

March 28, 2003

COMMISSION VOTING RECORD

DECISION ITEM: SECY-02-0176

TITLE: PROPOSED RULEMAKING TO ADD NEW
SECTION 10 CFR 50.69, "RISK-INFORMED
CATEGORIZATION AND TREATMENT OF
STRUCTURES, SYSTEMS, AND COMPONENTS"

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of March 28, 2003.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Meserve
 Commissioner Dicus
 Commissioner Diaz
 Commissioner McGaffigan
 Commissioner Merrifield
 OGC
 EDO
 PDR

VOTING SUMMARY - SECY-02-0176

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	PARTICIP	NOT COMMENTS	DATE
CHRM. MESERVE	X				X	1/31/03
COMR. DICUS	X				X	2/3/03
COMR. DIAZ	X				X	1/23/03
COMR. McGAFFIGAN	X				X	3/18/03
COMR. MERRIFIELD	X				X	1/8/03

COMMENT RESOLUTION

In their vote sheets, all Commissioners approved the staff's recommendation and provided some additional comments. Subsequently, the comments of the Commission were incorporated into the guidance to staff as reflected in the SRM issued on March 28, 2003.

Commissioner Comments on SECY-02-0176

Chairman Meserve

Staff seeks authorization to publish a proposed rule and related draft regulatory guidance concerning the risk-informed categorization and treatment of structures, systems and components (SSCs). I approve, subject to the following comments.

This rulemaking reflects the challenge in the implementation of a risk-informed regulatory paradigm. Our regulations were developed using a deterministic approach that imposed special treatment requirements for certain SSCs that were deemed necessary to protect against or mitigate the effects of design basis events. The subsequent development of probabilistic techniques and the accumulation of over 2000 reactor-years of operating experience have facilitated the extension and enhancement of the traditional approach by enabling the consideration of a wide spectrum of risks in a systematic manner. This enables a careful examination of the risk significance of those SSCs that are deemed to be safety-related and those that are not. This examination has shown that many of the safety-related SSCs are not in fact safety-significant (RISC-3 SSCs) and thus the imposition of stringent treatment requirements does not serve a legitimate regulatory purpose. Similarly, studies have shown that there are some SSCs -- far fewer -- that have not in the past been categorized as safety-related, but which in fact serve a risk-significant function (RISC-2 SSCs). There is thus opportunity both to enhance safety and to reduce needless regulatory burden by adjusting the treatment requirements to reflect risk as well as traditional engineering insights. The rulemaking thus provides an important opportunity to advance the Commission's efforts in risk-informed regulation.

The two central aspects of the proposed rule are the categorization of SSCs into one or another RISC classification and the designation of the treatment for each category. The rule appropriately demands a very careful categorization process. That process involves evaluation of the insights from plant-specific PRAs, as well as consideration of the defense-in-depth philosophy, the maintenance of sufficient safety margins, and SSC functional importance. In short, as Commissioner Diaz has noted, the process aims to apply both risk and traditional engineering information so as to ensure that the categorization is rigorous and that sufficient safety margins are maintained. The process reflects the balance of traditional engineering and risk insights that should be the central feature of our efforts to modernize and revise our regulatory program. Because of the central importance of a reliable PRA in this effort, I join in Commissioner Merrifield's comments concerning the importance of continued and parallel progress in the development of a PRA standard and implementing guidance. The achievement of the purpose of this rule will not be possible without confidence in the quality and scope of the underlying PRAs.

The treatment component of the proposed rule has proven more controversial. The proposed rule would maintain the existing treatments for RISC-1 and RISC-2 SSCs and, indeed, will require enhanced treatment if necessary to ensure that these SSCs have the reliability assumed in the categorization process. Proposed § 50.69(d)(1). The rule would eliminate the existing treatment requirements for RISC-3 SSCs (safety-related, but not risk significant), but will require the licensee to develop processes that ensure appropriate treatment so as "to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions

under design basis conditions throughout their service life.” Proposed § 50.69(d)(2).¹ Staff does not plan either to provide guidance as to appropriate treatment or to review a licensee’s determination as to the treatment requirements that will satisfy this obligation. See SECY-02-0176, 5; Proposed Federal Register Notice, 65 (SECY-02-0176, Att. 1) (hereinafter “Notice _”).

