[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AG42

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

AGENCY: Nuclear Regulatory Commission

ACTION: Proposed rule.

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

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

ADDRESSES: You may submit comments by any one of the following methods. Please include the following number (RIN 3150-AG42) in the subject line of your comments. Comments on rulemakings submitted in writing or in electronic form will be made available to the public in their entirety on the NRC rulemaking web site. Personal information will not be removed from your comments.

Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

E-mail comments to: SECY@ nrc.gov. If you do not receive a reply e-mail confirming that we have received your comments, contact us directly at (301) 415-1966. You may also submit comments via the NRC's rulemaking web site at http://ruleforum.llnl.gov. Address questions about our rulemaking website to Carol Gallagher (301) 415-5905; email cag@nrc.gov.

Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 am and 4:15 pm Federal workdays. (Telephone (301) 415-1966).

Fax comments to: Secretary, U.S. Nuclear Regulatory Commission at (301) 415-1101.

Publicly available documents related to this rulemaking may be examined and copied for a fee at the NRC's Public Document Room (PDR), Public File Area O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland. Selected documents, including comments, can be viewed and downloaded electronically via the NRC rulemaking web site at http://ruleforum.llnl.gov.

Publicly available documents created or received at the NRC after November 1, 1999, are available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, 301-415-4737 or by email to pdr@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

The NRC has established a set of regulatory requirements for commercial nuclear reactors to ensure that a reactor facility does not impose an undue risk to the health and safety of the public, thereby providing reasonable assurance of adequate protection to public health and safety. The current body of NRC regulations and their implementation are largely based on a “deterministic” approach.

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

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

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

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

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

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

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

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

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

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

To implement this Commission policy, the staff developed guidance on the use of risk information for reactor license amendments and issued Regulatory Guide (RG) 1.174. This RG provided guidance on an acceptable approach to risk-informed decision-making consistent with the Commission's policy, including a set of key principles. These principles include:

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

(2) Maintain sufficient safety margins;

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

(4) Incorporate monitoring and performance measurement strategies.

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

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

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

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

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

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

(6) defenses against human errors are preserved.

## II. Rule Initiation

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

In March 1996, STP Nuclear Operating Company (STPNOC) requested that the NRC approve a revised Operations Quality Assurance Program (OQAP) that incorporated the methodology for grading quality assurance (QA) based on PRA insights. The STP graded

QA proposal was an extension of the existing regulatory framework.  Specifically, the STP approach continued to use the traditional safety-related categorization, but allowed for gradation of safety significance within the "safety-related " categorization (consistent with 10 CFR Part 50 Appendix B) through use of a risk-informed process.  Following extensive discussions with the licensee and substantial review, the staff approved the proposed revision to the OQAP on November 6, 1997.  Subsequent to NRC's approval, STPNOC identified implementation difficulties associated with the graded QA program.  Despite the reduced QA requirement applied for a large number of SSCs in which the licensee judged to be of low safety significance, other regulatory requirements such as environmental qualification, the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, or seismic continue to impose substantial burdens.  As a result, the replacement of such a low safety significant component needs 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 go beyond the staff's previous approval of graded QA), STPNOC submitted a request, dated July 13, 1999, asking for an exemption from the scope of numerous special treatment regulations (including 10 CFR 50 Appendix B) for SSCs categorized as low safety significant or as non-risk significant.  STPNOC's exemption was ultimately approved by the staff in August 2001 (further discussed in section IV.4).

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

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

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

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

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

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

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

## III. Proposed Regulations.

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

**III.1.0 Categorization of SSCs.**

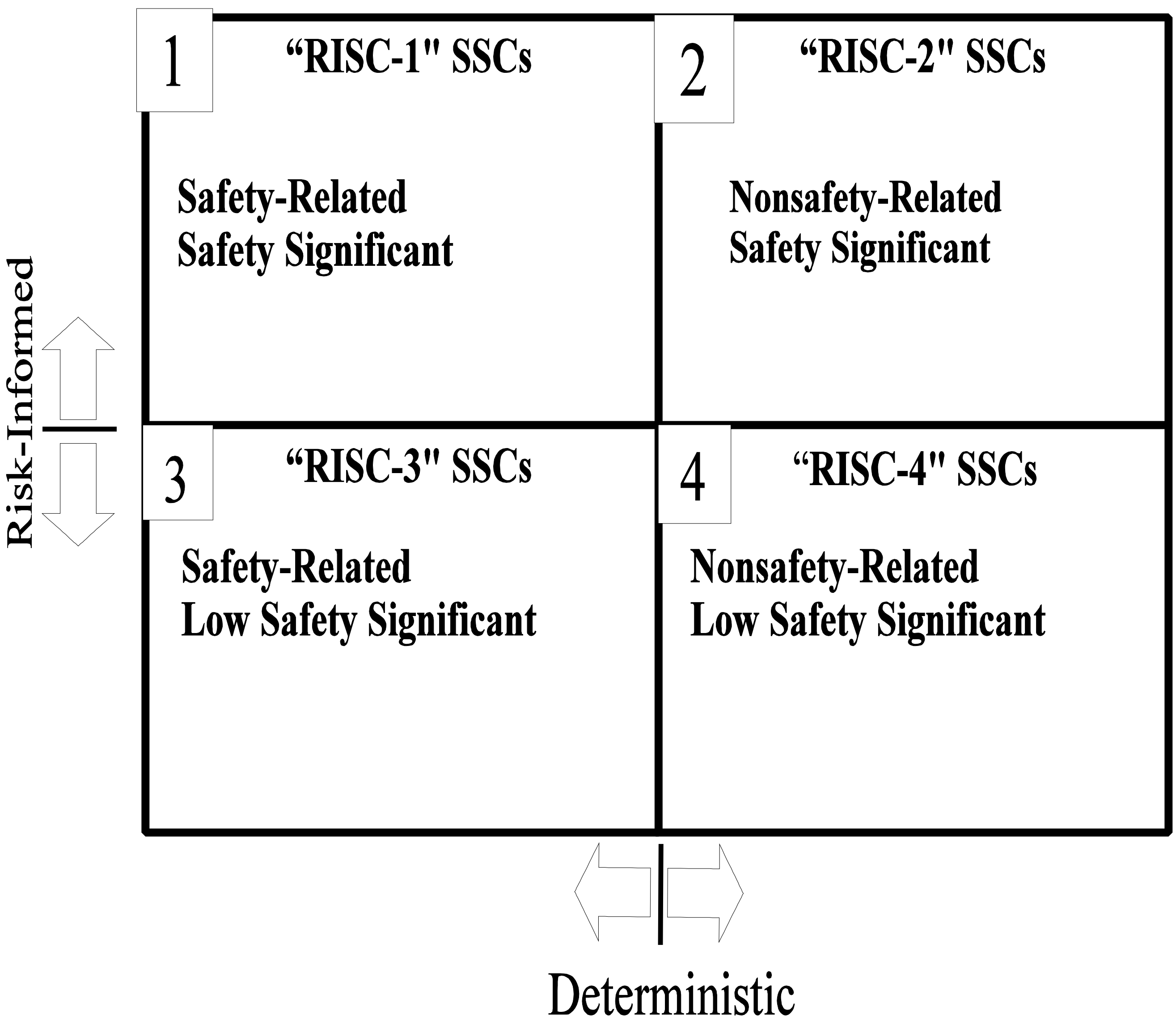
Section 50.69 would define four RISC categories into which SSCs are categorized. Four categories were chosen because it is the simplest approach for transitioning between the previous SSC classification scheme and the new scheme used in the proposed § 50.69. The depiction in Figure 1 provides a conceptual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

