Responses to Public Comments on the Proposed Rule

TABLE 1 - 50.69 Paragraph (b) Requirements

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

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

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

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

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

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

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

TABLE 2 - 50.69 Paragraph (c) Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 3 - 50.69 Paragraph (d) Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-32	Throughout the SOC, the terminology "Commission expects" is used. Utility implementation should allow for interpretation of the implementation processes to avoid undue disruption of their established practices. Another commenter has a similar comment referring to the "best practices" language for RISC-3 treatment in the SOC as being/becoming de facto requirements and which are unduly restrictive and unnecessary and should be deleted from the rule. Four other commenters indicate that in some cases the SOC and rule language are inconsistent and that specifically the expectations are impractical, not risk-effective, or in some cases actually exceed current safety-related requirements. A commenter asserts that, given the low safety significance of RISC-3 SSCs, exercising a pump or valve gives appropriate confidence that the pump or valve is functional, and that a requirement for measuring, trending of performance, and extrapolation of performance to design-basis conditions is an unnecessary burden given the low safety significance of these components. One commenter recommends deletion of SOC language discussing (1) SSC testing if no suitable alternative seismic capability method is available, (2) verification of correct procurement of SSCs, (3) testing under simulated design-basis conditions as one evaluation method, and (4) obtaining operational information or performance data to provide reasonable confidence that RISC-3 pumps and valves will be capable of performing their safety functions.	The NRC agrees with the thrust of the comments that the rule and SOC should be clarified. These comments illustrate the divergent interpretations of the high-level requirements for the treatment of RISC-3 SSCs in § 50.69. Therefore, the rule has been clarified with respect to the RISC-3 treatment requirements to ensure that licensees: 1) understand that design requirements continue to apply to RISC-3 SSCs (for example, fracture toughness); 2) establish documented processes for the treatment of RISC-3 SSCs consistent with the categorization process; and 3) consider potential common cause concerns as part of the corrective action process. In addition, the SOC has been revised to clarify the meaning of the rule language. Specifically, where the NRC considered expectations to be necessary, the final rule has incorporated those expectations as requirements and removed guidance from the SOC. Below, the revised portions of § 50.69(b)(1) and the high-level treatment requirements in § 50.69(d)(2) are indicated by underlining and strike-outs: (*b) Applicability and scope of risk-informed treatment of SSCs and submittal/approval process.* (1) A holder of a license to operate a light water reactor (LWR) nuclear power plant under this part, a holder of a renewed LWR license under Part 54 of this chapter; an applicant for a construction permit or operating license under this part; an applicant for a design approval, a combined license, or manufacturing license under Part 52 of this chapter; may voluntarily comply with the requirements in this section as an alternative to compliance with the following requirements for RISC-3 and RISC-4 SSCs: *** (ii)The portion of 10 CFR 50.46a(b) that imposes requirements to conform to Appendix B to 10 CFR Part 50. ***[Note all subsequent items are renumbered] (v) The inservice testing requirements in 10 CFR 50.55a(f); the inservice inspection, and repair and replacement <u>(with the exception of fracture toughness)</u>, requirements for ASME Class 2 and Class 3 SSCs in 10 CFR 50.55a(g); and the electrical component quality and qualification requirements in section 4.3 and 4.4 of IEEE 279, and sections 5.3 and 5.4 of IEEE 603-1991, as incorporated by

