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FROM:

William M. Dean
Assistant for Operations, OEDO

A handwritten signature in black ink, appearing to read "W. M. Dean", with a long horizontal line extending to the right.

SUBJECT: INDIVIDUAL STAFF RESPONSE TO INDUSTRY VIEWS ON 10 CFR 50.69

On July 28, 2004, Commissioner McGaffigan's office solicited feedback directly from NRR staff members regarding their thoughts on an NEI transmittal they received regarding 10 CFR 50.69 proposed rulemaking (attached). The staff's document, which was provided directly to Commissioner McGaffigan's office by the staff members, is being provided for your information.

Attachment: As stated

cc: L. Reyes, EDO (w/o attachment)
M. Virgilio, DEDMRS (w/o attachment)
W. Kane, DEDH (w/o attachment)
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EDO R/F (w/attachment)

Response to "Industry Views on 10 CFR 50.69"
prepared by J. Fair, D. Fischer, T. Scarbrough, and D. Harrison

In the undated paper titled "Industry Views on 10 CFR 50.69," the industry states that the 10 CFR 50.69 rule package is not a viable option because it (1) reverts to programmatic and prescriptive controls; (2) has attributes that contribute to regulatory risk, uncertainty, and instability; and (3) leaves doubtful any safety or cost benefit associated with categorization. The industry paper does not indicate how the few changes to the proposed rule cause the final rule to have these attributes. In particular, the comment regarding cost benefits is contradicted by South Texas which reported at the NRC/ASME Symposium on Valve and Pump Testing in July 2004 that it is saving hundreds of thousands of dollars per year implementing its exemption from the special treatment requirements, which provides fewer relaxations than will be allowed under 10 CFR 50.69.

The industry paper states that the rulemaking drifted from the original intent of SECY 98-300, which indicated that low risk safety-related SSCs would move from special treatment to normal industrial practice. However, SECY 99-256 stated that RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet their functional requirements. Industry comments on the proposed rule indicated that licensees intended to implement practices that might not maintain the design-basis functional capability of low risk safety-related SSCs. In response, the SOC for the final rule clarifies that treatment practices must satisfy the requirements of the rule.

The industry paper states that elements of the package undermine the SECY 98-300 intent by infusing prescriptive treatment requirements for RISC-3 SSCs into the categorization process. In particular, the industry paper asserts that 10 CFR 50.69(b)(2)(iv) causes this problem by requiring that a 50.69 license amendment application describe evaluations of the effects of common-cause interaction susceptibility, and potential impacts from known degradation mechanisms. As noted in the industry paper, the staff responded to several licensee comments on the proposed rule requesting modification of this rule language (e.g., see public comment table in rulemaking package at comment b-5). In those responses, the staff emphasized that the basis for the assumptions made for bounding reliability changes in RISC-3 SSCs can be significantly impacted by known degradation mechanisms and common cause failure.

The staff intends that 50.69(b)(2)(iv) will provide for the identification of those causes that could undermine the implementation of the rule (in particular, common cause failures that go across system boundaries and failures due to degradation mechanisms) and ensure that programs that defend against these causes are maintained in the treatment process. By doing this, there is no need to consider the impact of these causes in the 50.69(c)(1)(iv) delta risk calculation because there would be no changes in SSC failure rates due to these causes since the associated programs would be maintained. In essence, these programs are identified up-front, they pass through the categorization process, and then continue to be implemented in the treatment process. What the staff did not want to have happen is for degradation mechanism programs to not be considered in the categorization process (because their failures are not considered in the PRA - these programmatic elements are assumed to perform their intended purpose such that failures can be assumed to be so small that they can be ignored) and then eliminated or reduced in the treatment process for the RISC-3 SSCs.

The industry paper indicates that 50.69(b)(2)(iv) (as well as (c)(1)(iv)) can be met in a risk-informed, performance-based manner that addresses degradation mechanisms and common cause interactions, without the need for prescriptive, programmatic reviews. Contrary to the industry paper's implication, a performance-based approach should include consideration of degradation mechanisms and common cause interactions that might have significant detrimental impact on the performance of groups of safety-related components. Also, the NEI guidance document for categorization (NEI 00-04) under 10 CFR 50.69 provides for the consideration of degradation mechanisms through its reference to ASME Code Cases N-577 and N-578, which include detailed guidance in this regard.

With respect to degradation mechanisms, the industry paper asserts that PRA failure rates and initiating events include impacts from known degradation and other mechanisms, and that performance monitoring and PRA updates would continue to capture this data. Contrary to this assertion, the PRA failure rates are based on the performance of plant SSCs that have been designed, tested, and maintained using methods that satisfy the special treatment requirements that address known degradation mechanisms. The failure rates for SSCs not treated in a manner that addresses degradation is not adequately known. For example, improper lubrication of motor-operated valves (MOVs) may result in many MOVs not being able to perform their safety-related function under design-basis accident conditions. Further, performance monitoring will only obtain data for design attributes that can and will be tested as part of the monitoring process. Many aspects of design-basis capability, such as environmental and seismic capability, cannot be monitored, and the potential for degradation must be addressed as part of design control in the treatment process.

