POLICY ISSUE
INFORMATION

September 7, 2000 SECY-00-0194

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: RISK-INFORMING SPECIAL TREATMENT REQUIREMENTS

PURPOSE:

To inform the Commission of

1. Our preliminary views on the comments received on the advance notice of proposed rulemaking (ANPR) for risk-informing special treatment requirements (65 FR 11488).

2. Our approach for implementing the rulemaking plan described in SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," dated October 29, 1999.

SUMMARY:

We have completed our initial review of the public comments received in response to the ANPR. In general, the comments are supportive of the efforts to risk-inform the special treatment requirements and to establish rules for voluntary use by power reactor licensees. Our final response to the ANPR comments will be included as part of the proposed rulemaking.

We have developed a preliminary framework for our approach to implement the rulemaking. In this approach, structures, systems, and components (SSCs) that are categorized as safety-significant will remain subject to the special treatment requirements as currently implemented, with the possible imposition of additional requirements for the safety significant attributes not addressed by existing requirements. SSCs of low safety significance would be removed from the scope of the special treatment requirements. However, since the functional capability of

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these SSCs must be maintained in this rulemaking, minimum requirements that reflect the low safety significance of these SSCs need to be established to maintain their functional capability, albeit at a level of assurance that is less than that provided by the existing special treatment requirements. In support of this approach, we are (1) conducting a study to better understand the various plant processes and practices applied to safety-related and non-safety-related SSCs at a number of facilities, (2) continuing to review the related South Texas Project Nuclear Operating Company (STPNOC) exemption request, and (3) planning to carry out a pilot program at several other plants.

BACKGROUND:

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, we recommended that risk-informed approaches to the application of special treatment requirements be developed. 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. The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999.

In SECY-99-256, we discussed the identification and control of attributes requiring special treatment for the various categories of SSCs, and developed a new term, "risk-informed safety class" (RISC), for use in applying risk insights to the special treatment requirements. SSCs classified as safety-related and determined by a risk-informed categorization process as safety significant would be categorized as RISC-1. SSCs not classified as safety-related but determined to be safety significant would be categorized as RISC-2. SSCs classified as safety-related but determined to be of low safety significance would be categorized as RISC-3. SSCs not classified as safety-related and determined to be of low safety significance would be categorized as RISC-4. A new rule, 10 CFR 50.69, would specify the appropriate treatment requirements for each category. A new appendix to Part 50, Appendix T, would provide the requirements for categorizing the SSCs on the basis of their safety significance. The Commission approved the rulemaking plan, including issuance of an ANPR, in an SRM dated January 31, 2000.

On July 13, 1999, STPNOC submitted a request for exemption from some of the special treatment requirements contained in 10 CFR Parts 21, 50, and 100 for SSCs determined by the licensee's risk assessment to be of low safety significance. We are addressing the STPNOC exemption request in conjunction with the Option 2 rulemaking effort.

DISCUSSION:

We consider the views presented in this paper and its attachment to be preliminary and subject to change on the basis of stakeholder input and further staff evaluation during the rulemaking process.

ANPR Comments

The ANPR published in the *Federal Register* (65 FR 11488) on March 3, 2000, provided a summary of the rulemaking plan, a description of the Commission's approach, and a discussion of issues that represented significant challenges to completing the rulemaking. The ANPR posed specific questions to provide guidance on the type of information the Commission was seeking. The Commission provided a 75-day comment period, which ended on May 17, 2000.
In response to the ANPR, the Commission received 11 comment letters, including more than 200 comments, from six industry groups, two law firms, one consulting firm, one professional society, and one member of the public.

We have performed an initial review of the comments, which are grouped into eight topics: (1) selective implementation, (2) impact on other regulations, (3) need for prior NRC review, (4) identification and control of attributes requiring special treatment, (5) probabilistic risk assessment (PRA) quality appropriate to Option 2 applications, (6) approach, (7) pilot program, and (8) 10 CFR Part 21, "Reporting of Defects and Noncompliance." Although we have not yet finalized our positions on these issues, we are presenting our preliminary views to provide an indication of the direction that we are considering while developing the proposed rule. Tables of the summarized comments and our preliminary responses are provided in the attachment. We will finalize our responses to the ANPR comments as part of the proposed rulemaking.

1. Selective Implementation: Commenters indicated that selective implementation should be allowed by rule and by system and that no limits should be established for selective implementation.

   We agree that selective implementation should be allowed for rules, provided that no exemptions would be required. However, we disagree that there should be unlimited flexibility with respect to selective implementation for systems. We believe that licensees should, at a minimum, address all RISC-1 and RISC-2 SSCs.

2. Impact on Other Regulations: Commenters did not identify any impacts and indicated that the potential impacts discussed in the ANPR (e.g., Part 54 and 55) should not prevent risk-informing the affected rules. For Part 54, commenters suggested that license renewal could become more efficient since the impact of aging on SSCs of low safety significance would not need to be evaluated.

We disagree that RISC-3 SSCs should be removed from the scope of Part 54. We believe that licensees that implement Option 2 can renew their licenses in accordance with Part 54 by demonstrating that the treatment applied in accordance with §50.69 provides adequate aging management under Part 54.21.

3. Need for Prior NRC Review: Some commenters suggested that we proceed with a no-prior-review approach, while others indicated that some review should be required. Commenters suggested that the new Appendix T included in the ANPR is too detailed, prescriptive, and burdensome, even for the no-prior-review approach. Commenters suggested that it would be more appropriate to relocate the detail to a regulatory guide or a guidance document to provide flexibility in implementation.

   Our objective continues to be the development of an approach that either entails no prior NRC review and approval, or minimizes the level of prior review involved. An advantage to this approach is that a change control process would not be needed provided any changes continue to meet the requirements of Appendix T. We believe that a relatively detailed Appendix T is required in order to support this approach. However, we are also evaluating other approaches that involve more prior staff review and less detailed requirements in Appendix T.

4. Identification and Control of Attributes Requiring Special Treatment: Commenters suggested that additional treatment for the safety-significant attributes be determined by licensees and should rely, to the extent possible, on existing licensee programs. They also suggested that the combination of the additional treatment (as determined by the licensees), the monitoring requirements of the maintenance rule, and the periodic PRA updates should be sufficient to ensure that the reliability and availability of SSCs are consistent with those assumed in the PRA. Commenters also asserted that existing licensee programs provide sufficient treatment to maintain functionality of SSCs of low safety significance.

   We are still developing our position on the treatment requirements for this rulemaking. Our conceptual approach is discussed below in the “Treatment” section under “Option 2 Rulemaking Approach.”

5. PRA Quality Appropriate to Option 2 Applications: Some commenters suggested that the regulations not identify consensus PRA standards as the only acceptable methods for establishing PRA quality. Commenters provided examples of other methods and previously established criteria that they believed could also be used for judging PRA quality. One of the examples provided was the industry’s PRA certification and peer review program that the Nuclear Energy Institute (NEI) recently submitted for NRC approval.

