

**TABLE 1 - APPROACH**

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-2	<p>It is impossible to maintain overall safety provided by the existing Part 50 if you don't know what level of safety Part 50 provides. There is not a nuclear electric generating unit in the United States that knows the level of public health risk (prompt fatality rate and latent cancer fatality rate) represented by the unit when the unit is considered as a whole much less the part provided by the existing Part 50.</p>	<p>This comment is not directly relevant to the rulemaking approach outlined in the ANPR. Overall plant safety is maintained by adhering to the requirements of Part 50. Regulatory principles such as defense-in-depth and margin of safety have been utilized successfully to ensure that nuclear power does not impose undue risk to the health and safety of the public. As the industry has matured, gained operating experience, and as PRA technology has improved; we have used this information to better inform regulatory and safety decisions. The effort to risk-inform the special treatment requirements is one example of how we are using risk information to reevaluate requirements.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-3	<p>Option 2 should include the risk-informing of: 10 CFR 50.2, 50.12, 50.34, 50.36, 50.44, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.65, 50.71, 50.72, 50.73, Appendix A (GDCs 1, 2, 3, 4, 18, 37, 40, 42, 43, 45, 46, 53, 54, and 61), Appendix B, Appendix J, Appendix R, Appendix S, 10 CFR Parts 21, 52, 54, and Part 100, Appendix A.VI.</p> <p>Option 2 should include three phases. The first phase should include 10 CFR 50.44, 50.49, 50.54(a), 50.55, 50.55a, 50.65, Appendix A, Appendix B, Appendix J, Appendix S, Part 54, and Appendix A to Part 100; and conforming changes to 10 CFR 50.2 and 10 CFR 50.34. The second phase should include administrative requirements and include 10 CFR 50.34, 50.54, 50.59, 50.71, 50.72, 50.73, Part 52, Part 21 and a complete review of reporting requirements to reduce duplicative reports, data, and reporting functions. Technical specifications (the last phase) should be a separate activity in parallel to Option 2 and should risk-inform the SSC scope of Technical Specifications; address the current duplicative requirements in §50.36 and §50.65(a)(4), and assess the inclusion of administrative requirements.</p>	<p>The NRC has considered all the rules proposed by this comment. A discussion of the rules included and those not included in this rulemaking, as well as NRC's reasons, are provided in Section III.4.0 of the statement of considerations. The rules from the commenter's list that are part of the rulemaking are §§50.49, 50.55a, 50.65, 50.72, 50.73, Appendix B, Appendix J, Part 21 and Appendix A to Part 100.</p> <p>The Commission disagrees with the phased approach proposed in this comment because no advantages have been identified any advantages for proceeding with a phased approach. A single rulemaking can be completed in the same time frame as the proposed first phase. Therefore, a single rulemaking would be a more efficient use of our resources than two separate rulemakings.</p> <p>The NRC does agree that revisions to §50.36 should be accomplished under a separate rulemaking as part of the initiatives currently under development for §50.36, as discussed in Section III.4.0 of the statement of considerations.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-4	The new rule should be based on performance-based and risk-informed requirements that are linked to each regulation. One commenter proposed rule language for a new 10 CFR 50.69, Appendix T, and conforming changes to 10 CFR 50.2 and 50.54(a).	The NRC agrees that the new rule should be risk-informed, and in fact the proposed rule includes a risk-informed categorization process to categorize SSCs with respect to their significance to safety. The NRC is using performance-based techniques, such as performance and condition monitoring and licensee corrective action programs, as much as possible, to preserve attributes of regulatory interest. The rule language offered by the commenter was considered in the development of §50.69.
1-5	Any changes in requirements, new, or alternative requirements resulting from this rulemaking effort should be subject to the requirements in 10 CFR 50.109 (the backfit rule) in order for the Commission to fully understand the effects of the proposed changes. The well-established benefits that flow from a rigorous application of the backfit rule should not be avoided by characterizing the changes as voluntary.	We disagree that the backfit rule should be applied to this rulemaking effort. This is a voluntary regulatory approach, and as such, new requirements are not being imposed on licensees. Applying the concept of backfitting appears to be inappropriate, inasmuch as the development of a new, alternative, regulatory approach does not implicate the policies underlying the Backfit Rule, <i>viz.</i> upsetting of settled expectations by a regulated entity. However, the Commission has prepared a regulatory analysis that is designed to ensure that any regulatory burdens imposed are needed, justified, and the minimum necessary to achieve regulatory objectives.
1-6	Once a licensee adopts the risk-informed rules, any new requirements that the NRC believes should be added should be subject to the requirements in §50.109 (the backfit rule).	The NRC agrees with this comment.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
1-7	For proposed reductions in requirements, the Committee to Review Generic Requirements (CRGR) charter requires the staff to (1) explain how public health and safety would be adequately protected and (2) justify the reduction in requirements by showing a substantial enough cost savings.	A discussion of the technical basis for proposed §50.69 (including whether adequate protection is maintained) is provided in the statement of considerations accompanying the proposed rule. A regulatory analysis examining costs and benefits associated with the proposed rule has been performed and is referenced in the statement of considerations supporting the proposed rule. The CRGR's review is an internal NRC process and confers no rights upon any external stakeholder.
1-8	The risk-informed rules resulting from this rulemaking should be optional. The safety and economic benefits of implementing risk-informed special treatment requirements will vary from plant to plant, depending upon a multitude of factors. For some plants, there may be little or no safety or economic benefit from risk-informing their special treatment requirements, and the costs may be relatively high and would not be justified on a cost-benefit analysis.	The NRC agrees with the reasons expressed by the commenter that the risk-informed rules should be optional and the proposed rule is structured accordingly.
1-9	Licensees should be given significant flexibility in the development of a schedule to implement Option 2. The process of categorizing SSCs is long. To require full and complete implementation of all systems within a short time frame is impractical. A licensee must be permitted to develop a schedule for evaluating the safety significance of its systems in a phased and selective manner. It is expected because of system interdependencies and the need to improve efficiencies that a licensee would eventually categorize all systems.	The NRC agrees that flexibility should be allowed in the development of a schedule for licensees to implement §50.69, since existing requirements remain in effect until a licensee performs the implementation of the alternative requirements. However, a licensee is to keep the staff apprised of its progress in implementation of §50.69 through FSAR updates.

