

# RULEMAKING ISSUE NOTATION VOTE

September 30, 2002

SECY-02-0176

FOR: The Commissioners

FROM: William D. Travers  
Executive Director for Operations

SUBJECT: PROPOSED RULEMAKING TO ADD NEW SECTION 10 CFR 50.69,  
"RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES,  
SYSTEMS, AND COMPONENTS" (WITS 199900061)

PURPOSE:

To obtain Commission approval to publish the proposed rule and the draft regulatory guidance implementing the proposed rule for public comment.

SUMMARY:

The staff has prepared a proposed rulemaking to add a new section to 10 CFR Part 50 to provide an alternative set of requirements for treatment of structures, systems and components (SSCs), using a risk-informed categorization process to determine safety significance of the SSCs. These requirements can be voluntarily adopted by light-water reactor licensees and applicants. The proposed rule is based upon extensive interactions with stakeholders (including consideration of public comments on draft rule language made available on the NRC rulemaking web site), experience with pilot plants, and guidance development activities.

The staff has prepared a proposed rule package and draft implementing guidance. The paper summarizes the development of the proposed rule and the contents of the rule package. In addition, the paper discusses issues that arose during this rulemaking and some of the key

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stakeholder concerns with the rule and how it would be implemented. The staff recommends that the Commission approve publication of the proposed rule and draft implementation guidance in the *Federal Register* for public comment.

#### 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.<sup>1</sup> This initiative, referred to as Option 2, addresses the implementation of changes to the scope of structures, systems and components 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 of the plant or the design basis accidents. These technical risk-informed changes are addressed under Option 3 of SECY-98-300.

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 unique requirements identified in this discussion as "special treatment requirements." On October 29, 1999, the staff sent to 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 within Part 50, referred to as § 50.69, to contain these alternative requirements. By 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. With respect to treatment requirements, the staff stated that conceptually, licensees will be required to maintain the functional requirements of the low safety-significant, safety-related (RISC-3) SSCs. The staff further said that it expected to establish minimal requirements in the rule for this purpose. The requirements would involve measures and activities such as procurement control, monitoring and corrective action.

#### DISCUSSION:

The staff has developed a proposed rule that would permit power reactor licensees and license applicants to implement a voluntary alternative regulatory framework with respect to special treatment. Under this framework, licensees (or applicants), using a risk-informed process to categorize SSCs according to their safety significance, can remove SSCs of low safety significance from the scope of certain identified special treatment requirements. For SSCs of safety significance, existing requirements are retained, and the rule would add requirements

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

that ensure SSC performance remains consistent with that relied upon in the categorization process for beyond design basis conditions.

As discussed in more detail in the attached proposed rule, the staff has concluded that the proposed rule would maintain safety through a combination of elements, and that it is consistent with Commission guidance on risk-informed activities. The rule would reduce unnecessary regulatory burden by removing SSCs of low safety significance from the scope of certain special treatment requirements as well as identifying SSCs of greater significance which should receive potentially enhanced attention. As a result, both the NRC staff and industry should be able to better focus their attention and resources on regulatory issues of greater safety significance. With respect to efficiency and effectiveness, this rulemaking would aid in bringing the regulations in closer agreement with the risk-informed approaches to inspection and enforcement. The staff concludes that public confidence would be maintained through the opportunity for public comment on the rulemaking and guidance; by staff review of the probabilistic risk assessment (PRA) and categorization approach through the use of the license amendment process for plant-specific implementation, and by focusing licensee resources on SSCs of greatest safety significance.

