

May 12, 1999

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

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

PURPOSE:

This paper requests the Commission's approval to publish a final rule that will revise 10 CFR 50.59 and related requirements in Parts 50 and 72 concerning the authority for licensees of production and utilization facilities, such as nuclear reactors and for independent spent fuel storage facilities, and for certificate holders for spent fuel storage casks, to make changes to their facilities and procedures, or to conduct tests and experiments without prior NRC approval.

SUMMARY:

The final rule will revise 10 CFR 50.59 (and related sections) to clarify which type of changes, tests, or experiments require evaluation by the licensee and to clarify the criteria that determine when NRC prior approval is needed for implementation. This paper supplements the recommendations made in SECY-99-054, dated February 22, 1999, and transmits the staff's recommendations for the final rule.

BACKGROUND:

Section 50.59 defines the conditions under which reactor licensees may make changes to their facilities or procedures, or may conduct tests or experiments without prior NRC approval. In general, such changes, tests or experiments may be carried out without prior NRC approval unless they would either involve a change to the technical specifications or an unreviewed safety question (as defined in 50.59(a)(2)). Similar language exists in 72.48 for independent spent fuel storage installations (ISFSI) or monitored retrievable storage installations (MRS) for storage of spent nuclear fuel or high-level waste.

In SECY-98-171, the staff proposed a number of changes to 10 CFR 50.59, including addition of definitions and reformatting, deletion of the term "unreviewed safety question," revisions to criteria to allow changes involving minimal increases in probability or consequences or creation of malfunctions of a different type (but not with a different result than what was previously evaluated), to be made without prior NRC approval. In this proposed rulemaking, similar changes were proposed for those sections within Part 72 relating to change control, and also to extend the change control authority to Certificate of Compliance holders (for spent fuel storage cask designs).

The Commission approved the staff's proposal to issue a proposed rule for public comment in its staff requirements memorandum of September 25, 1998, with a number of changes and additions. The proposed rule was published in the *Federal Register* on October 21, 1998 (63 FR 56098) for a 60 day comment period ending December 21, 1998.

DISCUSSION:

In SECY-99-054, the staff submitted draft final rule language, and recommendations for resolving certain key policy issues associated with this final rule. SECY-99-054 also included a discussion of the public comments and the staff's proposed course for resolution of the issues raised by the public. This paper transmits the staff's final recommendations based upon feedback from a Commission briefing on March 2, 1999, concerning SECY-99-054, and continued interactions with stakeholders to enhance the clarity of the terminology and the criteria. This paper supplements SECY-99-054 and discusses those topics for which the staff's recommendations differ from those in SECY-99-054. The *Federal Register* (FR) notice (Attachment 1) contains the Statement of Considerations, the resolution of issues raised during the comment period, and the final rule language. Attachment 2 is the final Regulatory Analysis.

In a letter dated April 30, 1999, the Nuclear Energy Institute (NEI) provided comments on certain aspects of the rulemaking as discussed in SECY-99-054, and as reflected in public meetings held during the last few months. Some of the statements and comments in this letter are reflected in Attachment 1 based upon these interactions. However, the staff did not have sufficient time to fully review their proposals before submitting this paper. The staff will provide to the Commission its views about the NEI letter in a separate memorandum.

1. MINIMAL INCREASE IN FREQUENCY OF ACCIDENT OR LIKELIHOOD OF MALFUNCTION

As discussed in SECY-99-054, the staff recommends that the final rule state that a license amendment would be required (for a proposed change, test, or experiment) if there was more than a minimal increase in the frequency of an accident or likelihood of malfunction of structures, systems or components (SSCs) important to safety previously evaluated in the final safety analysis report (as updated). The staff had further noted that the guidance for implementation was qualitative and more consistent with "negligible" increases. During the Commission briefing, the staff was requested to provide a clearer definition of the term "minimal." The Statement of Considerations includes a discussion of how "minimal" should be interpreted, and provides guidance to aid in its implementation. The staff acknowledges that it would be helpful to supplement this discussion with examples, and plans to work with the industry to include examples in implementation guidance. The staff met with the Nuclear Energy Institute (NEI) on March 23, 1999, to discuss options for developing implementation guidance for the phrase "minimal increase in frequency or likelihood." The NEI concluded that it could not offer more definitive guidance than that currently contained in NEI 96-07. However, NEI offered to continue to work with the staff during the

development of the regulatory guidance to try to develop better examples in this area.

