DOCKET NUMBER
PROPOSED RULE PR 50
(68 FR 26511)

NEI

NUCLEAR ENERGY INSTITUTE

DOCKETED
USNRC

(13)

August 26, 2003 (11:52AM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Anthony R. Pietrangelo
SENIOR DIRECTOR, RISK REGULATION
NUCLEAR GENERATION

August 22, 2003

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

Subject: Comments on Notice of Proposed Rulemaking for 10 CFR 50.69, *Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors* (68 Federal Register 26511, May 16, 2003)

The Nuclear Energy Institute[1] offers the following comments on the subject *Federal Register* notice, which solicited public comments on the proposed 10 CFR 50.69. This significant rulemaking has the potential to substantially enhance the safety focus, coherence, and efficiency of current regulations governing nuclear power plant operation.

We recognize the NRC staff's substantial effort in developing the proposed rule, and believe the rule language is improved over earlier drafts. However, there remain two major issues that must be resolved for a successful final rule. First, the rule language and statements of consideration (SOC) are inconsistent with regard to expectations for treatment and monitoring of plant structures, systems and components (SSCs) that are safety related and of low safety significance (RISC-3 SSCs). In some cases, the proposed rule and SOC contain requirements and expectations that are impractical, not risk-effective, or that actually exceed current requirements for safety related equipment. Second, the issue of PRA (probabilistic risk assessment) scope and technical capability necessary for this application must be resolved.

---

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy industry.

Template = SECY-067

SECY-02

The proposed rule and the preceding effort to achieve risk-informed quality assurance using similar concepts (Regulatory Guide 1.176) have been discussed conceptually for over a decade. During this interval, PRA has become widely used and integrated into the plant operational framework through the maintenance rule, the reactor oversight process, risk-informed technical specifications and other applications. Efforts to address the technical adequacy of PRA have evolved considerably, with the finalization of a consensus standard for internal events at power PRA, and the completion of the industry peer review process at over 100 units. This proposed rule represents the next milestone in the evolutionary process of integrating risk insights into regulation. Promulgation of the final rule can provide the platform for the industry to further integrate risk insights into plant culture and operations, improve plant PRAs, and enhance safety. It would also allow the NRC to narrow the coherence gap in the regulatory framework and more effectively allocate its resources on safety. Both of these effects are clearly desirable and set the stage for further applications and associated safety improvements. However, this result is predicated on a final rule that is clear in its intent and an implementation process that is stable and predictable.

Throughout development of this rule, the predominant point of contention has been the degree to which regulatory controls should be applied to RISC-3 SSCs. While the proposed rule language, with some exceptions, provides appropriate high level requirements in this regard, the SOC conflicts with the rule language by including detailed expectations and "good practices" for treatment and monitoring of RISC-3 SSCs. Although the SOC contains statements intended to establish a context for this detailed information, the overall intent of the proposed rule language in combination with the SOC detail remains ambiguous, and subject to future regulatory instability. The SOC should explain the intent of the rule and its requirements, the justification or bases for those requirements, as well as why certain elements considered are not in the rule. The SOC is not the appropriate place for detailed guidance governing rule implementation. Further, we believe that regulatory guidance for treatment of RISC-3 SSCs is not necessary given their low safety significance. The final rule and SOC must clearly and consistently reflect the ultimate resolution of this issue.

With regard to PRA scope and capability, we believe the proposed rule provides appropriate requirements. However, the *Federal Register* notice raises the issue of whether a NRC reviewed full scope, all modes PRA should be a prerequisite for implementation of this rule. Inclusion of such a requirement would end consideration of 10 CFR 50.69 as a viable option.

As discussed in detail in Attachment 2, the categorization process described in NEI 00-04 is a rigorous, multi-layered approach that considers all the major sources of risk and operating modes. This process can be supported by existing PRA tools, engineering studies and expert judgment. There is no technical need for a full scope, all modes PRA for implementation of the proposed rule, and no U.S. plant currently has such a capability. Issues of technology and standards development remain before a full scope, all modes PRA would be practical. Additionally, such a requirement would nullify the multi-year effort by industry and NRC staff to develop and review the categorization process guidance in NEI-00-04. More significantly, the evolution of the use of risk insights in the regulatory process would be undermined and the opportunities for enhanced safety and efficiency severely limited.

NEI supports the comments made by the reactor vendor owners groups, the Seismic Qualification Users Group, and the Nuclear Utility Group on Equipment Qualification. These comments provide additional detail relative to the issues raised in this letter, particularly the regulatory treatment of RISC-3 SSCs.

The attachments address specific questions included by NRC in the *Federal Register* notice, and additional details on our comments. If there are any questions on these comments please contact Biff Bradley of the NEI staff (202-739-8083, reb@nei.org), or me.

