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PROPOSED RULEMAKING TO RISK-INFORM SPECIAL TREATMENT REQUIREMENTS

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ABSTRACT

This paper presents the status of Nuclear Regulatory Commission (NRC) rulemaking efforts to risk-inform special treatment requirements that reside in Title 10 of the Code of Federal Regulations, 10 CFR Part 21, Part 50, and Part 100. 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 NRC staff expects that stakeholder input provided in response to the proposed rule issuance will be valuable and support the efforts to issue the final rule.

1.0 INTRODUCTION

The NRC 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. The NRC staff provided the proposed rulemaking to the Commission in SECY-02-176 (reference 1). 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 would be retained, and the rule would add requirements that ensure SSC performance remains consistent with that relied upon in the categorization process for beyond design basis conditions. 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 would be 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 would also contain requirements for obtaining NRC approval as well as related supporting requirements.

It is important to note that this rulemaking effort, while intended to ensure that the scope of special treatment requirements imposed on SSCs is risk-informed, would not be intended to allow for the elimination of SSC functional requirements, or to allow equipment that is required by the deterministic design basis to be removed from the facility. Instead, by restructuring the regulations to allow an alternative risk-informed approach to special treatment, this rulemaking would enable licensees and the staff to focus their resources on SSCs that make a significant contribution to plant safety. Conversely, for SSCs that do not significantly contribute to plant safety, this approach would allow a reduced level of assurance that these SSCs will meet design basis functional requirements.

2.0 OVERVIEW OF PROPOSED RULE

An overall description of the proposed rule can be found in SECY-02-176 (reference 1). The proposed rule is built around three central components: 1) categorization, 2) treatment, and 3) monitoring/feedback. These are described below.

2.1 CATEGORIZATION

The cornerstone of proposed § 50.69 is the establishment of a robust, risk-informed categorization process that provides high confidence that the safety significance of SSCs is correctly determined considering all relevant information. As such, all the categorization requirements incorporated into proposed § 50.69 are to achieve this objective. Essentially the process is structured to ensure that all relevant information pertaining to SSC safety significance would be considered by a panel that has the expertise and capabilities for making a sound decision regarding the SSC's categorization, and that information would be considered in a manner that ensures the Commission's criteria for risk-informed applications are satisfied (i.e., that defense-in-depth is maintained, safety margins are maintained, any risk change is small, and a monitoring and performance assessment strategy is used). This process would enable SSCs to be placed in the correct RISC category such that the appropriate treatment requirements would be applied commensurate with their safety significance. A safety-significant SSC is an SSC that performs a safety-significant function. The proposed rule would require that SSC safety significance be determined using quantitative information from an up-to-date probabilistic risk assessment (PRA) reasonably representing the current plant configuration, which as a minimum covers internal events at full power, and other available risk analyses and traditional engineering information to supplement the quantitative PRA results. The proposed rule would contain requirements to ensure that the PRA is adequate for this application. The proposed rule would require that as part of the categorization process defense-in-depth is considered, and that the revised treatment applied to RISC-3 SSCs be considered for its potential impact on risk.

The risk insights and other traditional information would be required to be evaluated by an Integrated Decision-Making Panel (IDP) comprised of expert, plant-knowledgeable members whose expertise includes PRA, safety analysis, plant operation, design engineering, and system engineering. Because the IDP makes the final determination about the safety significance of an SSC, it is important that the membership include a variety of expertise about the plant, how it is operated, and the safety analyses (both deterministic and probabilistic), so that all pertinent information is considered. Hence the available deterministic and probabilistic information pertaining to SSC safety significance would be considered in the decision process. The information considered must reflect the as-built and as-operated plant, so that the decisions are based upon correct information, leading to proper categorization. Where applicable, the information would come from a PRA that is adequate for this application (i.e., categorization of SSC safety significance). From this perspective, the IDP decision process can be viewed as an extension of the previous process for determining SSC safety classification (i.e., safety-related or nonsafety-related), in that it is making use of relevant risk information which was either not considered, or not available when the SSCs were initially classified. The IDP would make the final determination of the safety significance of SSCs using a process that takes all this information into consideration, in a structured, documented manner. The structure would provide consistency to decisions that may be made over a period of time, and the documentation would give both the licensee and the NRC the ability to understand the basis for the categorization decision, should questions arise at a later date.

The PRA used to provide the risk information to the categorization process would be required to be subjected to a peer review. The peer review would focus on the PRA completeness and technical adequacy for determining importance of particular SSCs, including consideration of the scope, level of detail, and technical quality of the PRA model, the assumptions made in the development of the results, and the uncertainties that impact the analysis. This would provide assurance that for IDP decisions that utilize PRA information that the results of the categorization process provide a valid representation of the risk importance of SSCs.