**TABLE 2 - SCREENING**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
2-1	<p>GDCs in Appendix A to Part 50 are proposed to be included in the scope of applicability for the §50.69 rulemaking. This should preclude the need for exemptions. The basis for making the change to the scope of GDCs is the safety-significance categorization process.</p>	<p>All the GDCs were removed from the scope of §50.69. It is the NRC's conclusion that these GDCs contain design requirements and are not special treatment requirements. Since this proposed rule is not changing the design basis, the GDCs are not within its scope.</p>
2-2	<p>10 CFR 50.54(a), 50.54(p), and 50.54(q) impose limitations on changing controls and should be included in Option 2. As such, a licensee is prevented from making improvements to its programs because of the manner in which the regulations are crafted, "reduction in commitment" or the rigid and implacable interpretation in regard to the term "reduction in effectiveness."</p>	<p>Section 50.54(a) is not included within the scope of proposed §50.69 for the following reasons. The NRC has adopted a direct final rule addressing "reductions in commitments" under §50.54(a)(3). The result of this relaxation to date has been a significant reduction in the number of licensee submittals requesting NRC review under this regulation. The revised regulation provides for exceptions based on precedents when the bases of NRC approval applies to the licensee's facility. Therefore, the number of submittals under this regulation is expected to continue to decline.</p> <p>The NRC does not plan to address the change control requirements for security plans and emergency plans located in §50.54(p) and §50.54(q) respectively, because Part 73 and §50.47 are not within the list of regulations that we are considering in the current rulemaking efforts. They do not contain special treatment requirements as it has been defined by the Commission for this rulemaking.</p>

**TABLE 3 - CATEGORIZATION METHODOLOGY**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-1	It should be recognized that plants may be able to categorize some systems without exercising the categorization process.	Although in some cases exercising the categorization process may be very simple, the intent is for systems to be categorized in accordance with the defined categorization process. The NRC believes that exercising the categorization process is important in order to assure that all important considerations are addressed and to identify safety significant beyond design basis attributes.
3-2	The rule should not identify the consensus PRA standards (e.g., ASME and ANS) as the only acceptable methodologies for performing PRAs. Furthermore, a licensee should not be required to justify its PRA merely because it does not conform with these consensus standards. Acceptable methodologies for performing PRAs include: (1) the criteria in Generic Letter 88-20, (2) the criteria in Section 2.2.3 of Regulatory Guide 1.174, (3) the Industry PRA Certification and Peer Review Program, and (4) the PRA process described in the ANPR.	The NRC agrees that there may be other acceptable approaches for assuring PRA quality besides demonstrating conformance to the consensus ASME/ANS PRA standard documents. As such, the proposed rule does not specifically refer to the ASME/ANS PRA standard documents. The guidance endorsed by the NRC for implementation of §50.69 (e.g., NEI 00-04) refers to both the Industry's PRA Peer Review Process Guidelines for ensuring PRA quality and the ASME PRA standard.
3-3	Different types of PRAs (e.g., Fire, Seismic, Internal Events) have different degrees of conservatism and uncertainty. In addressing PRA quality and completeness concerns, it is very important to ensure that no bias is introduced when comparing quantified Core Damage Frequencies (or other figures of merit) between the different types of PRAs for individual plants.	The NRC agrees that different levels of conservatism and uncertainties associated with internal event, fire, and seismic risk analyses, could mask insights from these risk assessments if the core damage frequencies from these studies are merely added together. To avoid this concern, the NRC-endorsed guidance for implementation of §50.69 (e.g., NEI 00-04) specifies that the process for identifying safety significant SSCs should consider SSC importances for the different initiators individually as well as cumulatively.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-4	<p>Risk profiles associated with any plant outage are highly dependent on the schedule and activities conducted in the individual outage. Attempts to determine importance measures are only as valid as the assumption of a generic outage schedule. This should be addressed in the rulemaking process.</p>	<p>The NRC agrees that the risk profiles associated with a plant outage are dependent on the schedule and activities conducted during that particular outage, and will vary from outage to outage depending on work scope. Although risk insights determined on the basis of a generic outage schedule will not reflect all possible plant configurations, licensees will continue to be required to assess and manage any increase in risk that may result from maintenance activities, in accordance with §50.65(a)(4). In addition, if an unanalyzed plant configuration becomes important (in terms of frequency and safety significance) it is expected that the licensee's process will include the configuration in an update of the categorization process. Thus, acceptable risk levels will continue to be maintained.</p>



ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-5	<p>The proposed Appendix T is unduly detailed and prescriptive. Detailed and prescriptive rules will reduce the flexibility of licensees implementing them and may therefore discourage licensees from adopting them. Detailed and prescriptive rules will also make it harder to take advantage of and potentially discourage advances in technology. The rule should include only policy-level criteria and should allow different approaches for compliance with the rule. Details of an acceptable risk-ranking process should be included in a guidance document, not a rule. Furthermore, the production of the guidance document should be a living process and future changes as a result of operating experience should be easy to make. An approach that utilizes an endorsed guidance document for implementation does not necessitate prior NRC review. This has been demonstrated by the implementation of the maintenance rule.</p>	<p>The NRC agrees. Proposed §50.69 does not utilize a “no prior review” type approach, and therefore does not contain detailed, objective criteria that would obviate the need for NRC review and approval. Hence Appendix T has been eliminated from the approach.</p>
3-6	<p>The proposed Appendix T is unduly burdensome. Commenters provided specific examples of areas where they believed that Appendix T was unduly burdensome.</p>	<p>The proposed rule does not include Appendix T. The proposed rule utilizes a prior review and approval type of approach.</p>

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-8	<p>In the quadrant approach there should be two subcategories for RISC-2 SSCs. The first, RISC-2(1), should include nonsafety-related SSCs that are currently identified as "important-to-safety" and are categorized as safety-significant. This subcategory should continue to be subject to the existing requirements. The second subcategory, RISC-2(2), should include nonsafety-related SSCs that are categorized safety-significant. This subcategory should be subject to: (1) A performance monitoring program that provides reasonable assurance that the safety functions identified in the risk-informed evaluation process will be satisfied; (2) Commercial level controls and specifications imposed by the licensee that provide reasonable assurance that the safety-significant functions identified by the risk-evaluation process are satisfied. Such programs shall include a change control provision that provides reasonable assurance that the safety-significant function(s) will be satisfied following a facility change that involved RISC-2(2) SSCs; and (3) A performance-based reporting program for deficiencies that result in a failure to satisfy a safety-significant function identified in the risk-informed evaluation process.</p>	<p>The NRC disagrees with the comment about subcategories, believing that one category for RISC-2 SSCs is sufficient. The proposed rule contains the necessary requirements (referred to in the comment), but does it in a simpler framework.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-9	<p>The following insights on Integrated Decision making Panels (IDP) (Element 6 of Appendix T) were provided:</p> <p>The IDP membership should be maintained as consistent as possible. It is recommended that the use of alternate members be minimized, and that in general, the only alternate position permitted would be the Chairman position.</p> <p>The selection of the IDP chairman and IDP members should be the responsibility of a more-senior team that either offers oversight of the IDP, or serves as a sponsoring organization for the IDP</p> <p>The training of IDP members should be a combination of technical training prior to beginning the overall categorization process, and just-in-time training that addresses the specifics of the PRA insights for each particular system as it is addressed.</p> <p>IDP decision making should encourage the documentation of differing opinions when professional technical differences exist among IDP members that can not be resolved to each member's satisfaction.</p>	<p>The suggested insights were considered as part of the effort to develop guidance for implementing §50.69. The draft regulatory guide (DG-1121) (and the Nuclear Energy Institute (NEI) guidance on which it is based) includes statements about necessary training of members (on the overall categorization process and on PRA insights), and documentation of decision-making. The rule contains requirements about the constitution of the IDP.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-10	<p>The importance and classification of an SSC can be determined using factors such as the Fussell-Vesely (F-V) importance and Risk Achievement Worth (RAW). In addition, the use of sensitivity studies (in place of baseline CDF and LERF changes) to bound the overall change in treatment and CDF/LERF should be allowed.</p>	<p>The NRC agrees with this comment. The use of importance measures such as Fussell-Vesely and Risk Achievement Worth will help identify SSCs which are potentially low safety-significant and are potential candidates for reduced treatment requirements. Low safety significance is validated by the IDP process which will considers factors such as defense-in-depth, and risk insights outside the scope of the PRA. Low safety significance must be confirmed by demonstrating that risk increases (if any) are small. This demonstration can be in the form of sensitivity studies to bound the overall change in CDF and LERF from changes in treatment.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-11	The final rule should include a feedback mechanism for re-assessing SSC categorization based on operating experience to assure that the SSCs are properly categorized.	The NRC agrees with this comment. Feedback is necessary so that the licensee can monitor performance against expectations, and where these are not consistent, adjust treatment or categorization as needed. This maintains the validity of the categorization process that established the new treatment requirements. The proposed rule in paragraph (e) includes requirements for feedback and process adjustment based on operating experience, changes to the facility, changes to operating practices, and industry experience. Specifically, proposed §50.69(e)(1) applies to all SSCs and requires the licensee to review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization. The requirements in (e)(2) require the licensee to monitor the performance of RISC-1 and RISC-2 SSCs and make adjustments as necessary to either the categorization or treatment processes. The requirements in (e)(3) require the licensee to consider data collected in §50.69(d)(2)(iii) for RISC-3 SSCs to determine whether there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv).

