NRC inspection serving to verify acceptable compliance. The license amendment approach creates undue uncertainty regarding what will be found acceptable, and too much unpredictability regarding potential implementation costs. An alternative approach is suggested involving a commitment to the rule requirements with NRC review substantive differences from approved guidance. See comments b-9, b-16	The NRC disagrees with this comment. The NRC concludes that one important part of ensuring that a robust categorization process is used for the implementation of § 50.69 is that it be reviewed and approved by the NRC prior to implementation of § 50.69. Since the NRC review continues to conclude that (as discussed in SOC Section III.6.0) this review should be conducted within the license amendment process since it will involve substantial engineering judgment, 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. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-5	Proposed 50.69(b)(2(iv) requires licensees to evaluate the potential for known degradation mechanisms to determine the impact of changed treatment on RISC-3 SSCs. This requirement is extremely burdensome and unnecessary and would threaten the viability of the rule. The commenter states that the requirement to include known degradation mechanisms in the categorization process is unnecessary(i.e., no reason to suspect any significant change in RISC-3 reliability will occur), not addressed in the NEI 00-04 guidance, and overly burdensome. The commenter reports that methods have not been developed to utilize degradation mechanisms in the categorization process, and that consideration of known degradation mechanisms is appropriately performed in the treatment change process. It is commented that licensees are likely to conduct sensitivity studies rather than determine failure rate changes and that these sensitivity studies will bound any realistic changes in RISC-3 reliability. The rule should at least state that consideration of known degradation is not required when sensitivity studies are performed. Further, it is commented that the sensitivity studies identified in NEI-00-04 provide adequate assurance that any potential degradation in reliability due to changes in special treatment for RISC-3 SSCs would not have the potential to create more than a small increase in risk. The commenter asserts that continued monitoring of RISC-3 performance in the corrective action program will provide assurance that RISC-3 SSC performance degradations will be identified and addressed in a timely manner. See comments b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with this comment. The requirement (§ 50.69(b)(2(iv)) to include evaluations that provide reasonable confidence that potential increases in core damage frequency (CDF) and large early release frequency (LERF) are small is a central piece of this rule and key to the NRC's conclusion that the rule continues to maintain adequate protection of public health and safety. The foundation of this evaluation is the basis for the assumptions made for bounding reliability changes in RISC-3 SSCs and these can be significantly impacted by two factors: 1) known degradation mechanisms and 2) common cause failure. As such, requiring licensees to consider these factors as part of their effort to develop a basis for the CDF and LERF evaluations is important and will remain within the final rule. Known degradation mechanisms can be addressed qualitatively in this context by identification of and reliance upon licensee programs that address these degradation mechanisms for the affected SSCs. In addition, the NRC believes licensees can address degradation mechanisms in the categorization process using approaches similar to that used in Risk-Informed Inservice Inspection (RI-ISI) license applications and ASME Code Case N-660. Further, the NRC agrees with the commenter's recommendation that licensees need to address degradation mechanisms in their treatment process. However, these mechanisms must be identified and considered, at least qualitatively, in the categorization process to ensure they are carried forward and addressed in the licensee's treatment process. The NRC recognizes that licensees are likely to perform sensitivity studies, but disagrees that these sensitivity studies will necessarily a priori bound realistic changes in RISC-3 reliability. As an example, MOV failure rates prior to Generic Letter (GL) 89-10 were significantly higher than the values assumed in the risk sensitivity study described in NEI 00-04. In particular, the NRC stated in Supplement 1 to GL 89-10 on page 5 that the results from implementation of Bulletin 85-03 revealed that many more motor-operated valves (MOVs) than expected would not have been able to operate under design-basis conditions. The NRC notes in Supplement 1 to GL 89-10 that the approximately 8% failure rate suggested from the results was much higher than PRAs had assumed. This (past history) is also a reason why the NRC disagrees that there

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
		is no reason to suspect a significant change in RISC-3 reliability will occur. Past history suggests that unless this equipment is properly treated, significant changes in reliability can occur. No revisions to the final rule have been made as a result of this comment.
b-6	There is no need for a separate description of the § 50.69(c)(1)(iv) evaluations under § 50.69(b)(2)(iv) when this will be described as part of the categorization process to meet § 50.69(b)(2)(i). See comments b-5, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with this comment. It is true that licensees might readily meet both (b)(2)(i) and (b)(2)(iv) with one description of the categorization process, and that is allowed by the rule language. Removing the (b)(2)(iv) description could create confusion as to what submittal information is required since some of the information requested in (b)(2)(iv) could be at a lower level of detail than the more general categorization process description. Since the NRC believes the current rule structure provides more clarity as to what submittal information is required, it is retained for the final rule. No revisions to the final rule have been made as a result of this comment.
b-7	The entire § 50.69(b)(2)(iv) requirement should be deleted for multiple reasons: 1) the categorization process initially uses importance measures that "fail" SSCs regardless of degradation mechanisms, 2) common cause susceptibility is specifically addressed in the categorization process, 3) the integrated sensitivity study increases the RISC-3 failure rates simultaneously regardless of known degradation, and 4) the appropriate place to address known degradation is in the high level requirements of § 50.69(d)(2) and the associated licensee program for RISC-3 treatment. See comments b-5, b-6, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees that the § 50.69(b)(2)(iv) requirement should be deleted. The § 50.69(b)(2)(iv) requirement is a requirement to submit this information/description to the NRC for prior review and approval. The NRC considers this part of the categorization process to be central to its robustness. Hence it is essential that the staff review and approve this portion of the categorization process, and therefore the requirement to submit this description remains in the final rule. A licensee's submittal description may address the points that the commenter raised as part of their description of how their categorization process addresses this evaluation requirement. See response to comment b-5 for the reasons why this evaluation is required. No changes to the final rule were made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-8	The commenter recommended that the size of the line/penetration not be specified in the rule language in order to facilitate reasonable changes to that size to be used based on new information or analyses in the future.	The NRC disagrees with this comment. The Commission has made a determination that the size specified in § 50.69(b)(x) is acceptable. At this time, the NRC has not determined that a larger size is acceptable for application to § 50.69, nor has the NRC received a such a proposal. At this time, for the Commission to entertain a larger penetration/containment isolation valve (CIV) size, and subsequently revise the rule language to reflect any such review (assuming that such as size is acceptable) would likely cause the NRC to re-notice § 50.69 for stakeholder comment. Licensees and applicants are free to pursue exemptions (to § 50.69(b)(x)) to this criteria if they conclude a larger penetration opening can be justified for their containment design. If such a proposal is ultimately reviewed and accepted, and can be applied generically, the NRC will consider a revision to § 50.69 to reflect the new criteria. No revisions to the final rule have been made as a result of this comment.
b-9	The rule is ambiguous concerning the extent of implementation of § 50.69 to systems other than those specifically referenced in the license amendment. The rule language should be clarified such that only initial implementation requires approval. See comments b-4, b-16	The NRC disagrees with this comment. The NRC concludes the current rule language is sufficiently clear in describing the regulatory requirement. It indicates that the Commission will enable a licensee to utilize section 50.69 by approving a license amendment. It is not the intent of § 50.69 to require an approval each time the licensee decides to extend the scope of systems for § 50.69 approval. Instead, the § 50.69 approval is a “process” approval. As long as licensees remain within the scope of NRC’s safety evaluation approving the categorization process they do not require NRC review. It should also be noted that a list of systems is not required in the submittal, and as such, a change to the scope of systems for which a licensee intends to implement § 50.69 would not require NRC review and approval. Although the NRC believes the rule requirements are clear, the SOC has been revised to further clarify this issue in response to this comment.
b-10	The discussion of the NRC review of the PRA is inconsistent within the SOC and needs to be clarified. It is recommended that the SOC be clarified to be consistent with draft regulatory guide (DG) DG-1122 regarding the appropriate level of review of the PRA. See also comments b-1, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC agrees with this comment regarding the need to clarify the SOC regarding the NRC review of the PRA supporting implementation of § 50.69. DG-1122 was recently issued as RG 1.200 and is currently undergoing trial use. Reference has been made to that guide in the SOC. The SOC has been clarified regarding the use of RG 1.200 to ensure the adequacy of the PRA used for § 50.69 application.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-11	The SOC discussion supporting Part 21 is long and repetitive and should be shortened without losing the context of the basis. See also comments b-12, b-13	The NRC disagrees with this comment. The Part 21 discussion is long and thorough due to the need to set forth the Commission's bases for the application of Part 21, excluding RISC-2, RISC-3, and RISC-4 SSCs from reporting obligations under Part 21 and the need to explain the Commission's position on the relationship between 10 CFR Part 21 and criminal liability under Section 223.b of the Reorganization Act of 1974 (ERA). The commenter did not provide examples of any "repetitive" discussion. However, the NRC has made some changes to the Part 21 SOC discussion to clarify the Commission's discussion.
b-12	The only difference between RISC-1 and RISC-2 SSCs is based on the definition of safety-related in § 50.2. The Part 21 discussion where RISC-1 SSCs are compared to RISC-2 SSCs is not consistent with the definition of safety-related in § 50.2. The SOC discussion of "basic component" is virtually identical to the definition of safety-related in § 50.2. The applicable SOC text should be revised to be consistent with § 50.2. See comments b-11	The NRC agrees, in part, with this comment. The final rule SOC was revised to utilize language that is identical to § 50.2 when discussing the RISC-1 SSC functions in the portion of the SOC identified in the comment. It should also be noted that this portion of the SOC is discussing the relative safety significance of RISC-1 and RISC-2 SSCs from a broader perspective than the design basis and is attempting to put the RISC-1 design basis functions into this larger overall plant risk context recognizing the high safety significance of the design basis functions that remain within RISC-1. The NRC disagrees with the need to revise the SOC discussion where "basic component" is discussed. The basic component definition comes from Section 223.b of the Atomic Energy Act (AEA), and as such this is a statutory definition.
b-13	The WASH-1400 reference in the part 21 discussion is outdated. A more appropriate/recent reference is NUREG-1150. See comments b-11, b-12	The NRC agrees with this comment. The SOC has been revised to refer to more recent efforts.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
b-14	The SOC discussion for § 50.36 should clarify that SSCs that are RISC-1 and RISC-2 are not to be included within § 50.36(c)(2)(ii) Criterion 4 based on past agreements between the Commission and industry.	The NRC disagrees with this comment. As noted in the SOC, § 50.36 is not scoped into § 50.69 since other risk-informed efforts are addressing that regulation. As such, § 50.69 and § 50.36 are independent regulatory efforts, and § 50.69 does not impact § 50.36 or the meaning of its requirements. Additionally § 50.69 is not imposing TS requirements on RISC-2 SSCs. Instead § 50.69 contains the § 50.69(d)(1) requirements. Regardless, § 50.36(c)(2)(ii) requirements remain, and it is possible that an SSC identified through the § 50.69 categorization process as safety significant (and not previously recognized as such) could be considered for TSs per the § 50.36 criteria. Although the NRC believes this is somewhat unlikely (for something in RISC-2 to rise to a level of safety significance meriting TS requirements), it cannot be ruled out ahead of time. Any such consideration would be under § 50.36, not § 50.69. No revisions to the SOC have been made as a result of this comment.
b-15	Section 50.44 should be reviewed to determine if the new rule contains STRs that should be within § 50.69 scope as suggested in the SOC. See comments b-2, b-3	The NRC agrees with this comment. The NRC reviewed the revised § 50.44 and found no special treatment requirements. When § 50.44 was revised, a portion of the old § 50.44 regarding application of Appendix B requirements to high point vents was moved to § 50.46a where it was more appropriately located. This particular requirement was not risk-informed as part of the § 50.44 effort, and was instead simply relocated. Section 50.46a(b) requires the "design of the vents and associated controls, instruments and power sources must conform to appendix A and appendix B of this part." Since application of Appendix B is clearly a special treatment requirement, the Appendix B portion of § 50.46a(b) is now within § 50.69.
b-16	The licensee should not be required to wait until NRC approval before proceeding with performing the categorization and treatment processes. NRC approval should permit the licensee to implement the results of the categorization and treatment process. See comments b-4, b-9	The NRC agrees with this comment. Licensees are free to develop (at their own risk) the § 50.69 processes, and perform § 50.69 categorization prior to NRC approval. However licensees may not implement the results of these processes, in terms of revised treatment applied to SSCs, until NRC has approved the license amendment. The SOC has been revised to clarify this situation.

TABLE 2 - 50.69 Paragraph (c) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-1	The proposed rule does not restrict the reclassifications under the proposed rule to only those components performing a function for internal events at power. It is totally inappropriate to use a limited-scope tool to make unlimited scope reclassifications. The PRA used for this rulemaking should address how the plants are designed, constructed, and operated and not for some limited subset of their design, construction, and operation. Licensees should not be allowed to categorize SSCs that are outside the scope of the PRA (i.e., where an expert process is used without PRA input).	The NRC disagrees with this comment. The rule recognizes that the PRA results are but one input to the categorization process and that an integrated decision-making panel (IDP) is required to ensure the categorize of SSCs has been appropriately performed considering all aspects, including areas in which a plant-specific PRA does not address the subject SSC risk aspects completely. Additionally, see the response to comment b-1 regarding the use of a conservative categorization approach where PRA techniques are not used. While the NRC does not restrict categorization of SSCs outside the scope of the PRA as suggested by the comment, the regulatory structure is conservative in its application to these SSCs as explained in the response to comment b-1. The NRC finds the rule to adequately address this area and results in a conservative categorization approach if less than full-scope PRAs are used (resulting in no relief for SSCs relied upon in the non-PRA approaches, which effectively limits the scope of SSCs subject to relief and would be consistent with the basic intent of this comment). No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-2	The proposed rulemaking would require an “expert panel” or equivalent process be used to reclassify equipment outside the scope of the at-power, internal; events PRA. In theory, this approach seems like a viable alternative. But what prevents the expert panel from essentially blanket reclassifications of out-of-scope equipment on the flimsy excuse that if it were safety significant, it would appear in the PRA? The proposed rulemaking fails to establish appropriate expectations for “expert panels.” This failure will prevent plant owners from good faith efforts to meet or exceed those expectations and later prevent NRC inspectors from evaluating whether expert panels functioned appropriately. See comments b-1, c-1	The NRC disagrees with this comment. The rule requires that SSCs 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. Section 9 of NEI-00-04, which the NRC is endorsing with appropriate exceptions and clarifications in RG 1.201 as part of this rulemaking, provides more detailed guidance on the composition of the IDP and activities to be conducted by the IDP, including guidance for categorizing components outside the scope of the PRA. RG 1.201 provides additional guidance for SSCs not explicitly modeled in the PRA. This additional guidance should make it clear that it is not acceptable to lower the safety significance of an SSC solely on the basis that it is not explicitly modeled in the PRA. It is also important to note that the categorization process must be first reviewed and approved by the NRC and this review will, in part, look at the IDP process that is being implemented. It is also important to note that implementation of § 50.69 places limitations on the IDP by restricting the panel’s ability to lower the category of an SSC except under defined conditions (e.g., where the SSC is potentially safety significant only as a result of a sensitivity study). Finally, there are also IDP decision documentation requirements that will allow NRC inspection of the process which should allow the NRC the capability to identify any instances where categorization of an SSC was not justified. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-3	The NRC must establish minimum standards for full-scope, internal and external, level 2 PRAs and verify that PRAs meet or exceed those standards before using their results to lessen regulatory requirements. See comments b-1, b-10, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment for this specific application. The NRC has structured this framework such that a licensee or applicant that wishes to use non-PRA methods to address external events or other modes of operation (for areas where a PRA is not required by § 50.69) must maintain the SSCs that are credited in these non-PRA approaches as safety significant. As a result, the review and approval of § 50.69 categorization processes will limit what licensees can do as far as categorizing SSCs to RISC-3 and RISC-4 when non-PRA methods are utilized, and as a result this approach is both restrictive and conservative. It is also noted that a licensee or applicant that does wish to use PRA methods for these modes and events will receive greater NRC review since there are currently no consensus PRA standards addressing external events or modes of operation other than full power. The development of standards for full-scope level 2 PRAs is a separate regulatory activity from § 50.69 and is being specifically addressed by the development of a NRC action plan in response to a Commission staff requirements memorandum (SRM). The development of such standards is ongoing, but completion of these standards is not expected in the very near term. With regard to the specific application of § 50.69, the rule in conjunction with the implementation guidance (NEI 00-04 as endorsed by RG 1.201) provides sufficient PRA requirements and guidance. At this time, the NRC finds that the scope and review aspects of § 50.69 license applications are adequately addressed and are consistent with the NRC action plan. If the NRC action plan and resulting tasks impact the NRC review of § 50.69 license applications, these impacts will be addressed through revision of the associated regulatory guidance, consistent with the NRC action plan. See the response to comments b-1 and p-5. Based on the above discussion and the responses to comments b-1, p-5, et al, the NRC finds the final rule and supporting SOC adequately address this area. Thus, no revisions to the final rule and SOC have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-4	The NRC must determine the sanity of using results from even the best quality, all mode PRA for internal and external events to justify reducing regulatory oversight of safety-related equipment since PRAs use equipment reliability data that is the result of the equipment being subjected to higher regulatory oversight. Is the NRC stipulating that its past regulatory oversight had no value? If not, how can it reduce the regulatory oversight on equipment based on past performance results that benefitted from NRC oversight? See comments: b-1, b-10, c-3, c-5, c-14, c-16, c-21, c-22, d-34, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. Nuclear power plant operating data is not readily available regarding what impact special treatment requirements have on equipment reliability. Nonetheless, the rule is structured to address the potential for the reliability of RISC-3 SSCs to degrade. To address this issue, § 50.69 is structured to contain: 1) robust categorization and PRA requirements, 2) requirements to show that implementation risk is acceptably small, 3) feedback requirements of paragraph (e) to maintain the validity of the categorization process, 4) the high level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability, and 5) a requirement that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. Thus, the rule contains sufficient provisions to ensure that, even if there is a reduction in RISC-3 SSC reliability due to the reduction in special treatment requirements for these SSCs, the associated reliability data will be collected and fed back into the categorization process to maintain any associated risk increase acceptably small. Past regulatory oversight has been valuable in maintaining safe operations within the existing regulatory framework. Regulatory oversight will continue to be properly applied to SSCs, and even enhanced, as risk insights are used to focus that oversight on the more safety-significant SSCs.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-5	It seems redundant that both a peer review and a NRC review are required. See comments b-1, b-10, c-3, c-4, c-14, c-16, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. The industry peer reviews were an one-time general-scope review of a licensee's PRA covering internal events at full power. The peer reviews were performed by industry personnel using industry guidance and were done prior to the ASME standard on PRA quality for internal events at full power and the NRC's regulatory guide (RG 1.200) on PRA quality. Consistent with the industry guidance for this specific application (NEI 00-04), licensees will need to address the findings of their individual PRA peer review and also address any areas in which they do not meet Capability Category 2 as defined in the ASME standard on PRA quality (referred to as a delta review), as endorsed by RG 1.200. The NRC PRA-related review is specifically focused on the § 50.69 application and focuses on the peer review and ASME delta review findings, its relevancy to categorization, and the actions taken to address the relevant aspects including areas where the NRC concludes that the peer review may need to be supplemented by additional sensitivity studies and/or model changes. Thus, these two reviews (i.e., the industry peer reviews and the NRC § 50.69 application reviews) are quite different. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-6	The methodology for determining system boundaries is unclear and should be left to the licensees to determine in a clear and consistent method. Often, a licensee's PRA uses different system boundaries than the plant master data list. Examples provided include the diesel generator fuel oil transfer system, which can be considered separate from the diesel generator system, both of which can be considered separate from the plant electrical system. Similarly, the Westinghouse Owners Group (WOG) stated that clarification should be provided as to the definition of "system" for the purposes of implementing the rule and cited examples, including the use of tag numbers to identify SSCs belonging to a common system can result in different definition of the system boundaries compared to that used in the design basis documentation of the Maintenance Rule and also referred to the boundaries between mechanical and electrical components. See comments c-12, c-13, c-15, c-29	The NRC agrees with the basic intent of these comments in that licensees should determine appropriate system boundaries in a clear and consistent manner, but the NRC believes the current rule language is clear in requiring that entire systems or structures be addressed (not parts of systems or structures) when § 50.69 is implemented. The primary reason that § 50.69 requires the categorization to be performed for entire systems and structures is to ensure that all the functions (which are primarily a system-level attribute) for a given SSC within a given system or structure are appropriately considered for each SSC in determining its safety significance. The system boundary definitions should be consistent with the PRA used in categorizing the SSCs and careful consideration should be given by the licensee to ensure all important functions are captured for SSCs, especially those that are common to multiple systems (e.g., tank discharge valve that feeds to multiple systems). The methodology for determining systems boundaries is left to the licensee recognizing these important constraints (i.e., drawing system boundaries in such a way as to break apart a system when viewed from a system functional standpoint would not meet this requirement). No revisions to the final rule or SOC have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-7	Recovery actions should not unduly influence the risk categorization of SSCs. However, when such actions are justified by adequate equipment, procedures, and training, then these recovery actions are judged reasonable and should be considered acceptable. The consequential result is that the underlying equipment is of lower risk worth because its initial failure can be mitigated by timely action and this should be considered by the IDP. It is expected that recovery actions that replace equipment actuation, not equipment repair, will be important in the short term accident response. Such actions will have minimal impact on equipment "fail to run" type PRA data. In the long term accident response, actual equipment repair may be fully acceptable. See also comment c-35	The NRC agrees with the basic intent of this comment in that recovery actions can be considered. The intent of the rule as expressed in the SOC, which is consistent with the industry implementation guidance, is to ensure that these factors do not mask the importance of a SSC. The IDP should be provided information regarding SSCs that would be safety significant if less (or more) credit were given to recovery actions so that they can consider that information in making a final safety significance categorization for these SSCs. Also, the NRC notes, that there typically are very few repair actions modeled in PRAs and these actions should be reviewed to ensure they have been applied consistent with the current PRA technical adequacy consensus standards and should be reviewed by the IDP for this application. No revisions to the SOC have been made as a result of this comment.
c-8	The potential for CCF of SSCs is an important concern in the risk categorization. It is understood that the IDP is not expected to become expert in determination of CCF probability values which may appear in a PRA. The IDP scope should be limited to consideration of SSC redundancy, diversity of SSCs performing similar functions, existing treatments used to guard against CCF, and discerning if any suggested changes in treatment may significantly affect CCF. That is, the IDP performs a qualitative review of CCF impact. See comments c-2, c-9, c-10,c-11, c-37	The NRC agrees that the IDP is not expected to become experts in PRA methodologies, including CCF determinations, but disagrees with the limited scope of the IDP suggested by the comment. This description appears too limited. The IDP is provided with the relevant information pertaining to the safety significance of a SSC that comes from both the PRA and non-PRA/qualitative/deterministic sources. The IDP uses this information in making a decision on the safety significance of a SSC consistent with the requirements of § 50.69 (e.g., considering results of sensitivity studies, including studies that involve increasing and decreasing the CCF values for SSCs) and the approved categorization process. On this issue, the intent of the rule, as expressed in the SOC, is consistent with the industry implementation guidance. No revisions to the final rule or SOC have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-9	The risk metrics of interest for SSC categorization should be CDF and LERF, i.e., those that can be related to significant impact on public health and safety. While the 11 items listed in the SOC form a good checklist for IDP consideration, this consideration must not only focus on consequences, but also on the probability of these consequences to gain a perspective on risk. See comments c-8, c-10,c-11, c-37, n-4	The NRC disagrees with this comment. In determining safety significance of a SSC, other aspects must be considered including for example defense-in-depth, long-term containment integrity, etc. The intent of the list is to identify SSCs that are not modeled in the PRA that might be safety significant. The SSCs identified by this list are then to be qualitatively evaluated by the IDP to determine the impact of relaxing requirements on SSC reliability and performance. The second bullet on the list states in part ”..have minimal impact on failure rate increase..” Thus the IDP can consider probability as part of this qualitative decision-making process. As a result of other comments (see comment n-4), this list has been revised to reflect feed back from the ASME code case N-660 development process/pilots and has been removed from the SOC and placed in RG 1.201 and/or NEI 00-04.
c-10	In considering each item (per checklist), the IDP addresses qualitatively or quantitatively the contribution that each consideration may have on total plant risk (e.g., the probability or frequency of occurrence, the relative contribution of each factor, etc). See comments c-8, c-9, c-11, c-37, n-4	Refer to the response to comment c-9.
c-11	Detailed listings of all SSCs not included explicitly in the PRA need not be developed for IDP consideration. See comments c-8, c-9, c-10, c-37	The NRC disagrees with this comment. If, after categorizing a system at the “system level” as safety significant per the § 50.69 implementation guidance of NEI 00-04, a licensee elects to do a more detailed categorization at the component level, then any component within that system that is categorized as low safety significant must be identified to, and processed by, the IDP, including those SSCs that are not explicitly modeled in the PRA. Thus, this detail must be provided for component-level categorization. It should be noted that the definition for “component” should be the same as the component definition used in the PRA supporting the categorization process. In addition, all SSCs that are categorized under this rule must be identified and processed by the IDP, as they make the final decision regarding the category of the SSC and ensure that all factors have been adequately addressed, including non-risk-related factors such as defense-in-depth. No revisions to the final rule or SOC have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-12	Implementation of § 50.69 at a plant could stop after a single plant system. See comments c-6, c-13, c-15, c-29	The NRC agrees with this comment. Nothing in this regulation precludes a licensee from implementing § 50.69 for only one system. No revisions to the final rule or SOC have been made as a result of this comment.
c-13	Section 50.69(c)(1)(v) states that categorization be done at the system level. The application of STRs as well as safety classification of components are normally made at the component level. Similarly, the categorization needs to be at the component level since systems often have more than a single function and safety significance is established by the function. See comments c-6, c-12, c-15, c-29	The NRC agrees with this comment. Treatment must be done at the component level and the categorization is applied to individual components, though the manner in which the categorization is done may vary (i.e., may determine system-level functional importances and then map components to functions to determine the component-level importances). The § 50.69 SOC has been clarified to discuss this issue in Section V.4.5 by using the words that already exist in the discussion in III.2.0. The primary reason that § 50.69 requires the categorization to be performed for entire systems and structures is to ensure that all the functions, for a given SSC within a given system or structure, which stem from the system-level functions are appropriately considered for each SSC in determining its safety significance. Careful consideration should be given by the licensee to ensure all important functions are captured for SSCs, especially for those SSCs that are not modeled in the PRA and/or SSCs that are common to multiple systems (e.g., tank discharge valve that feeds to multiple systems). This requirement to address entire systems and structures also ensures the entire set of components within the system or structure are considered and addressed in order to assure that implicitly modeled SSCs are appropriately considered.
c-14	The requirement for a PRA peer review against a NRC endorsed standard appears to delay application of § 50.69 until existing draft guide DG-1122 is final, and then after licensees have either completed peer reviews under final guidance or completed delta studies and resolved differences between existing industry peer reviews and the newly completed NRC guidance. See comments b-1, b-10, c-3, c-4, c-5, c-16, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC agrees with this comment in that the requirement (§ 50.69(c)(1)(i)) for a PRA peer review against a NRC endorsed standard may delay applications for § 50.69 dependent on the state of a licensee's peer review and conformity with RG 1.200 (note that DG-1122 has been issued for trial use as RG 1.200). The comment correctly identifies what licensees will need to do to address PRA technical adequacy for this application. As discussed in Section VI of the SOC, NRC previously 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, as envisioned at that time. This additional guidance could be helpful to licensees in ensuring that their determination of PRA technical adequacy per RG 1.200 is appropriate for a § 50.69 application. See also the responses to comments b-1, c-3, and p-5.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-15	The requirement to evaluate entire systems should be understood to exclude entire support systems. For example, if system A is evaluated as RISC-3, but components of system A are in turn dependent on system B operation, and the particular system B components of interest are categorized as RISC-1 or RISC-2, then system A is understood not to include these system B components and is not to be categorized as RISC-1 or RISC-2. See also comments c-6, c-12, c-13, c-29	The NRC agrees with this comment. See also responses to comment c-6 and c-13. The SOC (Section V.4.5) for § 50.69 is clarified accordingly.
c-16	Previous PRA assumptions have been documented to be risk "misinformed" to the point that otherwise robust design and safety margins can be overridden by licensee "mismanagement." This does not provide a sound basis for the agency to expand the reliance on PRA. The Davis-Besse vessel head corrosion is cited as an example where it was not considered either a probable or possible event and was never considered in PRAs in risk-informing the surveillance and maintenance activities of licensee reactor pressure vessels. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-21, c-22, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. The NRC recognizes the need for robust categorization and PRA requirements. The rule contains PRA and categorization requirements against which the NRC staff is reviewing and approving a licensee's categorization process prior to implementation. Additionally, RG 1.201 provides more detailed guidance in this area to ensure a robust categorization process. Further, § 50.69 also contains feedback requirements to help maintain the validity of the categorization process and high-level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability. Also see NRC response to comment c-4 for the approach to ensuring the validity of the categorization process is maintained and NRC response to comment m-4 regarding the use of risk insights involving Davis-Besse. The Davis-Besse event indicates that there is always a possibility that a licensee may not comply with regulatory requirements or previous commitments and as a result not comply with applicable requirements. However, this possibility, exists for both deterministic and risk-informed regulation, and is not a reason for not moving forward with risk-informed regulation. It points out the importance of the NRC's inspection and enforcement processes, and the need for a licensee with the proper commitment and safety culture. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-17	The categorization and treatment processes are not adequately linked to ensure that changes to risk are maintained small. See comments c-4, d-32	The NRC agrees with this comment and the rule has been clarified in response to public comments on this issue and a provision has been added to the final rule to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. See also the responses to comments c-4 and d-32. Based on the above discussion and the responses to comments c-4 and d-32, the NRC finds the revised final rule and supporting SOC to adequately address this area.
c-18	The categorization process proposed by the rule relies on long-term average unavailabilities and failure probabilities of SSCs that are based on steady state assumptions. Observed surprises, and large areas of uncertainty regarding degradation mechanisms raise concerns about the validity of steady state assumptions used in the categorization process. See comments c-4, d-34, d-35	The NRC agrees that the data used in PRAs is, in many cases, based on long term unavailabilities. This is one of the reasons why approaches such as § 50.69 are not more risk-based, and instead are blended, risk-informed approaches. Section § 50.69 uses PRA as one piece of a risk-informed decision process that considers all relevant information pertaining to SSC safety significance. This process recognizes potential uncertainties and through the implementing guidance uses various sensitivity studies to ensure that SSC importance is not masked. This process also builds in defense-in-depth and requires that a licensee have reasonable confidence that any risk increase due to implementation be small. Additionally, the rule requires data to be collected and fed back into the PRA to reflect the performance of SSCs, to adjust the model itself to ensure the continued validity of the categorization process, and to take corrective actions if the data indicates unexpected impacts. Also see the responses to comments c-4, d-34, and d-35. No revisions have been made to the final rule as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-19	The proposed rule relies on sensitivity studies generated by the licensee to evaluate changes in SSC reliability and assess the change in risk to public health and safety rather than requiring the licensees to characterize and reasonably bound the effects of eliminating treatments on SSC reliability under design basis and severe accidents. See comments b-5, b-6, b-7, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC agrees that the rule does not require licensees to quantify/characterize the potential reduction in reliability resulting from the reduced treatment applied to a RISC-3 SSCs. It is difficult to explicitly relate changes in treatment to changes in SSC reliability. Recognizing this situation, § 50.69 has been constructed to account for this inability to quantify/characterize the potential reduction in reliability due to reduced treatment, as described in responses to comments c-4, d-32, d-34, and d-35, by ensuring the results of the licensee's categorization process are maintained valid throughout the treatment phase. The categorization process that a licensee utilizes must comply with § 50.69 requirements. This categorization process will be reviewed and approved by the NRC staff prior to implementation. Licensees are required to provide reasonable confidence that any risk increase due to implementation is small and they must have a technical justification that supports this risk assessment, including the basis for why it adequately addresses the potential reliability changes for RISC-3 SSCs. This basis may include reliance on the capability of the licensee's data collection and feedback processes. Further, the rule has been revised to clarify the linkage between treatment and categorization and specifically to ensure that the treatment process is consistent with the categorization process, including the risk sensitivity study (i.e., maintain any risk increase due to reduced treatment acceptably small). See also the responses to comments c-4, d-32, d-34, and d-35.
c-20	Due to the elimination of prescriptive regulatory special treatment requirements, safety-related equipment would likely become significantly degraded and this degradation would likely not be detected. Thus, the proposed rule does not provide reasonable assurance or adequate confidence that the proposed change in risk as a result of rule implementation will be insignificant and acceptably small. Also see comments d-11 and d-12. See comments b-5, b-6, b-7, c-4, c-19, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with the comment that the rule does not provide reasonable assurance or adequate confidence that the potential change in risk resulting from implementation of the rule will be acceptably small. The rule is structured to contain 1) robust categorization and PRA requirements, 2) requirements to show that implementation risk is acceptably small, 3) feedback requirements of paragraph (e) to help maintain the validity of the categorization process, and 4) the high-level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability. In addition, a provision has been added to the final rule to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. See the responses to comments c-4, d-32, d-34, and d-35. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-21	The proposed rule requires that SSC safety significance be determined using quantitative information from an up-to-date PRA reasonably representing the current plant configuration. The current PRAs are updated periodically by the licensee, but no firm schedule is required nor no NRC review is outlined to ensure that the PRA "reasonably represents" the current plant configuration. We recommend that the NRC review the licensee's PRAs, in depth, periodically. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-22, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. The NRC recognizes the need for robust categorization and PRA requirements. The rule contains PRA and categorization requirements against which the NRC staff is reviewing and approving a licensee's categorization process prior to implementation. Additionally, the guidance contained in NEI 00-04, as endorsed by the NRC, and RG 1.201 provide more detailed guidance in this area that most licensees are expected to follow (and where exceptions are taken, the NRC staff will review these in detail). One aspect of this NRC review will involve ensuring that the licensee has in place a process to ensure their PRA reasonably represents the plant and that the licensee has in place a process for updating the PRA to ensure it continues to meet this requirement. This would also be an area that could be inspected following initial implementation to ensure licensees are complying with the rule. Thus, mechanisms already exist (via NRC inspections) to ensure the licensee's PRA reasonably represents the plant configuration. Therefore, the NRC does not believe it is necessary to mandate that the NRC will perform an in-depth periodic PRA reviews as part of this rule. Given the nature of this rulemaking (i.e., revising special treatment requirements while maintaining the facility design basis), the NRC has concluded that these PRA requirements are adequate for this application. The rule requires the PRA to be updated periodically, and this information is available for NRC inspection. Also see the responses to comments b-1 and p-12. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-22	The NRC's inspections during the pilot verification of the Mitigating System Performance Index (MSPI) documented numerous findings of important components being inexplicably omitted from the at-power PRAs (and cites numerous examples), including the need for NRC to adjust PRA results for MSPI (and specifically uses support system initiator modeling differences as the rationale). The NRC knows that current PRA results are inadequate to be used without "adjustments." Yet the proposed rulemaking provides no adjustments. In theory, the 25 percent variance (the range in difference for certain components provided in a presentation on the MSPI pilots) between modeling approaches might allow some plant owners to downgrade components and prevent other plant owners from doing so. The NRC should not proceed with the § 50.69 rulemaking when it knows that PRAs require adjustments, and such adjustments are not required (examples are provided to support this conclusion). See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-21, p-5, p-9, p-12, m-4, m-5	The NRC disagrees with this comment. The NRC notes that § 50.69 requires the PRA to be peer-reviewed, and that the NRC staff will review the output of the peer review process as part of the submittal review and approval for § 50.69. The NRC is aware of issues associated with modeling support system initiators, and other similar PRA modeling issues, and these issues will be a focus of the NRC review of the licensee's application requesting to implement this rule. The NRC concludes that the peer review requirement as well as NRC review of the peer review results as part of the application process will, in conjunction with the other categorization features of § 50.69 provide high confidence that SSCs will be properly categorized. Also see responses to comments b-1, c-21, and p-12. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-23	The commenter agrees with the § 50.69(c)(2) requirements in that it provides licensees with the necessary flexibility to staff the IDP with appropriate expertise. However, the section-by-section analysis, which supports the § 50.69(c)(2) IDP requirements, provides much more prescriptive requirements for the IDP, including years of plant experience, minimum number of panel members, particular training requirements, etc., and is more restrictive than DG-1121[1] or NEI 00-04 and unnecessarily limits licensee flexibility. See comments c-2, c-24, c-28, c-32, m-7, m-11, m-12, m-18	The NRC agrees with the comment that the SOC was more prescriptive than needed. This portion of the SOC was reviewed to identify and relocate description and guidance that is placed in the guidance document for § 50.69 (i.e., RG 1.201) and this portion of the SOC has been simplified. Also see the response to comment c-2. The NRC finds the revised SOC and supporting guidance document to adequately address this area.
c-24	The section-by-section analysis, which supports the § 50.69(c) categorization requirements, provides the NRC's expectations on the results of the categorization process, rather than expectations on the process itself and provides a number of specific examples where the SOC presents the expected RISC category of a number of SSCs. The rule should not include NRC expectations on particular results of the categorization process. See comment c-23, c-28, c-32, m-7, m-11, m-12, m-18	The NRC agrees with this comment. This portion of the SOC was reviewed to identify places where expected categorization results were discussed and these discussions were eliminated unless they were solely being provided as an example of the process, in which case the discussion was clarified to ensure this discussion could not be misconstrued to imply the NRC was requiring certain results a priori. Thus, this portion of the SOC has been simplified. Also see the response to comment c-2.