Sincerely,

Anthony R. Pietrangelo

Anthony R. Pietrangelo

Attachments:
1. Response to questions for public input in FRN
2. Technical support for adequacy of the categorization process
3. Comments on specific language of proposed rule
4. Comments on specific language of the SOC

cc. The Honorable Nils J. Diaz, Chairman, NRC
The Honorable Edward McGaffigan Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
Dr. William D. Travers, Executive Director for Operations

Attachment 1: Questions for public input

The *Federal Register* notice sought comments on the following:

VI.2.1 PRA requirements

"The Commission is seeking comment as to whether the NRC should amend the requirements in § 50.69(c) to require a level 2 internal and external initiating events, all-mode, peer-reviewed PRA that must be submitted to, and reviewed by the NRC..."

We believe the NRC should retain the PRA requirements as currently specified in the proposed rule, for the following reasons:

1. First, we agree that the categorization process should reasonably address the major risk sources, including internal events at shutdown and power, and external events including fire and seismic. We agree that the categorization process should consider core damage frequency, large early release frequency, and containment performance.

2. For the reasons above, the categorization guidance document, NEI-00-04 explicitly addresses internal and external initiators, containment performance, and shutdown through use of existing methods (e.g., fire induced vulnerability evaluation, seismic margins analysis, NUMARC 91-06 shutdown defense in depth approach, etc). Use of these methods is designed to lead to a more conservative categorization result. Attachment 2 provides a detailed discussion of how the NEI-00-04 categorization process uses both PRA, and screening methods, to arrive at a robust categorization result.

3. Industry and NRC staff have already expended large amounts of time and resources in reviewing the above guidance document, and these efforts would be essentially obviated by a requirement for full quantification of all risk contributors. The document would need to be re-developed from scratch, and the existing pilot efforts would be halted.

4. A "level 2 internal and external initiating events, all mode" PRA does not currently exist for any U.S. plant. Research and development would be necessary to address all the combinations of initiators, modes, and containment issues not currently addressed, and this would require years of effort.

5. No consensus standards exist for PRAs other than level 1 and LERF, at power. Even this standard has undergone considerable revision since finalization, in order to accommodate NRC expectations. The Regulatory Guide endorsing this standard has taken over a year to develop, and is still not final. Subsequent standards and regulatory guides to address other modes, initiators, etc, would take many years to develop.

6. It is not efficient or productive to have a PRA both peer reviewed and submitted to NRC for review and approval. NRC and contractor resources necessary to review and approve all PRAs used to support this application would be massive, likely involving years of iteration and requests for additional information.

7. In summary, the inclusion of a requirement for an NRC reviewed, full scope all modes PRA would result in failure of this rulemaking.

VI.2.2 Review and Approval of Treatment for RISC-3 SSCs: "The Commission is interested in any benefits of this approach as well as any implications for this rulemaking and associated guidance."

Review and approval of treatment for RISC-3 SSCs is not necessary. These SSCs have been demonstrated through a rigorous categorization process to be of low safety significance, and the fundamental purpose of this rule is to concentrate plant and regulatory resources on areas of higher safety significance. In addition, such a requirement would create a major resource burden for NRC, and lead to a lengthy review process concentrating on low safety significant SSCs. NRC review and approval of treatment for safety related SSCs, with evolving expectations as plants were licensed, has led to disproportionate requirements on SSCs that can now be shown to have minimal safety significance.

We agree with the approach of the proposed rule, which delineates high level treatment requirements, with no detailed regulatory guidance or review. Industry will develop guidance documents to provide for consistent and appropriate consideration of design basis functions for RISC-3 SSCs.

VI.2.3 Inspection and Enforcement – "The Commission is seeking public comment on whether or not changes are needed in NRC's inspection and enforcement programs to enable NRC to exercise the appropriate degree of regulatory oversight of facility operations encompassed by the proposed rule".

No new NRC inspection and enforcement programs are needed to address implementation of §50.69. In fact, promulgation of this rule should provide additional consistency between the licensing basis and the plant oversight process, which is already risk informed. To reduce any special treatment requirements for SSCs, licensees must commit to maintain the design basis functional requirements of RISC-3 SSCs and must implement an NRC-approved categorization process. Further, licensees would be required to thoroughly document the categorization process and results, and the basis for any reduction in special treatment requirements. Given these facts, the 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 adequate to identify and address any performance deficiencies.

V1.2.4 Operating Experience – "The Commission is seeking public comment on the availability and role of relevant operational experience in reducing the uncertainty associated the effects of reducing special treatments on SSC performance and how such operational experience could be used to support this rulemaking."