2. REPLACEMENT CRITERIA FOR THE CRITERION OF "MARGIN OF SAFETY AS DEFINED IN THE BASIS FOR ANY TECHNICAL SPECIFICATION IS REDUCED"

The staff had proposed a criterion in SECY-99-054 to replace the existing criterion on "margin of safety." The staff considered adopting rule language proposed by NEI in its comments on the proposed rule but was concerned that that language could be interpreted too narrowly. Therefore, the staff proposed criteria in SECY-99-054 that would encompass mitigation and support systems as part of the process. Since that time, the staff has obtained a better understanding of the implementation process described by NEI in its comment letter of December 21, 1998, and the staff agrees that with certain restrictions, the process NEI proposed would appropriately address how changes to system performance are evaluated with respect to fission product barriers. Thus, the approach presented in the final rule is a combination of the NEI proposal contained in its comment letter and the staff's proposal contained in SECY-99-054.

This final rule eliminates the existing criterion on reduction in margin of safety. In its place, the rule adds two new criteria. New criterion (vii) will require prior NRC review of changes that result in a design basis limit related to the integrity of the fission product barriers being exceeded or altered. The final rule also contains a new criterion (viii) pertaining to the use and control of evaluation methods.

NEW CRITERION (vii)

Criterion (vii) will require a prior NRC review of any change that would "result in a design basis limit for a fission product barrier being exceeded or altered." The staff defines a "design basis limit" for a fission product barrier as being the controlling numerical value for a parameter established during the licensing review as presented in the FSAR for any parameter(s) used to determine the integrity of the barrier. Typically the controlling value for a parameter is set at a point that is far enough away from failure as to provide confidence in the capability of the barrier. The staff used the term "fission product barrier" so that the rule language would be appropriate for all Part 50 facilities (including nonpower reactors, and reactors undergoing decommissioning). The more general terminology is also appropriate for the Part 72 facilities. For operating power reactors, the fission product barriers will generally be limited to the fuel cladding, the reactor coolant system pressure boundary (including piping and emergency core cooling system alignments), and containment. For a reactor undergoing decommissioning, the barrier(s) would be the fuel cladding. For Part 72 facilities, the barriers would be, as applicable to the design, the fuel cladding and the confinement structure of the cask.

To satisfy new criterion (vii), the staff believes that licensees will need to determine if the change being made can ultimately affect any of the design basis limits for a fission product barrier. The effects of a change are not limited to the specific system in which the change is being made or to parameters that are only directly linked to the actual fission product barrier. Rather, the evaluation must include an assessment of all effects of the change, including effects on mitigation and support systems. The effects of the change can then be judged in terms of whether the parameters that are design basis limits would be exceeded or altered. In determining whether approval is required under this criterion, the parameters are measured against criteria to: determine whether the parameters have values established in the FSAR, or whether the parameters are controlling parameters that are reference bounds for the design. Finally, if the specific parameter values are already subject to controls established by the technical specifications or other rules or regulations, those processes are to be followed.

After a licensee assesses the information previously discussed, it must identify the specific design basis limits that could be affected for each of the identified parameters. After the licensee completes its assessment of the change against each design basis limit, if no design basis limit is altered or exceeded, criterion (vii) is satisfied, and the licensee may make the change to the facility without prior NRC review. The rule language that provides that a design basis limit may not be exceeded or altered provides important and needed assurance. Changes that involve alteration of the design basis limit for the fission product barriers involve such a fundamental alteration to the facility design that a change even in the conservative direction must receive prior NRC review.

NEW CRITERION (viii)

New criterion (viii) will require prior NRC review of any change in a methodology or evaluation method that "results in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses." The control of methods is essential in assuring a consistent application of the change review process, especially in light of the flexibility being afforded elsewhere by the final rule, such as criterion (vii) that uses design basis limits as the point at which NRC review is required.

For the purposes of this rule, a departure from a method of evaluation means (1) changing any of the elements of the method described in the FSAR (as updated) unless the results of the revised method are conservative or essentially the same, or (2) changing from a method described in the FSAR (as updated) to another method unless that method has been approved by the NRC for the intended application. A change is not conservative when a new method predicts a response that is further from a required limit than that predicted by the old method, for the same situation being analyzed. This can be determined by benchmarking (new vs. old method), or may be apparent from the nature of the changes between the methods. Results are essentially the same, even if tending slightly in the nonconservative direction if the variations are explained by routine analysis sensitivities and the differences are not a factor in determining whether or not any of the criteria are exceeded.