In addressing PRA quality, we will be consistent with SECY-00-162, "Addressing PRA Quality in Risk-Informed Activities," dated July 28, 2000. In that regard, our preliminary view is that methods other than consensus PRA standards may be acceptable. We have initiated the review of the industry's PRA certification and peer review program to determine whether it is adequate for Option 2.

6. Approach: Commenters suggested that the Commission pursue risk-informing the rules in a phased approach. In the suggested approach, special treatment requirements that include requirements on actual treatment of SSCs (e.g., seismic requirements, environmental qualification requirements, and quality assurance requirements) would be included in the first phase, while administrative and reporting requirements (e.g., updates to the final safety analysis report [FSAR]) would be included in the second phase. It was recommended that we address the technical specifications rule (§50.36) through a separate activity in parallel with Option 2.

   At this time, we have not identified advantages to proceeding with a phased approach, with the exception of §50.36. We believe that we can complete a single rulemaking in the same timeframe as the proposed first phase. Therefore, a single rulemaking would be a more efficient use of staff resources than two separate rulemakings. We agree that revisions to §50.36 should be accomplished under a separate rulemaking as part of the existing §50.36 initiatives.

7. Pilot Program: Some commenters expressed a concern that we might backfit the final rule on plants that participate in the pilot program. The commenters suggested that because the methods used by the pilot plants would have received NRC review and approval before implementation, licensees not be required to change these methods merely to align them with the final rule. The commenters further asserted that our review and approval as part of the pilot phase of this effort should be sufficient to establish acceptability of these methods. Some commenters also suggested that our plans to include a variety of SSCs as part of the pilot program are unnecessarily restrictive. They suggested that such an approach should not be necessary because STPNOC has demonstrated the viability of the concepts underlying the risk-informed categorization process.

   We do not intend to impose the requirements of the final rule on the pilot plants unless a significant safety issue is discovered during the rulemaking process that warrants backfitting consistent with the requirements of §50.109. We agree that pilot plants may not need to evaluate the same scope of SSCs as has STPNOC. However, until a specific proposal is received from industry for the pilot program, the scope of the pilot program remains to be determined.

8. 10 CFR Part 21, "Reporting of Defects and Noncompliance": Commenters provided suggestions in two general areas: (1) the application of Part 21 to RISC-3 SSCs and (2) the application of Part 21 to RISC-2 SSCs. Commenters suggested that Part 21 not be applied to RISC-3 SSCs because, as a result of their low safety significance, defects and deviations in these SSCs should not involve substantial safety hazards. Commenters also suggested that Part 21 requirements not be applied to RISC-2 SSCs because these are not basic components as defined in the Atomic Energy Act or in Part 21.

   We agree that when SSCs are correctly categorized with respect to their safety significance, deviations and failures to comply for RISC-3 SSCs are unlikely to cause the notification requirements of Part 21 to be exceeded. However, we believe that a change to Part 21 may be necessary to modify its scope to eliminate the associated requirements for RISC-3 SSCs. Since RISC-2 SSCs are safety significant, it would be consistent with the intent of risk-informed regulations to require licensees to provide information involving significant functional deficiencies of RISC-2 SSCs. We are assessing whether a regulatory requirement for reporting these deficiencies is needed. If so, we believe that the reporting requirement should be incorporated within §50.69 and only imposed upon licensees.

Option 2 Rulemaking Approach

As described in SECY-99-256, we are preparing a new rule, §50.69, and a new Appendix T to be included in Part 50 that would allow licensees to focus their resources on the performance of SSCs that are safety significant. The categorization process in Appendix T was described in some detail in the rulemaking plan. Our current approach remains consistent with that plan. For treatment, the rulemaking plan was conceptually described; we now have a better understanding of the appropriate requirements for treatment to be included in §50.69. In support of the rulemaking effort, we are (1) conducting a study to better understand the various plant processes and practices applied to safety-related and non-safety-related SSCs at a number of facilities, (2) continuing to review the related STPNOC exemption request, and (3) planning to carry out a pilot program at several other plants. We will also consider the application of the draft performance-based high-level guidelines for this rulemaking.

Categorization Process

When we created the "four-box" diagram to describe the risk-informed safety classes, we labeled the left-hand side (RISC-1 and RISC-3) as safety-related and the right-hand side (RISC-2 and RISC-4) as non-safety-related. We have identified an unintended consequence of this labeling that involves SSCs that are non-safety-related but that are covered by the current special treatment requirements. If these SSCs are of low safety significance, our four-box diagram would have allowed licensees to categorize these SSCs as RISC-4. Such a categorization would have taken these SSCs completely out of the regulatory scope for treatment. This is inconsistent with our intent, which was to ensure that even after

categorization those non-safety-related SSCs within the current scope of special treatment requirements would remain functional in the same manner as RISC-3 SSCs. To address the above limitation, we provide the following new approach for the use of the four-box diagram. SSCs within the scope of any special treatment requirement, with the exception of 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants," would be included on the left-hand side of the diagram. All other SSCs would be included on the right-hand side. By using this approach, SSCs of low safety significance within the current scope of special treatment requirements would be categorized as RISC-3. This would ensure that regulatory controls still exist for the interactions between such SSCs and the safety functions. We intend to create a new monitoring requirement in §50.69 that would apply to licensees implementing Option 2 in lieu of the monitoring requirements in §50.65. As such, the scope of §50.65 is not included in the determination of whether SSCs should be on the left-hand or right-hand side of the four-box diagram. This approach allows certain SSCs that are not within the scope of any other special treatment requirements but that are within the scope of §50.65 to be categorized as RISC-2 or RISC-4. We believe that this approach is appropriate because the scope requirements of the maintenance rule go beyond the technical requirements defining design basis events.

The rulemaking approach under Option 2 relies on a robust process to determine the safety significance of each SSC with its placement in the appropriate RISC category. With the reduction in treatment requirements anticipated for SSCs of low safety significance, and recognizing that this could constitute a large percentage of the safety-related SSCs (e.g., 50% or more, for some plants), it is important for the categorization of SSCs to be reliable in determining the safety significance of each SSC.

In the categorization process, the plant-specific PRA is used to identify SSCs that are potentially of low safety significance and, therefore, are candidates for reduction in requirements. As part of this process, the role of the PRA is to identify SSCs that are important in terms of severe accident risk (core damage frequency [CDF] and large early release frequency [LERF]). By use of sensitivity analyses to vary the failure rates of SSCs identified as candidates for reduction in treatment requirements, the PRA is also used to show that the change in risk resulting from changes in the requirements is small.

When an SSC is identified as potentially of low safety significance by the PRA, this low safety significance has to be confirmed by the licensee's integrated decisionmaking panel (IDP). Qualitative risk insights and traditional engineering insights based on plant-specific and generic industry experience will be used by the IDP. In addition, the IDP would show that the defense-in-depth philosophy and sufficient safety margin are maintained.

