

AF 94-2
PDR

AFFIRMATION VOTE
RESPONSE SHEET

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TO: Annette Vietti-Cook, Secretary

FROM: CHAIRMAN JACKSON

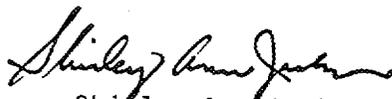
SUBJECT: SECY-99-130 - FINAL RULE - REVISIONS TO
REQUIREMENTS OF 10 CFR PARTS 50 AND 72
CONCERNING CHANGES, TESTS, AND EXPERIMENTS

Approved ^{in part} Disapproved ^{in part} Abstain _____

Not Participating _____

COMMENTS:

See attached comments.


Shirley Ann Jackson

SIGNATURE

May 26, 1999

DATE

Entered on "AS" Yes _____ No _____

Chairman Jackson's Comments on SECY-99-130

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.

In addition, the Commission proposed to make parallel changes applicable to independent spent fuel storage installations (ISFSIs) licensed in accordance with Part 72. As part of the proposed changes to Part 72, the Commission also proposed to extend the change control authority granted to ISFSI or monitored retrievable storage (MRS) license holders (in § 72.48) to holders of NRC Certificates of Compliance (CoC) for a spent fuel storage cask design.

II. Comments and Resolution on Proposed Rule Topics

The 60-day comment period for the proposed rule closed on December 21, 1998. Comments were received from 60 organizations or individuals. Copies of the comments are available for public inspection and copying for a fee at the Commission's Public Document Room, located at 2120 L Street, N.W., Washington D.C. All comments were considered in formulating the final rule. The comments were submitted by 35 utilities with power reactor facilities; 2 representatives of nonpower reactor licensees; 3 law firms representing several utilities; 2 submittals from the Nuclear Energy Institute (NEI); the U. S. Enrichment Corporation; a nuclear industry group; 6 nuclear utility vendors, service companies or consultants; 4 vendors or service companies for spent fuel storage casks; and 6 individuals. Forty commenters endorsed (sometimes with further comments) the NEI comments. NEI stated in its comment letter that it generally support the Commission's intent of the proposed rule but had a number of comments or modifications for certain specific provisions of the rule that it wished the Commission to consider in preparing the final rule. Of those commenters who did not endorse the NEI comments, most supported the concept of the proposed rule, and made recommendations to enhance or modify certain elements of the rule. A few commenters stated

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(such as Generic Letter 91-18, Revision 1), is still applicable. Further, commenters stated that a simple process should be established by which licensee technical specifications that use the term "USQ" could be revised.

The Commission agrees that the term USQ was used as a convenience to describe those changes that met the rule criteria for prior NRC review and approval, and that any guidance referring to the same category of plant changes is equally valid for describing plant changes that would require prior NRC review and approval under the revised § 50.59(c)(2).

The Commission considered the merits of including specific language in § 50.59 that would address this point, but ultimately did not include such language for a number of reasons. First, the NRC official record copy would not be modified if licensees made changes on their own (in accordance with the rule language). Second, the intent of the specific provision would be to permit such changes, however, the fact that the provision is contained in the rule may make it a requirement to do so. This is clearly an unintended consequence and argues against including such language. Finally, since there is no practical effect of the wording as contained within the TS, there is no compelling reason why licensees would need to promptly conform the wording of their TS. For administrative convenience, the NRC requests that upon such occasion as those sections of the TS require NRC approval for other reasons or a licensee is requesting a license amendment in some other area of the TS, the licensee should include any necessary changes to the existing TS language to bring the plant-specific technical specifications into conformance with the rule language. Such changes could be made at any time if a general formulation of the requirement is used, as for example, replacing "USQ" with "requires NRC approval pursuant to §50.59." Since these are viewed as editorial changes only, effectiveness of the existing TS is not impacted. The extended implementation period of

In the proposed rule, the Commission offered guidance concerning "minimal" with respect to increases in probability (now frequency). Several comments were received on certain of these statements, as noted below.

First, the Commission had noted that the current guidance in NEI 96-07 stating: "Where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e. there is no clear trend towards increasing the probability), the change need not be considered an increase in probability" satisfies the proposed NRC standard for increases in frequency of an accident. Commenters agreed with the characterization that this guidance would satisfy the rule, but also noted that the rule language provides more flexibility than is presently afforded by the NEI guidance.

