

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: Thomas G. Scarbrough */RA/*
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Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW REGARDING
PROPOSED 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND
TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS
FOR NUCLEAR POWER REACTORS"

For many years, NRC staff members in the NRR Division of Engineering (DE) have been reviewing and approving the application of risk insights in licensee programs at nuclear power plants through risk-informed inspection and testing programs. I have participated in these activities, including review of the application of risk insights in motor-operated valve (MOV) testing programs and assisting in the development of guidelines for the implementation of risk-informed testing programs at nuclear plants. Recently, I participated as a principal DE reviewer for the request by the South Texas Project for exemption from multiple special treatment requirements through the application of risk insights. Throughout this time, I and other members of the DE staff have supported the application of risk insights in NRC activities, and encouraged the implementation of risk-informed inspection and testing programs by nuclear plant licensees.

Over the last two years, I have participated as a principal DE reviewer for Option 2 of the NRC staff initiative to incorporate risk insights into the regulations. In this assignment, I have applied knowledge obtained from my experience during NRC activities to evaluate licensee programs to verify the design-basis capability of safety-related MOVs, review and acceptance of risk-informed and deterministic inservice testing programs established and implemented at nuclear plants, and participation in ASME code and standard activities including development of provisions for risk-informed component testing programs. Although the goal of the Option 2 effort is strongly supported by all internal and external stakeholders, significant differences exist regarding the interpretation of the Commission's directives for the Option 2 effort, the safety function of plant structures, systems, and components (SSCs) ranked as having low safety significance by the categorization process, and the implementation of high-level treatment requirements for low safety significant SSCs.

The NRC staff expended considerable resources to prepare proposed 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," to satisfy the directives in the Commission papers describing the Option 2 effort. For example, the staff provided an opportunity for advance public comment on drafts of the rule language per Commission direction. The staff also conducted several public meetings to discuss draft rule language and to consider comments submitted by stakeholders.

On July 31, 2002, the staff prepared a draft rule for Commission review that specified high-level requirements to provide sufficient regulatory treatment for plant SSCs consistent with the Commission papers describing the Option 2 effort. However, the 50.69 rulemaking package was significantly modified during the concurrence process. Based on my experience in component engineering and lessons learned from the Option 2 proof-of-concept effort, I consider the rulemaking package for proposed 10 CFR 50.69 submitted for Commission approval to be insufficient to maintain adequate protection of the public health and safety during operation of nuclear power plants implementing the rule. Therefore, I am submitting this Differing Professional View (DPV) regarding the rulemaking package for proposed 10 CFR 50.69.

As discussed in detail in the attachment to this memorandum, it is my opinion that the rulemaking package for proposed 10 CFR 50.69:

- does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs;
- is inconsistent with the Commission's Probabilistic Risk Assessment (PRA) Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation;
- does not provide a balanced discussion in the accompanying Commission paper of this first-of-a-kind regulation that will eliminate most special treatment requirements for most safety-related SSCs in operating and future nuclear power plants;
- provides a Statement of Considerations that is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements; and
- fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

If 10 CFR 50.69 is issued as proposed, I believe that treatment programs at some nuclear plants that implement the rule will be insufficient to maintain the reliability of SSCs to perform their safety functions assumed in the categorization process. These insufficient treatment programs can result in the unavailability of multiple SSCs to perform their safety functions under design-basis conditions. The unavailability of multiple SSCs to perform their safety functions might not be identified prior to a plant event, and increase the severity of the event or interfere with the licensee's ability to mitigate the event. If unacceptable SSC performance is identified, the absence of documentation allowed by the rule will increase the difficulty for regulatory and licensee staff to determine the extent of functionality concerns to other plant SSCs and the significance of the issue related to public health and safety.

I will be pleased to discuss my safety concerns with the proposed 50.69 rulemaking package.

Attachment: As stated

SAFETY CONCERNS WITH PROPOSED 50.69 RULEMAKING PACKAGE

- 1. The proposed 50.69 rule does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs.**

Proposed 50.69 Rule

The proposed 50.69 rule (as of September 25, 2002) provides a voluntary approach for nuclear power plant licensees to categorize SSCs according to their safety significance and then to establish treatment processes for the SSCs based on their risk category. The proposed rule identifies safety-related SSCs of high safety significance as RISC-1, nonsafety-related SSCs of high safety significance as RISC-2, safety-related SSCs of low safety significance as RISC-3, and nonsafety-related SSCs of low safety significance as RISC-4. The proposed rule would provide for review and approval of the categorization process for each licensee that submitted a license amendment request to implement 10 CFR 50.69. The NRC staff plans to review and endorse guidelines prepared by the Nuclear Energy Institute (NEI) for the categorization of SSCs. The staff also plans to conduct inspections of the categorization process established by licensees implementing the rule.

