June 22, 1999

COMMISSION VOTING RECORD

DECISION ITEM: SECY-99-130

TITLE: FINAL RULE - REVISIONS TO REQUIREMENTS OF 10 CFR PARTS 50 AND 72 CONCERNING CHANGES, TESTS, AND EXPERIMENTS

The Commission (with Chairman Jackson and Commissioners Diaz, McGaffigan, and Merrifield agreeing) approved in part and disapproved in part the staff's recommendation. Commissioner Dicus approved the staff's recommendation. The resulting Staff Requirements Memorandum (SRM) was issued on June 22, 1999.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission, and the SRM of June 22, 1999.

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Annette Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets
3. Final SRM

cc:
Chairman Jackson
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
EDO
PDR
DCS

VOTING SUMMARY - SECY-99-130

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACKSON	X	X			X	5/26/99
COMR. DICUS	X				X	6/13/99
COMR. DIAZ	X	X			X	6/17/99
COMR. McGAFFIGAN	X	X			X	6/11/99
COMR. MERRIFIELD	X	X			X	6/4/99

COMMENT RESOLUTION

In their vote sheets, Chairman Jackson and Commissioners Diaz, McGaffigan, and Merrifield approved in part and disapproved in part the staff's recommendation. Commissioner Dicus approved the staff's recommendation. Chairman Jackson and Commissioners Diaz, McGaffigan, and Merrifield disapproved the proposed enforcement criterion which would impose a Severity Level III violation for a licensee's failure to submit an amendment as required if a substantial review (based on the merits of the technical issues) is needed by the NRC before it could conclude that the licensee's actions were acceptable. Chairman Jackson and Commissioners Dicus and Merrifield disapproved early implementation (either voluntary or otherwise) prior to

Commission approval of the Regulatory Guide. Commissioners Diaz and McGaffigan would have preferred early implementation options. Although Commissioner Diaz would favor early implementation of a well defined 50.59 rule, given that the process for rulemaking appears to be in flux, Commissioner Diaz did not participate in determining the implementation schedule of the 50.59 rule. Commissioner Diaz recognizes that the Commission has agreed to an effective date of the final rule to be 90 days following Commission approval of the final Regulatory Guide which is due to the Commission on May 30, 2000. Subsequently, the final rule was affirmed by the Commission and the guidance to staff was reflected in the Affirmation Session SRM issued on June 22, 1999.

Commissioner Comments on SECY-99-130

Chairman Jackson

I congratulate the staff for completing this rulemaking effort, so long in the making and so necessary to ensure that the appropriate amount of regulatory burden is applied to control facility changes, tests and experiments by Part 50 and Part 72 licensees. While the NRC and its stakeholders can take a degree of pride in this action, we must all remain mindful of the fact that this rulemaking allows for the reduction of overly conservative aspects of designs which will, coincidentally, result in the reduction of existing safety margins (conservative margins, but margins nonetheless) designed into these facilities. The staff must ensure, through routine inspection in this area, that the changes, tests, and experiments authorized by this rulemaking are conducted in a consistent, prudent, and safety-conscious way. Also, I am pleased to note that the form of the rule now aligns well with the cornerstones of safety. While the rule always considered aspects of the probability of accidents (minimizing accidents) and malfunctions (mitigation reliability), the addition of criterion vii, which considers the impact of changes on principle fission product barriers, more fully expresses the concept of the cornerstones.

Much work has occurred in the area of 10 CFR 50.59 in terms of creating new language, improving the consistency of inspection, and addressing issues of enforcement since I first requested the staff to consider improvements to the rule in my memorandum to the EDO on October 27, 1995. Throughout the process, Commission and staff involvement of internal and external stakeholders has been laudable. However, on this rulemaking, much of the final rule language was deliberated very late in the process. Therefore, on a go-forward basis, I would hope that both the Commission and the staff will make it clear to stakeholders that the agency is committed to move more quickly toward closure (i.e., plan for timely and meaningful insight and discussion, follow that plan, and avoid last minute scrambles).