Before implementation of the proposed rule, the NRC would approve, through a license amendment, the categorization process

because of the importance of the PRA and categorization process to successful implementation of the proposed rule. This review would determine whether the licensee's application satisfies the rule requirements, and consider the adequacy of the PRA, focusing on the results of the peer review and the actions taken by the licensee to address any peer review findings.

The proposed rule would require that a licensee or applicant provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential changes in core damage frequency (CDF) and large early release frequency (LERF) resulting from the implementation of § 50.69 are small. That is, plants with total baseline CDF of 10^{-4} per year or less would be permitted CDF increases of up to 10^{-5} per year, and plants with total baseline CDF greater than 10^{-4} per year would be permitted CDF increases of up to 10^{-6} per year. Plants with total baseline LERFs of 10^{-5} per year or less would be permitted LERF increases of up to 10^{-6} per year, and plants with total baseline LERFs greater than 10^{-5} per year would be permitted LERF increases of up to 10^{-7} per year. However, if there is an indication that the baseline CDF or LERF may be considerably higher than these values, the focus of the licensee should be on finding ways to reduce risk and the licensee may be required to present arguments as to why steps should not be taken to reduce risk in order to consider the reduction in special treatment requirements. It should be noted that this allowed increase would be applied to the overall categorization process, even for those licensees that will implement the proposed rule in a phased manner. Thus, the allowable potential increase in risk would be determined in a cumulative way for all the SSCs being re-categorized.

To meet the proposed rule CDF and LERF requirement discussed above, licensees would be expected to perform sensitivity studies to assess the impact of changes in SSC failure probabilities or reliabilities that might occur due to the revised treatment. For example, a licensee would be expected to increase the failure rates of RISC-3 SSCs by appropriate factors to understand the potential effect of applying reduced treatment to these SSCs (e.g., reduced maintenance, testing, inspection, and quality assurance). For other SSCs, other types evaluations would be used to provide the basis for concluding that the potential increase in risk would be small. A licensee would need to submit its basis that supports the evaluations as being bounding estimates of the potential change in risk and that also describes whether the programs already in existence or implemented for the proposed rule can provide sufficient information that any potential risk change remains small over the lifetime of the plant. A licensee would be required to consider potential effects of common-cause interaction susceptibility and potential impacts from known degradation mechanisms. To meet this requirement, licensees would need to maintain an understanding of common-cause effects and degradation mechanisms and their potential impact on RISC-3 SSCs and of the programmatic activities that provide defenses against common cause failures (CCFs) and failures resulting from degradation; and to factor this knowledge into the treatment applied to the RISC-3 SSCs.

The proposed rule focuses on common-cause effects because significant increases in common-cause failures could invalidate the evaluations, such as sensitivity studies, performed to show a small change due to its implementation. With respect to known degradation mechanisms, this is an acknowledgment that certain treatment requirements have evolved over time to deal with such mechanisms (e.g., use of particular inspection techniques or frequencies), and that when contemplating changes to treatment, the lessons from this experience are to be taken into account.

For SSCs categorized by means other than PRA models including such approaches as seismic margins analysis or shutdown analysis for example, the licensee would need to provide a basis to conclude that the small increase in risk requirement would still be met in light of potential changes in treatment. All of these requirements would be included in the rule so that a licensee has a basis for concluding that the evaluations performed to show a small change in risk remains valid.

The proposed rule would contain requirements for maintaining the design basis of the facility. These requirements, considered in conjunction with the requirements to maintain the potential change in risk as small (as discussed above), would ensure that safety margins are maintained. The performance of candidate RISC-3 SSCs should not be significantly degraded by the removal of special treatment. This is because the licensee would be required to implement processes that provide reasonable confidence that SSCs remain functional.

In addition, the rule would require that implementation be done for an entire system or structure and not for selected components within a system or structure. This required scope would ensure that all safety functions associated with a system or structure are properly identified and evaluated when determining the safety significance of individual components within a system or structure and that the entire set of components that comprise a system or structure are considered and addressed.

