[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.

The NRC staff provided the Commission the draft final rule in SECY-04-0109 dated June 30, 2004. The Commission subsequently approved the final rule subject to the changes denoted during the session and documented in SRM dated October 7, 2004 (ADAMS accession

number ML042810516).

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 confidence (i.e., “reasonable confidence”) 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. After consideration of all stakeholder comments, the Commission revised § 50.69(d)(2) to adopt a more performance-based approach that provides licensees and applicants greater flexibility in establishing RISC-3 treatment consistent with the low safety significance of RISC-3 SSCs. Accordingly, the Commission has removed the more prescriptive

requirements regarding RISC-3 treatment activities and adopted rule language that focuses on the performance requirements for RISC-3 SSCs.

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 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, performance-based 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 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. 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 ensure with reasonable confidence 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. After consideration of these comments, the Commission has decided not to include detailed design control process requirements in the final rule. The final rule requirements require that licensees and applicants ensure with reasonable confidence that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions. With respect to design changes, as noted in several places in the notice for the final rule, § 50.69 is not changing design basis functional requirements and § 50.59 remains applicable to all changes to non-special treatment aspects of RISC-3 SSCs. The Commission believes that a performance-based requirement will allow licensees who choose to implement

§ 50.69 to have greater flexibility to implement treatment that they have determined is needed, commensurate with the safety significance of the SSCs in order to ensure with reasonable confidence that RISC-3 safety-related functional capability is maintained.

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, albeit at a lower level of confidence as compared to RISC-1 SSCs. 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. However, the Commission agrees that the applicable rule language can be simplified and has revised the final rule to utilize a performance-based approach to ensuring with reasonable confidence the functional capabilities of RISC-3 SSCs. Accordingly, the final rule has been revised by deleting the reference to the specific conditions that were parenthetically listed in the proposed rule.

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)(ii) 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. The revised corrective action requirement is consistent with a proposal 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. It is also consistent with the principle of performance-based regulation that non-compliance with the performance requirement should provide sufficient margin such that reasonable assurance of public health and safety continues to be provided.

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 does not intend to alter the existing seismic design requirements for RISC-3 SSCs in any plant's design basis. 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 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

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[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.

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 , 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 and concludes that both the proposed rule requirements and the final rule requirements maintain adequate protection for the reasons discussed in Section III.7.0 of this notice.

II.1.6.8 License Amendment.

A commenter stated that the requirement to prepare, submit, and then receive approval of a license amendment to implement § 50.69 is a disincentive to its use. The commenter argued 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.

