RULEMAKING ISSUE
(Affirmation)

June 30, 2004 SECY-04-0109

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

SUBJECT: FINAL RULEMAKING TO ADD NEW SECTION 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS FOR NUCLEAR POWER REACTORS"

PURPOSE:

To obtain Commission approval to publish the final rule and the regulatory guidance implementing the final rule.

SUMMARY:

The final rule amends the NRC's regulations governing the domestic licensing of production and utilization facilities. Specifically, the rule adds to 10 CFR Part 50 a new § 50.69 that provides an alternative set of requirements for treatment of structures, systems, and components (SSCs). The alternative requirements use a risk-informed categorization process to determine the safety significance of the SSCs. These requirements can be voluntarily adopted by light-water reactor licensees and applicants.

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BACKGROUND:

In SECY-98-300, "Options for Risk-Informed Revisions to 10 CFR Part 50–'Domestic Licensing of Production and Utilization Facilities'," dated December 23, 1998, the staff recommended the development of risk-informed approaches to the application of special treatment requirements.[1] This initiative, referred to as Option 2, revises the scope of SSCs that need special treatment, while still providing assurance that the SSCs will perform their design basis functions. Option 2 does not include changes to the requirements pertaining to the design basis functional requirements of the plant or the design basis accidents.

The Commission approved proceeding with Option 2 in a staff requirements memorandum (SRM) dated June 8, 1999. In that SRM, the Commission directed the staff to evaluate strategies to risk-inform the scope of the commercial nuclear reactor regulations that impose special treatment requirements. On October 29, 1999, the staff sent the Commission SECY-99-256, "Rulemaking Plan for Risk-Informing Special Treatment Requirements," to obtain approval for a rulemaking plan and issuance of an advance notice of proposed rulemaking (ANPR). In its rulemaking plan, the staff proposed to create a new section in Part 50, referred to as § 50.69, to contain these alternative requirements. By an SRM dated January 31, 2000, the Commission approved the rulemaking plan and publication of the ANPR. The ANPR was published in the *Federal Register* on March 3, 2000 (65 FR 11488), and the 75-day comment period ended on May 17, 2000. The Commission received more than 200 comments in response to the ANPR. On September 7, 2000, the staff sent the Commission SECY-00-0194, "Risk-Informing Special Treatment Requirements," which provided the staff's preliminary views on the ANPR comments.

On September 30, 2002, the staff sent the Commission SECY-02-0176 containing the proposed § 50.69 rule package. The Commission approved issuance of proposed § 50.69 for public comment in an SRM dated March 28, 2003. Consistent with Commission direction, the staff subsequently published proposed § 50.69 for public comment in the *Federal Register* on May 16, 2003 (68 FR 26511).

DISCUSSION:

The staff has developed § 50.69 as an alternative set of requirements whereby a licensee or applicant may voluntarily categorize its SSCs consistent with the requirements in § 50.69(c) and adjust treatment requirements per § 50.69(d) based upon the resulting significance. Under this approach, a licensee or applicant is allowed to remove the special treatment requirements listed in § 50.69(b) for SSCs that are determined to be of low individual safety significance. The regulatory requirements not removed by § 50.69(b) continue to apply, as well as the requirements specified in § 50.69. The rule contains requirements by which a licensee uses a risk-informed process to categorize SSCs, adjusts treatment requirements consistent with the

[1]Special treatment requirements are current requirements that go beyond industry-established requirements for equipment classified as commercial grade and provide additional confidence that equipment is capable of meeting its functional requirements under design basis conditions. These special treatment requirements include requirements for additional design considerations, qualification, change control, documentation, reporting, maintenance, testing, surveillance, and quality assurance.

relative significance of the SSCs and manages the process over the lifetime of the plant. To implement the rule, a risk-informed categorization process is employed to determine the safety significance of SSCs and place the SSCs into one of four risk-informed safety class (RISC) categories. The determination of safety significance is performed by an integrated decisionmaking process which uses both risk insights and traditional engineering insights. The safety functions include both the design basis functions (derived from the definition of "safety-related," which includes external events) and functions credited for severe accidents (including external events). The SSCs are required to be treated as necessary to maintain functionality and reliability. The treatment is a function of the category of the SSC. Finally, assessment activities are conducted to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The rule contains requirements for obtaining prior NRC review and approval of the categorization process and for maintaining certain plant records and reports.