Throughout this rulemaking process, there has been a great deal of discussion about the "zero" threshold in the current rule and about the importance of moving past this threshold. It could be argued that the NRC has never imposed a "zero" threshold for the impacts of changes, tests, and experiments under 10 CFR 50.59 and 10 CFR 72.48. Rather, in prohibiting changes, tests, or experiments that "may" increase probabilities or consequences, the existing requirements actually establish a "less than zero" threshold. Thus, allowing licensees to make changes that "do not" increase probabilities and consequences (moving to a true "zero" threshold) actually would have been a relaxation of regulatory restrictions (because the NRC, in deciding that a particular change, test, or experiment required prior review would first have to establish that an increase in probabilities or consequences clearly existed). Taking this into account, allowing licensees to make changes that correlate to "negligible" increases, as defined in the NEI guidance referenced in the subject paper, could be viewed as yet another degree of relaxation and "minimal" increases, as described by the Commission, might be interpreted as still more relaxation. As work progresses to develop more fully the concept of "minimal" increases, the staff should: 1) ensure that our stakeholders understand that the NRC will continue to oversee changes, tests, and experiments through our inspection program, regardless of the threshold requiring licensees to submit license amendment requests, and 2) focus on the goal of defining what is truly acceptable in a risk-informed environment and from a regulatory point of view (e.g., consistent with the balance of 10 CFR Part 50), rather than working to a goal of allowing more and greater change than had been allowed previously.

I approve in part, and disapprove in part, the publication of the final rule in the Federal Register, as follows:

- I approve of the final rulemaking language (although I do note that the use of the words "as updated" following references to the FSAR is clearly repetitive - I would define "FSAR" as meaning "the FSAR as updated" once, in the beginning of the rule).
- I disapprove of the 10 CFR 50.59 rulemaking becoming effective before regulatory guidance has been prepared and approved. While the staff has done an excellent job in assembling concepts and examples of how the specific criteria of the rule would be applied, the guidance provided in this paper is by no means exhaustive or ready for implementation. NRC inspectors will need additional guidance if they are consistently to evaluate licensee implementation of the new rule. The development of new inspection guidance (e.g., Part 9900 of the NRC Inspection Manual) should, necessarily, lag the approval of regulatory guidance. Although I support the staff's efforts to manage this transition process, I am concerned about possible inconsistencies in applying the rule until guidance has been completed, particularly with respect to imprecise terms such as "minimal." Thus, to ensure that the NRC can properly oversee the implementation of the new rule, any implementation (either voluntary licensee early implementation or final implementation) should be deferred until the Commission has approved a Regulatory Guide (which either expands NRC-provided guidance or endorses an industry guidance document). I believe that the NRC should strive for consistency in treatment between this rulemaking and the pending rulemaking revising 10 CFR 50.65, the maintenance rule. In both cases, rule language has been submitted to the Commission which is not supported by existing regulatory guidance. While I can approve of the revised language for 10 CFR 50.59 and 10 CFR 72.48 contained in the subject paper, I do so based on the interpretation guidance contained in the paper (which tends to define key concepts and phrases) and on the staff demonstrating in this paper that workable regulatory guidance is achievable based on the specifics of this rulemaking (e.g., terms can be further defined, additional examples can be developed). In the proposed rulemaking on the maintenance rule, the Commission is similarly faced with language which, while understood in concept, requires the development of regulatory guidance to ensure consistent implementation by both the NRC and its affected licensees. In the case of the maintenance rule, the effective date of the rulemaking is indexed to the date of regulatory guide issuance. The effective date for the revised 10 CFR 50.59 should be similarly indexed. To allow earlier implementation would perpetuate the instability and inconsistency we have worked to remove.

- I disapprove of the proposed enforcement criterion which would designate, as Severity Level III, any failure to perform an evaluation required under 10 CFR 50.59 for which a substantial review (based on the merits of the technical issues) is needed by the NRC before it could conclude that licensee actions were acceptable. I find this provision to offer substantial and unnecessary opportunity for subjectivity. Further, the criterion addresses neither the safety significance of the violation in question nor the impact of the violation on the ability of the NRC to regulate effectively.
- In discussing changes in consequences associated with a change, test, or experiment, the staff refers to dose "requirements" found in 10 CFR 100 and in General Design Criteria found in Appendix A to 10 CFR 50. I note that the dose values offered in these two citations are not "requirements" as such. Rather, they form a part of the licensing basis for individual licensees. The rulemaking package should be corrected in this regard before being published in the Federal Register. Additionally, I have attached editorial changes to the FRN which should be made before publication in the Federal Register.