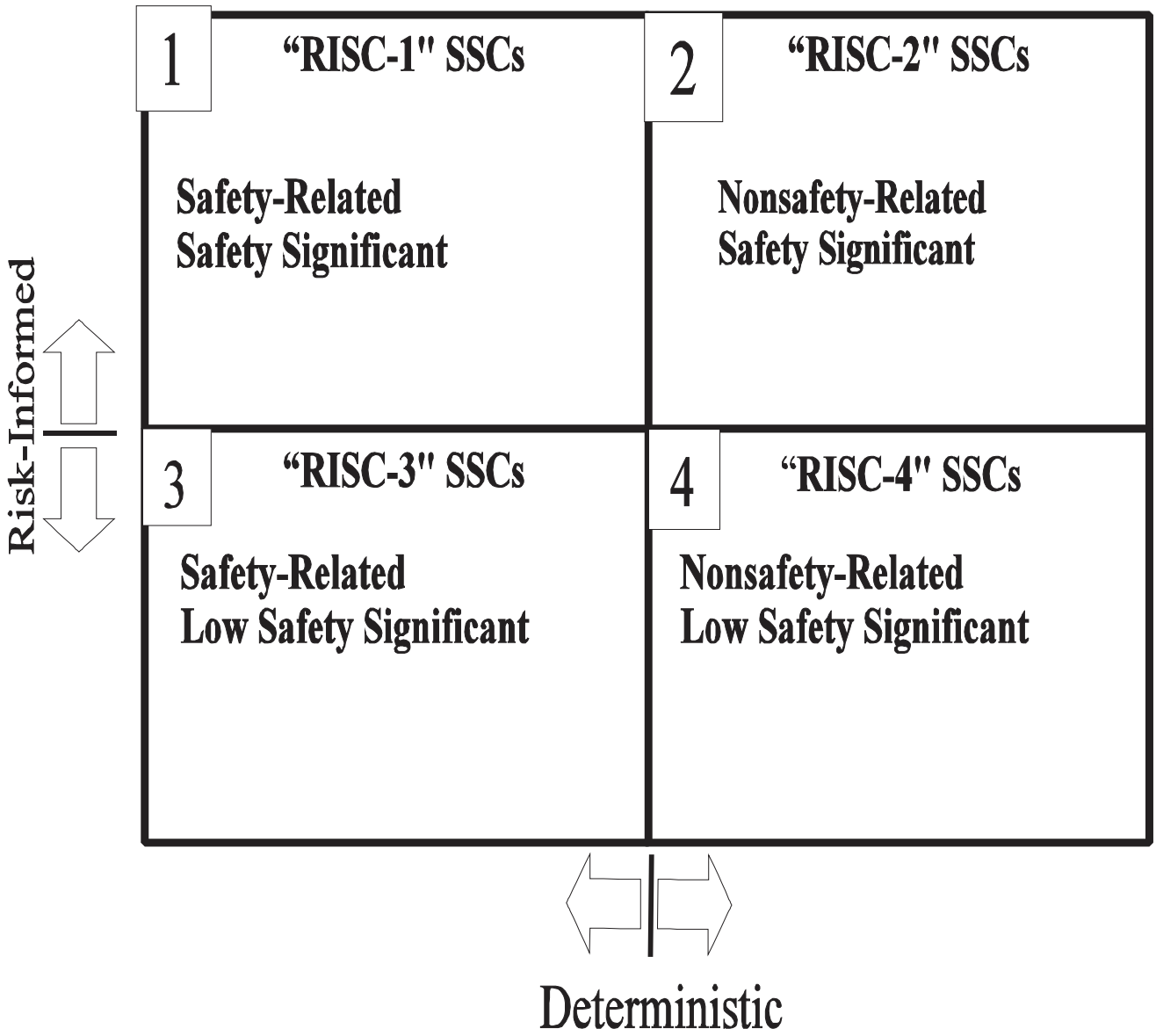

Figure 1

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 plant. 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 ensure with 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, e.g., by providing 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 that licensees or applicants ensure with reasonable confidence that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. To support this requirement, § 50.69(d)(2) contains inspection, testing, and corrective action requirements, and in addition requires that the treatment of RISC-3 SSCs be consistent with the categorization process. The requirements are performance-based and give licensees the flexibility to implement treatment that they have determined is needed, commensurate with the low safety significance of the SSCs in order to provide reasonable confidence that their safety-related functional capability is maintained. In this context, “reasonable confidence” is a somewhat reduced level of confidence as compared with the relatively high level of confidence provided by the current special treatment requirements. 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.

In implementing the rule requirements, 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, 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 should result in reasonable confidence that RISC-3 SSCs will 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 the low individual safety significance of RISC-3 SSCs.

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. The Commission, in developing § 50.69, is drawing 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 treatment 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 inspection, testing, and 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

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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.

not be imposed on RISC-2 SSCs.

The Commission also considered if notification of component defects should be required from the perspective of other potentially-affected licensees. The set of SSCs that are RISC-2 would vary from site to site because it depends upon 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 SSC should result in only a small change in risk and should not result in a major degradation of essential safety-related equipment (see NUREG-0302, 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 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).

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[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.

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 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). 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. 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), ensures with reasonable confidence, without the need for Type B testing, 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 ensures with 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 ensuring with 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 ensure with reasonable confidence 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 has issued 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 has addressed 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. The Commission, in

developing § 50.69, is drawing 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.

II.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)(ii)). 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.

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 shall ensure with reasonable confidence functionality and further specifies some high-level requirements for RISC-3 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 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 does 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, performance-

based requirements in § 50.69(d)(2) that require the licensee to provide reasonable confidence that RISC-3 SSCs will continue to be capable of performing their safety-related functions under design basis conditions. These performance-based RISC-3 requirements in paragraph (d)(2) are discussed below in greater detail. 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, consisting of, at a minimum, inspection, testing, and corrective action, to maintain RISC-3 SSC functionality as required by § 50.69(d)(2). This treatment need not 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 inspection, testing, and corrective action activities are adequate to prevent, detect and correct significant SSC performance and reliability degradation. Later sections of this SOC provide discussion on the treatment the licensee will implement to ensure with 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 must ensure with reasonable confidence that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. By "reasonable confidence", the Commission means that the licensee or applicant is required to provide a "reasonable confidence" level with regard to maintaining the capability of RISC-3 safety-related functions. As indicated previously in this notice, "reasonable confidence" is a level of confidence that is both less than that associated with RISC-1 SSCs which are subject to all the special treatment requirements, and consistent with their individual low safety significance. The term "ensure" is intended to convey the Commission's determination that the licensee is under a legally-binding regulatory requirement to provide the requisite "reasonable confidence."