[1]Draft Regulatory Guide DG-1121 was finalized as RG 1.201. Public comments on proposed § 50.69 referred to DG-1121 since it was part of the proposed rule package. The responses refer to the final regulatory guide: RG 1.201.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-25	The SOC discusses why safety margins are maintained by this rule. There are no evaluations necessary to demonstrate that sufficient safety margins are maintained because there are no actions allowed by the rule that can alter safety margins. Thus, delete the words "sufficient safety margins are maintained" from § 50.69(c)(1)(iv).	The NRC disagrees with this comment. Section III.7.3 discusses the integral part that "having reasonable confidence that any increases in CDF and LERF are small" plays in this determination. The requirements in § 50.69(c)(1)(iv) will provide this confidence and when considered in combination with other rule features (as discussed in III.7.3) maintain safety margins. Contrary to NEI's assertion, the elimination of special treatment requirements for all low-risk safety-related SSCs in a nuclear power plant can have significant impact on the safety margin if some of those SSCs are incapable of performing their safety functions under accident conditions. This is, at least partly, why the licensee is required to provide reasonable confidence that RISC-3 SSCs will continue to meet design basis functionality requirements. No revisions to the final rule have been made as a result of this comment.
c-26	The evaluation to provide reasonable confidence that any risk increases due to the implementation of § 50.69 are small will be accomplished by an integrated sensitivity study that simultaneously increases the failure rate of RISC-3 SSCs. This should be the only evaluation required by § 50.69(c)(1)(iv). See comments b-5, b-6, b-7, c-19, c-20, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with this comment. The assumptions in the (c)(1)(iv) evaluation can change significantly as a result of common cause failures and known degradation mechanisms. To have confidence in the risk sensitivity study results, it is necessary to have an understanding of these factors, and hence this is an integral part of the evaluation. This does not imply that the risk sensitivity study must quantify the impact of known degradation mechanisms, but these potential impacts and the programs that address these mechanisms must be identified to ensure they are carried forward into the treatment phase and that these programs are not eliminated for RISC-3 SSCs. Also see the responses to comments b-5 and d-34. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-27	SOC Section III.2.0 contains two sentences on page 26516 beginning with "A licensee is required to consider the potential effects of common-cause failures. To meet this requirement, a licensee would need to: (a) Maintain an understanding . . . and (c) factor this knowledge into the treatment of RISC-3 SSCs. " These sentences should be deleted, because this is an unrealistic expectation and an example of prescriptive methods for RISC-3 treatment in the SOC that goes beyond the requirements. Very few, if any, current PRAs include cross-system common cause modeling. Therefore, consideration of cross-system common cause is not warranted and is inconsistent with the earlier sentences. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC agrees that the cited second sentence in the SOC is too prescriptive per the comment in that it presents how the NRC expects the rule requirement to be met. The SOC text has been revised to reflect the need to address CCF and degradation mechanisms without providing prescriptive detail. Detail concerning this issue is addressed in the implementing guidance.
c-28	Various sections of the SOC provide expected results from the categorization regarding a specific SSC and what the staff expects its RISC classification to be. This is inappropriate and subverts the categorization process. The categorization process is robust enough to determine appropriate safety significant outcomes without the NRC imposing an outcome before the process even begins. See comments c-23, c-24, c-32, m-7, m-11, m-12, m-18	The NRC agrees with this comment in that the SOC discussions do not a priori require licensees to have the same results if they have an adequate basis for a different result. The SOC was reviewed to identify places where expected categorization results were discussed and these discussions were eliminated unless they were solely being provided as an example of the process, in which case the discussion was clarified to ensure this discussion could not be misconstrued to imply the NRC was requiring certain results a priori. Thus, this portion of the SOC has been simplified. Also see the response to comment c-2.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-29	The proposed rule should clarify the extent of a “categorized system.” While it is understood that major and minor components would be included, it is unclear if completion of a system categorization would include piping, cabling, fuses, relays, etc. which may not have explicit numbering designations consistent with the other components “contained” within the system. See comments c-6, c-12, c-13, c-15	As provided in response to comment c-6, system boundaries are to be defined by the licensee and should be consistent with the PRA used in the categorization process. In addition, as provided in response to comment c-13, the primary reason that § 50.69 requires the categorization to be performed for entire systems and structures is to ensure that all the functions, for a given SSC within a given system or structure, which stem from the system-level functions are appropriately considered for each SSC in determining its safety significance. Careful consideration should be given by the licensee to ensure all important functions are captured for SSCs, especially for those SSCs that are not modeled in the PRA and/or SSCs that are common to multiple systems (e.g., tank discharge valve that feeds to multiple systems). This requirement to address entire systems and structures also ensures the entire set of components within the system or structure are considered and addressed in order to assure that implicitly modeled SSCs are appropriately considered. Note that “component” as used in this context should be consistent with the PRA used to support the categorization process. If the identified components are part of the categorized system as defined by the licensee, then these components must be included even if they do not have explicit numbering designations. See also responses to comments c-6 and c-13.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-30	The SOC states that the proposed rule requires licensees to perform evaluations to assess the potential impact on risk from changes to treatment. The industry position is that reduced treatment on RISC-3 SSCs will not have an appreciable effect on component failures. The intent of Option 2 was to apply industrial controls to RISC-3 SSCs and in so doing provide sufficient confidence that SSCs continue to perform their design functional requirements when demanded. The commenter (South Texas Project (STP)) references its industry-wide database in support of the industry position that reduced treatment on RISC-3 SSCs will not have an appreciable effect on component failure rates. The commenter states that there has been no objective evidence provided by the NRC to substantiate the claim that reducing the regulatory-imposed special treatment requirements will directly relate to reduced component reliability if industrial practices are applied. The commenter asserts that performing sensitivity studies of modeled RISC-3 SSCs, with a bounding multiple of postulated failure rate increases, would provide sufficient assurance that any increase in a RISC-3 SSC failure rate would be recognized and compensatory measures taken well before the bounding condition was challenged. The commenter believes that this would eliminate the need to specifically consider changes in SSC reliability due to alternate treatment during the categorization process. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with the comment in that it implies a priori that there will be no appreciable effect on RISC-3 SSCs from reduced treatment, without establishing any means for ensuring this outcome or that the risk sensitivity study will adequately bound any degradation in performance of these SSCs. The industry position on this issue is essentially an assertion that is based on the analysis of a data base of commercial failure rates versus safety-related SSC failure rates. As discussed in the response to comment p-26, this data base has too many variables to make a clear conclusion. The initial concept of treatment for SSCs removed from STRs was industrial practice as discussed in SECY-98-300. However, the NRC's thoughts have evolved over the ensuing 5 years during the development of § 50.69 such that the NRC now concludes a minimum level of requirements must be established for RISC-3 treatment given the large range of industrial practices. The NRC does recognize that some licensee industrial practices may meet these minimum requirements. Contrary to the commenter's assertion, the NRC is not responsible for proving that nuclear plant operation would be unsafe if the special treatment requirements are eliminated for most safety-related plant SSCs. No experience exists with the operation of nuclear power plants with only high-level treatment requirements for safety-related SSCs. Sensitivity studies alone (without adequate basis for the factors assumed) are insufficient to demonstrate that changes in treatment will not result in degradation of SSC performance that exceeds the categorization process risk sensitivity study results. As nuclear power plant operating data is not readily available regarding what impact, if any, special treatment requirements have on equipment reliability, § 50.69 is structured to contain: 1) robust categorization and PRA requirements, 2) requirements to show that implementation risk is acceptably small, 3) feedback requirements of paragraph (e) to maintain the validity of the categorization process, and 4) the high level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability, and 5) a requirement to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. Also see the response to comment c-4. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-31	Performing sensitivity studies of modeled RISC-3 SSCs with a bounding multiple of postulated failure rate increases would provide sufficient assurance that any increase in a RISC-3 failure rate would be recognized and corrected prior to exceeding the bound. This approach would eliminate the need to specifically consider changes to SSC reliability due to alternate treatment . Performing sensitivity studies for non-modeled SSCs is not required due to the safety significance of these SSCs not meeting the threshold to require modeling. Requiring licensees to perform and submit bounding analyses of non-modeled RISC-3 SSCs to justify that existing programs are in place to ensure that potential changes in risk remain small places an unjustified and undue burden on licensees. This added burden is neither necessary nor appropriate, and is inconsistent with the granted STP exemptions. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-33, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with this comment. As discussed in comments c-4 and c-30, solely using a "bounding multiple" is not sufficient since there is no data within the nuclear power plant industry for safety-related SSCs that only have high-level treatment requirements. In addition, licensees are not quantitatively characterizing the reduction in reliability of RISC-3 SSCs as a result of reduced treatment, but rather are relying on the feedback and corrective action processes to capture RISC 3 SSC performance degradation prior to invalidating the categorization process results. Therefore, the basis for the "bounding multiple" is not quantitative, but relies on licensee programmatic processes to ensure it is not invalidated. It should also be noted that it is the population of RISC-3 SSCs for which reliability is an issue, not individual SSCs since a given RISC-3 SSC can fail with minimal safety impact (and hence the reason it is in RISC-3). Further, there may be numerous reasons as to why components are not modeled, especially if a limited scope PRA is used, and it should not necessarily be inferred that such non-modeled SSCs are not safety significant. It is true that for non-modeled SSCs, that have been specifically excluded because they cannot impact CDF and LERF, bounding increases in unreliability for these SSCs would not impact the overall delta risk conclusion. See also the responses to comments c-4 and c-30. No revisions to the final rule have been made as a result of this comment.
c-32	The 5 criteria for IDP assessment on page 26537 and subsequent discussion is guidance as opposed to information that clarifies language intent and as such is inappropriate and should be removed from the SOC. In addition, the criterion are sufficiently vague as to invite interpretation issues and cites an example with one criterion. See comments c-23, c-24, c-28, m-7, m-11, m-12, m-18	The NRC agrees with this comment. The SOC has been revised to remove this information and the subject criteria are addressed in the implementation guidance. Thus, this portion of the SOC has been simplified. Also see the response to comment c-2.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-33	For SSCs not modeled in the quantitative PRA, candidate RISC-3 SSCs have already been determined to be low safety significant because the basis for not modeling them is that their failure does not contribute to risk. For the qualitative PRA assessments, if an SSC is candidate RISC-3, then the screening assessment should identify these SSCs as low risk significant and therefore their complete failure does not contribute to the qualitative risk results. We should rely on the fact that the qualitative PRA assessments are much more bounding than the quantitative assessments and therefore there should be no requirements to assess the impact of reduced treatment for any SSC that is not modeled in either a qualitative or quantitative PRA. Thus, there should be no requirement to provide the "basis to support that the evaluations are bounding estimates of the potential change in risk" as the basis should be that it is not modeled in the PRA. The comment identified another group of SSCs not modeled in the PRA, those that are indirectly related to or support SSCs that are modeled in the PRA and states that it is the licensee's responsibility to ensure these SSCs are correctly categorized consistent with their associated modeled SSCs. The commenter states that it is the IDP's responsibility to ensure that those SSCs not modeled in the PRA do not impact CDF and LERF. The commenter suggests replacing the bounding analysis with text that identifies the two types of not-modeled SSCs and the requirement that each type of SSC be independently reviewed by the IDP to ensure they are correctly assessed for their potential to impact CDF and LERF. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-34, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with the comment that there is no need for a licensee using § 50.69 to provide a basis for supporting that its evaluations are bounding the potential change in risk. This does not imply that the basis must be quantitative, but may be a recognition that there are licensee programs that address some aspects that are not quantified, such as those that address known degradation mechanisms. These qualitative recognitions provide a basis for why these areas are adequately addressed even though they are not part of the quantitative analysis and ensure these required programs are carried forward and maintained in the treatment phase for RISC-3 SSCs, as appropriate. The NRC agrees that it is the responsibility of the IDP to ensure that those SSCs not modeled in the PRA are correctly assessed for their potential impacts, but this consideration includes more than just CDF and LERF contribution, such as defense-in-depth. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-34	The requirement to consider the potential effects of common cause interaction susceptibility, including cross-system interactions and potential impacts from known degradation mechanisms is inconsistent with the requirements of other parts of this regulation and further, is unnecessary from a technical perspective. The commenter also stated that cross-system common cause failures are rarely modeled in PRAs due to the incorporation of safeguards against common cause failures that are incorporated into plant practices. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-38, d-13, d-34, d-35, d-36, m-5	The NRC disagrees with this comment. Since individual RISC-3 SSCs will be demonstrated to have low safety significance, the potential for common cause failure among multiple RISC-3 SSCs (such as resulting from reduced controls for design, procurement, installation, testing, inspection, maintenance, repair, or replacement) is the principal reason for establishing a minimum set of high-level treatment requirements for RISC-3 SSCs. In order to effectively implement § 50.69, licensees must recognize the potential for SSC performance to degrade due to existing degradation mechanisms and/or as a result of reductions in treatment. Section 50.69(b)(2)(iv) does not mandate quantitative analyses, but rather, requires the licensee to identify the aspects of the licensee's programs (including design control, performance monitoring, and corrective action/feedback) that address these potential impacts to ensure the categorization process remains valid and the overall impact due to reductions in treatment are maintained acceptably small. Also see the responses to comments b-5, c-26, and d-34. No revisions to the final rule have been made as a result of this comment.
c-35	The SOC should be revised to clarify the issue of recovery actions versus human error probability (HEP) and what specifically is wanted. In some PRAs, recovery has a different meaning compared to the human error probabilities (HEPs). HEPs are modeled for all operator actions; some are the direct result of instructions in the emergency operating procedures (EOPs) and their actions are relatively straight-forward. Another class of operator actions involves recovery of previously failed equipment or functions and are typically referred to as recovery models. See comment c-7	The NRC agrees with this comment that the terminology could be confusing and requires clarification. The Section V.4 of the SOC is revised to clarify that it is intended to address all the human error probabilities including recovery actions and repair actions credited in the PRA, to ensure they do not mask the importance of the SSC. As stated in the response to comment c-7, the IDP should be provided information regarding SSCs that would be safety significant if less (or more) credit were given to HEPs, including recovery actions, so that they can consider that information in making a final safety significance categorization for these SSCs. Also, the NRC notes, that there typically are very few repair actions modeled in PRAs and these actions should be reviewed to ensure they have been applied consistent with the current PRA quality consensus standards and should be reviewed by the IDP for this application.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-36	The IDP discussion in the SOC appears to have been extracted from an early version of ASME code case N-660 that was developed for categorization of pressure boundary SSCs. There are problems with usage of this information in the SOC because the ASME code case considerations have changed as a result of pilot applications and it is difficult to apply to active components (since the focus of the considerations is passive boundary components). There are also differences in terminology between the NEI 00-04 and ASME N-660 that make the use of the code case considerations difficult in this application. The commenter recommends that the detailed considerations be left to the licensee and provided for NRC review in the documentation of the licensee's categorization process and that it be removed from the SOC. See comment n-4	The NRC agrees with this comment in that an early version of the ASME code case had been relied upon. This portion of the SOC has been revised to remove the guidance as it was too prescriptive and based on out-of-date information. Regarding the specific issue associated with IDP guidance, that is addressed as part of the NRC staff's review in RG 1.201 of NEI 00-04. As a result of other comments (see comment n-4), this list has been revised to reflect feed back from the ASME code case N-660 development process/pilots and has been removed from the SOC and the list of considerations is contained in RG 1.201 and/or NEI 00-04.
c-37	It should not be necessary to reconvene the IDP each time the PRA is updated to consider the impact of the PRA update on the previous categorization. This should be an engineering determination to judge whether the changes are significant in terms of IDP considerations. The SOC should be clarified accordingly. See comments c-8, c-9, c-10,c-11	The NRC agrees with this comment. PRA updates should not require the IDP to be reconvened, if the update does not involve or impact the importance of any categorized systems. However, it is the responsibility of the licensee to maintain the validity of the categorization process and if a PRA update results in a potential categorization change, then it is expected that the licensee will need to reconvene the IDP to address this change. The result of a licensee's PRA update effort could be inspected by the NRC to ensure the rule requirements on updating the PRA and SSC categorizations is being performed appropriately. The SOC is clarified consistent with the comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
c-38	Section V.5.2 of the SOC on page 26541 discusses the evaluations necessary for § 50.69(c)(1)(iv) and states a licensee is required to conduct evaluations that assume failure rates that might occur as a result of the revisions to treatment. These required evaluations that “assume” rates that “might” occur as a result of monitoring program changes are inconsistent with § 50.69(d)(2)(iii) and (e)(3), which require “consideration” of actual performance data and adjustment (if needed) to categorization or treatment. See comments b-5, b-6, b-7, c-4, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, d-13, d-34, d-35, d-36, m-5	The NRC agrees with the comment in that the wording was vague and open to being misinterpreted. This part of the SOC has been revised to reference the proper SOC section regarding the (c)(1)(iv) evaluations. Refer to comments c-4 and c-34 regarding the need for licensees to address the potential impact of changes in treatment on RISC-3 SSCs as part of satisfying 10 CFR § 50.69(c)(1)(iv) and how the final rule language appropriately addresses the factor used in the risk sensitivity study and maintains the validity of the categorization process.
c-39	The scope of “initiating events not modeled in the PRA” in the SOC needs to be better defined as events such as internal fire, seismic, shutdown events, etc. Otherwise, some could interpret this scope as including events screened out of internal events based on their low frequency.	The NRC disagrees with this comment. As stated elsewhere, there may be a situation in which an internal initiating event has not been modeled which must be evaluated. At this point in the SOC it is not necessary to provide the explicit examples, since the intent is to justify NRC staff review and approval of the categorization process. Also note that more detailed guidance is provided in RG 1.201 and NEI 00-04. No revisions to the SOC rule have been made as a result of this comment.
c-40	The term, “unmodeled events,” needs clarification in the context of the 5 criterion presented in the SOC. These IDP assessment criteria are sufficiently vague to invite interpretation issues and are not risk-related (i.e., they are deterministic) and would result in most safety-related SSCs being categorized as RISC-1. The commenter suggests that the NRC should either delete the text, or revise to reflect NEI 00-04 and ASME code cases (for categorization of passive SSCs), which provides adequate guidance for considering unmodeled events.	The NRC disagrees with this comment in the need to clarify the meaning of “unmodeled” events. As stated elsewhere (see responses to comment c-9), there may be a situation in which an internal initiating event has not been modeled which must be evaluated and as such is an “unmodeled” event. In other cases, an initiating event may not be modeled due to its extremely low frequency of occurrence or may be grouped with other events and addressed by a general transient. The discussion cannot be more definitive as to all situations and must be addressed on a plant-specific basis. The IDP must evaluate both risk information and deterministic information in determining the safety significance of a SSC; the rule is not risk-based, but risk-informed. The guidance has been revised and refers to RG 1.201, NEI 00-04 and ASME code cases, as appropriate.

TABLE 3 - 50.69 Paragraph (d) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-1	The lower standards for components reclassified as RISC-3 makes it more likely that nuclear power plants will operate with substandard parts, thus increasing the potential for common mode failures. A report by the Idaho National Engineering and Environmental Laboratory (NUREG/CR-6752) which concluded that, based on discussions with utility representatives, commercial codes and standards by themselves are insufficient to provide reasonable confidence of SSC functionality. The commenter indicates that NRC has every right to be concerned about common-cause failure potential from reclassified equipment. The commenter asserts that the proposed rule failed to compensate for the increased risk of common-mode failures, and that safety margins would be compromised by the rule as proposed. UCS points to instances where non-safety related equipment had provided important safety functions during plant events, such as the non-safety related control rod drive system during the Browns Ferry fire in 1975, and the non-safety related reactor vessel liner at Davis Besse. See comments d-9, d-11, d-12, m-3, m-6	The NRC agrees that significant increases in common-cause failures could invalidate the evaluations, such as sensitivity studies, performed to show that any potential change in risk due to implementation of § 50.69 would be small. The rule has been clarified in response to this and other public comments. 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 §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. To meet this requirement, licensees need to: (a) maintain an understanding of common-cause effects and their potential impact on RISC-3 SSCs; (b) maintain an understanding of the programmatic activities that provide defenses against common cause failures (CCFs); and (c) factor this knowledge into the treatment applied to the RISC-3 SSCs. The final rule has been revised to require that the treatment of RISC-3 SSCs be consistent with the categorization process. In addition, the final rule now requires that licensees determine the cause of significant conditions adverse to quality and take corrective action to preclude repetition. See response to comment d-32.
d-2	The wording in the SOC supporting the RISC-1 and RISC-2 beyond design basis requirements portion of the rule is inconsistent. The supporting SOC should indicate "sufficient" treatment is required (in all places), and additional description on what this is should be provided. See comments d-4, d-14, d-23, d-24, d-30	The wording has been revised to make the rule and SOC language consistent. The NRC does not agree that revising the SOC to state that "sufficient" treatment is required for RISC-3 SSCs adds clarity to the rule requirements. Therefore, no adjustments to the rule or SOC were made in this regard.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-3	The SOC words on page 26516 regarding the need to maintain design basis “in order to provide reasonable confidence that SSCs remain functional” should be considered as the appropriate guidance for establishment of the licensee’s design control process and that any further guidance in V.5.2.1 be understood in this context. See comments d-5, d-6, p-27	The NRC does not agree that the SOC discussion of the design control process for RISC-3 SSCs should be limited to “providing reasonable confidence that SSCs remain functional,” as suggested in the comment. Section 50.69(d)(2)(i) of the rule and the related SOC section contains more specificity. Section V.5.2.1 of the SOC has been revised to more clearly describe the meaning of the revised rule requirements related to the design control process for RISC-3 SSCs.
d-4	Additional performance conditions (beyond what is assumed in the DB) to address PRA performance assumptions should not be subject to Appendix B requirements that remain for RISC-1 SSCs. Furthermore, the design control documentation necessary to capture the assumptions made in the categorization process will place a large implementation cost on plants. See comments d-2, d-14, d-23, d-24, d-30	The NRC agrees that the performance conditions for beyond design basis capabilities of RISC-1 SSCs credited in the PRA are not subject to Appendix B requirements. However, plant SSCs credited for beyond design basis capabilities must have a valid technical basis for the credit (i.e., the failure rate/probability of the SSC performing the beyond deign basis function) given in the PRA. Furthermore, the basis for this credit should already be established and documented in the PRA supporting documentation so this should not be an additional burden for licensees to capture and implement. If an existing technical basis does not exist or is insufficient to support the credit taken for beyond design basis capability then § 50.69(d)(1) would require that a technical basis be developed for the credit taken in the PRA potentially including a treatment program for the SCC that validates the capability credited.
d-5	The wording on page 26518 regarding replacing STRs and the need to maintain functionality with the more general requirements should be used in Section V.5.2.1. See comments d-3, d-6, p-27	See response to comment d-3.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-6	The statements on page 26542 of the SOC appear to be more prescriptive than the current regulation and have the potential to add burden beyond that specified in § 50.69(d)(2)(i). See comments d-3, d-5, p-27	Where the NRC concluded that meeting the more prescriptive guidance (or expectations) contained in the SOC was necessary to provide reasonable confidence in the functionality of RISC-3 SSCs, the NRC incorporated that guidance into the final rule requirements. For example, § 50.69(d)(2)(i) of the final rule is now more prescriptive (per underlines portion below) regarding design control and specifically states that "Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled, <u>including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes.</u>" Section V.5.2.1 of the SOC has been revised to more clearly describe the meaning of the revised rule requirements related to the design control process for RISC-3 SSCs.
d-7	It is recommended that the language "Licensees may decide to apply current practices at their facilities..." be added to the final rule for completeness.	In establishing treatment requirements for RISC-3 SSCs, the NRC believes that it would be inappropriate to conclude that "Licensees may decide to apply current practices at their facilities..." The application of the licensee's current practices would be acceptable provided they meet the high-level treatment requirements of the final rule. No revisions to the final rule have been made as a result of this comment.
d-8	The proposed rule no longer requires significant conditions adverse to quality to be evaluated for their applicability to other components. See comment d-10	The NRC agrees with this comment. In response to this comment and one similar from NEI, the rule has been revised to require in § 50.69(d)(2)(iv) that, in the case of significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition. See response to comment d-32.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-9	The proposed rule is technically inadequate to provide reasonable assurance that SSCs will be capable of performing their safety functions under design basis conditions. See comments d-1, d-11, d-12, m-3, m-6	Given the way some the proposed rule was interpreted, the NRC recognized the need to clarify the final rule. However, the NRC believes that the proposed rule, if effectively implemented by licensees consistent with the Commission's expectations as articulated in the SOC accompanying the proposed rule, would have provided reasonable confidence that RISC-3 SSCs would have been capable of performing their safety functions under design basis conditions. Nonetheless, in response to public comments on the proposed rule, and in an effort to remove some apparent inconsistencies between the proposed rule and the supporting SOC, the treatment requirements in the final rule for RISC-3 SSCs have been strengthened in § 50.69(d)(2) as shown in the response to comment d-32. The NRC believes that the revised requirements for RISC-3 SSCs in § 50.69(d)(2) of the final rule adequately addresses the comment.
d-10	The proposed rule does not contain a requirement for potential common cause problems to be evaluated and corrected, particularly with common cause failures that extend from one system to another that can invalidate the categorization process. See comment d-8	As noted in response to d-1 above, for RISC-3 SSCs the rule has been revised to clarify that, in the case of significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition. Further, § 50.69 does not remove special treatment requirements for RISC-1 SSCs. Therefore, RISC-1 SSCs remain subject to applicable special treatment requirements such as Appendix B, and paragraph (e) requires performance data to be fed back into the categorization process and adjustments made to the treatment or categorization so that the process continues to be valid. These requirements would potentially be applicable to a situation where common cause failures develop.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-11	Elimination of prescriptive regulatory special treatment requirements as provided by the proposed rule would likely result in significant degradation to safety-related equipment and unduly increase the risk to public health and safety. See comments d-1, d-9, d-12, m-3, m-6	The NRC agrees that the elimination of all special treatment requirements could adversely affect the capability of RISC-3 SSCs to perform their safety functions. However, the rule requirements are intended to provide a sufficiently robust categorization process such that only safety-related SSCs that have low individual safety importance will receive reduced treatment. The high-level treatment requirements included in the final rule for RISC-3 SSCs, if effectively implemented by licensees, will provide reasonable confidence in the continued functionality of these components under design-basis conditions. In addition, the feedback and corrective action requirements are strengthened in § 50.69(e)(1) and § 50.69(d)(2)(iv) of the final rule. These feedback and corrective action requirements, together with evaluation of the implementation of § 50.69 by NRC inspectors, are considered to provide sufficient regulatory control to minimize the potential for multiple safety-related SSCs to be incapable of performing their safety functions. As a result, the § 50.69 rule, if effectively implemented by licensees, will maintain public health and safety. See response to comment d-32.
d-12	Degradation (d-11)in safety-related equipment due to elimination of special treatment requirements would likely go undetected as a result of exemptions from monitoring, maintenance, in-service testing, and regulatory oversight. See comments d-1, d-9, d-11, m-3, m-6	Section 50.69(d)(2) of the final rule is revised to require that the treatment of RISC-3 SSCs must be consistent with the categorization process. This clarification to § 50.69 in conjunction with inspection of the implementation of § 50.69 under the Reactor Oversight Process will provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety-related functions, if effectively implemented. Section 50.69 contains maintenance, inspection, testing, and surveillance requirements in § 50.69(d)(2)(iii); corrective action requirements in § 50.69(d)(2)(iv); feedback and monitoring requirements in § 50.69(e); and requirements to maintain an acceptably low change in risk in § 50.69(c) that will provide confidence degradation does not go undetected as suggested by the comment. With these modifications in the final rule language, significant degradation in RISC-3 SSCs should not go undetected.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-13	The proposed rule focuses on common-cause effects because significant increases in common-cause failures could invalidate the evaluations. The proposed rule does not provide enough guidance on common cause failures for the licensee to make sure that this phenomenon is properly accounted for by the licensee. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38,d-34, d-35, d-36, m-5	Section 50.69(d)(2)(iv) in the final rule has been revised to specify that, in the case of significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition. In addition, the rule has been clarified to ensure that the treatment process is consistent with the categorization process. The incorporated clarifications including the recognition that the NRC also has the inspection process as another means to address such issues, are considered to address this comment.
d-14	The commenter supports the proposed lack of specific IST requirements for RISC-2 SSCs. Current ASME Code Cases have the same IST requirements for high safety significant components, which are equivalent to RISC-1 and RISC-2 SSCs in the proposed rule. See comments d-2, d-4, d-23, d-24, d-30	This comment could be read as implying that the rule will require licensees to use the ASME Code Cases for RISC-2 SSCs. The rule does not require licensees to apply ASME Code Cases for any plant SSCs. However, the NRC considers the application of the ASME Code Cases as endorsed by NRC regulatory guides to be sufficient to satisfy the applicable requirements in 10 CFR 50.69. Therefore, the SOC accompanying the final rule was revised to indicate "The provisions for risk-informed inspection and testing in applicable ASME Code Cases (as incorporated in § 50.55a) would constitute one effective approach for satisfying the § 50.69 requirements."

