



NUCLEAR ENERGY INSTITUTE

Anthony R. Pietrangelo
DIRECTOR, RISK & PERFORMANCE-
BASED REGULATION
NUCLEAR GENERATION

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Mr. Samuel J. Collins
Director, Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Collins:

This letter provides industry comments on the *Section 50.69 Draft Rule Language as of April 3, 2002*, published on the NRC's Rulemaking Forum website. Our intent is to resolve and clarify as many issues as possible prior to the submittal of the proposed rule package to the Commission later this year.

We believe substantive issues remain to be resolved in this rule, particularly those associated with the treatment of RISC-3 structures, systems and components (SSCs). While the scope of the rule has been revised to include the pertinent special treatment requirements, the revised treatment language now includes additional requirements that negate certain scope changes made or fail to adequately convey the intent of the rule. With regard to categorization, the requirement to characterize the effects of reduced treatment on RISC-3 SSCs is totally speculative and would add burden with no safety benefit. Finally, the continued inclusion of the need for a license amendment in order to adopt the rule is not supported by past regulatory precedent or the current regulatory framework. The enclosure discusses these issues and other concerns in detail.

The industry remains committed to resolving these concerns expeditiously. To this end, we would support a meeting with the NRC in the near term.

If you or your staff have any questions regarding this letter, please contact me.

Sincerely,

A handwritten signature in black ink that reads 'Anthony R. Pietrangelo'. The signature is written in a cursive, flowing style.

Anthony R. Pietrangelo

Enclosure

Yes!



Enclosure

Industry Comments on the NRC's Draft Rule Language for 10 CFR 50.69, Dated April 3, 2002

General Comments

In recent years the NRC has made progress in setting the foundation for an improved risk-informed, performance-based regulatory process. Yet, implementing a significant change, even though it will result in an improved safety focus, is often difficult because of familiarity with, and reliance on, the traditional, deterministic regulatory framework. As such, it is important that the bases and the language of any new or revised rules are clear and unambiguous.

While we believe that clarification can be provided in NRC endorsed industry guidance documents and in the Statements of Consideration (SOC) for the rule, over reliance on such measures can be counter productive. It can result in years of unnecessary regulatory interactions debating the proper interpretation of the final rule language.

The draft rule language, especially in paragraph (d), is confusing, sometimes conflicting, and open to varying interpretation. It does not reflect the principles of risk-informed regulation or good regulation.

The draft does not acknowledge selective implementation, i.e., licensees may opt to implement the rule for certain SSCs over time, or may opt to implement alternatives to certain special treatment requirements. If selective implementation is not addressed in the rule, we urge that the SOC include this topic.

Title of 50.69

Concern: The current title, "Risk-Informed Treatment of Structures, Systems, and Components," inadequately conveys the main purpose of the rule, which is categorization of SSCs based on safety significance to determine the scope applicability of NRC special treatment requirements.

Proposal: Rename 50.69, "Risk-Informing the Scope of Special Treatment Requirements."

Rationale: The proposed title more accurately describes the primary focus of the rule.

Categorization Process

Paragraph (c)(1)(ii)(A)

Concern: The third sentence states, “The PRA must model the current plant configuration and operating practices...” No plant PRA models the entire plant or all operating practices. In addition, components and subcomponents are often subsumed within super-components in the model.

Proposal: Change the third sentence to read: “The PRA must reasonably reflect the current plant configuration and operating practices”...

Rationale: The proposed wording captures the intent in a practical manner.

Paragraph (c)(1)(iii)(A)

Concern: The requirement to characterize the effects of reduced treatment on SSC capability and performance characteristics under design basis and severe accident conditions amounts to total guesswork. Neither the industry nor NRC knows how to quantify the change in CDF, LERF or reliability due to treatment changes. The proposed requirement would add significantly to the resources necessary to perform the categorization process without any attendant benefit in safety.

Proposal: Delete paragraph (c)(1)(iii)(A)

Rationale: There is no value added by this requirement. The categorization process requires the complete failure of a function to initially determine safety significance and other considerations, including defense in depth, are further required. Additional confidence in the robustness of the process is provided by sensitivity studies that assume increased failure rates for SSCs categorized as RISC-3.

Requirements for SSCs

Paragraph (d)(1) - Requirements for RISC-1 and RISC-2 SSCs

Concern: The draft language is ambiguous and should be more explicit.