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

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

**III.2.0 Methodology for Categorization.**

The cornerstone of proposed § 50.69 is the establishment of a robust, risk-informed



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

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

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

The proposed rule would contain general requirements for consideration of SSCs, modes of operation or 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. As noted in the

ANPR, the Commission could include more requirements in the rule itself, rather than only being in the guidance. Public comment is requested on the merits of placing the additional detail shown in the guidance and discussed in Section V.4 of the Statement of Considerations (SOC) in the rule.

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

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

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

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

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

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

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

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

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

**III.3.0 Treatment Requirements.**

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

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

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

RISC-2 SSCs is consistent with the performance credited in the categorization process. This includes credit with respect to prevention and mitigation of severe accidents. In some cases, licensees might need to enhance the treatment applied to RISC-1 or RISC-2 SSCs to support the credit taken in the categorization process, or conversely adjust the categorization assumptions to reflect actual treatment practices. In addition, requirements exist for monitoring and adjustment of treatment processes (or categorization decisions) as needed based upon performance.

**III.3.2 RISC-3 Treatment.**

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

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

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

In implementing the processes required by the proposed rule, licensees will need to obtain data or information sufficient to make a technical judgement that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions.

These requirements are necessary because they require the licensee to obtain the data necessary to continue to conclude that RISC-3 SSCs remain capable of performing design basis functions, and to enable the licensee to take actions to restore equipment performance consistent with corrective action requirements included in the proposed rule.

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

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

**III.3.3 RISC-4 Treatment**

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

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

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

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

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

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

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

The Commission's regulations implementing Section 206 are set forth in 10 CFR Part 21 and § 50.55(e) for license holders and construction permit holders, respectively. The definitions of "basic component," "defect," and "substantial safety hazard" in Part 21 were established by the Commission based upon the premise that the deterministic regulatory paradigm embedded in the Commission's regulations would continue to be the appropriate basis for determining the safety significance of an SSC, and therefore the extent of the reporting obligation under Section 206. This is most evident in the § 21.3 definition of "basic component," which is very 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 which represent a "substantial safety hazard." Thus, Part 21 limits the reporting requirement to instances of noncompliance and defects representing "substantial safety hazard," which Part 21 defines as:

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

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 defect within five (5) working days of completion of evaluations for determining whether noncompliance or defect 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 would substitute a risk-informed approach for regulating nuclear power plant SSCs for the current deterministic approach. Therefore, it is necessary from the standpoint of regulatory coherence to determine: (1) what categories of SSCs (*i.e.*, RISC-1, RISC-2, RISC-3 and RISC-4) should be subject to Part 21 and § 50.55(e) reporting under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to ensure proper reporting of substantial safety hazards; and (2) the appropriate reporting obligations of licensees and vendors under proposed § 50.69, and whether changes to Part 21 and/or § 50.55(e) are necessary to impose the intended reporting obligations on these entities under proposed § 50.69.

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

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

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

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

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

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

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

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

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

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

For RISC-2 SSCs that provide backup mitigation to RISC-1 SSCs, the Commission also finds it prudent and desirable from a risk-informed standpoint to provide an enhanced level of assurance that RISC-2 SSCs can perform their safety-significant functions, but the failure or malfunction of such RISC-2 SSCs also does not raise a concern about imminent safety hazards.

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

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

necessary to provide adequate protection of public health and safety).

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

The Commission believes that the multiple simultaneous failures of either RISC-2 or RISC-3 components, in the same or in different systems, is not a concern such that Part 21 reporting is necessary. Even for components of the same type, it is not likely that the installed components are identical in terms of their specific characteristics or operating and maintenance history such that a defect would lead to simultaneous failure of multiple components at the same time. For both RISC categories, there are requirements to collect data about performance of the SSCs, to review the data to determine if adverse performance is occurring and to take appropriate action (e.g., correct failures and adjust treatment processes). Thus, it would be expected that degradation or problems affecting a component type would be detected and dealt with before multiple failures becomes likely. For many RISC-2 SSCs, failures tend to be self-revealing (as it is initiation of a transient as a result of failure of many RISC-2 SSC that makes them significant). For RISC-3 SSCs, requirements exist for design and procurement for any replacement components to meet their design conditions, thus making it unlikely that unsuitable components would be installed. Further, for the RISC-3 SSCs, evaluations will be performed, assuming significantly increased failure rates for large number of components occurring simultaneously to show that there is no more than a small (potential) change in risk. Therefore, the Commission believes appropriate regulatory attention has been given to the potential for multiple simultaneous failures.