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-12	<p>The categorization process may identify other safety-related SSCs that are not categorized as safety-significant, and that are not directly and specifically referenced in the regulation or directly referenced in the safety analyses required by regulation. These SSCs may be categorized as RISC-4 on completion of a satisfactory 50.59 evaluation.</p>	<p>The NRC agrees that reclassification of SSCs from safety-related to nonsafety-related would be acceptable provided the licensee performs a satisfactory §50.59 evaluation and ensures that other documents which refer to such SSC are appropriately changed as necessary (e.g., technical specifications, orders, license conditions). The proposed rule does not address reclassification of SSCs from safety-related to nonsafety-related because such reclassification is not part of the risk-informed consideration of special treatment requirements.</p>
3-13	<p>Relative risk rankings of plant systems and components can change. An SSC categorized as RISC-3 or RISC-4 can later be categorized as RISC-1 or RISC-2, respectively, as a result of new information, a change in performance, or modifications to the plant. The rulemaking process should establish clear requirements for dealing with such situations.</p>	<p>The NRC agrees that changes in classification can occur. When this occurs, the rule requires SSCs whose categorization changes to be treated consistent with the treatment required for the revised RISC category (i.e., a change of SSC categorization from RISC-3 to RISC-1 requires that the component meet the RISC-1 treatment requirements). It is the licensee's responsibility to manage the process in a manner that avoids such situations.</p>
3-14	<p>ASME has developed risk-informed code cases for categorization, testing, and inspection. In addition, ASME is currently developing risk-informed code cases for other areas, including a code case on repair/replacement/modification activities. It would be more appropriate to reference those code cases instead of including detailed requirements in the rules.</p>	<p>The detailed requirements (on categorization) referred to in the comment (Appendix T) are no longer part of the proposed rule. The rule requirements on repair and replacement are not detailed. The proposed rule would permit the use of approved ASME risk-informed code cases for implementation of proposed §50.69.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
3-15	<p>Since substantial effort has already been expended in the development and publishing of ASME Code Cases (as well as NRC Regulatory Guides), it would seem that the terminology that the industry has agreed to use should continue to be consistently utilized. The ASME Code Cases (and NRC Regulatory Guides) use terms High/Low Safety Significant Components vice Safety Significant Components/Low Safety Significant Components (as used in the ANPR).</p>	<p>The NRC disagrees with this comment. The terminology used in the ANPR as reflected in the proposed rule represents the Commission's views about the overall significance of the two categories for a broad range of SSCs. Terminologies used in specific code cases can be aligned with the categories as expressed in the rule.</p>