Summarizing then:

- I approve the rule language.
- I disapprove allowing licensees to implement the new rule until regulatory guidance is approved by the Commission.
- I disapprove the enforcement provision which ties severity level of a failure to perform a required evaluation under 50.59 to the degree of difficulty associated with finding the change acceptable.
- The staff should clarify the standing of 10 CFR 100 and the GDCs in the Federal Register Notice and correct other identified editorial errors.

Commissioner Dicus

I approve issuance of the final rule to amend portions of 10 CFR Parts 50 and 72 regarding changes, tests, and experiments. The staff has done an outstanding job in formulating the final rule based on extensive internal and external stakeholder input. I do, however, have some specific comments.

I do not approve the use of a flexible implementation schedule for the rule. I believe confusion will ensue if licensees are implementing our regulations at different points in time. The staff should ensure that the regulatory guidance is available prior to full implementation 18 months from the date of publication of the final rule.

Should a flexible implementation schedule be allowed, I believe a licensee who wishes to implement the new 50.59 before the 18-month period should notify the NRC in writing and not simply document the fact in the FSAR.

Several typographical errors need to be corrected before final publication:
Federal Register

Page 90, second paragraph, third sentence: "...this has been changed to require...."

Page 111, paragraph (a): "...final safety analysis report (as updated)..."

Page 112, paragraph (c)(2), second sentence "...malfunction of equipment of a difference type).
(No quotation mark)

Page 142(c)(2)(ii): Result in more than a minimal increase in the likelihood of occurrence of a malfunction.....

Commissioner Diaz

I am pleased to see that we are approaching the end of this long standing rulemaking activity through an arduous but open road. When I first arrived at the NRC, the "zero", "less than zero", or "negligible" criterion was negating the effective use of the 50.59 process for facility changes not significant for public health and safety. This practice was neither safety-focused nor realistic. I am gratified that the revised rule will eliminate the "zero" criterion for licensees' proposed changes while maintaining the level of safety at the licensed facilities. Therefore, I approve publication of the enclosed *Federal Register* notice and propose the following comments and changes to the rule language.

I believe it is necessary for the NRC to define and use the term "minimal" in this rule. Codifying the term "minimal" is another necessary step for the Commission to define "adequate protection of public health and safety." At both the policy and the implementation level, there are requirements subordinate to "adequate protection", expressed as "safety-related", "important to safety", and "safety and/or risk significant" that have yet to be defined. The proper use of "minimal" will allow for regulatory acceptance of small variations that fall within the adequate protection envelope.

To achieve internal consistency of the rule and to clearly express its intent, the staff should revise 50.59(c)(2)(viii) to read: "[r]esults in more than a minimal departure from a method of evaluation..." This would reduce potential misinterpretations of the methods of evaluation as well as backfit controversy.

The regulatory guide can also benefit from having better examples on how to determine "more than a minimal increase in the frequency of occurrence of an accident." The staff should consider using the "10% change in frequency" as a guide for determining whether a licensee proposed change results in a minimal increase in frequency. In addition, licensee changes that do not result in a different event classification should be considered not more than a minimal increase in frequency. I agree with the guidance on "minimal increase in consequences" contained in the Statements of Consideration.

I also agree with the staff recommendation to allow early implementation of 50.59. For almost two years, the proposed 50.59 rulemaking and the industry guidance NEI 96-07 have been the subject of extensive public discussions and comments. I believe optional early implementation by licensees

can contribute to a better final implementation guidance. Licensees that choose to use the new 50.59 process early should benefit from the reduced regulatory burden. However, to establish a demarcation for those licensees who choose early implementation from those who do not, as well as acquiring information to be used in the development of the final regulatory guidance, the staff should recommend how they plan to identify the dates of the voluntary licensee early implementation. The draft final regulatory guidance should be submitted for Commission approval.

Regarding the enforcement policy related to 50.59 and 72.48, I disapprove the staff proposed "substantial review" criterion. The staff proposes to use this criterion to elevate infractions to Severity Level III violation. This "substantial review" criterion is overly subjective and does not address the safety significance of a violation.

Contingent on the adoption of the above comments, I authorize the EDO to sign the attached letter with the approved *Federal register* notice and forward to Ms. Shillinglaw to close out the action on the petition PRM-72-3.