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

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

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

The Commission also proposes that RISC-3 SSCs should not be subject to Part 21 and § 50.55(e) reporting.  A failure of a properly-categorized RISC-3 SSC should result in, at most,  only a small change in risk, and should not result in a major degradation of essential safety-related equipment (see NUREG-0302, Rev. 1)[2].  As discussed above, the body of regulatory requirements (the retained requirements and the requirements contained in this proposed rule) are sufficient such that simultaneous failures in multiple systems (as would be necessary to lead to a substantial safety hazard involving RISC-3 SSCs) would not occur. Thus, there is little regulatory need for the NRC to be informed of instances of noncompliance and defects with RISC-3 SSCs.  This is consistent with the NRC's current position that a "substantial safety hazard" involves a major degradation of essential safety-related equipment (see NUREG-0302).  Accordingly, the Commission proposes that RISC-3 SSCs should not be subject to reporting requirements of Part 21 and § 50.55(e).

In sum, the Commission proposes that Part 21 reporting requirements should extend only to SSCs classified as RISC-1 SSCs, since these SSCs are those that are important in

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

ensuring public health and safety and minimizing risk. RISC-2 SSCs should not be subject to reporting because play a lesser role than RISC-1 SSC in protection of public health and safety and no regulatory purpose would be served by Part 21 reporting (as discussed above). RISC-3 and RISC-4 SSCs have little or no risk significance and no regulatory purpose would be served by subjecting RISC-3 and RISC-4 SSCS to Part 21 and § 50.55(e).

The Commission does not believe that any changes to Part 21 or § 50.55(e) are necessary to accomplish the Commission's proposals with respect to RISC-2 and RISC-3 SSCs, and that this proposal is consistent with the statutory requirements in Section 206 of the ERA. As discussed above, Section 206 does not contain any definition of "substantial safety hazard," 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 § CFR 21.3 is broadly written to permit the Commission to interpret it as applying, in the context of a risk-informed regulatory approach, only to RISC-1 SSCs. As discussed earlier, § 50.69 embodies a risk-informed regulatory paradigm which is different in key respects from the Commission's historical deterministic approach, and applies the risk-informed approach to classifying a nuclear power plant's SSCs according to the SSC's risk significance. SSCs that are classified as RISC-1 are those that represent the most important SSCs from both a risk and deterministic standpoint: they perform the key functions of preventing, controlling and mitigating accidents and controlling risk. Failure of RISC-1 SSCs represent, from a risk-informed regulatory perspective, the most important and significant safety concerns (i.e., a "substantial safety hazard)." Therefore, the Commission believes that, in the context of the risk-informed regulatory approach embodied in § 50.69, it is reasonable for the Commission to interpret "substantial safety hazard" as applying to RISC-1 SSCs and that reporting under Section 206 may be limited to RISC-1 SSCs.

The Commission considered two alternative approaches for limiting the reporting requirements in Part 21 and § 50.55(e) to RISC-1 SSCs: (i) interpreting "basic component" to encompass a risk-informed view of what SSCs the term encompasses, and (ii) including a second definition of "basic component" in § 21.3, which would apply only to those portions of a plant which have been categorized in accordance with § 50.69, and would be defined as an SSC categorized as RISC-1 under § 50.69.

The Commission does not believe that the Part 21 definition of "basic component" may easily be read as simultaneously permitting both a deterministic concept of basic component and risk-informed concept, inasmuch as the Part 21 definition was drawn from, and was intended to be consistent with the definition of "safety-related SSC" in § 50.2. The § 50.2 definition of "safety-related SSC" refers to the ability of the SSC to remain functional during "design basis events." The term, "design basis events" in Commission practice has referred to the deterministic approach of defining the events and conditions (*e.g*., shutdown, normal operation, accident) for which an SSC is expected to function (or not fail). Identification of design basis events is inherently different conceptually when compared to a risk-informed approach, which attempts to identify all possible outcomes (or a reasonable surrogate) and assign a probability to each outcome and consequence before integrating the probability of the total set of outcomes. The Commission rejected the second approach of adopting an alternative definition of "basic component," because a change to the definition in § 21.3 could be misunderstood as a change to the reporting requirements for licensees who choose not to comply with § 50.69.

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

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

Thus, a vendor who supplied a safety-related component to a licensee that was subsequently classified by the licensee as RISC-3 would no longer be legally obligated to comply with Part 21 or § 50.55(e) reporting requirements. However, as a practical matter that vendor would likely continue to comply with Part 21 or § 50.55(e). Vendors are informed of their Part 21 or § 50.55(e) obligations as part of the contract supplying the basic component to the licensee/construction permit holder. Vendors supplying basic components that have been categorized as RISC-3 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 which they provided under contract as safety-related are now categorized as RISC-3, thereby removing the vendor’s reporting obligation under either Part 21 or § 50.55(e). Failing to inform a vendor that a safety-related SSC which it provided is no longer subject to Part 21 or § 50.55(e) reporting because of its reclassification as a RISC-3 SSC could result in unnecessary reporting to the licensee and the NRC. It may also result in unnecessary expenditure of resources by the vendor in determining whether a problem with a supplied SSC rises to the level of a reportable defect or noncompliance under the existing provisions of Part 21 and § 50.55(e).

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

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

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

> For the purposes of this subsection, the term "basic component" means a facility structure, system, component or part thereof necessary to assure--
>
> (1) the integrity of the reactor coolant pressure boundary,
>
> (2) the capability to shut-down the facility and maintain it in a safe shut-down condition, or
>
> (3) the capability to prevent or mitigate the consequences of accidents which could result in an unplanned offsite release of quantities of fission products in excess of the limits established by the Commission.