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-15	The commenter agrees with the need for periodic maintenance, test, and examination activities to provide confidence in the operational readiness of RISC-3 SSCs. However, current industry practice including the use of applicable Codes and Standards and Code cases is an example of an effective approach to satisfy the proposed § 50.69 (d)(2) requirements. See comments d-17, d-25, d-31, d-32, d-33, d-37, e-3, p-11, p-19, p-23	The NRC agrees that current industry practices as implemented by licensees may be adequate to meet the RISC-3 requirements. However, the comment implies that licensees will use the requirements of the ASME Code or provisions in ASME Code Cases in providing confidence in the operational readiness of RISC-3 SSCs. While the NRC encourages the use of applicable ASME codes and standards as endorsed by NRC, the final rule will not require licensees to apply the ASME Code or Code Cases in the treatment of RISC-3 SSCs. Whatever approach a licensee implements (whether an ASME code, standard, code case; or other industry standard; or licensee-developed practice), it must comply with the § 50.69(d)(2) requirements.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-16	The commenters expressed concern with the language in Section V.5.2.1 of the SOC regarding use of earthquake experience data to demonstrate that SSCs will remain functional during earthquakes. The commenters asserted that the SOC language is overly prescriptive, inconsistent with NRC's position regarding the use of experience-based method, and that retaining such language is not only inappropriate for RISC-3 SSCs but would increase the burden for the A-46 plants which represent the majority of operating plants (which are allowed to use seismic experience based methods for safety-related SSCs). One commenter (South Texas Project) also asserted that this SOC language was inconsistent with its exemption from Appendix A to Part 100, Section VI(a)(1) and VII(a)(2). See also comment d-32	The commenters implied that the SOC language could be interpreted to increase the burden at some existing plants. It is not the intent of the Commission to impose additional requirements on unresolved safety issue (USI) A-46 plants. The SOC has been clarified to indicate that implementation of § 50.69 does not change the seismic design basis for USI A-46 facilities and therefore does not impose additional requirements. With regard to the application of seismic experience data to RISC-3 SSCs at non-USI A-46 plants (i.e., plants designed to Part 100 requirements), the application of earthquake experience data must be justified. The rule in § 50.69(d)(2) requires a licensee or applicant to develop or implement processes to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions. The rule does not change the design requirements for these SSCs. A licensee or applicant must have an adequate technical basis in order to conclude that an SSC will perform its safety-related function under design-basis conditions, which includes the number and magnitude of the earthquake events specified for the SSC design. The commenters imply that it is acceptable to use "experience data" alone to have sufficient confidence that an SSC is capable of functioning during an earthquake even if there is no actual "experience data" for the SSC. While the use of "experience data" is not prohibited by the rule, it may be difficult for licensees and applicants to show that "experience data" alone will satisfy the applicable design requirements of Part 100 (which § 50.69 leaves intact). The SOC language was included to prevent such misunderstandings of the rule requirements. As stated in SOC V.5.2.1, "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 apply." The design basis for most newer facilities include multiple operating basis earthquake events, which remains a design requirement for these plants, and which is different from USI A-46 plants where the requirement was to verify the adequacy of plant equipment for the safe shutdown earthquake. USI A-46 did not

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-16 cont'		address the operating basis earthquake. In response to South Texas Project's comment regarding its exemption request, the NRC SE dated August 3, 2001, granting the exemption states on page 104 that "STPNOC would not be able to satisfy the OBE design requirements by relying solely on seismic experience data without supplemental evaluation or analysis." Therefore, the safety evaluation is consistent with the language in the SOC
d-17	The RISC-3 treatment requirements are too prescriptive and not necessary for low safety significant SSCs. Proposed § 50.69(d)(2) imposes several requirements intended to maintain design basis functionality and while the proposed requirements are less stringent than the full Appendix B requirements, they are still burdensome. Commercial practices provide the necessary assurance of RISC-3 functionality. See comments d-15, d-25, d-31, d-32, d-33, d-37, e-3, p-11, p-19, p-23	The NRC disagrees with this comment because the high-level treatment requirements contained in the final rule are not overly prescriptive. Commercial practices can, and do vary significantly. Section 50.69(d)(2) establishes the minimum set of requirements necessary to maintain the design basis capability of the RISC-3 SSCs. In some cases, licensee's commercial practices may be sufficient to meet these minimum RISC-3 requirements. No revisions to the final rule or SOC have been made as a result of this comment.
d-18	Paragraph § 50.69(d)(1) should be deleted as it is redundant to § 50.69(e)(2).	The NRC disagrees with this comment. The two requirements cited are not redundant and have different objectives. The (d)(1) requirement is to evaluate treatment applied to RISC-1 and RISC-2 SSCs with respect to credited performance in beyond design basis scenarios to ensure that the treatment supports the credit taken for the SSC (i.e., have a basis to support the performance of these SSCs credited in the PRA for beyond design basis situations). The § 50.69(e)(2) requirement is to monitor RISC-1 and RISC-2 SSCs, and feed back into the categorization process performance data for these SSCs and make appropriate adjustments. No revisions to the final rule or SOC have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-19	Paragraph § 50.69(d)(2)(i) should be modified to read "(i) Design control measures shall preserve the design bases; select suitable materials; verify design adequacy, and control changes to the design." for reasons stated. The commenter states that there is no need to specify environmental or seismic qualification rules because RISC-3 SSCs are exempt from those rules. The commenter also asserts that requirements for consideration of aging and synergism effects exceed the existing design requirements, such as General Design Criterion (GDC) 4, for qualification of safety-related SSCs. See comments d-20, d-27, d-28, d-29, d-32	The NRC agrees that § 50.69(d)(2)(i) would be improved by clarification. The NRC notes the special treatment requirements in § 50.49 are removed but that GDC-4 requirements continue to apply as well as the § 50.69(d)(2) requirements. As a result, RISC-3 SSCs must remain capable of performing their safety-related function under design basis conditions for their entire design lifetime. To comply with this requirement means that components determined to have a significant aging mechanism(s) and/or that is susceptible to synergistic effects must be designed such that these considerations are accounted for as part of the design process (reference IEEE 323-2003). Essentially a designer must still consider the factors that could affect an SSC's capability to perform its safety-related functions under design basis conditions at end of design life. The change then is that the additional special treatment in § 50.49 is no longer required. The SOC supporting this requirement has been revised consistent with this comment response. Paragraph § 50.69(d)2)(i) of the final rule was modified consistent with the recommendation in the comment.
d-20	Paragraph § 50.69(d)(2) should be revised to delete the word "could" because it appears to exceed Appendix B requirements. To address common cause concerns, add "For significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition." See comments d-8, d-19, d-27, d-28, d-29, d-32	With the suggested addition to address common cause concerns, the NRC agrees that the word "could" can be deleted from the § 50.69(d)(2)(iv) requirement regarding correction of conditions that prevent RISC-3 SSCs from performing their safety-related functions. See response to comment d-32. This is an improvement to the language of the rule and it clarifies the corrective action requirements.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-21	Section V.5.2 of the SOC stated “exercising 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.“ A commenter asserts that the quoted SOC language is unnecessarily prescriptive for all cases. See comments d-22, d-31, d-32	The NRC disagrees with this comment. The commenter’s basis for suggesting that exercising a valve or starting a pump alone, would satisfy the treatment requirements for RISC-3 SSCs is not valid. The rule clearly requires licensees to provide reasonable confidence that RISC-3 SSCs are capable of performing their safety-related functions under design-basis conditions throughout their service life. Extensive plant-specific experience and research have revealed that simply exercising a valve does not provide reasonable confidence in the capability of that component. Similar concerns exist regarding the starting of a pump. This comment reveals the importance of providing clear language in the rule and its SOC to ensure that the intent of the rule requirements is understood by licensees. The final rule’s SOC has been revised to indicate that § 50.69(d)(2)(iii) requires a licensee or applicant 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-related functions under design basis conditions until the next scheduled activity, and that exercising a valve or starting a pump, by itself, does not meet this requirement.
d-22	Section V.5.2.1 of the SOC stated “[t]o 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 commenter argues that the SOC language on the need to control design interfaces and coordinate participation of design organizations for all instances for RISC-3 SSCs is excessively prescriptive. See comments d-32, d-21, d-31	The NRC agrees that the SOC discussion of the need to control design interfaces and to coordinate participation of design organizations might be more detailed than necessary for RISC-3 SSCs based on their low individual safety significance and provisions to avoid common cause failures in § 50.69(d)(2)(iv) of the final rule. Therefore, those specific provisions have been removed from the SOC and they are not included as requirements in the final version of § 50.69(d)(2) in light of the additional provisions included in the final rule in § 50.69(d)(2)(i) and (iv) regarding design control and corrective action, respectively.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-23	The commenter agrees that RISC-1 beyond design basis functions and RISC-2 SSCs may require additional special treatment requirements to be applied, but also believes that the NRC's intent is for all safety significant SSCs(RISC-1 and RISC-2) to be subjected to enhanced regulatory control. This is neither necessary nor in agreement with the intent of SECY-98-300. One commenter, STP, quotes a portion of its revised FSAR submitted in support of its exemption request which stated that safety-related high and medium risk SSCs would continue to receive treatment required by NRC regulations and STP's associated procedures. Another commenter (WOG) states that any additional treatment requirements for RISC-1 and RISC-2 SSCs should be removed from the SOC. See comments d-2, d-4,d-14,d-24, d-30	The NRC disagrees with these comments. First, it is not the intent of § 50.69(d)(1) to extend special treatment requirements to RISC-1 beyond design basis functions and to RISC-2 SSCs. Section 50.69(d)(1) does impose a greater degree of regulatory control. It requires that a licensee or applicant ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization process by evaluating treatment being applied to these SSCs to ensure that it supports the performance capabilities credited in the categorization process. Since these are the safety significant SSCs, and their performance as credited in the PRA is important to maintaining an acceptable level of plant risk given that special treatment requirements are being removed from RISC-3 SSCs, it is a key and necessary part of § 50.69. The response to comment m-13 addresses the issue of consistency between final § 50.69 and SECY-98-300. In addition to the selected reference in STP's comment, the NRC SE dated August 3, 2001, supporting the grant of the STP exemption request, indicated that the revised STP FSAR was to provide for the evaluation of RISC-1 and RISC-2 SSCs to ensure that existing controls are sufficient to maintain the reliability and availability of the component in a manner that is consistent with the categorization process. The commenters suggestion to remove any consideration of additional treatment for RISC-1 and RISC-2 SSCs is inconsistent with the intent of the § 50.69 rulemaking to focus resources on the most safety significant SSCs. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-24	The statements in Section V.5.1 specifically obligate a licensee implementing § 50.69 to evaluate treatment applied to all safety significant SSCs to ensure adequacy of treatment. This is an added burden that is neither necessary nor appropriate. Since RISC-1 SSCs are currently subjected to full regulatory requirements, reviewing the regulatory imposed treatment adds no value. To meet the proposed rule language of § 50.69(d)(1) a licensee would be obligated to evaluate the treatment applied to all safety significant SSCs to ensure adequacy of treatment. This added burden is neither necessary nor appropriate, and is inconsistent with the STP exemption. Since RISC-1 SSCs are currently subjected to full regulatory requirements, reviewing regulatory-imposed treatment adds no value. See comments d-2, d-4, d-14, d-23, d-30	Section 50.69(d)(1) requires licensees adopting the provisions of § 50.69 to have a basis to support the performance of RISC-1 and RISC-2 SSCs credited in the PRA used in the categorization process for beyond design basis situations. Special treatment requirements (STRs) are applied to maintain (with a high level of assurance) design basis functions. As such there is no need to review the STRs as to whether design basis functions are being maintained. The focus of this requirement is on beyond design basis functions. The SOC for the final rule has been clarified at Section V.5.1. This comment appears inconsistent with the revised FSAR referenced in the NRC SE granting the STP exemption request which indicates that the licensee will evaluate the treatment of RISC-1 SSCs where credit is taken in the categorization process for those SSCs to perform functions that are beyond the design basis or perform safety-related functions under conditions that are beyond the design basis.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-25	Section V.5.2.3 of the SOC states "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." This requirement as clarified by examples goes beyond normal industrial practices and indeed imposes another program on licensees that was never intended by SECY-98-300. STP states that, in its exemption, it was clear that STP would rely on the existing industrial programs and practices in place at the station, and that these programs would only be revised if STP determined that a change was necessary to satisfy its basis for a reasonable assurance determination. See comments d-15, d-17, d-31, d-32, d-33, d-37, e-3, p-11, p-19, p-23	The NRC disagrees with this comment. As noted in the response to comment c-30 and m-13, the NRC's thoughts on § 50.69 have evolved since 1998. The commenter's assertions appear to be based upon the incorrect assumption that licensees only need to apply normal industrial practices regardless of whether such practices will provide confidence in the capability of RISC-3 SSCs to perform their safety-related functions consistent with the performance/reliability credited in the categorization process. The NRC does not believe that applying normal industrial practices will in all circumstances sufficient to meet § 50.69(d)(2) requirements. In response to STP's comment, the revised STP FSAR referenced in the NRC SE dated August 3, 2001, specifies that the purpose of the maintenance process for low risk safety-related SSCs (RISC-3 as defined in § 50.69) is to establish the scope, frequency, and detail of maintenance activities necessary to support STP's determination that these SSCs will remain capable of performing their safety-related functions. Contrary to STP's assertion that it would only apply existing industrial programs, the STP FSAR also discusses justification where vendor recommendations are not followed, justification for reliance on SSCs beyond their designed life, and performance of post-maintenance testing. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-26	Section V.4.3 of the SOC states that for RISC-3 containment isolation valves(CIVs) "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." It is not clear what is intended (with additional explanation for confusion). The revised STP FSAR supporting its exemption request did not require an assessment of treatment impact with respect to the exemption from Appendix J. The commenter points to the Appendix J exemption criteria in support of its assertion that no additional evaluation or analysis should be required for RISC-3 SSCs.	This comment reveals the confusion surrounding the treatment and Appendix J leakage testing of containment isolation valves under § 50.69. As specified in § 50.69(b)(1)(x)(B) , the rule removes Appendix J leakage testing for RISC-3 containment isolation valves that meet one of several criteria. However, the acceptability of the removal of Appendix J leakage testing for the RISC-3 containment isolation valves meeting one of those criteria is based on the assumption that those valves are capable of achieving the full seated position by means of the actuator. Therefore, even though a RISC-3 containment isolation valve might be exempt from Appendix J leakage testing based on meeting one of several criteria, the RISC-3 containment isolation valve must meet the treatment requirements in 10 CFR 50.69(d) to provide reasonable confidence that the containment isolation valve can perform its safety function(e.g., to close) under design-basis conditions. Because it is likely that most containment isolation valves will be categorized as RISC-3, licensees will be expected to evaluate the proposed change in the treatment of RISC-3 containment isolation valves to maintain defense-in-depth by providing reasonable confidence that the RISC-3 containment isolation valves are capable of performing their safety-related functions under design-basis conditions. The SOC indicates that licensees have flexibility in addressing this issue. With respect to STP's comment, the NRC SE dated August 3, 2001, granting the STP exemption request states on page 97 that, in consideration of the Appendix J exemption request, the containment isolation valves are assumed to be capable of being closed, if necessary, to perform their containment isolation safety function. Therefore, the NRC SE assumes that containment isolation valves are capable of closing under their design-basis conditions in support of the Appendix J exemption. Further, based on STP's response to requests for additional information during the NRC review of the exemption request, a large number of containment isolation valves (more than those that might meet the Appendix J exemption criteria) might be categorized as RISC-3 by a licensee implementing § 50.69. The rule intends that licensees have reasonable confidence in the capability of RISC-3 containment isolation valves to perform their safety functions in order to maintain defense-in-depth as discussed in RG 1.174.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-27	Section 50.69(d)(2)(i) states that “RISC-3 SSCs must be capable of performing their safety-related functions including design requirements for environmental conditions and effects; and seismic conditions.” This language should be clarified to ensure that environmental conditions and effects and seismic conditions apply to those SSCs previously qualified for such conditions. A similar comment recommends elimination of “aging and synergism effects” from § 50.69(d)(2)(i) for reasons stated - including (1) aging and synergism are not design basis conditions but rather STR required by § 50.49 and (2) it appears that the rule would require this for all RISC-3 SSCs not just those currently subject to § 50.49. See comments d-19, d-20, d-28, d-29, d-32	Section 50.69(d)(2) indicates that the processes (in § 50.69(d)(2)(i), (ii), (iii), and (iv)) “must meet the requirements, as applicable.” As such the environmental and seismic conditions identified in § 50.69(d)(2)(i) are to be applied “as applicable”, and are not required to be applied to RISC-3 SSCs which are not normally subject to environmental and seismic requirements. The SOC supporting the final rule has been revised to clarify that seismic and environmental design requirements are not being applied to RISC-3 SSCs beyond those to which they currently apply. Also see response to comment d-19.
d-28	The Section V.5.2.1 statement regarding a beyond design life “expectation” for electrical equipment is ambiguous and appears unwarranted. The commenter objects to this expectation because (1) 10 CFR 50.69 exempts RISC-3 electrical equipment from consideration of aging issues; and (2) the high-level requirements in § 50.69 do not include establishment of design life values. This commenter suggests that continued confidence that RISC-3 electrical devices will be able to perform design-basis functions is achieved by inclusion of high-level requirements for maintenance, inspection, test, and surveillance. See comments d-19, d-20, d-27, d-29, d-32	The NRC disagrees that providing this clarification in the SOC is unwarranted. If RISC-3 electrical equipment are relied on to perform a safety-related function beyond their design life, licensees need to have a basis to justify the continued capability of the equipment under adverse environmental conditions. The design control process under § 50.69 is expected to address the life expectancy of RISC-3 electrical equipment. The rule allows the licensee to apply various methods (such as replacement or technical justification) to provide reasonable confidence that RISC-3 electrical equipment can continue to perform their safety-related function upon reaching the end of the expected life. The SOC supporting the final rule has been clarified to remove any ambiguity relative to design requirements for RISC-3 electrical equipment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-29	The rule contains requirements in a parenthetical statement for environmental qualification of SSCs that can be interpreted to be quite similar to current special treatment requirements (STRs). The parenthetical statement should be deleted from (d)(2)(i). As it now stands, the RISC-3 requirements can exceed requirements imposed on RISC-1 SSCs at some plants. See comments d-16, d-19, d-20, d-27, d-28, d-32	The NRC disagrees that the proposed rule requirements for RISC-3 SSCs exceed those imposed on RISC-1 SSCs at some plants. As discussed in the response to comment d-27 above, RISC-3 SSCs must meet environmental design requirements "as applicable." However, there is no intention to impose environmental design requirements on SSCs to which they currently do not apply. The parenthetical statement containing environmental design requirements in § 50.69(d)(2)(i) of the rule is necessary to make it clear what the NRC considers to be design requirements for RISC-3 SSCs that are currently environmentally qualified. The SOC supporting the final rule has been clarified to remove any ambiguity relative to design requirements for RISC-3 SSCs. Also see responses to comments d-16 and d-19. No revisions to the final rule language have been made as a result of this comment.
d-30	No additional regulatory controls need to be placed on RISC-2 SSCs for several reasons. The categorization process assumes that the reliability is consistent with the existing treatment. Since RISC-2 SSCs might be "augmented quality" SSCs as a result of specific regulatory requirements, those RISC-2 SSCs would be within the scope of the Maintenance Rule. Therefore, the licensee's corrective action program will be adequate to identify and resolve any performance issues related to RISC-2 SSCs. A possible exception relates to beyond design basis functions that are not adequately addressed by the current treatment (e.g., testing of valve stroke that is not credited in the design basis). The SOC should be clarified to address the specific beyond design basis scope of additional regulatory controls on RISC-2 SSCs. See comments d-2, d-4, d-14, d-23, d-24	The NRC disagrees with this comment. In implementing § 50.69, licensees must ensure that the treatment applied to RISC-2 SSCs is sufficient to provide assurance that those SSCs can perform their safety significant functions consistent with the categorization process. Licensees implementing 10 CFR 50.69 might find that the safety significant functions for those RISC-2 SSCs have not been sufficiently addressed by current plant practices. No revisions to the final rule have been made as a result of this comment. However, the NRC has clarified Section V.5.1 of the SOC regarding RISC-2 SSC requirements.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-31	Some of the RISC-3 discussion implies that more is required for RISC-3 SSCs than for RISC-1 SSCs since current testing and surveillance requirements for many SSCs involves simply starting a pump or exercising a valve. The commenter asserts that, since current testing and surveillance requirements for many SSCs involves simply starting a pump or exercising a valve as a means of verify its operability, this provides assurance that the pump or valve can perform its design basis function. See comments d-15, d-17, d-21, d-22, d-25,d-32, d-33, d-37, e-3, p-11, p-19, p-23	The NRC disagrees with this comment in that it incorrectly describes surveillance requirements for pumps and valves, is inconsistent with operational experience, and does not meet the intent of the requirements of § 50.69. Section 50.69(b)(1)(v) of the rule specifies that, for RISC-3 SSCs, a licensee may voluntarily comply with the requirements in § 50.69 as an alternative to compliance with the inservice testing requirements in § 50.55a(f) which incorporate by reference the prescriptive testing methods and intervals of the ASME *Code for Operation and Maintenance of Nuclear Power Plants* (ASME OM Code). In § 50.69(d)(2)(iii), the rule specifies that 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. To satisfy the requirements of § 50.69, licensees must collect sufficient data to provide confidence in the design-basis capability of RISC-3 SSCs and to feed back that information into the categorization and treatment processes. The assertion by the commenter that exercising SSCs (by itself) provides confidence of their design-basis capability is inconsistent with lessons learned from numerous NRC and licensee activities over the last 20 years. For example, the NRC modified § 50.55a to require licensees implementing the ASME OM Code to periodically verify the design-basis capability of motor-operated valves to perform their safety functions in light of the recognized inadequacies in stroke-time testing (essentially exercising) to assess the operational readiness of those valves. The NRC issued Regulatory Issue Summary 00-03 (March 15, 2000), “Resolution of Generic Safety Issue 158, Performance of Safety-Related Power-Operated Valves under Design-Basis Conditions,” to discuss the importance of this issue relative to safety-related air-operated and other power-operated valves. Further, the ASME developed comprehensive pump testing provisions to provide more appropriate testing under significant flow conditions in light of the weakness of the previous Code testing under minimal loading conditions. In some cases, a licensee implementing § 50.69 might apply more rigorous test methods than previously applied to satisfy the ASME Code Inservice Testing (IST) provisions because § 50.69 does not specify restrictive time limits on test intervals that were provided in the ASME Code. As a result, § 50.69

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-31 cont'		will allow significant flexibility by licensees in verifying the design-basis capability of their safety-related SSCs categorized as RISC-3. However, licensees need to consider the lessons learned over the last 20 years regarding SSC performance in establishing more flexible performance-based treatment processes.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-32	Throughout the SOC, the terminology "Commission expects" is used. Utility implementation should allow for interpretation of the implementation processes to avoid undue disruption of their established practices. Another commenter has a similar comment referring to the "best practices" language for RISC-3 treatment in the SOC as being/becoming de facto requirements and which are unduly restrictive and unnecessary and should be deleted from the rule. Four other commenters indicate that in some cases the SOC and rule language are inconsistent and that specifically the expectations are impractical, not risk-effective, or in some cases actually exceed current safety-related requirements. A commenter asserts that, given the low safety significance of RISC-3 SSCs, exercising a pump or valve gives appropriate confidence that the pump or valve is functional, and that a requirement for measuring, trending of performance, and extrapolation of performance to design-basis conditions is an unnecessary burden given the low safety significance of these components. One commenter recommends deletion of SOC language discussing (1) SSC testing if no suitable alternative seismic capability method is available, (2) verification of correct procurement of SSCs, (3) testing under simulated design-basis conditions as one evaluation method, and (4) obtaining operational information or performance data to provide reasonable confidence that RISC-3 pumps and valves will be capable of performing their safety functions.	The NRC agrees with the thrust of the comments that the rule and SOC should be clarified. These comments illustrate the divergent interpretations of the high-level requirements for the treatment of RISC-3 SSCs in § 50.69. Therefore, the rule has been clarified with respect to the RISC-3 treatment requirements to ensure that licensees: 1) understand that design requirements continue to apply to RISC-3 SSCs (for example, fracture toughness); 2) establish documented processes for the treatment of RISC-3 SSCs consistent with the categorization process; and 3) consider potential common cause concerns as part of the corrective action process. In addition, the SOC has been revised to clarify the meaning of the rule language. Specifically, where the NRC considered expectations to be necessary, the final rule has incorporated those expectations as requirements and removed guidance from the SOC. Below, the revised portions of § 50.69(b)(1) and the high-level treatment requirements in § 50.69(d)(2) are indicated by underlining and strike-outs: (*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 this part, a holder of a renewed LWR license under Part 54 of this chapter; an applicant for a construction permit or operating license under this part; an applicant for a design approval, a combined license, or manufacturing license under Part 52 of this chapter; 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: *** (ii)The portion of 10 CFR 50.46a(b) that imposes requirements to conform to Appendix B to 10 CFR Part 50. ***[Note all subsequent items are renumbered] (v) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement <u>(with the exception of fracture toughness)</u>, 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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-32 cont	A commenter states that the SOC discussion includes NRC expectations for developing and evaluating RISC-3 treatment that are more appropriately considered regulatory guidance for acceptable methods of implementing the requirements. Although recommending that NRC retain the proposed rule language and deleting the SOC information, it is suggested that the NRC prepare a regulatory guide if the NRC considers it necessary to suggest acceptable methods for determining appropriate treatment methods. See comments d-15, d-17, d-19, d-20, d-21, d-22, d-25, d-27, d-28, d-29, d-31, d-33, d-37, e-3, p-11, p-19, p-23	reference in 10 CFR 50.55a(h). (2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement <u>documented</u> 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. <u>The treatment of RISC-3 SSCs must be consistent with the categorization process.</u> 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<u>, including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes.</u> RISC-3 SSCs must be capable of performing their safety-related functions including <u>meeting</u> 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 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. <u>For significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.</u>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-33	The SOC states, in Section III.3.2, that “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. “ This is ambiguous. NEI 00-04 identifies a corrective action program that addresses this concern. See comments d-15, d-17, d-25, d-31, d-32, d-37, e-3, p-11, p-19, p-23	The NRC disagrees that corrective action alone will be sufficient to provide confidence that RISC-3 SSCs will remain operable. The SOC is addressing the rule requirement that the surveillance and testing process for RISC-3 SSCs under 10 CFR 50.69 must obtain sufficient performance data to provide reasonable confidence that RISC-3 SSCs are capable of performing their safety-related functions under design-basis conditions. The corrective action process addresses deficiencies that are identified from testing, inspection, and operating experience. The corrective action process alone is not sufficient to satisfy the requirements of § 50.69(d)(2)(iii). For example, without the surveillance and testing process required by § 50.69(d)(2)(iii), performance information for standby equipment would not be available to identify degradation in the capability of the equipment until it failed to perform its safety function under design-basis conditions. If the surveillance and test process is inadequate, the corrective action process could fail to identify a performance problem with multiple RISC-3 SSCs until they are called upon to perform their safety function under accident conditions. With respect to reliance on NEI-00-04, the NRC staff found the previous treatment guidance prepared by NEI to be insufficient to satisfy § 50.69 and, since then, has been reviewing NEI-00-04 only in terms of the categorization process. The NRC does not currently plan to review treatment guidance prepared by industry for acceptability. Section V.5.2.3 of the final rule SOC has been revised to clarify the maintenance, inspection, testing, and surveillance requirements for RISC-3 SSCs.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-34	The commenter asserts that the SOC establishes an ambiguous standard for evaluating treatment by stating that "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." The commenter stated that NEI-00-04 addresses this issue by crediting: (1) the corrective action program for identifying and modifying treatment changes which produce unacceptable trends in SSC performance; and (2) the sensitivity analyses which demonstrates that small changes in SSC performance can be tolerated without undue increase in CDF or LERF. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-35, d-36, m-5	The NRC agrees that more clarity is appropriate as discussed below. Although the specific effects of the reduction in treatment under § 50.69 will not be known until the rule is implemented, licensees will need to consider whether the planned reduction in treatment for RISC-3 SSCs will be consistent with the credited capability of those SSCs in the categorization process. The corrective action process alone will not be sufficient to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety-related functions because that process does not monitor the performance of RISC-3 SSCs. Further, the risk sensitivity study alone are not sufficient to evaluate the impact of the reduction in treatment because the studies typically only assume a reduction in SSC reliability of a few tenths of a percentage point with a limited consideration of common cause interaction across plant systems. The SOC has been revised to more clearly indicate the meaning of the § 50.69 requirements, and that it is the collective parts of the rule that address the potential for changes in RISC-3 reliability, specifically; 1) robust categorization and PRA requirements, 2) requirements to show with reasonable confidence that implementation risk is acceptably small, 3) feedback requirements of paragraph (e) to maintain the validity of the categorization process, 4) the high level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability, and 5) a requirement that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. See the response to comment c-4.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-35	One commenter states that for PRA methods the special treatment applied to an SSC does not impact its credit in PRAs, unless it directly affects its reliability and availability. SSCs are credited in PRAs based on their historical reliability and availability, design functions, and design capabilities, and not their treatment. Consideration of treatment impact on the categorization process is unnecessary. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-36, m-5	The NRC agrees that PRA methods do not readily address the impact of treatment changes on SSC reliability or availability. However, treatment changes can adversely affect the reliability and availability of SSCs, both individually or as a group. Under § 50.69, most special treatment requirements for a significant number of safety-related SSCs in a nuclear power plant will be eliminated. These special treatment requirements will be replaced with the § 50.69(d)(2) high-level treatment requirements that will allow significant reduction in the treatment applied to safety-related SSCs categorized as having low individual safety significance. This reduction in treatment can introduce common cause concerns and weaken defenses against them. Therefore, if the requirements of § 50.69 are not effectively implemented, there is a potential that the reliability and availability of a significant number of RISC-3 SSCs could be affected. The available PRA methods provide only limited consideration of potential common-cause interaction of plant SSCs across system boundaries. Further, the risk sensitivity study typically will only decrease the reliability of RISC-3 SSCs a few tenths of a percentage point. The final rule and SOC have been revised to more clearly indicate that the extensive change in treatment allowed under § 50.69 results in the need for licensees to ensure that the treatment of RISC-3 SSCs will be consistent with the categorization process. See also the response to comment c-4.
d-36	The commenter asserts that the only practical means to measure the impact of treatment is through trending of failures in the corrective action program. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, m-5	The NRC disagrees with the statement that the only practical means to measure the impact of treatment is through trending of failures in the corrective action program. The corrective action process alone is insufficient to monitor the effects of reduced treatment on RISC-3 SSCs because it primarily addresses failures after they have occurred. The surveillance and test process needs to provide sufficient performance data of RISC-3 SSCs to determine whether the reduction in treatment has adversely affected their design-basis capability. The SOC has been revised to more clearly indicate the importance of the treatment processes, including monitoring, for RISC-3 SSCs in maintaining any change in risk acceptably small. Also see response to comment c-4.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-37	The SOC establishes an unnecessary and burdensome data collection and analysis process where it states that "to determine that SSCs will remain capable until the next scheduled activity, a licensee 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." The use of feedback mechanisms in the licensee's corrective action program are adequate to ensure that appropriate surveillance frequencies are selected for low safety significant SSCs. See comments d-15, d-17, d-25, d-31, d-32, d-33, e-3, p-11, p-19, p-23	The NRC disagrees with this comment. In implementing § 50.69, a licensee's corrective action process will not be adequate to ensure that appropriate surveillance frequencies are selected unless the surveillance and testing process gathers sufficient data to identify degradation in the performance of RISC-3 SSCs. As a result, the commenter's suggestion is not adequate for providing reasonable confidence of RISC-3 design basis functional capability throughout the service life. The SOC has been revised to more clearly indicate the importance of the treatment processes for RISC-3 SSCs. Also see response to comment c-4.
d-38	Licensees should be allowed to exclude or replace portions of voluntary consensus standards where a suitable basis for exclusion or replacement is justified and documented. See comment p-13	The NRC agrees with this comment in principle. The SOC for the final rule has been revised to clarify the appropriate use of voluntary consensus standards in satisfying the treatment requirements for RISC-3 SSCs. Under § 50.69, licensees will be allowed to follow approaches other than those specified in voluntary consensus standards. However, mixing and matching provisions of different standards might not provide adequate reliability. For example, the higher allowable stresses using a stringent design method of one standard should not be applied when using a less stringent design method of another standard. As required in § 50.69(d)(2), licensees will need to establish treatment processes that provide reliability levels consistent with those used in the categorization process.