Commissioner McGaffigan

I join with Chairman Jackson and Commissioner Merrifield in commending the staff for their hard work that has been effective in crafting a rule that will reduce unnecessary burden on licensees while maintaining public health and safety. Sound and coherent implementation guidance is critical to realize the benefits of the new rule and such guidance remains to be finalized. I share the reservations of Chairman Jackson and Commissioner Diaz in this respect, but I believe that the NRC staff and our stakeholders have a workable guidance document very near completion in a revision of NEI 96-07, which could be submitted very rapidly by NEI for endorsement. For this reason, I am reluctant to delay early implementation of this much-needed rule change.

The rule should have an effective date of January 1, 2001, but with implementation permitted starting January 1, 2000. The staff should be tasked to provide the implementation guidance, whether it be a regulatory guide articulating staff positions or one endorsing an update of NEI 96-07 (my preference), to the Commission for information in time for the final guidance to be issued by January 1, 2000. Should the guidance not be finished or otherwise not meet Commission expectations, then the Commission could intervene to delay the initial implementation date of the rule. Licensees would be allowed to adopt the new rule on a voluntary basis any time after the new guidance was issued, but licensees would be required to adopt the rule before the end of calendar year 2000. I would urge that the process for developing the guidance be as transparent as possible, with successive drafts of the guidance available to all on the NRC's Web site. Besides encouraging good discussion and providing access for all interested parties, a transparent process can speed implementation by enabling licensees to begin revising their procedures as matters in controversy are resolved. I note that in a similar case the transparency of NRC's endorsement of NEI's FSAR update guidance (NEI-98-03 (Revision 0)), has permitted at least two licensees (Virginia Power and Washington Public Power Supply System) already to implement the guidance, with good results, even though NRC has not completely finalized its endorsement.

As important as implementation guidance is, however, I don't want to lose sight of the fact that such a document (e.g., a regulatory guide) is not intended to be the definitive methodology but, rather, simply a presentation of one acceptable way to meet a requirement. For this reason, the staff need not resolve every possible nuance of the new rule (e.g., the exact limits of "minimal" in criteria (i) and (ii)), because doing so will result in licensees being delayed in benefitting from the increases in clarity and the decreases in unnecessary regulatory burden that the new rule provides. As one stakeholder voiced in a meeting with the Commission, the search for the "perfect" can become the enemy of the "good enough." Should NEI 96-07, with its "so small," be acceptable for implementation by licensees, then the fact that "minimal" provides additional flexibility not full utilized should not be a matter of immediate concern. If, at a later date, staff and stakeholders should want to resolve the difference between "so small" and "minimal" and permit licensees to utilize some or all of the margin between the terms, then the resulting interchange between the staff and stakeholders could provide the basis to revise the regulatory guide.

In a June 10th letter to Chairman Jackson, Ralph Beedle of NEI recommended two minor clarifications of proposed rule language and five deletions from the Statements of Consideration (SOC) on pages 68, 23, 64, 59, and 71. He also recommended a correction on page 77, which in turn requires a correction on page 136. The pages 77 and 136 corrections (attached) should be made. I lean toward making the five proposed deletions from the SOC without prejudice to their final resolution in the guidance document because all of these issues can be resolved in the guidance development process to follow the rule and retaining them in the SOC would prejudge that guidance development process. I also lean toward making the two rule language clarifications. In the first case, I assume that "a design basis limit for a fission product barrier" would be described in the FSAR as updated. In the second case, NEI is offering specific examples of facility changes (e.g., security barriers and emergency response facilities) that are governed by other, more specific requirements and criteria and for which a 50.59 evaluation would be superfluous. By the time the Commission is considering the staff requirements memorandum on this paper, the staff should advise the Commission whether, and if so why, it would oppose the five SOC deletions and two minor rule language changes.

I approve in part, and disapprove in part:

1) I approve the final rulemaking language, with the two minor clarifications proposed in NEI's June 10th letter.
2) The final guidance should be publicly available on January 1, 2000, with all licensees required to implement the new rule no later than January 1, 2001. Early implementation should be allowed after final guidance is issued.
3) I join with Chairman Jackson and Commissioner Merrifield in disapproving the "substantial review" enforcement criterion for determining if a failure to submit a license amendment should be classified as a Severity Level III violation (this will require a deletion on page 100 of the draft Federal Register notice, and perhaps conforming changes elsewhere). Consistent with my vote on SECY-99-087, the staff has discretion to approach the Commission if the facts of any particular case warrant extraordinary treatment.
4) The following clarifying addition (underlined) should be made to the last sentence of the 2nd full paragraph under the heading, "Q. Enforcement Policy," on page 109 in the draft Federal Register notice.