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 would be removed from the scope of the requirements of § 50.49 through § 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 section § 50.49 for testing, documentation files and application of margins, are not necessary (see Section III.4.0).  The requirements from GDC-4 as they relate to RISC-3 and RISC-4 SSCs, and the design basis requirements for these SSCs, including the environmental conditions such as temperature and pressure, remain in effect.  Thus, these SSCs must continue to remain capable of performing their safety-related functions under design basis environmental conditions.

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

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

Section 50.55a(f) incorporates by reference provisions of the ASME Code as endorsed by NRC that contains inservice testing requirements. These are special treatment requirements. Through this proposed rulemaking, RISC-3 SSCs would be removed from the scope of these requirements, and instead would be subject to the requirements in § 50.69(d)(2)(iii). For the reasons discussed in section III.4.0, the Commission has determined that for low safety-significant SSCs, it is not necessary to impose the specific detailed provisions of the Code, as endorsed by NRC, and these requirements can be replaced by the more "high-level" alternative treatment requirements, which allow greater flexibility to licensees in implementation.

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

Section 50.55a(h) incorporates by reference the requirements in either Institute of Electrical and Electronics Engineers (IEEE) 279, "Criteria for Protection Systems for Nuclear

Power Generating Stations," or IEEE 603-1991 "IEEE Standard Criteria for Safety Systems for Nuclear Power Generating Stations." Within these IEEE standards are special treatment requirements. Specifically, sections 4.3 and 4.4 of IEEE 279 and sections 5.3 and 5.4 of IEEE 603-1991 contain quality and environmental qualification requirements. RISC-3 SSCs are being removed from the scope of this special treatment requirement consistent with the Commission decision already discussed.

**III.4.4 Section 50.65 Monitoring the Effectiveness of Maintenance**.

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

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

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

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

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

**III.4.5   Sections 50.72 and 50.73 Reporting Requirements**.

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

Sections 50.72 and 50.73 contain requirements for licensees to report events involving certain SSCs.  These reporting requirements are special treatment requirements .  NRC requires event reports in part so that it can follow-up on corrective action for these circumstances.   Through this rulemaking, the Commission proposes to remove RISC-3 and

RISC-4 SSCs from the scope of these requirements. The low safety-significance of these SSCs does not warrant the burden associated with reporting events or conditions only affecting such SSCs, for the reasons already discussed.   In particular, under NRC's risk-informed inspection process, NRC follow-up of corrective action will be focused upon safety-significant situations.

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

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

The intent of Appendix B 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 apply to safety-related SSCs.  In the implementation of Appendix B, a licensee is bound to detailed and prescriptive quality requirements to apply to activities affecting those SSCs.  As such, these requirements meet the Commission's definition of special treatment requirements. These requirements are removed from application to RISC-3 and RISC-4 SSCs because their low safety-significance does not warrant the level of quality requirements that currently exist with

Appendix B.

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

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

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

The discussion contained in Appendix J to 10 CFR 50 can be divided into two categories. Parts of Appendix J contain testing requirements. Other parts contain information, such as definitions or clarifications, necessary to explain the testing requirements. A review of Appendix

J did not identify any technical requirements other than those describing the methods of the required testing. Therefore, Appendix J was considered to be, in its entirety, a special treatment requirement.

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

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

**III.4.7.1 Types of Tests Required by Appendix J.**

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

C tested are identified in Appendix J.

**III.4.7.2 Reduction in Scope for Appendix J Testing.**

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

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

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

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

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

**III.4.7.3 Basis for Reduction of Scope**.

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

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

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

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

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

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

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

would leak because containment penetrations typically have redundant isolation valves. While one valve may leak, the other may remain leak-tight. The study assumed that failure of one valve in a series failed the penetration; however, the probability of failure was that for a single valve.

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

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

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

The proposed rule would remove RISC-3 and RISC-4 SSCs from the requirement in Appendix A to Part 100 to demonstrate that SSCs are designed to withstand the safe shutdown earthquake (SSE) by qualification testing or specific engineering methods. GDC 2 requires that SSCs "important to safety" be capable of withstanding the effects of natural phenomena such as earthquakes. The requirements of 10 CFR Part 100 pertain to reactor site criteria and its Appendix A addresses seismic and geologic siting criteria used by the Commission to evaluate suitability of plant design bases in consideration of these characteristics. Sections VI(a)(1) and (2) of Appendix A to 10 CFR Part 100 address the engineering design for the SSE and Operating Basis Earthquake (OBE), respectively. The rule change would exclude RISC-3 and RISC-4 SSCs from the scope of the requirements of sections VI(a)(1) and (2) of Appendix A to 10 CFR Part 100, only to the extent that the rule requires testing and specific types of analyses to demonstrate that safety-related SSCs are designed to withstand the SSE and OBE. It is only these aspects of Appendix A to 10 CFR Part 100 that are considered special treatment. As discussed in Section III.4.0, because of the low safety significance of the RISC-3 and RISC-4 SSCs, the additional assurance provided by qualification testing (or engineering analyses) is not considered necessary.

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

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

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

**III.4.9.1 Section 50.34 Contents of applications.**

Section 50.34 identifies the required information that applicants must provide in preliminary and final safety analysis reports. 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.4.9.2 Section 50.36 Technical specifications**.

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

**III.4.9.3 Section 50.44 Combustible Gas Control**.

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

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

Initially, fire protection requirements were considered to be within the scope of this rulemaking effort. There are augmented quality provisions applied to fire protection systems and these augmented quality provisions are considered special treatment requirements. However, these provisions are not contained in the rules themselves. The Commission has developed a proposed rulemaking (see November 1,2002, 67 FR 66578) to allow licensees to voluntarily adopt National Fire Protection Association (NFPA)-805 requirements in lieu of other fire protection requirements. NFPA-805 would permit a licensee to implement a risk-informed fire protection program as a voluntary alternative to compliance with § 50.48 and 10 CFR Part 50, Appendix R. Accordingly, changes to these regulations were not included in the scope of the § 50.69 rulemaking.