Qualitative risk insights will be used to complement the quantitative insights provided by the PRA. The IDP would deliberate on whether failure of the SSC would significantly increase the frequency of an initiating event; failure of the SSC would fail a safety function, including SSCs that were assumed to be inherently reliable in the PRA (e.g., piping and tanks) and those that may not be explicitly modeled (e.g., room cooling systems and instrumentation and control systems); the SSC supports operator actions credited in the PRA; and failure of the SSC would

result in failure of safety-significant SSCs (e.g., through spatial interactions). Qualitative risk insights will also be used by the IDP to determine if SSCs are safety significant for initiating events and plant operating modes not modeled in the PRA.

In addition to being safety significant in terms of CDF and LERF, the IDP would consider other risk measures. For example, the IDP would evaluate whether an SSC plays an important role as part of a system that acts as a barrier to fission product release during severe accidents, whether the SSC is depended upon in the Emergency Operating Procedures or the Severe Accident Management Guidelines, and whether the SSC is relied upon to control or to mitigate the consequences of accidents.

When categorizing SSCs as being of low safety significance, the IDP must demonstrate that the defense-in-depth philosophy is maintained. An approach consistent with RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decision on Plant-Specific Changes to the Licensing Basis," could be used to show, for example, that (1) a reasonable balance would be preserved among prevention of core damage, prevention of containment failure or bypass, and mitigation of consequences of an offsite release; (2) system redundancy, independence, and diversity should be preserved commensurate with the expected frequency of challenges, consequences of failure of the system, and associated uncertainties in determining these parameters; (3) there is no over-reliance on programmatic activities and operator actions to compensate for weaknesses in the plant design; and (4) the potential for common-cause failures is taken into account. In addition, when categorizing SSCs as being of low safety significance, the IDP would demonstrate that there is sufficient safety margin to account for uncertainty in the traditional and probabilistic engineering analyses and in the supporting data.

Treatment

As noted, Option 2 only addresses special treatment issues. The design of the facility, as described in the updated FSAR, cannot be modified without an evaluation of the proposed design change under §50.59, the same as the current regulatory framework. That is, no design changes could occur under Option 2 that would not also be acceptable under the current regulatory framework. Therefore, when licensees replace an existing safety-related, fully qualified RISC-3 SSC with another SSC, the replacement component must meet existing functional requirements for the SSC, including capabilities (e.g., pressure, flow) and design conditions (e.g., loads imposed by a seismic event, harsh environment).

The specific rule language remains to be developed, but conceptually, licensees will be required to maintain the functional capability of SSCs using existing or new programs. When functionality is not maintained, licensees will be required to take corrective actions to restore functionality. For RISC-2 SSCs, licensees would be required to control the reliability, availability, and capability of the SSCs consistent with the assumptions in the categorization process. For RISC-3 SSCs, licensees would be required to maintain the design functions of the SSCs at the conditions under which the intended functions are required to be performed as described in the updated FSAR. It is expected that minimal requirements would be established in the rule for this purpose. For both RISC-2 and RISC-3 SSCs, licensees would be required to describe in the updated FSAR how they will meet these requirements through measures and activities such as procurement control, monitoring, and corrective action.

Guidance describing acceptable methods for meeting the requirements of the rule will also be developed. Examples of guidance documents that may be utilized include regulatory guides and NRC-endorsed industry guideline documents. Further, a draft Code Case is currently under development by the American Society of Mechanical Engineers (ASME) that may provide a risk-informed process for repair, replacement, and modification of nuclear power plant equipment.

In support of this effort, the staff is sponsoring a study by the Idaho National Engineering and Environmental Laboratory (INEEL) to compare the various processes and practices applied to safety-related and non-safety related SSCs at nuclear power plants. The INEEL study includes visits to two licensees, an architect-engineering firm, a valve manufacturer, and a manufacturer of electric equipment. During these visits, the staff and its contractor are discussing with industry personnel the differences in processes and practices used in (1) design; (2) procurement; (3) installation; (4) maintenance and repair; (5) inspection, test, and surveillance; (6) corrective action; (7) management oversight; and (8) configuration control, for safety-related and non-safety related power plant equipment. Preliminary findings of the INEEL study indicate that there is a wide variability in the commercial processes and practices used for non-safety related nuclear power plant equipment. The study will be completed in early fall 2000, and the results will be used in the review of the STPNOC exemption request and the Option 2 rulemaking.

STPNOC Exemption Request

Review of the STPNOC exemption request of July 13, 1999, is proceeding in parallel with, but ahead of, the Option 2 rulemaking effort. We will ensure our positions are consistent in both efforts. STPNOC seeks approval of processes for categorizing the safety significance of SSCs and treatment of those SSCs consistent with their categorization as the basis for granting the exemption. STPNOC has categorized a number of SSCs under its graded quality assurance program. The scope of the exemption request includes only those safety-related SSCs that have been categorized as low safety significant (LSS) or as non-risk significant (NRS). We expect that these processes would be implemented over the remaining licensed period of the facility. Several meetings have been held with STPNOC to discuss the exemption requests and the information needed in response to our request for additional information dated January 18, 2000.

We have found that STPNOC's categorization process, which incorporates both deterministic and PRA insights, is generally sound. There are two minor issues remaining on categorization. As with the Option 2 rulemaking, the specific implementation of treatment for safety-related LSS and NRS SSCs (RISC-3) and of non-safety-related, high safety significant or medium safety significant SSCs (RISC-2) needs to be finalized. Another issue that applies to the STPNOC exemption request is change control. We need to maintain sufficient regulatory oversight to ensure that the basis for our findings remains bounding, while giving the licensee sufficient flexibility to change its processes as it implements its program.

STPNOC submitted its revised exemption request on August 31, 2000. We will use the revised exemption request to prepare a draft safety evaluation documenting our preliminary findings and identifying any open items. In parallel, we will inform the Advisory Committee on Reactor Safeguards (ACRS) of our preliminary findings. When the open items are resolved, we will

prepare a final safety evaluation documenting our basis for granting or denying each exemption requested. After we brief the Commission, the final safety evaluation and the granting or denial of the exemptions will be issued.

Pilot Program

We described our expectations for the Option 2 pilot program in a letter to NEI dated October 9, 1999. In this letter, we stated that the categorization process should be applied to a variety of plant systems, including mechanical, fluid, and electrical, and to safety-related and non-safety-related systems. We also stated that the pilot program should address how design basis functions will be preserved when treatment of RISC-3 components is reduced and how safety-significant functions of RISC-2 components will be preserved.

We understand that the Boiling Water Reactors Owners Group (BWROG), the Westinghouse Owners Group, and the Combustion Engineering Owners Group are planning Option 2 pilot activities. As we have not yet received a formal description of any of these planned pilot programs, we are unable to assess the role these pilots will play in the rulemaking.

On the basis of limited information provided in public meetings, we understand that the BWROG pilot program will address only two systems: one safety-related and one non-safety-related. Industry representatives have described plans to seek an exemption from special treatment requirements for all boiling water reactors (BWRs) on the basis of the completion of this pilot program at a limited number of facilities. We have indicated during these meetings that a generic exemption may not be consistent with agency policy because broadly applicable exemptions can preempt rulemaking. Processing of a large number of exemptions would also represent a significant technical and administrative burden. When compared to the rulemaking process, the additional resources consumed do not result in a significantly improved product. Exemptions also do not provide opportunities for public comment and interaction, which are provided by the rulemaking process.