In implementing 10 CFR 50.69, the licensee would establish treatment processes for individual SSCs based on their safety significance categorization. For RISC-1 and 2 SSCs, the licensee will be required to maintain current regulatory requirements and to adjust treatment to be consistent with credit assumed for those SSCs in the categorization process. For RISC-3 SSCs, the proposed rule would specify high-level treatment requirements, and eliminate most special treatment requirements, including the quality assurance requirements in Appendix B to 10 CFR 50; the inservice inspection and testing requirements for most SSCs within the scope of 10 CFR 50.55a; equipment qualification requirements in 10 CFR 50.49; most maintenance requirements in 10 CFR 50.65; reporting requirements in 10 CFR 50.72 and 73; and seismic qualification testing requirements in 10 CFR Part 100. For RISC-4 SSCs, the proposed rule would eliminate a similar list of special treatment requirements, where applicable, and not specify any high-level treatment requirements.

In lieu of the eliminated special treatment requirements for RISC-3 SSCs, the proposed 50.69 rule contains the following treatment requirements:

The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life. The processes must meet the following requirements, as applicable:

- (i) *Design control.* Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled. 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);
- (ii) *Procurement.* Procured RISC-3 SSCs must satisfy their design requirements;
- (iii) *Maintenance, Inspection, Testing, and Surveillance.* Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design-basis conditions until the next scheduled activity; and
- (iv) *Corrective Action.* Conditions that 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.

The NRC staff does not plan to prepare implementation guidance for the RISC-3 treatment requirements in 10 CFR 50.69 (other than that provided in the Statement of Considerations) to replace the guidance in regulatory guides, standard review plans, bulletins, generic letters, regulatory information summaries, and information notices applicable to the eliminated special treatment requirements. Further, the staff does not plan to conduct any inspections of the implementation of the treatment processes established by licensees implementing the rule to evaluate the effectiveness of those processes.

RISC-3 SSC Importance

The categorization process will identify SSCs that perform safety-related functions that have a low safety significance on an individual basis. The robust nature of nuclear power plant design results in redundant and diverse means to satisfy most safety functions. Consequently, the individual importance of any particular safety-related SSC will typically be small, and most safety-related SSCs will be ranked as having low safety significance at a nuclear plant. Experience with risk-informed programs has revealed that typically 50 to 80 percent of safety-related SSCs are ranked as low safety significant at nuclear plants. For example, in the proof-of-concept effort, the licensee categorized about 75% of its safety-related SSCs as low safety significant, including main steam isolation valves (MSIVs); all feedwater system valves (including control and isolation valves); valves in the diesel generator air start system; spent fuel pool pumps and valves; most residual heat removal (RHR) system valves; all (but one) valves in the service water system; reactor head vent throttle and isolation valves; most chemical, volume, and control system valves; high pressure safety injection (HPSI) and low pressure safety injection (LPSI) flowpath MOVs; all component cooling water MOVs; containment spray pumps and valves; and most containment isolation valves (including 9 intersystem LOCA valves).

The Statement of Considerations for the proposed rule asserts that the categorization process has been improved since the South Texas review such that only safety-related SSCs with low or negligible significance will be categorized as RISC-3. However, there are no requirements in the proposed rule that would indicate such a significant change in the categorization process. Further, the Statement of Considerations does not discuss the differences between the

previous categorization approach accepted in the South Texas review and a more robust categorization process asserted to be required by the proposed rule.

The categorization process can provide a reliable ranking of safety-related SSCs based on their individual safety importance. However, the categorization process does not eliminate the safety functions required to be performed by SSCs categorized as being of low safety significance. The proposed rule improperly relies on a categorization process that is asserted to rank only safety-related SSCs of low or negligible significance as RISC-3 without adequate consideration of the treatment requirements necessary to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions.

