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November 13, 2001

The Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001
Attention: Mr. Timothy Reed

Re: Comments on Draft Language – Risk Informed Special Treatment Requirements

Dear Secretary:

On September 26, 2001, the NRC staff issued background material on “Option 2” – Risk-Informing Special Treatment Requirements in 10 CFR Part 50. That material provides draft language for the Option 2 rule to risk-inform NRC’s special treatment requirements, outlines the NRC’s “boundary conditions” for the Option 2 rulemaking, and provides three alternatives for special treatment of RISC-3 structures, systems, and components (SSCs). In response to the staff’s request for stakeholder comments on the draft Option 2 language, we are submitting the following consensus comments on behalf of our clients Exelon Generation, LLC; South Texas Project Nuclear Operating Company; TXU Electric; AmerenUE; and Arizona Public Service Company.

We appreciate the opportunity to submit comments on this very important rulemaking for the industry, and we fully support the Commission’s efforts to risk-inform special treatment requirements in 10 CFR Part 50. However, we remain concerned that the provisions in the draft language in general, and the special treatment requirements for RISC-3 SSCs in particular (as provided in NRC’s alternatives 2 and 3), are overly restrictive and prescriptive. Given the low safety significance of RISC-3 SSCs, such prescriptive requirements are not necessary for safety. Furthermore, we believe that the detailed requirements in the draft language would render the rule economically non-viable, and would discourage many licensees from deciding to implement the rule. Consequently, we believe that the Option 2 rule should be more flexible, and should allow licensees to implement their normal commercial practices for RISC-3 SSCs.

Attachment 5-1

We also are concerned that two of the three Boundary Conditions that NRC has established for Option 2 rulemaking appear to establish unnecessary and burdensome new restrictions. While the NRC states that all three conditions have bounded the Option 2 rulemaking process from the start, Boundary Conditions 2 and 3 were not discussed in the NRC's safety evaluation report (SER) for the South Texas Project (STP) risk-informed exemption request. They also are unnecessary for safety, and are not consistent with the Commission's stated intent to reduce unnecessary regulatory burden for SSCs of low safety significance. Moreover, by applying the Boundary Conditions to the three special treatment alternatives being considered for RISC-3 SSCs, the NRC has all but eliminated from consideration the first alternative (Commercial Treatment) that would provide the greatest benefit to the industry with no adverse effect on public health and safety.

We also believe that the draft rule language is unnecessarily narrow in terms of the relief from special treatment requirements provided to RISC-3 and 4 SSCs. For example, the draft rule would not provide relief from the environmental qualification test requirements in 10 CFR § 50.49 or from the seismic qualification analysis requirements in Appendix A to Part 100, and would not provide any relief from the special treatment requirements applicable to RISC-4 components (except for the requirements in the Maintenance Rule). Additionally, the draft rule would not provide any relief for RISC-3 and 4 components from the special treatment requirements in the fire protection rule in Appendix R to Part 50, or from the license renewal in Part 54. There is no basis for applying all of these special treatment requirements to RISC-3 and 4 SSCs.

Finally, several of the provisions in the draft language were not included in the approved STP exemption request. In general, these new provisions would increase the burden associated with implementation of the rule and are not necessary to safety. These more burdensome provisions should be deleted from the Option 2 rule.

Attachment A provides our detailed comments on the draft language.

Sincerely,

Steven P. Frantz

SPF/emh
Enclosure

**Comments on Proposed Language for
Risk-Informing Special Treatment Requirements**

We strongly support the Commission's effort to move forward on Option 2 rulemaking, and we encourage the Commission to continue to give high priority to completing this important rulemaking. However, we do have several concerns regarding the provisions in the draft language. Specifically:

- NRC's "Boundary Conditions" for the Option 2 rule are unnecessary for safety and would impose an undue burden on licensees.
- Alternatives 2 and 3 for special treatment of RISC-3 SSCs are too prescriptive and are unnecessary to ensure their functionality.
- The scope of the Option 2 rule is unduly narrow and does not take full advantage of the opportunity to risk-inform NRC's special treatment requirements.
- Draft § 50.69 contains a number of burdensome new requirements and restrictions that were not imposed on the STP exemption.
- NRC should establish a method for implementing the rule that does not require prior NRC review and approval.

