September 26, 2002

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

FROM: David C. Fischer, Senior Mechanical Engineer ***/RA/***
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SUBJECT: DIFFERING PROFESSIONAL VIEW — RISK-INFORMED PART 50, OPTION 2

The purpose of this memorandum is to express my concern over a proposed rule aimed at risk-informing 10 CFR Part 50 (RIP-50) which is about to be issued for public comment. Since the mid-1980s, I have been actively involved with bringing risk insights into the regulatory process (e.g., risk-informing technical specifications, risk-informing inservice test requirements). I am a strong supporter of increased use of probabilistic risk assessments (PRAs) for regulatory activities in a manner that supports the Agency's Performance Goals. Since June 1999, I have been working on the RIP-50 Option 2 rule with the RIP-50 Option 2 Core Team. I was also actively involved with reviewing the related South Texas Project requests for exemptions from certain special treatment regulations and was a principal contributor to our safety evaluation which served as the basis for granting some of those exemptions. I take writing this memorandum to you very seriously and I do so only because I believe that the proposed rule, if ultimately issued in its current form and implemented, would not provide adequate protection of public health and safety.

Summary of Management's Current Approach for Option 2 Rulemaking

The current approach for risk-informing 10 CFR Part 50 relies on a "robust categorization process" to identify which safety-related components can be exempted from special treatment requirements (e.g., quality assurance, maintenance rule, inservice inspection, inservice testing, reporting). These components would, however, remain in the plant and would still be required to function under design-basis conditions.

The proposed rule identifies minimum high-level requirements for both the categorization and treatment processes. The staff has developed regulatory guidance related to the categorization process for Option 2. Licensees that choose to adopt 10 CFR 50.69 would be required to submit their categorization process to the NRC staff for review and approval prior to implementation. The proposed rule, as currently constructed, uses very high level treatment objectives to provide regulatory confidence that the safety-related components categorized as having low safety significance (RISC-3 components) will remain functional. The staff does not plan to develop regulatory guidance related to the treatment of RISC-3 SSCs. The licensee's treatment process will not be reviewed and approved by the staff prior to implementation. The proposed rule requires no information relative to the treatment of the RISC-3 SSCs.

The proposed rule relies on evaluations, such as sensitivity studies, to show that any potential change in core damage frequency (CDF) and large early release frequency (LERF) is small (i.e., potential change in risk that might result from any decrease in SSC capability/reliability as a result of reduced treatment being applied to RISC-3 SSCs). The proposed rule also requires that licensees provide the basis for the acceptability for these evaluations. For example, increasing the unreliability of all RISC-3 SSCs by a factor of 2 to 5 could, as stated in NEI-00-04, provide an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of all low safety-significant SSCs. The factor of 2 to 5 is assumed to be appropriate because it is representative of the change in reliability between a mean value and an upper bound (95th percentile) for typical equipment reliability distributions.

The following is the proposed general high-level treatment objective to ensure the functionality of RISC-3 SSCs (there are other high-level requirements related to design control; procurement; inspection, maintenance, testing, and surveillance; and corrective action).

> "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."

Management asserts that the rule should only specify <u>what</u> the NRC's expectations are related to RISC-3 SSCs as opposed to specifying <u>how</u> those expectations are to be satisfied. Management's position is that, as a matter of policy, such high-level treatment requirements provide the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements is consistent with Commission expectations. Furthermore, management states that these high-level treatment requirements, if effectively implemented by licensees, will provide reasonable confidence in the functionality of the RISC-3 SSCs.