We also note that in our October 19 letter to NEI, we discussed our intent to waive fees for review of licensing actions processed as part of the pilot program. The waiver is limited to six dockets and is not limited only to BWRs. We do not intend to waive fees for the review of generic BWR pilot program exemptions. We expect to apply the waiver only to those facilities that provide timely information useful for development of the final rule and implementing guidance.

We are also reviewing guidelines submitted by NEI for PRA peer certification, and categorization and treatment implementation. We expect these guidelines to be exercised by the pilot program, with the eventual goal of endorsing them as an acceptable means of implementing Option 2 rule changes.

COORDINATION:

The ACRS was briefed on August 29, 2000, on the status of the Option 2 rulemaking. OGC has reviewed this paper and has no legal objection.

CONCLUSIONS:

1. The comments received in response to the ANPR generally support rulemaking to risk-inform the application of special treatment requirements in the NRC reactor regulations.

2. Our approach for implementing the rulemaking plan for Option 2 is consistent with SECY-99-256.

3. We are continuing our review of the STPNOC exemption request.

4. We will continue our interactions with stakeholders in the development of the proposed rulemaking and to solicit pilot plants for Option 2.

/RA/

William D. Travers
Executive Director
for Operations

Attachment: As stated

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Attachment: As stated
ACCESSION NO. SECY ML003743264 WITS199900061
*See previous concurrence

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Review of ANPR Comments and Preliminary Responses

We have performed an initial review of the public comments received in response to the ANPR. This attachment groups the ANPR comments into eight areas emphasized by commenters with a table addressing each area. The general areas and associated tables are:

Table 1 Approach
Table 2 Screening
Table 3 Categorization Methodology
Table 4 Pilot Program
Table 5 Treatment
Table 6 Selective Implementation
Table 7 Impact on Other Regulations
Table 8 Need for Prior NRC Review

TABLE 1 - APPROACH

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

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

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
1-3	Option 2 should include the risk-informing of: 10 CFR 50.2, 50.12, 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, 50.73, Appendix A (GDCs 1, 2, 3, 4, 18, 37, 40, 42, 43, 45, 46, 53, 54, and 61), Appendix B, Appendix J, Appendix R, Appendix S, 10 CFR Parts 21, 52, 54, and Part 100, Appendix A.VI. Option 2 should include three phases. The first phase should include 10 CFR 50.44, 50.49, 50.54(a), 50.55, 50.55a, 50.65, Appendix A, Appendix B, Appendix J, Appendix S, Part 54, and Appendix A to Part 100; and conforming changes to 10 CFR 50.2 and 10 CFR 50.34. The second phase should include administrative requirements and include 10 CFR 50.34, 50.54, 50.59, 50.71, 50.72, 50.73, Part 52, Part 21 and a complete review of reporting requirements to reduce duplicative reports, data, and reporting functions. Technical specifications (the last phase) should be a separate activity in parallel to Option 2 and should risk-inform the SSC scope of Technical Specifications; address the current duplicative requirements in §50.36 and §50.65(a)(4), and assess the inclusion of administrative requirements.	We disagree with the phased approach proposed in this comment. At this time we have not identified any advantages to proceeding with a phased approach. We believe that we can complete a single rulemaking in the same time frame as the proposed first phase. Therefore, a single rulemaking would be a more efficient use of our resources than two separate rulemakings. In addition, the approach proposed by the commenter includes Part 21 in the second phase. This is inconsistent with other comments which indicated that Part 21 is high priority and key to success of Option 2, from a cost perspective. We do agree that revisions to 10 CFR 50.36 should be accomplished under a separate rulemaking as part of the initiatives currently under development for 10 CFR 50.36. We will consider the additional rules proposed in the comments as part of our continuing efforts and interactions with stakeholders.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
1-4	The new rule should be based on performance-based and risk-informed requirements that are linked to each regulation. One commenter proposed rule language for a new 10 CFR 50.69, Appendix T, and conforming changes to 10 CFR 50.2 and 50.54(a).	We agree that the new rule should be risk-informed and performance-based to the extent practicable. Our proposal includes a risk-informed categorization process to categorize SSCs with respect to their significance to safety, and will utilize performance-based techniques, such as performance and condition monitoring and licensee corrective action programs, to preserve attributes of regulatory interest, to the extent practicable. The format and language of the new rule is still under development. The rule language offered by the commenter will be considered in this development process. We agree that provisions for incorporating conforming language to 50.54(a) may be necessary.
1-5	Any changes in requirements, new, or alternative requirements resulting from this rulemaking effort should be subject to the requirements in 10 CFR 50.109 (the backfit rule) in order for the Commission to fully understand the effects of the proposed changes. The well-established benefits that flow from a rigorous application of the backfit rule should not be avoided by characterizing the changes as voluntary.	We disagree that the backfit rule should be applied to this rulemaking effort. However, we will adhere to the requirements for rulemaking as specified in Management Directive 6.3, “The Rulemaking Process.” These requirements include performing a detailed regulatory analysis that is designed to ensure that any regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.
1-6	Once a licensee adopts the risk-informed rules, any new requirements that the NRC believes should be added should be subject to the requirements in 10 CFR 50.109 (the backfit rule).	We agree with this comment.
1-7	For proposed reductions in requirements, the CRGR charter requires the staff to (1) explain how public health and safety would be adequately protected and (2) justify the reduction in requirements by showing a substantial enough cost savings.	We intend to address all of the applicable CRGR charter requirements in this rulemaking.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
1-8	The risk-informed rules resulting from this rulemaking should be optional. The safety and economic benefits of implementing risk-informed special treatment requirements will vary from plant to plant, depending upon a multitude of factors. For some plants, there may be little or no safety or economic benefit from risk-informing their special treatment requirements, and the costs may be relatively high and would not be justified on a cost-benefit analysis.	We agree that the risk-informed rules should be optional.
1-9	Licensees should be given significant flexibility in the development of a schedule to implement Option 2. The process of categorizing SSCs is long. To require full and complete implementation of all systems within a short time frame is impractical. A licensee must be permitted to develop a schedule for evaluating the safety significance of its systems in a phased and selective manner. It is expected because of system interdependencies and the need to improve efficiencies that a licensee would eventually categorize all systems.	We agree that flexibility should be allowed in the development of a schedule for licensees to implement Option 2. However, a licensee should be able to provide a reasonable schedule, agreeable to the staff, for completing implementation of this effort. We believe that 3 years should be sufficient for this task.