As part of the South Texas project exemption request, a large database of operating experience information was referenced. This operating experience demonstrates that the failure rates of commercial components are comparable to the failure rates of safety-related components. While the data do not encompass all design basis conditions, they demonstrate that commercial controls are effective in providing high equipment performance and reliability. We believe that the same commercial practices can be applied, with equal success, to address design basis conditions. These data provide strong support for the elimination of prescriptive requirements and controls for treatment of RISC-3 SSCs from the proposed §50.69 rule language and SOC.

VII.1 Regulatory Guide and Implementation Guidance for §50.69 – The Commission is also seeking public comment on DG-1121, which would address the industry categorization guidance document, NEI-00-04.

Industry is continuing it's interaction with NRC staff relative to NEI-00-04. Revisions to the guidance are in process to address NRC issues and objections. Our intent is for the final version of the guidance to be acceptable to NRC without the need for DG-1121 to take exceptions.

Attachment 2

TECHNICAL BASIS FOR ADEQUACY OF THE NEI 00-04 CATEGORIZATION PROCESS

The categorization process described in NEI 00-04 utilizes a series of evaluations to determine the proper risk-informed safety classification for systems, structures, and components (SSCs). The overall process involves a risk characterization of the safety significance of all SSCs in a plant system, a defense-in-depth characterization to assure adequate redundancy and diversity for design bases events are maintained, an integrated risk sensitivity study to assure any potential increases in risk are small, and presentation of the results of these evaluations to an expert panel which determines the final categorization of the SSCs. Figure 1 provides an overview of the categorization process.

The purpose of this attachment is to describe how NEI 00-04 provides a comprehensive, systematic process for categorization, and why the tools that can be utilized in the process are sufficient for this application.

Risk Characterization

The NEI 00-04 categorization process addresses a full scope of hazards, as well as plant shutdown safety. Due to the varying levels of uncertainty and degrees of conservatism in the spectrum of risk contributors, the safety significance of SSCs is assessed separately from each of five perspectives:

- Internal Event Risks
- Fire Risks
- Seismic Risks
- Other External Risks (e.g., tornados, external floods, etc.)
- Shutdown Risks

It is appropriate to assess these contributors separately to avoid reliance on a combined result that fails to address their differences in methods and associated uncertainties.