#### Proposed Rule

The proposed rule would establish a risk-informed process by which a licensee (or applicant) would categorize SSCs, adjust treatment requirements consistent with the relative significance of each SSC, and manage the process over the lifetime of the plant. This proposed rule is a voluntary alternative to existing requirements. First, a licensee would employ a risk-informed categorization process to determine the safety significance of SSCs and to place the SSCs into one of four risk-informed safety class (RISC) categories. The determination of safety significance would be performed through an integrated decision-making process which uses both risk insights and traditional engineering insights. The safety functions would include both the design basis functions (derived from the "safety-related" definition, which includes external events), as well as functions credited for severe accidents (including external events). The categorization process would also require the licensee to determine that any resultant potential increase in risk is small. Treatment requirements for the SSCs would then be applied dependent on the RISC category into which the SSC is categorized. Finally, a licensee would conduct assessment activities to make adjustments to the categorization and treatment processes as needed so that SSCs continue to meet applicable requirements. The proposed rule also contains requirements for obtaining NRC approval as well as related supporting requirements.

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

#### Stakeholder Feedback on Draft Rule Language

On November 29, 2001, the staff published a first draft of rule language on the NRC rulemaking web site, along with a brief explanation of the intent of the rule and its guidance. The NRC received comments on this draft from the Nuclear Energy Institute (NEI), licensees, and individuals. The comments led the staff to revise the draft rule language. A second version of the draft rule was made available on April 5, 2002. Additional comments were received in

response to this posting. A final version of the draft rule was posted on the web site on August 2, 2002. Comments that resulted in substantive changes in rule language are addressed in the statement of considerations for the proposed rule (Attachment 1). The staff has responded to many other comments through the discussions in the statement of considerations that explain the basis for, and the means of complying with, the proposed rule.

### Contents of the Proposed Rulemaking Package

This rulemaking package includes the proposed *Federal Register* notice for the proposed rule, which includes the proposed rule language and statement of considerations (Attachment 1), the regulatory analysis (Attachment 2), an environmental assessment (Attachment 3), and the staff's final recommendations regarding the ANPR comments (Attachment 4). The package also contains the Draft Regulatory Guide, DG-1121 (Attachment 5), and the NEI categorization guidance document, NEI 00-04, "10 CFR 50.69 SSC Categorization Guideline" (Attachment 6), which are further discussed below.

Finally, the rule amends information collection requirements that must be submitted to the Office of Management and Budget no later than the date the proposed rule is forwarded to the *Federal Register* for publication. The staff has prepared its supporting statement for this rulemaking, which will be finalized upon Commission approval to publish the proposed rule.

### ISSUES OF INTEREST

This rulemaking is the first instance<sup>2</sup> in which the NRC would establish, by rule, specific requirements concerning the conduct of a PRA in support of a particular regulatory action. Thus, during the development of the rulemaking, issues arose concerning what attributes of the PRA are important for this application (e.g., the scope, level of detail, and technical quality expected, and updating requirements), and specific technical issues (such as how to address initiating events, modes or SSCs that are not modeled in the PRA). In lieu of putting all of these details into an appendix to the rule (as initially envisioned in SECY-99-256), the staff recommends more general rule requirements, supported by detailed implementation guidance, based upon ANPR comments (see Attachment 4). Further, a focused staff review and approval of the categorization process will be conducted.

The NRC staff plans to complete a regulatory guide (RG) that would endorse NEI 00-04 with clarifications and exceptions as necessary. At the present time, there are a number of issues that need further discussion and development before the staff can complete such a document. For purposes of the proposed rule, the staff has prepared a draft guide, DG-1121, "Guidelines for Categorizing Structures, Systems and Components in Nuclear Power Plants According to their Safety Significance" (Attachment 5), which identifies these areas. The NRC staff has also provided these comments to NEI so that NEI 00-04 can be revised accordingly. In a few specific areas, the staff recommends that the industry develop guidance to assist licensees in implementing the rule, which could then be endorsed in the final RG. The proposed *Federal Register* notice containing the proposed rule includes a request for stakeholder input on these documents, so that the implementation guidance is ready to be issued when the final rule is sent to the Commission.