Proposal: Change the paragraph as follows:

The licensee or applicant shall monitor the performance of SSCs against licensee-established performance criteria in a manner sufficient to provide reasonable assurance that the SSCs are capable of performing their intended functions. The performance criteria shall be established commensurate with the safety-significance

of the functions of the SSCs. When SSC performance does not meet the established performance criteria, corrective action shall be taken.

Rationale: The proposed change would make the §50.69 language consistent with other performance-based requirements, such as the maintenance rule-monitoring requirement. For those licensees that monitor for all functional failures, their existing maintenance rule implementation would meet this requirement. If a licensee is only monitoring for maintenance preventable functional failures, that licensee would have to broaden its program to include all functional failures. This approach is performance-based in providing assurance of functionality with the performance criteria being based on the licensee's PRA, which encompasses the categorization process assumptions.

Treatment of RISC-3 SSCs

Paragraph (d)(3) – Requirements for RISC-3 SSCs

Concern: The draft language is overly prescriptive and focused on documentation of processes. It does not adequately convey the intent of Option 2 to exclude RISC-3 SSCs from NRC special treatment requirements. The use of the word “pertinent” does not adequately convey the intent of graded treatment measures for low safety-significant SSCs.

Proposal: Change the language to read:

The licensee or applicant shall control the design; procurement; inspection, maintenance, testing and surveillance; and corrective action of RISC-3 SSCs in a manner that provides adequate confidence in their capability to perform their safety-related functions under design basis conditions. These controls shall be established through applicable national, local, or industry codes and standards, vendor recommendations, operating experience, or licensee documents. Implementation measures shall be applied commensurate with the relative importance and complexity of the activity, and shall be accomplished through plant procedures, guidelines, work instructions, or by skill of the craft, as appropriate.

Rationale: The first sentence in our proposed language states what the licensee must do and why it must do it. The second sentence states the origin for the controls established in the first sentence, without the prescriptiveness and emphasis on documentation in the draft NRC language, which should be reserved for RISC-1 SSCs. The third sentence conveys the intent to apply graded measures to the treatment of low safety-significant SSCs, rather than relying on the single word “pertinent” to convey this intent.

Paragraph (d)(3)(i) – Design Control

Concern. The tone and language mirrors the language in the regulations for environmental qualification and codes and standards, which are included in the scope of this rule. As such, our concern is the same as for paragraph (d)(3) above. When read together, it reinforces the potential for an incorrect interpretation that the level of detail and substance of licensee activities should be almost identical to treatment for safety-significant SSCs.

Proposal: Change the language to read:

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

Rationale: Paragraph (d)(3) already requires the licensee to provide adequate confidence that the design bases functions will be satisfied. There is no need to repeat the phrase in this subsidiary paragraph to (d)(3).

Paragraph (d)(3) also requires the use of applicable codes and standards. No need to repeat the phrase.

The draft language on control of installation and post-installation testing is covered under verification of design adequacy and in the subsequent treatment element that includes testing.

There is no need to repeat any language from any of the special treatment requirements, like EQ, seismic qualification, and 50.55a, because they are within the scope of 50.69 that exempts RISC-3 SSCs from these special treatment requirements.

Paragraph (d)(3)(iii) – Maintenance, Inspection, Testing and Surveillance

Concern: The requirement re-imposes on RISC-3 SSCs §50.65 requirements that were exempted under paragraph (d)(2). Further, it requires licensees to monitor RISC-3 SSC reliability against sensitivity studies, which is neither practical nor relevant.

The purpose of the sensitivity studies is to add confidence in the robustness of the categorization process. Requiring licensees to establish reliability monitoring for each RISC-3 SSC against the sensitivity studies would impose an unnecessary resource burden on licensees for equipment that has minimal or no safety significance. The assumptions made in the sensitivity studies are extremely

conservative, and because the SSCs are of low safety significance, this level of monitoring is an unnecessary diversion of resources.

Proposal: Change the language to read:

Periodic maintenance, inspection, testing, and surveillance activities shall be established and conducted, and their results evaluated against licensee-established functional acceptance criteria.

Rationale: The proposed language restores the intent of this treatment provision, which is to provide confidence in the functionality of equipment, not to validate extreme assumptions made in the categorization process or in sensitivity studies. Examples of functional testing under this treatment requirement are pump flow rates, vibration, thermography, and starting current.