It is important to note that this rulemaking effort, while intended to risk-inform the scope of special treatment requirements imposed on SSCs, is not intended to allow licensees to eliminate SSC functional requirements or to remove equipment from the facility that is required by the deterministic design basis. Changes to the design of the facility must continue to meet the current requirements governing design change, most notably § 50.59.

As discussed in more detail in the attached *Federal Register* notice (Attachment 1), the staff concludes that the final rule maintains safety through a combination of elements and that it is consistent with Commission guidance on risk-informed activities. The rule allows both the NRC staff and industry to better focus their attention and resources on regulatory issues of greater safety significance. This rule would reduce unnecessary regulatory burden by removing SSCs of low individual safety significance from the scope of certain special treatment requirements and would also identify more significant SSCs that receive enhanced attention. As a result, this rulemaking would aid in bringing the regulations in closer agreement with the risk-informed approaches to inspection and enforcement.

The staff notes that the rule does not contain criteria for determining whether a safety function is "significant," or whether a SSC has "low" safety significance. There are several factors that tend to minimize these weaknesses: (i) the existence of high-level requirements in the § 50.69 rule governing the categorization process, (ii) more detailed regulatory guidance on the categorization process and suggested criteria for assessing safety significance, which the majority of applicants are likely to use, (iii) the staff's intention to impose a license condition requiring continued use of the regulatory guidance for those applicants committing to using the regulatory guidance, and (iv) the weaknesses are confined to the application of special treatment, while the design basis for the plants remain unchanged by § 50.69 and must continued to be maintained. Nonetheless, the lack of such criteria could have the following effects: (i) for those plants that use an alternative to the regulatory guidance for the § 50.69 categorization process, NRC staff review may be more difficult to complete; (ii) NRC inspection may have greater variation as different plants have different working definitions of "high" and "low" safety significance, and (iii) defending challenges to the adequacy of the categorization process, and the adequacy of implementation may be more difficult. Although it may be possible to develop criteria for inclusion in the rule which would be utilized in determining "significant" safety functions, and "low" safety significance, there are significant technical issues

which would have to be resolved requiring substantial additional time, resources, and interactions with stakeholders.

Stakeholder Feedback on the Proposed Rule

The Commission received 26 sets of comments comprising about 200 individual comments in response to the proposed rule and the specific areas of interest indicated in the *Federal Register* notice for the proposed rule. The comments reflected divergent views among the stakeholders on many aspects of the proposed rule and the specific areas of interest. The staff has reviewed each of the comments in detail in developing the final rule. The more significant comments are summarized in Section II of the attached *Federal Register* notice and all of the comments are discussed in more detail in the "Response to Public Comments on the Proposed Rule" (Attachment 4). Several of the key issues are highlighted below.

With respect to categorization, stakeholder comments ranged from those supporting more extensive probabilistic risk assessment (PRA) requirements to those stating that the PRA requirements specified in proposed § 50.69(c) were sufficient. For example, industry commenters stated that additional PRA requirements were not necessary because the other categorization requirements in § 50.69(c) addressed modes and events not addressed by the PRA. The comments from State organizations and public interest groups supported additional and more stringent PRA requirements. The staff concludes that the § 50.69 PRA requirements in the proposed rule are sufficient for this application, and has maintained those requirements in the final rule. The staff also concludes that the § 50.69 PRA requirements are consistent with the direction provided in the Commission's SRM dated December 18, 2003, such that a Level 2 internal and external initiating events, all-mode, peer-reviewed PRA is not necessary for implementation of this rule.

With respect to the treatment of RISC-3 SSCs (i.e., safety related, low safety significant SSCs), the divergent views of stakeholders revealed that the RISC-3 treatment requirements needed to be clarified and the supporting description in the Statements of Consideration (SOC) revised to focus on the meaning of the rule language. For example, some industry commenters asserted that general industrial practices would be sufficient to satisfy the requirements in § 50.69 for the treatment of RISC-3 SSCs. In this regard, industry commenters pointed to exercising valves and pumps as a means of satisfying the proposed rule language. It is the staff's view, based upon operational experience and research, that exercising is not sufficient to provide confidence in the design basis capability of pumps and valves. Therefore, exercising pumps and valves would not provide reasonable confidence in the capability of those components to perform their design basis safety functions in accordance with the reliability values assumed in the categorization process. As a result, the staff clarified the rule to specify that the treatment of RISC-3 SSCs must be consistent with the categorization process, and has revised the SOC to indicate that exercising a pump or valve alone is insufficient to satisfy the treatment requirements of the rule. Some comments suggested that licensees might not implement sufficient processes to determine that RISC-3 SSCs are capable of performing their safety-related functions under design basis environmental and seismic conditions. As a result, the staff clarified the rule to specify that the treatment processes for RISC-3 SSCs, including determination of design basis capability, must be documented, and revised the SOC to indicate that the requirements for RISC-3 SSCs to be capable of performing their safety-related functions under design basis conditions continue to apply. Several stakeholders also indicated