Second, the Commission had stated that in order to be considered as a minimal increase, the resulting frequency of occurrence (considering the change, test, or experiment) must still satisfy the event frequency classification provided in the licensee's FSAR (as updated). Typically, these would be anticipated operational occurrence (expected once a year) or design basis accidents (not expected during life of plant, but sufficiently credible to require mitigation). The use of frequency classifications will not apply for all facilities subject to §§ 50.59 or 72.48, but is included here because it was a consideration in the licensing of most operating power plants. Some commenters sought clarification as to whether increases that remain within the frequency classification would satisfy the "no more than minimal increase" criterion. Changes that result in a change in classification do not meet the standard; however, remaining within the classification is not sufficient to conclude that no more than a minimal increase has occurred because qualitative judgments are not as rigorous as quantitative

rem as being within the error or uncertainty of design basis-type radiological consequences analysis such that NRC review of such changes is not needed.

The Commission has taken these comments into account in revising the "minimal" increases in consequences aspects of the final rule. The Commission will conclude that the requirements of the rule are met if the calculated doses from a change at a facility would be less than 10 percent of the remaining margin between current calculated dose values and acceptance values in the ^{REGULATIONS} regulatory requirements³ (e.g., GDC 19 or Part 100) for the particular accident. Under this approach, the threshold for what constitutes a minimal change varies as a licensee approaches the regulatory limit. The amount of change allowed would decrease as the limit is approached, and the limit could not be exceeded without prior NRC review. Specifically, it is no more than a minimal increase in consequences if the increase is less than or equal to the more limiting of either 10 percent of the difference between the existing calculated value and the regulatory guideline value (10 CFR Part 100 or GDC 19 as applicable), or has reached the SRP guideline value for the particular design basis event.

Examples

The Commission has selected several examples to illustrate the implementation of this criterion. In each example, the Commission assumes that the calculated consequences do not include changes in methodology. As discussed later, changes in methodology used to

³GDC 19 requires adequate radiation protection to permit access and occupancy of the control room under accident conditions without personnel receiving radiation exposure in excess of 5 rem whole body or its equivalent to any part of the body, for the duration of the accident. Part 100 establishes requirements for exclusion area and low population zones around the reactor so that an individual located at any point on its boundary immediately following onset of the postulated fission product release would not receive a total radiation dose to the whole body in excess of 25 rem or a total radiation dose of 300 rem to the thyroid for iodine exposure. For future applications, as noted in Subpart B to 10 CFR Part 100, the radiological consequences are to meet the criteria stated in 50.34(a)(1), which sets a dose of 25 rem total effective dose equivalent (TEDE).

Example 4: A licensee is considering removal of thermal relief valves on a ASME Code Class 2 piping system that is part of the reactor coolant pressure boundary during a design basis accident. For many plants, ASME Code Class 2 and 3 rules are not requirements in accordance with § 50.55a, but are instead specified in the FSARs for these facilities as the basis for determining acceptability of the piping design. The licensee evaluation shows that stress limits contained in the FSAR would be exceeded if the relief valves are removed. This is another case where NRC approval would be required for the change because the design basis limit for a fission product barrier would be exceeded (exceeding design stress limits would also be considered more than a minimal increase in either the frequency of an accident or the likelihood of malfunction (depending upon the function of the system)).

Example 5: As a variant on the above example, had the licensee wished to install relief valves with smaller capacity, for which piping stresses still satisfied the Code limit, this change would satisfy criterion (vii). (The licensee would also have to determine whether the other criteria of § 50.59, as well as TS requirements, are satisfied in order to make that change without approval).

NEW CRITERION (viii) - CONTROL OF EVALUATION METHODS

In the proposed rule notice as part of the options presented on margin of safety, the Commission had discussed the issue of controlling methods (also, as noted, the proposed rule had explicitly stated that changes to methods were changes to the facility, and as such, required § 50.59 evaluations). Specifically, the Commission sought comment on whether the rule should include a statement that "all analyses and evaluations for assessing the impact of plant changes must be performed using methodology and analytical techniques which are