Each of these concerns is discussed in more detail below.

I. The Second and Third Boundary Conditions for Rulemaking Under Option 2 Are Overly Restrictive and Are Unnecessary

The NRC recently established three Boundary Conditions that are to guide the NRC staff in its consideration of alternatives for RISC-3 special treatment requirements. The Boundary Conditions govern component functionality, component availability and reliability, and continued regulatory assurance. The NRC has stated that any alternative that does not meet all three Boundary Conditions will not be considered for implementation.

Boundary Condition 1 states, in part, that RISC-3 SSCs must meet their existing functional requirements and capabilities during design basis conditions. This condition is equivalent to the functional constraint applied by the NRC during its review of the STP exemption request. The NRC, however, unnecessarily has imposed two additional Boundary Conditions on its consideration of RISC-3 alternatives.

A. Boundary Condition 2 – Reliability and Availability of RISC-3 Components

Boundary Condition 2 states that the special treatment process must maintain the functionality of RISC-3 SSCs consistent with the reliability and availability assumptions in the categorization process. This condition is intended to ensure that any reduction in the special treatment requirements for RISC-3 components does not adversely impact the failure rate assumptions for these components in the plant's probabilistic risk assessment (PRA) or characterization process. We do not believe that this requirement is warranted given the low safety significance of RISC-3 components.

In general, it may be expected that only a small fraction of RISC-3 components will be modeled in the PRA. This is because they generally have no or, at most, a negligible contribution to the initiation or mitigation of accidents modeled in the PRA. Therefore, at a minimum, there should be no requirement to maintain any particular quantitative availability or reliability of those SSCs, because no credit is taken for the reliability or availability of those SSCs in the PRA.

For those SSCs that are modeled in the PRA, NRC is proposing to require the licensee to perform a sensitivity analysis on failure rates of RISC-3 SSCs to demonstrate that a three- to five-fold increase in the failure rates would not affect their categorization. Therefore, requiring a licensee to maintain the availability and reliability of these RISC-3 SSCs is not justified, because even a substantial decrease in availability or reliability would not adversely affect the public health and safety, or the categorization, of those SSCs. We believe that normal corrective action and commercial processes are sufficient to provide reasonable assurance that functionality of RISC-3 SSCs is maintained.

We also note that this Boundary Condition would impose restrictions beyond those considered during the NRC review and approval of the STP exemption request. STP has not committed and is not required to monitor the availability and reliability of its LSS components on an ongoing basis, nor have they committed to maintain the availability or reliability of LSS components. STP only is required to address significant negative performance changes in LSS components that are attributed to the relaxation of special treatment requirements.

We believe that the NRC has not explained or justified why Boundary Condition 2 is warranted given the low safety significance of RISC-3 SSCs, and the negligible contribution of the failure rates of these SSCs on core damage frequency (CDF) and large early release frequency (LERF). Therefore, we recommend that NRC delete this boundary condition, since it imposes an unnecessary burden. Public health and safety can be ensured adequately by Boundary Condition 1 alone, and by requiring licensees to address significant negative performance changes in RISC-3 SSCs that could affect a SSC's risk-informed categorization.

B. Boundary Condition 3 – Maintenance of a Level of Regulatory Assurance of the Continued Functionality of RISC-3 SSCs

Boundary Condition 3 states that RISC-3 SSCs need to receive sufficient regulatory treatment such that the continued functionality of these SSCs is maintained, albeit at a reduced level of assurance. We do not believe this separate regulatory oversight condition is warranted given the low safety significance associated with RISC-3 SSCs.

Boundary Condition 1 already states that RISC-3 SSCs must meet their existing functional requirements and capabilities during design basis conditions. An additional condition requiring a minimum (but as yet undefined) level of regulatory oversight on these components is not required for public health and safety.