Common-Cause Interactions

Assuming a proper safety significance ranking of SSCs at a nuclear power plant, the safety impact of eliminating treatment requirements and regulatory guidance for most safety-related SSCs depends primarily on the potential for multiple SSCs failing to perform their safety functions when called upon during an accident. The complexity of the categorization process does not allow common-cause interactions among SSCs across system boundaries to be evaluated on a quantitative basis except for a few limited instances (such as specific circuit breakers). NUREG/CR-5485, "Guidelines on Modeling Common-Cause Failures in Probabilistic Risk Assessment," discusses the challenges of modeling common cause failure events in nuclear power plants and provides a set of guidelines to help PRA analysts in this effort. The proposed rule requires that licensees submit information related to their consideration of common-cause interactions as part of their categorization process. However, common-cause interactions also need to be addressed as part of the establishment and implementation of treatment programs. For example, NUREG/CR-5485 indicates that defense strategies for common-cause failures typically include design control; use of qualified equipment; testing and preventive maintenance programs; procedure review; personnel training; quality control; barriers; diversity (functional, staff, equipment); and staggered testing and maintenance. The proposed rule does not provide confidence that defense strategies for common-cause failures will be established as part of the treatment processes for RISC-3 SSCs.

Commercial Practices

In NUREG/CR-6752 (January 2002), "A Comparative Analysis of Special Treatment Requirements for Systems, Structures, and Components (SSCs) of Nuclear Power Plants with Commercial Requirements of Non-Nuclear Power Plants," the Idaho National Engineering and Environmental Laboratory (INEEL) found that normal commercial and industrial practices at nuclear power plants not only vary widely between plants, but apply to a wide range of activities regarding the functionality of balance-of-plant SSCs. A criticism raised regarding the INEEL study is that the use of varying amounts of practices and treatment for commercial SSCs is not relevant because there are no regulatory requirements for that equipment. Once the NRC imposes a regulatory requirement, the criticism asserts that licensee practices will be changed accordingly. The assumption that licensees will change their commercial treatment to satisfy regulatory requirements in 10 CFR 50.69 is only valid if the regulatory requirements are sufficiently clear to ensure that licensees understand that the treatment must be consistent with the categorization process assumptions. Further, licensees might have widely varying levels of expertise in determining which specific commercial practice needs to be applied to low-risk

safety-related SSCs that would be treated under commercial practice according to 10 CFR 50.69. For example, the INEEL study found that licensees base the amount of treatment applied to balance-of-plant SSCs on their relationship to power generation. Therefore, a licensee might apply specific controls for design, installation, and monitoring of a balance-of-plant SSC that directly supports the generation of electric power, but allow a balance-of-plant SSC that does not directly support power generation to degrade with repairs performed when the SSC is found to not be functional. RISC-3 SSCs associated with the response to plant events (such as containment isolation valves) that do not directly support power generation might be treated as standby equipment with minimal attention under current commercial practices. The results of the INEEL study are consistent with an NRC inspection effort of licensee quality assurance activities applied to nonsafety-related equipment documented in a memorandum dated December 7, 1984, by P. McKee. Further, the conclusions in NUREG/CR-6752 were reinforced by the NRC staff's findings during the review of the South Texas exemption request where the licensee initially planned to apply commercial practices (such as MOV stroke-time testing) to low-risk safety-related SSCs without adequate consideration of the ability to provide reasonable confidence in the functionality of those SSCs. A study referenced by the South Texas licensee in support of its reliance on commercial practice based on an assertion that the reliability of nonsafety-related SSCs exceeded that of safety-related SSCs was found to have several weaknesses, including relying on reported failures over a 25-year time period for nonsafety-related equipment that have minimal testing and reporting requirements. As a result, reliance in the proposed 50.69 rule on general industrial and commercial practices without a clear understanding of the treatment requirements is insufficient to provide confidence in the functionality of RISC-3 SSCs.

Specific Inadequacies in Proposed 50.69 Rule

a. Consensus Standards, Vendor Recommendations, and Operational Experience

Based on the importance of RISC-3 SSCs on a multiple SSC basis, lessons learned from the proof-of-concept effort, and NRC studies of balance-of-plant practices in the nuclear industry, the proposed rule's allowance for each licensee to develop unique methods based on their individual levels of expertise in SSCs, including design, construction, installation, operation, repair, and replacement, does not provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions under design-basis conditions. To resolve this safety concern, the DE staff recommended that the proposed rule include a requirement that the RISC-3 treatment processes meet voluntary consensus standards and to address applicable vendor recommendations and operational experience. Such a requirement was supported by the American Society of Mechanical Engineers (ASME) in its comments submitted on June 17, 2002, that exemption of the inservice inspection and testing requirements in 10 CFR 50.55a for RISC-3 SSCs would be acceptable provided a framework is developed to ensure that risk-informed ASME Code Cases and Codes & Standards are used. In its comments submitted on May 15, 2002, NEI supported a similar requirement to apply applicable codes and standards. At a public meeting between NRC, ASME, and NEI representatives on June 18, 2002, the participants did not object to a requirement for licensees to use applicable voluntary consensus standards in implementing the proposed rule.