At South Texas Project, the proof-of-concept plant for the Option 2 rulemaking effort, approximately 75% of the safety-related pumps and valves were categorized as having low safety significance (analogous to RISC-3 SSCs under Option 2). Examples of equipment categorized as LSS at South Texas Project include:

- diesel generator air start valves;
- main steam isolation valves;
- all feedwater system valves (including flow control and isolation valves);
- spent fuel pool pumps and valves;
- most RHR system valves;
- all (but one) valve in the service water system;
- reactor head vent throttle and isolation valves;
- most chemical, volume, and control system valves;
- HPSI and LPSI flowpath motor-operated valves (MOVs);
- all component cooling water MOVs;
- containment spray pumps and valves;
- most containment isolation valves (including 9 ISLOCA valves)
- centrifugal charging pumps

As you can see, RISC-3 SSCs are not limited to vents and drains and other unimportant components as some often characterize them. Many are important components that need to function reliably in order to run the plant safely or mitigate the consequences of accidents.[1]

Differing View/Opinion

For the following reasons, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

- The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.

- The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.

- The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.

<u>The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.</u>

The categorization process uses long-term average unavailabilities and failure probabilities that are based on steady state assumptions. Other than common cause failures among selected basic events, dependencies among basic events, such as might be introduced by changes to the treatment applied to these SSCs, are generally not modeled. As a result, the importance of certain components or groups of components may not be appropriately categorized. In addition, the treatment portion of the proposed rule is so generally worded and subject to mis-interpretation that licensees could easily establish treatment processes that are ineffective at ensuring that RISC-3 SSCs would be capable of reliably performing their design-basis functions. As a result, licensees that implemented treatment programs, that they believe comply with the proposed rule, could fail to detect degradation that could result in multiple component failures during a single design-basis event.

The proposed rule no longer requires licensees to “characterize the effects of the treatment to be applied to RISC-3 SSCs on SSC capability and performance characteristics under design basis and severe accident conditions.” As such, neither the licensee nor the NRC will be able to make a quantitative assessment of the change in risk associated with the proposed treatment changes. Rather, the proposed rule relies on evaluations (e.g., sensitivity studies) performed by the licensee that assume a certain change in SSC reliability to obtain a sense of what the potential change in risk might be. There is no requirement that the evaluations produce a bounding assessment of the potential change in risk associated with the change in treatment that will be applied to RISC-3 SSCs. While the rule does require “a description of, and basis for acceptability of the evaluations,” there is no standard and very little guidance on what would constitute an acceptable basis (particularly in the areas of fire, seismic, high winds,

and other external events). Changes to treatment practices (such as not performing maintenance on a vendor-recommended schedule) could have a significant impact on SSC reliability such that the evaluations (e.g., sensitivity studies) would not be valid. There is no technical basis for assuming that the factor of 2 to 5 will bound the potential change in reliability or failure rates associated with changes to the treatment of RISC-3 components. There needs to be a process that either ensures that what we are allowing by 50.69 is safe (e.g., by doing either a best estimate or bounding sensitivity studies) or the process should monitor SSC capability/reliability sufficiently to ensure that the unavailabilities are adequately maintained (i.e., ensure that unavailabilities and reliabilities do not exceed the values assumed in the sensitivity studies). In other words, a sensitivity study where the unreliability of all RISC-3 SSCs are increased by a factor of 2 to 5 is only valid if 1) there is data to support the assertion that reduced treatment will not have a significant affect on availability and reliability of these components, or 2) measures are taken to ensure that the failure rate distributions of these SSCs do not shift unexpectedly as a result of the reduced treatment (i.e., by monitoring and corrective action).[2]

Total elimination of regulatory special treatment requirements and reliance on high-level treatment objectives and the licensee's commercial practices would likely result in significant degradation to safety-related equipment that is not directly involved with power production (e.g., standby safety systems) as a result of reduced maintenance, QA, testing, and inspection. Even if the licensee initially established effective maintenance, QA, inspection, testing and surveillance processes for the treatment of these components, economic pressures at some utilities could ultimately result in marginally acceptable or ineffective programs. This degradation would also likely go undetected as a result of being exempt from maintenance rule monitoring, Appendix B, inservice inspection, inservice testing, and regulatory oversight. The potentially widespread degradation of these safety-related components might only manifest itself during a design-basis event. This would be an unacceptable situation (and one which has not been explicitly evaluated by the staff in terms of changes to CDF and LERF).[3]