Differing Professional Views (DPVs) concerning the treatment requirements have been filed by three staff. They urge that the proposed rule include language that had been part of earlier drafts to require treatment for RISC-3 SSCs consistent with certain specific standards, rather than to leave the determination of treatment as a matter to be addressed by the licensee.

I also am concerned with the treatment for RISC-3 SSCs, although my proposed resolution is somewhat different from that proposed in the DPVs. There is the potential for the common-cause failure of RISC-3 SSCs under accident conditions, and thus there is agreement on the need for some means of ensuring adequate treatment for these SSCs. See Notice, 23. The staff’s approach would seek to ensure adequate treatment by focusing on the assumptions as to reliability used in the categorization process and imposing a requirement that licensees ensure that the treatment is sufficient to ensure that these assumptions are valid.² But this aspect of the categorization/treatment process is likely to present major challenges. Licensees and the NRC may face significant difficulties in modeling the effect of treatment on reliability and common-cause failure and thus may not be able to choose appropriate treatment with a high degree of certainty. Functional testing is not typically performed under the conditions that may exist during an accident and thus data on the actual reliability of the SSCs subject to the postulated treatment under accident conditions may not be available. Indeed, staff acknowledges that treatment requirements have had to evolve over time in response to even known degradation mechanisms. Id. at 21. Therefore, in light of the uncertainty in the effects of treatment on reliability and common-cause failure and the difficulty in determining reliability under accident conditions, the exercise of conservative judgment is necessary.

In light of the uncertainty as to appropriate treatment, I conclude that staff guidance to assist the licensees as well as staff review of the licensee’s determinations are appropriate so as to ensure that rigor and consistency in the determination of the treatment for RISC-3 SSCs. Indeed, the staff acknowledges that the pilot effort to respond to a risk-informed exemption request from the special treatment requirements demonstrated in many instances that the treatment contemplated by the licensee was inadequate. Notice, 106-107; Briefing on Proposed Rulemaking to Add New Section 10 CFR 50.69 (SSCs), 95-97 (Nov. 21, 2002) (hereinafter “Tr. _”). This experience reinforces the need for staff review of the treatment for RISC-3 SSCs in connection with the proposed rule.

¹ The proposed rule provides that these processes must include: design control; procurement; maintenance, inspection, testing, and surveillance; and corrective action. Id. § 50.69(d)(1)(i)-(iv). The rule would not impose any treatment requirements for RISC-4 SSCs.

² Id. at 21. The proposed rule provides for continuous verification of the assumptions used in the categorization process as part of a feedback and adjustment process. Proposed §§ 50.69(d)(2), (e)(3). But because challenges to RISC-3 SSCs should not occur during normal operations, it is not apparent that this feedback process is sufficient to ensure functionality.

Staff has sought to explain its proposed approach as an effort to develop a performance-based rule. Tr. at 22, 28, 36. But performance-based requirements are appropriate when the results can be measured (or calculated) and compared with objective performance criteria. See Guidance for Performance-Based Regulation, 5-6 (Dec. 2002) (NUREG/BR-0303). Unfortunately, functionality under design-basis conditions may be indeterminate until an accident occurs and thus objective and routine measurements by which to assess performance do not exist. And, in any event, the staff does not explicitly contemplate examination of the adequacy of treatment on either a performance or a prescriptive basis. I thus conclude that the draft proposed rule does not reflect an appropriate application of performance-based rulemaking.