In addition to requiring use of applicable voluntary consensus standards, a requirement to consider applicable vendor recommendations and operating experience is necessary in light of

the history of SSC functionality problems where such recommendations and experience were not addressed. For example, NRC Information Notice 95-31, "Motor-Operated Valve Failure Caused by Stem Protector Pipe Interference," reported multiple MOV operational problems resulting from licensee-fabricated valve stem protector pipes. Also, NRC Information Notice 97-32, "Defective Worm Shaft Clutch Gears in Limitorque Motor-Operated Valve Actuators," discussed the failure of a non-safety related MOV as a result of improper refurbishment using parts from a supplier other than the original equipment manufacturer. Similarly, a requirement to consider operating experience is necessary to provide confidence that common-cause problems that might affect multiple SSC functionality are addressed. For example, in the proof-of-concept effort, the licensee initially proposed that it would eliminate all regulatory commitments related to RISC-3 SSCs based on only risk categorization without consideration of operating experience that might have a potential impact on SSC functionality. Similarly, the proof-of-concept licensee initially indicated that RISC-3 electrical equipment exceeding their environmental design life would be assumed to remain functional simply because of their risk categorization.

b. Consistency of Treatment with Categorization

The categorization process assumes a specific reliability for RISC-3 SSCs. In sensitivity studies, a licensee implementing 10 CFR 50.69 would reduce the RISC-3 SSC reliability based on its assumptions for the impact of the reduced treatment. Factors of 3 to 4 for reduced RISC-3 SSC reliability have been discussed in conducting those sensitivity studies. These reductions in RISC-3 SSC reliability continue to assume a very high reliability for the functionality of RISC-3 SSCs. For example, a typical MOV reliability assumption of 99.9% assumed in the categorization process might be adjusted to 99.6% in the sensitivity study evaluating the impact of elimination of special treatment requirements. Although changes in design control associated with paperwork might be considered to result in such small changes in the probability of SSC failure, changes in maintenance (such as not performing preventive maintenance on a vendor-recommended schedule) can have a significant impact on SSC reliability such that the categorization process would not be valid. The proposed rule should require that the treatment processes be consistent with the assumptions credited in the categorization process.

c. Design Requirements

An Option 2 directive specifies that the design of the plant not be changed as part of this rulemaking effort. The NRC staff has interpreted this directive to mean that the design functional requirements and bases for safety-related SSCs are not directly affected by the proposed rule. For example, in the proof-of-concept effort, the staff accepted the proposal by the licensee that RISC-3 SSCs designed to ASME Code provisions could be replaced with SSCs designed to less restrictive codes and standards. However, the licensee also indicated that it planned to apply portions of multiple codes and standards in designing RISC-3 SSCs. The staff considered such hybrid designs of safety-related SSCs to have potential adverse safety implications if installed in a nuclear plant without a history of their performance. To prevent this safety problem from occurring with the implementation of 10 CFR 50.69, the proposed rule should require that licensees follow all of the provisions of the code or standard selected for the design of RISC-3 SSCs. A similar concern relates to the design aspect of fracture toughness of ASME Class 2 and 3 SSCs and parts categorized as RISC-3. The

proposed rule should specify this design requirement because lessons learned from the proof-of-concept effort indicate that licensees might not recognize this aspect of design for replacement SSCs.

d. Design Control Aspects

In the proof-of-concept effort, the licensee did not request exemption for Criterion III, Design Control, of 10 CFR 50, Appendix B, to help support its exemption from other special treatment requirements. In light of the importance of adequate design control, the NRC staff identified the most important aspects of design control described in Criterion III that would continue to allow licensees to have flexibility in implementing 10 CFR 50.69. The staff considered the selection of suitable materials, methods, and standards; verification of design adequacy; and control of design changes as the aspects of design control necessary to provide reasonable confidence in RISC-3 SSC functionality. In its May 15 letter, NEI also suggested rule language specifying design control requirements for selection of suitable materials, verify design adequacy, and control changes to the design. The staff had included the control of installation and post-installation testing under design control to allow the elimination of a separate rule requirement for an installation process. The proposed rule specifies no requirements for the control of installation, including installation activities such as welding or post-installation testing. The proposed rule should include specific aspects of design control for selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes.