Figure 1
Overview of NEI 00-04 Categorization Process

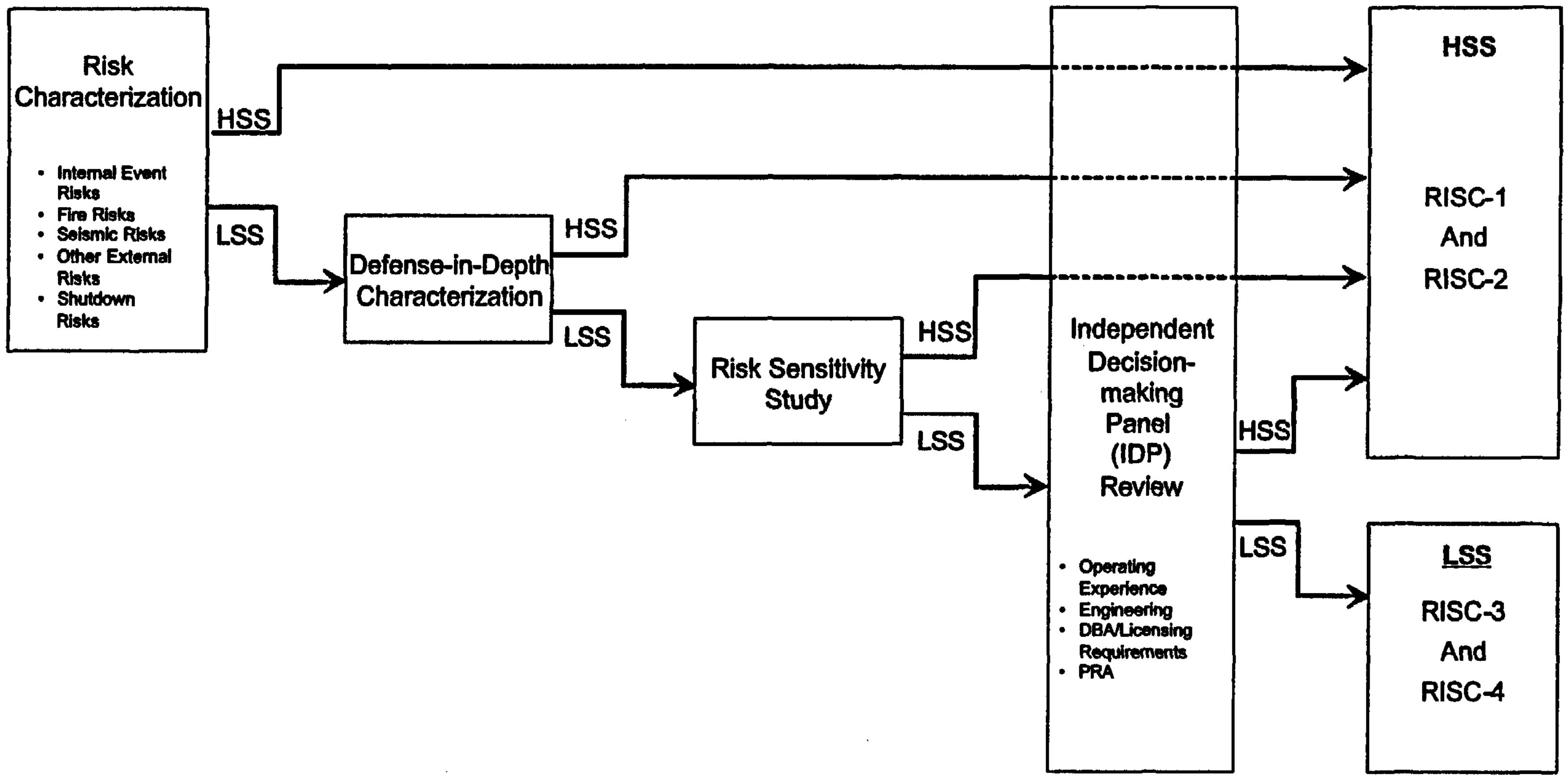

Table 1 provides a summary of the alternative approaches taken to address each risk contributor. A brief description of each of these elements is described.

Table 1
Summary of Risk Significance Characterization Used in NEI 00-04

Risk Source	Alternative Approaches	Scope of Safety Significant SSCs
Internal Events	PRA Required	Per PRA Risk Ranking
	Screening Approaches Not Allowed	n/a
Fire	Fire PRA	Per PRA Risk Ranking
	FIVE (Fire Induced Vulnerability Evaluation)	All SSCs Necessary to Maintain Low Risk
Seismic	Seismic PRA	Per PRA Risk Ranking
	SMA (Seismic Margins Analysis)	All SSCs Necessary to Maintain Low Risk
High Winds, External Floods, etc.	PRA	Per PRA Risk Ranking
	IPEEE Screening	All SSCs Necessary to Protect Against Hazard
Shutdown	Shutdown PRA	Per PRA Risk Ranking
	Shutdown Safety Plan	All SSCs Required to Support Shutdown Safety Plan

Internal Event Risks

A high quality PRA is required for the categorization of SSCs relative to internal events, at-power risks. Importance measures related to Core Damage Frequency (CDF) and Large Early Release Frequency (LERF) are used to identify the safety significant functions and *all* SSCs that support those functions are initially categorized as safety significant (RISC-1 or -2). In addition, several sensitivity studies are defined which exercise key areas of uncertainty in the PRA (e.g., human reliability, common cause failures, and normal plant configuration). If an SSC that had been initially identified as low safety significant is found to exceed the safety significance thresholds in a sensitivity study, this information is provided to the IDP, along with an explanation of why the sensitivity study identified the SSC to be safety significant.

Fire Risks

A fire risk analysis, either a plant-specific fire PRA or a Fire Induced Vulnerability Evaluation (FIVE) analysis that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to fire risks. If a fire PRA is available, then importance measures are once again used to identify the safety significant functions and *all* SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the fire risk contribution is shown to be sufficiently small (in comparison to the internal events risk), the overall safety significance of the SSC low (RISC-3 or -4) in the Integrated Importance Assessment (see below). Sensitivity studies, including fire-specific sensitivity studies, are also identified and used in a similar manner.

In the event a FIVE analysis is used, the categorization process is necessarily more conservative (i.e., designed to identify more SSCs as safety significant). This is due to the fact that FIVE is a screening tool. As such, the resulting scenarios and frequencies have an uneven level of realism. Thus, importance measures are not an effective means for identifying safety significance. The NEI 00-04 approach identifies *all* system functions and associated SSCs that are involved in the mitigation of *any* unscreened fire scenario (i.e., retained for consideration in the FIVE analysis) as safety significant. In addition, *all* screened scenarios are reviewed to identify *any* system functions and associated SSCs that would result in a scenario being unscreened, if that system function was not credited. This measure of safety significance assures that the SSCs that were required to maintain low fire risk are retained as safety significant.