Paragraph (d)(3)(iv) – Corrective Action

Concern: The April 3 proposal is more restrictive than Criterion XVI of Appendix B to Part 50, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. Appendix B states, "...failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected..." The corrective action requirement is focused on actual failures not on possible failures.

Proposal: Change the language to read:

Where the licensee determines that a RISC-3 SSC is not capable of performing its safety related functions under design-basis conditions, the licensee must identify, document, and correct such deficiencies in a timely manner. In the case of significant conditions adverse to quality that would impact and degrade safety-significant SSCs, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.

Rationale: The proposed change would make the basis for low safety-significant equipment corrective action the same as that for safety-significant equipment.

The industry and the NRC have a long-standing interpretation of the phrase, "significant conditions adverse to quality." It would only be applicable if such a significant adverse quality condition existed that degraded safety significant equipment.

Submittal and Approval Process

Paragraph (e)(1)

Concern: The need to seek authority for adopting §50.69 through a license amendment introduces an unnecessary complexity into the regulatory process for review and approval of a licensee's §50.69 application. This rulemaking as well as the development of a regulatory guide that endorses the industry guidance on categorization are subjected to formal public review and comment. There is no need for further public participation when an individual licensee seeks to adopt what has already been approved for use by the NRC.

Proposal. Change the paragraph to read:

A licensee or construction permit holder who chooses to implement §50.69 shall submit an application for NRC review and approval that contains the following information:

- (i) A description of the categorization process that meets the requirements of §50.69(c).
- (ii) A description of the measures taken to assure that the quality and level of detail of the plant-specific PRA is adequate for the categorization process.
- (iii) Results of the PRA review process conducted to meet §50.69(e)(ii).

Rationale: Section 161.i of the Atomic Energy Act (AEA) authorizes the NRC to prescribe such regulations or orders as it may deem necessary to govern any activity authorized pursuant to the AEA, "including standards and restrictions governing the design, location, and operation of facilities used in the conduct of such activity, in order to protect health and to minimize danger to life or property." This language does not constrain the Commission to reliance on license provisions to control license activities; to the contrary, it authorizes the use of regulations and orders.

The provision of the Act that speaks most directly to license amendments is section 187, "Modification of License," which states that the "terms and conditions of all licenses shall be subject to amendment, revision, or modification, by reason of amendments of this Act, or by reason of rules and regulations issued in accordance with the terms of this Act." This provision, on its face, authorizes the Commission to amend licenses, but does not specify any circumstance in which a license amendment is required.¹

¹ See also section 183.d of the AEA, providing that every license is subject to "all valid rules and regulations of the Commission."

Similarly, nothing in current Commission regulations would require that the NRC prescribe that a license amendment be sought to implement the substantive provisions of section 50.69. The most relevant regulation is 10 C.F.R. § 50.59, which permits licensees to make certain changes to a facility without obtaining a license amendment. The types of changes provided for in section 50.69 are similar to the types of changes allowed under the recent revision of section 50.59 (see 64 Fed. Reg. 53,582 (1999)) in that the changes to be authorized are only those that a licensee's analysis show have minimal impact on safety.

Further, provisions of NRC regulations also provide mechanisms other than license amendments to effect changes to regulatory requirements. For example, changes can be made through written authorization to deviate from codes (§ 50.55a(a)(3)); changes to quality assurance programs (§ 50.54(a)(3), (4)); and changes to security plans (§ 50.54(p)(2)). In this connection, it is relevant to note that licensees adopting section 50.69 would need to reflect this election in their current licensing basis (CLB). The change to the CLB would primarily consist of a reduction in the special treatment provisions for safety-related SSCs that are categorized as low safety significant (RISC-3). Special treatment provisions for safety-related SSCs are typically described in a licensee's quality assurance (QA) topical report, which is referenced in the updated safety analysis report. A summary description of the alternative treatment practices for the RISC-3 SSCs would need to be added to the QA topical report. This change would be equivalent to a change to the QA program description that reduces commitments per 10 C.F.R. § 50.54(a)(4); and, in accordance with 50.54(a)(4)(i), the change must be submitted as specified in 10 C.F.R. § 50.4, not through a license amendment of 10 C.F.R. 50.90.