**III.4.9.5 Section 50.59 Changes, Tests and Experiments**.

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

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

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

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

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

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

**III.4.9.8 10 CFR Part 54 License Renewal**.

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

In SECY-00-0194, the NRC staff provided its preliminary view that RISC-3 SSCs should not be removed from the scope of Part 54, and that licensees can renew their 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 prior to renewing a licensing or after license renewal.

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

The use of risk in establishing the scoping criteria within Part 54 was addressed by the Commission on May 8,1995 (60 FR 22461), when amending Part 54. In the 1995 amendment, the Commission stated that the current licensing basis for current operating plants is largely based on deterministic engineering criteria. Consequently, there was considerable logic in establishing license renewal scoping criteria that recognized the deterministic nature of a plant's licensing basis. Without the necessary regulatory requirements and appropriate controls for plant-specific PRAs, the Commission concluded that it was inappropriate to establish a license renewal scoping criterion that relied on plant-specific probabilistic analyses. Therefore, the

Commission concluded further that within the construct of the final rule, PRA techniques were of very limited use for license renewal scoping (60 FR 22468).

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

**III.4.9.9 Other Requirements**.

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

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

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

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

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

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

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

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

**III.6.0 Implementation Process Requirements.**

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

The Commission is making the provisions of § 50.69 available to both applicants for licenses or design certification rules and to holders of facility licenses for light-water reactors.

The proposed rule would be limited to light-water reactors because it was developed to risk-inform the scope of special treatment requirements which are applied to light-water reactors. Consequently, the technical aspects of the rule (e.g., providing reasonable confidence that risk increases (e.g.,changes in CDF and LERF are small) including the implementation guidance, are specific to light-water reactor designs.

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

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

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

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

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

**III.7.0 Adequate Protection.**

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

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

(2) Defense-in-depth is maintained;

(3) Safety margins are maintained; and

(4) Monitoring and performance assessment strategies are used.

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

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

**III.7.1 Net Increase in Risk is Small.**

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

**III.7.2 Defense-in-Depth is Maintained.**

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

**III.7.3. Safety Margins are Maintained**.

Proposed § 50.69 maintains sufficient safety margins by a combination of: (1) maintaining all existing functional and treatment requirements on RISC-1 and RISC-2 SSCs and additionally ensuring that any credit for these SSCs for beyond design basis conditions is valid and maintained; (2) maintaining the design basis of the facility for all SSCs, including RISC-3 SSCs as described above; and (3) requiring a licensee to have reasonable confidence that the overall increase in risk that may result due to implementation of proposed § 50.69 is small.

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

**III.7.4 Monitoring and Performance Assessment Strategies are Used**.

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

**III.7.5 Summary and Conclusions.**

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

## IV. Public Input to the Proposed Rule

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

The Commission published an ANPR (March 3, 2000; 65 FR 11488) to solicit public input on the direction and scope of this rulemaking. A number of comments were received. The NRC staff provided its preliminary responses to the issues raised by the commenters in SECY-00-194, dated September 7, 2000. The Commission has considered these issues in developing the proposed rule. More detailed discussion of the comments and the Commission's preliminary positions are contained in a separate document (see Section X, Availability of Documents). A summary of some of the more substantive issues follows.

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

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

**IV.1.2 Treatment Attributes.**

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

**IV.1.3 Selective Implementation.**

The Commission received a number of comments on selective implementation, both during the ANPR process and later. The Commission concludes that selective implementation of § 50.69 should be allowed to permit a licensee/applicant to depart from compliance with a limited set of the special treatment rules delineated in § 50.69(b)(1). This topic is discussed further in section V.5.1. Because of the existing requirements that would remain in place, a licensee could choose not to revise requirements for all of the rules within the scope of § 50.69(b). However, there is no selective implementation for the overall requirements in § 50.69. Thus for example, a licensee could not elect to adopt paragraph (b)(1) and not (d)(2).

The other question was whether selective implementation with respect to the scope of SSCs to be categorized should be allowed. The Commission has determined that selective implementation on a system basis should be allowed, but not for components within a system. The rule includes specific language about this limitation. This required scope ensures that all safety functions associated with a system or structure are properly identified and evaluated when determining the safety significance of individual components within a system or structure and that the entire set of components that comprise a system or structure are considered and addressed. As further discussed in section III.2, the implementation, including the categorization process must address an entire system or structure, not selected components within a system.

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

**IV.2.0 Draft Rule Comments.**

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

Many of the comments received related to the way in which the high-level treatment requirements for RISC-3 SSCs were organized and worded.  Based upon these comments, the NRC reduced the number of separate subsections (from 8 to 4), and simplified the wording by removing duplication of phrases.  Suggested simplifications that were accepted were the deletion of details of the types of maintenance (corrective, predictive), and deletion of the words "design inputs."   Some stakeholders, such as the NEI, stated that the requirements were overly prescriptive and were not consistent with the concept of removing SSCs from the scope of NRC special treatment requirements.  The issue about level of detail is the topic that drew the most comment during the draft rule language process.  At the same time, comments and input from other stakeholders (including the Advisory Committee on Reactor Safeguards (ACRS), were resulting in strengthening of the categorization process such that any individual SSC categorized as RISC-3 is of very low safety significance.  Specific consideration was also added in the rule requirements to deal with potential common-cause failures.  Based upon this evolution, concerns about prescriptiveness as stated in these comments led the Commission to simplify the requirements on treatment for RISC-3 SSCs.