Seismic Risks

A seismic risk analysis, either a plant-specific seismic PRA or a seismic margins analysis (SMA) that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to seismic risks. If a seismic PRA is available, then importance measures are once again used to identify the safety significant functions and *all* SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the seismic risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (RISC-3 or -4) using the integrated importance assessment. Sensitivity studies, including seismic-specific sensitivity studies, are also identified and used in a similar manner.

In the event an SMA is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant). This is due to the fact that SMA is a screening tool. As a screening tool, importance measures are not available to identify safety significance. The NEI 00-04 approach identifies *all* system functions and associated SSCs that are involved in the seismic margins success paths as safety significant. This criterion of safety significance assures that the SSCs that were required to maintain low seismic risk are retained as safety significant. The seismic PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the SMA identifies them as safety significant regardless of their capacity, frequency of challenge or level of functional diversity.

Other External Risks

For other external event risks, either a plant-specific external event PRA or a screening analysis that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to other external risks. If an external hazard PRA is available, then importance measures are once again used to identify the safety significant functions and *all* SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the other external hazard risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (see integrated importance assessment below). Sensitivity studies are also identified and used in a similar manner.

In the event an screening analysis is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant). The NEI 00-04 approach identifies *all* system/structure functions and associated SSCs that are involved in protecting against the external hazard as safety significant. An example might be a tornado missile barrier. Using a PRA, some barriers might be found to be of low safety significance, depending on the site-specific frequency of tornadoes and the equipment protected by the barrier. Using a screening method, the barrier would be identified as safety significant without regard to those other factors. This measure of safety significance is much more restrictive than the importance measures used in the external hazard PRA and would be expected to yield a larger set of safety significant SSCs than the external hazard PRA. The PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the screening approach identifies them as safety significant regardless of their capacity, frequency of challenge or level of functional diversity.

Shutdown Risks

A shutdown risk analysis, either a plant-specific shutdown PRA or a shutdown safety management plan that reflects the current as-built, as-operated plant is used to identify SSCs that are safety significant due to shutdown risks. If a shutdown PRA is available, then importance measures are once again used to identify the safety significant functions and *all* SSCs that support those functions are categorized as safety significant (RISC-1 or -2), unless the shutdown risk contribution is shown to be sufficiently small as to make the overall safety significance of the SSC low (see integrated importance assessment below). Sensitivity studies, including shutdown-specific sensitivity studies, are also identified and used in a similar manner.

In the event a shutdown safety management plan is used, the categorization process is, once again, more conservative (i.e., designed to identify more SSCs as safety significant) than a plant specific PRA. This is due to the fact that the shutdown safety management plan provides safety function defense in depth without regard to the likelihood of demand or reliability of the functions credited. The NEI 00-04 approach identifies *all* SSCs necessary to support primary shutdown safety systems as safety significant. This measure of safety significance assures that the SSCs that were required to maintain low shutdown risk are retained as safety significant. The shutdown PRA credits all of the same SSCs in a probabilistic framework so some may avoid being identified as safety significant using the PRA, but the shutdown safety management plan approach identifies them as safety significant regardless of the frequency of challenge or level of functional diversity.

Integrated Importance Assessment

Each risk contributor is initially evaluated separately due to the significant differences in the methods, assumptions, conservatisms and uncertainties associated with the risk evaluation of each. In general, the quantification of risks due to external events and non-power operations tend to contain more conservatisms than internal events, at-power risks. As a result, performing the categorization simply on the basis of a mathematically combined total CDF/LERF would lead to inappropriate conclusions. However, it is desirable in a risk-informed process to understand safety significance from an overall perspective, especially for SSCs that were found to be safety significant due to one or more of these risk contributors.

In order to facilitate an overall assessment of the risk significance of SSCs, an integrated computation is performed using the available importance measures. This integrated importance measure essentially creates a weighted-average importance based on the importance measures and the risk contributed by each hazard (e.g., internal events, fire, seismic PRAs). The weighted importance measures can be significantly influenced by the relative contribution of the hazard. For example, an SSC that is very important for a hazard that contributes only 1% to the total CDF/LERF would be found to have very low importance measures when the integrated assessment is performed. In no case will the integrated importance measure be larger than the largest of the individual hazard importance measure. This integrated assessment allows the IDP to determine whether the safety significance of the SSC should be based on the significance for that individual hazard or from the overall integrated result, avoiding a strict reliance on a mathematical formula that ignores the significant dissimilarities in the calculated risk results.

Defense in Depth Characterization

For safety related SSCs initially identified as low safety significant (RISC-3) from the results of the risk significance categorization, an additional defense-in-depth assessment is performed. The defense in depth assessment is based on a set of deterministic criteria based on design basis accident considerations to assure that adequate redundancy and diversity will be retained. This assessment evaluates the SSC functions with respect to core damage mitigation, early containment failure/bypass, and long term containment integrity. If one of these SSCs is found to be safety significant with respect to defense-in-depth, then it is considered safety significant and re-categorized as safety significant (RISC-1) for presentation to the IDP.