The proposed rule also no longer requires timely monitoring and adjustment of the categorization or treatment processes to ensure that sensitivity study assumptions remain valid (e.g., provide prompt adjustment of the treatment being applied to the RISC-3 SSC if the monitoring and corrective action programs suggest that the reduced treatment is having an adverse effect of SSC functionality) and thereby ensure acceptable levels of safety are maintained. The proposed rule also no longer requires that significant conditions adverse to quality be evaluated for their applicability to other components (as such, common-cause failures could go uncorrected).

Requiring the use of the ASME risk-informed Code Cases (or an equivalently effective approach developed by the licensee) could be used to provide reasonable confidence that any substantive shift in RISC-3 SSC capability/reliability would be detected and corrected in a timely manner. This approach was presented to the Risk-Informed Licensing Panel (RILP) and Executive Team (ET), but was rejected because it was viewed as a "how" as opposed to a "what."

The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.

In 2001 and in direct support of the 10 CFR 50.69 rulemaking effort, the Division of Engineering contracted the Idaho National Engineering and Environmental Laboratory to compare the special treatment requirements applied to safety-related components at nuclear power plants to commercial practices applied to non-nuclear components. That study concluded, in part, that commercial practices varied widely and that commercial standards by themselves are not adequate to provide reasonable confidence of functionality. Measures such as using a combination of detailed engineering specifications, plant processes and procedures, and multilevel QA programs that provide for less rigor than required for the full 10 CFR 50, Appendix B, but augmented commercial requirements might be one way to establish reasonable confidence of functionality. The study also concluded that plant processes will have a significant effect on providing reasonable confidence of component functionality, and that the adequacy of the commercial standards and reduced plant processes would have to be evaluated on a plant-by-plant basis. Thus, the construct and content of the proposed rule are not consistent with the conclusions of this study.

Based on the South Texas Project exemption request review (RIP-50 Option 2, proof-of-concept review) such high-level objectives were proven to be ineffective in conveying the staff's expectations relative to the treatment of these SSCs. During the South Texas Project exemption review, the staff and the licensee had extensive discussions and negotiations on each treatment process. For example, with high-level objectives as are currently included in the proposed rule, the licensee stated that bumping a pump or exercising a motor-operated valve would provide them with confidence that the pump or valve would be capable of performing their safety-related functions under design-basis conditions.[4] These approaches were found by the staff to be inadequate in providing reasonable confidence of the components' ability to function under design-basis conditions. The high-level objectives were adjusted based on these discussions and are reflected in the licensee's FSAR (Section 13.7.3) which are subject to specific regulatory controls. Language was included in the STP FSAR to preclude ineffective implementation of their high-level treatment objectives.

The Division of Engineering used the INEEL report (NUREG/CR-6752) and the lessons learned from the South Texas Project exemption request review to identify a minimal set of treatment requirements to be included in the 10 CFR 50.69 rule. Over about a two year period, NRR management (via direction from various management teams and partially in response to stakeholder input on draft versions of the rule) whittled away at this minimal set of treatment requirements (e.g., by voting on alternatives with varying level of detail, by using boundary conditions to define the appropriate content of the rule, by deciding that the proposed rule should only contain high-level treatment requirements that specify what the NRC's expectations are related to RISC-3 SSCs as opposed to specifying how those expectations are to be satisfied, by arguing that the proposed rule is a categorization rule). The process used to develop the proposed rule did not focus on safety and certainly was not efficient and effective. Nevertheless, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC external website version). Then, during the concurrence process, senior management made significant technical and policy adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Alternative Treatment Requirements* portion of the proposed rule for RISC-3 SSCs is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is not in the proposed rule.]