"Design bases" as used in criterion (viii) for determining which evaluation methods are subject to this criterion, is that information meeting the definition contained in 50.2 for controlling values for SSC. Safety analyses are those evaluations that demonstrate that facility response to or capability to withstand postulated events meets the applicable acceptance criteria.

To assure consistent implementation of criterion (viii), it is important to clearly distinguish between methods of evaluation and input parameters to the methods. The staff defines *methods of evaluation* to mean the calculational framework for evaluating behavior or response, as for the reactor or any

SSC. Input parameters are defined as those values derived directly from the physical characteristics of SSC or processes in the facility. Changes to input parameters (described in the FSAR) are to be evaluated as facility changes, and criterion (viii) would not be applicable. Further, the staff plans to develop additional guidance to describe the specific elements of the evaluation methods or methodology that would require review and to clearly define specific types of input parameters. The staff intends to work closely with the NEI and other stakeholders to revise the existing guidance related to implementation of 50.59 to reflect these definitions.

Specific examples of implementation of criteria (vii) and (viii) are presented in the Statement of Considerations to aid in understanding.

3.0 OTHER REGULATIONS


3.1 PART 52 CHANGES

In SECY-99-054, the staff included draft final rule revisions to [Appendices A and B to Part 52](#) (Design Certification Rules for the ABWR and CE System 80+ designs, respectively). In [SECY-99-101](#), dated March 31, 1999, the staff forwarded the proposed rule for Appendix C to Part 52 for the AP600 design, which did not include these proposed changes. Further, the staff stated in [SECY-99-101](#) that Appendix C should emulate the existing versions of Appendices A and B to Part 52. In addition, the staff notes that a rulemaking is currently planned to examine Part 52 for areas of improvement (see [SECY-98-282](#)). The staff will consider the final revisions to 50.59 within the context of the goals and objectives of Part 52 during the future rulemaking to update 10 CFR Part 52. Therefore, consideration of the changes to Appendices A and B to Part 52 are being deferred to a later date and they have been removed from this final rule.

3.2 IMPLICATIONS FOR PART 54

In preparing the final rule on 50.59, the staff considered the relationship between 50.59 and the license renewal rule, [Part 54](#). Specifically, [54.21\(d\)](#) states that each renewal application must contain an FSAR supplement that contains a summary description of the programs and activities for managing the effects of aging and the evaluation of time-limited aging analyses for the period of extended operation, and [54.37\(b\)](#) requires the FSAR supplement to include any newly-identified SSC that would be subject to an aging management review or evaluation of time-limited aging analysis. As discussed in the Statement of Considerations for the final Part 54, including the program descriptions in the FSAR provides the appropriate regulatory oversight such that subsequent changes are controlled by 50.59. The staff concludes that the definition proposed for "facility" is such that these summary descriptions fall within the definition and thus that changes that affect this information require evaluation under 50.59. Furthermore, the staff regards the evaluations and analyses required by [54.21\(d\)](#) and [54.37\(b\)](#) as needing evaluation under criterion (viii), to the extent that evaluation methods are described in the FSAR for such evaluations. The Statement of Considerations specifically notes this relationship and further notes the staff's intention to provide further information in implementation guidance.

3.3 PART 71 AND 72 CHANGES

In SECY-99-054, the staff noted that it may be necessary to issue a supplemental notice for proposed rule changes to Part 72 to respond to certain issues raised by the commenters. The staff has concluded that this supplemental notice is not necessary to implement the final rule change for Part 72 included in the attached notice. In addition, the rule changes for Part 72 respond to a petition for rulemaking (PRM 72-3), submitted by Ms. Fawn Shillinglaw, concerning final safety analysis updates for cask certificate holders. This petition is being closed out in this final rulemaking notice. A letter to the petitioner closing out the petition will be signed by the Executive Director for Operations upon approval of the final rule. A copy of this letter is attached ([Attachment 3](#) ).