TABLE 2 - SCREENING

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
2-1	GDCs in Appendix A to Part 50 are proposed to be included in the scope of applicability for the §50.69 rulemaking. This should preclude the need for exemptions. The basis for making the change to the scope GDCs is the safety-significance categorization process.	We agree with this comment. We intend to draft the new rule such that no exemptions will be required.
2-2	10 CFR 50.54(a), 50.54(p), and 50.54(q) impose limitations on changing controls and should be included in Option 2. As such, a licensee is prevented from making improvements to its programs because of the manner in which the regulations are crafted, "reduction in commitment" or the rigid and implacable interpretation in regard to the term "reduction in effectiveness."	We disagree with this comment. We have already completed actions with respect to “reductions in commitments” under 50.54(a)(3). This regulation has been relaxed with the direct final rule that became effective on April 26, 1999 (64 FR 9034, February 23, 1999.) The result of this relaxation to date has been a significant reduction in the number of licensee submittals requesting NRC review under this regulation. The revised regulation provides for exceptions based on precedents when the bases of NRC approval applies to the licensee’s facility. Therefore, the number of submittals under this regulation is expected to continue to decline. We do not plan to address the change control requirements for security plans and emergency plans located in 50.54(p) and 50.54(q) respectively, because Part 73 and 50.47 are not within the list of regulations that we are considering in the current Option 2 efforts. Note, however, that the Commission is beginning a separate effort to risk-inform Part 73.

TABLE 3 - CATEGORIZATION METHODOLOGY

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-1	It should be recognized that plants may be able to categorize some systems without exercising the categorization process.	We disagree with this comment. Although in some cases the categorization may be simple, the intent is for systems to be categorized in accordance with the defined categorization process. We believe that exercising the categorization process is important in order to identify safety significant beyond design basis attributes.
3-2	The rule should not identify the consensus PRA standards (e.g., ASME and ANS) as the only acceptable methodologies for performing PRAs. Furthermore, a licensee should not be required to justify its PRA merely because it does not conform with these consensus standards. Acceptable methodologies for performing PRAs include: (1) the criteria in Generic Letter 88-20, (2) the criteria in Section 2.2.3 of Regulatory Guide 1.174, (3) the Industry PRA Certification and Peer Review Program, and (4) the PRA process described in the ANPR.	We agree that there may be other acceptable approaches for assuring PRA quality besides demonstrating conformance to the consensus ASME/ANS PRA standard documents. Our approach on PRA quality will be consistent with SECY-00-162. In addition, the draft review guidelines currently provide such flexibility. The language in Appendix T will be modified accordingly. We do not yet have a position with regard to the acceptability of the four methods provided in the comment with respect to Option 2.
3-3	Different types of PRAs (e.g., Fire, Seismic, Internal Events) have different degrees of conservatism and uncertainty. In addressing PRA quality and completeness concerns, it is very important to ensure that no bias is introduced when comparing quantified Core Damage Frequencies (or other figures of merit) between the different types of PRAs for individual plants.	We agree that different levels of conservatism and uncertainties associated with internal event, fire, and seismic risk analyses, could mask insights from these risk assessments if the core damage frequencies from these studies are merely added together. To avoid this concern, Appendix T and our draft review guidelines specify that the process for identifying safety significant SSCs should consider SSC importances for the different initiators individually as well as cumulatively.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-4	Risk profiles associated with any plant outage are highly dependent on the schedule and activities conducted in the individual outage. Attempts to determine importance measures are only as valid as the assumption of a generic outage schedule. This should be addressed in the rulemaking process.	We agree that the risk profiles associated with a plant outage are dependent on the schedule and activities conducted during that particular outage, and will vary from outage to outage depending on work scope. Although importance measures determined on the basis of a generic outage schedule will not reflect all possible plant configurations, licensees will be required to assess and manage any increase in risk that may result from maintenance activities, in accordance with 10CFR50.65(a)(4). In addition, if an unanalyzed plant configuration becomes important (in terms of frequency and safety significance) it is expected that the licensee's process will include the configuration in an update of the categorization process. Thus, acceptable risk levels will continue to be maintained. This comment will be further considered as part of our ongoing interactions with stakeholders and feedback from the pilot program.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-5	The proposed Appendix T is unduly detailed and prescriptive. Detailed and prescriptive rules will reduce the flexibility of licensees implementing them and may therefore discourage licensees from adopting them. Detailed and prescriptive rules will also make it harder to take advantage of and potentially discourage advances in technology. The rule should include only policy-level criteria and should allow different approaches for compliance with the rule. Details of an acceptable risk-ranking process should be included in a guidance document, not a rule. Furthermore, the production of the guidance document should be a living process and future changes as a result of operating experience should be easy to make. An approach that utilizes an endorsed guidance document for implementation does not necessitate prior NRC review. This has been demonstrated by the implementation of the maintenance rule.	In developing the draft Appendix T, we took the detailed and prescriptive approach in order to support an implementation process that would meet our goal of no prior review or extensive follow-up inspection. The option of including high level requirements within the rule, and relocating the detailed guidance to a Regulatory Guide is being evaluated. In this case, some level of prior staff review and approval may be needed before a licensee implements 10 CFR 50.69.
3-6	The proposed Appendix T is unduly burdensome. Commenters provided specific examples of areas where they believed that Appendix T was unduly burdensome.	We disagree with this comment. However, we plan to further assess the efficacy and burden associated with key elements of the Appendix T guidance as part of our ongoing interactions with stakeholders and insights from pilot applications of the guidance (i.e., the pilot program). Modifications and refinements to the guidance will be considered based on feedback received.