that the proposed rule did not address potential common-cause failures of RISC-3 SSCs. Since SSCs are categorized as RISC-3 primarily on their low individual safety significance, the failure of several RISC-3 SSCs can have a significant impact on the response of a nuclear power plant to design basis events and the risk associated with those design basis events. To emphasize the importance of avoiding common-cause failures of RISC-3 SSCs, the staff clarified the requirements for the corrective action process for RISC-3 SSCs by adding a requirement that, for significant conditions adverse to quality, the cause of the condition must be determined and action taken to preclude repetition. This requirement was proposed by the Nuclear Energy Institute (NEI) and uses language that is similar to 10 CFR Part 50, Appendix B, Criterion XVI. As such, this should be a well-understood requirement that minimizes the potential for common-cause failures.

Comments from public interest groups and State organizations generally stressed the need for the NRC to review and approve RISC-3 treatment processes in advance of the implementation of § 50.69 to confirm that appropriate treatment will be applied to RISC-3 SSCs for the performance of their safety-related functions. On the other hand, industry commenters did not consider prior review and approval of RISC-3 treatment to be necessary in light of the low individual safety significance of RISC-3 SSCs, other requirements that help maintain safety, and the availability of inspection and enforcement by the NRC. The staff believes that licensees should be allowed to establish treatment processes for RISC-3 SSCs without NRC review prior to implementation of those processes, given the low individual safety significance of RISC-3 SSCs and the high-level treatment requirements in § 50.69. To provide additional assurance, the staff intends to conduct sample inspections at nuclear power plants implementing § 50.69 to address programmatic issues related to the categorization and treatment processes. Public comments on the proposed rule indicated general support for providing regulatory oversight of the implementation of processes established under § 50.69 through the NRC's inspection and enforcement process.

Some stakeholders commented that operating experience argues against removal of special treatment requirements and that regulatory attention should be increased for all safety-related equipment. To emphasize the importance of applying operating experience in maintaining plant safety, the staff revised the rule to clarify that § 50.69(e)(1) requires the feedback of plant operational experience in addition to the requirements to feed back performance data, plant changes, operational changes, and industry experience. This plant operational information may be obtained from the corrective action program and processes, as well as other sources.

Implementation Guidance for § 50.69

NEI submitted a proposed implementation guide for this rulemaking in the form of NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline." As part of the effort to develop the rule, the NRC staff reviewed drafts of this document. The objective of the staff's review was to determine the acceptability of the proposed implementing guidance, with the intent that the NEI guidance could be endorsed in an NRC regulatory guide (RG). The final draft revision of NEI 00-04 (Attachment 6), submitted on April 14, 2004, forms the basis for the NRC Regulatory Guide (Attachment 5). The NRC staff's review of NEI 00-04 revealed several areas where the staff finds it necessary to identify exceptions to, and/or clarify, the NEI guidance or to include further guidance to supplement the document as it is currently written. These areas are discussed in RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in

Nuclear Power Plants According to Their Safety Significance." These remaining few technical interpretation/implementation issues of the guidance are best resolved by testing the guide against actual applications. Therefore, this RG is being issued for trial use.

ACRS and CRGR Review

The draft final rule was reviewed by the Advisory Committee on Reactor Safeguards (ACRS) on June 2, 2004. The Committee To Review Generic Requirements (CRGR) reviewed the final rule and elected to waive a briefing on the final rule. Neither the ACRS nor the CRGR object to issuance of the final rule.

Implementation

Section 50.69 requires licensees or applicants, who voluntarily elect to implement § 50.69, to submit information concerning the categorization process for prior NRC review and approval. For licensees, this review and approval will be in the form of a § 50.90 license amendment. The NRC staff expects that licensees and applicants will follow RG 1.201. As part of the NRC approval of a license amendment, the NRC staff intends to impose a license condition upon which the categorization process approval is based to control categorization process changes. The license condition will require the licensee to notify the NRC in advance of implementing changes with respect to specific aspects of the categorization process. With experience in the application of § 50.69, the NRC might modify the rule to specify generic criteria for the control of changes to the categorization process during implementation of the rule.