(2) *RISC-3 SSCs*. 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. **These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process.** The processes must also meet the following requirements, as applicable:

(i) *Design Control*. Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled**, including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes**. RISC-3 SSCs must **have a documented basis to demonstrate that they are** 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 synergisms); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions). **Replacements for ASME Class 2 and Class 3 SSCs or parts must meet either: (1) the requirements of the ASME *Boiler & Pressure Vessel (BPV) Code*; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced.**

(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements. **Upon receipt, the licensee shall verify that the item received is the item that was ordered.**

(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.

(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. **In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.**

Management's position is that, as a matter of policy, such high-level treatment requirements [i.e., without the bold language] provides the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements [i.e., without the bold language] is consistent with Commission expectations and that including the bolded language would be inconsistent with the Commission's expectation. However, it is not clear why this language has been deleted from the proposed rule when the accompanying Statements of Consideration clearly states that licensees will be expected to do these things.

The text which was deleted from the proposed rule is necessary to provide reasonable regulatory confidence that the RISC-3 SSCs will remain functional. For example, deleting the requirement that licensees comply with voluntary consensus standards removes the technical basis for asserting that the proposed rule will provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. Ad hoc treatment of RISC-3 SSCs by licensees fails to take advantage of the technical expertise of industry standard setting groups, is inconsistent with the National Technology Transfer and Advancement Act of 1995, Public Law 104-113), and could result in inadequate or ineffective treatment of RISC-3 SSCs. In many cases, these consensus standards already explicitly address how to treat low safety significant components. Further, deletion of the requirement to consider vendor recommendations and industry operating experience could result in use of outdated technical information, repetition of poor practices of the past, and common-cause problems that would affect multiple SSC functionality. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations in support of the proposed rule clearly states (on page 75) that "the proposed rule permits, but does not require, use of the Code Cases for purposes of meeting rule requirements," and "the Commission expects licensees will utilize the ASME Code Cases as part of their implementation of §50.69." However, nothing in the rule would prompt licensees to utilize the Code Cases and there will be no regulatory guidance to steer licensees in this direction. If the Commission's expectation is that licensees use the Code Cases then the deleted language (i.e., these processes must meet voluntary consensus standards which are generally accepted in industrial practice) should be included in the rule.

As a second example, documented procedures and guidelines are needed for RISC-3 treatment processes and assessments of their effectiveness to provide reasonable confidence in the functionality of RISC-3 SSCs for initial implementation and follow-up activities. Allowing treatment processes to be undocumented will fail to provide reasonable confidence that activities related to RISC-3 SSCs will be implemented adequately. Absence of a requirement to control assessments of the effectiveness of the licensee's treatment processes will result in the inability to rely on the licensee's internal processes to manage and audit the treatment processes.

As a final example, the requirement that measures be taken to assure that the cause of significant conditions adverse to quality be determined and corrective action taken to preclude repetition is also necessary to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. The licensee's treatment processes must guard against widespread common cause failures. Experience indicates the changes to treatment (e.g., maintenance, test, and inspection practices) can have a significant and widespread effect on component capability and reliability and could invalidate the safety analysis performed to justify the changes. The proposed rule only requires specific failed SSC to be repaired. The proposed rule does not contain a requirement for potential common-cause problems to be evaluated and corrected. Common-cause problems that extend across system boundaries can invalidate the categorization process and result in inadequate protection of public health and safety. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations clearly states that "effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis".

Reliance on the very high-level treatment objectives, as contained in the proposed rule, will not provide reasonable confidence that the RISC-3 SSCs will remain functional. As learned from the RIP-50 Option 2 proof-of-concept exemption request review, high-level requirements alone are inadequate to provide reasonable confidence that licensees will implement sufficient treatment such that RISC-3 SSCs will perform their safety function under design-basis conditions. Moreover, reliance on very high-level treatment objectives will not ensure that degradation that could significantly affect the ability of groups of RISC-3 SSCs to perform their safety function reliably will be detected and corrected in a timely manner.