With respect to common cause interaction, the industry paper asserts this is addressed in the categorization and treatment processes as follows:

1. Common cause treatment in the PRA must meet the PRA standard.

Contrary to this assertion, PRAs address common cause primarily only within individual systems, and do not address potential common cause interaction across systems for most plant SSCs.

2. A common cause RAW is used in the categorization process to maintain components with high common cause impacts in the RISC-1 and RISC-2 categories.

Contrary to this assertion, an adequate common cause RAW cannot be established if programs to address known degradation mechanisms are not maintained as assumed in achieving the reliability values used in the risk calculations.

3. The defense in depth evaluation assures that key safety functions are maintained by redundant RISC-1 SSCs.

Contrary to this assertion, many SSCs (such as low pressure core spray, containment spray, and containment isolation valves) with important safety-related functions on a group basis might not be categorized as RISC-1 SSCs.

4. The sensitivity study will conservatively increase the failure rate of all RISC-3 SSCs simultaneously to assure that CDF increases are small.

Contrary to this assertion, the industry has not demonstrated that decreasing the reliability of all RISC-3 SSCs by a fraction of a percent will bound the potential risk impact of failing to maintain groups of safety-related SSCs properly (such as not adequately lubricating valve stems in high temperature areas).

5. Performance monitoring will ensure that potential increases in failure rates will be addressed before reaching the rate assumed in the sensitivity study.

Contrary to this assertion, the industry has not indicated plans to implement 10 CFR 50.69 in such a manner that would identify a reduction in the reliability of each RISC-3 SSC by fraction of a percent as assumed in the sensitivity study. Further, the staff has not intended that the industry implement such a detailed monitoring program for RISC-3 SSCs.

6. The corrective action requirement specifically addresses conditions adverse to qualify.

While this statement is correct, the corrective action process only responds to identified performance problems, and cannot address common cause interaction of design attributes in SSCs that cannot be monitored.

The industry paper concludes that the rulemaking package must be modified to achieve its original intent, and that a risk-informed, performance-based approach can address the concerns expressed in the rulemaking package. As discussed above, the assertions made in the industry paper do not support modifying the rule. The final rule includes the same requirements for addressing known degradation mechanisms and common cause interactions as the proposed rule. Failure to address degradation mechanisms and common cause interactions can cause multiple RISC-3 SSCs to be incapable of performing their safety functions under accident conditions, and result in public health and safety not being maintained at plants implementing the rule. Therefore, it is not appropriate to remove the requirement to consider known degradation mechanisms and common cause interactions from 10 CFR 50.69.

The issue raised in the industry paper also relates to the one major technical issue the staff identified with NEI 00-04 involving how, during implementation of 10 CFR 50.69, licensees would ensure that the categorization process evaluations were being maintained valid. The industry needs to ensure through their guidance that, if a failure of a RISC-3 SSC is detected, it is not an indication of a potential common cause failure (CCF) or degradation mechanism failure due to a change in special treatment requirements (STRs). Under the rule, for degradation mechanisms, the industry would be relying on the continuation of the associated programs that already exist (including those associated with risk-informed inservice inspection). For CCF, the industry would be relying on the fact that they recommended the addition to the rule (which was accepted) to identify conditions adverse to quality. This aspect still needs to be spelled out in the industry guidance (NEI 00-04) to ensure licensees will actually consider the potential for CCF whenever a failure of a RISC-3 SSC is discovered. This does not imply invoking a detailed root cause analysis, but only a high-level consideration of the cause of the failure and the potential for that cause to be an indication of an across-system CCF due to a change in STRs.

Industry Views on 10 CFR 50.69

The final rulemaking package on 10 CFR 50.69 has drifted far from its original intent. It is not a viable option for licensee implementation in its current form. This is because the package:

- reverts back to programmatic and prescriptive controls for plant equipment demonstrated to have low safety significance (RISC-3 SSCs) that pave over risk-informed, performance-based regulatory principles;
- has all the attributes that contribute to regulatory risk, uncertainty and instability; and
- leaves doubtful any safety or cost benefit associated with categorization.

Since the issuance of SECY 98-300, the "options" paper for risk-informing 10 CFR Part 50, the intent of Option 2 (10 CFR 50.69) was to revise the scope of SSCs that need special treatment. SECY 98-300 states:

Under this option [2], SSCs of low safety significance (from a risk-informed assessment) would move from "special treatment" to normal industrial (sometimes called "commercial" treatment), but would remain in the plant and be expected to perform their design function but without additional margin, assurance or documentation associated with high safety significant SSCs.