In SECY-99-054, the staff noted that it planned a supplemental rulemaking to revise Part 71 to provide a "71.48" change control process for spent fuel transportation packages used in domestic commerce only. In lieu of providing this supplemental rule for Commission consideration, the staff now will include a new 71.48 as part of the already budgeted and planned revision to [10 CFR Part 71](#), to take advantage of rulemaking process and staff efficiencies. Under the schedule for the update to Part 71 to make NRC transportation regulations compatible with the most recent International Atomic Energy Agency (IAEA) transportation standards (1996), the staff proposes issuance of a final rule by December 2001. Thus, the new 71.48 would be issued after the revised [72.48](#) is issued. This interim period would provide time for the staff to develop regulatory guidance for the Part 71 changes, which will facilitate immediate implementation after final rule issuance. The guidance would be based upon the 50.59 and 72.48 guidance being developed during this same time period. Further, it would allow time for appropriate coordination of proposed changes with the U.S. Department of Transportation.

Neither the IAEA transportation standards nor the international transportation practices include a 71.48-type provision. Therefore, the staff currently intends to focus the proposed new 71.48 only on domestic transportation for spent nuclear fuel. The broader Part 71 rulemaking will also allow the staff to address the issue of whether a "71.48-type" process is appropriate for any other Part 71 transportation packages in the Part 71 rulemaking plan. The new section would incorporate a process similar to that described in the revised [72.48](#) that would enable a licensee or certificate of compliance holder to perform changes, tests, and experiments relative to transportation package designs without prior NRC approval if specified criteria are met.

4.0 BACKFITTING

The backfitting discussion for the proposed rule acknowledged that the proposed definitions of "change," "facility as described," and the proposed change to the "reductions in margin of safety" criterion could represent backfits, and the staff prepared a backfit analysis which set forth a basis for determining that the proposed changes represented a "substantial increase" in protection to public health and safety whose costs are justified in view of the increase. Although NEI did not file any backfitting comments, the law firm of Winston and Strawn, on behalf of the Nuclear Backfitting and Reform Group (NUBARG), filed significant comments on backfitting. In addition, the staff has modified somewhat the final rule in response to public comments by inclusion of criteria (vii) and (viii) as a substitute for the "margin of safety" criterion. NUBARG stated that the rule should be made prospective only, and that the proposed backfit analysis was "very weak" since it failed to identify all new positions, together with a detailed discussion of the costs and benefits of the proposed positions, and made no finding with respect to the "substantial increase" standard in 50.109.

The staff believes that there are several alternatives for addressing the requirements of 50.109 and 72.62 for this rulemaking. Upon consideration, the staff recommends that the Commission determine that this rulemaking does not involve backfitting as defined in 50.109(a)(1) or 72.62(a), on the basis that the final rule's provisions constitute permissive relaxations, and clarifications and codifications of existing NRC interpretations and practices. The statement of considerations for the final rule has been modified to reflect this recommendation.

5.0 ENFORCEMENT POLICY CLARIFICATION

In SECY-99-054, the staff recommended that until the revised rules were implemented, some enforcement discretion should continue to be exercised. SECY-99-054 then detailed five graded approaches to dispositioning violations of 50.59 and 72.48. The staff recommends some clarifications to approaches 1 and 3 (renumbered below to 2), as shown in the following bolded text, and deletion of approaches 2, 4 and 5 as discussed below.

(1) Following publication of the revised rule, for situations that violate the "old" requirements, but that would not be violations had the evaluation been performed under the revised rule, the NRC will exercise enforcement discretion pursuant to VII.B.6 of the Enforcement Policy and not issue citations against the "old" rule. The staff will document in inspection reports that the issue was identified, but that no enforcement action is being taken because the revised rule requirements are met. However, for those situations identified prior to the effective date of the revised rule, that involve a violation of the existing rule requirements but that would not be violations under the revised rule, licensees still need to take the required corrective action for the violation within a reasonable time frame commensurate with safety significance.

(2) A failure to submit an amendment as required would be considered a Severity Level III violation if either (1) a substantial review **(based on the merits of the technical issues)** is needed by the NRC before it could conclude the licensee's actions were acceptable, or (2) the NRC would not have found the licensee's actions acceptable.