2.2 TREATMENT

For SSCs determined by the IDP to be safety-significant (i.e., RISC-1 and RISC-2 SSCs), the proposed rule would maintain the current regulatory requirements (i.e., it does not remove any requirements from these SSCs) for special treatment. These current requirements are adequate for addressing design basis performance of these SSCs. Additional requirements would be added to these SSCs to ensure that their performance remains consistent with the assumed performance in the categorization

process (including the PRA) for beyond design basis conditions. For example, in developing the PRA model, a licensee would make assumptions regarding the availability, capability, and reliability of RISC-1 and RISC-2 SSCs in performing specific functions under various plant conditions. These functions may be beyond the design basis for individual SSCs. Further, the conditions under which those functions are assumed to be performed may exceed the design-basis conditions for the applicable SSCs. In the proposed rule, a licensee would be required to ensure that the treatment applied to RISC-1 and RISC-2 SSCs is consistent with the performance credited in the categorization process. This includes credit with respect to prevention and mitigation of severe accidents. In some cases, licensees might need to enhance the treatment applied to RISC-1 or RISC-2 SSCs to support the credit taken in the categorization process, or conversely adjust the categorization assumptions to reflect actual treatment practices. In addition, requirements exist for monitoring and adjustment of treatment processes (or categorization decisions) as needed based upon performance.

For RISC-3 SSCs, the proposed rule would impose requirements which are intended to maintain their design basis capability. Although individually RISC-3 SSCs are not significant contributors to plant safety, they do perform functions necessary to respond to certain design basis events of the facility. Thus, collectively, RISC-3 SSCs can be safety-significant and it is important to maintain their design basis functional capability. Maintenance of RISC-3 design basis functionality is important to ensuring that defense-in-depth and safety margins are maintained. As a result, the proposed rule would require licensees or applicants to have processes in place that provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design basis conditions throughout the service life. The proposed rule would contain high-level requirements for the treatment of RISC-3 SSCs with respect to design control; procurement; maintenance, inspection, test, and surveillance; and corrective action. These alternative treatment requirements for RISC-3 SSCs represent a relaxation of those special treatment requirements that are removed for RISC-3 SSCs by the proposed rule. For example, the alternative treatment requirements for RISC-3 SSCs in the proposed rule are less detailed than provided in the special treatment requirements, and would allow significantly more flexibility to licensees for treating RISC-3 SSCs. The proposed rule would allow greater flexibility and a lower level of assurance to be provided for RISC-3 SSCs in recognition of their low safety significance, and this recognition includes a consideration for the potential change in reliability that might occur when treatment is reduced from what had previously been required by the special treatment requirements.

The proposed rule would specify four processes that must be controlled and accomplished for RISC-3 SSCs: Design Control; Procurement; Maintenance, Inspection, Testing, and Surveillance; and Corrective Action. The high level RISC-3 requirements would be structured to address the various key elements of SSC functionality by focusing in these areas. When SSCs are replaced, RISC-3 SSCs must remain capable of performing design basis functions. Hence, the high level requirements would focus on maintaining this capability through design control and procurement requirements. During the operating life of a RISC-3 SSC, a sufficient level of confidence is necessary that the SSC continues to be able to perform its design basis function; hence, the inclusion of high level requirements for maintenance, inspection, test, and surveillance. Finally, when data is collected, it must be fed back into the categorization and treatment processes, and when important deficiencies are found, they must be corrected; hence, requirements would be provided in these areas.

2.3 MONITORING/FEEDBACK

The validity of the categorization process relies on ensuring that the performance and condition of SSCs continues to be maintained consistent with applicable assumptions. Changes in the level of treatment applied to an SSC might result in changes in the reliability of the SSCs which are used in the categorization process. Additionally, plant changes, changes to operational practices, and industry operational experience may impact the categorization assumptions. Consequently, the proposed rule would contain requirements for updating the categorization and treatment processes when conditions warrant to assure that continued SSC performance is consistent with the categorization process and results.

Specifically the proposed rule would require licensees to review in a timely manner, but no longer than every 36 months, the changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization. In addition, licensees would be required to obtain sufficient information on SSC performance to verify that the categorization process and its results remain valid. For RISC-1 SSCs, much of this information may be obtained from present programs for inspection, testing, surveillance, and maintenance. However for RISC-2 SSCs and for RISC-1 SSCs credited for beyond design basis accidents, licensees would need to ensure that sufficient information is obtained. For RISC-3 SSCs, there would be a relaxation of requirements for obtaining information when compared to the applicable special treatment requirements; however sufficient information would need to be obtained, and rule requirements are being proposed to consider performance data, to see if adverse changes in performance might occur, and to make necessary adjustments such that desired performance is achieved so that the evaluations conducted to meet the proposed rule remain valid. The feedback and adjustment process is crucial to ensuring that the SSC performance is

maintained consistent with the categorization process and its results.