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

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-8	In the quadrant approach there should be two subcategories for RISC-2 SSCs. The first, RISC-2(1), should include nonsafety-related SSCs that are currently identified as "important-to-safety" and are categorized as safety-significant. This subcategory should continue to be subject to the existing requirements. The second subcategory, RISC-2(2), should include nonsafety-related SSCs that are categorized safety-significant. This subcategory should be subject to: (1) A performance monitoring program that provides reasonable assurance that the safety functions identified in the risk-informed evaluation process will be satisfied; (2) Commercial level controls and specifications imposed by the licensee that provide reasonable assurance that the safety-significant functions identified by the risk-evaluation process are satisfied. Such programs shall include a change control provision that provides reasonable assurance that the safety-significant function(s) will be satisfied following a facility change that involved RISC-2(2) SSCs; and (3) A performance-based reporting program for deficiencies that result in a failure to satisfy a safety-significant function identified in the risk-informed evaluation process.	We disagree with this comment. As described in our preliminary approach to categorization in the draft review guidelines, we believe that one category for RISC-2 SSCs is sufficient.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-9	The following insights on IDPs (Element 6 of Appendix T) were provided: The IDP membership should be maintained as consistent as possible. It is recommended that the use of alternate members be minimized, and that in general, the only alternate position permitted would be the Chairman position. The selection of the IDP chairman and IDP members should be the responsibility of a more-senior team that either offers oversight of the IDP, or serves as a sponsoring organization for the IDP The training of IDP members should be a combination of technical training prior to beginning the overall categorization process, and just-in-time training that addresses the specifics of the PRA insights for each particular system as it is addressed. IDP decision making should encourage the documentation of differing opinions when professional technical differences exist among IDP members that can not be resolved to each member's satisfaction.	We agree with many of the proposed elements for the IDP. We will consider adopting these elements.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-10	The importance and classification of an SSC can be determined using factors such as the Fussell-Vesely (F-V) importance and Risk Achievement Worth (RAW). In addition, the use of sensitivity studies (in place of baseline CDF and LERF changes) to bound the overall change in treatment and CDF/LERF should be allowed.	We agree with this comment. The use of importance measures such as Fussell-Vesely and Risk Achievement Worth will help identify SSCs which are potentially low safety significant and are potential candidates for reduced treatment requirements. Low safety significance is validated by the IDP process which will consider factors such as defense-in-depth, safety margins, and risk insights outside the scope of the PRA. Low safety significance should also be shown by demonstrating that risk increases (if any) are small. This demonstration can be in the form of sensitivity studies to bound the overall change in CDF and LERF from changes in treatment.
3-11	The final rule should include a feedback mechanism for re-assessing SSC categorization based on operating experience to assure that the SSCs are properly categorized.	We agree with this comment. The approach described in the ANPR includes a feedback mechanism for changing the SSC categorization based on operating experience.
3-12	The categorization process may identify other safety-related SSCs that are not categorized as safety significant, and that are not directly and specifically referenced in the regulation or directly referenced in the safety analyses required by regulation. These SSCs may be categorized as RISC-4 on completion of a satisfactory 50.59 evaluation.	We agree that reclassification of SSCs from safety-related to nonsafety-related would be acceptable provided the licensee performs a satisfactory 10 CFR 50.59 evaluation. Option 2 does not address reclassification of SSCs from safety-related to nonsafety-related.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
3-13	Relative risk rankings of plant systems and components can change. An SSC categorized as RISC-3 or RISC-4 can later be categorized as RISC-1 or RISC-2, respectively, as a result of new information, a change in performance, or modifications to the plant. The rulemaking process should establish clear requirements for dealing with such situations.	We agree that changes in classification can occur and agree that the rulemaking process should clearly establish the requirements for dealing with such situations. We will further consider this comment as part of our ongoing interactions with stakeholders and feedback from the pilot program.
3-14	ASME has developed risk-informed code cases for categorization, testing, and inspection. In addition, ASME is currently developing risk-informed code cases for other areas, including a code case on repair/replacement/modification activities. It would be more appropriate to reference those code cases instead of including detailed requirements in the rules.	We agree that the ASME code cases may provide an acceptable alternative to 10 CFR 50.55a. We will further consider this comment as part of our ongoing interactions with stakeholders and feedback from the pilot program.
3-15	Since substantial effort has already been expended in the development and publishing of ASME Code Cases (as well as NRC Regulatory Guides), it would seem that the terminology that the industry has agreed to use should continue to be consistently utilized. The ASME Code Cases (and NRC Regulatory Guides) use terms High/Low Safety Significant Components vice Safety Significant Components/Low Safety Significant Components (as used in the ANPR).	We disagree with this comment. We intend to continue with the terminology used in the ANPR.

TABLE 4 - PILOT PROGRAM

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
4-1	A higher degree of regulatory predictability and benefit must be established before piloting the proposed regulatory framework. This can be accomplished by development of an NRC endorsed industry guideline.	We agree with this comment. The Nuclear Energy Institute is preparing guidelines to support implementation of Option 2 rule changes. We are currently reviewing drafts of these guidelines.
4-2	The purpose of the pilot program should be to verify that the requirements and associated guidance of the categorization process can be implemented by industry, to demonstrate the viability of risk categorization processes to establish alternative risk-informed special treatment requirements, and to test out special treatment requirements. The pilot program should also provide estimates of implementation costs and benefits from this effort.	We agree with the comment. These objectives are consistent with those described by the NRC in an October 19, 1999 letter regarding the pilot program from Samuel Collins to Ralph Beedle, and in SECY-99-256.
4-3	There is no need to specifically pilot each rule. Testing the guideline against a sample set of regulations and systems is sufficient for resolving implementation issues and providing the bases and confidence for generic implementation on the complete spectrum of Option 2 regulations.	On the basis of our current knowledge and experience, we agree with this comment. The pilot effort should provide sufficient information to confirm this preliminary conclusion.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
4-4	As with any unknown process, when you start the process it will be difficult to determine what schedules and resources must be applied to the process to come up with a "good" product. All that can be done is to initially define the best scope of work possible with well defined deliverables and schedules. As one proceeds with the pilot programs, continuous feedback must be used to adjust the process as one goes. It makes no technical sense to commit to schedules and requirements in advance.	We agree with this comment. We recognize the difficulties in planning activities that lack good precedent and experience. We also understand that schedules and scope of activities may require adjustment as experience is gained, and problems are identified and resolved.
4-5	The requirements on pilot plants are unnecessarily restrictive. The requirements that pilot plants must include a variety of plant systems is not necessary because South Texas Project has demonstrated the viability of the concepts underlying the risk-informed classification process.	We agree with this comment to the extent that all pilot plants may not need to evaluate the same scope of SSCs as has STP. Until a specific proposal is received from industry, the scope of the pilot program remains to be determined.
4-6	The STP exemption request should be completed prior to rulemaking. Potential pilot plants are closely watching the status of the STP exemption request. If the eventual outcome is that STP is not granted the exemption request, other potential pilot plants will likely consider the ability to categorize SSCs and adjust the special treatment requirements to be overtly difficult and will not pursue this possibility.	We agree with this comment and expect to complete our review of the STP exemption well before issuance of a final rule. We understand the potential influence of a partial or full denial on the other pilot activities. Presently, it is our understanding that additional pilot activities are planned to begin before we complete the STP review.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
4-7	Pilot plants should not be forced to adopt the final rule because their methodologies would have been reviewed and found acceptable. Pilot plants will seek exemptions to NRC regulations to apply and pilot the special treatment requirements defined in Option 2. Some pilot plants may wish to deviate from the generic guidance because of differing designs and established licensee practices. This is both necessary and beneficial from a pilot project perspective. The varying approaches, approved by the NRC in the exemption process, will be assessed and evaluated by the NRC staff. As necessary and appropriate, a licensee might adjust its approach based on implementation insights and NRC input during the pilot project.	We agree with this comment. We believe that because we would have reviewed and approved a pilot plants' processes prior to their implementation those processes would be sufficient for maintaining safety. Should a significant safety issue be identified during the rulemaking that warrants backfitting on pilot plants, we would pursue the issue consistent with 10 CFR 50.109.