**TABLE 4 - PILOT PROGRAM**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-1	A higher degree of regulatory predictability and benefit must be established before piloting the proposed regulatory framework. This can be accomplished by development of an NRC-endorsed industry guideline.	This comment describes a situation in which an industry guideline is first endorsed by the NRC and then piloted. The NRC elected not to follow such an approach. Instead, as discussed in Section IV.3 of the SOC, pilot activities focused upon categorization of SSCs. The NEI 00-04 implementation guidelines reflect lessons-learned from this pilot program. The staff's review of drafts of the proposed guidelines was undertaken in parallel with the pilot program.
4-2	The purpose of the pilot program should be to verify that the requirements and associated guidance of the categorization process can be implemented by industry, to demonstrate the viability of risk categorization processes to establish alternative risk-informed special treatment requirements, and to test out special treatment requirements. The pilot program should also provide estimates of implementation costs and benefits from this effort.	These objectives are consistent with those described by the NRC in an October 19, 1999 letter regarding the pilot program from Samuel Collins to Ralph Beedle, and in SECY-99-256. However, the pilot activities focused primarily on the categorization process. The NRC staff's interaction with the pilots was to observe the IDP (the culmination of the categorization process) and provide feedback. This focus is consistent with the NRC's objective of developing a robust categorization process.
4-3	There is no need to specifically pilot each rule. Testing the guideline against a sample set of regulations and systems is sufficient for resolving implementation issues and providing the bases and confidence for generic implementation on the complete spectrum of Option 2 regulations.	The NRC agrees with this comment. The main purpose of the pilots as they were conducted was to test categorization.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-4	<p>As with any unknown process, when you start the process it will be difficult to determine what schedules and resources must be applied to the process to come up with a "good" product. All that can be done is to initially define the best scope of work possible with well defined deliverables and schedules. As one proceeds with the pilot programs, continuous feedback must be used to adjust the process as one goes. It makes no technical sense to commit to schedules and requirements in advance.</p>	<p>The NRC agrees with this comment. We recognize the difficulties in planning activities that lack good precedent and experience. We also understand that schedules and scope of activities may require adjustment as experience is gained, and problems are identified and resolved.</p>
4-5	<p>The requirements on pilot plants are unnecessarily restrictive. The requirements that pilot plants must include a variety of plant systems is not necessary because South Texas Project has demonstrated the viability of the concepts underlying the risk-informed classification process.</p>	<p>The NRC agrees with this comment. In practice, a variety of systems were piloted by the different pilot plants as discussed in Section IV.3 of the SOC. The participants obtained NRC staff input concerning the systems which should be piloted and this ensured that the staff was satisfied with the variety of systems that were ultimately piloted. The pilot program was implemented in a manner different than was initially envisioned in the extent of the pilots was limited to categorization of SSC, and not implementation of any revised special treatment. Thus, it was not necessary for pilot program participants to apply for exemptions from the current special treatment requirements.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
4-6	<p>The STP exemption request should be completed prior to rulemaking. Potential pilot plants are closely watching the status of the STP exemption request. If the eventual outcome is that STP is not granted the exemption request, other potential pilot plants will likely consider the ability to categorize SSCs and adjust the special treatment requirements to be overly difficult and will not pursue this possibility.</p>	<p>The NRC agrees with this comment. The NRC staff's review of the STP exemption request was completed in August 2001, well before issuance of the proposed rule.</p>
4-7	<p>Pilot plants should not be forced to adopt the final rule because their methodologies would have been reviewed and found acceptable. Pilot plants will seek exemptions to NRC regulations to apply and pilot the special treatment requirements defined in Option 2. Some pilot plants may wish to deviate from the generic guidance because of differing designs and established licensee practices. This is both necessary and beneficial from a pilot project perspective. The varying approaches, approved by the NRC in the exemption process, will be assessed and evaluated by the NRC staff. As necessary and appropriate, a licensee might adjust its approach based on implementation insights and NRC input during the pilot project.</p>	<p>Because of the manner in which the pilot program was implemented, this comment is not applicable. No exemptions were requested for any pilot plants.</p>