e. Corrective Action

The proposed rule does not specify that corrective action will include evaluation of performance problems with RISC-3 SSCs for generic implications and resolution. Common-cause problems can invalidate the conclusion that treatment reductions for RISC-3 SSCs will not result in a safety concern. For example, improper performance of a RISC-3 SSC resulting from use of inaccurate measuring and test equipment can have widespread generic implications for the functionality of other RISC-3 SSCs. The importance of an adequate corrective action process was recognized in the proof-of-concept effort where the licensee did not request exemption from Criterion XVI, "Corrective Action," of 10 CFR 50, Appendix B, so as to support its exemption requests. The proposed rule should include a corrective action requirement that the cause of the functionality problems be determined and action taken to address generic implications.

f. Process Control and Assessment

The proposed rule will rely on licensee initiative for providing reasonable confidence in the functionality of RISC-3 SSCs. The proposed rule provides almost no documentation requirements for RISC-3 SSCs. For example, licensees will not be required to maintain any documentation associated with design, procurement, installation, testing, or maintenance associated with RISC-3 SSCs. Licensees will not be required to prepare any written procedures for activities associated with RISC-3 SSCs or maintain any records of those activities. Licensees will not be required to perform any audits of the treatment processes to provide confidence that the processes are meeting expectations. Allowing treatment processes for RISC-3 SSCs to be undocumented fails to provide reasonable confidence that activities

related to RISC-3 SSCs will be implemented adequately. For example, some licensees in the past reportedly considered complete disassembly and reassembly of MOVs to be within the skill of the craft which lead to numerous performance problems. The lack of requirements for licensee assessments of the effectiveness of the treatment processes will result in the inability to rely on a licensee's internal processes to oversee its treatment processes. Further, absence of documentation will prevent the NRC from conducting an evaluation of plant safety in the event of the loss of control of SSC functionality by a licensee without significant resource expenditures by the licensee and NRC staff. The proposed rule should require that implementation of the treatment processes and assessment of their effectiveness be controlled and accomplished through documented procedures and guidelines.

g. Control of Procured SSCs

The proposed rule contains no requirements for the control of procured items upon receipt. Improper control and inspection of procured RISC-3 SSCs can result in multiple SSCs being incapable of performing their safety functions if called upon during an accident. The categorization process, and its conclusion that adequate protection of the public health and safety will be maintained, are not valid if multiple SSCs are incapable of performing their safety functions. NEI did not object to the procurement requirement for receipt verification. The proposed rule should include a requirement that, upon receipt, the licensee shall verify that the item received is the item ordered.

h. Feedback

The proposed rule does not require that the performance of RISC- 3 SSCs be evaluated in a timely manner to provide confidence that their performance is consistent with the categorization process assumptions. The proposed rule only requires that RISC-3 performance data be considered to determine whether any performance changes are due to treatment changes, and to make necessary adjustments. The proposed rule does not require that the categorization process assumptions for reliability be assessed either before or during implementation on a timely basis. The proposed rule should require sufficient feedback to provide confidence that the treatment reductions have not invalidated the categorization process and the finding that implementation of the rule continues to maintain adequate protection of the public health and safety.

2. The proposed rule package is inconsistent with the Commission's PRA Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation.

The Commission's PRA Policy Statement states that "use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art in PRA methods and data." The actual effect of reduced treatment on the reliability of RISC-3 SSCs cannot be determined in advance of implementation of the rule. However, the proposed rule fails to recognize this fact. The proposed rule should provide confidence that assumptions made in the categorization process of the potential effects of treatment reductions are reasonable; that means are in place to monitor SSC performance and to provide sufficient treatment controls where performance monitoring is not sufficient; and that corrective action will be taken and

feedback will be implemented as necessary to maintain the validity of the categorization process and its conclusion that the impact on plant safety from the implementation of 10 CFR 50.69 will be small.

Under Option 2 of the NRC initiative to risk-inform the regulations discussed in SECY-98-300, 99-256, and 00-0194, RISC-3 SSCs need to receive sufficient regulatory treatment such that these SSCs will continue to meet their functional requirements, albeit with a reduced level of assurance. The rulemaking plan provided an example of the hydrogen recombiners and the challenge in specifying adequate treatment requirements in the rule. The proposed rule does not recognize the safety significance of RISC-3 SSCs on a multiple SSC basis, and fails to provide sufficient regulatory treatment for RISC-3 SSCs. The Statement of Considerations for the proposed rule claims that the categorization process has been modified to ensure that SSCs with only negligible safety significance will be categorized as RISC-3. However, no requirements are specified in the proposed rule or described in the Statement of Considerations that would support such a claim.