"The Commission has concluded that enforcement of potential violations of 50.59 and 72.48 by licensees who have not implemented the rule early will be handled as described below, and also in accordance with the NRC Enforcement Policy, NUREG-1600, Revision 1."

5) I tentatively approve the five SOC deletions proposed by NEI's June 10th letter.
6) I suggest corrections on Pages 77 and 136 to conform the two versions of 50.71(e) that appear in the SOC.

Commissioner Merrifield

I commend the staff for their hard work on this very difficult and important rulemaking effort. I especially want to recognize the staff for the excellent job they did facilitating stakeholder involvement and incorporating stakeholder insights into the revisions to 10 CFR 50.59 and related requirements in Parts 50 and 72. However, despite the difficulty of this rulemaking, there should be many lessons learned from the manner in which the final rule language was developed and debated so late in the process. I hope the staff utilizes these lessons to ensure that these last minute scrambles, especially on such important rulemaking efforts, are not repeated in the future. As Commissioner Diaz discussed at the Regulatory Information Conference, the staff and our stakeholders must do a better job in reaching closure on these important regulatory matters.

I approve in part, and disapprove in part, the publication of the final rule in the Federal Register as discussed below:

1. I approve the final rulemaking language.
2. I disapprove of the proposed enforcement criterion which would impose a Severity Level III violation for a licensee's failure to submit an amendment as required if a substantial review (based on the merits of the technical issues) is needed by the NRC before it could conclude that the licensee's actions were acceptable. I agree with the ACRS and the Chairman that the "substantial review" standard is unduly subjective, fails to address the safety significance of the violation in question, and fails to address the extent to which the violation impacted the ability of the NRC to oversee the activities of licensees. Even with an oversight panel, I believe the subjectivity of the "substantial review" standard would lead to inconsistency in our enforcement and be difficult to defend against challenge.
3. Consistent with my vote on SECY-99-133 (Maintenance Rule), approval of the final rule language is but a first step in the process. Clearly, the staff has a great deal of work remaining on the development of regulatory guidance. This should include careful consideration of stakeholder comments and a very thorough review of the operational implications of such guidance. Given the importance of this guidance to both our licensees and inspectors, I believe that the final rule should not become effective until the final regulatory guidance is in place. I also believe it is prudent for the Commission to review this final guidance prior to issuance by the staff. As such, I disapprove of the 10 CFR 50.59 rulemaking becoming effective before regulatory guidance is developed and ultimately reviewed by the Commission. I agree with the Chairman that while the staff has done an excellent job in assembling concepts and examples of how specific criteria of the rule would be applied, the guidance provided in the paper is not complete or ready for implementation. Throughout the paper, the staff has highlighted areas where additional implementation guidance is absolutely necessary, such as for the phrase "minimal increase in frequency or likelihood", and for criterion (viii) to describe the specific elements of the evaluation methods or methodology that would require review and to clearly define specific types of input parameters. Furthermore, the staff still has to develop revised inspection guidance so that our inspectors have the guidance necessary to consistently evaluate licensee implementation of the new rule. Therefore, to ensure consistency in licensee implementation of the new rule as well as consistency in inspector evaluation of licensees, I believe that voluntary early implementation by licensees should not be permitted and that the new rule should not become effective until after issuance of the final regulatory guidance.
4. Finally, I believe the staff should reassess the time it needs for developing and implementing new guidance. The staff has indicated that it will work with the industry and other stakeholders to revise the existing NEI 96-07 to satisfy the requirements of the final rule such that it could be endorsed. Given the importance of the revisions to 10 CFR 50.59, I believe it is critical for the staff, industry, and other stakeholders to move forward in a more prompt manner. I go back to my earlier comments about reaching closure on important regulatory matters. I believe the proposed 18 month schedule is excessive and warrants a second look to determine if efficiencies can be achieved such that implementation can be accomplished in a significantly shorter time frame. Accelerating the schedule associated with developing regulatory guidance should result in more timely implementation of the final rule.