TABLE 4 - 50.69 Paragraph (e) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-1	The language in § 50.69(e)(1) that states "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," should be changed to delete the words "the PRA" in the last sentence because the need to update the supporting analyses should be maintained as part of the "quality" of these analyses embodied in compliance with NRC endorsed standards, already addressed in § 50.69(c)(1)(i). See also comments e-2, e-8, e-9	The NRC disagrees that the language in § 50.69(e)(1) must be changed to delete the referenced words. The NRC considers the rule with the words "the PRA" to be clearer than if the words were removed. No revisions to the final rule have been made as a result of this comment.
e-2	The PRA update frequency should be " no longer than 36 months *after licensee implementation of SSC categorization per 10 CFR 50.69*.." because updates of PRA applications typically follow updates of the PRA itself, and because licensee implementation of § 50.69 may fall on a schedule which does not correspond to existing Licensee PRA update processes. See also comments e-1, e-8, e-9	The NRC disagrees with this comment. In order to have a recognizable date for updating the PRA, the rule in § 50.69(e)(1) intends that the starting date begin when the NRC grants the license amendment to begin implementation of § 50.69. However, depending on the timing of the issuance of the license amendment and the subsequent level of § 50.69 implementation, the licensee or applicant might have minimal plant changes, operational practices, or operational experience to review to update the categorization and treatment processes if in fact there has been little or no implementation of § 50.69 at the time when updating is required. The final rule SOC has been revised to reflect this discussion.
e-3	Licensees implementing the proposed rule could fail to detect significant degradation that could cause multiple component failure during a single design basis accident.	The NRC disagrees with the comment about detection of degradation, but agrees that additional requirements on corrective action for significant conditions are appropriate. In response to this comment and a similar comment from NEI, the rule has been revised to require in § 50.69(d)(2)(iv) that, in the case of significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action is taken to preclude repetition. See response to comment d-32.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-4	The proposed rule no longer requires timely monitoring and adjustment of the categorization process to ensure that sensitivity studies remain valid. See comment e-5	The NRC agrees that clarification of the feedback requirements is needed. The final rule has been revised to more closely link the categorization and treatment processes in § 50.69(d)(2) and § 50.69(e) with regard to establishment of treatment and feedback processes to ensure that the categorization process including the risk sensitivity study remains valid. The rule has been clarified in § 50.69(e)(1) to read (with additions underlined): (1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs*. In a timely manner but <u>no longer than once every two refueling outages</u>, the licensee shall review changes to the plant, operational practices, applicable <u>plant and</u> industry operational experience, and, as appropriate, update the PRA, the SSC categorization, and <u>treatment processes</u>. The final rule more clearly indicates that licensees are required to evaluate RISC-3 SSC performance data, described in § 50.69(e)(3) and obtained under § 50.69(d)(2)(iii), in a timely manner and to update, as applicable, the categorization or treatment processes. The feedback of performance data includes evaluation of the validity of the sensitivity studies applied in the categorization process. The rule in § 50.69(e)(1) also requires licensees to review applicable plant operational experience from other sources such as that obtained from the corrective action process.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-5	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 process as necessary to maintain safety. See comment e-4	The NRC agrees that clarification to the rule requirements is needed. The final rule has been strengthened in each of the areas mentioned in the comment. Specifically, the final rule in § 50.69(d)(2) requires that “the treatment of RISC-3 SSCs must be consistent with the categorization process.” The final rule also requires that, “for significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action is taken to preclude repetition.” In addition, and as stated in response to comment e-4 above, the final rule requires licensees in § 50.69(e)(1) to evaluate RISC-3 SSC performance data, described in § 50.69(e)(3) and obtained under § 50.69(d)(2)(iii), in a timely manner and to update, as applicable, the categorization or treatment processes. The feedback of performance data includes evaluation of the validity of the sensitivity studies applied in the categorization process. Section 50.69(e)(1) of the final rule also requires licensees to review applicable plant operational experience from other sources such as that obtained from the corrective action process. If effectively implemented by licensees, the final rule will maintain any changes in risk acceptably small and, therefore, will maintain safety.
e-6	Since all but the safety analysis (a)(4) requirement of the maintenance rule could be pre-empted by this proposed rule we believe that RISC-1,2, and 3 SSC reliability data should be required to be fed back into the PRA as part of the update process. See comment e-7	The NRC disagrees that all of the information referred to must be incorporated into the PRA because changes in treatment might be more effective in addressing performance information. Nevertheless, the feedback of performance information in a timely manner as specified in § 50.69(e)(1) is important to ensure that the categorization process and its results remain valid. The addition of “plant” operational experience in § 50.69(e)(1) explicitly requires that RISC-3 SSC performance information from such sources as the corrective action process and the surveillance performed under § 50.69(d)(2)(iii) be fed back into the categorization process. The plant and industry operational experience referred to in § 50.69(e)(1) includes reliability data for RISC-3 SSCs. Thus, the enhanced monitoring and feedback incorporated into the final rule when coupled with the tighter linkage between the categorization and treatment processes, makes reliability monitoring of RISC-3 SSCs unnecessary.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-7	Proposed § 50.69(e)(3) imposes requirements for monitoring RISC-3 SSCs that are similar to, if not greater than, the requirements in the Maintenance Rule. Whereas Maintenance Rule monitoring would generally occur at a system or train level, the proposed RISC-3 monitoring would generally occur at a component level and include a review of all periodic maintenance, testing, and surveillance activities for RISC-3 SSCs. The low safety significance of RISC-3 SSCs and the negligible contribution of the failure rates of these SSCs on CDF and LERF do not support a burdensome new monitoring requirement. See comment e-6	The NRC agrees that RISC-3 monitoring per § 50.69(d)(2(iii) would typically be at the component level. However, most special treatment requirements, including the ASME Code inservice inspection and testing program, will be eliminated for RISC-3 SSCs under § 50.69. Therefore, licensees will need to establish adequate surveillance and testing processes for RISC-3 SSCs to collect performance data to provide reasonable confidence that those SSCs are capable of performing their safety-related functions, and to feed back that information to provide confidence that the categorization and treatment processes and their results remain valid. Adequate treatment processes under § 50.69 are necessary because performance problems with multiple RISC-3 SSCs can have a significant impact on plant safety. No revisions to the final rule have been made as a result of this comment.
e-8	Section 50.69(e) requires the PRA and categorization to be updated every 36 months. No mandated period should be specified and PRA updates should be performed on an as needed basis as determined by the licensee. See also comments e-1, e-2, e-9	The NRC disagrees with this comment and concludes that a vital piece of this regulatory framework is a requirement to periodically update the categorization and PRA. Refer to the comment e-4 and e-9 response regarding changes to the update periodicity. No revisions to the final rule have been made as a result of this comment.
e-9	Paragraph § 50.69 (e)(1) should be modified to "once every two refueling cycles" rather than every 36 months for reasons of practicality. See also comments e-1, e-2, e-8	The NRC agrees with this recommendation because it accommodates plants with different operating intervals. The final rule requirement has been revised accordingly.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-10	In SOC Section V.6.0 it is stated "[i]f a 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." A commenter stated that this implies a potentially enormous program to monitor, track, and compare to the categorization process practically every SSC within the PRA (as well as inputs and assumptions) and every performance aspect. Conformance to the literal SOC words is likely impossible, and certainly impractical, and out of context with the low safety significance of RISC-3 SSCs. The words should be removed.	The NRC disagrees that the rule mandates an enormous program to monitor, track, and compare every SSC in the PRA. The final rule in § 50.69(d)(2) and § 50.69(e) requires licensees to develop treatment processes that are consistent with the categorization process and to feedback information to maintain the validity of those processes. To maintain the validity of the categorization process, and more importantly to maintain any potential risk increase as small, it is necessary to maintain the "credited" SSCs (i.e., the SSCs that are safety significant in order that others can be low safety significant) per § 50.69.
e-11	Section 50.69 (e)(2) states that "[t]he 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." The second sentence should be clarified. The only available categorization adjustment for these SSCs is to re-categorize them as RISC-3 or RISC-4. Generally this will only occur if an error in the original process occurred or new insights are made available to the IDP. These are nonroutine types of situations.	The NRC disagrees with the comment. There are various alternatives in responding to RISC-1 and RISC-2 performance information. If performance of RISC-1 and/or RISC-2 SSCs declines such that assumptions are no longer valid, and/or the categorization results are no longer valid in terms of maintaining delta CDF and delta LERF small, a licensee may either adjust the treatment (to improve RISC-1 and RISC-2 reliability and/or availability), or re-categorize RISC-3/4 SSCs back into RISC-1/2 until the change in risk is acceptably small. The final rule SOC has been revised to reflect this discussion.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-12	The assessment of data collected should be an engineering function and the decision to “feedback” into the categorization and treatment processes should not be required unless there is a significant deviation in SSC performance compared to that used during the categorization process. The SOC should be clarified to match the “appropriate” rule language text. See also comment c-37	The NRC agrees with the comment. The rule specifies in § 50.69(e)(3) that licensees feedback performance data and make adjustments “as necessary” to either the categorization or treatment processes so that the categorization process remains valid. The SOC has been revised to focus on the meaning of the rule language.
e-13	Section III.3.2 of the SOC states that “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.“ This implies that an SSC performance monitoring process will be developed to track SSC performance. The industry has proposed in NEI-00-04 that RISC-3 performance be monitored via the corrective action program, not a new reliability trending program. The commenter asserts that a new reliability trending program for RISC-3 SSCs would be unduly burdensome and unnecessary based on the low safety significance of RISC-3 SSCs. The above text should be clarified that a corrective action program satisfies this expectation.	The NRC disagrees with this comment. The final rule does not require a new reliability trending program as suggested by the comment. Rather, the final rule requires licensees to evaluate RISC-3 SSC performance data, described in § 50.69(e)(3) and obtained under § 50.69(d)(2)(iii), in a timely manner and to update, as applicable, the categorization or treatment processes. The feedback of performance data includes evaluation of the validity of the sensitivity studies applied in the categorization process. The rule in § 50.69(e)(1) also requires licensees to review applicable plant operational experience from other sources such as that obtained from the corrective action process. The text of the final rule and SOC have been revised accordingly.

TABLE 5 - 50.69 Paragraph (f) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
f-1	The proposed rule should contain a process for making changes to licensee's commitments for implementation of the rule. The proposed rule's standard for changing commitments would not allow a licensee to make any changes in its commitments without prior NRC approval. This is unduly restrictive and it transforms commitments into requirements.	The NRC disagrees with this comment. At this time, the NRC was unable to determine generic criteria for the control of changes to the categorization process during its implementation that could be included in § 50.69. As a result, the NRC intends to impose a license condition regarding the control of categorization process changes when granting each license amendment that allows implementation of § 50.69. The license condition will require the licensee to notify the NRC in advance of implementing changes with respect to specific aspects of the categorization process. With experience in the application of § 50.69, the NRC might modify the rule to specify generic criteria for the control of changes to the categorization process during implementation of the rule. Licensees submitting a license amendment request to implement § 50.69 will need to identify actions supporting the license amendment such that the NRC can specify appropriate conditions for application of § 50.69 in the license amendment. The provisions of § 50.69 do not modify commitments that licensees have made to the NRC for plant SSCs in response to other regulatory issues. For example, licensees may adjust their non-legally binding commitments (such as those in response to generic letters or bulletins) through the approach that has been coordinated by the Nuclear Energy Institute and accepted by the NRC staff. It should be noted that § 50.69(d)(2)(i) continues to require that the design functional requirements for RISC-3 SSCs be maintained and controlled. Therefore, changes to licensee commitments that impact the design functional capability for RISC-3 SSCs might receive additional scrutiny by the NRC as part of the inspection process.

TABLE 6 - 50.69 Paragraph (g) Requirements

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
g-1	A commenter does not support the new reporting requirements for RISC-1 and RISC-2 SSCs. Creating separate reporting requirements under § 50.69 would be redundant and confusing when compared to § 50.72/50.73. Existing reporting requirements are well defined and implemented. The proposed reporting requirements for RISC-1 and RISC-2 SSCs under § 50.69 are vague. Lessons learned from the implementation of § 50.72 and § 50.73 were that vague reporting requirements created substantial burden and inconsistency for the industry. Any additional data that might be generated by the proposed reporting requirement of § 50.69 for RISC-2 SSCs would be of very limited value. It is sufficient to state that reporting requirements for RISC-1 SSCs under § 50.69 are unchanged for existing reporting requirements. Another commenter stated that the NRC did not adequately justify the new reporting requirement for RISC-1 and RISC-2 SSCs and does not think there is a safety basis for the requirement which is characterized as a burdensome programmatic requirement. See comments p-2, p-4	The NRC disagrees with this comment. The categorization process crediting of RISC-1 and RISC-2 SSC capabilities to perform functions outside of the design basis makes the scope of the reporting requirements in § 50.69 more broad than those in 10 CFR 50.72 and 50.73. The NRC agrees that the current § 50.72/50.73 reporting requirements are well-defined, but these requirements do not apply to beyond design basis situations. The reporting requirements under 10 CFR 50.69 for RISC-1 and RISC-2 SSCs are consistent with one of the main objectives of this rulemaking, which is to focus resources on the most safety significant SSCs. The NRC disagrees that these reports would be of limited value since the failure to perform a safety significant function may result in a significant increase in risk at the facility, and therefore should warrant both licensee and NRC attention. The NRC would use the information from such reports to inform other licensees. The NRC disagrees that the § 50.69 reporting criteria are vague, and notes instead that the § 50.69 reporting criteria is pretty simple and well-defined and requires reports for events or conditions that could have prevented a RISC-1 or RISC-2 SSC from performing a safety-significant function. No revisions to the final rule have been made as a result of this comment.

TABLE 7 - "Questions for Public Input"

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-1	The NRC must verify that plant owners not only have adequate high level process guidance, but are also adequately implementing their processes, that components conform with all the established criteria for placement in RISC bins, and that any RISC binning errors are found and corrected in a timely manner. The commenter points to Davis Besse Lessons Learned Task Force recommendation 3.2.2(1) that the NRC should inspect the adequacy of the pressurized water reactor (PWR) plant boric acid corrosion control programs, including their implementation effectiveness. In "special treatment" space, the NRC must go beyond spell checking each licensee's translation of the NEI guidance. A report prepared by the Idaho National Engineering and Environmental Laboratory (NUREG/CR-6752) found that plant processes will have a significant effect on providing reasonable confidence of component functionality, but the adequacy of commercial standards and reduced plant processes would have to be evaluated on a plant-by-plant basis. The need for the NRC to do more than a superficial, high-level process review is supported by a 1997 enforcement action against the owner of Three Mile Island Unit 1 for inadequate engineering controls, poor implementation of the process for classifying components, failure to ensure that reactor building cooling fans were properly qualified, and failure to take timely and appropriate corrective actions. [CONTINUED]	The NRC disagrees with these comments. The NRC considers that the low risk significance of the individual RISC-3 SSCs, in addition to all the features built into the § 50.69 framework (enumerated in the response to comment p-6) provides adequate support for allowing licensees to establish treatment processes under 10 CFR 50.69 without prior NRC staff review on a plant-specific basis. The NRC also notes that the example of Davis Besse is not applicable to § 50.69 since the reactor vessel would remain subject to all the special treatment requirements (it is clearly RISC-1) and that the Davis Besse event reveals problems that can exist with any regulation. However, the public comments received on the proposed rule and its SOC reveal divergent interpretations of the high-level treatment requirements for RISC-3 SSCs in § 50.69. Therefore, the NRC concludes that evaluation of the implementation of 10 CFR 50.69 programs is necessary consistent with the NRC's reactor oversight process. The details regarding those evaluations of the categorization and treatment processes will be determined, in part, based on the information provided by licensees as part of their § 50.69 submittal. The NRC has revised the § 50.69 RISC-3 treatment requirements and supporting SOC discussion. Refer to the response to comment d-32.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-1 cont	Based on past applications of risk-informed initiatives, a commenter asserts the need for NRC examination of implementation of the § 50.69 rule. Another commenter recommends that licensees be required to submit their RISC-3 treatment programs for NRC review and approval prior to implementation of § 50.69, because the licensee's RISC-3 SSC treatment program is critical in ensuring that appropriate requirements for systems that are safety-related based on deterministic analyses are not deleted. It was also stated that there is precedent for such inspections (MSPI inspections). See comments p-6 , p-1, p-6 , p-10, p-14, p-15, p-21, p-24	
p-2	Removal of reporting requirements on RISC-3 SSCs will lead to inconsistent reporting which may in turn result in events/information not getting reported for § 50.69 plants that may have helped non-50.69 plants avoid similar situations. The commenter points to numerous NRC information notices that alert licensees to performance concerns with plant SSCs. See comments g-1, p-2, p-4, p-7, p-10, p-16, p-21, p-24	The NRC disagrees with this comment. The NRC agrees that reporting will be different for § 50.69 licensees, but the NRC concludes that significant deficiencies will be captured by 10 CFR 50.72 and 50.73 requirements (either because significant events would need to involve several RISC-3 SSCs which in turn make it more probably that these events involve TS issues, plant transients, plant shutdown, or simply involve RISC-1 SSCs within the same system any of which would trip the § 50.72/50.73 reporting criteria) and the new reporting requirements in § 50.69 (for events or conditions involving safety significant functions not captured by § 50.72/50.73). Further, the NRC inspection program will be alert for significant performance concerns with RISC-3 SSCs as part of the evaluation of the corrective action process at plants implementing § 50.69. See the response to comment p-4 for further discussion of the relevance of the RISC-3 information for other facilities. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-3	Relevant operating experience suggests that regulatory oversight of equipment credited with lowering risk should be increased rather than moving more of this equipment to owner control. The nuclear industry's Equipment Performance Information Exchange (EPIX) system is not adequate for monitoring operating experience because of the uncertainties for reporting under this system, and the lack of public access to the system. Apparent contradictions in the NRC's attention to safety-related equipment are identified (e.g., containment spray versus containment sump). See comments p-8, p-17, p-20, p-22, p-25, p-26	One of the main objectives of the 10 CFR 50.69 rule is to allow licensees and the NRC to focus resources on the plant SSCs with the highest safety significance. In this way, the goal is to provide an increased, or at least an equivalent, level of safety in the operation of nuclear power plants. The NRC agrees that operating experience will need to be evaluated to provide assurance that common cause interactions from the reduction in treatment do not result in a significant risk increase for those plants implementing § 50.69. As a result, the rule has been clarified to specify the consideration of plant operating experience as part of the feedback of information in § 50.69(e)(1). See response to comment e-4. The NRC also will evaluate implementation of § 50.69 programs consistent with the NRC's reactor oversight process. As indicated by the comment, this new approach will require careful oversight by the NRC as well as licensee management to ensure that the new programs are effectively implemented. The example by the commenter of increased attention to the containment sump system is consistent with § 50.69(d)(2)(i) that RISC-3 SSCs must be capable of performing their safety-related functions.
p-4	Relevant operating experience also argues against the removal of reporting/notification requirements for RISC-3 equipment. If the reclassification of this equipment resulted in the equipment being unavailable, neither the NRC nor the public would know until its too late. See comment g-1, p-2	The NRC disagrees with this comment. See the response to comment p-2 regarding removal of § 50.72/50.73 reporting requirements for RISC-3 SSCs. The NRC determined that the changes in design, procurement, installation, maintenance, testing, inspection, and repair that will likely occur for RISC-3 SSCs as a result of implementation of § 50.69 will cause information regarding the performance of RISC-3 SSCs to be applicable primarily on a plant-specific basis. Where information might be relevant, the NRC clarified § 50.69(e)(1) to specify the consideration of plant operating experience as part of the feedback of RISC-3 performance information. With regard to the last portion of this comment, the categorization process is intended to ensure that only SSCs of low individual safety significance are categorized as RISC-3 such that the failure of an individual RISC-3 SSC would not be of concern. See response to comment e-4.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-5	Implementation of § 50.69 should not be dependent on development of a full scope, all modes, level 2 PRA - followed by justification as applicable. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-9, p-12, m-4, m-5	The NRC agrees with this comment. The supporting guidance for the rule has been structured such that licensees will gain more benefit when PRA methods are used (beyond the minimum required), and where non-PRA methods are used the requirements and associated implementation guidance account for this situation by requiring a process that tends to conservatively categorize SSCs into RISC-1 and RISC-2 (i.e., no STRs are removed). There are several other features to the regulatory framework that also contribute to ensuring sound PRA is used such as requiring aspects of the categorization process to be reviewed and approved prior to implementation, requiring the PRA to be peer reviewed, IDP requirements, provisions for addressing all modes and events regardless of whether in the PRA, feedback and update requirements, and supporting standards. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-6	Many commenters do not support RISC-3 treatment review and approval. One commenter asserts that, the low safety significance of RISC-3 SSCs, combined with the NRC inspection and enforcement process, should be sufficient to provide the NRC with the necessary regulatory assurance. Another commenter (NEI) states that industry will develop guidance documents to provide for consistent and appropriate consideration of design-basis functions for RISC-3 SSCs. The commenter also states that no new inspection programs are needed in that the existing NRC inspection and enforcement process already addresses all affected functional areas including procurement, maintenance, testing and surveillance, design bases, and corrective actions, and that process will be appropriate to adequately identify and address any performance deficiencies. Two commenters (Strategic Teaming and Resource Sharing (STARS) and STP) assert that it is in the licensees' best interest to operate their facilities safely and reliably, and in a cost-effective manner. They point to NRC and industry performance indicators, and improved industry operating capacity factors reaching 90% or greater. These same safety and economic approaches will be applied to ensure their continued reliability. Another commenter (BWR Owners Group (BWROG)) asserts that the requirement for licensees to monitor performance and revise treatment as needed to maintain design basis performance is sufficient. One commenter (WOG) believes that the level of NRC review and approval of treatment processes specified in the proposed rule language is adequate to assure that the SSCs will be capable of reliably performing their design-basis functions.	The NRC agrees that individual low safety significance of RISC-3 SSCs supports allowing licensees to establish treatment processes for RISC-3 SSCs without prior NRC review. This conclusion is based on the rule containing 1) robust categorization and PRA requirements, 2) requirements to show that implementation risk is acceptably small, 3) feedback requirements of paragraph (e) to help maintain the validity of the categorization process, and 4) the high-level RISC-3 requirements designed to maintain RISC-3 SSC design basis functional capability. In addition, a provision has been added to the final rule to make it clear that the treatment applied to RISC-3 SSCs must be consistent with (i.e., maintain the validity of) the categorization process. Together all these requirements support both no prior review of RISC-3 treatment, and the conclusion that § 50.69 maintains adequate protection of public health and safety when effectively implemented. High operating capacity factors have been achieved, in part, by attention greater than commercial industrial practice (referred to at some plants as augmented programs) provided to non-safety related equipment used for the generation of electricity. The industry has not indicated that similar augmented practices will be applied to RISC-3 SSCs. Further, although a commenter states that the industry will develop guidance documents for RISC-3 treatment, previous industry efforts were insufficient to provide confidence in the capability of RISC-3 SSCs to perform their safety-related functions. Although another commenter asserts that the high-level requirements for monitoring and corrective action in the proposed rule would have ensured that any important deficiencies are identified, several licensees suggested that simply exercising a valve or pump would satisfy the monitoring requirements in the proposed rule despite the fact that, based on experience, such exercising would not identify potential degradation in the design-basis capability of those components to perform their safety functions until called upon during an accident. Further, the potential for common cause failures as a result of elimination of special treatment requirements for most safety-related SSCs at a nuclear power plant is inconsistent with the commenter's suggestion that any RISC-3 SSC deficiencies would have low risk-significance.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-6 cont	Another commenter (Licensing and Design Basis Clearinghouse) suggests that the high-level objectives will provide adequate assurance for protection of public health and safety because (1) RISC-3 SSCs are required to remain capable of performing design-basis functions; (2) high-level requirements for monitoring and corrective action will assure that a licensee monitors RISC-3 SSCs and that any important deficiencies are corrected; (3) any deficiencies with RISC-3 treatment are likely to be of low risk-significance; (4) licensees may apply varying levels and types of treatment; (5) the industry has initiated efforts to develop generic guidance on acceptable RISC-3 treatment alternatives which licenses will likely use; (6) the NRC finds it acceptable to allow some increased likelihood of failure of RISC-3 SSCs; and (7) the NRC has concluded that effective implementation of the treatment requirements provides reasonable confidence in the capability of RISC-3 SSCs. See comments p-1, p-14, p-15	

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-7	Additional training and guidance should be provided to NRC inspectors charged with oversight of § 50.69 activities (with specific suggestions). One commenter suggests that guidance be added to NRC inspection modules and that the NRC hold public workshops. A second commenter states that the existing NRC inspection and enforcement process which already address all affected functional areas including procurement, maintenance, testing and surveillance, design bases, and corrective actions, would appear adequate to identify and address any performance deficiencies. The commenter did not recommend any additional guidance but recommends that inspectors be trained to focus on RISC-1 and -2 SSCs, rather than RISC-3 SSCs. Two commenters assert that the NRC inspection and enforcement program should not require modification, but that inspector training will be necessary to allow effective § 50.69 implementation. Finally, a commenter believes it appropriate to develop guidance and training for NRC inspectors who would be auditing § 50.69 programs to assure consistency. See comments p-2, p-10, p-16, p-21, p-24	The NRC agrees with this comment. Additional training for NRC inspectors will be necessary with respect to § 50.69 programs being implemented at nuclear power plants. There were various views among commenters regarding whether additional written guidance is necessary. However, the NRC concludes that written guidance is important to provide consistency among NRC inspectors in addition to training. The NRC will develop appropriate training and guidance following review of requests from licensees to implement § 50.69.
p-8	Any data collection program should be commensurate with the RISC significance of the SSC of interest (i.e., data collection for RISC-3 SSCs should not be any more laborious than current STRs). See comments e-7, p-3, p-17, p-20, p-22, p-25, p-26	The NRC agrees that the collection of operating experience information regarding RISC-3 SSCs will be less applicable to other nuclear power plants because of the significant changes in the design, procurement, installation, inspection, testing, and maintenance that will result from implementation of 10 CFR 50.69. The rule has been clarified in § 50.69(e)(1) to indicate that plant operating experience must be considered as part of the feedback of RISC-3 SSC performance information. See response to comment e-4.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-9	State of the art PRAs should be required before major RIP50 licensing actions or regulatory changes are made. The evaluation of CDF and LERF should be performed with a full scope PRA including external events and all modes of operation. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-12, m-4, m-5	The NRC disagrees with this comment. The rule PRA requirements and supporting guidance has been structured such that licensees will gain more benefit when PRA methods are used (beyond the minimum required), and where non-PRA methods are used the requirements and associated implementation guidance account for this situation by requiring a process that tends to conservatively categorize SSCs into RISC-1 and RISC-2 (i.e., no STRs are removed). This structure ensures that there are incentives to use more PRA, while at the same time ensuring that the minimum requirements are conservative in terms of the relief in special treatment requirements. There are several other features to the regulatory framework that also contribute to ensuring sound PRA is used such as requiring aspects of the categorization process to be reviewed and approved prior to implementation, requiring the PRA to be peer reviewed, IDP requirements, provisions for addressing all modes and events regardless of whether in the PRA, feedback and update requirements, and supporting standards. No revisions to the final rule have been made as a result of this comment. We disagree with this comment.
p-10	Inspecting a sampling of RISC-3 SSC failures for adequate categorization and corrective action should be part of the Problem Identification and Resolution baseline inspections. This check would assure the integrity of the categorization and treatment of a failed SSC. See also comments p-1, p-2, p-7, p-10, p-16, p-21, p-24	The NRC agrees with the comment that evaluation of the implementation of 10 CFR 50.69 programs consistent with the NRC's reactor oversight process is appropriate as part of the NRC inspection and enforcement process. The NRC intends to provide training and guidance for the inspectors.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-11	Additional details on treatment of RISC-3 SSCs discussed in the SOC should be included in the final rule. The extra wording [regarding RISC-3 treatment requirements] provides some amount of clarity and if not in the rule should be included in the SOC, guidance documents, or standard review plans (SRPs). See comments d-15, d-17, d-25, d-31, d-32, d-33, d-37, e-3, p-19, p-23	The NRC does not agree that the detailed RISC-3 language in the SOC needed to be included in the rule itself if it the rule is effectively implemented as discussed in the SOC. However, the wide range of interpretations of the proposed rule language revealed by the public comments indicated that the rule and the SOC needed to be clarified. The RISC-3 requirement language has been clarified as discussed in comment responses to d-32 and e-4. It is believed that the clarified rule language in § 50.69(d)(2) and § 50.69(e)(1), and clarified SOC in Section V.5 and V.5, together with plans to evaluate the implementation of the categorization and treatment processes under § 50.69 consistent with the NRC's reactor oversight process, will provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety-related functions under design-basis conditions.
p-12	PRAs were generally published over 10 years ago and do not reflect current plant configurations. If these PRAs are to be used for § 50.69 there must be an effort to update them, get NRC review, maintain them on an ongoing basis and make them available to stakeholders. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-9, m-4, m-5	Section 50.69 requires the review and approval of the licensee's categorization process, and this review also will look at the scope and quality of the PRA taking into account peer review results. The PRA must reasonably reflect the current plant configuration and operating practices, and applicable plant and industry operational experience as required by § 50.69(c)(1)(ii). Additionally, paragraph (e) contains requirements for maintaining the validity of the categorization process and PRA over time. With regard to making the PRA publicly available to stakeholders, sufficient information is publicly available to enable external stakeholders to constructively comment on this rulemaking effort. Some information is not available to the public for security reasons and whether that information will, or should become publicly available is an issue separate from this rulemaking. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-13	The RISC-3 treatment language in the proposed rule SOC regarding meeting consensus codes and standards and replacements for ASME Code class 2 and 3 SSCs should not be included in the rule. The SOC provides adequate guidance regarding voluntary consensus standards, documented procedures and guidelines, and consistency of the treatment processes with the assumptions in the categorization process. With regard to replacements for ASME Class 2 and Class 3 SSCs or parts meeting the ASME Code or a voluntary consensus standard including fracture toughness requirements, ASME states that it has developed appropriate requirements for repair/replacement of pressure-retaining items that could be used by licensees in the treatment of RISC-3 SSCs with these requirements contained in ASME Code Case N-662. The WOG also does not support rule language requiring use of voluntary consensus standards. See comments d-38	The NRC agrees that a specific requirement to use voluntary consensus standards is not appropriate in the rule because of the difficulty in applying a regulation that does not specify the applicable standard. Therefore, the NRC decided not to include rule language on consensus standards, and instead addressed this issue in the SOC supporting the § 50.69(d)(2) requirements. The NRC recognizes that voluntary consensus standards, when effectively implemented, can be used to comply with the rule requirements, and encourages such use in the SOC. On the issue of fracture toughness, the NRC decided to revise the rule language to preclude removal of these requirements (which are beyond the scope of special treatment requirements). Contrary to ASME's implication, ASME does not develop regulatory requirements unless referenced in the NRC regulations. Based on public comments, the NRC has determined that additional clarifications (to those discussed above) of the rule and SOC are warranted. The issues above are further discussed in the response to comment d-32 .