Risk Sensitivity Study

To confirm the rigor of the characterization of SSCs into risk-informed safety classifications, an integrated risk sensitivity study is performed to assess the potential risk implications of changes in special treatment. This risk sensitivity study is performed using the available PRAs to evaluate the potential impact on CDF and LERF, based on a postulated change in reliability. In this risk sensitivity study, the unreliability of all low safety significant SSCs is increased simultaneously by a common multiplier as an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of all low safety significant SSCs. A simultaneous degradation of all SSCs is extremely unlikely for an entire group of components. Licensee corrective action programs would see a substantial rise in failure events and corrective actions would be taken long before the entire population experienced such degradation. Individual components may see variations in performance on this order, but it is exceedingly unlikely that the performance of a large group of components would all shift in an unfavorable manner at the same time. In general, since one of the guiding principles of this process is that changes in treatment should not degrade performance for RISC-3 SSCs, and RISC-2 SSCs would be expected to maintain or improve in performance, it is anticipated that there would be little, if any, actual net increase in risk.

In cases where the licensee does not use a PRA in the categorization process, the sensitivity study remains a viable indication of potential limiting risk increases. This is due to the fact that the categorization processes for hazards that do not have a PRA is done in a manner that assures the risk sensitivity SSCs are categorized as safety significant. For example, in the event a seismic margins analysis (SMA) is used for the categorization, all of the SSCs necessary to maintain the current risk levels are considered safety significant. As a result, there would not be any change in the treatment for the SSCs that are credited in mitigating seismic risk.

Integrated Decision-making Panel Review

The Integrated Decision-making Panel (IDP) is a multi-discipline panel of experts that reviews the results of the initial categorization and finalizes the categorization of the SSCs/functions. The purpose of the IDP is to assure that the appropriate considerations from plant design and operating practices and experience are reflected in the categorization input.

The IDP considers the safety significance of the SSCs based on:

- the PRA assessments and sensitivity studies,
- a defense in depth assessment from an operational perspective,
- insights from other risk informed programs (e.g., Maintenance Rule, Risk Informed ISI, etc.), and
- operational and maintenance experience.

In order for an SSC/function to be recommended to the IDP as low safety significant, it must have failed to be identified as safety significant from the perspective of

- Internal Event Risks
- Fire Risks
- Seismic Risks
- Other External Risks
- Shutdown Risks

If it is an SSC that is currently safety related, then the defense in depth assessment must also have shown that the SSC is not safety significant. Finally, the risk sensitivity study verify that the combined impact of a postulated simultaneous degradation in reliability of all low safety significant SSCs would not result in a significant increase in CDF & LERF.

If an SSC is only identified as safety significant based on a non-internal events PRA (and failed to be significant in the integrated importance assessment), or by one of the mandatory sensitivity studies, then the IDP will be presented the results and will use other knowledge and experience to decide whether the SSC should be safety significant.

The IDP will not over-rule the categorization process to make an SSC/function low safety significant when the process identifies it as safety significant (i.e., will not move it from RISC-1 to RISC-3). The IDP may, however, identify that the SSC/function was not appropriately reflected in engineering assessment which may result in a new categorization, based on a revised evaluation.

Attachment 3: Comments on specific language of the proposed rule

1. 10 CFR 50.69(b)(2)(iv) states that the license application shall include the following information:

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

The evaluations referred to in 50.69(c)(1)(iv) are to provide reasonable confidence that safety margins are maintained and that any increases in risk due to changes in treatment are small.

With regard to safety margins, the SOC in Section III.7.3 discusses why safety margins are maintained by this rule, i.e., (1) that all existing functional and treatment requirements for RISC-1 and RISC-2 SSCs are maintained, and that any credit for these SSCs for beyond design basis conditions are valid and maintained; and (2) that the design basis for the facility for all SSCs, including RISC-3 SSCs, is 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, the language, "sufficient safety margins are maintained," should be deleted from 50.69(c)(1)(iv).

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 cited in 50.69(c)(1)(iv). In addition, this evaluation is part of the overall categorization process, which will be described as required by 50.69(b)(2)(i). There is no need for a separate description under 50.69(b)(2)(iv).

The effects of common cause interaction susceptibility are part of the overall categorization process. The description of the process required by 50.69(b)(2)(i) will include this element. There is no need for a separate description under 50.69(b)(2)(iv).