Although § 50.69(b)(1) removes for RISC-3 SSCs the environmental qualification requirements of § 50.49, it 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. If RISC-3 electrical equipment is relied on to perform its safety-related function beyond its design life, § 50.69(d)(2) requires the licensee or applicant to have 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.

Section 50.69(d)(2) should not be interpreted to extend or expand design basis conditions to SSCs where such conditions were not previously part of its design basis.

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 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 the design basis capability of RISC-3 SSCs, based on plant-specific and industry-wide operational experience and vendor information. In establishing treatment for RISC-3 SSCs, the licensee or applicant is responsible for addressing applicable vendor recommendations and operational experience such that the treatment established for RISC-3 SSCs provides reasonable confidence for 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 that provides reasonable confidence SSCs perform their safety-related functions under design basis conditions and is consistent with the assumptions in the categorization process (e.g., reliability levels). The licensee or applicant

must either establish treatment that provides 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, § 50.69(d)(2) requires that inspection, testing and corrective action be provided for RISC-3 SSCs. The inspection and testing requirement in § 50.69(d)(2)(i) is to provide sufficient performance data for 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 throughout their service life. The corrective action requirement in § 50.69(d)(2)(ii) is to address SSC failures and provide reasonable confidence in avoiding future problems. These requirements are necessary to provide reasonable confidence that RISC-3 safety related functional capability is maintained and thereby 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 and invalidate the risk sensitivity 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 for RISC-3 SSCs so there is a reasonable basis to support the assumptions made for the risk sensitivity study.

V.5.2.1 Section 50.69(d)(2)(i) Inspection and Testing

Section 50.69(d)(2)(i) requires the licensee to conduct periodic inspection and testing activities to determine whether RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions.

The prescriptive 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 prescriptive requirements, the final rule requires the licensee or applicant to implement inspection and testing of RISC-3 SSCs sufficient to provide reasonable confidence that RISC-3 SSCs 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.

With respect to RISC-3 pumps and valves, the rule language in § 50.69(d)(2)(i) means that the licensee or applicant must implement periodic testing or inspection 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, the licensee or applicant will need to obtain sufficient operational information or performance data to provide with 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)(i) for use in identifying the need for corrective action under § 50.69(d)(2)(ii) 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 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 of 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)(i). 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.5.2.2 Section 50.69(d)(2)(ii) Corrective Action Process.

Section 50.69(d)(2)(ii) requires that conditions that would prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be corrected in a timely manner. In the case of significant conditions adverse to quality, the rule requires that measures be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition. Significant conditions adverse to quality include 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)(i) 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).

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 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 revision of NEI 00-04 submitted on April 14, 2004 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 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.

The NRC staff and NEI continue to interact on the implementation guidance. Consequently, it is expected that NEI will submit an improved revision to NEI 00-04 that will enable the NRC to issue a RG with fewer clarifications, limitations, and conditions, and as a consequence, the NRC is delaying issuance of the RG.

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.

Note: Public access to documents, including access via ADAMS and the PDR, has been temporarily suspended so that security reviews of publicly available documents may be performed and potentially sensitive information removed. However, access to the documents identified in this rule continues to be available through the rulemaking web site at http://ruleforum.llnl.gov, which was not affected by the ADAMS shutdown. Please check with the listed NRC contact concerning any issues related to document availability.

Document	**PDR**	**Web**	**PERR**
Response to Public Comments	X	X	ML042990011
Environmental Assessment	X	X	ML041040236
Regulatory Analysis	X	X	ML041000474
Industry Implementation Guidance	X	X	ML041120253
Regulatory Guide	X	X	ML041340087
Final Rule SRM	X	X	ML042810516
SRM on PRA Quality	X	X	ML033520457

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.

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 seq.). These requirements were approved by the Office of Management and Budget, approval number 3150-0011.

The burden to the public for these information collections is estimated to average 1,032 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, John A. Asalone, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011), Office of Management and Budget, Washington, DC 20503. You may also e-mail comments to John_A._Asalone@omb.eop.gov or comment by telephone at (202) 395-4650.

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 ensure, with reasonable confidence, that RISC-3 SSCs remain capable of performing their safety-related functions under design basis conditions, including seismic conditions and environmental conditions and effects throughout their service life. The treatment of RISC-3 SSCs must be consistent with the categorization process. Inspection and testing, and corrective action shall be provided for RISC-3 SSCs.

(i) *Inspection and Testing*. Periodic inspection and testing activities must be conducted to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions; and

(ii) *Corrective Action*. Conditions that would prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be 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)(i) 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 15th day of November 2004.

For the Nuclear Regulatory Commission.

/RA/

Annette L Vietti-Cook,
Secretary of the Commission.