On the other hand, it may not necessary to impose specific treatment requirements for RISC-3 SSCs as part of the regulation, as advocated in the DPVs. RISC-3 SSCs have a lesser risk significance than RISC-1 and RISC-2 SSCs and thus do not warrant excessively prescriptive requirements. Moreover, as the staff notes, the rigid application of standards may not adequately reflect the differing environments in which these SSCs may be deployed. See Notice, 99. Accordingly, I would not pursue the recommendation in the DPVs to introduce prescriptive requirements in the rule. Rather, I would demand staff review of the licensee's proposed treatment for RISC-3 SSCs as a counterpart to the staff examination of the licensee's categorization process. The aim should be to provide licensees with flexibility appropriate to the circumstances.³

In light of the foregoing, I conclude that the following actions are necessary in connection with this rulemaking:

- Modify the rule and the statements of consideration to provide for NRC review and approval of a licensee's proposed treatment for RISC-3 SSCs;
- Prepare regulatory guidance that explores the means to ensure adequate treatment of RISC-3 SSCs;
- Ensure that development of the rule proceeds in parallel with the issuance of the PRA standard and associated guidance;
- Evaluate relevant operational experience with the aim of reducing the uncertainty in assessing the effect of treatment on reliability and common-cause failures.

Although I propose some modifications to the staff's proposed approach, the staff should be complimented for its efforts in connection with this difficult rulemaking. Moreover, the three staff who submitted the DPVs have served to illuminate an important issue and their contribution is significant and welcome.

Commissioner Dicus

I wish to commend the staff for their efforts in this area and wish to thank the stakeholders who have participated in these efforts over the last four years. SECY-02-0176 represents the

³Of course, because of the difficulty in assessing the effect of treatment on reliability, many licensees may choose to rely on standards as justification for their proposed treatments.

culmination of what was obviously a great deal of thought and labor which would not have been possible without the earnest effort and participation by both the staff and our stakeholders.

As was exhibited at the Commission Meeting held on October 31, 2002, there appears to be a consensus that equipment of lesser risk significance warrants lesser treatment. This tenet is the foundation upon which the proposed rulemaking is built; and it is a good, solid foundation which I strongly support.

However, as was also exhibited at the Commission Meeting, the subject of what level of treatment is necessary to ensure that equipment performs as designed is somewhat nebulous. While there is consensus that a gold standard, i.e., the full spectrum of special treatment, provides reasonable assurance that equipment will perform as designed, there is much less consensus as to what level of lesser treatment continues to provide such assurance. This assurance is important because that safety-related equipment, including that of low safety significance, will still be expected to perform for those design basis situations for which it is credited and failures of multiple low safety significant pieces of equipment could be risk significant.

It is for these reasons that, while I generally support the staff's proposal, I do not entirely agree with the proposal in its current form. As my questioning during the Commission meeting indicated, I was seeking compromises that would satisfy both the staff and the authors of the Differing Professional Views. I believe such a compromise exists and believe it takes form in the way that the staff conducts its review of individual applications. Specifically, I believe that, in addition to reviewing the applicant's categorization process, the staff should additionally review the applicant's processes for treatment of RISC-3 (safety-related but low risk significance) equipment. Such review will allow the staff to have reasonable assurance that this equipment will perform as expected. Inherent in this review is the availability of appropriate standards and review guidance and here I join my fellow Commissioners in stressing the importance of achieving consensus on and issuing standards on the quality of probabilistic risk assessments. I also stress the importance of achieving consensus on and issuing review guidance for the treatment of RISC-3 equipment. I believe that the Statements of Consideration for the proposed rule provide a good starting point for such review guidance and I believe this guidance should be developed in parallel with the final rule. Finally, because of I feel that these reviews will be fairly complex and have the potential to grant greater operating authority to licensees, I believe that the license amendment process should be used to ensure an appropriate level of rigor and stakeholder involvement.

Commissioner Diaz

The proposed risk-informed rule constitutes a significant change from our deterministic regulatory history and change can be controversial and uncomfortable. I strongly believe that risk-informed regulatory changes are well worth the discomfort because they are focused on improving safety, using state-of-the-art know how. Risk-informed regulation, in my own words, is an integral, increasingly quantitative approach to regulatory decision making that incorporates deterministic, experiential and probabilistic components to focus on issues important to safety. The proposed rule meets this definition and I support the staff proposal to proceed with rulemaking.

There are several key aspects of the proposed rule that I find particularly consistent with the enhanced safety-focus inherent to risk-informed regulation, as well as important to move the agency toward more effective use of these regulatory improvements. First is the implementation of the risk-informed approach itself. The categorization process described in the proposed rule is

truly a risk-informed approach in that it uses both risk insights and traditional engineering insights, including defense-in-depth, to rigorously evaluate and prioritize safety functions, including both design basis functions and functions credited for severe accidents. As the staff indicated, in categorizing structures, systems, and components (SSCs) it should be demonstrated that the defense-in-depth philosophy and sufficient safety margins are maintained, and that increases in risk (if any) are small.