The requirement in 50.69(b)(2)(iv) to address the potential impacts from known degradation mechanisms for both active and passive components must be deleted for multiple reasons. First, the categorization process initially uses PRA importance measures, such as risk achievement worth, that assumes a component always fails regardless of the cause or degradation mechanism. Second, common cause interaction susceptibility is specifically addressed in the process. Third, the integrated sensitivity study will increase the failure rate of RISC-3 SSCs simultaneously, regardless of the cause or degradation mechanism. Finally, the appropriate place for licensees to address the effects of known degradation mechanisms is in their treatment programs. The high level treatment requirements in 50.69(d)(2) provide the framework that adequately addresses this concern for RISC-3 SSCs.

In summary, 50.69(b)(2)(i), (ii), and (iii) provide all the relevant aspects of the categorization process and the tools used to support the process that should be included in the application. 50.69(b)(2)(iv) asks for information that is either already covered in the description of the categorization process, or that is not part of the categorization process. Thus, 50.69(b)(2)(iv) should be deleted in its entirety.

2. 10 CFR 50.69(d)(1) states the following:

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

This entire paragraph must be deleted. It is redundant to 50.69(e)(2), which states the following:

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

Paragraph 50.69(e)(2) fulfills the same intent of 50.69(d)(1) in a performance-based manner, which is clearly more objective, clear, efficient, and demonstrable of the desired outcome.

3. 10 CFR 50.69(d)(2)(i) states the following:

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

and seismic conditions (design load combinations of normal and accident conditions with earthquake motions);

This paragraph must be modified. Recommended language follows:

"Design control measures shall preserve the design bases; select suitable materials; verify design adequacy, and control changes to the design."

There is no need to repeat language from any of the special treatment requirements from the environmental qualification or seismic qualification rules because they are within the scope of 50.69(b)(1) that exempts RISC-3 SSCs. Additionally, the level of detail in this paragraph is disproportionate to the other high level treatment requirements, and can be replaced with the more simple, direct actions given above. Finally, the requirement to specifically consider aging and synergism effects exceeds existing design requirements, such as General Design Criteria 4, for qualification of safety related SSCs.

4. 10 CFR 50.69(d)(2)(iv) states the following:

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

Conditions that "could prevent a RISC-3 SSC from performing its safety related function..." are open-ended and not clearly defined. This language is broader than Criterion XVI of 10 CFR 50, Appendix B, which states, "...failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected..." The corrective action requirement in Criterion XVI is focused on actual conditions, not conditions that "could" occur. The word "could" should be deleted from 50.69(d)(2)(iv).

To address common cause concerns, the following language should be added to 50.69(d)(2)(iv):

"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."

5. 10 CFR 50.69(e)(1) states the following:

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

The requirement must be modified to once every two refueling cycles. This periodicity is more practical with respect to the incorporation of plant modifications and data into the updated PRA.

Attachment 4: Comments on specific language of the Statements of Consideration for the proposed rule

Our major concerns with the SOC language involve the inclusion of guidance for treatment of RISC-3 SOCs that narrowly interprets the rule language and conflicts with the rule's intent to provide only high level requirements for treatment of these low risk SSCs.

[Note: The following paragraphs provide examples of problems with the SOC language, but are not intended to be comprehensive. Due to the length of the SOC, such a listing would be impractical. In order to properly resolve issues with the SOC, we request that public meetings be conducted such that all issues can be addressed prior to promulgation of the final rule.]

Section III.2.0, Methodology for Categorization, states the following:

> *A licensee is required to consider potential effects of common-cause interaction susceptibility and potential impacts from known degradation mechanisms. To meet this requirement, a licensee would need to: (a) Maintain an understanding of common-cause effects and degradation mechanisms and their potential impact on RISC-3 SSCs; (b) maintain an understanding of the programmatic activities that provide defenses against common cause failures (CCFs) and failures resulting from degradation; and (c) factor this knowledge into the treatment applied to the RISC-3 SSCs.*

The expectation that all the above would be factored into treatment for all RISC-3 SSCs is unrealistic, and is an example of prescription in the methods for RISC-3 treatment that goes beyond the level of the rule language. This language should be removed from the SOC.