It is unclear why the NRC has added this Boundary Condition. Any licensee planning to implement Option 2 must commit to maintain the design basis functional requirements of RISC-3 SSCs and must implement an NRC-approved categorization process. Given the low safety significance of RISC-3 components, this process should be sufficient to provide the NRC with the necessary regulatory assurance. It is not essential for the NRC to maintain regulatory oversight of the details of a licensee's treatment of those SSCs. Application of normal commercial practices will provide sufficient assurance of the functionality of RISC-3 SSCs, commensurate with their low safety significance. Thus, there appears to be no safety basis for regulatory oversight of the treatment for RISC-3 components.

We recommend that NRC delete this Boundary Condition. It imposes an unnecessary restriction on RISC-3 SSCs. Public health and safety can be ensured by Boundary Condition 1 alone and by normal commercial practices and corrective action processes.

II. Commercial Practices Provide Reasonable Assurance of Functionality

NRC is considering a range of alternatives for special treatment requirements for RISC-3 SSCs. In particular, the NRC is considering three alternatives: (1) reliance on commercial practices; (2) specification of high-level treatment attributes; and (3) specification of detailed treatment attributes. For the reasons discussed below, we strongly urge the Commission to adopt the first alternative.

Initially, we note that when the NRC initiated the Option 2 rulemaking more than two years ago, both NRC and the industry were under the impression that RISC-3 and 4 SSCs would be subject to normal commercial practices. As stated in SECY-98-300:

Under this option, SSCs of low safety significance (from a risk-informed assessment) would move from “special treatment” to normal industrial (sometimes called “commercial” treatment), but would remain in the plant and expected to perform their design function but without additional

margin, assurance or documentation associated with high safety significant SSCs.

Thus, adoption of either Alternative 2 or 3 would constitute a significant departure from the assumptions underlying the Option 2 rulemaking.

NRC has concluded (based on the INEEL report on this subject) that commercial practices are not sufficiently defined within the nuclear industry to provide reasonable confidence that RISC-3 SSCs are capable of performing their safety functions under design-basis conditions, throughout their service life, consistent with the assumptions in the categorization process. We disagree and believe that no special treatment requirements beyond normal commercial practices are warranted given the low safety significance of RISC-3 SSCs.

We believe that the INEEL commercial practices study referenced by the NRC does not provide a sufficient basis for imposing special treatment on RISC-3 SSCs. Rather than focusing on whether commercial programs at nuclear power plants are sufficient to provide reasonable assurance of component functionality, it focused instead on differences between commercial standards and the requirements in Appendix B to Part 50 and other NRC requirements. Additionally, INEEL never examined how licensees actually implement their commercial practices, nor did it examine whether commercial practices, in actuality, have been sufficient in the past to assure the functionality of components.

The commercial practices to be applied to RISC-3 SSCs are the same controls and practices that are applied to non-safety-related components at nuclear plants. Commercial practices include design, procurement, inspection, testing, work processes, maintenance, assessment, and corrective action. The nature and level of commercial treatment applied to each component can vary depending on its design function. Commercial practices are based on various factors, including nationally recognized standards and vendor recommendations. More importantly, commercial practices have been proven to be effective in practice – scram rates are at an all-time low and capacity factors for nuclear plants are at an all-time high, thereby demonstrating the efficacy of commercial practices.

Commercial practices are sufficiently rigorous and effective to provide reasonable assurance of functionality of RISC-3 SSCs, commensurate with their low safety significance. A licensee's sensitivity studies will demonstrate that even a substantial increase in the failure rates of these SSCs will have a negligible effect on CDF and LERF. Overall, we believe that commercial practices are sufficiently robust for RISC-3 SSCs given their low safety significance and the proven effectiveness of commercial practices.