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<sup>2</sup>The staff notes that § 52.47(v) requires submittal of a design-specific PRA in connection with an application for a design certification rule (DCR), but includes no additional details on its requirements or on how the PRA is to be used in decisionmaking with respect to the issuance of a DCR.

As reported in the Option 2 status reports, an area that received considerable attention during preparation of the proposed rule was the development of the alternative treatment requirements for the low safety-significant, safety-related (RISC-3) SSCs. During the development of this rulemaking (as well as during the review of the South Texas exemptions request, which concerned similar issues), there was considerable debate among internal and external stakeholders, as to the extent of treatment requirements that the NRC needs to specify for RISC-3 SSCs in order to have sufficient confidence that such SSCs remain capable of performing design basis functions. As discussed in SECY-00-0194, the proposed rule includes high-level requirements that are structured to address the key elements of SSC functionality, while giving licensees significant flexibility regarding the means of implementation.

Some staff<sup>3</sup> feel that absent more specific and detailed RISC-3 treatment requirements, licensees may implement practices that allow RISC-3 SSC degradation, potentially increasing the probability of common cause failures. For example, absent specific requirements, licensees might conclude that it is acceptable to allow RISC-3 SSCs to run to failure. These concerns were heightened with the proposed removal of portions of § 50.55a (the regulation that imposes the requirements of the American Society of Mechanical Engineers (ASME) Code on safety-related SSCs) as requirements for RISC-3 SSCs. In its selection of the proposed rule requirements, and in the presentation in the statement of considerations, the staff has addressed these issues with clear requirements for continued functionality. The staff also concludes that the enhancements made to the categorization process that have developed over time (see DG-1121 for details) also support removal of treatment details for RISC-3 SSCs. The proposed rule specifies the minimum attributes for the treatment processes (to be in place at the facility), but allows flexibility in application provided that functional performance is maintained. The staff had decided not to develop implementation guidance on treatment for RISC-3 SSCs, or to review in advance the programs that a licensee or applicant would have in place. Rather, the proposed rule places the responsibility on the licensee (or applicant) to implement those elements of the treatment processes that are necessary (for the particular SSCs and activity) to maintain the safety-related functions under design basis conditions.

In its draft rule language for proposed § 50.69, the staff considered including more detailed requirements for RISC-3 SSCs in § 50.69(d)(2). For the reasons discussed above, and on the basis of stakeholder comments on the draft rule language, the staff concludes that this level of specificity is beyond what is necessary to provide reasonable confidence in RISC-3 design basis capability in light of the robust categorization requirements incorporated into the proposed § 50.69. The staff recognizes that some stakeholders may wish to provide further input on these former provisions of draft § 50.69, and has included a section in the *Federal Register* notice that invites public comments on the previously considered rule language. This would enable the Commission to fully consider stakeholder feedback on this issue when formulating the final rule.

As a result of the more performance-based approach for RISC-3 treatment, the staff concludes that the RISC-3 requirements are more closely aligned with the reactor oversight process in its approach to inspection and enforcement. Because there are few details about how a licensee or applicant should implement its processes to maintain functionality of SSC, should NRC have concerns about particular licensee practices, NRC would need to establish a basis for enforcement that the licensee's approach is not providing reasonable confidence in the

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<sup>3</sup>Note that on September 26, 2002, three members of the staff filed Differing Professional Views (DPVs) on this proposed rulemaking. The staff concerns described in this paper, and other concerns, are raised by these DPVs. The DPVs will be addressed in accordance with agency practice.

capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions, rather than because a specific treatment requirement was not met. The *Federal Register* notice invites public comments on inspection and enforcement considerations.

Some stakeholders raised concerns about the proposed rule provisions that require a § 50.90 license amendment before implementation of the remainder of the proposed rule. The staff has concluded that use of the license amendment process is appropriate for this application because the approvals would change the authority granted to licensees under their operating licenses, and the determinations about suitability of the PRA for the application will involve substantial staff judgment and discretion.