The requirements associated with Probabilistic Risk Assessment (PRA) quality are another important aspect. The proposed rule states that the PRA must be of sufficient quality and level of detail to support the categorization process of SSCs, and must be subjected to a peer review process assessed against a standard or set of acceptance criteria endorsed by the NRC. I believe that high quality PRAs are necessary for use as an input to the categorization process.

The proposed rule is appropriately focused on the safety categorization of SSCs. Treatment details associated with low safety significant SSCs are specified by the use of systematic general quality requirements (design control; procurement; maintenance, inspection, testing, and surveillance; and corrective action) that address key elements of SSC functionality, while giving licensees flexibility regarding the means of implementation. Given the importance that this type of approach places on categorization, I believe that it is essential that the actual plant and industry experience be reviewed periodically to ensure that the categorization assumptions remain valid and that there is no significant impact on safety. The proposed rule addresses this issue by requiring that the licensee periodically review changes to the plant, operational practices, applicable industry operational experience, and update the PRA and SSC categorization. In addition, the licensee is required to consider data collected on RISC-3 SSCs to determine whether there are any adverse changes in performance such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to classify SSCs as RISC-3. I also believe that an effective corrective action process is requisite to provide reasonable assurance that RISC-3 SSCs will maintain the capability to perform their safety-related functions.

Much attention has been focused on the *reduced* treatment of the safety-related, low safety significant (RISC-3) SSCs in the proposed rule. I believe that not enough consideration has been given to the positive effect on safety by the *increased* emphasis on the safety significant SSCs under the proposed rule. The proposed rule should enable the NRC and licensees to focus resources on SSCs that make a significant contribution to plant safety by restructuring the regulations to allow an alternative risk-informed approach to special treatment thereby *improving the safety* of the nuclear power plants. The increased emphasis on both RISC-1 and RISC-2 SSCs constitutes a significant safety improvement.

It is important to point out what the proposed rule does not do. The proposed rule does not change the design basis of the facility, which was established based on defense-in-depth considerations. Changes to the design of the facility must continue to meet the current requirements governing design change. As the staff indicated, the proposed rule is not intended to allow licensees to change or eliminate SSC functional requirements.

As with any significant regulatory change, careful consideration should be given to the proper process for implementation by our licensees, as well as to the appropriate oversight necessary by the NRC. I look forward with great interest and an open mind to the discussion that I expect to be presented regarding the proposed use of the license amendment process.

There are other issues associated with the proposed rule, including those documented in the public comments received and the differing professional views submitted by members of the NRC staff, that point to the need for a robust and open rulemaking. I understand that there are deeply held beliefs and opinions on many of these issues and I especially commend the staff on the openness they exhibited by sharing differing views with NRC management and the Commission. I encourage continued participation by all stakeholders and will take all the information into consideration when making my decision on the final rule. Although I would have preferred this rule be completed in a more timely manner, I commend all parties for their hard work on this important issue.

Commissioner McGaffigan

I join my fellow Commissioners in applauding the staff's efforts to produce the proposal rule. I particularly wish to thank the three staff members who filed differing professional views on the proposal and who testified at our hearing on the paper.

I approve the publication of the proposed rulemaking package subject to the following comments.

The version of the proposed rule contained in SECY-02-0176 differs from the last version (dated July 31, 2002) made available on the NRC website (posted on August 2, 2002) as part of the process of producing this paper. The three DPV submitters believe that the July 31 text should be the basis for the proposed rule, in particular its treatment requirements. They believe that the July 31 text reflects the NRC decisions made during the long and arduous South Texas exemption process. The senior staff has accommodated the DPV submitters by specifically asking for comments on their alternative text. I would prefer that this be reversed, that the proposed rule adhere to the July 31 proposal on treatment and that comments be requested on the alternative text on treatment now incorporated into the proposed rule. Whichever text is in the proposed rule, I assure all stakeholders that I have made no even preliminary decision on this matter. I look forward to the comments we will receive in making a final determination.