TABLE 5 - TREATMENT

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

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-3	Consideration of normal operation or the existing design basis accidents should be included in the proposed rulemaking only in clear areas (e.g., sabotage) where information from a Probabilistic Risk Assessment has not been applied.	We disagree with this comment. Under Option 2 of RIP-50, we expect safety-related SSCs to remain functional under design basis conditions. We are considering risk-informed changes to the existing design basis accidents under Option 3 of RIP-50.
5-4	It is not clear what the Commission means by the last sentence in the proposed meaning for special treatment (i.e., “This definition does not encompass functional design requirements; that is, an SSC's functional design requirement is not considered a special treatment requirement.”)	It is our position that regardless of the treatment imposed, SSCs must continue to be functional for the design basis events. Option 2 is risk-informing the “assurance” requirements. It is not changing the design basis functional requirements. Hence, we expect that RISC-3 SSCs would continue to perform their design functions at the conditions under which the intended functions are required to be performed as described in the updated FSAR. Since these SSCs are of low safety significance, the assurance that these SSCs would perform their design functions would be reduced.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-5	Existing special treatment requirements will continue to apply to RISC-1 SSCs. Any additional requirements considered for RISC-1 SSCs in order to satisfy PRA assumptions or beyond design basis events should be qualified to account for existing special treatment requirements and licensee programs being applied to these SSCs and the actual performance of the SSCs. An evaluation of the need for additional special treatment requirements for non-safety-related functions of RISC-1 SSCs should only be undertaken if a licensee: (1) takes credit in the PRA for a RISC-1 SSC functioning at a level that is better than the reliability/availability levels associated with existing operating experience; or (2) determines that a significant reduction in risk can be achieved through additional specific treatment requirements.	We generally agree with this comment. We have described a preliminary approach to treatment in the draft review guidelines.
5-6	The final rule should include a general performance-based standard for RISC-2 SSCs that would allow licensees to establish their own treatment programs or take credit for existing programs to maintain the reliability/availability of these SSCs as assumed in the PRA. This, when combined with the monitoring requirements of the maintenance rule and periodic PRA updates, should be sufficient to ensure the reliability/availability of the RISC-2 SSCs as assumed in the PRA.	We agree in principle to allowing flexibility in licensee implementation of performance monitoring methods. However, we have determined that maintenance rule monitoring alone is insufficient for use in Option 2, because the maintenance rule only requires performance monitoring for maintenance activities. The Option 2 rulemaking will likely include monitoring requirements to assess all RISC-2 SSC failures/performance related to safety significant attributes or functions.
5-7	The functional capability of RISC-3 SSCs should be maintained.	We agree with this comment.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-8	Because RISC-3 SSCs are by definition low safety-significant, no special treatment requirements, beyond normal commercial practices (as determined by the licensee), are warranted.	We have not established what minimal treatment will be needed to maintain the functional capability of RISC-3 SSCs.
5-9	Monitoring of RISC-3 SSCs should only be required if a change in performance of the SSC could affect its safety classification.	We have not established what minimal treatment will be needed to maintain the functional capability of RISC-3 SSCs.
5-10	RISC-4 SSCs should continue to be treated in accordance with normal commercial grade standards.	We agree with this comment.
5-11	A change-control process covering beyond design basis functions should be incorporated in the new 10 CFR 50.69.	We agree that a change-control process is needed to cover beyond design basis functions. At this time, we believe such a process should be incorporated in the new 10 CFR 50.69
5-12	RISC-1 and RISC-3 SSCs should remain subject to the requirements of 10 CFR 50.59 for design basis functions.	We agree with this comment with respect to the application of 10 CFR 50.59 to RISC-1 and RISC-3 SSCs. Note that the current scope of applicability of 10 CFR 50.59 is more broad than the SSCs that will be categorized as RISC-1 and RISC-3. We do not plan on modifying the scope of applicability of 10 CFR 50.59 as part of Option 2.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-13	RISC-3 SSCs should not be subject to 50.72 or 50.73 reporting requirements based on the assumption that these SSCs have minimal or no safety significance.	The Commission recently approved a revision to the reporting requirements that will make them risk-informed. Specifically, 10 CFR 50.72, 50.73, and 72.216 have been amended to 1) better align the reporting requirements with the NRC's current reporting needs for information to carry out its safety mission, 2) reduce unnecessary reporting burden, 3) clarify the reporting requirements where needed, and 4) to be consistent with NRC actions to improve integrated plant safety assessments. We currently believe that the revised rules will address the reporting requirements for RISC-3 SSCs consistent with the intent of Option 2 and that further rulemaking under Option 2 is not warranted.
5-14	All commitments related to low safety-significant SSCs should be replaced by a single commitment that imposes commercial level (balance-of-plant) special treatment requirements (monitoring or controls) to provide reasonable assurance that the functions required by regulation or credit in the safety analyses required by regulations will be satisfied. Evaluation of individual SSCs with respect to commitment is not necessary or practical.	We disagree with this comment. Licensees should follow the NEI commitment guidance document as evaluated and accepted by the NRC.
5-15	Part 21 should not be included in the Option 2 scope. Part 21 is a complex regulation with hard links to the Atomic Energy Act. As such, any change to the scope of Part 21 would be a complex and prolonged activity that may involve a change to the Atomic Energy Act.	We disagree with this comment. We believe, as was suggested by other comments, that risk-informing the special treatment requirements in Part 21 is critical to the success of Option 2 from a cost perspective. While it is true that Part 21 has hard links to the AEA, we believe that we can risk-inform Part 21 to make it consistent with Option 2.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-16	Part 21 does not currently apply to RISC-3 SSCs because a failure of these SSCs could not cause a substantial safety hazard. There also is no safety reason to impose risk-informed Part 21 requirements on SSCs that are not safety-significant.	We agree that when SSCs are correctly categorized with respect to their safety significance, deviations and failures to comply for RISC-3 SSCs are unlikely to cause the notification requirements of Part 21 to be exceeded. However, we believe that a change to Part 21 may be necessary to modify its scope to eliminate the associated requirements for RISC-3 SSCs.
5-17	Part 21 does not currently apply to RISC-2 or RISC-4 SSCs because these SSCs are not basic components as defined in the Act or in Part 21. In addition, Part 21 requirements should not be imposed on RISC-2 SSCs because: (1) it would be unfair to vendors who have already sold the SSCs to incur the resulting costs, and (2) 50.72 and 50.73 are sufficient to alert the NRC to significant adverse conditions and failures in RISC-2 SSCs.	We agree that Part 21 should not be imposed on RISC-2 or RISC-4 SSCs. Since RISC-2 SSCs are safety significant, it would be consistent with the intent of risk-informed regulations to require licensees to provide information involving significant functional deficiencies of RISC-2 SSCs. We are assessing whether a regulatory requirement for reporting these deficiencies is needed. If so, we believe that the reporting requirement should be incorporated within §50.69 and only imposed upon licensees. We will determine whether current reporting (e.g., §50.72/73) or data base systems (e.g., EPIX) could be used, and the type of information, the threshold, and frequency of reported information.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
5-18	Making Part 21 risk-informed would not be inconsistent with Section 206 of the Energy Reorganization Act or Section 223.b of the Atomic Energy Act. The Commission has previously taken the position that Section 206 does not require Part 21 to apply to all safety-related SSCs and that the NRC has discretion to determine what kinds of SSCs should be considered "basic components," and this position has been accepted by the courts. See Natural Resources Defense Council v. NRC, 666 F.2d 595, 603 (D.C. Cir. 1981). Therefore, NRC is free to risk-inform the definition of "basic component" in Part 21. The definition of "basic component" in Section 223.b is restricted to that section, does not apply to Section 206, and does not require that the NRC use the same definition of "basic component" in Part 21.	We agree with the comment.
5-19	A performance-based 10 CFR 50.73 type reporting requirement should be included in the new 50.69 for RISC-2 SSCs.	We agree that a reporting requirement for RISC-2 SSCs should be included in 50.69.