The NRC staff will update, as appropriate, the current inspection procedures under the NRC Reactor Oversight Process to incorporate inspection guidance for monitoring the implementation of 10 CFR 50.69 at nuclear power plants. The staff intends to conduct sample inspections of plants implementing 10 CFR 50.69 in a manner that is sensitive to conditions that could significantly increase risk. These sample inspections are intended to gather information that will enable the staff to assess whether modifications are needed to the ongoing baseline inspection program. The sample inspections will focus on the implementation of the categorization process approved as part of the NRC review of the 10 CFR 50.69 license amendment request. The sample inspections will also evaluate the treatment processes established under 10 CFR 50.69 with primary attention directed to programmatic and common-cause issues, including those associated with known degradation mechanisms. Inspector training will be conducted to support rule implementation.

The final rule excludes applicants for standard design certifications from the group of entities who may take advantage of the provisions of § 50.69. In considering whether to extend the applicability of § 50.69 to design certifications, the staff identified a number of difficult issues which would have to be resolved to support such an extension. For example, it is unclear whether the dynamic process of recategorizing SSCs under § 50.69 would be consistent with the special change restrictions in § 52.63(a), thereby requiring the inclusion of a special change provision in the individual design certification rule. Inasmuch as the proposed rule did not include a provision that would have allowed design certification applicants to use § 50.69, the NRC has not had the benefit of the views of the industry and the public on these issues. Moreover, the industry has not expressed any interest in submitting a design certification using the principles of § 50.69. Accordingly, the staff recommends that the final rule not address the

issue of applying § 50.69 to new design certifications; issues associated with the application of § 50.69 to design certification rulemaking can be addressed on a case-by-case basis as necessary. In the future, the Commission could initiate rulemaking to extend § 50.69 to new design certifications after the staff has had some experience in this area.

Contents of the Final Rulemaking Package

This rulemaking package includes the *Federal Register* final rule document, which includes the final rule language and SOC (Attachment 1), the regulatory analysis (Attachment 2), an environmental assessment (Attachment 3), the staff's response to the public comments on the proposed rule (Attachment 4), Regulatory Guide 1.201 (Attachment 5), and the NEI categorization guidance document, NEI 00-04 (Attachment 6).

RESOURCES:

The resources to complete the final rule and associated guidance (for NRR: 0.3 FTE in FY 2004) are included in the budget for FY 2004. These resources are for the staff's effort to develop guidance for the review of licensee amendment submittals and to develop guidance for the inspection of plants implementing § 50.69. This estimate does not contain the resources for inspector training and the actual inspection of § 50.69 implementation since we do not currently know how many plants will implement § 50.69 and when implementation will occur.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking for publication in the *Federal Register* (Attachment 1) with an effective date 30 days after the date of issuance.

2. Certify that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities. The certification is needed to satisfy requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note:

    a. That the final rule (Attachment 1) will be published in the *Federal Register*:

    b. That a final regulatory analysis has been prepared for this rulemaking.

    c. That a final environmental assessment has been prepared for this rulemaking.

    d. The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding economic impact on small entities and the basis for it, as required by the Regulatory Flexibility Act.

    e. The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 and has confirmed this determination with the Office of Management and Budget.

f. Copies of the final rule will be distributed to all affected Commission licensees. The document will be sent to other interested parties upon request. Copies of the documents are also available in the NRC's Agencywide Document Access and Management System (ADAMS), and the Public Document Room and on the NRC rulemaking Web site.

g. That a press release will be issued by the Office of Public Affairs when the final rule is filed with the Office of the Federal Register.

h. The appropriate congressional committees will be informed.

i. The NRC will publish separately the implementation guidance for this rulemaking in the form of RG 1.201.

COORDINATION:

The Office of General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. The ACRS and CRGR have no objection to issuing this final rule. The Office of the Chief Information Officer has reviewed the final rule information technology and information management implications and concurs in it.

/RA/

Luis A. Reyes
Executive Director
for Operations

Attachments:
1. *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Response to Public Comments on the Proposed Rule
5. Regulatory Guide 1.201
6. Final draft of NEI 00-04

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Executive Director
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ACCESSION NO.: (Package) ML041170141 **WITS NOS.: 199900061**
Commission Paper: ML041030062 Attachment 1: ML041000458
Attachment 2: ML041000474 Attachment 3: ML041040236
Attachment 4: ML041040190 Attachment 5: ML041340087
Attachment 6: ML041120253

*Concurred by Email **via memo

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