Second, and more important, I am troubled by the discussion in the proposed rule and draft regulatory guide (DG-1121) about PRA quality. 50.69(c)(1)(i) states: "This PRA must at a minimum model severe accident scenarios resulting from internal-initiating events occurring at full power operation. The PRA must be of sufficient quality and level of detail to support the categorization process, and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by NRC." Later 50.69(c)(1)(iv) has a requirement that the categorization process "must include evaluations that provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of 50.69(b)(1) and 50.69(d)(2) are small." In the Statements of Consideration and DG-1121 on these provisions, there is for me a very unsatisfactory explanation. DG-1121 on page 4 states: "The NRC staff believes that current state-of-the-art PRA methods are available to quantitatively address the full spectrum of potential events and the full range of plant operating modes for this type of application and thus, it is desirable (emphasis added) for licensees to use such broad-scope PRAs. However, Draft Revision of NEI-00-04 allows the use of non-PRA type evaluations (e.g., FIVE, seismic margins analysis, NUMARC 91-06), when PRAs have not been performed. It should be recognized that the degree of relief that can be expected will be commensurate with the assurance provided by the evaluation." After two years of discussion of NEI-00-04, DG-1121 still reflects

numerous differences between staff and industry. I am troubled by the discussion of the meaning of the word “small” on pages 101 and 102 of the Statements of Consideration. Essentially we define small in terms of “total baseline CDF.” If that number is less than 10^{-4} per year, then small means a delta CDF of 10^{-5} per year or less. If that number is greater than 10^{-4} per year, then small means a delta CDF of 10^{-6} per year or less, and staff basically says it will give any such licensee a hard time.

All of this strikes me as very unsatisfactory. I do not believe any baseline CDF number to be accurate to better than a factor of about 10. Yet we are proposing to make distinctions based on such numbers. It isn’t even clear whether the baseline CDF being referred to is the baseline CDF for a level 1 internal-initiating event full-power PRA, which is all the rule requires, or the baseline CDF for an all-mode, internal- and external-initiating event PRA. The staff is not willing to require a good all-mode, internal- and external-initiating event level 2 PRA, but the staff acts as if we have one at times, and at other times applies band-aids to try to deal with the problems that arise in dealing with less comprehensive PRAs.

I believe that not only this proposed rule, but all of our risk-informed initiatives will be impaired until we establish a requirement in the rules for comprehensive high-quality PRAs, which the NRC staff itself examines and endorses. In 50.69(c)(1)(i), we are not even requiring that the PRA itself meet “a standard or set of acceptance criteria that is endorsed by NRC,” as recommended by the Office of Research. We are only requiring that the PRA peer review process meet such as standard. I believe that both NRC and the industry would be better off if 50.69(c)(1)(i) read “(i) Consider the results and insights from the plant-specific PRA. This PRA should be a level 2 internal- and external-initiating event all mode PRA, which has been subjected to a peer review process and submitted to and endorsed by the NRC.” Many will argue that this is more than needed for this application, that the staff is not up to endorsing comprehensive full-scope PRAs at this time, and that this will derail risk-informed regulation. But I believe that the single greatest impediment to risk-informed regulation is that 28 years after WASH-1400, 14 years after NRC requested IPEs, 8 years after the PRA policy statement, we have never made a decision that high-quality PRAs are the entrance fee for participating in our risk-informed initiatives. The best of our licensees have such PRAs, but what we end up with from the industry as a whole are lowest-common-denominator positions which try to allow those who have made minimal investments in their plant-specific PRAs still to get the benefits of these risk-informed initiatives. Band-aids are placed on band-aids. I believe it is time for this to stop and for the Commission to up the entrance fee. I would request that we at least ask for specific comment in the Statements of Consideration on whether NRC should amend 50.69(c)(1)(i) to require a comprehensive high-quality PRA.

Commissioner Merrifield

I approve the staff’s recommendation to publish the notice of proposed rule and draft implementation guidance in the Federal Register, allowing 75 days for public comment.