<u>The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.</u>

The proposed rule should describe (i.e., require) a treatment process that will provide reasonable confidence in the functionality of the RISC-3 SSCs. As currently constructed, the proposed rule relies too heavily on the categorization process. It is overly risk-based and fails to embrace one of the key safety principles identified in RG 1.174, that is, "The impact of the proposed change should be monitored using performance measurement strategies." RG 1.174 clearly states that "[t]he staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that supports the change to the LB." The proposed Option 2 rule should propose monitoring that is consistent with this guidance or there should be a technical basis for why such monitoring is no longer considered necessary.

As stated earlier, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC website version). Then, during the concurrence process, senior management made significant adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Feedback and Process Adjustment* portion of the proposed rule is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is not in the proposed rule.]

Feedback and process adjustment.

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

(2) *RISC-1 and RISC-2 SSCs*. The licensee shall monitor the performance of RISC-1 and RISC-2 SSCs and **in a timely manner and no later than every 36 months, perform an evaluation to assess whether the performance is consistent with the performance credited in the categorization process. Based upon that evaluation, the licensee shall** make adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

(3) *RISC-3 SSCs*. The licensee shall consider **performance** data collected in § 50.69(d)(2)(iii) for RISC-3 SSCs to determine **if the performance is consistent with performance credited in the categorization process, and** whether there are any adverse changes in performance **are due to changes in treatment applied to that SSC. In a timely manner and no later than every 36 months, the licensee shall make** such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv) and shall adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

My concern with the *Feedback and process adjustment* portion of the proposed rule is twofold. First, it does not require that the categorization process assumptions and treatment applied to RISC-3 SSCs be maintained consistent (as is required for the RISC-1 and RISC-2 SSCs). Second, it does not require timely adjustment to the treatment, or categorization process, if RISC-3 performance degrades significantly.

Recognizing that data does not currently exist to predict the effect of reduced treatment on RISC-3 SSC availability and reliability, it is particularly important to establish a process that maintains the treatment applied to the RISC-3 SSCs consistent with the categorization process assumptions. The overall process should require timely evaluation of performance problems that occur with RISC-3 SSCs, particularly problems that could pose a common cause concern, and require prompt adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. In this way, the change in risk can be maintained acceptably small while data is obtained on the effects of reduced treatment on RISC-3 availability and reliability. This linkage between categorization and treatment needs to be unambiguously clear in the rule. The categorization portion of the proposed rule at (c)(1)(iv) currently states:

> Provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of § 50.69(b)(1) and § 50.69(d)(2) are small [where § 50.69(b)(1) lists the rules that RISC-3 SSCs are being exempted from and § 50.69(d)(2) lists the alternate treatment requirements for RISC-3 SSCs].

This requirement does not clearly require that the categorization process assumptions and treatment applied to RISC-3 SSCs be maintained consistent. The proposed rule requirement above also does not require timely adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. As a result, this portion of the proposed rule does not provide reasonable confidence that risk associated with the reduced treatment will be maintained acceptably small and does not provide adequate feedback to ensure RISC-3 functionality.

In addition to the above safety concerns, I have the following process concerns with the proposed rule and the way it was developed.

The proposed rule is inconsistent with the Commission's PRA Policy Statement and with the Commission-approved description of Option 2.

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." There is insufficient data regarding the effect of reduced treatment on RISC-3 reliability to assess the change in CDF and LERF associated with the proposed rule. While sensitivity studies can be used to assess the potential change in CDF and LERF, the rule needs to require that any assumptions made in those sensitivity studies remain valid. This provision of the draft rule (published on the NRC's website) was deleted without any official public comment from stakeholders. SECY-99-256 indicates that "RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance." As mentioned above, the proposed rule does not provide reasonable confidence that the RISC-3 SSCs will remain functional.

The proposed rule is not responsive to public comments received from ASME and exceeds some suggestions provided by NEI.