TABLE 6 - SELECTIVE IMPLEMENTATION

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
6-1	The risk-informed rules resulting from this rulemaking should allow for selective implementation with respect to both rules and systems. Selective implementation of rules does not present any adverse impacts because if a licensee decides not to implement a risk-informed regulation, the licensee would be required to meet the existing deterministic regulation which provides adequate protection of the public health and safety. Therefore, although there may be benefits from full implementation of the risk-informed rules, licensees should be allowed to determine whether the benefits outweigh the costs. With respect to systems, some safety-related systems will obviously be safety significant while other non-safety-related systems will obviously be low safety significant. There is no benefit to implementing the risk-informed rules for such systems. Implementation on a system basis should proceed with first priority on systems with components that are very likely to be categorized as RISC-2 or RISC-3, second priority for systems whose components have some potential for being categorized as RISC-2 or RISC-3, and no priority for systems whose components are highly likely to be categorized as RISC-1 or RISC-4.	We agree that selective implementation with respect to rules should be allowed provided that no exemptions would be required. However, we disagree that there should be unlimited flexibility with respect to selective implementation for systems. Licensees should, at a minimum, identify all RISC-1 & RISC-2 SSCs.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
6-2	The final rule should provide licensees with the option of categorizing the different functions of an SSC instead of forcing all functions of the same SSC to be categorized in the same RISC class.	We agree with this comment. We recognize that many licensees have used a “functional categorization” approach for the maintenance rule. If a function-based approach is feasible, as it was found to be for the maintenance rule, we intend to create such flexibility in Option 2.

TABLE 7 - IMPACT ON OTHER REGULATIONS

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
7-1	Maintaining a single NRC Form 3 posting (as required by 10 CFR Part 19) would not confuse licensee staff and contractors. Under either a risk-informed or deterministic regulatory regime, the NRC Form 3 intent remains the same.	We are evaluating this matter. The resolution of this issue depends upon whether the definition of “basic component” in Section 223.b of the AEA can be interpreted to include RISC-2 SSCs and exclude RISC-3 SSCs.
7-2	A risk-informed Option for Part 54 should be developed. Since licensees in general rely upon existing special treatment requirements to satisfy Part 54, the scope of SSCs subject to Part 54 should not be broader than the scope of SSCs subject to special treatment. Risk informing Part 54 would likely result in a more efficient process for both licensees and NRC, since neither would be required to evaluate the impact of aging on SSCs that are not safety-significant.	We disagree that RISC-3 SSCs should be removed from the scope of Part 54. We believe that licensees that implement Option 2 can renew their licenses in accordance with Part 54 by demonstrating that the treatment applied in accordance with §50.69 provides adequate aging management under Part 54.21.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
7-3	The terms "operability" and "functionality" are not equivalent terms. A system can be “functional,” yet declared inoperable, e.g., because it has missed a required surveillance test or because a support system is not functional. In other words, a safety-related system can be declared inoperable even though the system is capable of providing its specified safety function. Although there is a difference in meaning between “functional” and “operable,” we do not believe that this difference has any importance with respect to the type of treatment to be afforded to RISC-3 SSCs. Such SSCs should be subject to commercial practices, which will be sufficient to ensure that they have sufficient availability and reliability to perform their safety-related functions. To the extent that such SSCs are also controlled by the technical specifications, they will also need to satisfy the operability requirements in the technical specifications, including passing all required surveillance tests (unless the licensee seeks and justifies a license amendment to remove such SSCs from the scope of the technical specifications).	We are evaluating this matter. While the commenter is correct in that operability and functionality are different concepts, we are evaluating if risk information may allow the licensee to alter various aspects of “operability” in the technical specifications, and if so what would be the consequences from a regulatory standpoint.

TABLE 8 - NEED FOR PRIOR NRC REVIEW

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
8-1	Performing a 50.59 evaluation (and, as necessary, obtaining NRC approval) for each change in a special treatment requirement in the UFSAR would be extremely burdensome and prohibitively costly for both licensees and the NRC. There are two options to dealing with 10 CFR 50.59. 10 CFR 50.59 could be made risk-informed to eliminate the need for individual 50.59 evaluations (and prior NRC approval) for each change in special treatment described in the UFSAR. Alternatively, the revised 50.59 could be interpreted as not requiring a full evaluation for revisions of the special treatment described in the UFSAR.	We agree that it may be burdensome to perform a 50.59 evaluation for each change in special treatment requirements resulting from the categorization. However, we disagree with the comment that 50.59 should be changed or reinterpreted to implement Option 2. Instead, we intend to construct 50.69 to allow licensees to categorize SSCs and implement the resulting changes in treatment without having to complete separate 50.59 evaluations. We believe that the robustness of Appendix T categorization processes combined with the requirements of the resulting 50.69 will be adequate to meet the underlying intent of 50.59 and that additional 50.59 evaluations would be unnecessary and redundant.
8-2	Ultimately, 10 CFR 50.59 should be risk-informed to allow licensees to make design changes that do not have risk-significance.	We disagree with this comment. The recent revisions to 50.59 are risk-informed in the sense that it now allows licensees to make changes to the plant that have a minimal impact on safety. We do not plan to make any further changes to 50.59 as part of Option 2.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
8-3	The industry fully supports and encourages the open dialogue that has been established by the NRC to provide public, licensee, and NRC staff participation. It is only through such open dialogue that a complete understanding of risk-informed regulatory improvements can be established. The existing process provides significant material for public review and provides sufficient opportunity for public input and participation on matters that have safety-significance. The public will have the opportunity to participate in developing the criteria for the classification process in the rulemaking. It is difficult to envision a higher degree of opportunity for public participation or access to information. Once the rule is approved, the public should have no special participation rights.	We agree with this comment. It is still our intent to propose a rule that would not require prior approval for implementation. The current rulemaking process does provide the public with an opportunity to participate in the decision-making process.

ISSUE NO.	COMMENT SUMMARY	PRELIMINARY STAFF RESPONSE
8-4	NRC review of a licensee's implementation of the final rule should be limited to certain process aspects of the categorization and treatment determination to ensure compliance with the final rule. A template submittal to notify the NRC of a licensee's intent to adopt the resulting risk-informed rules is being developed by NEI. This would include statements on PRA quality, the methodology used in the risk-evaluation process, the list of regulations being adopted, and a discussion of the extent to which the licensee's approach is consistent with an endorsed guideline. NRC review of the information provided in the template should be sufficient to ensure compliance. After implementation of the resulting rules, the inspection process should be sufficient to confirm reasonable assurance that public health and safety is maintained.	It is still our intent to pursue a rulemaking approach that involves minimal prior review and approval. However, we agree that some notification of a licensee's intent to adopt the risk-informed rules will be necessary. The scope of this submittal is still under development.
8-5	The objective to establish categorization and treatment criteria that are sufficiently clear and robust such that if a licensee's program meets the criteria there is not a need for prior NRC review and approval of the plant-specific program is impossible to do in actual practice.	As stated in SECY-99-256, it was our goal to have no prior review. We recognize the difficulties associated with this option. We continue to have the objective of minimizing prior NRC review and approval. Refer also to the response to Issue 3-5.