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-14	If there is no mention of ASME codes and standards as a means for meeting rule requirements in the rule package, then ASME has no position on whether RISC-3 treatment should be reviewed and approved. If the rule allows for the use of ASME codes and standards, then ASME does not support prior review and approval of RISC-3 treatment. See comments p-1, p-6 , p-15	The NRC has determined that § 50.69 will not require the use of ASME codes and standards. In addition, the rule will not require prior NRC review and approval of licensee RISC-3 treatment programs. The SOC has been revised to indicate the possible use of voluntary consensus standards in satisfying the rule requirements.
p-15	There is no evidence provided by the Commission to support an argument of requiring an additional layer of NRC review and approval (for RISC-3 treatment review and approval). The commenter claims that the intent of this rulemaking is to provide licensees with more flexibility in regulatory implementation. See comments p-1, p-6 , p-14	The NRC agrees that prior NRC staff review is not necessary for RISC-3 treatment processes established under § 50.69. However, the suggestion that the intent of the rulemaking is to provide more flexibility to licensees is an example of the misunderstanding regarding this rulemaking effort. One of the main objectives of the 10 CFR 50.69 rule is to allow licensees and NRC to focus resources on the most safety significant plant SSCs to improve, or at least maintain an equivalent level of safety in the operation of nuclear power plants.
p-16	No new inspection and enforcement programs are required to implement § 50.69. For example, two commenters state that existing NRC inspection and enforcement process, which already addresses all affected functional areas including procurement, maintenance, testing and surveillance, design bases, and corrective actions, would be appropriate to adequately identify and address any performance deficiencies. Another commenter states that there are numerous opportunities within the proposed regulation and the overall risk informed regulatory regime to assess and monitor licensee processes and programs. See comment p-7 that additional training is required. See comments p-2, p-7, p-10, p-21, p-24	The NRC agrees that no new inspection and enforcement programs are necessary for § 50.69. However, the NRC concludes that additional guidance and training is needed for NRC inspectors in order to ensure a consistent assessment of the implementation of the categorization and treatment processes under § 50.69 at nuclear power plants.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-17	Regarding the role of operational experience, there is already a wealth of information that demonstrates that failure rates of commercial and safety-related SSCs are comparable. This should be used to eliminate all STRs (and allow commercial practice) from RISC-3 SSCs. Three commenters point to a study by STP that was said to demonstrate that the failure rates of commercial components are comparable to the failure rates of safety-related components. See also comments p-3, p-8, p-20, p-22, p-25 p-26	The NRC disagrees with this comment. The database referenced by the three commenters was not submitted for formal review to the NRC staff as part of the STP exemption request. However, the staff's informal review has identified numerous inadequacies in the STP analysis. For example, STP considered reported failures of non-safety related equipment that have no reporting or testing requirements over a multiple-year period as an acceptable method of comparing reliability to safety-related equipment with frequent reporting and testing requirements. In that the design requirements for non-safety related and safety-related equipment can be quite different, it is not possible to directly compare their reliabilities by simply summing reported failures over long periods of time. Even assuming that the reliabilities can be compared, the more recent data collected by STP indicated significantly higher failure rates for some non-safety related components (such as valve operators) than safety-related components. No revisions to the final rule have been made as a result of this comment.
p-18	The commenter does not support putting additional detail into the rule regarding categorization requirements.	The NRC agrees with this comment. The basis for our agreement is set forth in Section II(f) of the regulatory analysis which accompanies the final rule. The regulatory analysis notes that 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 (that contains more detailed categorization requirements) approach. Accordingly, the NRC elected to incorporate less detailed categorization requirements into the rule, and to require licensees to provide a license amendment submittal for staff review and approve prior to implementation of § 50.69. This approach (regarding the incorporation of more high level categorization requirements into the rule versus a detailed appendix) is supported by industry based on the comments on the proposed rule. Additionally (and as noted in the regulatory analysis), it was clear that the staff would need to review some aspects of the PRA to determine its acceptability for application to § 50.69 under any circumstance. As such, a true "no-prior-review" type (as originally envisioned) of approach simply does not appear to be technically feasible at this time. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-19	Additional detailed language for RISC-3 treatment should not be included in § 50.69(d)(2). See comments d-15, d-17, d-25, d-31, d-32, d-33, d-37, e-3, p-11, p-23	The NRC agrees that the specific RISC-3 treatment language referred to by this comment should not be added back into the final rule. The NRC concludes that the final rule requirements for RISC-3 treatment and the supporting SOC when considered in conjunction with all the other features of the § 50.69 are sufficient (see the discussion in the response to comment p-6). The commenters state that the proposed level of detail is beyond what is necessary to provide reasonable confidence in RISC-3 design basis capability in light of the robust categorization process. However, the commenters do not discuss whether licensees have written procedures and records, establish treatment consistent with categorization assumptions, or consider common cause issues with respect to performance of RISC-3 SSCs. The varying interpretations of the high-level requirements in § 50.69 indicated the need to clarify the rule language. This is discussed further in the response to comment d-32.
p-20	Ongoing opportunities for sharing and incorporating experience data on a broader basis, including those associated with existing industry (e.g., INPO, NEI and Owners Group) and regulatory (e.g., Maintenance Rule) programs already provide a substantial data source for licensees to draw upon in both categorizing SSCs and recognizing impacts and changes in performance. See comments p-3, p-8, p-17, p-22, p-25, p-26	The NRC agrees that the categorization process will need to address operating experience in determining the impact of changes in treatment on the categorization process assumptions. The comment points to existing industry and regulatory programs for the sharing of operating experience. However, some of those programs (e.g., maintenance rule) will be eliminated for RISC-3 SSCs. Therefore, the NRC clarified the feedback requirements for operating experience in § 50.69(e)(1).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-21	A commenter provided detailed proposals on how the NRC's inspection program should be modified to reflect § 50.69: 1) the current enforcement policy and manual are adequate to broadly address § 50.69, 2) the staff should consider revising manual chapter 305 to acknowledge the potential for § 50.69 implementation, 3) the staff should consider revising manual chapter 609 to address potential overlap of § 50.69 with the significance determination process (SDP) and how such overlap should be addressed, 4) NRC should consider a period of enforcement discretion for licensees implementing § 50.69, 5) inspection should focus on the categorization process, including the PRA, periodic evaluations of the process, and corrective action for identified deficiencies (rather than on specific equipment issues regarding the elimination of special treatment of RISC-3 SSCs) with RISC-3 SSC deficiencies receiving reduced enforcement focus, 6)NRC should ensure the integration of the reactor oversight process (ROP), maintenance rule (MR), and § 50.69 is coherent and inspectors trained, 7) NRC should consider a focused team inspection for the first two cycles of inspection to ensure consistency in the NRC's oversight of this element (licensee implementation of increased treatment for RISC-1 and RISC-2 SSCs) as well as others. See also comments p-1, p-2, p-6, p-7, p-10, p-16, p-24	The NRC agrees that the NRC inspection and enforcement program is sufficient to encompass the § 50.69 programs for the reasons previously stated in response to comment p-16. The suggestions in the comment will be considered as part of the NRC preparation of inspector guidance and training.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-22	The feedback process should ensure that licensees who implement § 50.69 will make appropriate programmatic adjustments and that therefore public health and safety is maintained on a continuing basis. Three elements of § 50.69 that are aimed at minimizing uncertainty in the effects of treatment on performance are the requirements to (1) perform sensitivity studies; (2) periodically review performance information to determine whether there are any adverse changes such that RISC-3 SSC unreliability values approach unacceptable values; and (3) make necessary adjustments to categorization and treatment processes, based on plant changes, operational practices, and applicable industry operational experience. The proposed rule to provide adequate controls to ensure adequate protection of public health and safety because (1) the proposed rule requires special treatment to apply to high risk-significant SSCs and that treatment supports categorization process assumptions; (2) in addition to the defense-in-depth requirement, uncertainties are minimized by incorporating elements to add conservatisms (e.g., IDP, alternate treatment, periodic implementation review, and selective implementation limitations); (3) adjustments based on operating experience will allow for improvements; and (4) high-level treatment requirements for RISC-3 SSCs are sufficient to address concerns from reduction in treatment. See comments p-3, p-8, p-17, p-20, p-25, p-26.	The NRC agrees with this comment. With clarification of the rule, the NRC agrees that the feedback process specified in the rule will provide information that can be used to ensure that licensees implementing 10 CFR 50.69 will make appropriate programmatic adjustments. The comment reflects the importance of sufficient testing and inspection of RISC-3 SSCs to provide performance information that can be fed back into the categorization and treatment processes. For example, starting pumps and exercising valves would not provide sufficient performance information. The NRC agrees with this comment that the controls built into the § 50.69 framework will maintain public health and safety. This conclusion is based on the elements discussed in the response to comment p-6. NRC inspection program might also gather information on operating experience through review of the licensee's corrective action program.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-23	A commenter (WOG) does not support putting back into the rule the detailed RISC-3 treatment language that appeared in previous rule drafts, for several reasons: (1) design basis functions are required to be maintained; (2) operational considerations are considered by IDP; (3) defense in depth and safety margins are maintained; and (4) risk assessment considerations provide assurance that there is negligible change in risk. The robustness of the categorization process to assure that defense in depth, safety margins, and risk are properly considered. The SOC should be significantly revised to delete detailed expectations and requirements that do not directly support an explanation of the intent of the rule language. See comments d-15, d-17, d-25, d-31, d-32, d-33, d-37, e-3, p-11, p-19	The NRC agrees with the comment that the detailed RISC-3 draft rule language does not need to be reinserted into § 50.69 for the reasons already discussed in response to comment p-19. This comment reveals the differences in interpretation regarding the maintenance of defense in depth and safety margins under § 50.69. For example, the commenter considers defense in depth and safety margins to be maintained only through the categorization process. However, if the treatment process is inadequate such that multiple RISC-3 SSCs are incapable of performing their safety functions, the categorization process cannot maintain defense in depth or safety margins. While the NRC decided not to add back the specific detailed RISC-3 language to which this comment refers, it did decide to clarify the rule and SOC. Refer to the response to comment d-32 for a discussion of the specific changes to the RISC-3 treatment requirements.
p-24	A commenter supports additional inspection and enforcement guidance for the specific reasons stated. Licensees will develop a new set of procedures and processes for treatment of RISC-3 SSCs, and therefore, new inspection guidance will be needed. The commenter also believes that new enforcement guidance is required to enable a fair assessment of the potential risks presented by non-compliance findings. See also comments p-1, p-2, p-7, p-10, p-16, p-21	The NRC agrees with this comment. Additional NRC inspector guidance and training is needed to monitor the implementation of 10 CFR 50.69. The NRC will develop the new guidance and training during the review of licensee's § 50.69 submittals.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-25	A commenter suggests that operational experience data for balance-of-plant SSCs is available but not in a convenient format for the purposes of assessing the uncertainty associated with relaxation of RISC-3 treatment. Collection and assessment of this data on the reliability of nuclear balance-of-plant SSCs would provide a quantitative measure to support the intuitive level of confidence based on high plant capacity factors. See comments p-3, p-8, p-17, p-20, p-22, p-26	The NRC agrees that operational experience data for balance-of-plant SSCs is available but not in a form that enables the assessment of the impact of changes of RISC-3 treatment. However, the data are not readily comparable to safety-related SSCs, because of the varying practices applied to non-safety related SSCs (e.g., equipment used to generate electricity may receive significantly more attention than standby equipment) and the differing design-basis conditions under which the equipment is expected to operate.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-26	A commenter (STP) states that it conducted an extensive review of industry experience databases to compare the impact of treatment on both safety-related and non-safety related SSCs. The commenter indicates that the review included over 74 billion component hours of direct industry operating experience. For all 33 component type categories contained within the databases, the failure frequencies were comparable for both safety-related and non-safety related SSCs in each of the component type categories. Therefore, future deficiencies noted on RISC-3 SSCs will continue to be captured and documented on Condition Reports that will permit continuing evaluation of RISC-3 operating experience by the IDP during periodic reviews, and allows the IDP to adjust the SSC treatment or categorization level if deemed necessary. This commenter implies that nothing additional to what is explicitly required in the rule is necessary to address operating experience. See comments p-3, p-8, p-17, p-20, p-22, p-25	The NRC disagrees with this comment. The NRC has concluded that additional changes to the final rule framework are necessary to address the issue of operating experience. Refer to the response to comment e-4. With regard to some of the specific points mentioned in the comment, the STP database comparing reliability of safety-related and non-safety related equipment was not submitted to the NRC for formal review. However, the staff's informal review has identified numerous inadequacies in the STP analysis. For example, STP compared reported failures of non-safety related equipment that had neither testing nor reporting requirements over a multiple-year interval to the failures reported for safety-related equipment with frequent testing and reporting requirements to arrive at its assertion that non-safety related equipment has the same or greater reliability as safety-related equipment. Further, the more recent data collected by STP indicated that some non-safety related components (such as valve operators) had a much higher failure rate than safety-related components. In any event, non-safety related and safety-related equipment can have significantly different design-basis functional requirements that make comparison of their reliabilities difficult at best. Regarding the assertion that RISC-3 SSC deficiencies will be captured on Condition Reports, several licensee commenters appear to consider exercising pumps and valves to be sufficient alone to satisfy the surveillance requirements in § 50.69 for RISC-3 SSCs. With only component exercising, there would be no information to feed back to the IDP on performance degradation until a component degraded to such a point that it failed an exercise. Therefore, the inability of the component (and possibly a large number of similar components) to perform safety-related functions under design-basis conditions might be unidentified for a long period of time prior to the exercise failure. Further, the potential for multiple RISC-3 SSCs in different systems being incapable of performing their safety functions under accident conditions is not considered (except in limited instances) in the categorization process.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-27	A commenter states that some explanation of the proposed rule requirements in the SOC is appropriate, but states that the discussion is overly prescriptive and could be construed as inappropriately modifying or expanding the actual regulatory requirements. The commenter recommends that the NRC retain the proposed rule language, and delete the prescriptive information from the SOC. However, if the NRC considers it necessary to prescribe acceptable methods for determining appropriate treatment methods, then the NRC should include this information in a regulatory guide. See comments d-3, d-5, d-6, d-32	The NRC agrees with the underlying premise of the comment, viz. that the rule requirements and the SOC language need to be consistent. Section 50.69(d)(2) and (e)(1)of the final rule, and the final rule's SOC were clarified to provide additional assurance that the meaning of the rule language is understood. In addition, certain guidance was removed from the SOC. With regard to the comment on a regulatory guide, the NRC has determined that a regulatory guide will not be prepared to provide guidance for the establishment and implementation of treatment processes under 10 CFR 50.69. The NRC has concluded that such a RG is not needed due to the low individual safety significance of RISC-3 SSCs.

TABLE 8 - Miscellaneous Comments

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-1	This rulemaking effort must be suspended and resumed after the NRC finalizes where the line that determines what information should be publicly available concerning PRAs, IPEs, and UFSARs is drawn and makes relevant information on PRAs from the public side of that line available. Absent at least that information, the public cannot adequately comment on this important question.	The NRC disagrees with this comment. Sufficient information relating to the details of the categorization process is publicly available, and this information is sufficient to enable external stakeholders to constructively comment on this rulemaking effort. The question as to whether additional PRA information should be made publicly available is a question that need not be resolved to permit the public to constructively comment on this rulemaking. No revisions to the final rule have been made as a result of this comment.
m-2	The proposed § 50.69 language issued for public comment differed significantly from the language developed through the open, public consensus process. NRC senior management did not follow the "principles of good regulation" in making significant changes to the draft rule prepared through a consensus process with public participation. NRC senior management sent a strong message that it's pointless for NRC staff and external stakeholders to participate in meetings to develop proposed rules because NRC management may develop their own version. The NRC must re-issue the proposed rulemaking with the basis for the language clearly articulated and available or revise its principles to match its practices. The language must be consistent with the statements of consideration and elements of the rulemaking package.	The NRC agrees that rule language, and the supporting SOC should be consistent, and the NRC has revised the final rule to accomplish that objective. Regarding the specific events that occurred during the proposed rule development and concurrence process, the NRC followed the procedures that govern the rulemaking process as set forth in Management Directive 6.3. NRC management plays an important role in the rulemaking process. At certain points, the NRC made draft rule language available to external stakeholders to facilitate that interaction and with the objective of improving the rulemaking. Nonetheless, external stakeholders must realize that rule language can change during the rulemaking process, and that nothing in this process requires the language to be frozen at any point in time based on the previous interactions with external stakeholders. Hence, the NRC disagrees with assertions made in this comment and will not reissue the proposed rulemaking as suggested by the commenter. See also response to comment m-6.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-3	The proposed rule in its current form, if implemented, would not provide adequate protection to the public's health and safety. The commenter contends that the proposed rule runs the grave risk of risk-misinforming the regulatory process, which the commenter states is intended to oversee and enforce compliance with technical specifications and licensing agreements of nuclear power stations through a prescriptive process. See comments d-1, d-9, d-11, d-12, m-6	Given the way some the proposed rule was interpreted, the NRC recognized the need to clarify the final rule. However, the NRC believes that the proposed rule, if effectively implemented by licensees consistent with the Commission's expectations as articulated in the SOC accompanying the proposed rule, would have provided reasonable confidence that RISC-3 SSCs would have been capable of performing their safety functions under design basis conditions. Nonetheless, in response to public comments on the proposed rule, and in an effort to remove some apparent inconsistencies between the proposed rule and the supporting SOC, the treatment requirements in the final rule for RISC-3 SSCs have been strengthened in § 50.69(d)(2) as shown in the response to comment d-32. The NRC believes that the revised requirements for RISC-3 SSCs in § 50.69(d)(2) of the final rule adequately addresses the comment.
m-4	The proposed rulemaking should not proceed without first addressing the confusion and inconsistency that currently affects the NRC risk-informed approach as outlined under RG 1.174. The commenter points to concerns with the implementation of the criteria within RG 1.174 in reaching the decision to allow continued operation of Davis Besse beyond December 31, 2001, per the advisory in Bulletin 2001-01. The commenter asserts that agency actions that include disregarding the key safety attributes in risk-informing the Davis-Besse decision-making seriously damages NRC credibility. See comments b-1, b-10, c-3, c-4, c-5, c-14, c-16, c-21, c-22, p-5, p-9, p-12, m-5	The NRC disagrees with this comment. Section 50.69 was developed around the principles of RG 1.174 and these principles are clearly described in the notice supporting the final rule. The commenters view that there is confusion and inconsistency with RG 1.174 applications is not directly relevant to implementation of § 50.69. Although based on the principles of RG 1.174, 50.69 is nonetheless a separate regulation supported by its own separate guidance (RG 1.201 and NEI 00-04) that has been developed over the last 4 years. As a result, the NRC does not agree that the 10 CFR 50.69 rulemaking process needs to be delayed. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-5	The established process for developing the proposed rule was not followed. The commenter also notes that the proposed rule relies excessively on risk-based assessments and fails to acknowledge and adhere to the key safety principles in RG 1.174. For example, RG 1.174 is said to identify that changes to be monitored include tracking the performance of the equipment that when degradation can significantly affect the conclusions of engineering judgments and integrated decision-making that supports the licensing basis. The commenter states that data does not currently exist to predict the effect of reduced treatment on currently identified safety-related SSCs and this is equated to over-driving a car's headlights at night. See comments b-5, b-6, b-7, c-19, c-20, c-26, c-27, c-30, c-31, c-33, c-34, c-38, d-13, d-34, d-35, d-36	The NRC disagrees with this comment. The established process for rulemaking in NRC Management Directive 6.3 was followed. The NRC also disagrees with the comment that the principles of RG 1.174 were not adhered to (see the response to comment m-4). In fact, § 50.69 was built around the main principles of RG 1.174 as is evident from the extensive discussion in the SOC. With regard to predicting the effect of treatment changes on RISC-3 reliability, the NRC does not agree with the commenters view that § 50.69 equates to over-driving a car's headlights, but we do note that the clarifications to the rule requirements in addition to the other rule features that require monitoring, feedback of data, and reasonable confidence that overall implementation risk increase to remain small, are considered to address this comment. Regarding the comment about the need to track the performance of equipment when degradation can affect conclusions, § 50.69 incorporates monitoring and feedback requirements into § 50.69(e) and (d)(2)(iii) that perform these functions for this rulemaking. See response to comments d-32 and e-4. Further, the NRC intends to provide improved inspection guidance and training for evaluating the implementation of 10 CFR 50.69. See also response to comment m-2.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-6	It is apparent the aim of the proposed rule is to significantly reduce costs, but at the same time the proposed rule does not provide adequate protection (this assertion appears to be based on all the comments provided in the commenter's letter and discussed elsewhere in this table). See comments d-1, d-9, d-11, d-12, m-3	The NRC disagrees with this comment. While one of the objectives of § 50.69 is to reduce costs, that is not the principal objective as is clearly stated in numerous places in the SOC for the proposed and final rule. The main objective is to risk-inform special treatment requirements and through the consideration of risk information provide a better focus on the plant activities and SSCs that contribute to plant safety, and in so doing ensure that public health and safety is maintained. All other objectives are secondary to these. The NRC also disagrees that the proposed rule would not provide adequate protection (refer to the response to comment p-6), nonetheless, the clarification of the rule and the SOC, together with inspection of the implementation of the categorization and treatment processes, is considered to address this comment. See also the response to comments d-32 and e-4 for a discussion of the specific changes to the final rule requirements. No revisions to the final rule have been made as a result of this comment.
m-7	The equipment necessary for emergency action levels, classifying accidents, and reporting them to off-site officials deserve some attention in the categorization scheme and perhaps some special treatment. See comments c-23, c-24, c-28, c-32, m-11, m-12, m-18	The NRC disagrees with the need to a priori categorize the subject equipment. If licensees choose to categorize the subject equipment, and it is determined to be safety significant then any current STRs will be retained and new requirements of § 50.69(d)(1) would apply. No revisions to the final rule have been made as a result of this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-8	Proposed § 50.69 is an enhancement to plant safety and all licensees should be required to implement it for all SSCs, and that the rule be imposed within two years, and require a level 2 internal and external events, all mode, peer reviewed PRA reviewed by the NRC.	The NRC disagrees with this comment. The commenter asserted that § 50.69 would enhance safety but did not provide a basis to support that assertion. The NRC notes that some stakeholders have expressed their opinion that § 50.69 may enhance safety due to the improved focus on SSCs and supporting activities that are important to plant safety. The NRC believes that the rule will at least maintain the current level of safety if effectively implemented, but we do not conclude that it will necessarily enhance safety. Licensees have indicated that § 50.69 may be cost beneficial for some newer licensees with recent designs when they are free to select the systems assuming actual implementation costs are not too high (which are a function of the final rule requirements). For older facilities, where fewer STRs were imposed, and where these is less potential cost reduction, and greater potential for new requirements and costs, this regulation is probably not cost beneficial. Imposing it as suggested (on all SSCs, within a 2 year time frame, with review of RISC-3 treatment, and requiring a level 2 all mode, peer reviewed, NRC reviewed PRA) is likely to not be cost beneficial for any licensee and therefore could not be supported under such provisions within the Commission Backfit Rule, § 50.109 (i.e., substantial implementation costs with minimal benefits if any in terms of risk reduction). Current operating facilities are safe, and there is no need to impose this regulation in order to achieve adequate protection to public health and safety. No revisions to the final rule have been made as a result of this comment.
m-9	ASME code case numbers have changed and need to be revised in the package. Code Case N-658 was issued as N-660 and former code case N-660 was issued as N-662.	The NRC agrees with this comment. The final rule SOC has been revised to reflect this comment.
m-10	It is recommended that specific references to code cases be replaced with a more generic reference to ASME Codes and Standards as means for satisfying the proposed rule requirements.	The NRC agrees with this comment. Specific ASME Code Cases are not referenced in the SOC.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-11	The NRC should consider moving the detailed SOC discussion to DG -1121 since this discussion reflects current knowledge which will change as experience is gained. See comments c-23, c-24, c-28, c-32, m-7, m-12, m-18	The NRC agrees with this comment. Where practical (i.e., where the discussion of how to implement the requirements can be clearly separated from the portion of the SOC that explains the meaning of the rule requirements), categorization guidance is relocated in the guidance documents (RG 1.201 and NEI 00-04). With respect to treatment, the NRC has decided not to provide any additional information in the SOC regarding the rule requirements other than information that relates directly to the explanation of the rule requirements.
m-12	The section by section analysis and supporting NRC statements on the proposed rule contain detailed requirements some of which are more restrictive and prescriptive than the actual proposed rule language, DG-1121, or NEI 00-04. These requirements should be omitted from the final rule SOC. See comments c-23, c-24, c-28, c-32, m-7, m-11, m-18	The NRC agrees, in part, with this comment. The SOC is intended to explain the high-level categorization and treatment requirements in § 50.69. The comment reflects the differing interpretations of the high-level requirements in the rule. The NRC agrees that some information on categorization in the SOC may be moved to RG 1.201(see the response to comment m-11). In issuing the proposed rule, the NRC concluded that the high-level treatment requirements were sufficient to encompass the SOC discussion. In response to public comments, the NRC has clarified the treatment requirements in the rule to include more detailed requirements (listed in the response to comment d-32 and e-4) for those aspects of the treatment requirements where there was confusion concerning what is required. In support of the revised treatment requirements, the SOC was revised to explain the meaning of the rule language (rather than how to implement the requirements) and detailed guidance was removed from the SOC.
m-13	The approach described in SECY-98-300 has not been followed, and the proposed rule is no longer fully reflective of the original Option 2 approach.	The NRC agrees that proposed § 50.69 differs in some ways from the initial concepts described in SECY-98-300. The differences are a natural result of the extensive interactions with stakeholders that have occurred since 1998 and reflect a much greater depth of thought, as well as lessons learned, and experience gained from the STP exemption review, as well as the development of NEI 00-04 and the pilot efforts that supported § 50.69 development.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-14	The proposed rule's SOC is open to interpretation and confusion due to the use of inconsistent terminology. To aid in appropriate implementation, consistent and accurate terminology must be utilized. Three examples are provided.	The NRC disagrees with this comment. Nonetheless, where inconsistent or confusing terminology has been identified by stakeholders, the NRC has clarified the corresponding portion of the SOC.
m-15	The staff should consider, in conjunction with the overall risk-informed initiatives, addressing the potential implications of these initiatives for requirements and guidance regarding degraded and nonconforming conditions and equipment operability.	In response to this comment, the NRC reviewed GL 91-18 and determined that GL 91-18 does not need revision prior to issuance of 10 CFR 50.69. The scope of GL 91-18 covers all SSCs described in the FSAR so RISC-3 SSCs would remain covered by the generic letter. For degraded SSCs, GL 91-18 refers licensees to Appendix B for corrective action, which is a special treatment requirement removed for RISC-3 SSCs. However, some SSCs within the scope of GL 91-18 are not covered by Appendix B (e.g., ATWS and station blackout). Therefore, licensees have experience in applying GL 91-18 to SSCs not covered by Appendix B. With regard to JCOs for RISC-3 SSCs, NRC Inspection Manual Part 9900 guidance on operability (referenced in GL 91-18) states that PRAs cannot be used to determine operability. The NRC will consider updating GL 91-18 in the future to reflect its application to § 50.69 licensees.
m-16	In Section III.7.3 it is stated that the "design basis of the facility" is maintained and since the design basis could be interpreted to include the STRs which are being removed this should be revised to the "design basis functions are being maintained."	The NRC agrees with this comment. Section 50.69 is maintaining the design basis functional requirements, and allowing treatment aspects of the current design basis to be changed for SSCs categorized as RISC-3 or RISC-4. The SOC was revised to reflect this comment.
m-17	WOG provide several editorial comments in Section E of their comment letter.	The comments were considered as appropriate.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
m-18	The SOC sections contain many “shalls”, “shoulds”, “musts” that either have not been discussed with stakeholders, are impractical, or cost-prohibitive, are inconsistent with industry guidance in NEI 00-04, or exceed current requirements. We request that these statements be discussed further and if retained be removed to a guidance document. See comments c-23, c-24, c-28, c-32, m-7, m-11, m-12	The NRC agrees that the SOC was not always consistent with the governing requirements. Numerous public comments revealed that the proposed rule requirements were not clear in all cases, and that the supporting SOC could be improved. As discussed in several other comments responses, the NRC has clarified the rule and revised the accompanying SOC and these changes are considered to address this comment. See response to comments d-32 and e-4 for more information.

TABLE 9 - Comments Regarding Implementation Guidance

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-1	DG-1121 should be changed to incorporate the BWROG industry exceptions.	The comment did not identify the specific exceptions that they are referring to and the NRC is not aware of any exceptions to RG 1.201 or the industry categorization implementation guidance contained in NEI 00-04. The NRC has considered all industry and external stakeholder feedback in developing RG 1.201, whether that input was in response to the proposed rule notice for comment or in response to interactions on the implementation guidance. RG 1.201 is based on the final draft version of NEI 00-04 and it endorses NEI 00-04 with appropriate exceptions and clarifications. With the endorsement of NEI 00-04, it is identified as an acceptable approach to categorizing SSCs for § 50.69 applications. Other approaches may be developed and proposed for use, if they can be shown to meet the requirements set forth in § 50.69.
n-2	There are so many significant exceptions, clarifications, and differences of opinion in DG-1121, in endorsing draft C of NEI 00-04, that the commenter urges the differences be resolved and the guidance submitted for public comment again before it is issued in its final form and § 50.69 license amendments are accepted.	The NRC disagrees that RG 1.201 should be subject to another opportunity for public comment. No revisions to the final rule have been made as a result of this comment. At the proposed rulemaking phase, it was recognized that the NEI 00-04 guidance would probably be revised to address the NRC exceptions and clarifications. The NRC promulgated the draft regulatory guidance (DG-1121) to enable external stakeholders to understand fully the categorization implementation issues and to constructively comment on the current guidance. The NRC staff also held public meetings (at which external stakeholders were welcome to attend and comment) with industry on the implementation guidance. Stakeholder input was considered in developing the final regulatory guide and resulted in a regulatory guide with fewer exceptions and clarifications. The industry has revised NEI 00-04 to address the exceptions and clarifications identified in DG-1121. At the time of the completion of the rulemaking phase, the final draft version of NEI 00-04 was issued and the NRC finalized the regulatory guide to endorse the industry guidance with appropriate exceptions and clarifications, including any other pertinent changes resulting from the public comments on the proposed § 50.69 rulemaking package. The NRC is not aware of any categorization implementation issues that would necessitate another public comment phase on the final regulatory guidance.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-3	In DG-1121, the NRC states that it is not satisfactory for a multi-disciplined station management review committee to act as a surrogate for the IDP, and authorize categorization changes once the initial categorization is completed. We agree that continuity of rigor and consistency is important to the long term success of § 50.69. As members of the IDP will not be around forever, we think NRC should give licensees guidance on acceptable options for maintaining this continuity for the IDP.	The NRC agrees with the basic comment, though the NRC has not developed additional guidance for licensees on how to maintain the continuity of the IDP. No revisions to the final rule or supporting RG have been made as a result of this comment. It is not necessary for the IDP to maintain the same membership over time, but the members of the IDP must have the appropriate experience, knowledge, and capabilities. These IDP requirements are important since it is the IDP that makes the decision on SSC safety significance. To lessen those requirements for a re-categorization effort could undermine the process since at a minimum the panel making the decision to change SSC categories must thoroughly understand the initial categorization decision and so it makes sense that the panel addressing a potential re-categorization effort would be equally capable. In addition, it should be noted that the latest revision of NEI 00-04 has eliminated the use of a multi-disciplined station management review committee as a surrogate for using an IDP. Finally, § 50.69 requires that categorization decisions be documented and one of the principle reasons for this requirement is to enable a future IDP to understand previous categorization decisions.
n-4	The eleven elements (questions for IDP to consider in determining safety significance for initiating events, plant operating modes, and SSCs not modeled in the plant-specific PRA) shown in the SOC and in DG-1121 do not reflect the experience fed back into the Code development process to finalize Code Case N-660. The ninth element in the list is cited as an example of where the feedback from pilots has not been incorporated. Also see comment c-36	The NRC agrees with this comment in that not all pilot experience during the code case N-660 development process had been incorporated into the list of IDP considerations that were listed in DG-1121 during the proposed rulemaking phase. In addition, the NRC agrees that this list does not need to be in the SOC, as it is detailed guidance on implementation of the rule by the IDP and is more appropriately addressed by the guidance provided in RG 1.201, as it endorses NEI 00-04, with appropriate exceptions and clarifications. The NRC has considered these comments, as well as the revisions to NEI 00-04, in developing the final regulatory guide. The final regulatory guidance regarding initiating events, plant operating modes, and SSCs not modeled in the plant-specific PRA has been revised to reflect the experience from the code case N-660 development process (as appropriate) and provides flexibility to licensees in assessing safety significance within the context of the revised industry guidance contained in the final version of NEI 00-04.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-5	The requirements for all SSCs that participate in the FIVE vulnerability evaluation, or are credited in the seismic safe shutdown path, or are identified in the plant specific outage risk management guideline should be considered safety significant, is too broad. The proposed NEI processes provide a more valid analysis.	The NRC agrees with this comment with regard to the licensee's use of the outage risk management guideline, considering recent revisions to the industry guidance contained in NEI 00-04 that better describes the industry process. However, it should be noted that the industry guidance does not allow SSCs to be designated as low safety significant (i.e., RISC-3) if they are credited in the FIVE approach used to address fire risks or are identified in the seismic safe shutdown path in a seismic margins approach used to address earthquake risks. Therefore, the NRC position on the FIVE and seismic margins analysis approaches are consistent with the current industry guidance contained in NEI 00-04. The NRC has considered these comments, as well as the revisions to NEI 00-04, in developing the final regulatory guide.
n-6	DG-1121 provides criteria to determine the safety significance of SSCs not modeled in the PRA. The criteria are too broad and do not provide sufficient flexibility for assessing actual safety significance. The ninth element in the list is cited as an example of where the criteria does not provide the licensee the flexibility to determine whether the SSC serves a principal function and then refers to the flexibility provided in the implementing guidance for the Maintenance Rule.	The NRC agrees with this comment as discussed in the response to comment n-4.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-7	DG-1121 states that any proposed changes in SSC categories must be reviewed and accepted by the IDP at the same level of rigor and depth applied to the initial categorization. The NRC further rejects the concept of a multi-disciplined station management review committee to make a final determination on changes in SSC categorization. We disagree with the proposed change process. Due to the expense associated with implementing the IDP, it is not realistic to require that a licensee perpetually maintain the IDP, which is essentially what the NRC has mandated. Once initial categorization is complete, licensees should be allowed to disband the IDP, and implement a simpler, but equally rigorous, change process using appropriate management controls.	The NRC disagrees with this comment for the reasons set forth in the response to comment n-3.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-8	DG-1121 states that licensees must expand their design/configuration control program to ensure that categorized SSCs are maintained within the assumptions of the categorization process, including design basis and beyond design basis functions. This DG-1121 statement is unnecessary and inconsistent with the original purpose of the rulemaking, which is to focus on reducing special treatment, not adding new design requirements for components that remain subject to special treatment. A licensee should be allowed to make design changes that are consistent with § 50.59 and that provide reasonable assurance that safety-significant beyond design basis functions will be satisfied following a design change. There is no regulatory basis for freezing the assumptions in the categorization process. Additionally there is no basis for prohibiting significant increases in risk if the risk is low to begin with.	The NRC disagrees with this comment. No revisions to the final rule have been made as a result of this comment. Maintaining configuration control over the categorization process is essential to maintaining its validity over time as plant modifications and procedure changes occur, and as new performance data is acquired. From a practical standpoint, incorporating the categorization process within the facility configuration appears to be the most straight forward approach and hence that is the guidance. In addition, the NRC is not inferring that the assumptions, specifically the factor of reduction in reliability (increase in failure rate) assumed for RISC-3 SSCs in the risk sensitivity study that demonstrates any potential changes will be small, used in the categorization process are frozen. If a new technical basis is developed for the assumed factor of reduction in reliability for RISC-3 SSCs due to implementation of the rule, then that new technical basis could be used. However, the basis would need to be documented and retained available for NRC inspection. Industry developed an approach/basis for determining the appropriate factor to use, which is to be incorporated into the final version of NEI 00-04. Finally, the NRC believes it is consistent with the rule language and existing Commission policy in allowing only small increases in risk due to implementation of this rule and other risk-informed applications. This topic is discussed in the SOC supporting § 50.69(c)(1)(iv) and recognizes higher risk increases from implementation of this rule may be allowed for plants that have a relatively low baseline risk (i.e., the definition of what constitutes a small risk increase depends on the plant's baseline risk). It should be noted that the NRC agrees with the industry guidance (NEI 00-04) on this issue.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
n-9	DG-1121 indicates that categorization documentation must be maintained for the lifetime of the plant. The NRC does not provide an adequate basis for this lifetime retention requirement that would impose unnecessary paperwork requirements. For example, under this requirement, licensees may be required to maintain records of categorization changes to components that may have long since been replaced by other components or systems. Licensees should be required to maintain such records as mandated by station procedures.	The NRC disagrees with this comment. The general regulatory approach for Part 50 regulation is to require records to be maintained for the lifetime of the facility. Considering that § 50.69 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, and that it may become necessary to reconstruct the previous history of an SSC as a result of conditions that develop over time and cause the licensee to revisit an SSC's categorization, the NRC concludes that the requirement to maintain records for the life of the plant is appropriate. No revisions to the final rule have been made as a result of this comment.
n-10	The discussion of required PRA scope within DG-1121 Section C.1 should be revised to be consistent with the SOC. Specifically, the SOC describes the minimum PRA scope as the internal events occurring at full power operations and describes the use of non-PRA type risk assessment and management methodologies as acceptable methods to obtain insights for the categorization process for initiating events and plant operating modes not modeled in the PRA.	The NRC agrees with the need for the SOC and DG-1121 (now RG 1.201) to be consistent, and changes have been made to the SOC and RG 1.201 to ensure they are consistent with each other and that their intents are clearly presented. The NRC disagrees with the last part of the comment. The discussion in RG 1.201 Section C.1 is a recognition that the greater the scope of the PRA used in the categorization process, the greater the potential relief that may be obtained by the licensee. This recognition is consistent with the rule, which establishes the minimum required PRA scope to implement the rule, and the industry categorization implementation guidance contained in NEI 00-04, which effectively limits the relief that can be gained from non-PRA type approaches.

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Division 1
RG 1.201
REGULATORY GUIDE
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REGULATORY GUIDE 1.201 FOR TRIAL USE

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 a regulation, § 50.69, to permit power reactor licensees and applicants for licenses to implement an alternative regulatory framework with respect to “special treatment,” where special treatment refers to those 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 § 50.69, to contain these alternative requirements.

This regulatory guide describes a method acceptable to the NRC staff for complying with the requirements of § 50.69 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.

The draft of this guide, Draft Regulatory Guide DG-1121, was issued for public review and comment as part of the § 50.69 rulemaking package in May 2003. Public comments were received and addressed in developing the current regulatory guide. However, there remain a few technical interpretation/implementation issues with specific aspects of the guidance that are best resolved by testing the guide against actual applications. Therefore, this regulatory guide is being issued for trial use. This regulatory guide does not establish any final staff positions, and may be revised in response to experience with its use. As such, this trial regulatory guide does not establish a staff position for purposes of the Backfit Rule, § 50.109, and any changes to this regulatory guide prior to staff adoption in final form will not be considered to be backfits as defined in § 50.109(a)(1). This will ensure that the lessons learned from regulatory review of pilot applications and follow-on applications are adequately addressed in this document and that the guidance is sufficient to enhance regulatory stability in the review, approval, and implementation in the use of PRAs and their results in the risk informed categorization process required by § 50.69.