NRC has expressed concern that commercial practices are variable throughout the industry, and that there is no set definition of the controls that comprise commercial practices. However, such variation should be viewed as a strength, not a weakness. This

variation enables each licensee to optimize its controls based upon its particular needs and the design function of the component. For example, a licensee with a strong and experienced workforce may not need the same level of proceduralized controls as a licensee with a less experienced workforce. Additionally, a simple mechanical component that operates in an environmentally controlled environment may need less commercial controls than a more complicated digital component that operates in a steam environment. Requiring each licensee to establish the same type of controls for each SSC will impose undue burdens without necessarily resulting in any improvements in performance of RISC-3 SSCs.

In any event, variation in performance of RISC-3 SSCs is not a safety concern. Such variation will be more than accounted for by the sensitivity studies conducted during the categorization process. Furthermore, based upon the good performance of non-safety-related SSCs at nuclear plants, there is no basis for believing that a change from special treatment to commercial practices will have any significant impact in equipment performance. To the contrary, as shown in STP's exemption request, available data on the failure rates of safety-related and non-safety-related components demonstrates that there is no appreciable difference in failure rates.

Alternatives 2 and 3 each would require special treatment that goes beyond normal commercial practices. We believe that these alternatives (and Alternative 3 in particular) are too prescriptive and restrictive given the low safety significance of RISC-3 SSCs. Additionally, neither alternative may be commercially viable. We know of no commercial vendor that maintains programs that satisfy the special treatment requirements in alternatives 2 and 3. As a result, both alternatives would require licensees to develop new treatment processes governing design control, procurement, installation, maintenance, inspection, and configuration controls for RISC-3 components. While these processes are admittedly less stringent than full Appendix B treatments, they are more burdensome than commercial practices, and will require significant resources to develop, implement and maintain. This effort will significantly dilute any burden-reduction benefit gained from risk-informed special treatment requirements. In fact, we believe the effort necessary to develop these separate programs may be so significant as to discourage many licensees from deciding to implement the rule.

In short, it is simply not economically viable for licensees to establish and maintain three types of controls: 1) special treatment controls, 2) commercial controls, and 3) a third level of controls intermediate to the first two. The risk-informed rule will be of little value if it merely substitutes one set of special treatment requirements for another set of special treatment requirements. Furthermore, proliferation of the number of different types of controls is undesirable from a human-factors perspective, and thus may be contrary to safety. Instead, the risk-informed rule will have significant benefit only if licensees are allowed to apply their normal commercial practices for low safety significant SSCs.

III. The Scope of the Option 2 Rule is Unduly Narrow

Draft § 50.69 is unnecessarily narrow in terms of the relief from special treatment requirements provided to RISC-3 and 4 SSCs. For example, the draft language would continue to impose, without justification, certain special certain treatment requirements for RISC-3 and 4 SSCs that were eliminated in the approved STP exemption request. Additionally, the draft rule would impose other special treatment requirements that reasonably should not be applied to RISC-3 and 4 SSCs.

The scope of the Option 2 rule should be expanded to take full advantage of the opportunity to risk inform NRC's special treatment requirements. In particular, NRC should address the following issues.

- 1) Environmental Qualification -- NRC should exempt RISC-3 SSCs fully from the qualification requirements of § 50.49. Draft § 50.69(e)(3) would only provide an exception for RISC-3 SSCs from the environmental qualification requirements on documentation and margin in 10 CFR § 50.49(e)(8) and (j), but not other relevant requirements (such as the requirements for replacement equipment in 10 CFR 50.49(l) and for qualification testing in § 50.49(f)). As currently worded, draft § 50.69(e)(3) would provide essentially no relief from the qualification requirements in § 50.49. The draft language also is more restrictive than the STP exemption. STP was granted an exemption from the qualification requirements of § 50.49 in general, including the requirements on qualification testing in § 50.49(f).
- 2) Special Treatment for RISC-4 SSCs -- NRC should explicitly exempt RISC-4 SSCs from all current and proposed special treatment requirements. Draft § 50.69(d)(3) (under alternatives 2 and 3) would require RISC-4 SSCs to satisfy all existing applicable special treatment requirements except for the Maintenance Rule, plus establish new monitoring requirements for RISC-4 components that perform a function "credited" in the categorization process. We believe there is no safety basis or justification for imposing any existing special treatment requirements on non-safety-related low safety significant components. There is certainly no basis for imposing new or additional special treatment requirements (such as monitoring) on RISC-4 components. Furthermore, the draft rule could result in the somewhat anomalous situation in which RISC-4 SSCs are subject to more special treatment requirements than RISC-3 SSCs. NRC's proposal also is inconsistent with the STP exemption, which does not impose any regulatory controls on non-safety-related LSS components.
- 3) License Renewal -- NRC should remove RISC-3 and 4 SSCs from the scope of the license renewal rule in 10 CFR Part 54. There is no reason to exclude RISC-3 and 4 SSCs from the scope of NRC's other special treatment requirements, and, at the same time, to subject them to requirements for aging management in Part 54. Instead, RISC-3 and 4 SSCs should be subject to the same treatment during the