The Commission's White Paper indicates that risk-informed, performance-based approaches use risk insights, engineering analysis and judgement including the principle of defense-in-depth and the incorporation of safety margins and performance history. The Statement of Considerations indicates that the proposed rule relies on a "cornerstone" of a robust categorization process. With an assumption that the categorization process has been enhanced, the proposed rule is now characterized as a "categorization rule" or, in other words, a risk-based rule. In the White Paper, the Commission states that it does not endorse an approach that is "risk-based" because of heavier reliance on risk assessment results than is currently practicable for reactors due to uncertainties in PRA such as completeness.

The proposed rule should provide sufficient requirements such that the categorization and treatment processes meet the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations while remaining consistent with the Commission's PRA Policy Statement and White Paper.

3. The rulemaking package does not provide a balanced discussion of this first-of-a-kind regulation that will eliminate most special treatment requirements for most of the safety-related SSCs in operating and future nuclear power plants.

The preparation of the proposed 50.69 rule represents the most significant NRC regulatory action related to the treatment of safety-related equipment at nuclear power plants in many years. The proof-of-concept effort and smaller scale risk-informed treatment programs reveal that most of the safety-related SSCs in nuclear plants will be categorized as RISC-3. The impact of the proposed replacement of the current regulations, regulatory guides, and standard review plan for most safety-related SSCs with a few high-level treatment requirements cannot be determined in advance. As illustrated by the lessons learned from the proof-of-concept effort, incorrect interpretation of high-level treatment requirements by licensees might lead to multiple SSCs being incapable of performing their safety functions. With minimal design and procurement control, general inspection and testing provisions, limited corrective action, and almost no documentation, the implementation of 10 CFR 50.69 will significantly reduce the ability of licensees and regulatory staff to verify the functionality of low-risk safety-related SSCs.

The Commission paper provided with the proposed rule does not discuss the potential safety issues that might result if the categorization or treatment processes fail to meet expectations. While the NRC staff will review the categorization process prior to implementation of 10 CFR 50.69, licensees will implement the treatment processes without staff review. If unacceptable performance is identified for multiple RISC-3 SSCs in the future, it could be difficult to determine the impact of those performance issues on the remaining SSCs, plant safety, and public health and safety, with reduced documentation and records. If a licensee implemented an ineffective treatment process, the inability of multiple RISC-3 SSCs to perform their safety functions might not be identified in advance, and might only be discovered during an accident.

Overall, the potential benefits of focused attention on high-risk SSCs and reduced costs might outweigh the disadvantages of reduced confidence in the capability of low-risk SSCs to perform their safety functions. The Commission paper should provide a balanced discussion of these issues.

4. The Statement of Considerations is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements.

The Statement of Considerations for the proposed rule includes numerous instances where NRC expectations are indicated. Many of these expectations were specified as requirements in the July 31 draft of the proposed rule. As discussed above, the requirements were included in the July 31 draft rule as a result of component engineering experience and lessons learned from plant-specific and generic review of licensee treatment programs. A discussion of expectations in the Statement of Considerations that are not connected with requirements in the rule does not provide confidence that licensees will follow the expectations rather than their own interpretation of the general requirements in the rule. Further, the Statement of Considerations is typically used for historical reference and not for daily interpretation of regulatory requirements during nuclear plant operations. Rather than relying on discussion in the Statement of Considerations, the proposed rule should specify the requirements necessary to provide reasonable confidence in the functionality of RISC-3 SSCs, and a regulatory guidance document should describe acceptable methods of implementing the requirements as appropriate.

The Statement of Considerations was originally prepared to support the July 31 draft of the proposed 50.69 rule. Following the significant changes to the draft rule during the management concurrence process, the Statement of Considerations was hurriedly modified in an effort to reflect the proposed rule. As a consequence, the Statement of Considerations contains inaccurate and misleading statements regarding the requirements in the proposed rule. Examples include:

Section III.1.0, "Categorization of SSCs," states that RISC-3 SSCs are not significant contributors to plant safety. This statement is accurate for individual RISC-3 SSCs. However, inadequate performance of multiple RISC-3 SSCs can have a significant impact on plant safety.

Section III.2.0, "Categorization Requirements," of the Statement of Considerations states that the proposed rule will require that the revised treatment applied to RISC-3 SSCs be considered for its potential impact on risk. However, the proposed rule only specifies that the licensee have reasonable confidence that the change in risk is small.