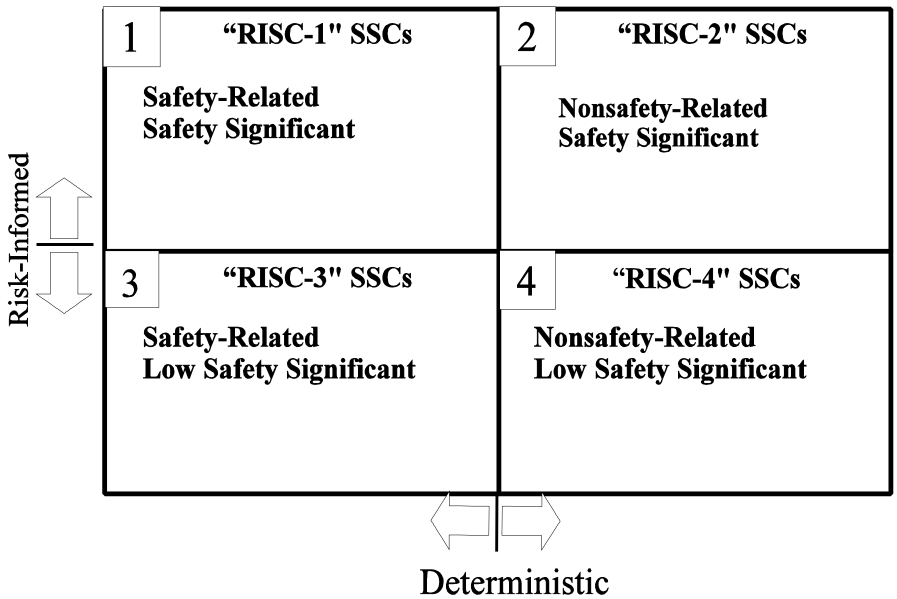
The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 50, which were approved by the Office of Management and Budget, approval number 3150-0011. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information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

B. DISCUSSION

This regulatory guide provides interim guidance for categorizing SSCs in accordance with their safety significance under § 50.69, using the process described in the Final Draft of Nuclear Energy Institute (NEI) 00-04, “10 CFR 50.69 SSC Categorization Guideline,” dated April 2004. 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.

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 § 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 the risk-informed categorization process determines to be significant contributors to plant safety. Licensees must continue to ensure that RISC-1 SSCs perform their safety-significant functions consistent with the categorization process, including those safety-significant functions that go beyond the functions defined as safety-related for which credit is taken in the categorization process.

RISC-2 SSCs are SSCs that are not defined as safety-related, but the risk-informed categorization process determines them to be significant contributors to plant safety. It is recognized that some RISC-2 SSCs may not have existing special treatment requirements. As a result, the focus for RISC-2 SSCs is on the safety-significant functions for which credit is taken in the categorization process.

The third category defines those SSCs that are safety-related SSCs that a risk-informed categorization process determines are not significant contributors to plant safety on an individual basis. These SSCs are termed RISC-3 SSCs. Special treatment requirements are removed for RISC-3 SSCs and replaced with high-level requirements. These high-level requirements are intended to provide sufficient regulatory treatment such that these SSCs are still expected to perform their safety-related functions under design basis conditions, albeit at a reduced level of assurance when compared to the current special treatment requirements. The proposed rule, however, does not allow these RISC-3 SSCs to be removed from the facility or to have their functional capability lost.

Finally, there are SSCs that are not identified as safety-related that a risk-informed categorization process determines are not significant contributors to plant safety. These SSCs are termed RISC-4 SSCs. The proposed § 50.69 rule does not impose alternative treatment requirements for these RISC-4 SSCs. However, as with the RISC-3 SSCs, changes to the design bases of RISC-4 SSCs must be made in accordance with current applicable design change control requirements(if any), such as § 50.59.

This 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 this regulatory guide.

C. REGULATORY POSITION

This regulatory guide is being developed to provide interim guidance for trial use of the process and criteria for determining the safety significance of SSCs under § 50.69 using the categorization process described in the Final Draft of NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline," dated April 2004.

1. Other Documents Referenced in the Final Draft of NEI 00-04

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

2. Use of Examples in the Final Draft of NEI 00-04

The Final Draft of NEI 00-04 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in the Final Draft of NEI 00-04, the NRC's endorsement of the Final Draft 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.

3. Use of Methods Other Than the Final Draft of NEI 00-04

To meet the requirements of § 50.69 for categorization of SSCs, licensees may use methods other than those set forth in the Final Draft of NEI 00-04. The NRC will determine the acceptability of these other methods by evaluating them against the § 50.69 rule requirements.

4. Limitations of Types of Analyses Used in Implementing the Final Draft 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 § 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. However, the Final Draft 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, which will result in more conservative categorization in that special treatment requirements will not be allowed to be relaxed from SSCs relied upon in the non-PRA type evaluations. It should be recognized that the degree of relief (i.e., SSCs subject to relaxation of special treatment requirements) that the NRC will accept under § 50.69 will be commensurate with the assurance provided by the evaluation.

5. Technical Adequacy Attributes of Analyses Implementing the Final Draft of NEI 00-04

The peer review process described in NEI 00-02, as amended to incorporate NRC comments provided in the NRC letter to NEI, dated April 2, 2002 and as endorsed in RG 1.200, provides a mechanism for licensees to determine if their internal events PRA meets the attributes required for this application. An alternative to NEI 00-02 is the ASME Standard for Probabilistic Risk Assessment for Nuclear Power Plant Applications, as amended to incorporate NRC comments and as endorsed in RG 1.200. Both NEI 00-02 and the ASME Standard are endorsed for trial use by the NRC in RG 1.200, with appropriate clarifications and exceptions. These documents currently cover only internal events at full power. There is not currently a similarly endorsed standard for the external events PRA and non-PRA type analyses (e.g., FIVE, seismic margins analysis, NUMARC 91-06) and there is limited guidance provided in Section 3.3 of the Final Draft of NEI 00-04 for determining the technical adequacy attributes required for these types of analyses for this specific application. Industry standards have been or are being prepared for external events (seismic, high winds, and other external events), fire, and low power and shutdown PRAs. Therefore, the NRC staff expects that the applicant or licensee will prepare arguments for why the method employed is adequate to perform the analysis required to support the categorization of SSCs. Applicants or licensees will have to provide arguments supporting the technical adequacy of the external events, other operating modes, and non-PRA type analyses for each plant-specific submittal requesting to implement § 50.69. As standards are developed by the industry and endorsed by the NRC via revisions to RG 1.200 for external events, fires, and low power and shutdown, the NRC expects applicants or licensees to use these standards to demonstrate the technical adequacy of the PRAs addressing these events and operating modes.

6. Uncertainty Considerations in the Final Draft of NEI 00-04

The NRC staff notes that the Final Draft of NEI 00-04 does not address modeling or data uncertainties explicitly. However, the sensitivity studies performed to support the categorization of SSCs are intended to address some of the major sources of uncertainty (i.e., human error probabilities, common cause failure probabilities, and those items identified during the assessment of PRA technical adequacy). When assessing the potential increase in core damage frequency (CDF) and large early release frequency (LERF) as a result of implementing § 50.69, the applicant or licensee must address uncertainties consistent with Section 2.2.5 of Regulatory Guide 1.174.

7. Common Cause Failure and Degradation Mechanism Considerations in the Final Draft of NEI 00-04

Mechanisms that could lead to large increases in CDF and LERF are extensive, across system common cause failures (CCFs) and unmitigated degradation. However, for such extensive impacts 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.

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, should be identified by the applicant or licensee and such aspects of treatment 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 would 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. 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 risk sensitivity study results remain valid (i.e., bounding).

The appropriate factor to use in the risk sensitivity study to represent the potential reduction in reliability due to the relaxation of special treatment requirements should be determined in concert with the consideration of the potential for (and retained defenses against) cross-system common cause failures and known degradation mechanisms. As part of this determination, the NRC expects licensees to: (a) demonstrate an understanding of common cause effects and known 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 known degradation; and (c) to factor this knowledge into both the treatment applied to and the factors used for the RISC-3 SSCs.

In addition, the factor used in adjusting the unreliability of RISC-3 SSCs in the risk sensitivity study should be set at a level such that an actual increase in unreliability of a RISC-3 SSC would be detected and corrected through the monitoring, corrective action, and feedback processes. The licensee must develop and document an 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 the monitoring and corrective action program.

8. NRC Endorsement of the Final Draft of NEI 00-04; Specific Limitations and Conditions

The Final Draft of NEI 00-04 provides an approach that is acceptable to the NRC staff in meeting the categorization requirements in § 50.69, subject to the above position statements and the following specific clarifications, limitations, and conditions.

Section 1

The first paragraph (p.1) references Appendix B of NEI 00-04 as an example of a submittal, but this appendix has been deleted as a result of NRC comments on an earlier draft of NEI 00-04. Appendix B provided an outline/example of the information to be provided to the NRC for those applicants or licensees implementing § 50.69. It is envisioned that a “template” may be created for submittals under § 50.69, however, at this time a template has not been developed or endorsed by the staff. Thus, applications to implement § 50.69 will be evaluated on a plant-specific basis to ensure that they properly implement the categorization process requirements of § 50.69.

The first paragraph (p.1) also states that implementation of § 50.69 in accordance with the Final Draft of NEI 00-04 guidelines should involve minimal NRC review. Though the endorsement of the Final Draft of NEI 00-04 in this regulatory guide will enable an applicant or licensee to have more assurance that the NRC will find their application acceptable, as opposed to a licensee developing their own approach, it is incorrect to characterize the NRC review of the application submitted per § 50.69(b)(2)(i) as “minimal.” The NRC will perform an appropriately thorough review of each application submitted under § 50.69.

Section 1.2

The second paragraph of this section (p.3) discusses a third set of equipment referred to as “important-to-safety” and its relation to safety-related and nonsafety-related equipment. This usage is incorrect. Endorsement of this guidance is not an endorsement of this usage of the phrase “important-to-safety” for regulatory purposes. Though incorrect, in the context of this guidance, the NRC interprets the intent of the usage of this phrase to refer to nonsafety-related SSCs that have been determined to be important. These nonsafety-related SSCs would be categorized as either RISC-2 or RISC-4 based on their determined safety significance per the § 50.69 categorization process.

The fourth paragraph of this section (p.3) 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.

Section 1.3

On page 4, 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 sixth guiding principle indicates that the attribute(s) that make an SSC safety-significant should be documented. This is done to ensure that the treatment applied to the SSC is consistent with the safety-significance cause determined in the categorization process. While the NRC staff agrees that the safety-significant attribute(s) need to be documented, the applicant or licensee must also document the justification for SSCs determined to be LSS. In other words, documentation must be available and maintained by the applicant or licensee supporting the categorization of every SSC addressed under § 50.69. This is consistent with the discussion in Section 11.1 of the Final Draft of NEI 00-04.

Section 1.4

The first paragraph (p.4) states that “US nuclear generating plants have attained and maintained an outstanding safety performance record.” While the NRC does not disagree with this statement, endorsement of this guidance is not an endorsement of this statement.

The third paragraph of this section (p.5) states that the applicant or licensee can determine the appropriate set of equipment to re-categorize under § 50.69. The NRC staff agrees that categorization under § 50.69 can be partially implemented by an applicant or licensee and the implementation can be phased in over a period of time. However, since the categorization process described in § 50.69 and in NEI 00-04 is primarily based on system/structure functions, the categorization process must be implemented for an entire system/structure; not selected components within a system. Section 50.69(c)(1)(v) requires this categorization for entire systems/structures. The primary reason that § 50.69 requires the categorization to be performed for entire systems and structures is to ensure that all the functions (which are primarily a system-level attribute) for a given SSC within a given system or structure are appropriately considered for each SSC in determining its safety significance. The system boundary definitions should be consistent with the PRA used in categorizing the SSCs and careful consideration should be given by the licensee to ensure all important functions are captured for SSCs, especially those that are common to multiple systems (e.g., tank discharge valve that feeds to multiple systems). The methodology for determining systems boundaries is left to the licensee recognizing these important constraints (i.e., drawing system boundaries in such a way as to break apart a system when viewed from a system functional standpoint would not meet this requirement).

Section 1.5

In the first paragraph (p.5) it is stated that the IDP cannot re-categorize an SSC identified as high safety significant (HSS)[1] by the plant-specific risk analysis. This could be interpreted to conflict with the allowance to use the integrated importance assessment. To avoid confusion, and consistent with Figure 1-2, the NRC interprets this statement in this context as meaning the IDP cannot re-categorize an SSC that is identified as HSS as an outcome of the risk characterization portion of the process, which includes the assessments from the plant-specific probabilistic risk analyses (PRAs) of internal events, external events, and non-power operations and the integrated importance assessment.

A major part of the rationale for the integrated assessment is to address the potential conservatisms that are more typical in the PRAs for the external events and non-power operations. It is possible that an SSC that is not significant for external events and non-power operations, but is for internal events, could be determined in the integrated assessment to not be significant due to the high CDF or LERF estimates from the conservative analyses. To avoid the conservative PRA approaches from masking the significance of an SSC from the more realistic internal events PRA, SSCs identified as HSS by the internal events assessment should be retained as HSS and not be allowed to be re-categorized by the IDP, even if the integrated assessment indicates a potentially lower significance.

For example, if an SSC is determined by a PRA approach to be HSS for seismic, but is determined to be low safety significant (LSS) for all other events and operating modes, and seismic events are such a small contributor to total risk that the integrated assessment indicates the SSC is LSS, then all this information, including the results of the individual sensitivity studies, is provided to the IDP and the IDP can determine and document the final

[1] NEI 00-04 uses the terminology "high safety significant (HSS)" to refer to SSCs that perform safety significant functions. The NRC understands HSS to have the same meaning as "safety significant" (i.e., SSCs that are categorized as RISC-1 or RISC-2) as used in § 50.69.

categorization for the SSC. A part of the IDP considerations in making the final categorization determinations should include the relative conservatisms in the analyses that support the various significance determinations. However, if an SSC is determined to be HSS from the internal events assessment, but is determined to be LSS for all other events and operating modes, and due to the conservative nature of the other analyses the internal events is a small contributor to total risk such that the integrated assessment indicates the SSC is LSS, then the SSC should still be designated to be HSS due to the internal events analyses and IDP will not be allowed to re-categorize the SSC.

In the second paragraph (p.5) it is stated that the IDP cannot re-categorize an SSC identified as HSS by the plant-specific risk analysis, but the context of this paragraph is the defense-in-depth characterization portion of the process; not the risk characterization portion. Consistent with Figure 1-2, the NRC interprets this statement in this context as meaning the IDP cannot re-categorize an SSC that is identified as HSS as an outcome of the defense-in-depth characterization portion of the process.

Section 1.5, Section 5, & Section 5.3

The NRC notes that there are numerous SSCs that are not explicitly modeled in a seismic PRA, but are screened out due to their designed seismic robustness. Many of these SSCs are inherently safety significant for seismic events. In addition to using the results of a seismic PRA in determining the significance of an SSC for seismic events, the applicant or licensee should either designate those SSCs that were screened out of the PRA due to their seismic robustness as safety significant or establish the robustness (i.e., seismic capacity) of these SSCs as a design aspect if any screened out SSC is designated as LSS. This information should also be provided to the IDP for consideration in determining the final categorization of the SSC.

Section 3.3

On page 20, for the full power internal events PRA, in addition to providing a high level summary of the results of the peer review, the applicant or licensee should provide a summary of the findings of the self-assessment performed per RG 1.200.

Section 5

The first decision block in Figure 5-1 (p.26) refers to prevention or mitigation of core damage. This phrase could be misunderstood to not include important safety considerations related to containment performance or releases (i.e., LERF). To be consistent with the intent of the safety significance categorization process and the associated text in Section 5, this first decision block should be understood to include the prevention or mitigation of severe accidents.

Section 5.1

In the discussion of the Internal Event Assessment (pp. 29-34), the NEI guidance states that the safety significant attributes are identified by the component failure mode that contributes significantly to the importance of the SSC. It should be recognized that there may be multiple component failure modes that contribute significantly to the importance of an SSC; especially if no individual failure mode alone exceeds the screening criteria, but a number of failure modes collectively exceed the screening criteria. In these cases, the guidance should not be inferred to limit the identification of safety significant attributes based on a single highest contributing failure mode, but should include all significantly contributing failure modes.

Section 5.4 (& Section 1.5)

Figure 5-6 (p.40) addresses approaches that rely on the identification of safe shutdown paths. However, if the evaluation of an external event is performed using a screening approach, then the logic presented in Figure 5-4 would be more appropriate than the current Figure 5-6. In this approach, if an SSC participates in an unscreened scenario or is credited in the screening of the scenario (i.e., failure to credit the SSC would result in the scenario being unscreened), then that SSC would be considered safety significant. The evaluation of other external events needs to recognize the different approaches and implement the proper logic for the specific approach.

Section 6.2

In this section (p.47), the guidance presents containment isolation criteria to support the assessment of defense-in-depth. The NRC notes that § 50.69(b)(1)(x) establishes the governing criteria for which containment isolation valves and penetrations are within the scope of § 50.69.

The NRC believes that the first criteria listed for containment bypass (p.47) needs to also include mitigation of an ISLOCA event as well as the initiation and isolation of these events. This is especially true if an event tree/fault tree logic approach is utilized to address ISLOCA events.

Section 7.2

The second bullet of the second set of bullets on page 50 states that if the SSC is categorized as low safety significant based on the internal events, but potentially high safety significant because of external events or shutdown risks, then the integral assessment should be relied upon. This may be misinterpreted to mean that the non-internal events results should be disregarded and not considered. All the information should be provided to the IDP for consideration, including the individual and integral assessment results; consistent with the example worksheet provided as Figure 7-2. Under these circumstances, if the integral assessment indicates that the SSC is candidate low safety significant, the IDP should consider those aspects that indicate the SSC is safety significant and then make a determination of the appropriate category and document its rationale.

Section 8

The factor used in the risk sensitivity study to represent the potential increase in unreliability of RISC-3 SSCs due to relaxation of special treatment requirements must be set at a level such that an actual increase in unreliability of a RISC-3 SSC would be detected and corrected through the monitoring, corrective action, and feedback processes. The example for implementation (7th paragraph in this section on page 53) is overly simplistic and technically not acceptable. An acceptable process would need to have a focused cause analysis when a RISC-3 SSC failed to determine if its failure was due to the reduction in treatment and/or an indication of a potential common cause failure or degradation mechanism. If there is indication that one of these factors is the cause of the failure, then the applicant or licensee should have a process for immediately expanding testing to similar SSCs to demonstrate their functionality and for initiating a corrective action to the treatment and/or categorization processes. Likewise, if the expected number of failures, based on plant experience and reliability values used in the PRA, of a group of RISC-3 SSCs is exceeded over the evaluation interval, then a similar process should be implemented to determine the cause of the higher than expected failure rate and corrective action should be initiated to the treatment and/or categorization processes. The description of such an approach might more appropriately belong as a subsection of Chapter 11 or as its own chapter dealing with implementation (i.e., monitoring, detecting, corrective action, and feedback).

Until a technically defensible approach is provided in a revision of the NEI 00-04 guidelines, the NRC will review the applicant's or licensee's approach and process as part of the application requesting to implement § 50.69. Thus, the applicant's or licensee's application will need to describe their approach and process for monitoring, detecting, and correcting increases in unreliability of RISC-3 SSCs prior to reaching a level that could invalidate the categorization process results as required by § 50.69(c)(1)(iv) and (e)(3).

Section 9.2

Under the review of risk information (pp. 57-58), the licensee's or applicant's considerations should be supplemented with the following additional considerations:

In the third bullet, the IDP should also consider spatial effects as well as direct, should specifically consider the failure of the SSC on its safety significant function, and should not be limited to only those aspects not modeled in the PRA.

In the fourth bullet, the IDP should also consider functions/SSCs that are necessary for significant operator action required to mitigate accidents and transients, regardless if they are in the PRA or not.

In the fifth bullet, the IDP should also consider functions/SSCs associated with monitoring post-accident conditions.

The staff believes that in addition to the five considerations listed, the IDP should also consider the following items:

- Failure of the function/SSC will not prevent or adversely affect the plant's capability to reach or maintain safe shutdown conditions and is not significant to safety during mode changes or shutdown.

- The function/SSC does not act as a barrier to fission product release during severe accidents.

- The function/SSC does not support a significant mitigating or diagnosis function for accidents and transients.

- Failure of the function/SSC will not result in releases of radioactive material that would result in the implementation of off-site emergency response and protective actions

Section 10.2

The specific considerations that permit an 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 endorse the examples provided under the specific considerations (pp.60-61) that permit an 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.

Section 11.1

In addressing regulatory commitments associated with special treatment requirements listed in § 50.69(b)(1) for RISC-3 SSCs, NEI 00-04 specifies that licensees should ensure that any design related commitments for RISC-3 SSCs continue to be maintained. The NRC staff interprets this guidance as applying to any commitment related to the design basis functionality of RISC-3 SSCs.

Section 11.2

No specific change control process is established within § 50.69 governing changes to the NRC approved categorization process. As part of its approval of the license amendment submittal, the NRC will establish a license condition that governs changes to the categorization process. If a licensee or applicant wishes to change their categorization process, and the change is outside the bounds of the NRC's license condition, then the licensee or applicant will need to seek NRC approval of the revised categorization process.

Section 12

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 results of the risk sensitivity study, as described in Chapter 8, must be confirmed to still be acceptable following each revision or update of the PRA to ensure that the categorization process is maintained valid. If the risk sensitivity study results indicate a greater than small cumulative risk increase from implementation of § 50.69, then the categorization and/or treatment of SSCs must be revised until an acceptably small risk increase is determined.

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. No backfitting is intended or approved in connection with the issuance of this guide.

The draft guide (DG-1121) was released to encourage public participation in the development of this regulatory guide. 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 § 50.69 for the categorization of SSCs.

Value/Impact Statement

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

NEI 00-04 (DRAFT - Final Draft)

10 CFR 50.69 SSC Categorization Guideline

NUCLEAR ENERGY INSTITUTE

April 2004

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This report has been prepared by the NEI Risk Applications Task Force, the NEI Option 2 Task Force, and the NEI Risk-Informed Regulation 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, *Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors*. 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 with the 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.

The categorization process described in this section is one acceptable way to undertake the categorization of SSCs. Other methods using a different combination of probabilistic and deterministic approaches and criteria can be envisioned. However, it is expected that the guiding principles (Section 1.3) of this guidance would be maintained. Licensees wishing to use a different method for categorizing SSCs using risk-informed insights need to submit the methodology for NRC review and approval.

[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.

Changes to this guideline are controlled through the normal regulatory change control processes. Section 11 provides guidance on program documentation and change control.

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 could occur, 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

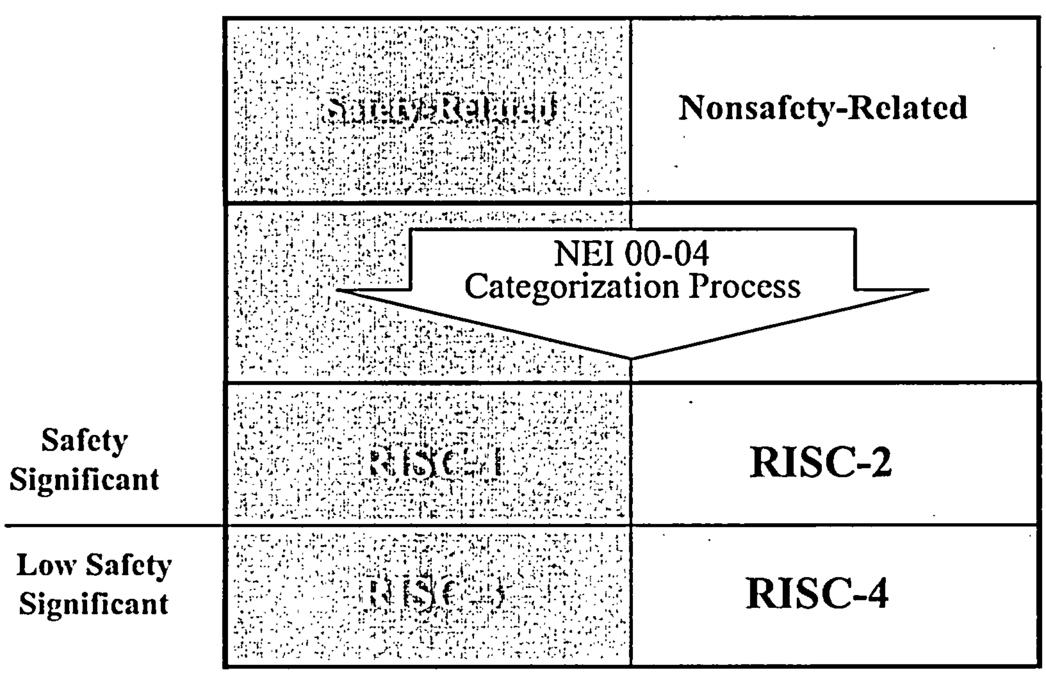
The objective of this regulatory initiative is to adjust the scope of equipment subject to special regulatory treatment (controls) to better focus licensee and NRC attention and resources on equipment that has safety significance. This guideline addresses the use of risk insights to define the scope 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 augmented 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 safety related SSC will be re-categorized as RISC-1 unless a basis can be developed for re-categorizing it as RISC-3.
- 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 an 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.

1.5 CATEGORIZATION PROCESS SUMMARY

The NEI 00-04 categorization process embodies the principles of risk-informed regulation described in Reg. Guide 1.174 (Figure 1-2). The plant-specific risk analyses provide an initial input to the process. SSCs identified as high safety significant (HSS) by the risk characterization process are identified for an integrated decision-making panel (IDP). The IDP cannot re-categorize an SSC identified by the risk analysis as HSS. The IDP function is to review the assessment and assure that the system functions and operating experience have been appropriately considered in the risk analyses.

SSCs that are safety related and considered to be low safety significant (LSS) based on the plant-specific risk analyses are evaluated in a defense-in-depth characterization process. This deterministic process addresses the role of the SSC with respect to both core damage prevention and containment performance. If defense-in-depth characterization identifies that the SSC should be considered HSS, then it is re-categorized as HSS and recommended to the IDP as a RISC-1 SSC. Here again, the IDP cannot re-categorize an SSC identified by the risk analysis as HSS. The IDP function is to review the assessment and assure that the system functions and operating experience have been appropriately considered.

If an SSC is found to be LSS by both the risk categorization process and the defense-in-depth characterization process, then it is recommended to the IDP to be LSS. The IDP reviews the categorization process applied to the SSC and, if the IDP feels that the operating experience or functions merit a HSS categorization, they can re-categorize it.

Thus, only if an SSC is found to be of low safety significance by all three (i.e, the risk characterization process, the defense-in-depth characterization process and IDP review), will it be categorized as low safety significant.

Risk Characterization

The NEI 00-04 categorization process addresses a full scope of hazards, as well as plant shutdown safety. Due to the varying levels of uncertainty and degrees of conservatism in the spectrum of risk contributors, the risk significance of SSCs is assessed separately from each of five risk perspectives and used to identify SSCs that are potentially safety significant:

- Internal Event Risks
- Fire Risks
- Seismic Risks
- Other External Risks (e.g., tornados, external floods, etc.)

- Shutdown Risks

Separate evaluation is appropriate to avoid reliance on a combined result that may mask the results of individual risk contributors..

Table 1-1 provides a summary of the alternative approaches taken to address each risk contributor. A brief description of each of these aspects is described.

Internal Event Risks

A high quality PRA is required for the categorization of SSCs relative to internal events, at-power risks. Importance measures related to Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) are used to identify the safety significant functions and all SSCs that support those functions are categorized as safety significant (RISC-1 or -2). In addition, several sensitivity studies are defined which exercise key areas of uncertainty in the PRA (e.g., human reliability, common cause failures, and no maintenance plant configuration). If an SSC that had been initially identified as low safety significant is found to exceed the safety significance thresholds in a sensitivity study, this information is provided to the IDP, along with an explanation of the results of the sensitivity study.

Fire Risks

A fire risk analysis, either a plant-specific fire PRA or a Fire Induced Vulnerability Evaluation (FIVE) analysis that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to fire risks. If a fire PRA is available, then importance measures are once again used to identify the safety significant functions and all SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the fire risk contribution is shown to be sufficiently small (in comparison to the internal events risk) as to make the overall safety significance of the SSC low (RISC-3 or -4) in the Integrated Importance Assessment (see below). Sensitivity studies, including fire-specific sensitivity studies, are also identified and used in a similar manner.

In the event a FIVE analysis is used, the categorization process is necessarily more conservative (i.e., designed to identify more SSCs as safety significant). This is due to the fact that FIVE is a screening tool. As such, the resulting scenarios and frequencies have an uneven level of realism. Thus, importance measures are not an effective means for identifying safety significance. The NEI 00-04 approach identifies all system functions and associated SSCs that are involved in the mitigation of any unscreened fire scenario (i.e., retained for consideration in the FIVE analysis) as safety significant. In addition, all screened scenarios are reviewed to identify any system functions and associated SSCs that would result in a scenario being unscreened, if that system function was not credited. This measure of safety significance assures that the SSCs that were required to maintain low fire risk are retained as safety significant.

Figure 1-2
Summary of NEI 00-04 Categorization Process

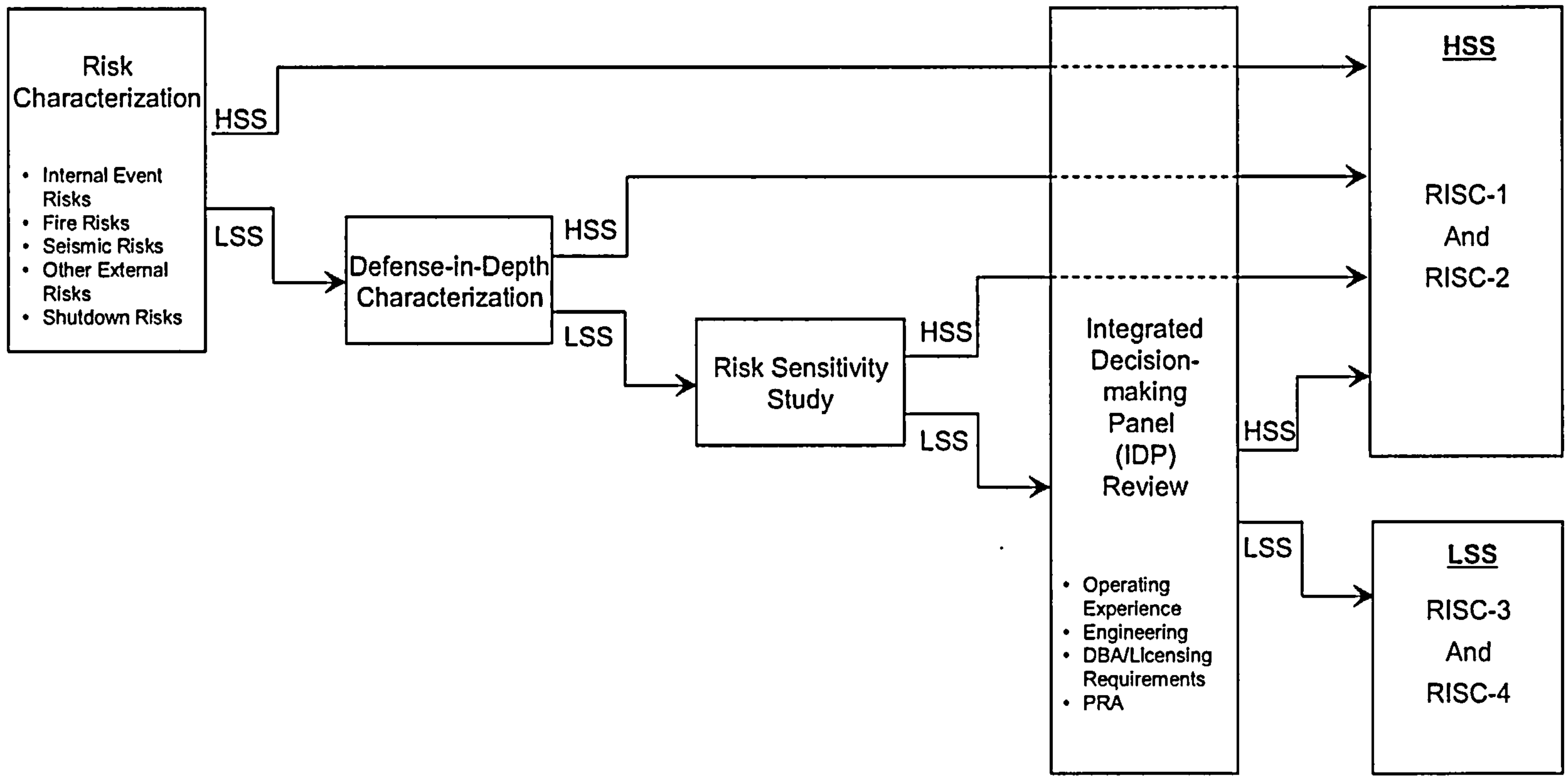


Table 1-1
Summary of Risk Significance Characterization Used in NEI 00-04

Risk Source	Alternative Approaches	Scope of Safety Significant SSCs
Internal Events	PRA Required	Per PRA Risk Ranking
	Screening Approaches Not Allowed	n/a
Fire	Fire PRA	Per PRA Risk Ranking
	FIVE (Fire Induced Vulnerability Evaluation)	All SSCs Necessary to Maintain Low Risk
Seismic	Seismic PRA	Per PRA Risk Ranking
	SMA (Seismic Margins Analysis)	All SSCs Necessary to Maintain Low Risk
High Winds, External Floods, etc.	PRA	Per PRA Risk Ranking
	IPEEE Screening	All SSCs Necessary to Protect Against Hazard
Shutdown	Shutdown PRA	Per PRA Risk Ranking
	Shutdown Safety Plan	All SSCs Required to Support Shutdown Safety Plan

Seismic Risks

A seismic risk analysis, either a plant-specific seismic PRA or a seismic margin analysis (SMA) that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to seismic risks. If a seismic PRA is available, then importance measures are once again used to identify the safety significant functions and all SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the seismic risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (RISC-3 or -4) using the integrated importance assessment. Sensitivity studies, including seismic-specific sensitivity studies, are also identified and used in a similar manner.

In the event an SMA is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant). This is due to the fact that SMA is a screening tool. As a screening tool, importance measures are not available to identify safety significance. The NEI 00-04 approach identifies all system functions and associated SSCs that are involved in the seismic margin success paths as safety significant. This measure of safety significance assures that the SSCs that were required to maintain low seismic risk are retained as safety significant. The seismic PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the SMA identifies them as safety significant regardless of their capacity, frequency of challenge or level of functional diversity.