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
d-32 cont	A commenter states that the SOC discussion includes NRC expectations for developing and evaluating RISC-3 treatment that are more appropriately considered regulatory guidance for acceptable methods of implementing the requirements. Although recommending that NRC retain the proposed rule language and deleting the SOC information, it is suggested that the NRC prepare a regulatory guide if the NRC considers it necessary to suggest acceptable methods for determining appropriate treatment methods. See comments d-15, d-17, d-19, d-20, d-21, d-22, d-25, d-27, d-28, d-29, d-31, d-33, d-37, e-3, p-11, p-19, p-23	reference in 10 CFR 50.55a(h). (2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement documented 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 treatment of RISC-3 SSCs must be consistent with the categorization process. The processes must meet the following requirements, as applicable: (i) *Design control.* Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled, including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes. RISC-3 SSCs must be capable of performing their safety-related functions including meeting design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation and submergence) and effects (i.e., aging and synergism); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions); (ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements; (iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design basis conditions until the next scheduled activity; and (iv) *Corrective Action*. Conditions that prevent a RISC-3 SSC from performing its safety-related functions under design basis conditions must be identified, documented, and corrected in a timely manner. For significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action taken to preclude repetition.

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

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

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

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

TABLE 4 - 50.69 Paragraph (e) Requirements

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

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-5	The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment process as necessary to maintain safety. See comment e-4	The NRC agrees that clarification to the rule requirements is needed. The final rule has been strengthened in each of the areas mentioned in the comment. Specifically, the final rule in § 50.69(d)(2) requires that "the treatment of RISC-3 SSCs must be consistent with the categorization process." The final rule also requires that, "for significant conditions adverse to quality, measures shall be taken to provide reasonable confidence that the cause of the condition is determined and corrective action is taken to preclude repetition." In addition, and as stated in response to comment e-4 above, the final rule requires licensees in § 50.69(e)(1) to evaluate RISC-3 SSC performance data, described in § 50.69(e)(3) and obtained under § 50.69(d)(2)(iii), in a timely manner and to update, as applicable, the categorization or treatment processes. The feedback of performance data includes evaluation of the validity of the sensitivity studies applied in the categorization process. Section 50.69(e)(1) of the final rule also requires licensees to review applicable plant operational experience from other sources such as that obtained from the corrective action process. If effectively implemented by licensees, the final rule will maintain any changes in risk acceptably small and, therefore, will maintain safety.
e-6	Since all but the safety analysis (a)(4) requirement of the maintenance rule could be pre-empted by this proposed rule we believe that RISC-1,2, and 3 SSC reliability data should be required to be fed back into the PRA as part of the update process. See comment e-7	The NRC disagrees that all of the information referred to must be incorporated into the PRA because changes in treatment might be more effective in addressing performance information. Nevertheless, the feedback of performance information in a timely manner as specified in § 50.69(e)(1) is important to ensure that the categorization process and its results remain valid. The addition of "plant" operational experience in § 50.69(e)(1) explicitly requires that RISC-3 SSC performance information from such sources as the corrective action process and the surveillance performed under § 50.69(d)(2)(iii) be fed back into the categorization process. The plant and industry operational experience referred to in § 50.69(e)(1) includes reliability data for RISC-3 SSCs. Thus, the enhanced monitoring and feedback incorporated into the final rule when coupled with the tighter linkage between the categorization and treatment processes, makes reliability monitoring of RISC-3 SSCs unnecessary.