I commend the staff for their considerable efforts on the proposed rule and associated draft regulatory guide, DG-1121. In addition, I appreciate the staff’s extensive open dialogue and coordination with external stakeholders throughout the process on this rulemaking.

I agree with the staff’s recommendation to have more general rule requirements, supported by detailed implementation guidance for licensees that voluntarily choose to adopt this rule. Although I would like to see a regulatory framework which supports implementation of risk-

informed regulatory alternatives without prior NRC review and approval, I am not ready to do so at this time for implementation of the proposed §50.69. Similar to my vote on SECY-02-0132, elimination of prior NRC review and approval for this rulemaking is a complicated issue that warrants further consideration and analysis by the staff.

However, I am less persuaded at this point that the NRC's review and approval must take the form of a license amendment. The staff says that the amendment process is required because NRC approval would increase a licensee's operating authority, and review of a licensee's proposal would require professional judgment and discretion. The staff also says that the amendment process would help ensure public confidence. Perhaps all of these claims are right. On the other hand, the NRC has not used the amendment process in every case to which the staff's arguments applied. Moreover, it could be argued that a process that could involve adjudicatory hearings is neither necessary nor sufficient for good judgment and public confidence. I note that the staff met recently with stakeholders on the subject of the threshold for license amendments. I take this as an indication that the staff and OGC will carefully review the comments received from stakeholders and provide the Commission with their analysis of these comments and lay out fully the basis for its position on this issue in the final rule.

I agree with the staff that by providing licensees with this voluntary regulatory framework, this proposed rule should enable licensees and our staff to focus their resources on structures, systems and components (SSCs) that make a significant contribution to plant safety. I believe that this framework better aligns with our inspection philosophy in the reactor oversight process (ROP). However, the details of any ROP changes to address issues that may arise from licensees who implement this rulemaking still needs to be assessed. The staff should provide its assessment of the potential impact on future inspection efforts associated with licensee implementation in the final rulemaking package.

I agree with the staff approach to remove risk-informed safety class 3 (RISC-3) SSCs which are safety-related, but of low safety significance, from the scope of requirements in 10 CFR Part 50, Appendix B. I am pleased to see our risk-informed efforts address, to some degree, an area for which I have previously discussed concerns. Proposed 50.69(d)(2) includes high-level programmatic requirements for RISC-3 SSCs. I believe these high-level requirements will provide a licensee's commercial program added flexibility to use any standard that meets these programmatic requirements, such as those from our international community. Though there is greater flexibility, plants must still continue to meet their design basis requirements, as specified in proposed 50.69(d)(3). As we move to a more global marketplace, this certainly will play an important part in encouraging high-quality component suppliers to participate in the U.S. nuclear market, who otherwise may not due to the prescriptive nature of Appendix B. While this rulemaking is a step in the right direction, I continue to believe that we must take a more fundamental look at our quality assurance requirements to determine whether they are effectively and efficiently achieving their intended outcomes.

Currently, the rule requires that an applicant's probabilistic risk assessment (PRA) be of sufficient quality and level of detail to support the categorization process, and must be subjected to a peer review process assessed against a standard or set of acceptance criteria that is endorsed by the NRC. The staff is working on draft Regulatory Guide 1122 (DG-1122) to address PRA quality which I understand was recently put out for public comment. I expect that licensees would want to utilize the Regulatory Guide as they are refining their PRA's. Therefore, I encourage the staff to proceed with DG-1122 on a parallel schedule with the proposed rulemaking, so that it is in place

and available for use by applicants when the final rule is issued.

One area of particular concern to me involves adequate review guidance. The paper discusses review guidance concerning PRA quality and peer review and a draft supporting standard review plan, but it is not clear to me how the staff intends to merge all of this guidance into one comprehensive package for our reviewers to utilize. The staff should ensure that adequate review guidance (i.e., a review standard) is developed in order to ensure that these reviews are conducted in an objective, consistent, complete and timely manner.

This rulemaking is a significant accomplishment for our risk-informed initiatives and although there are still some issues that may warrant further discussion, the public comment period provides an excellent opportunity for these views to be raised. I look forward to the staff's analysis of all the stakeholder comments, as they will most likely provide valuable insights for this rulemaking.