Other External Risks

For other external event risks, either a plant-specific external event PRA or a screening analysis that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to other external risks. If an external hazard PRA is available, then importance measures are once again used to identify the safety significant functions and all SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the other external hazard risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (see integrated importance assessment below). Sensitivity studies are also identified and used in a similar manner.

In the event a screening analysis is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant). The NEI 00-04 approach identifies all system/structure functions and associated SSCs that are involved in protecting against the external hazard as safety significant. An example might be a tornado missile barrier. Using a PRA, some barriers might be found to be of low safety significance, depending on the site-specific frequency of tornadoes and the equipment protected by the barrier. Using a screening method, the barrier would be identified as safety significant without regard to those other factors. This measure of safety significance is much more restrictive than the importance measures used in the external hazard PRA and would be expected to yield a larger set of safety significant SSCs than the external hazard PRA. The PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the screening approach identifies them as safety significant regardless of their capacity, frequency of challenge or level of functional diversity.

Shutdown Risks

A shutdown risk analysis, either a plant-specific shutdown PRA or a shutdown safety management plan that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to shutdown risks. If a shutdown PRA is available, then importance measures are once again used to identify the safety significant functions and all SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the shutdown risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (see integrated importance assessment below). Sensitivity studies, including shutdown-specific sensitivity studies, are also identified and used in a similar manner.

In the event a shutdown safety management plan is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant) than a plant specific PRA. This is due to the fact that the shutdown safety management plan provides safety function defense in depth without regard to the likelihood of demand or reliability of the functions credited. The NEI 00-04 approach identifies all SSCs necessary to support primary shutdown safety systems as safety significant. This measure of safety significance assures that the SSCs that were required to maintain low shutdown risk are retained as safety significant. The shutdown PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the shutdown safety management plan approach identifies them as safety significant regardless of the frequency of challenge or level of functional diversity.

Integrated Importance Assessment

Each risk contributor is initially evaluated separately in order to avoid reliance on a combined result that may mask the results of individual risk contributors. The potential masking is due to the significant differences in the methods, assumptions, conservatisms and uncertainties associated with the risk evaluation of each. In general, the quantification of risks due to external events and non-power operations tend to contain more conservatisms than internal events, at-power risks. As a result, performing the categorization simply on the basis of a mathematically combined total CDF/LERF would lead to inappropriate conclusions. However, it is desirable in a risk-informed process to understand safety significance from an overall perspective, especially for SSCs that were found to be safety significant due to one or more of these risk contributors.

In order to facilitate an overall assessment of the risk significance of SSCs, an integrated computation is performed using the available importance measures. This integrated importance measure essentially creates a weighted-average importance based on the importance measures and the risk contributed by each hazard (e.g., internal events, fire, seismic PRAs). The weighted importance measures can be significantly influenced by the relative contribution of the hazard. For example, an SSC that is very important for a hazard that contributes only 1% to the total CDF/LERF would be found to have very low importance measures when the integrated assessment is performed. In no case will the integrated importance measure be larger than the largest of the individual hazard importance measure. This integrated assessment allows the IDP to determine whether the safety significance of the SSC should be based on the significance for that individual hazard or from the overall integrated result, avoiding a strict reliance on a mathematical formula that ignores the significant dissimilarities in the calculated risk results.

Defense in Depth Characterization

For safety related SSCs initially identified as low safety significant (RISC-3) from the results of the risk significance categorization, an additional defense-in-depth assessment is performed. The defense in depth assessment is based on a set of deterministic criteria based on design basis accident considerations to assure that adequate redundancy and diversity will be retained. This assessment evaluates the SSC functions with respect to core damage mitigation, early containment failure/bypass, and long term containment integrity. If one of these SSC functions is found to be safety significant with respect to defense-in-depth, then it is considered safety significant and re-categorized as safety significant (RISC-1) for presentation to the IDP.

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. This risk sensitivity study is performed using the available PRAs to evaluate the potential impact on CDF and LERF, based on a postulated change in reliability. In this risk sensitivity study, the unreliability of all modeled low safety significant SSCs is increased simultaneously by a common multiplier as an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of low safety significant SSCs. A simultaneous degradation of all SSCs 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 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. 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, actual net increase in risk.

In cases where the licensee does not use a PRA in the categorization process, the sensitivity study remains a viable indication of potential limiting risk increases. This is due to the fact that the categorization processes for hazards that do not have a PRA is done in a manner that assures the risk sensitive SSCs are categorized as safety significant. For example, in the event a seismic margins analysis (SMA) is used for the categorization, all of the SSCs necessary to maintain the current risk levels are considered safety significant. As a result, there would not be any change in the treatment for the SSCs that are credited in mitigating seismic risk.

Integrated Decision-making Panel Review

The Integrated Decision-making Panel (IDP) is a multi-discipline panel of experts that reviews the results of the initial categorization and finalizes the categorization of the SSCs/functions. The purpose of the IDP is to assure that the appropriate considerations from plant design and operating practices and experience are reflected in the categorization input.

The IDP considers the safety significance of the SSCs based on:

- the PRA assessments and sensitivity studies,
- a defense in depth assessment from an operational perspective,
- insights from other risk informed programs (e.g., Maintenance Rule, Risk Informed ISI, etc.), and
- operational and maintenance experience.

In order for an SSC/function to be recommended to the IDP as low safety significant, it must have been identified as low safety significant from the perspective of

- Internal Event Risks
- Fire Risks
- Seismic Risks
- Other External Risks
- Shutdown Risks

If it is an SSC/function that is currently safety related, then the defense in depth assessment must also have shown that the SSC/function is not safety significant. Finally, the risk sensitivity study verifies that the combined impact of a postulated simultaneous degradation in reliability of all low safety significant SSCs would not result in a significant increase in CDF & LERF.

If an SSC/function is only identified as safety significant based on a non-internal events PRA (and was not found to be significant in the integrated importance assessment), or by one of the mandatory sensitivity studies, then the IDP will be presented the results and will use other knowledge and experience to decide whether the SSC should be safety significant.

The IDP will not over-rule the categorization process to make an SSC/function low safety significant when the process identifies it as safety significant (i.e., will not move it from RISC-1 to RISC-3). The IDP may, however, identify that the SSC/function was not appropriately evaluated which may result in a new categorization, based on a revised evaluation.

Conclusions

The categorization methodology used to define the low safety significant SSCs, as described in NEI-00-04, assures any reduction in component reliability as a result of changes in treatment will have a negligible impact on plant risk. This degree of assurance is provided by a multi-layered approach to identifying the low safety significant SSCs that includes PRA, deterministic assessments and engineering judgment. In addition, two different plant organizational functions (engineering and the IDP) perform assessments from their own unique perspective. In either the engineering or the IDP assessment, if any of these three elements indicates that an SSC is safety significant, then that categorization (safety significant) is assigned.

In terms of the scope of the PRA used in the risk assessment portion of the categorization process, a reasonable degree of confidence that risk significant SSCs will be appropriately identified can be maintained with a quality internal events at-power PRA. Screening assessments for other initiating events and other modes of operation identify the SSCs necessary to maintain low risk.

The number of independent criteria that an SSC must satisfy in order to be categorized as low safety significant provides a high level of assurance that only SSCs that are truly low safety significant will be categorized as such.

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 sections of this document. This section provides a brief overview of the elements of each step and the inter-relationships between steps.

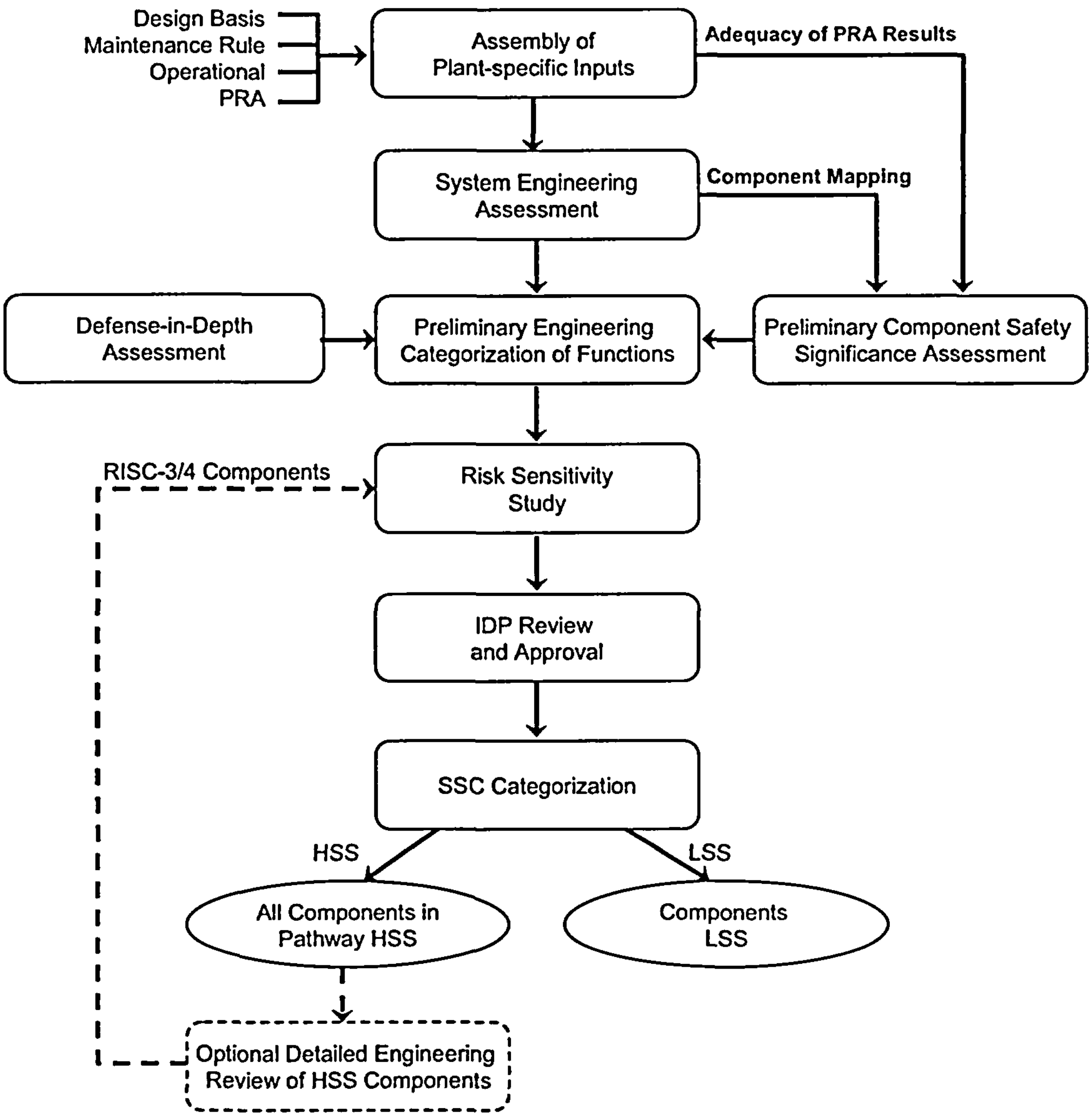
<u>Assembly of Plant-Specific Inputs</u>

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 risk information to assure that they are adequate to support this application. More detail is provided on this step in Section 3.

<u>System Engineering Assessment</u>

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, Maintenance Rule assessments 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



<u>Component Safety Significance Assessment</u>

This step involves the use of the plant-specific risk information to identify components that are candidate 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 functions may be used to define the safety significance of each SSC. 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 HSS SSCs that can be categorized as LSS, the results of that re-categorization are re-evaluated 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 is 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 Risk 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 satisfy 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.

When risk information is used to provide insights into the integrated decision-making panel, it is expected that the risk information will have been subject to quality measures. The following describes methods acceptable to ensure that the risk information is of sufficient quality to be used for regulatory decisions and meets the quality standards described in Reg. Guide 1.174:

- 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 the adequacy of the risk information used in the categorization process (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 risk information can be used to support the categorization process, provided it can be shown that the appropriate quality provisions have been met.

Other 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.

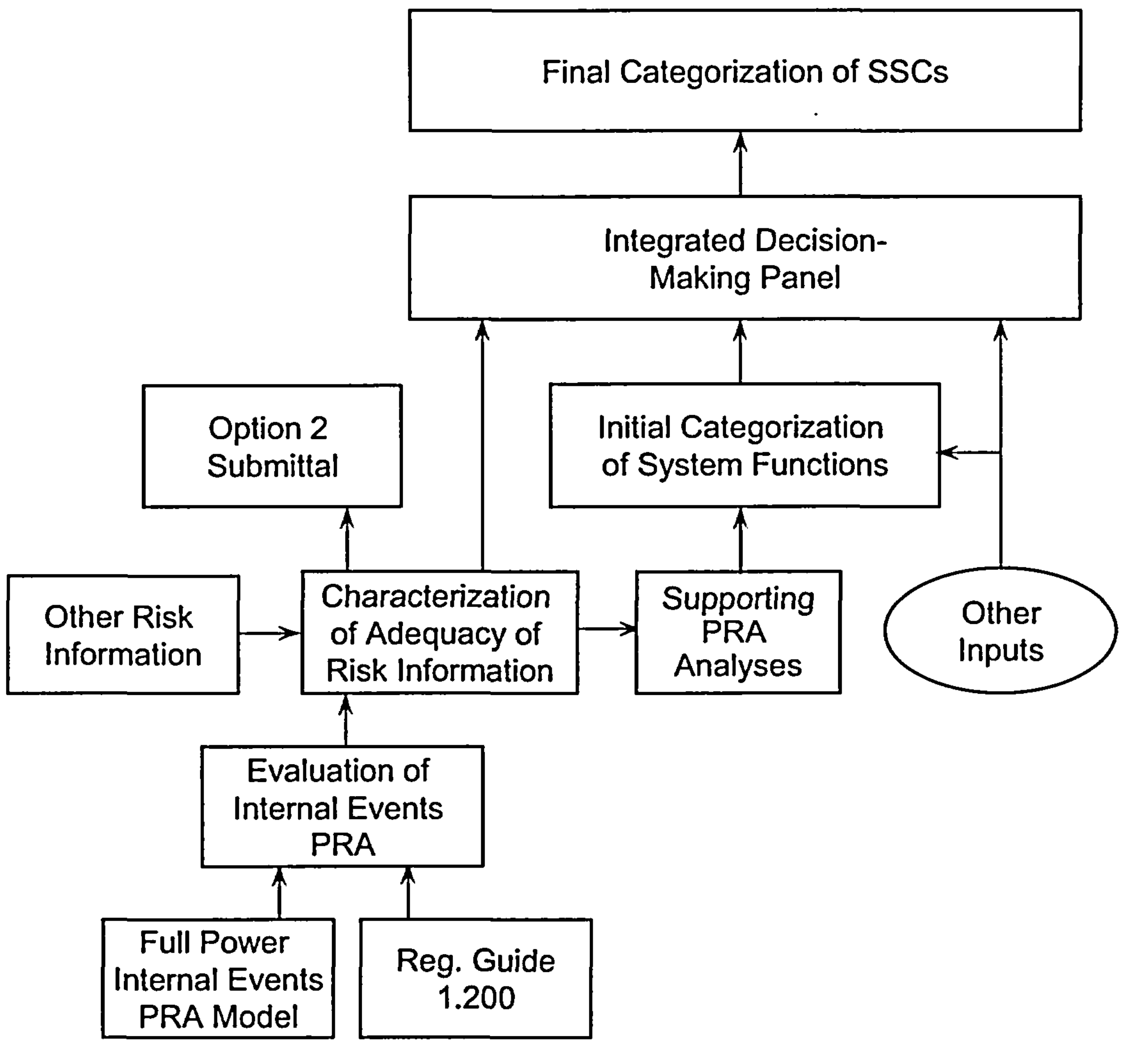
3.3 Characterization of the Adequacy of Risk Information

Figure 3-1 depicts the approach to be employed in demonstrating the adequacy of risk information used in the categorization of SSCs. The adequacy of the risk information builds upon the efforts to review and evaluate the adequacy of the plant-specific internal event full power PRA.

The primary basis for evaluating the technical adequacy of PRA studies relies upon Regulatory Guide 1.200, "An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities." This guide provides guidance on 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"). Ultimately, 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 supporting Standard Review Plan, SRP 19.1, to provide guidance to the staff on how to determine whether a PRA providing results being used in a decision is technically adequate.

Figure 3-1

PROCESS FOR ASSURING PRA ADEQUACY
FOR OPTION 2 CATEGORIZATION



In addition, it may be useful for the licensee to consider the guidance provided by the NRC staff in a letter to NEI dated April 2, 2002 (ADAMS accession number ML020930632). This letter provides draft staff review guidance that was developed as a result of its review of NEI 00–02 for intended use for § 50.69 applications.

Peer review findings are a significant part of justifying the adequacy of the PRA results. All significant peer review findings will 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 risk information used in the categorization process, such as Fire PRAs, FIVE, Seismic PRAs, SMAs 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 risk information to be used should be documented in a characterization of the adequacy of the PRA. This characterization will be provided to the IDP as a basis for the adequacy of the risk information used in the categorization process and will be summarized in the submittal to the NRC. At a minimum, this characterization should include the following:

<u>Full Power Internal Events PRA</u>

- 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, if NEI 00-02 is used, or lower than ASME Capability Category II, if the DG-1122 process is used.
- The disposition of any significant peer review findings.
- Identification of and basis for any sensitivity analyses necessary to address identified findings.
- Considerations identified by the NRC in their letter to NEI [Ref. 15], if the NEI 00-02 process is used.

<u>Other Risk Information (including other PRAs and screening methods)</u>

- A basis for why the other risk information adequately reflects the as-built, as-operated plant.
- A disposition of the impact of significant findings on the other risk information.
- Identification of and basis for any sensitivity analyses necessary to address issues identified in the other risk information.

The Integrated Decision-making Panel (IDP) should consider the adequacy of the PRA to support the categorization of the functions/SSCs of the system being considered. The process to be used to justify the adequacy of the risk information is also summarized in the submittal to the NRC.

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

System Selection and System Boundary Definition

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 within the defined boundaries 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.

An SSC shall be categorized as HSS if it is safety significant for the particular system being considered. However, there may be circumstances where the categorization of a candidate low safety significant SSC within the scope of the system being considered cannot be completed because it also supports an interfacing system. In this case, the SSC will remain uncategorized until the interfacing system is considered. For example, cooling water system piping on a ventilation system cooler is designated as part of the ventilation system. The impact of failure of the SSC on the ventilation system can be considered, but the impact of failure of the SSC on the cooling water system cannot be fully assessed until it that system is considered as part of a future categorization process. Therefore, the SSC will remain uncategorized and continue to receive its current level of treatment requirements.

Identification of System Functions

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 Considered in the Plant-specific Risk Information
- 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 components associated with a given function. Additional functions may be identified (e.g., fill and drain) to group and consider potentially low safety significant components that may have been initially associated with a safety significant function but which do not support the critical attributes of that safety significant function..

The classification of SSCs having a pressure retaining function (also referred to as passive components) should be performed using the ASME Code Case N-660, "*Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities*" (Ref. 16) in lieu of this guidance.

<u>Coarse Mapping of Components to Functions</u>

This step involves the initial breakdown of system components into the system functions they support. System components and equipment associated with each function are identified and documented. There are several options to this implementation element:

1) Define the pathway associated with each function and then define the components associated with that pathway. In this case, the pathway definition must consider branch lines and interfaces with other pathways to assure that the entire pathway is appropriately modeled and the boundaries clearly delineated.

2) If passive components have been categorized according to guidance for risk-informed inservice inspection (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-660, is being implemented at the same time. [2]

   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 pathway 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.

[2] If this code case is not endorsed at the time of submittal, then the licensee will describe the process to be used in the Option 2 submittal.

This is a conservative approach because not every component associated with 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 pathway, but the components associated with these functions can be readily identified from system drawings once the system boundaries are identified.

The assignment of SSCs to 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. In later subsequent steps, the categorization of all system functions will be performed and will be presented to the IDP for review. The categorization assigned to each of the system functions will initially be applied to the SSCs associated with that function. The detailed categorization process of Section 10.2 may then be applied to further refine the categorization based on other considerations that may make the safety significance of an SSC lower than that of the initially associated function.

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.

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, including containment functions, then the risk screening process is terminated and the system functions are categorized as candidate low safety significant. However, the system/structure must still be assessed for defense in depth considerations and presented to the IDP.

Significance from Internal Events

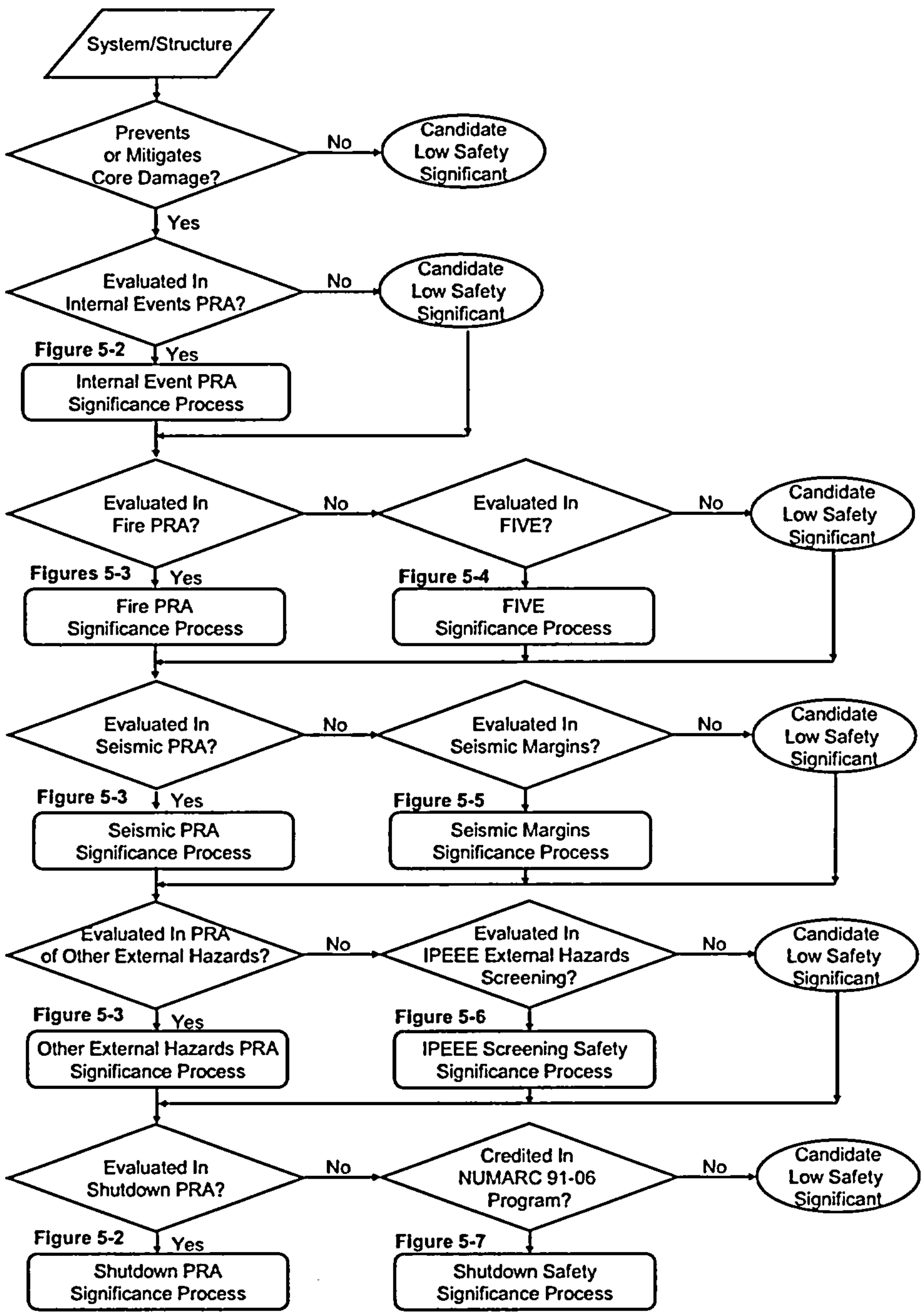
If a system or structure is involved in the prevention or mitigation of severe accidents, then the first risk contributor evaluated is from the internal events PRA. The question of whether a system or structure is evaluated in the internal events PRA (or any of the analyses considered in this guideline) 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 event sometimes used in PRAs. The term "evaluated" means:

- Can its failure contribute to an 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.

Figure 5-1

USE OF RISK ANALYSES FOR SSC CATEGORIZATION



If the system/structure is not evaluated in the internal events PRA, then the SSC is categorized as candidate low safety significant from the standpoint of internal event risks. The evaluation is continued with fire risk.

Significance 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 they 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 SSC is categorized as candidate low safety significant from the standpoint of fire risks.

Significance 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 SSC is categorized as candidate low safety significant from the standpoint of seismic risk.

Significance 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 an external hazards PRA or external hazards screening evaluation, then the SSC is categorized as candidate low safety significant from the standpoint of other external risks.

Significance 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 SSC is categorized as candidate low safety significant from the standpoint of shutdown risk.

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.

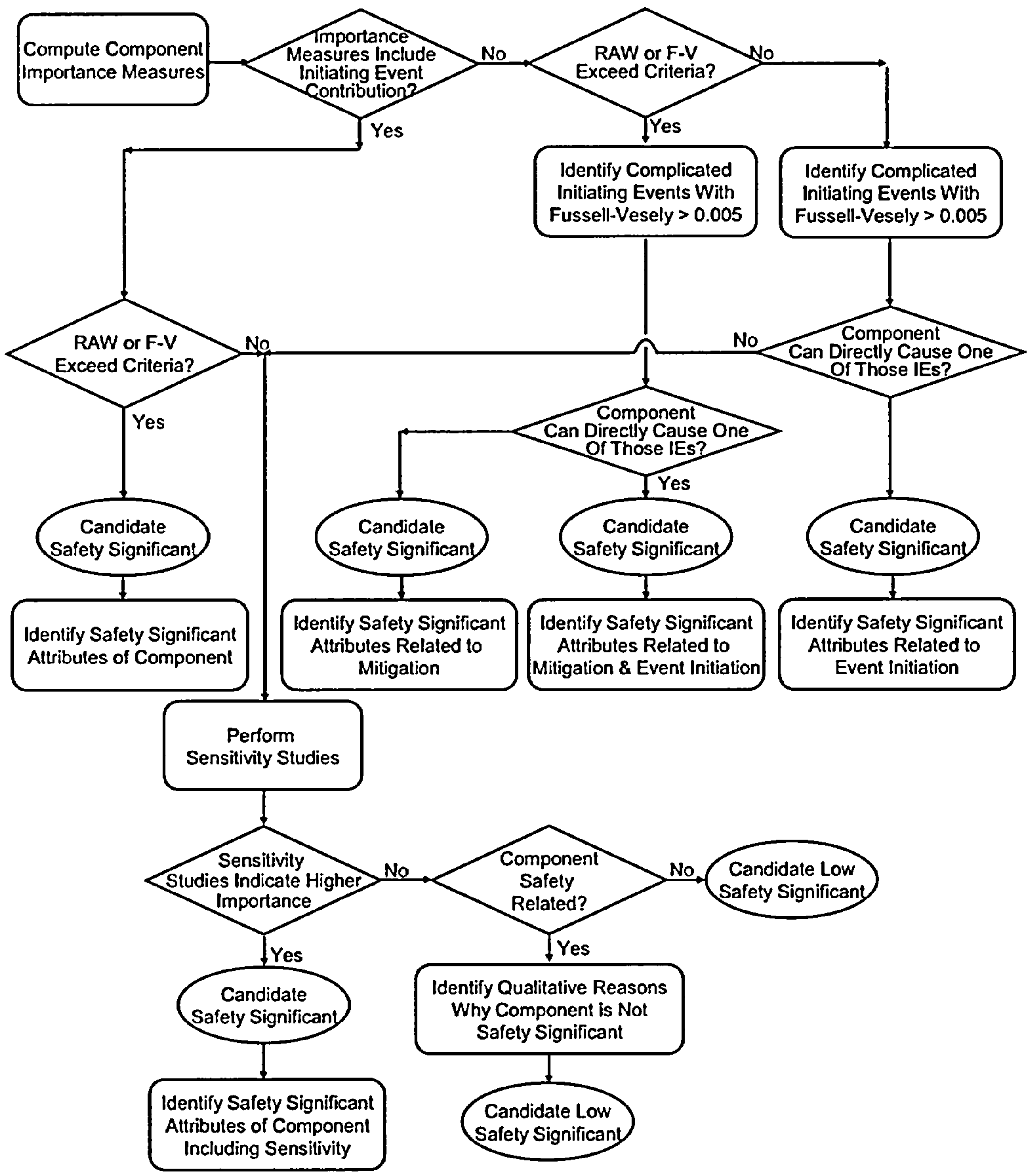
The assessment of importance for an SSC involves the identification of PRA basic events that represent the SSC. This can include events that explicitly model the performance of an SSC (e.g., pump X fails to start), events that implicitly model an SSC (e.g., some human actions, initiating events, etc.) 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. For obtaining risk insights from the PRA for passive pressure boundary components, additional guidance is provided in ASME Code Case N-660, 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[3].

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. The criteria chosen for safety significance using these importance measures are based on previously accepted values for similar applications. Risk reduction worth (RRW) is also an acceptable measure in place of Fussell-Vesely

[3] If these code cases and methods are not endorsed at the time of submittal, then the licensee will describe the process to be used in the Option 2 submittal.

Figure 5-2

RISK IMPORTANCE ASSESSMENT PROCESS FOR COMPONENTS ADDRESSED IN INTERNAL EVENTS AT-POWER PRAs



because 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 failure modes of the component relevant to the function being evaluated.

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 failure modes of the individual component. In the case of RAW, the common cause event is considered using a different criterion than the individual component RAW. The RAW for common cause events reflects the relative increase in CDF/LERF that would exist if a set of components or an entire system was made unavailable. As a result, the risk significance of the RAW values of common cause basic events is considered separately from the basic events that reflect an individual component. A RAW value of 20 was conservatively selected to reflect that fact that the common cause RAW is measuring the failure of two or more trains, including the higher failure likelihood for the second train due to common causes. As with the individual component RAW values, if the component being evaluated is included in more than one common cause basic event, the maximum of the common cause RAW values is used to evaluate the significance.

The importance measure criteria used to identify candidate safety significance are:

- Sum of F-V for all basic events modeling the SSC of interest, including common cause events > 0.005
- Maximum of component basic event RAW values > 2
- Maximum of applicable common cause basic events RAW values > 20.

If any of these criteria are exceeded it is considered candidate safety significant.

For example, a motor operated valve may have a number of basic events associated with it (e.g., "failure to open" and "failure to close"), 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). Some SSCs perform multiple functions (e.g., circuit breakers can perform a function necessary for pump operation and a function necessary to protect the bus in case of a fault. In these cases, basic events should be mapped to the appropriate functions so that the significant functions can be identified.

An analysis of the impacts of parametric uncertainties on the importance measures used in this categorization process was performed and documented in EPRI TR- 1008905, *Parametric Uncertainty Impacts on Option 2 Safety Significance Categorization.* The conclusion of this analysis was that the importance measures used in combination with identified set of minimum sensitivity studies adequately address parametric uncertainties.

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	CCF RAW
1) Valve 'A' Fails to Open	0.002	1.7	n/a
2) Valve 'A' Fails to Remain Closed	0.00002	1.1	n/a
3) Valve 'A' In Maintenance (Closed)	0.0035	1.7	n/a
4) Common Cause Failure of Valves 'A', 'B' & 'C' to Open	0.004	n/a	54
5) Common Cause Failure of Valves 'A' & 'B' to Open	0.0007	n/a	5.6
6) Common Cause Failure of Valves 'A' & 'C' to Open	0.0006	n/a	4.9
Component Importance	0.01082 (sum)	1.7 (max)	54 (max)
Criteria	> 0.005	>2	>20
Candidate Safety Significant?	**Yes**	**No**	**Yes**

In the above example, Valve 'A' would be considered candidate safety significant on two bases, either one would be sufficient to identify the component as candidate safety significant. The total Fussell-Vesely exceeded the criterion of 0.005 and the RAW criterion was also met for the common cause group including Valve 'A'. Thus, both Valve 'A', Valve 'B' and Valve 'C' would be identified as candidate safety significant due to this criterion. The component failure mode which contributes significantly to the importance of Valve 'A' is failure to open (failure modes 1, 4, 5 and 6). 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.

In cases where the internal events core damage frequency is dominated by an internal flooding result that has a conservative bias, it is appropriate to break the evaluation of importance measures into two steps. This prevents the conservative bias of the flooding analysis from masking the importance of SSCs not involved in flood scenarios. 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 being 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 95^{th} percentile value
• Decrease all human error basic events to their 5^{th} percentile value
• Increase all component common cause events to their 95^{th} percentile value
• Decrease all component common cause events to their 5^{th} 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, including sensitivity studies, 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 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. The selected truncation level must be within the capability of the software used. In addition, the truncation level used should support an overall CDF/LERF which has converged. In addition, the truncation level used should be sufficient to identify all functions with RAW>2. 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 is reasonable. In linked fault tree PRAs that do not use pre-solved cutsets, the truncation limit should be evaluated to ensure that converged solution identifies all safety significant functions. If the model relies on a pre-solved set of cutsets to calculate CDF, then the RAW values may be underestimated and the nominal truncation level may not be capable of identifying all the RAW>2 SSCs, even in a converged solution. Therefore, the truncation of pre-solved set of cutsets should be checked to ensure that the CDF and LERF solutions are sufficiently adequate by justifying the omitted SSCs with RAW>2. In some cases, this may be best handled by complete re-solution of the model without credit for the SSC.