The final rule package contains the elements necessary to achieve this original intent. The scope of applicable special treatment requirements are clearly identified; a rigorous risk-informed categorization process using a high quality PRA is required; provisions are included that specify what elements of treatment are required to maintain the functionality of low safety significant SSCs; and a feedback process is required to ensure that any potential increases in risk are small. However, other elements of the package undermine this intent by infusing prescriptive treatment requirements for RISC-3 SSCs into the categorization process and carrying them forward into implementation. These elements negate the safety and cost benefits of removal of RISC-3 SSCs from the scope of special treatment requirements.

The rule language that initiates the problem described above is § 50.69(b)(2)(iv):

(2) A licensee voluntarily choosing to implement this section shall submit an application for license amendment under § 50.90 that contains the following information:

(iv) A description of, and basis for acceptability of, the evaluations to be conducted to satisfy § 50.69(c)(1)(iv). The evaluations must include the effects of common cause interaction susceptibility, and the potential impacts from

known degradation mechanisms for both active and passive functions, and address internally and externally initiated events and plant operating modes (e.g., full power and shutdown conditions).

This requirement modifies the evaluation that is conducted per the categorization process requirements in § 50.69(c)(1)(iv):

(iv) Include evaluations that 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 (d)(2) are small.

The following statements from the rulemaking package explain what is intended by §§ 50.69(b)(2)(iv) and (c)(1)(iv):

From NRC response to comment c-26:

The assumptions in the (c)(1)(iv) evaluation can change significantly as a result of common cause failures and known degradation mechanisms. To have confidence in the risk sensitivity study results, it is necessary to have an understanding of these factors, and hence this is an integral part of the evaluation. This does not imply that the risk sensitivity study must quantify the impact of known degradation mechanisms, but these potential impacts and the programs that address these mechanisms must be identified to ensure they are carried forward into the treatment phase and that these programs are not eliminated for RISC-3 SSCs.

From NRC response to comment b-5:

... Further, the NRC agrees with the commenter's recommendation that licensees need to address degradation mechanisms in their treatment process. However, these mechanisms must be identified and considered, at least qualitatively, in the categorization process to ensure they are carried forward and addressed in the licensee's treatment process. The NRC recognizes that licensees are likely to perform sensitivity studies, but disagrees that these sensitivity studies will necessarily a priori bound realistic changes in RISC-3 reliability.

From NRC response to comment c-34:

... Section 50.69(b)(2)(iv) does not mandate quantitative analyses, but rather, requires the licensee to identify the aspects of the licensee's programs (including design control, performance monitoring, and corrective action / feedback) that address these potential impacts to ensure the categorization process remains valid and the overall impact due to reductions in treatment are maintained acceptably small.

From NRC response to comment d-1:

... A licensee will need to submit its basis to support that the evaluations are bounding estimates of the potential change in risk and that programs already in existence or implemented for §50.69 can provide sufficient information that any potential risk change remains small over the lifetime of the plant.

To summarize, as part of the categorization process, the rule will require licensees to (1) identify known degradation mechanisms and common cause interaction susceptibilities for all RISC-3 SSCs (active and passive); (2) identify either existing or new programs that address these potential impacts; and (3) submit for NRC review and approval its basis that any potential changes in risk will be small as a result of (1) and (2). This approach is more akin to what licensees and the NRC staff do in license renewal for long-lived passive components. It is certainly not consistent with the original intent of Option 2, nor does it have any resemblance to a risk-informed, performance-based approach.

We strongly believe that §§ 50.69(b)(2)(iv) and (c)(1)(iv) can be met in a risk-informed, performance-based manner that addresses both known degradation mechanisms and common cause interactions, and without the need for prescriptive, programmatic reviews. First, all of the failure rates for equipment and initiating event frequencies used in the PRA include the impacts from known degradation mechanisms, as well as any other mechanisms (e.g., design errors, manufacturing deficiencies, human errors, etc.). Subsequent performance monitoring and PRA updates required by the rule will continue to capture this data.

With regard to common cause interaction, this is addressed in both the categorization process and in treatment as follows:

- Common cause treatment in the PRA must meet the ASME Level I PRA Standard Requirements;
- A common cause risk achievement worth is used in the categorization process to assure that groups of components with potentially high common cause impacts are maintained in the RISC-1 or 2 categories.
- The defense in depth evaluation assures that key safety functions are maintained by redundant RISC-1 SSCs.
- The integrated risk sensitivity study conservatively increases the failure rate of all RISC-3 SSCs simultaneously to assure that potential increases in delta CDF due to changes in treatment are small.
- Performance monitoring will ensure that potential increases in failure rates will be addressed before reaching the rate assumed in the sensitivity study.
- The corrective action requirement in the rule specifically addresses conditions adverse to quality (i.e., common cause failures).

In conclusion, we believe the rulemaking package must be modified to achieve the original intent, and that a risk-informed, performance-based approach can address the concerns expressed in the rulemaking package.