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

Other comments proposed that the scope of rules being removed should be expanded to include the requirements in § 50.55a (ASME code requirements), and Appendix A to Part 100. Rule language was added to accomplish this by listing specific subsections of § 50.55a and Appendix A to Part 100 in the list of requirements removed, and through other changes to the rule designed to maintain the necessary reliability of SSCs. The ASME provided comments on the draft rule language stating that the risk-informed Code Cases and Standards developed by ASME should not be directly referenced in the rule, but that there should be a framework developed to ensure that the Code Cases are used, and that partial use does not occur. The proposed rule permits, but does not require, use of the Code Cases for purposes of meeting rule requirements. The Commission notes that these Code Cases cover both categorization and treatment requirements in the areas of inservice inspection, inservice testing, and repair/replacement. The Commission expects licensees will utilize the ASME Code Cases as part of their implementation of § 50.69.

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

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

**IV.3.0 Pilot plants.**

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

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

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

- Potential treatment changes and their potential effects need to be understood by the IDP as part of the deliberations on categorization.
- The pilots showed the importance of documentation of the IDP decisions and the basis. The rule contains a requirement for the categorization basis to be documented (and records retained) in § 50.69(f).
- The pilots experienced difficulty in explicit consideration about safety margins, especially in view of the fact that functionality must be retained. In the first draft rule language posted, requirements were included for the IDP to consider safety margins in its deliberations. Based upon the pilot experience, NRC adjusted its approach to margins to include this in the section of the rule that requires consideration of effects of changes in treatment and the use of evaluations as the means of providing reasonable confidence safety margins are maintained.
- The need for a number of improvements to the implementation guidance in NEI 00-04 were noted, for instance, improvement in a defense-in-depth matrix presented therein, and the need for more specific guidance on making decisions where quantitative information is not available. These lessons-learned were factored into the revised version of NEI 00-04.
- During the pilot activity, pressure boundary ("passive") functions were also categorized using the draft version of an ASME Code Case on categorization available at that time. A separate categorization process was used for these passive functions because it was recognized by pilot participants that the approach for these SSCs must be somewhat different than for "active" functions

because of such considerations as spatial interaction. Specifically, if a pressure boundary SSC failed, the resulting high-energy release or flooding might impact other equipment in physical proximity, so the process needed to account for those effects in addition to the significance of the SSC that initially failed. Improvements to the ASME Code Case for categorization of piping (and related components) were identified and fed back into the code development process.

- The pilot experiences also revealed the intricacies of the relationship between "functions" (which play a role in decisions on safety significance) and "components" (importance measures are associated with components and treatment is also generally applied on a component basis). Because a particular component may support more than one function, the categorization of the component needs to correspond with the most significant function and means must be provided for a licensee to "map" the components to the functions they support.
- At each pilot, the NRC noted that the IDP needed to include consideration of long term containment heat removal in characterizing SSCs. The NRC considers retention of long term containment heat removal capability important to defense-in-depth for light water reactors.
- Finally, a number of lessons were learned about how to conduct the IDP process, such as training needs, materials to be provided to the panel, etc. As a result of this feedback, NEI revised NEI 00-04 and developed draft revision C of the implementation guidance (discussed in section VI).

**IV.4.0 South Texas Exemption as Proof of Concept.**

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

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

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

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

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

## V. Section by Section Analysis

**V.1.0 Section 50.8 Information Collection**.

This proposed rule includes a revision to § 50.8(b). This section pertains to approval by the Office of Management and Budget (OMB) of information collection requirements associated with particular NRC requirements. 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 XIII of the SOC for discussion about information collection requirements of § 50.69.

**V.2.0 Section 50.69(a) Definitions.**

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

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

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

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

**V.3.0 Section 50.69(b) Applicability.**

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

(1) Holders of § 50.21(b) or § 50.22 light water reactor (LWR) operating licenses;

(2) Holders of Part 54 renewed LWR licenses;

(3) A person seeking a design certification under Part 52 of this chapter; or

(4) Applicants for a LWR license under § 50.22 or under Part 52.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 50.69(b)(3) would further provide that the Commission will approve a licensee's implementation of this section by license amendment 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) would require that an applicant for a license (or for a design certification) that chooses to implement proposed § 50.69 must submit the information listed in

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

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

Section 50.69(c) would establish the requirements for the risk-informed categorization process including requirements for the supporting PRA.  Licensees or applicants who wish to adopt the requirements of § 50.69 will need to make a submittal (per § 50.69(b)(2) or § 50.69(b)(4)) that discusses how their proposed categorization process, supporting PRA, and evaluations meet the § 50.69(c) requirements.  As described above in section III.2.0, these requirements are intended to ensure that the risk-informed § 50.69 categorization process determines the safety significance of SSCs  with a high level of confidence.  The introductory paragraph states that SSCs must be categorized as RISC-1, 2, 3, or 4 by a process that 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. How this is to be accomplished is discussed in section V.4.1.1. The PRA and associated sensitivity studies are used primarily in the categorization of the SSCs as to their safety significance as discussed in section V.4.1.2, and the PRA is also used to perform evaluations to assess the potential risk impact of the proposed change in treatment of the RISC-3 SSCs as discussed in section V.4.4.

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

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

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

**V.4.1.2  Risk Categorization Process Based on PRA Information.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Prevent or mitigate accident conditions,

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

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

(4) Maintain containment integrity, or

(5) Allow monitoring of post-accident conditions.

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

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

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

**V.4.2.2 SSCs not Modeled in the PRA.**

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

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

(2) Failure of the SSC will compromise the integrity of the reactor coolant pressure

boundary. It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

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

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

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

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

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

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

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

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

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

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

- The categorization is consistent with the defense-in-depth philosophy (per section V.4.3 below).
- Operating experience indicates that degradation mechanisms (e.g., for piping flow accelerated corrosion or microbiologically-induced corrosion), for passive and active SSCs are not present, relaxing the requirements will have minimal impact on the failure rate increase, and degradation in the ability of the SSC to perform its safety function can be detected in a timely fashion.
- Relaxing the requirements will have a minimal impact on the expected onsite occupational or offsite doses from transients and accidents that do not contribute to CDF or LERF.