Taking timely corrective action is an essential element for maintaining the validity of the categorization and treatment processes used to implement the proposed rule. For safety-significant SSCs, all current requirements would continue to apply and, as a consequence, Appendix B corrective action requirements would be applied to RISC-1 SSCs to ensure that conditions adverse to quality are corrected. For both RISC-1 and RISC-2 SSCs, requirements would be included in the proposed rule for monitoring and for taking action when SSC performance degrades.

When a licensee or applicant determines that a RISC-3 SSC does not meet its established acceptance criteria for performance of design basis functions, the proposed rule would require that a licensee perform timely corrective action. Further, as part of the feedback process, review of operational data may reveal inappropriate assumptions for reliability or performance and a licensee would need to re-visit the findings made in the categorization process or modify the treatment for the applicable SSCs. These provisions would then restore the facility to the conditions that were considered in the categorization, and would also restore the capability of SSCs to perform their functions.

3.0 CHALLENGES

In developing the proposed rulemaking, the staff faced several challenges. The proposed rule 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 recommended to the Commission that there be more general rule requirements, supported by detailed implementation guidance. Further, a focused staff review and approval of the categorization process would be conducted.

The NRC staff plans to complete a regulatory guide (RG) that would endorse industry implementation guidance (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 (These issues are discussed briefly in section 5 of this paper). 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," which identifies these areas. 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.

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 stakeholders 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 also support removal of treatment details for RISC-3 SSCs. The proposed rule would specify the minimum attributes for the treatment processes (to be in place at the facility), but would allow flexibility in application provided that functional performance is maintained. The staff 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 would place 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 the proposed rule, the staff considered including more detailed requirements for RISC-3 SSCs. 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 rule. Nonetheless, the staff offered stakeholders an opportunity to provide further input on these issues by including a section in the *Federal Register* notice that invites public comments on the previously considered rule language.

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 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.

Another aspect of the proposed rule that concerns some stakeholders is the requirement in the proposed rule that licensees provide reasonable confidence that increases in core damage frequency (CDF) and large early release frequency (LERF) due to implementation of the rule requirements would be small. 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. It should be noted that the proposed rule would require 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 would also include 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.

4.0 STATUS OF RULEMAKING EFFORT

As mentioned above, the staff provided the proposed rulemaking package for 10 CFR 50.69 to the Commission in the form of SECY-02-176 on September 30, 2002. The staff subsequently briefed the Commission on November 21, 2002. The major tasks that remain to be completed to issue a final rule for 10 CFR 50 69 at this time are: 1) issuance of the proposed rule in the Federal Register following Commission approval, 2) evaluation of the public comments received on the proposed rule, 3) resolution of the open issues associated with implementation guidance, 4) development of any unique inspection or enforcement guidance necessary to support the final rule issuance, and 5) preparation of the final rule package. The most significant task is the resolution of issues associated with the implementation guidance contained in NEI 00-04. These issues are discussed in the next section

5.0 PROPOSED RULE GUIDANCE DEVELOPMENT

The staff and the Nuclear Energy Institute (NEI) are continuing to interact to resolve the following issues concerning implementation guidance:

- PRA quality. The staff expects that licensees will use the ASME PRA standard as endorsed by the staff, or a peer reviewed PRA that accounts for the issues that the staff has identified to industry concerning the peer review process. Proposed 50.69 requires prior review and approval of a submittal before implementation can begin, and this submittal will focus primarily on PRA quality.

- Use of non-PRA methods. Use of simplified or non-PRA methods must represent plant conditions and give conservative results (i.e., tend to categorize SSCs as safety significant). The staff wants to encourage the use of PRA methods and structure the guidance to enable licensees to gain greater benefit through the use of PRA methods as compared to non-PRA methods.

- Evaluations of CDF and LERF changes. A key aspect to proposed 50.69 is the evaluation of changes to CDF and LERF that may result due to treatment changes to RISC-3 SSCs. These evaluations need to have a technical basis to support them, and the staff continues to work with industry to reach agreement concerning guidance in this area.

- Defense-in-depth. Proposed 50.69 is maintaining defense-in-depth, and its an explicit part of the categorization process. The details of how to consider defense-in-depth in a structured manner remain to be worked out.

6.0 REFERENCES

1. SECY-02-0176, September 30, 2002, Proposed Rulemaking to Add New Section 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components" (ML022630007).

2. NEI 00-04, "Option 2 Implementation Guidance", June 15, 2001 (ML013200546).

3. SECY-99-256, October 29, 1999, Rulemaking Plan for Risk-Informing Special Treatment Requirements.

4. SECY-00-194, September 7, 2000, Risk-Informing Special Treatment Requirements.