period of license renewal as they are during the original 40 year term of the license.

- 4) Fire Protection -- NRC should remove RISC-3 and 4 SSCs from the scope of the special treatment requirements in Appendix R to Part 50 (e.g., the special treatment requirements in Appendix R.II.C, III.E, III.M, and III.N).
- 5) Seismic Qualification -- NRC should exempt RISC-3 SSCs fully from the requirements of Part 100. Draft § 50.69(e)(11) provides an exception for RISC-3 SSCs from only the seismic qualification testing requirements in Appendix A to Part 100. There is no basis for limiting the exception to the testing requirements. This also is inconsistent with the STP exemption, which provided an exemption from both the testing and analytical methods specified in Appendix A to Part 100.

IV. Proposed § 50.69 Specifies Programmatic Requirements Not Included in the STP Exemption Request

Draft § 50.69 specifies requirements that generally are consistent with those approved by the NRC in the STP exemption request. However, there are several new or more burdensome programmatic requirements that were not included in the approved STP exemption request. In SECY-00-0194, Risk Informing Special Treatment Requirements, the NRC stated that it would ensure that the positions in both efforts (Option 2 rulemaking and the STP exemption) would be consistent. We believe that the NRC should, as a minimum, review and revise these requirements to be consistent with the approved STP exemption.

The following is a description of the programmatic requirements that appear to be new or more burdensome than those approved by the NRC in the STP exemption request:

- 1) PRA Updates -- No mandated period for PRA updates should be specified in the rule. PRA updates should be performed on an as-needed basis as determined by the licensee. Draft § 50.69(c)(5)(i) would require that the PRA be updated at least once every 36 months to account for both current plant configuration and operational data. A complete update of the PRA every 36 months would be costly and unnecessary and is inconsistent with current industry practices. This also is inconsistent with the approved STP exemption. STP is only required to update the PRA every 36 months to account for design and procedure changes, and once every 60 months to reflect changes in SSC failure rates and human reliability.
- 2) Reliability and Availability Assumptions for RISC-1 and 2 SSCs -- Draft § 50.69(d)(1)(iii) would require that licensees take action to ensure conformance with the reliability, capability, and availability assumptions in the categorization process for RISC-1 and 2 SSCs. In contrast, STP is only required to monitor the performance of RISC-1 and 2 components to provide reasonable assurance of their ongoing capability to perform their risk significant functions. This generally is done through the Maintenance Rule, and the corrective action and operating

experience programs. The approach used for the STP exemption is more appropriate, since slight changes in reliability and availability will not have a significant impact on risk.