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

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

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

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

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

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

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

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

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

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

The treatment for all RISC-3 SSCs may not need to be the same.  As an example, motor operated valves (MOVs) operating in a severe environment (e.g., in the steam tunnel) would be more susceptible to failure because of grease degradation if they were not regularly maintained and tested.  However, not all MOVs, even if they have the same design and are identical in other respects, will be exposed to the same environment.  Therefore the other

MOVs may not be as susceptible to failure as those in the steam tunnel and less frequent maintenance and testing would be acceptable. While it may be simpler to increase the unreliability or unavailability of all the RISC-3 SSCs by a certain bounding factor to demonstrate that the change in risk is small and acceptable, the above example suggests that it may also be appropriate to use different factors for different groups of SSCs depending on the impact of reducing treatment on those SSCs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The categorization process assumes that the functionality of SSCs in performing their safety functions will be retained, although the treatment applied to RISC-3 SSCs may be reduced under proposed § 50.69. Further, the categorization process may include specific reliability assumptions for plant SSCs in performing their intended functions. Therefore, when establishing the performance-based treatment process for RISC-3 SSCs, the licensee should take these assumptions into account to support the evaluations of small increase in risk resulting from implementation of the changes in treatment. It is important to obtain sufficient information on SSC performance to allow the results of the categorization process to remain valid. The Commission considers the risk-informed, performance-based ASME Code Cases (as endorsed in § 50.55a) to be one acceptable method of establishing treatment processes that are consistent with the categorization process.

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

The Commission notes that use of voluntary consensus standards is an effective means of establishing treatment requirements to achieve functionality. As an example, ASME risk-informed Code Cases have been developed with the purpose of determining appropriate treatment requirements for low safety-significant SSCs in their specific functional areas. Further, the Commission expects that related standards (such as ASME Code Cases N-658 and N-660 on SSC categorization and treatment for purposes of repair and replacement) be used in conjunction with each other as intended by the accredited standards writing body. Where suitable standards do not exist or available standards are not sufficient, the Commission expects the licensee to establish sufficient controls to provide reasonable confidence in the functionality of RISC-3 SSCs, based upon such factors as operating experience and vendor recommendations. However, the Commission also notes that use of a voluntary consensus standard in and of itself might not be sufficient to maintain functionality for particular SSCs under certain service conditions, and that the licensee might need to supplement its processes to achieve the desired results.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Engineering Analysis - In cases involving substantial differences between the procured

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

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

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

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

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

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

With respect to RISC-3 pumps and valves, the Commission expects licensees to implement periodic testing or inspection, and evaluation of performance data, sufficient to provide reasonable confidence that these pumps and valves will be capable of performing their safety function under design basis conditions. To determine that SSC will remain capable until the next scheduled activity, a licensee would have to obtain sufficient operational information or performance data to provide reasonable confidence that the RISC-3 pumps and valves will be capable of performing their safety function if called upon to function under operational or design basis conditions over the interval between periodic testing or inspections. A licensee may develop the type and frequency of the test or inspection for RISC-3 pumps and valves where sufficient to conclude that the pump or valve will perform its safety function. These tests or inspections may be less rigorous and less frequent than those performed on RISC-1 pumps and valves. For example, a licensee might establish more relaxed criteria for grouping of similar RISC-3 components, or might apply less stringent test acceptance criteria for RISC-3 pumps and valves, than specified for RISC-1 components. The licensee could apply staggered test intervals for the RISC-3 components to provide confidence that the relaxed grouping or acceptance criteria had not resulted in SSC performance that is inconsistent with the categorization process or its assumptions. Licensees should note that performance data obtained for pumps and valves operating under normal conditions may not be capable of predicting their capability to perform safety functions under design basis conditions without additional evaluation or analysis. This does not mean that pumps and valves must be tested or inspected under design basis conditions. Methods exist for collecting performance data at conditions different than design basis conditions that can be used to reach conclusions regarding the design basis capability of components. Examples of such methods are described in Regulatory Guide 1.175, *An Approach for Plant-Specific, Risk-Informed Decision making: Inservice Testing*, and applicable risk-informed ASME Code Cases (e.g., OMN-1, OMN-4, OMN-7, OMN-12) as accepted by 10 CFR 50.55a.

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

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

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

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

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

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

Commission expects licensees to monitor all functional failures (i.e., not just maintenance preventable unavailabilities and failures as is currently required by § 50.65) so that they can determine when adjustments are needed. Licensee monitoring programs will also need to include the monitoring of SSCs that support beyond design basis functions (if applicable) that are not necessarily included in the scope of an existing maintenance rule monitoring program.

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

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

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

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

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

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

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

Once the NRC has completed its review of a licensee's § 50.69 submittal as it relates to categorization, the licensee or applicant would be able to adjust its treatment processes provided that the rule requirements are met. NRC does not plan to perform a pre-implementation review of the revised treatment requirements under § 50.69(d). However, the Commission recognizes that existing information in the quality assurance (QA) plan or in the FSAR may need to be revised to reflect the changes to treatment that would be made as a result of implementation of § 50.69. Any revisions to these documents are to be submitted in accordance with the existing requirements of § 50.54(a)(2) and § 50.71(e) respectively. For instance, § 50.71(e) states that the FSAR is to contain the latest information developed and is to reflect information submitted to the Commission since the last update. The regulations further state in the cited sections how a licensee is to submit to the NRC revisions to the QA plan or to the FSAR. Information in these documents that would no longer be accurate upon implementation of § 50.69 must be updated. Details of the processes would be expected to be contained in plant procedures, procurement documents, surveillance records, etc.

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

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

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

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

**V.8.0 Section 50.69(g) Reporting**.

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

## VI. Other Topics for Public Comment

**VI.1.0 Additional potential requirements for public comment**.

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

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

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

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

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

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

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

**VI.2.0 Questions for public input.**

In addition to seeking comment on the proposed rule and its supporting documents, the Commission is also specifically seeking public comment on the following questions. Comments should be submitted as noted in the ADDRESSES section of this notice.