In its letter dated June 17, 2002, ASME agreed with the provision in the draft versions of the rule to exempt licensees that implement 50.69 from the requirements of 50.55a provided a framework is developed to ensure that the ASME's risk-informed Code Cases and Codes & Standards are used. In its letter dated May 15, 2002, NEI did not object to requirements regarding use of national codes and standards, specific design control aspects, and procurement receipt verification. At a public meeting on June 18, 2002, NEI stated that it did not have a problem with requiring that applicable voluntary consensus standards be used. The provision of the draft rule (published on the NRC's website) which would require that the treatment processes meet voluntary consensus standards, as well as other provisions in the draft rule, were deleted without any official public comment from stakeholders.

The established process for developing the proposed rule was not followed.

Significant technical and policy changes were made to the proposed rule package during the concurrence process without consulting with the technical staff, without providing a technical basis, without discussing the changes with the teams that were involved with developing the rule (e.g., RIP-50 Core Team, Risk Management Team, Risk-Informed Licensing Panel), and without receipt of official public comments. As a result of hastily making these changes to the proposed rule, there are significant inconsistencies between the proposed rule and associated Statement of Considerations. Staff expectations and requirements described in the Statement of Considerations are often not supported by language in the proposed rule.

For example, the Statement of Considerations states (page 80) that "Licensees will have to establish appropriate performance-based SSC treatment processes to maintain the validity of the categorization process and its assumptions." Page 101 of the Statement of Considerations discusses "developing and maintaining a technical basis for concluding that SSC performance is consistent with the categorization assumptions and with those evaluations performed to show that there is no more than a small increase in risk associated with implementation of § 50.69." The Statement of Considerations also states (page 101) that "changing levels of treatment on several similar components that might be sensitive to CCF potential would require consideration as to whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective in sufficiently minimizing CCF potential such that the sensitivity studies remain bounding." Similarly, the Statement of Considerations (page 108) indicates that "the categorization process may include specific reliability assumptions for plant SSCs in performing their intended functions. Therefore, when establishing the performance-based treatment process for RISC-3 SSCs, the licensee must take these assumptions into account. It is important to obtain sufficient information on SSC performance to allow the assumptions and results of the categorization process to remain valid." However, the development and maintenance of this linkage between the categorization and treatment processes is not required by the proposed rule and cannot be reasonably be read into the rule.

In addition, the Statement of Considerations identifies expectations related to the categorization process that are not supported by language in the proposed rule. For example (page 96):

- It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

- It is expected for PWRs that a sufficiently robust categorization process would categorize high energy ASME Section III Class 2 piping of the main steam and feedwater systems as RISC-1.

- It is expected that a sufficiently robust categorization process would result in fission product barriers (e.g., the containment shell or liner) being categorized as RISC-1.

The Statement of Considerations also identifies expectations related to the treatment process that are not supported by language in the proposed rule. For example:

- The Commission expects that related standards (such as ASME Code Cases N-658 and N-660 on SSC categorization and treatment for purposes of repair and replacement) be

used in conjunction with each other as intended by the accredited standards writing body (page 109).

- 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 (page 112).

- The Commission also expects licensees to control special processes associated with installation, such as welding, to provide reasonable confidence in the design-basis capability of RISC-3 SSCs (page 114).

- For a RISC-3 SSC in service beyond its design life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety-related function (page 117).

These types of expectation should be reasonably linked to specific language in the proposed rule. Furthermore, I believe that turning these expectations into requirements of the rule would not be inconsistent with the Commission's expectations as articulated in the Staff Requirements Memoranda (SRMs) in response to SECY-98-300, SECY-99-256, and SECY-00-0194 (SRMs dated 6/8/99, 1/31/00, and 11/9/00, respectively).

As a final note, the strategy of publishing *Additional potential requirements for public comment* (Section VI of the Statement of Considerations) containing the treatment portion of the August 2, 2002, NRC website version of the rule for public comment, in addition to the less prescriptive proposed rule language, will probably not yield any fruitful responses and should be abandoned.