- 3) Reliability and Availability Assumptions for RISC-3 and 4 SSCs -- Draft § 50.69(d)(2)(iii) would require that licensees monitor the performance and condition of RISC-3 SSCs and take action to ensure that the assumptions in the categorization process continue to be satisfied. A similar requirement would be imposed on RISC-4 SSCs under alternatives 2 and 3. In contrast, STP is only required to address significant negative performance changes that are attributed to the relaxation of special treatment requirements. For the reasons discussed in Section I.A above, the approach used for the STP exemption is preferable to the approach in the draft rule.
- 4) Schedule and Scope of Implementation -- Draft § 50.69(f)(iv) and (v) would require licensees to submit a schedule for implementation and identification of the scope of the SSCs to be subject to the risk-informed rule. There is no comparable provision in the approved STP exemption. Furthermore, there is no reason to require a licensee to commit to any particular schedule or scope of components (as long as a licensee does not “cherry-pick” individual components within a system). Until such time as the licensee implements the risk-informed rule for a particular structure or system, it will be subject to all of the special treatment requirements in the current rules. This will provide adequate protection of safety, even if the licensee does not implement the rule per its schedule or is unable to address all of the structures or systems in its plans.
- 5) Design Change Control Process -- Draft § 50.69(g)(2) states that, with respect to design changes for safety significant (RISC-1 and 2 SSC) functions, the licensee shall take actions to provide reasonable assurance that these functions continue to be satisfied consistent with the assumptions in the categorization process, or shall determine that the risk associated with not crediting these functions is not significantly increased. This section imposes new design control requirements on components that remain subject to special treatment requirements. There is no comparable provision in the approved STP exemption. Furthermore, such a requirement is unnecessary and is inconsistent with the purpose of Option 2 rulemaking (which is to focus on special treatment, not design issues). A licensee should be allowed to make design changes that are consistent with 10 CFR § 50.59. 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. For example, if the frequency of a particular event is E-8/yr, even a ten-fold increase in the frequency of that event would not be significant to safety and would not require prior NRC approval under NEI-96-07 (which states that prior NRC approval is not required for increases in frequency where the resultant frequency remains below E-6/yr).

- 6) Documentation of Basis for Treatment -- Draft § 50.69(h)(3) would require that licensees document the basis for treatment of SSCs made pursuant to § 50.69. The STP exemption contains no comparable provision. Furthermore, there is no reason to document the basis for the particular treatment of an SSC (even NRC's current special treatment requirements do not require such documentation). This appears to be a burdensome paperwork requirement with no basis in safety.
- 7) Records -- Draft § 50.69(h)(5) would require a licensee to maintain records applicable to § 50.69 until the license is terminated. This section would appear to impose new lifetime record retention requirements on licensees. In contrast, STP only was required to retain such records as mandated by station procedures. Furthermore, there is no reason to maintain all of the records required by § 50.69. For example, under the draft language, the licensee would be required to maintain records of performance and design changes of components that may have long since been replaced by other components. This is an unnecessary and burdensome paperwork requirement.

In addition to the above special treatment requirements, Alternative 3 does not contain several of the burden-reduction provisions or clarifications included in the STP exemption for RISC-3 components. The following is a list of burden reduction provisions that are included in the approved STP exemption request that we believe should be added to the language of the proposed rule if NRC decides to adopt Alternative 3.

- 1) Post-installation testing may necessitate placing an SSC in service to validate the acceptance of its performance testing. This testing is not necessarily performed under design basis conditions.
- 2) The basis for extending the life of an SSC beyond its design life, while documented, need not be retained as quality records.
- 3) The technical bases for deviations from vendor recommendations are not required to be documented.
- 4) Numerous state and federal consensus and commercial standards are used in the maintenance of SSCs consistent with normal commercial and industrial practices. There is no requirement to itemize the standards in use or perform an evaluation of all referenced consensus standards.

V. Licensee Implementation of Option 2

As noted in Commissioner comments on SECY-99-256, Rulemaking Plan for Risk Informing Special Treatment Requirements, a regulatory approach that requires prior NRC review and approval of the categorization methodology may be viewed by licensees as having too much uncertainty regarding what will be acceptable and too much unpredictability regarding the potential costs to implement the Option 2 alternative. To

address this issue, the NRC proposes to create a new Appendix T to Part 50, which will specify a process for risk-ranking SSCs. Proposed § 50.69(f)(3) states that licensees who implement the requirements of Appendix T, may implement the requirements of § 50.69 without prior NRC approval. If a licensee chooses not to fully implement Appendix T, it must submit a license amendment request. As noted in the Advanced Notice of Proposed Rulemaking (ANPR) on Option 2, Appendix T would be very detailed and prescriptive.