There is no fundamental requirement, either pursuant to statute or regulation, necessitating approval of a licensee's election of alternative treatment requirements through the license amendment process. Accordingly, such a requirement is not necessary as a matter of law. The Commission recently observed in a related context:

By reducing the total number of technical specifications, the Commission's policy also aims to reduce license amendment requests and thereby avoid unnecessarily taxing the resources of the NRC and licensees, while at the same time assuring that technical specifications focus on the most safety-critical features, posing the greatest immediate threats to public health and safety. (Dominion Nuclear Connecticut, Inc. (Millstone Nuclear Power Station, Units 2 and 3), CLI-01-24, 54 NRC 349, 362 (2001) (*emphasis added*), *rehearing denied*, 2002 WL 130427 (NRC Jan. 30, 2002))

As a result we do not believe a license amendment is necessary for approving the adoption of §50.69.

Program Description, Documentation and Change Control

Paragraph (f)(1)

Concern: This requirement is redundant to 50.71(e), which requires periodic updating of the UFSAR, as well as QA Topical Reports incorporated by reference in the FSAR.

Proposal: Delete paragraph (f)(1).

Rationale: See concern above.

Paragraph (f)(5) Change Control Process for Changes to Categorization

Concern: We do not know what the term, “decrease the effectiveness of the process in identifying safety-significant SSCs” means, nor have we been able to develop suitable metrics for determining when effectiveness has been reduced.

Proposal: Delete paragraph (f)(5).

Rationale: The industry and NRC staff have struggled with other regulatory program change control processes that use the “reduced effectiveness standard.” We recommend that we use the proven change control process associated with management of NRC commitments, as described in the NRC endorsed NEI 99-04, *Guidelines for Managing NRC Commitment Changes*.

Other programs, such as those related to §50.65, §50.49, risk-informed in-service inspection (ISI), and the programmatic requirements of Appendix J do not list the specific change control mechanism in those specific regulations because other existing regulatory change control mechanisms are applicable. The same is true for §50.69.

Paragraph (f)(6)

Concern: This paragraph requires that all records required by §50.69, which would include records associated with categorization, design, inspections and tests be retained on site in a readily retrievable form for a period of three years beyond when the SSCs to which they apply are no longer subject to NRC requirements. Such a requirement for SSCs that have no or low safety-significance is extreme and unwarranted.

Proposal: Change the paragraph to read:

- (i) The licensee or applicant shall retain records required by this section for the categorization process for a period of five years after the date of categorization.
- (ii) Technical support documentation for RISC-1 and RISC-2 SSCs shall be retained per the documentation requirements of the applicable regulations.

Rationale: The record retention period for the programmatic changes should be consistent with other regulatory change control processes, such as §50.59, which is five years.

Documentation retention requirements for RISC-1 and RISC-2 SSCs should be as defined by existing requirements for safety-related SSCs.

For low safety-significant SSCs, test, design, and support documentation often is not held on site for nonsafety-related SSCs. A literal interpretation would result in a licensee having to have a complete test package on site for RISC-3 SSCs to demonstrate that the equipment is capable of satisfying its design bases function under design bases conditions. This is no different than the requirements imposed under §50.49. As such, there is no resource benefit to a licensee of implementing the robust, rigorous and resource intensive categorization process.

Presently, there are no retention documentation requirements for nonsafety-related SSCs. There is no need to impose documentation retention requirements for low safety-significant RISC-3 SSCs. Licensee's choosing to adopt §50.69, should keep records of programmatic changes for a period of five years. Records pertaining to low safety-significant SSCs should be held for a period of time, as determined by the licensee, sufficient to support the licensee needs pertaining to design records files.

Reporting

Paragraph (g)

Concern: It is unclear whether this reporting requirement replaces §50.73 requirements or is addition to §50.73 requirements

Proposal: Change the paragraph to read:

In addition to the reporting requirements of §50.73, a licensee adopting the requirements of this section shall submit a licensee event report to the NRC for any event or condition that prevents a RISC-1 or RISC-2 SSCs from performing a safety significant function. The report shall be submitted consistent with the requirements of §50.73(b).

Rationale: While the existing regulation for license events reports provide a very comprehensive listing of reporting requirements for numerous systems and events, it does not encompass all safety-significant functions, because the categorization process may identify some safety-significant functions that are not subject to current NRC reporting requirements.