Conclusion

The proposed rule, as it is currently constructed, does not provide reasonable confidence that the change in risk associated with implementation of the rule will be maintained acceptably small. The proposed rule, as it is currently constructed, also does not provide sufficient regulatory assurance that RISC-3 SSCs (most of the safety-related equipment at the plant) will function reliability. The proposed rule simply requires that licensee establish processes to ensure that the RISC-3 SSCs will perform their safety functions under design-basis conditions. Finally, because of the construct of the current Reactor Oversight Process, the NRC won't periodically check to see if the licensee treatment processes for this "low-risk" equipment are effective. Consequently, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

Recommendations

The proposed rule should describe a process that considers the potential effects of reduced treatment on SSC reliability and availability both in categorizing components and in assessing the potential change in risk associated with implementing the rule. The proposed rule should describe a process (i.e., monitoring, corrective action, and feedback) that ensures PRA

assumptions are maintained or that adjusts the treatment being applied to the RISC-3 SSCs as appropriate.

In order to demonstrate that the potential changes in CDF and LERF from the reduced treatment being applied to RISC-3 SSCs are small, the licensee should either 1) determine the effects of reduced treatment to be applied to RISC-3 SSCs on their unavailability and reliability, 2) perform a bounding analysis, or 3) perform sensitivity studies that reasonably assess potential changes that could occur and then monitor RISC-3 performance against the assumptions made in the sensitivity studies. Whichever option is chosen, the licensee should have a technical basis for any assumptions made or the licensee should establish a process that ensures that the assumptions are not inadvertently invalidated.

The proposed rule should make use the ASME's Risk-Informed Code Cases, as endorsed by the NRC staff, or an approach developed by the licensee that provides an equivalent level of effectiveness, as an acceptable method for meeting the high-level objectives of the rule (i.e, maintaining the ability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions). These Code Cases were developed by technical experts as part of a national consensus process. They will address all the major areas in the Code (e.g., ISI, IST, repair and replacement). The Risk-Informed Code Cases define appropriate, generally performance-based test and inspection strategies specifically for low safety significant components. Use of the ASME risk-informed Code Cases would provide reasonable confidence that RISC-3 SSCs would remain functional and would result in a more consistent approach towards the treatment of the RISC-3 SSCs. Such monitoring, if adequately coupled to the licensee's corrective action program, could also be used as a technical basis for asserting that sensitivity studies adequately bound potential increases in CDF and LERF associated with reduced treatment.

Referencing the ASME Code Cases, as endorsed by the NRC staff, will demonstrate that the Agency has a preeminent concern for maintaining public health and safety and will, at the same time, significantly reduce unnecessary regulatory burden (e.g., consistent with procurement of RISC-3 SSCs to commercial standards). It will also preclude any appearance, to the public or the Congress, of coziness with the regulated nuclear industry by working through the ASME and a national consensus process. Use of the ASME Code Cases, as endorsed by the NRC Staff, would also be consistent with the National Technology Transfer and Advancement Act of 1995.

Rather than relinquish specific regulatory controls for over approximately 75% of the safety-related equipment all at one time (and without having specified our expectations regarding how to meet the high-level objectives identified in the proposed rule), I believe it would be more prudent to significantly reduce the regulatory treatment to be applied to the RISC-3 SSCs by referencing the ASME risk-informed Code Cases as endorsed by the NRC. This would allow licensees to gain experience with the reduced maintenance, testing, inspection, and surveillance strategies and allow both licensees and the NRC to get a better understanding of the effect of reduced treatment on component availability and reliability. As experience is gained applying 10 CFR 50.69, the staff can always revisit whether certain categorization or treatment requirements in the rule are necessary.

The aforementioned concerns and recommendations can be ameliorated, in large part, by issuing the August 2, 2002, NRC website version of the rule (as published on the NRC external website) as the proposed rule.