Paragraph V.5.2 addresses Section 50.69(d)(2) RISC-3 Treatment. The following explanatory paragraph is provided in the SOC (emphasis added):

> *To ensure more consistent implementation of §50.69, the SOC discusses some of these areas for the implementation of proposed §50.69 about how the treatment processes for low-risk safety-related SSCs should be conducted. The Commission is also giving examples of what it considers good practice to achieve confidence of functionality. <u>The Commission does not believe that it is necessary to include these "expectations" as specific requirements because there may be other means of achieving the specified outcome and failure to implement a particular expectation would not, by itself, be a regulatory concern.</u> The Commission's intent is to place on the licensee the responsibility*

to determine the necessary treatment to maintain functionality without the Commission having to establish prescriptive requirements

This paragraph is consistent with the rule language, and industry is in full agreement with the approach of allowing alternative methods to satisfy the rule requirements. However, the following paragraphs in the SOC use language that suggests that certain methods must be employed, or that others are not suitable. The language of these paragraphs conflicts with the above statement of intent. This creates uncertainty, ambiguity, and potential regulatory instability, and would serve as a disincentive to adoption of the rule. As a threshold matter, it is inappropriate to present detailed instructions for implementing regulations in the SOC. The purpose of the SOC is to provide general "guidance," to be consulted "for background information and the resolution of ambiguities." See *Long Island Lighting Co.* (Shoreham Nuclear Power Station, Unit 1), ALAB-900, 28 NRC 275, 290-291 (1988). The SOC is appropriately provided for contextual and general informational purposes, and not to prescribe detailed instructions for implementation.

While there is value in providing good practices for consideration, the range of low safety significant equipment is very large, and expectations cannot be expected to be universally applied. Further, the language of the SOC does not appear to recognize the low safety significance of the components, and much of the language resembles existing regulatory requirements for safety related SSCs. Some examples include the following (emphasis added):

> *To provide a basis to conclude that the potential increase in risk would be small, <u>a licensee is required to conduct evaluations that assume failure rates that might occur as a result of the revisions to treatment. These evaluations would need to consider, for instance, any planned alteration in a licensee's program for diagnostic testing of motor-operated valves.</u> If a likely result of a contemplated change in treatment is an increase in failure rate, outside the bounds of the evaluations, that change in treatment would not be acceptable under proposed Sec. 50.69 because the criterion in Sec. 50.69(c)(1)(iv) about providing reasonable confidence of a small increase in risk would not be met.*

These required evaluations that "assume" rates that "might" occur as a result of monitoring program changes are inconsistent with the 50.69(d)(2)(iii) and (e)(3) which require "consideration" of actual performance data and adjustment (if needed) to categorization or treatment.

> *As an example, <u>exercising of a valve or simply starting a pump does not provide reasonable confidence in design basis capability, will not detect service-induced aging or degradation that could prevent the component from</u>*

performing its design basis functions in the future, and is insufficient by itself to satisfy the intent of the rule.

The SOC section on reporting concludes that the retained body of regulatory requirements combined with the requirements contained in this proposed rule are sufficient such that simultaneous failures in multiple systems (as would be necessary to lead to a substantial safety hazard involving RISC–3 SSCs) would not occur. Thus, the declaration that exercising a particular pump or valve "does not provide reasonable confidence" is unnecessarily prescriptive for all cases.

> *To meet this performance objective, the licensee's design control process would be expected to specify appropriate quality standards; select suitable materials, parts, and equipment; control design interfaces; coordinate participation of design organizations; verify design adequacy; and control design changes.*

Statement of need to control design interfaces and coordinate participation of design organizations for all instances for RISC-3 components is excessively prescriptive.

> *The use of earthquake experience data has been mentioned as a potential method to demonstrate SSCs will remain functional during earthquakes. However, it would be difficult to rely on earthquake experience alone to demonstrate functionality of SSCs if the design basis includes multiple earthquake events or combinations of loadings unless these specific conditions were enveloped by the experience data. Additionally, if the SSC is required to function during or after the earthquake, the experience data would need to contain explicit information that the SSC actually functioned during or after the design basis earthquake events as required by the SSC design basis. The successful performance of an SSC after the earthquake event does not demonstrate it would have functioned during the event. Qualification testing of an SSC would be necessary if no suitable alternative method is available for showing that the SSC will perform its design basis function during an earthquake.*

The highlighted language in the paragraph above is inconsistent with the NRC's position regarding the use of an experience-based method for assuring the seismic capability and adequacy for safety related SSCs in the majority of licensed nuclear plants, as described in Supplement 1 to Generic Letter 87-02. Retaining the language in the final SOC is not only inappropriate for RISC-3 SSCs, but would increase the burden for the A-46 plants (which represent the majority of currently operating plants). These plants are currently allowed to use seismic experience based methods for safety related SSCs. This language should be removed from the SOC.

Performance monitoring expectations for RISC-3 SSCs are described as follows:

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

This paragraph implies a potentially enormous program to monitor, track, and compare to the categorization process practically every SSC within the PRA (as well as its "inputs and assumptions") and every performance aspect considered in the IDP deliberations. Conformance to the literal words of the SOC is likely impossible, and certainly impractical and out of context with the low safety significance of RISC-3 components. These words should be removed from the SOC. A more flexible and practical approach can be established that would meet the rule language.