**TABLE 5 - TREATMENT**

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

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-3	Consideration of normal operation or the existing design basis accidents should be included in the proposed rulemaking only in clear areas (e.g., sabotage) where information from a Probabilistic Risk Assessment has not been applied.	The NRC disagrees with this comment. Under the proposed rule, safety-related SSCs must remain functional under design basis conditions, because the design basis for a plant remains unaffected by the 50.69 rule. The NRC is considering risk-informed changes to the existing design basis accidents under Option 3 of RIP50.
5-4	It is not clear what the Commission means by the last sentence in the proposed meaning for special treatment (i.e., "This definition does not encompass functional design requirements; that is, an SSC's functional design requirement is not considered a special treatment requirement.")	It is the NRC's position that regardless of the treatment imposed, SSCs must continue to be functional for the design basis events because the proposed rule does not change the design basis for any SSCs in the plant. The proposed rule is risk-informing the "assurance" requirements. The design basis functional requirements remain unchanged by the proposed rule. Hence, the proposed rule contains requirements intended to provide confidence that RISC-3 SSCs continue to perform their design basis functions at the conditions under which the intended functions are required to be performed.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-5	Existing special treatment requirements will continue to apply to RISC-1 SSCs. Any additional requirements considered for RISC-1 SSCs in order to satisfy PRA assumptions or beyond design basis events should be qualified to account for existing special treatment requirements and licensee programs being applied to these SSCs and the actual performance of the SSCs. An evaluation of the need for additional special treatment requirements for non-safety-related functions of RISC-1 SSCs should only be undertaken if a licensee: (1) takes credit in the PRA for a RISC-1 SSC functioning at a level that is better than the reliability/availability levels associated with existing operating experience; or (2) determines that a significant reduction in risk can be achieved through additional specific treatment requirements.	<p>The NRC agrees that existing special treatment requirements will continue to apply to RISC-1 SSCs. Additional treatment requirements for RISC-1 SSCs are included in the proposed rule. These requirements do not preclude taking credit for existing requirements and programs.</p> <p>The NRC disagrees with the criteria in the comment for when an evaluation of the need for additional treatment is to be undertaken. We conclude that the licensee should ensure that RISC-1 and RISC-2 SSCs perform their functions consistent with the categorization assumptions by evaluating treatment applied to these SSCs to ensure that it supports the key assumptions for performance. The NRC recognizes that in many cases, licensees may determine that no additional treatment is necessary.</p>
5-6	The final rule should include a general performance-based standard for RISC-2 SSCs that would allow licensees to establish their own treatment programs or take credit for existing programs to maintain the reliability/availability of these SSCs as assumed in the PRA. This, when combined with the monitoring requirements of the maintenance rule and periodic PRA updates, should be sufficient to ensure the reliability/availability of the RISC-2 SSCs as assumed in the PRA.	The NRC agrees in principle to allowing flexibility in licensee implementation of performance monitoring methods. The proposed rule allows licensees to establish treatment programs or take credit for existing programs to maintain the reliability/availability of these SSCs as assumed in the PRA.
5-7	The functional capability of RISC-3 SSCs should be maintained.	The NRC agrees with this comment and the proposed rule has been developed to include requirements that provide sufficient assurance that RISC-3 functional capability is maintained.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-8	Because RISC-3 SSCs are by definition low safety-significant, no special treatment requirements, beyond normal commercial practices (as determined by the licensee), are warranted.	The NRC believes that an acceptable treatment program for RISC-3 SSCs must meet the minimum requirements specified in proposed §50.69(d)(2). We believe that some commercial programs do in fact satisfy these minimum requirements. However, we do not believe that all commercial programs satisfy these requirements, and therefore these requirements were included in proposed §50.69.
5-9	Monitoring of RISC-3 SSCs should only be required if a change in performance of the SSC could affect its safety classification.	NRC does not agree with this comment. The rule requires inspection, tests and surveillance for RISC-3 SSCs to obtain information about their capability to perform their functions in proposed §50.69(d)(2)(iii). The rule also requires the licensee to use this information to determine if the categorization, or the treatment being applied needs to be revised in proposed §50.69(e)(3).
5-10	RISC-4 SSCs should continue to be treated in accordance with normal commercial grade standards.	The NRC agrees with this comment. These SSCs are of low significance both from the “safety-related” and PRA perspectives, and thus there is no reason to alter the treatment requirements for these SSC (which is presently in accordance with commercial standards).
5-11	A change-control process covering beyond design basis functions should be incorporated in the new 10 CFR 50.69.	The proposed rule contains feedback and process adjustment requirements such that the PRA and categorization process are to be reviewed and revised to account for plant design changes. Refer to the response to issue 3-11 for a detailed discussion of feedback requirements. Thus, if changes are made that affect beyond design basis functions, this would be reflected in the SSC categorization.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-12	RISC-1 and RISC-3 SSCs should remain subject to the requirements of 10 CFR 50.59 for design basis functions.	The NRC agrees with this comment with respect to the application of §50.59 to RISC-1 and RISC-3 SSCs. Note that the current scope of applicability of §50.59 is more broad than the SSCs that will be categorized as RISC-1 and RISC-3.
5-13	RISC-3 SSCs should not be subject to 50.72 or 50.73 reporting requirements based on the assumption that these SSCs have minimal or no safety significance.	The NRC agrees with this comment. We have included §50.72 and §50.73 in the scope of §50.69(d)(2).
5-14	All commitments related to low safety-significant SSCs should be replaced by a single commitment that imposes commercial level (balance-of-plant) special treatment requirements (monitoring or controls) to provide reasonable assurance that the functions required by regulation or credit in the safety analyses required by regulations will be satisfied. Evaluation of individual SSCs with respect to commitments is not necessary or practical.	The NRC disagrees with this comment. Changes to treatment requirements for low safety-significant SSCs should only be made upon consideration of whether functionality under design basis conditions would be maintained with the planned change, not whether they are commitments.
5-15	Part 21 should not be included in the Option 2 scope. Part 21 is a complex regulation with hard links to the Atomic Energy Act. As such, any change to the scope of Part 21 would be a complex and prolonged activity that may involve a change to the Atomic Energy Act.	NRC disagrees with this comment. The burden associated with Part 21 requirements is not appropriate for RISC-3 SSCs given their low safety significance. While it is true that Part 21 has hard links to the AEA, the NRC has included Part 21 within the scope of §50.69 and discusses why the requirements of the AEA are still satisfied in Section III.4.1 of the supporting statement of considerations. As a practical matter, vendors are still likely to report defects in RISC-3 SSCs per Part 21 for the reasons stated in Section III.4.1.2 of the supporting statement of considerations.



ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-16	<p>Part 21 does not currently apply to RISC-3 SSCs because a failure of these SSCs could not cause a substantial safety hazard. There also is no safety reason to impose risk-informed Part 21 requirements on SSCs that are not safety-significant.</p>	<p>We agree that when SSCs are correctly categorized with respect to their safety significance, deviations and failures to comply for RISC-3 SSCs are unlikely to create a substantial safety hazard and thus cause the notification requirements of Part 21 to be exceeded. A failure of a properly-categorized RISC-3 SSC should result in only a small change in risk, and should not result in a major degradation of essential safety-related equipment (see NUREG-0302). Thus, there is little regulatory need for the NRC to be informed of instances of noncompliance and defects with RISC-3 SSCs. This is consistent with the NRC's current position that a "substantial safety hazard" involves a major degradation of essential safety-related equipment (see NUREG-0302). Accordingly, the Commission proposes that RISC-3 SSCs should not be subject to reporting requirements of Part 21 and § 50.55(e).</p>
5-17	<p>Part 21 does not currently apply to RISC-2 or RISC-4 SSCs because these SSCs are not basic components as defined in the Act or in Part 21. In addition, Part 21 requirements should not be imposed on RISC-2 SSCs because: (1) it would be unfair to vendors who have already sold the SSCs to incur the resulting costs, and (2) 50.72 and 50.73 are sufficient to alert the NRC to significant adverse conditions and failures in RISC-2 SSCs.</p>	<p>The NRC agrees that Part 21 should not be imposed on RISC-2 or RISC-4 SSCs, as discussed in greater detail in section III.4.1 of the SOC. As noted below, the 50.72 and 50.73 reporting requirements are being supplemented with a specific criterion for reporting concerning RISC-2 SSCs.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
5-18	<p>Making Part 21 risk-informed would not be inconsistent with Section 206 of the Energy Reorganization Act or Section 223.b of the Atomic Energy Act. The Commission has previously taken the position that Section 206 does not require Part 21 to apply to all safety-related SSCs and that the NRC has discretion to determine what kinds of SSCs should be considered "basic components," and this position has been accepted by the courts. See <i>Natural Resources Defense Council v. NRC</i>, 666 F.2d 595, 603 (D.C. Cir. 1981). Therefore, NRC is free to risk-inform the definition of "basic component" in Part 21. The definition of "basic component" in Section 223.b is restricted to that section, does not apply to Section 206, and does not require that the NRC use the same definition of "basic component" in Part 21.</p>	<p>The NRC agrees that implementing Part 21 in a risk-informed manner is not inconsistent with Section 206 of the Energy Reorganization Act. The NRC also agrees that the definition of basic component in Section 223.b of the Atomic Energy Act is restricted to that section. The U.S. Department of Justice has the authority and responsibility for criminal prosecutions under Section 223.b.</p>
5-19	<p>A performance-based 10 CFR 50.73 type reporting requirement should be included in the new 50.69 for RISC-2 SSCs.</p>	<p>The NRC agrees that a reporting requirement for RISC-2 SSCs should be included in §50.69. Since these SSC are now viewed as safety-significant, the NRC, as part of its risk-informed oversight activities, wants to be informed about conditions impacting upon functionality of these SSC. This is included in the proposed rule.</p>

**TABLE 6 - SELECTIVE IMPLEMENTATION**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
6-1	<p>The risk-informed rules resulting from this rulemaking should allow for selective implementation with respect to both rules and systems. Selective implementation of rules does not present any adverse impacts because if a licensee decides not to implement a risk-informed regulation, the licensee would be required to meet the existing deterministic regulation which provides adequate protection of the public health and safety. Therefore, although there may be benefits from full implementation of the risk-informed rules, licensees should be allowed to determine whether the benefits outweigh the costs. With respect to systems, some safety-related systems will obviously be safety- significant while other nonsafety-related systems will obviously be low safety- significant. There is no benefit to implementing the risk-informed rules for such systems.</p> <p>Implementation on a system basis should proceed with first priority on systems with components that are very likely to be categorized as RISC-2 or RISC-3, second priority for systems whose components have some potential for being categorized as RISC-2 or RISC-3, and no priority for systems whose components are highly likely to be categorized as RISC-1 or RISC-4.</p>	<p>The NRC agrees with this comment for the reasons noted. The proposed rule is constructed to allow implementation for select rules or select systems. As discussed in section IV.1.3 and V.5.0 of the SOC, selective implementation will necessitate that the categorization process assumptions continue to be valid, which involves satisfying certain requirements for evaluation and monitoring.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
6-2	The final rule should provide licensees with the option of categorizing the different functions of an SSC instead of forcing all functions of the same SSC to be categorized in the same RISC class.	The NRC agrees with this comment, as being a viable way to determine the appropriate classification of a particular SSC. We recognize that many licensees have used a “functional categorization” approach for the maintenance rule. The proposed rule allows this categorization approach. However, this can be a difficult and cumbersome process from the standpoint of record keeping.

**TABLE 7 - IMPACT ON OTHER REGULATIONS**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
7-1	Maintaining a single NRC Form 3 posting (as required by 10 CFR Part 19) would not confuse licensee staff and contractors. Under either a risk-informed or deterministic regulatory regime, the NRC Form 3 intent remains the same.	Licensees and applicants who implement §50.69 should examine their posting practices (for required notices) to be sure that appropriate information is provided to employees.
7-2	A risk-informed Option for Part 54 should be developed. Since licensees in general rely upon existing special treatment requirements to satisfy Part 54, the scope of SSCs subject to Part 54 should not be broader than the scope of SSCs subject to special treatment. Risk informing Part 54 would likely result in a more efficient process for both licensees and NRC, since neither would be required to evaluate the impact of aging on SSCs that are not safety-significant.	The NRC disagrees that RISC-3 SSCs should be removed from the scope of Part 54 as part of this rulemaking. We believe that licensees that implement §50.69 can renew their licenses in accordance with Part 54 by demonstrating that the treatment applied in accordance with §50.69 provides adequate aging management under Part 54.21. Part 54 already allows consideration of risk in terms of the robustness of the aging management program, as discussed in Section III.4.9.8 of the SOC.