Another aspect of the proposed rule that concerns some stakeholders is the requirement in § 50.69(c)(1)(iv) that licensees provide reasonable confidence that increases in core damage frequency (CDF) and large early release frequency (LERF) due to implementation of § 50.69 would be small. The previous drafts of the rule language for § 50.69 had a stronger link between RISC-3 treatment and the potential for this treatment to change RISC-3 reliability, requiring licensees to characterize the effects of revised treatment on RISC-3 reliability. Some external stakeholders believe that it is not possible to comply with this requirement because of the difficulty in quantifying the impact that revised treatment might have on RISC-3 SSC reliability. Conversely, some staff believed that there should be even a stronger link, such as requiring that a licensee monitor performance against the categorization assumptions. Because many of the SSCs involved are in standby systems, and the treatment changes include a range of activities, the staff concluded that "monitoring" RISC-3 SSCs against specific values of reliability or unavailability would not be effective and furthermore is not necessary given the low safety significance of these SSCs. Thus, the proposed rule would require that the licensee consider the reliability of the RISC-3 SSCs used in their evaluations of the impact on risk and have an acceptable basis to support the evaluations to show that no greater than a small change in risk may occur due to implementation of § 50.69. It should be noted that § 50.69 requires inspection, test and surveillance processes to be conducted to provide information that SSCs are still capable of performing their safety-related functions. The proposed rule also includes a feedback requirement for the licensee to use such performance information to determine if adverse changes in performance are occurring and to take appropriate action.

#### RESOURCES:

The resources needed to complete the proposed rulemaking and guidance (4 FTE for FY 2003 and 3 FTE for FY 2004) are included in the current budget. Plant-specific implementation will be achieved through individual licensing actions. Inspection of licensee implementation will be performed through the normal inspection process. As discussed above, the staff is still considering whether any different inspection efforts on performance of SSCs or audits of the categorization process would be appropriate. The staff does not expect to need additional resources to complete this effort beyond current budgets.

#### COORDINATION:

The Office of the 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 staff met with the Advisory Committee on Reactor Safeguards (ACRS) concerning the rulemaking approach and implementation guidance, on a number of occasions, most recently on September 13, 2002. In a memorandum dated September 18, 2002, the Committee agreed with the staff's proposal to issue the proposed rule and draft regulatory guide for public comment.

The Committee to Review Generic Requirements has deferred its review of the rule until the final rule stage.

**RECOMMENDATIONS:**

That the Commission:

1. *Approve* the notice of proposed rulemaking for publication (Attachment 1).
2. *Certify* that this rule, if promulgated, will not have a negative economic impact on a substantial number of small entities in order to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).3.

**Note:**

1. The proposed rule will be published in the *Federal Register* with a 75-day public comment period.
2. 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.
3. Copies of the *Federal Register* Notice of proposed rulemaking will be distributed to all affected Commission licensees. The notice 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), the Public Document Room and on the NRC rulemaking web site.
4. A public announcement will be issued.
5. The appropriate Congressional committees will be informed.

6. The supporting statement concerning changes in information collection requirements will be sent to the Office of Management and Budget.
7. Unless otherwise directed, the staff plans to end preparation of the quarterly status report on this rulemaking (WITS 200000111).

***/RA/***

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Executive Director  
for Operations

Attachments:

1. *Federal Register* Notice
2. Regulatory Analysis
3. Environmental Assessment
4. Disposition of ANPR Comments
5. Draft Regulatory Guide (DG-1121)
6. NEI 00-04, Rev. C, dated June 28, 2002



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**ADAMS ACCESSION NO.: (Package) ML022630164**

**Commission Paper: ML022630007**

**Attachment 1:ML022630018 Attachment 2: ML022630028**

**Attachment 3:ML022630050 Attachment 4: ML022630030**

**Attachment 5:ML022630041 Attachment 6: ML021910534**

**WITS NO.:WITS 199900061 and 200000111**

**\*See previous concurrence**

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