5.2 Fire Assessment

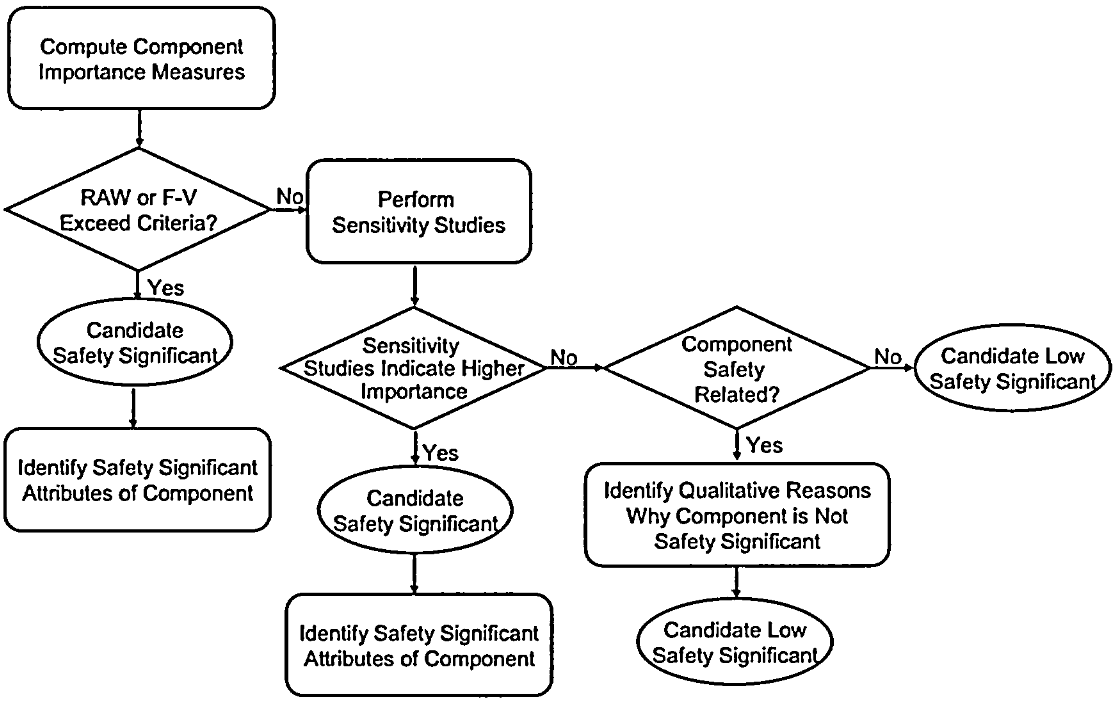
The fire safety significance process takes one of two forms. For plants with a fire PRA, the process is similar to that described for an internal events PRA. This process is shown on Figure 5-3, and is discussed below. Plants that relied upon a FIVE analysis to assess fire risks for the IPEEE should 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 in the scope of this guideline unless the fire risk analysis allows the quantification 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, including all screened scenarios, 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.

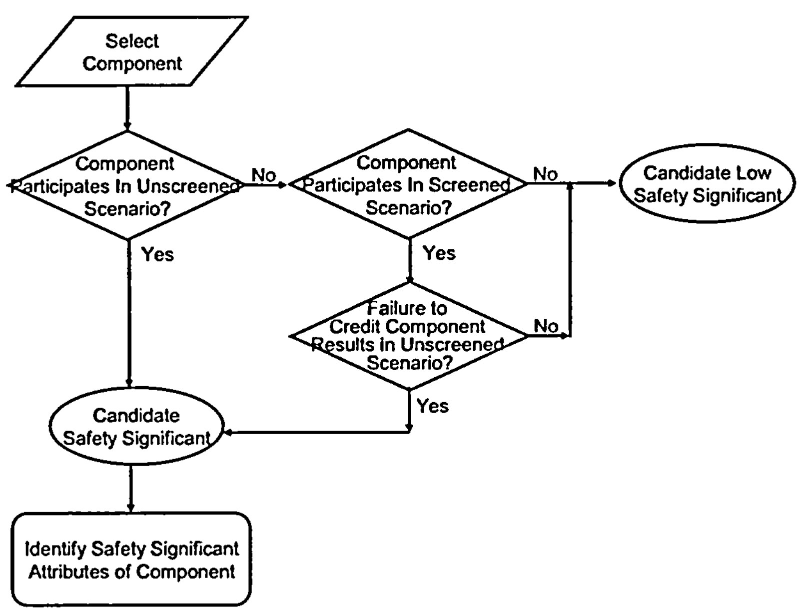
The recommended sensitivity studies for fire PRA are identified in Table 5-3.

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 • No credit for manual suppression • 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



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. This is conservative since the screening process used in FIVE does not generate numerical estimates of core damage frequency values. However, the option always exists for the licensee to perform a fire PRA to remove this conservatism.

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 SSC 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 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.

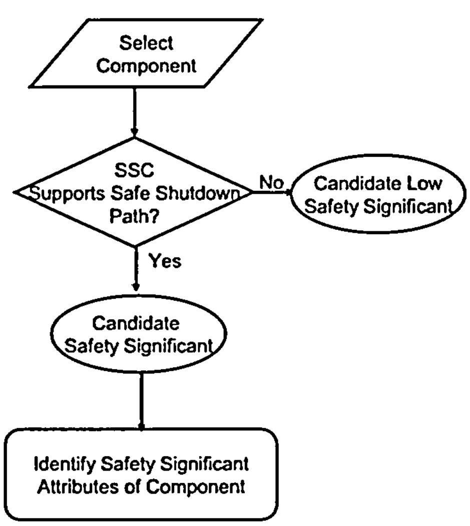
The recommended sensitivity studies for seismic PRA are identified in Table 5-4:

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 conservatism.

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.

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 that 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

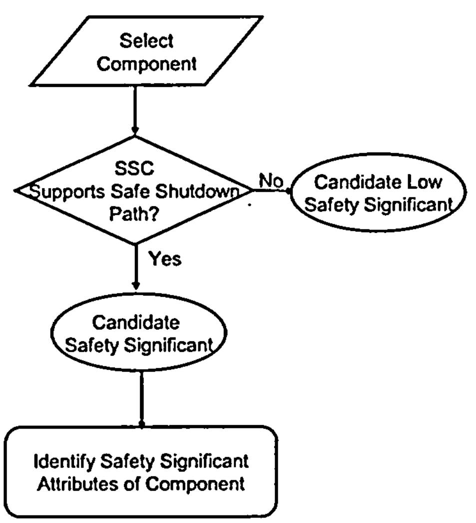
Sensitivity Study
• Increase all human error basic events to their 95th percentile value
• Decrease all human error basic events to their 5th percentile value
• Increase all component common cause events to their 95th percentile value
• Decrease all component common cause events to their 5th percentile 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.

Figure 5-6
OTHER EXTERNAL HAZARDS



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 safe 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 conservatism.

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) Determine if the SSC is credited as part of the identified safe shutdown path. If a component is credited, it is considered safety significant. The SRP on the NUREG-1407 analysis can be used as guidance in this determination.
    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.

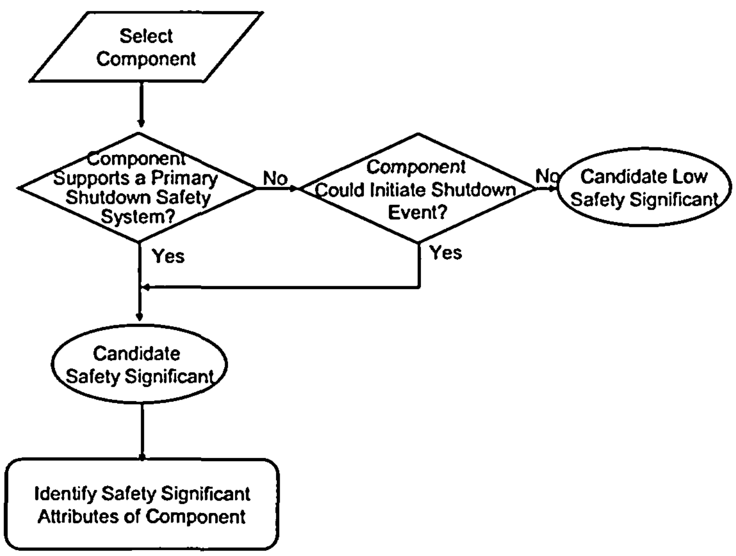
However, if the shutdown PRA CDF is a small fraction of the internal events CDF (i.e., <1%), then safety significance of SSCs considered in the shutdown PRA can be considered low safety significant from a shutdown perspective.

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 either of the following reasons:

- NUMARC 91-06 specifies that a defense in depth approach should be used with respect to each defined shutdown key safety function. This is accomplished by designating a running and alternative system/train to accomplish the given key safety function. When multiple systems/trains are available to satisfy the key safety function, only SSCs that support the primary and first alternative methods to satisfy the key safety function are considered to be the "primary shutdown safety system" and are thus candidate safety significant.

- Its failure would initiate a shutdown event (e.g., loss of shutdown cooling, drain down, etc.),

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 margin to fulfill the safety function.
- It does not require extensive manual manipulation to fulfill its safety function.

5.6 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,RAW > 2.0 for individual basic events, and RAW > 20 for common cause basic events. 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 risk 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 internally initiated design basis events considered in the licensee's safety analysis report (i.e., the events that were used to identify the SSC as safety related) 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.

The following process is used in applying Figure 6-1. For each active component/function categorized as low risk significant,

- Identify the design basis events that the function is required for.
- For each design basis event, identify the other systems and trains that can support the function or can provide an alternative success path to avoid core damage.
- For each design basis event, identify which region of Figure 6-1 the plant mitigation capability lies **without** credit for the SSC being classified as low safety significant and any identical, redundant SSCs within the system also classified as low safety significant.
- If the result is in the region entitled "Low Safety Significance Confirmed", then the low safety significance of the SSC has been confirmed for that function.
- If the result is in the region entitled "Potentially Safety Significant", then the SSC should be classified as safety significant for the IDP.

When complete, if all SSC functions are confirmed as low safety significant, then the SSC remains Candidate Low Safety Significant for the IDP.

For example, if a BWR found that the low pressure core spray (LPCS) system pumps were low safety significant in the categorization process using risk information, then their categorization would be confirmed using Figure 6-1. In this case, the LPCS pumps have the function of providing coolant makeup to the RPV at low pressure. This function is required either (a) in response to a large LOCA, or (b) in response to other transients and LOCAs where other coolant makeup systems are failed.

For mitigation of a large LOCA, the low pressure coolant injection (LPCI) function of the RHR system can also support the coolant inventory makeup function. The LPCI function is automatic and consists of at least two redundant trains. Thus, for this LOCA event, in the bottom row of Figure 6-1, the presence LPCI as a redundant automatic system confirms the low safety significance of LPCS.

In order to confirm low safety significance in high frequency transient events, such as reactor trip, either two automatic redundant systems are required or 3 or more trains must exist. At BWRs there are multiple coolant inventory makeup systems that could be used without crediting LPCS (i.e., HPCI, RCIC, main feedwater, condensate, and LPCI with ADS). This exceeds the redundancy and diversity requirements for mitigation of these events.

In order to confirm low safety significance for mitigation of a stuck open relief valve, one train plus one redundant system is required. In this case, BWRs have LPCI with ADS and HPCI plus CRD to provide success paths. This provides a redundant system (LPCI/ADS) and one additional diverse train (HPCI/CRD).

In order to confirm low safety significance for mitigation of loss of one safety related DC bus, at least two diverse trains are required. In this case, BWRs would have one train of LCPI and either HPCI (a one train system) or RCIC (a one train system) available to meet the requirement for two diverse trains.

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). Containment defense-in-depth is also assessed for SSCs that play a role in preventing large containment failures (e.g., due to loss of containment heat removal). For each SSC function categorized as candidate low safety significant, its defense-in-depth is assessed using the following criteria:

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				

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:
    - Directly connected to containment atmosphere, and
    - > 2" in diameter, and
    - not locked closed or only locally operated?
- Does the SSC support containment isolation for containment penetrations that are:
    - Part of the reactor coolant system pressure boundary, and
    - > 3/8" in diameter, and
    - not locked closed or only locally operated?

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 support a system function that is not considered in CDF and LERF, but would be the only means for preserving long-term containment integrity post-core damage (i.e., containment heat removal)?

In cases where the answer to any of the above questions is "yes," the SSC should be categorized as candidate safety significant. If all of the above questions are answered "no," then low safety significance is confirmed. When complete, if all SSC functions are confirmed as low safety significant, then the SSC remains Candidate Low Safety Significant for the IDP.

In cases where SSCs are identified as safety significant, the safety significant attributes should be defined. 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.

7 PRELIMINARY ENGINEERING CATEGORIZATION OF FUNCTIONS

7.1 Engineering Categorization

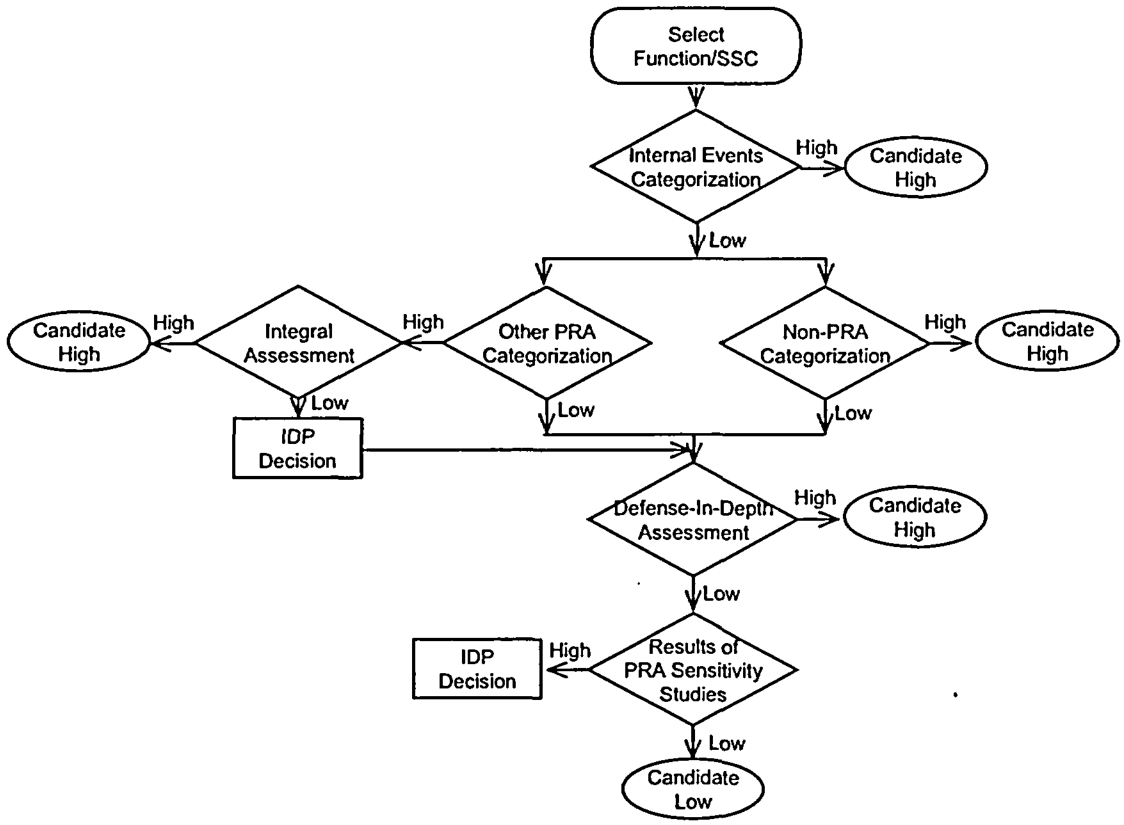
This step involves the assignment of preliminary safety significance to each of the functions identified previously. The safety significant SSCs from the component safety significance assessment (Section 5) are mapped to the appropriate function for which they had high safety significance. If any SSC 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 associated system function is preliminarily assigned high safety significance. All other functions/SSCs can be preliminarily assigned low safety significance. All preliminary categorization assigned as candidate high or low is then taken to the IDP for final review and approval. The overall process used in integrating the various categorization inputs is depicted in Figure 7-1.

Once a system function has been identified as safety significant, then all components that support this system function are assigned a preliminary safety significant categorization. All other components are 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 or part thereof should be assigned the highest risk significance for any function that the SSC or part thereof supports.

For safety significant functions/SSCs, the critical attributes that make the function/SSC safety significant need to be identified. Critical attributes should include high level features of the SSCs that contribute to the safety significance of the function, such as provide flow, isolate flow, etc. These "critical" attributes provide information to the treatment activity implementers to assure that correct levels of treatment requirements are applied to monitor or maintain the SSC critical attributes. The identification of important to safety attributes may also be used as a means of justification for RISC-2 categorization of nonsafety related SSCs.

Figure 7-1
Overview of Process for Assigning Preliminary Safety Significance



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 7-2 provides an example, conceptual layout of the information that summarizes the results and insights that were generated in the categorization process and could be useful for the IDP. This format is for the purposes of identifying the key information that should be communicated to the IDP for use in their decision process. It is expected that additional information will be available at the IDP session that documents the basis for the summary example in the Figure 7-2.

At a minimum, the IDP should be provided with the following information for each system function:

- System name
- The function(s) evaluated and the SSCs supporting those functions.
- 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 7-2
EXAMPLE RISK-INFORMED SSC ASSESSMENT WORKSHEET
(FUNCTIONAL BASIS)

System: ______________ Function: ______________________________

Associated Components: ______________________________

Function Evaluated for Risk? _______ Yes _______ No

SSCs Modeled (explicitly or implicitly) in Risk Assessments: ______________________

Significance Based on Probabilistic Risk Assessment Tools			
		Potential Risk Significance (High or Low)	Basis for Risk Significance (Include RAW and F-V values where applicable)
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 Individual Sensitivity Studies		
	Change in Risk Significance?	Summary of Findings (Include Delta CDF and LERF or RAW and F-V values where applicable)
Human Error Rates		
Common Cause Failure		
Maintenance Unavailability		
Common Cause Failure		
Others		

Insights From Cumulative Sensitivity Study for the System: ______________________

Defense-in-Depth Assessment: ______________________

Categorization in Other Risk Informed Applications (Maintenance Rule, ISI, etc): ______________________

Recommended Categorization for Function:

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, because one of the guiding principles of this process is that changes in treatment should not significantly degrade performance for RISC-3 SSCs and should maintain or improve the performance of RISC-2 SSCs, 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. It is not necessary to address the cumulative impact of SSCs for hazards where screening tools such as SMA were used because if they are included in the screening analysis they are considered high safety significant, thus there would be no change in treatment and no change in performance. For categorizations that rely on PRAs, this sensitivity 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 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 degradation. In the extreme, individual components could 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 components that were identified in the categorization process as having low safety significance because they do not support a safety significant function. The basic events for both random and common cause failure events should be increased for failure modes of the component relevant to the function being considered.

In identifying the specific factor to be used in the risk sensitivity study, two considerations should be addressed:

- The cumulative risk increase that would be computed if the unreliability of those SSCs were assumed to simultaneously increase by that factor. That is, the factor used can not lead to exceeding the quantitative acceptance guidelines of Reg. Guide 1.174.
- The ability of a monitoring program to detect a change of that factor. This includes consideration of currently expected number of failures for the number of demands/hours of operation and the expected number of failures for the expected

future number of demands/hours of operation for the population of SSCs that are expected to be classified as low safety significant. Standard practices used for setting performance criteria based on failures under the maintenance rule are applicable.

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.

In cases where the categorization process identifies beyond design basis functions that will be addressed for RISC-1, reducing the unreliability of these safety significant SSCs by a similar factor may be called for, depending upon the specific changes in special treatment. The cumulative 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.

Failures of RISC-3 SSCs will be addressed in a corrective action program consistent with the associated high level treatment requirement in the rule. Periodic assessments of failures of low safety significant SSCs will be performed to assure that the number of failures in a given time period has not increased over the pre-implementation number by a factor greater than the factor used in the sensitivity study. For example, assume the pre-implementation number of failures of all RISC-3 MOVs in a three year period was 5 failures and the multiplier used in the sensitivity was 3. Then the assessment would monitor the post implementation performance at 15 failures in three years. If the number of failures exceeded this value, then the appropriate changes to treatment would be made to return performance to an acceptable level.

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., 0.0025) for a re-evaluation of SSCs risk ranking. This may result in re-categorizing 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 risk information 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. This training is for IDP familiarity (i.e., it is not intended to make the IDP PRA "experts").

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, including a list of exempted regulations for low safety significant SSCs,

- The categorization process (e.g., a brief description of Figure 2-1),

- The risk-informed defense-in-depth philosophy and criteria to maintain this philosophy,

- PRA fundamentals,

- Details of the plant-specific PRA analyses that are relied upon for the preliminary categorization, including

    - the modeling scope and assumptions,
    - interpretation of risk importance measures, and
    - the role of sensitivity studies and change in risk evaluations

- The IDP process, including roles and responsibilities.

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, if possible. However, a simple majority of the panel is sufficient for final decisions regarding HSS and LSS.

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.

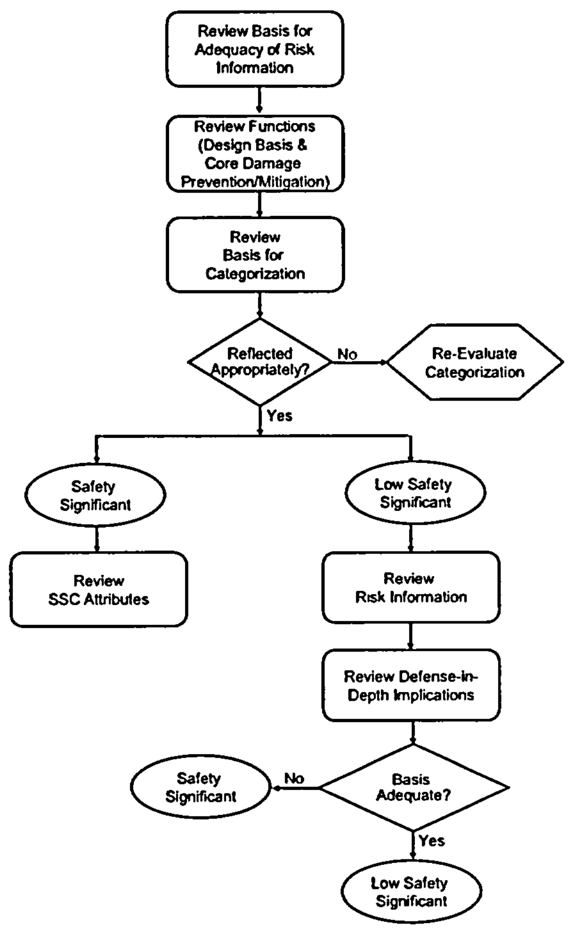
The IDP should be described in a formal plant procedure that includes:

- 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 of each function in the plant-specific risk analyses and defense-in-depth, is provided to the IDP for review. The overall categorization process to be used by the IDP is shown in Figure 9-1.

Figure 9-1
IDP PROCESS



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 IDP should conclude that the risk information is adequate to support categorization of the selected system. The appropriateness of the manner in which the function/ SSC has been reflected should be judged based on the scope of functions considered and the manner in which the risk information incorporate those functions. If the IDP determines that the function/SSC has not been appropriately reflected, then it is returned to the preliminary categorization process to be re-evaluated based on the insights from the IDP.

The IDP review of the categorization of the functions/SSCs does not need to include the verification that all of the SSCs mapped to that function are appropriate. The IDP approval of the categorization of system functions, based on the coarse mapping of components to system functions, would be used to define the safety significance of each SSC as described in Section 10. Thus, if a system function is found to be safety significant by the IDP, then all components associated with that function would initially be considered safety significant (HSS).

If a more detailed categorization of the SSCs associated with a safety significant function is performed after the initial IDP, then the basis for that re-categorization must be considered in a follow-up IDP session. In this follow-up session, the IDP would be expected to review the basis for the re-categorization and to assess the impact of this re-categorization on the risk importance and defense in depth implications using the same criteria as in the original IDP session for candidate low safety significant SSCs.

Review of Safety Significant Functions/SSCs

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, then the IDP cannot move that SSC to a low safety significant category. For safety significant functions/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. The identification of the critical attributes is important because they provide information to the treatment activity implementers.

Review of Safety Related Low Safety-Significant Functions/SSCs

The IDP's role for these functions is to perform a risk-informed assessment of the function/SSC categorization including consideration of the risk information, defense-in-depth and safety margins.

Review of Risk Information

For functions/SSCs that have been identified as candidate low safety significant, the IDP should determine whether these functions/SSCs are not implicitly depended upon for risk-significant functions. The IDP should consider whether:

- Failure of the function/SSC will not 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 function/SSC will not compromise the reactor coolant pressure boundary or containment integrity.

- Failure of the function/SSC will not directly fail another safety significant function/SSC, 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). "Safety Significant Function" here is considered to be one of the "high level" general mitigation categories such as "reactivity control", "high pressure RPV injection from all sources", etc. That is, the IDP reviews the impact of loss of the function/SSC against the defense-in-depth remaining to perform the function.

- The function/SSC is not necessary for safety significant operator actions credited in the PRA, including instrumentation and other equipment.

- The function/SSC is not necessary for significant operator actions to assure long term containment integrity or offsite emergency planning activities, including instrumentation and other equipment.

Review Defense-In-Depth Implications

When categorizing a function/SSC as low safety significant, the IDP should consider whether the defense-in-depth philosophy is maintained. Defense-in-depth is maintained if:

- 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).

- There is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design.

- System redundancy, independence, and diversity are preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters (Section 7).

- Potential for common cause failures is taken into account in the risk analysis categorization.

- The overall redundancy and diversity among the plant's systems and barriers is sufficient to ensure that no significant increase in risk would occur.

If any of the above conditions for either the risk information or the defense-in-depth implications are not true, low safety significance can still be assigned, if the following condition is met:

- Historical data show that these failure modes are unlikely to occur and such failure modes can be detected and mitigated in a timely fashion, or
- A condition monitoring program would identify the degradation of the SSC prior to its failure in test or an actual demand event.

If the IDP concludes that the categorization of the function/SSC as low safety significant is not justified, based on the risk review or the defense in depth review, then the IDP can re-categorize the SSC to RISC-1. 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.

Review Safety Margin Implications

Because the only requirements that are relaxed for low safety significant SSCs are those related to treatment, existing safety margins for SSCs arising from the design technical and functional requirements would remain. It is also required 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 50.69. 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, it can be concluded that the sufficient safety margins are preserved. Consequently, no specific assessment of safety margin is required by the IDP.

Review of Nonsafety Related LSS Functions/SSCs

The functions/SSCs initially categorized as LSS may 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

After the IDP approves the categorization of system functions, then the initial coarse mapping of components to system functions is used to define the safety significance of each SSC. Thus, if a system function is found to be safety significant by the IDP, then all components that support the system function should 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 supports <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 or system functions, the SSC categorization based on the course mapping may provide adequate benefits to the licensee. In other cases, this approach may be too conservative, so a more detailed categorization may be utilized as discussed in Section 10.2.

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, RISC categorizing all SSCs within a system or subsystem according to whether the system or subsystem as a whole performs a risk significant function (Section 10.1). 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.

The two options can be explained in more detail as:

1) Assignment of all SSCs supporting a function to the safety significance classification of that function. While this is a conservative assignment, it may best suit the cost-benefit assessment for 50.69 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 selected SSCs to a lower classification based on the attributes of the function that the SSC supports. This applies primarily to categorizing selected SSCs on 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 supporting a safety significant function 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 supporting a safety significant function would include, but is not limited to:

    - 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 that is not a significant flow diversion path, SSCs downstream of the first isolation valve from the active pathway 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.).

For SSCs that retain the categorization of the function that they support, no IDP review should be required; there should be no differences from the assessments considered in the initial IDP. For SSCs that are re-categorized to a lower classification (e.g., components in a safety significant function that are determined to be low safety significant based on the above considerations), the new categorization and its basis should be presented to another session of the IDP to be recategorized using the same rigor as described in Section 9. If the SSCs being considered for re-categorization to a lower classification are modeled in the PRA, then the Risk Sensitivity described in Section 5 would need to be completed prior to presentation to the IDP.

11 PROGRAM DOCUMENTATION AND CHANGE CONTROL

10 CFR 50.69(f) includes requirements for program documentation, change control and records. In general, the implementation of 10 CFR 50.69 can be divided into two phases: 1) the initial implementation that includes the categorization of SSCs and the application of treatment based on that categorization; and 2) the control of changes to the plant that may impact those SSCs or their categorization basis following the initial implementation. This section provides guidance on meeting the requirements of 10 CFR 50.69(f) for these two phases.

11.1 Initial Implementation

The rule requires the licensee or applicant to document the basis for categorization of any SSCs subjected to the categorization process. The heart of this documentation is the procedure used to conduct the categorization process, and a concise summary of the results of the process. For RISC-1 and RISC-2 SSCs, the documentation should include information on any applicable safety-significant beyond design basis functions that were identified. This information is important to the control of any subsequent changes affecting these SSCs following initial implementation. For RISC-3 and RISC-4 SSCs this information should include the basis for concluding that the SSC is low safety significant.

For the purposes of this guidance, initial implementation refers to the first application of the 50.69 rule to a particular system. This may be at the time the first system(s) are categorized under 50.69 or it may be at later time if the licensee chooses a phased approach to categorization wherein only a few systems are categorized each year, for several years.

The rule requires the licensee or applicant to update the FSAR in accordance with 10 CFR 50.71(e) to reflect which systems have been categorized. Following NRC approval to implement 10 CFR 50.69, any changes to the FSAR that reflect alternative treatment of categorized systems should be captured in the licensee's FSAR update process. NEI 98-03, Guidelines for Updating Final Safety Analysis Reports, provides ample guidance on implementing the update process. Any changes to the FSAR associated with initial implementation need not include a supporting review or evaluation under 10 CFR 50.59.

Initial implementation may entail changes to the licensee's quality assurance plan to reflect alternative treatment for categorized systems. Any changes to the quality assurance plan associated with initial implementation need not include a supporting review under 10 CFR 50.54(a). In addition, any regulatory commitments associated with the special treatment requirements in 10 CFR 50.69(b)(1) for SSCs categorized as RISC-3 are no longer applicable to these SSCs and may be dropped at the licensee's discretion. However, licensees should ensure that any design related commitments continue to be maintained.

The waiver of supporting reviews under 10 CFR 50.59 and 10 CFR 50.54(a) is only applicable to the initial implementation of 10 CFR 50.69, i.e., for changes in treatment to SSCs based on the results of the categorization process. Any other changes to these SSCs are subject to the applicable change control requirements.

11.2 Following Initial Implementation

Subsequent to initial implementation, any changes to alternative treatment for categorized SSCs are subject to applicable change control requirements, e.g., 10 CFR 50.59 and 10 CFR 50.54(a), and must continue to meet the alternative treatment requirements in 10 CFR 50.69.

Changes to categorized SSCs not associated with treatment continue to be governed by the same applicable change control requirements. For RISC-1 and RISC-2 SSCs that have safety-significant beyond design bases functions, the licensee must also maintain reasonable assurance that these functions will be satisfied following the change.

The periodic update of the plant PRA may affect the results of the categorization process. If the results are affected, the licensee must make adjustments as necessary to either the categorization or treatment processes to maintain the validity of the processes.

For example, if new information results in a change in categorization of an SSC from RISC-3 to RISC-1, the licensee must reestablish the level of assurance consistent with its safety-significant treatment program that meets the applicable special treatment requirements.

12 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 or the defense in depth implications considerations in previous categorizations have been changed as a result of these later categorization activities. If such changes are found, they should be presented to the IDP for consideration in their deliberations on the categorization of the latest system.

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 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 review of the importance measures used for screening in the categorization process[4].

Additional guidance on PRA updates is provided in Section 5 of the ASME PRA Standard.

[4] 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

In most cases, the categorization would be expected to be unaffected by changes in the plant-specific PRA. However, in some instances, an updated PRA could result in new RAW and F-V importance measures that are sufficiently different from those in the original categorization so as to suggest a potential change in the categorization. In these cases, the assessment of whether a change in categorization is appropriate should be based on the absolute value of the importance measures. The absolute importance is the product of the base CDF/LERF and the importance measure ([RAW-1] or Fussell-Vesely). This is done in order to not inadvertently assess an SSCs as safety significant when its relative importance (FV and RAW) has gone up, but only due to a decrease in overall CDF & LERF. In cases where the importance measures are different between a prior categorization and an updated result, the categorization reassessments of SSCs that have been previously categorized should be based on the following table:

Table 12-1
IMPACT OF PRA UPDATES ON CATEGORIZATION

Prior Categorization	Updated CDF/LERF	Updated Significance Based on Importance	Updated Absolute Importance	Updated 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

When a change to the categorization of an SSC is suggested either by a change in plant design or operation that would prevent a safety-significant function from being satisfied or by a change in the PRA model as determined from the absolute importance measures, they should be presented to the IDP for concurrence. In these cases, the IDP would assess the basis for the re-categorization by:

- Review of the primary technical bases for the initial categorization, including the system function(s), the risk importance and the basis for their original categorization,
- Review of the technical basis for the change (in plant design and operation of PRA model) that has resulted in a suggested change to the SSC categorization including the appropriateness of the manner in which the SSC has been reflected as a result of the change, and
- Review of the new risk importance and defense in depth implications.

The IDP has the final decision regarding the suggested re-categorization based on the IDP process described in Section 9.

13 REFERENCES

1. 10 CFR50.69, *Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors, May 16, 2003.*
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. Regulatory Guide 1.200, *An Approach for Determining The Technical Adequacy Of Probabilistic Risk Assessment Results For Risk-Informed Activities*, Issued For Trial Use, February 2004.
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 00-02, Probabilistic Risk Assessment Peer Review Process Guideline*
14. *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."*
15. ASME Code Case, N-660, "*Risk-Informed Safety Classification for Use in Risk-Informed Repair/Replacement Activities*", *July 23, 2002.*
16. ASME RA-s-2002, *Standard for Probabilistic Risk Assessments for Nuclear Power Plant Applications*
17. EPRI TR- 1008905, *Parametric Uncertainty Impacts on Option 2 Safety Significance Categorization*, June 2003.

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.

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

Plant-specific Risk Information – Plant-specific evaluations of beyond design basis capability used in the categorization process including PRAs, FIVE, seismic margins assessments, shutdown safety assessments, etc.

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