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
7-3	<p>The terms "operability" and "functionality" are not equivalent terms. A system can be "functional," yet declared inoperable, e.g., because it has missed a required surveillance test or because a support system is not functional. In other words, a safety-related system can be declared inoperable even though the system is capable of providing its specified safety function.</p> <p>Although there is a difference in meaning between "functional" and "operable," we do not believe that this difference has any importance with respect to the type of treatment to be afforded to RISC-3 SSCs. Such SSCs should be subject to commercial practices, which will be sufficient to ensure that they have sufficient availability and reliability to perform their safety-related functions. To the extent that such SSCs are also controlled by the technical specifications, they will also need to satisfy the operability requirements in the technical specifications, including passing all required surveillance tests (unless the licensee seeks and justifies a license amendment to remove such SSCs from the scope of the technical specifications).</p>	<p>The NRC agrees that the difference in meaning between "functional" and "operable" is not relevant to this rulemaking. The NRC's position on treatment of RISC-3 SSCs sufficient to maintain functionality is covered by the responses to the issues in Section 5 of these tables and by the requirements in proposed §50.69. The NRC also agrees that to the extent that RISC-3 SSCs are controlled by technical specifications, they are required to satisfy the operability requirements in the technical specifications, including passing all required surveillance tests.</p>

**TABLE 8 - NEED FOR PRIOR NRC REVIEW**

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-1	<p>Performing a 50.59 evaluation (and, as necessary, obtaining NRC approval) for each change in a special treatment requirement in the UFSAR would be extremely burdensome and prohibitively costly for both licensees and the NRC. There are two options to dealing with 10 CFR 50.59. 10 CFR 50.59 could be made risk-informed to eliminate the need for individual 50.59 evaluations (and prior NRC approval) for each change in special treatment described in the UFSAR. Alternatively, the revised 50.59 could be interpreted as not requiring a full evaluation for revisions of the special treatment described in the UFSAR.</p>	<p>The NRC agrees that it would be unnecessarily burdensome to perform a §50.59 evaluation for each change in special treatment requirements resulting from the categorization. However, it is not necessary to change or reinterpret §50.59 to implement §50.69. Instead, the proposed §50.69 allows licensees to revise treatment without the need for a §50.59 evaluation to support the resulting FSAR changes. This rulemaking is being undertaken to establish the requirements for the revised treatment for the SSC. Performing §50.59 evaluations to determine if NRC review and approval of these changes would be unnecessary and redundant.</p>
8-2	<p>Ultimately, 10 CFR 50.59 should be risk-informed to allow licensees to make design changes that do not have risk-significance.</p>	<p>Risk-informing §50.59 is beyond the scope of the Option 2 regulatory effort.</p>

ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-3	<p>The industry fully supports and encourages the open dialogue that has been established by the NRC to provide public, licensee, and NRC staff participation. It is only through such open dialogue that a complete understanding of risk-informed regulatory improvements can be established. The existing process provides significant material for public review and provides sufficient opportunity for public input and participation on matters that have safety-significance. The public will have the opportunity to participate in developing the criteria for the classification process in the rulemaking. It is difficult to envision a higher degree of opportunity for public participation or access to information. Once the rule is approved, the public should have no special participation rights.</p>	<p>The proposed rule requires licensees to submit a license amendment to implement §50.69. The categorization process and supporting PRA information will be reviewed and approved by NRC. Under proposed §50.69, that review will entail considerable judgment and discretion on the part of the NRC, and the NRC approval effectively changes the authority afforded by the operating license. Accordingly, the NRC believes that such approvals must be implemented as a license amendment under the authority of <i>Cleveland Electric Illuminating Co. (Perry Nuclear Power Plant, Unit 1)</i>, CLI-96-13, 44 NRC 315 (1996).</p>



ISSUE NO.	COMMENT SUMMARY	NRC RESPONSE
8-4	<p>NRC review of a licensee's implementation of the final rule should be limited to certain process aspects of the categorization and treatment determination to ensure compliance with the final rule. A template submittal to notify the NRC of a licensee's intent to adopt the resulting risk-informed rules is being developed by NEI. This would include statements on PRA quality, the methodology used in the risk-evaluation process, the list of regulations being adopted, and a discussion of the extent to which the licensee's approach is consistent with an endorsed guideline. NRC review of the information provided in the template should be sufficient to ensure compliance. After implementation of the resulting rules, the inspection process should be sufficient to confirm reasonable assurance that public health and safety is maintained.</p>	<p>The NRC agrees with this comment as it related to treatment but disagrees with this comment as it relates to categorization. Because of the heavy reliance on a robust categorization process, the NRC believes that a thorough review of the categorization process (and in particular of the supporting PRA information) is necessary. The information that is required to be included in an application for implementation of §50.69 is in the proposed rule.</p>
8-5	<p>The objective to establish categorization and treatment criteria sufficient that if a licensee's program meets them there is no need for prior NRC review and approval of the plant-specific program is impossible to do in actual practice.</p>	<p>The NRC agrees with this comment. The NRC developed proposed §50.69 to utilize a "prior review and approval" type approach on categorization.</p>