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
e-10	In SOC Section V.6.0 it is stated "[i]f a licensee chooses to categorize a selective set of SSCs as RISC-3, and the categorization of SSCs as RISC-3 is based on credit taken for the performance of other plant SSCs (whether or not these SSCs are within the selective implementation set), then the licensee must maintain the credited performance." A commenter stated that this implies a potentially enormous program to monitor, track, and compare to the categorization process practically every SSC within the PRA (as well as inputs and assumptions) and every performance aspect. Conformance to the literal SOC words is likely impossible, and certainly impractical, and out of context with the low safety significance of RISC-3 SSCs. The words should be removed.	The NRC disagrees that the rule mandates an enormous program to monitor, track, and compare every SSC in the PRA. The final rule in § 50.69(d)(2) and § 50.69(e) requires licensees to develop treatment processes that are consistent with the categorization process and to feedback information to maintain the validity of those processes. To maintain the validity of the categorization process, and more importantly to maintain any potential risk increase as small, it is necessary to maintain the "credited" SSCs (i.e., the SSCs that are safety significant in order that others can be low safety significant) per § 50.69.
e-11	Section 50.69 (e)(2) states that "[t]he licensee shall monitor the performance of RISC-1 and RISC-2 SSCs. The licensee shall make adjustments as necessary to either the categorization or treatment processes so that the categorization process and results are maintained valid." The second sentence should be clarified. The only available categorization adjustment for these SSCs is to re-categorize them as RISC-3 or RISC-4. Generally this will only occur if an error in the original process occurred or new insights are made available to the IDP. These are nonroutine types of situations.	The NRC disagrees with the comment. There are various alternatives in responding to RISC-1 and RISC-2 performance information. If performance of RISC-1 and/or RISC-2 SSCs declines such that assumptions are no longer valid, and/or the categorization results are no longer valid in terms of maintaining delta CDF and delta LERF small, a licensee may either adjust the treatment (to improve RISC-1 and RISC-2 reliability and/or availability), or re-categorize RISC-3/4 SSCs back into RISC-1/2 until the change in risk is acceptably small. The final rule SOC has been revised to reflect this discussion.

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

TABLE 5 - 50.69 Paragraph (f) Requirements

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

TABLE 6 - 50.69 Paragraph (g) Requirements

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

TABLE 7 - "Questions for Public Input"

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

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

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

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

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

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

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

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

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

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

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
p-17	Regarding the role of operational experience, there is already a wealth of information that demonstrates that failure rates of commercial and safety-related SSCs are comparable. This should be used to eliminate all STRs (and allow commercial practice) from RISC-3 SSCs. Three commenters point to a study by STP that was said to demonstrate that the failure rates of commercial components are comparable to the failure rates of safety-related components. See also comments p-3, p-8, p-20, p-22, p-25 p-26	The NRC disagrees with this comment. The database referenced by the three commenters was not submitted for formal review to the NRC staff as part of the STP exemption request. However, the staff's informal review has identified numerous inadequacies in the STP analysis. For example, STP considered reported failures of non-safety related equipment that have no reporting or testing requirements over a multiple-year period as an acceptable method of comparing reliability to safety-related equipment with frequent reporting and testing requirements. In that the design requirements for non-safety related and safety-related equipment can be quite different, it is not possible to directly compare their reliabilities by simply summing reported failures over long periods of time. Even assuming that the reliabilities can be compared, the more recent data collected by STP indicated significantly higher failure rates for some non-safety related components (such as valve operators) than safety-related components. No revisions to the final rule have been made as a result of this comment.
p-18	The commenter does not support putting additional detail into the rule regarding categorization requirements.	The NRC agrees with this comment. The basis for our agreement is set forth in Section II(f) of the regulatory analysis which accompanies the final rule. The regulatory analysis notes that this is a voluntary rulemaking initiative, and since it was clear that industry would not utilize the appendix approach, it was not appropriate, nor an efficient use of NRC resources, to continue to develop the appendix (that contains more detailed categorization requirements) approach. Accordingly, the NRC elected to incorporate less detailed categorization requirements into the rule, and to require licensees to provide a license amendment submittal for staff review and approve prior to implementation of § 50.69. This approach (regarding the incorporation of more high level categorization requirements into the rule versus a detailed appendix) is supported by industry based on the comments on the proposed rule. Additionally (and as noted in the regulatory analysis), it was clear that the staff would need to review some aspects of the PRA to determine its acceptability for application to § 50.69 under any circumstance. As such, a true "no-prior-review" type (as originally envisioned) of approach simply does not appear to be technically feasible at this time. No revisions to the final rule have been made as a result of this comment.

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

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

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

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

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

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

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

TABLE 8 - Miscellaneous Comments

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

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

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

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

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

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

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

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

TABLE 9 - Comments Regarding Implementation Guidance

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

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

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

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

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

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