Section III.3.2, "RISC-3 Treatment," states that the Commission concludes that it would be acceptable to allow ASME Class 2 and 3 SSCs categorized as RISC-3 to meet a voluntary consensus standard. This statement is misleading by implying that the proposed rule contains requirements for the approaches that would be acceptable in lieu of the current ASME Code requirements in 10 CFR 50.55a. Further, Section III.3.2 states that "effective implementation" of the treatment requirements provides reasonable confidence of the capability of RISC-3 SSCs, but the Statement of Considerations does not discuss its reliance on effective implementation of the rule to maintain adequate protection of the public health and safety.

Section III.4.0, "Removal of RISC-3 and RISC-4 SSCs from the Scope of Special Treatment Requirements," states that it is no longer necessary to have the same high level of assurance that less significant SSCs would perform as specified. However, the sensitivity studies required by the proposed rule may increase the failure rate for RISC-3 SSCs by only a factor of 3 to 4 (for example, a typical MOV might have its reliability reduced from 99.9% to 99.6%). Thus, the categorization process continues to assume a high reliability for RISC-3 SSCs.

Section III.4.3, "§50.55a(f), (g), and (h) Codes and Standards," states that the proposed rule would not remove provisions pertaining to design requirements established in §50.55a. However, as discussed above, the proposed rule has removed several design requirements.

Section III.5.0, "Evaluation and Feedback, Corrective Action and Reporting Requirements," states that the proposed rule contains requirements for updating the categorization and treatment processes when conditions warrant to assure that continued SSC performance is consistent with the categorization assumptions. The proposed rule does not contain such requirements for RISC-3 SSCs, but rather only a requirement to consider RISC-3 performance data to determine whether any adverse performance changes are due to treatment, and to make necessary adjustments. Section III.5.0 also states that feedback and adjustment is crucial to ensuring that SSC performance is maintained consistent with the assumptions of the categorization process and its results. However, the proposed rule only requires that changes in performance of RISC-3 SSCs be considered in whether to make changes to the categorization or treatment processes without a timeliness provision. Section III.5.0 also states that taking timely corrective action is an essential element for maintaining the validity of the categorization and treatment processes, but the proposed rule does not contain requirements for evaluations of performance problems with RISC-3 SSCs on a generic basis in a timely manner.

Section III.7.1, "Net Change in Risk is Small," under Section III.7.0, "Adequate Protection," states that the proposed rule requires that the potential net risk change from implementation of its requirements be assessed, and these requirements will ensure

that the net risk change is small. However, the proposed rule only requires reasonable confidence that the net change in risk is small.

Section III.7.2, "Defense-in-Depth is Maintained," asserts that defense-in-depth will be maintained simply because the proposed rule requires that defense-in-depth be considered in the categorization process, and relies on the consideration of the defense-in-depth in the facility design basis without addressing the removal of treatment (such as for most containment isolation valves).

Section III.7.3, "Safety Margins are Maintained," states that the proposed rule preserves safety margins. However, the proposed rule only requires reasonable confidence that safety margins are maintained. Section III.7.3 asserts that, because only treatment requirements are relaxed, existing safety margins arising from design technical and functional requirements would remain, but does not address the significant impact that treatment can have on SSC performance and, therefore, safety margins. This section also asserts that the proposed rule will place a limit on how much the reliability of RISC-3 SSCs can change, although such a requirement is not in the proposed rule.

Section III.7.4, "Monitoring and Performance Measurement Strategies are Used," asserts that the proposed rule contains requirements that reports are made to NRC of conditions preventing SSCs from performing their safety-significant functions. The proposed rule does not require generic aspects of corrective action to be addressed, nor does it require safety significant impacts of multiple RISC-3 SSC problems to be reported.

Section IV.2.0, "Draft Rule Comments," asserts that the categorization process has been strengthened such that any individual SSC categorized as RISC-3 is of very low safety significance. No technical basis for this assertion is provided.

Section IV.4.0, "South Texas Exemption as Proof of Concept," states that the NRC has applied the lessons learned from the review of the South Texas exemption request in developing the proposed rule. However, as discussed above, the proposed rule has not applied lessons learned from the proof-of-concept effort. Further, the Statement of Considerations does not include lessons learned from the proof-of-concept effort for the need to specify that 10 CFR 50.69 would not affect the commitment change process approved by the NRC.

Section V.5.2.1, "§50.69(d)(2)(i) Design Control Process," states that a design requirement exists for fracture toughness, but the proposed rule does not indicate that this design requirement for repair and replacement of SSCs is retained. Section V.5.2.1 also states that licensees are responsible for proper installation and post-installation testing of RISC-3 SSCs, including welding and other special processes, as part of design control and other treatment processes. The proposed rule does not contain such requirements.