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ADAMS ACCESSION NUMBER: ML022690452

Endnotes:

1. Some NRC staff and managers have recently argued that the categorization process proposed under Option 2 is more robust than that which was approved during the South Texas Project exemption review and would result in far fewer, and less safety significant, components being categorized as having low safety significance. However, the proposed rule neither defines nor requires a robust PRA. The categorization requirements in the proposed rule are also written at a very high level and do not ensure that only very insignificant components get categorized as RISC-3. The examples of robustness that have been mentioned are contained in draft regulatory guide DG-1121, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance."

2. While a study conducted by the South Texas Project licensee asserted that non-safety-related failure rates were not appreciably greater than corresponding safety-related failure rates for similar component types, the study was flawed for the following reasons.

- Failure data in NPRDS and MRRI is generally obtained during normal plant operating conditions and may not provide an indication of how the equipment will function under accident conditions.

- There was generally more safety-related equipment experience reported in the databases (because of reporting requirements) than for corresponding types of non-safety-related equipment. The reporting of non-safety-related failure data into NPRDS was voluntary and licensee dependent. As acknowledged in the report, there is incomplete data reporting in NPRDS and MRRI raw data for all component engineering and failure records. As a result, the non-safety-related failure frequencies will tend to be underestimated.

- Counting functional or operational failures over calender hours of plant operation does not give a reasonable estimate of a component's availability/unavailability or a component's reliability if called upon to function under design basis conditions.

- Detailed calculation of demand-based and run-time based failure "rates" similar to those applied in the probabilistic risk assessment (PRA) was not possible within the NPRDS database, because detailed failure mode and demand exposure (or success) data was not included therein. For both demand and run failure rate calculations, most component success or total "exposure" data (i.e., total demands and total run time) values in the MRRI database are estimated, not actually recorded like failure events. The estimates for the demand-based and run-time based failure "rates" assume that safety-related and non-safety-related components have similar demand profiles and run-time profiles. The basis for this assumption needs to be explained.

- Only functional or operational failures were considered in the analysis. There was no indication that other component records were evaluated to determine whether deficiencies identified in them would have prevented the component from functioning under design-basis-accident conditions.

- Only NPRDS safety class S (safety-related equipment) and safety class N (non-safety-related equipment) data was considered in the analysis. Safety class Z (other) was omitted from the analysis.

3. A more meaningful sensitivity study (than varying the unavailabilities of all RISC-3 SSCs by a factor of 2 to 5) might be to significantly reduce, or set to 1, the unavailabilities of selected RISC-3 SSCs to see the potential effect on CDF and LERF. It is noteworthy that modeling of common cause failures typically would not go across system boundaries. Inasmuch as, reducing the treatment applied to a group of components can both introduce common cause failure mechanisms (e.g., test or maintenance errors) and eliminate the defensive strategies against proximate causes (e.g., design controls, use of qualified equipment, testing and preventive maintenance programs, procedural review, personnel training, quality control) it is particularly important to either understand (i.e., up front) the effects of reduced treatment on common cause failure mechanisms or monitor for potentially more widespread common cause concerns. While increasing the failure rates by a factor of 2 to 5 also increases the common-cause failure contribution to the overall system unavailability by a factor of 2 to 5, it generally does not address inter-system common cause concerns and it is not mathematically correct in that parametric multipliers are neither known nor estimated.

4. The Commission previously concluded in NRC Generic Letter 89-10, “Safety-Related Motor-Operated Valve Testing and Surveillance,” dated June 28, 1989, and again in the Supplementary Information in support of the September 22, 1999, revision to 10 CFR 50.55a (64 FR 51370) that the quarterly stroke-time testing requirements for MOVs in the Code are not sufficient to provide assurance of MOV operability under design-basis conditions. Therefore, elimination of a licensee’s commitment to conduct periodic diagnostic testing (on an interval as long as once every 10 years based on valve performance) in conjunction with more frequent exercise testing [i.e., once a year or every refueling outage (whichever is longer)], in lieu of the quarterly stroke-time testing, would be unsafe.