**VI.2.1 PRA requirements**

The proposed rule requires as a minimum, a PRA that includes internal events, at power, which has been subjected to a peer review process. The PRA (for that scope) must be capable of determining both CDF and LERF (i.e., provide level 2-type results). Proposed § 50.69 allows licensees to use non-PRA methods to address other modes and hazards in the categorization process (see in particular NEI 00-04 and DG-1121). The proposed rule requires the licensee to submit information about its PRA and these other methods, including information about the quality and level of detail about all of the methods to be used.

The Commission is seeking comment as to 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. Thus, instead of employing other methods to account for the contribution from modes and events not modeled in the PRA, this more comprehensive PRA would allow for quantification of the contribution from these scenarios. This approach would involve substantive changes in the implementing guidance as well. The Commission is interested in both the benefits of this approach as well as any implications for this specific application of risk insights. The Commission is also seeking comment on whether a different set of PRA requirements, from either of the alternatives described above, should be required for this application.

**VI.2.2 Review and approval of treatment for RISC-3 SSCs**

In the proposed rule, the Commission is proposing to review and approve the categorization process to be used by the licensee. For treatment requirements, the proposed rule sets forth high-level requirements, and does not require NRC review and approval of specific processes a licensee would implement to meet these requirements. Another way to structure the rule would be to require NRC review and approval of the licensee's proposed treatment program for RISC-3 SSCs. The Commission is interested in any benefits of this approach as well as any implications for this rulemaking and its associated guidance.

**VI.2.3 Inspection and enforcement.**

As discussed above, the Commission recognizes that the final rule may have implications with respect to NRC's reactor oversight process including the inspection program, and enforcement. In its final decision on this rulemaking, the Commission proposes to document its conclusions as to whether or not new or revised inspection or enforcement guidance is necessary. Public comment is requested on whether or not changes are needed in our inspection and enforcement programs to enable NRC to exercise the appropriate degree of regulatory oversight of these aspects of the facility operation.

**VI.2.4 Operating experience**.

One of the areas of uncertainty associated with this rulemaking has been the potential effects of changes in treatment on SSC reliability and common-cause failure potential. This is reflected in the requirement for evaluations (sensitivity studies) to provide reasonable confidence that any potential increase in risk would be small, with a basis provided for the factors to be assumed in these evaluations. Further, the rule requires the licensee to consider performance information to determine whether there are any adverse changes such that SSC unreliability values approach the values used in these evaluations, and to make necessary adjustments to the categorization and treatment processes.  As discussed in Section VII.2, below, draft RG (DG-1121) provides some discussion about techniques that might be used in determining the factors for these evaluations.  The Commission is interested in the role that relevant operational experience could play in reducing the uncertainty associated with the effects of treatment on performance and specifically seeks public comment as to what information might be available and how  it could be used to support implementation of this rulemaking.

## VII.  Guidance

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

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

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

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

The NRC has prepared a draft regulatory guide DG-1122, “An Approach for Determining the Technical Adequacy of Probabilistic Risk Assessment Results for Risk-Informed Activities.” This guide provides guidance on the NRC position on voluntary consensus standards for PRA (in particular on the ASME standard for internal events PRAs) and industry PRA documents (e.g., NEI 00-02, “Probabilistic Risk Assessment Peer Review Process Guideline”). 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 whether a PRA providing results being used in a decision is technically adequate.

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

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

## VIII. Criminal Penalties

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

## IX. Compatibility of Agreement State Regulations

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

## X. Availability of Documents

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

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

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

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

| Document | PDR | Web | PERR |
|---|---|---|---|
| Comments on the ANPR | X | X | Available |
| Comments on the draft rule language | X | X | Available |
| ANPR Comment Resolution | X | X | ML022630030 |
| Environmental Assessment | X | X | ML022630050 |
| Regulatory Analysis | X | X | ML022630028 |
| OMB Supporting Statement | X | X | ML031000685 |
| Industry Implementation Guidance | X | X | ML021910534 |
| Draft Regulatory Guide | X | X | ML022630041 |

## XI. Plain Language

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

## XII. Voluntary Consensus Standards

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

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

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

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

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

## XIV. Paperwork Reduction Act Statement

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

The burden to the public for these information collections is estimated to average 1032 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in the proposed rule and on the following issues:

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

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

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

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

## Public Protection Notification

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

## XV. Regulatory Analysis

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

## XVI. Regulatory Flexibility Certification

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

## XVII. Backfit analysis

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

## List of Subjects in 10 CFR Part 50

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

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

## PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

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

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

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

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

§ 50.8 Information collection requirements: OMB approval.

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

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

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

(a) *Definitions.*

*“Risk-Informed Safety Class (RISC)-1 structures, systems, and components (SSCs)*” means safety-related SSCs that perform safety-significant functions.

*“Risk-Informed Safety Class (RISC)-2 structures, systems and components (SSCs)*”

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

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

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

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

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

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

(i) 10 CFR Part 21.

(ii) 10 CFR 50.49.

(iii) 10 CFR 50.55(e).

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

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

(vi) 10 CFR 50.72.

(vii) 10 CFR 50.73.

(viii) Appendix B to 10 CFR Part 50.

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) The Commission will approve a licensee's implementation of this section 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 for a license voluntarily choosing to implement this section shall include the information in § 50.69 (b)(2) as part of application for a license. The Commission will approve an applicant's implementation of this section 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 whether an SSC performs one or more safety-significant functions and identifies those functions. The process must:

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

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

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

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

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

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

(d) *Alternative treatment requirements*.

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

(2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout their service life. The processes must meet the following requirements, as applicable:

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

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

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

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

(e) *Feedback and process adjustment*.

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

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

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

categorization or treatment processes so that the categorization process and results are maintained valid.

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

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

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

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

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

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

Dated at Rockville, Maryland this 6th day of May 2003

For the Nuclear Regulatory Commission.

***/RA/***

Annette L Vietti-Cook,

Secretary of the Commission.