Section V.5.2.2, "§50.69(d)(2)(ii) Procurement Process," states that the licensee would be expected to conduct activities upon receipt to confirm that the received component is what was ordered. The proposed rule does not contain such a requirement.

Section V.5.2.3, “§50.69(d)(2)(iii) Maintenance, Inspection, Test, and Surveillance Process,” states that, for a RISC-3 SSC in service beyond its service life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety function. However, the proposed rule does not contain requirements for documentation of technical bases for RISC-3 SSC functionality, other than as part of the corrective action process. Section V.5.2.3 also states that, as discussed under design control, licensees are responsible for proper installation (including welding) and post-installation testing of RISC-3 SSCs during the maintenance process. As noted, the proposed rule does not contain such requirements.

Section V.5.2.4, “§50.69(d)(2)(iv) Corrective Action Process,” asserts that effective implementation of the corrective action process would include timely response to information that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis. However, the proposed rule does not require generic corrective action for RISC-3 SSCs.

Section VI, “Additional potential requirements for public comment,” lists changes to the July 31 draft rule that was posted on the NRC website. The Statement of Considerations does not provide a technical bases for those significant changes.

5. The proposed 50.69 rule fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

The NRC staff prepared a draft version of the 50.69 rule (dated July 31, 2002) based on the experience and technical expertise of staff members, lessons learned from plant-specific and generic evaluations of risk-informed programs and commercial practices at nuclear plants, and stakeholder input provided in public comment letters from ASME and NEI on an earlier version of the draft rule (dated April 3, 2002). The staff also held several public meetings and workshops, including most recently on June 18, 2002, to discuss the draft rule language. Following the completion of the staff’s activities to develop a proposed rule that was technically valid, significant changes were made to the proposed rule during the concurrence process without sufficient technical basis.

Various reasons have been indicated for the significant changes made to the July 31 draft rule. None of the reasons is adequate to support the changes. Examples of those reasons are discussed below:

a. The July 31 draft rule was said to be too detailed to meet Commission expectations. However, the July 31 draft of the proposed rule fully met the Commission’s directives for a technically valid rule that provides minimal but sufficient treatment requirements for low-risk safety-related SSCs while applying state-of-the-art PRA methods. Following successful experience with the implementation of the rule as described in the July 31 draft, the NRC could evaluate whether further reductions in treatment for RISC-3 SSCs could be accomplished. Issuance of a less detailed but inadequate rule would result in safety problems as a result of licensees implementing ineffective treatment programs.

b. The July 31 draft rule was said to contain requirements specifying how to implement the overall functionality requirement for RISC-3 SSCs. As part of the preparation of the draft rule,

the staff focused on specifying what are the treatment requirements for RISC-3 SSCs. One arguable exception to this focused effort was the requirement for licensees to use of applicable voluntary consensus codes and standards in their treatment processes for RISC-3 SSCs. This particular treatment requirement (whether termed a “what” or a “how” requirement) was based on safety concerns resulting from plant-specific and generic evaluations that licensees might have limited expertise and understanding of design, procurement, installation, maintenance, testing, and replacement of particular safety-related SSCs.

c. The categorization process was said to be improved such that only SSCs of negligible importance will be ranked as RISC-3. Improvements in the categorization process such that less significant SSCs are categorized as RISC-3 are commendable and may allow further reductions in treatment requirements. However, the proposed rule does not require that the categorization process only rank SSCs of negligible importance as RISC-3. During the proof-of-concept effort, the robust nature of the South Texas categorization process was said to result in mostly “vents and drains” being categorized as low risk, but the process was found to also categorize MSIVs and other equipment that together perform important safety functions as low risk.

d. Proposed 10 CFR 50.69 is said to be a “categorization rule” such that only general treatment requirements for RISC-3 SSCs are necessary. The removal of treatment requirements based on the assertion that proposed 10 CFR 50.69 is a categorization or risk-based rule is inconsistent with the Commission’s White Paper discussing risk-informed approaches.

e. The technical staff is told to simply trust licensees and PRAs. The staff has been reviewing and approving the application of risk insights in licensee and regulatory programs for many years. The staff trusts licensees to follow the regulatory requirements and the categorization process to rank SSCs according to the relative safety significance. The NRC needs to ensure that regulatory requirements are clear with sufficient specificity such that licensees will implement effective treatment programs that maintain the validity of the categorization process and, thereby, adequate protection of the public health and safety.

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