We believe that many utilities may find it difficult, or choose not to, meet the prescriptive requirements of Appendix T. Any decision to implement Appendix T will be licensee-specific, and it will be based on whether that licensee's existing processes and programs can adopt or adapt to the Appendix T requirements. Based on our earlier review of Appendix T as part of the ANPR, we believe that many licensees may choose not to implement Appendix T. This would result in licensees having to request an amendment to their license in order to implement the risk-informed rule. As noted in SECY-99-256, and based on the length of the STP exemption approval process (more than 2-½ years from the date of submission of STP's draft exemption request to issuance of the exemption), the amendment process may be viewed as too unpredictable, uncertain, and costly. Additionally, it would impose an unnecessary administrative burden on the NRC staff to review numerous detailed individual amendment requests.

We believe that there are several acceptable alternatives to this rigid process that would ensure SSC functionality, while providing licensees with some flexibility with regard to characterization methods and techniques. We recommend that rather than issuing detailed and prescriptive criteria in Appendix T, the NRC should instead issue a set of high-level criteria in the regulations, with detailed criteria in a guidance document on the categorization process (or better yet, endorse an NEI guidance document on categorization). A licensee could either implement the guidance document or establish alternatives that satisfy the high-level criteria in the regulation. NRC would not be required to grant prior approval for deviations from the guidance but would verify proper implementation of the rule through the normal inspection and enforcement process. This process would allow utilities at least some minimal flexibility on how to comply with the rule but ensure overall industry consistency. This process is also consistent with how the NRC and licensees have implemented the Maintenance Rule.

Alternatively, a licensee could submit a letter to the NRC committing to implement the risk-informed regulations and include a general description of its program. If the licensee chooses to deviate from the regulatory guidance, the letter would include justification and any supporting analyses for such deviations. Only substantial deviations from regulatory guidance would require prior NRC approval (*i.e.*, deviations that decrease the effectiveness of the categorization process in identifying RISC-1 and 2 SSCs). The detailed program for implementing the risk-informed special treatment requirements would be maintained on-site for NRC inspection. This alternative process would provide NRC with prior review and approval authority for substantial deviations from its regulatory guidance, while avoiding some of the burdens (on the NRC and licensees) associated with the license amendment process. It also would allow utilities at least some minimal flexibility on how to comply with the rule.

VI. Other Clarifications and Comments

We also have the following clarifications and comments regarding the draft language:

- 1) National Consensus Standards -- Alternative 3 requires the use of applicable state and national consensus standards consistent with commercial practices. Consistent with the STP exemption, these provisions should be clarified to refer to “commercial practices *used by the licensee.*”
- 2) Calculating Changes in CDF and LERF -- Draft § 50.69(c)(3) would require a licensee to calculate the change in CDF and LERF resulting from the effect of the change in treatment. As the NRC has recognized, there is no data on such effects, except for the data presented in STP’s exemption request that shows no appreciable differences in failures rates of safety-related and commercial SSCs. Therefore, this section should be clarified explicitly to allow the use of sensitivity studies.
- 3) Categorization of Pressure Boundary Components -- Draft § 50.69(c)(4) requires that the methodology for categorizing pressure boundary functions be “approved.” This imposes an undue burden and unnecessary restriction on licensees. Instead, the rule (or NRC guidance) should specify the criteria for an acceptable categorization process.
- 4) Changes to QA Program Description -- Draft § 50.69(h) should include a provision which states: “Changes to the quality assurance program description to implement 10 CFR 50.69 do not require prior NRC approval under § 50.54(a).”
- 5) Commitment Change Control Process -- Alternative 3, § (iii)(G) would require a licensee to use an NRC-endorsed commitment change control process. This requirement is over-reaching the scope of the risk-informed rule. First, it is not limited to RISC-3 SSCs. Second, it is not limited to special treatment commitments. Furthermore, licensees use different commitment control processes, and a licensee should not be required to change its commitment control processes merely because it is implementing this risk-informed rule.