Approach 1 addresses the transition period until the rule is implemented, when, absent an exemption, licensees will need to comply with the existing rule. To avoid the potential for a willful violation, licensees will need to initiate corrective action even if the violation would not constitute a violation under the new rule. (The staff recognizes that given the limited safety significance of such violations, a schedule for corrective action commensurate with safety may extend past the effective date of the new rule in which case corrective actions would not need to be completed.) Enforcement actions could be taken between the publication date for the rule and the effective date of the revised rule for these violations of the old rule. However, the staff does not believe that is an effective use of staff resources in light of the criteria of what changes the agency now believes is appropriate to approve. Therefore, the staff is proposing to exercise discretion and not make citations for violations of the old rule that would not be violations of the new rule once the final rule is published in the FR.

Approach 2 establishes a two part test for significance. This approach will be used for violations resulting from failure to submit an amendment as required, due to a failure to perform evaluations or for inadequate evaluations. In assessing the severity level for a failure to submit a required license amendment, the staff believes it is appropriate to consider the impact of the failure to submit the change, i.e., whether the staff would have approved it, and the importance of preserving the agency's ability to review changes that meet the thresholds of the rule. The staff will focus on the complexity and technical substance of the change. If a substantial review is needed before being in a position to approve the change, then the failure to submit the change should be considered to have had a significant impact on our ability to oversee the activities of licensees. A substantial review is one where a reasonable staff reviewer familiar with the subject matter of the change concludes that the acceptability of the change is not obvious such that a technical review of the merits is needed. On the other hand, if the knowledgeable reviewer concludes at the outset that it is likely that the change would be acceptable and it was, the failure to submit the amendment would be considered a Severity Level IV violation. As with any severity decision, the staff recognizes that there is subjectivity involved. However, the use of the 50.59 oversight panel should provide for a consistent approach to these decisions.

The staff proposes to delete Approaches 2 and 4 as presented in SECY-99-054 as not being needed as specific guidance for 50.59 and 72.48 as these statements are in accordance with the NRC Enforcement Policy. Approach 5 is being deleted based on the conclusion that it does not add any additional guidance that Approach 2 above does not already provide. Further, the staff believes it unlikely that there will be violations of 50.59 or 72.48 that will reach to Severity Level II, absent other more risk-significant violations occurring as a result of the 50.59 or 72.48 problems. In these cases, the staff would propose to cite licensees for the more risk significant violations, rather than for violations of either 50.59 or 72.48. The staff has included a section discussing enforcement policy in the Statement of Considerations in [Attachment 1](#).

The staff will submit proposed changes to NUREG-1600, Rev.1, General Statement of Policy and Procedures for NRC Enforcement Actions (Enforcement Policy), within 60 days of Commission approval of this paper. Included will be changes to the Enforcement Policy Supplements to delete Severity Level examples which are inconsistent with the approach described herein.

6.0 IMPLEMENTATION

In SECY-99-054, the staff recommended that the rule be implemented in 18 months to allow time for development and implementation of guidance, with the provision for earlier implementation by individual licensees if they wished. Rule text has been included that implements this position. The staff believes 18 months is sufficient time for revision of the existing guidance for licensees and NRC staff, and for all licensees to become familiar with those areas where their programs may need to be supplemented. The 18 month date is compatible with the recommendation from NEI in their April 30, 1999, memorandum, and from discussions with NEI management that supported options for individual licensees who may want to take advantage of the flexibility being offered sooner. The staff is not recommending early implementation for 72.48 since guidance is not developed. However, there are other sections in Part 72 that are being revised by this rulemaking for which guidance is not needed (for instance, the sections on amending certificates). For these sections, the staff recommends implementation in 120 days.

RESOURCES

For implementation, revision of inspection guidance, regulatory guidance and conduct of training of inspectors will be needed. Resources for these activities have been included in the budget and operating plan. No impacts on the inspection program are anticipated as a result of this rulemaking because oversight of licensee section 50.59 (and 72.48) processes are already part of the regular inspection program. There may be a slight reduction in license amendment submittals associated with changes of the type that would presently require approval, but that would not under the revised rule.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection to its contents.

The Advisory Committee on Reactor Safeguards was briefed on the staff's plans for the final rule (as discussed in SECY-99-054) in March 1999. In a letter dated March 22, 1999, the Committee expressed its support for completion of the rulemaking. The staff briefed the Committee on the contents of this paper on May 5, 1999.

The Committee to Review Generic Requirements was briefed on the final rule on May 6, 1999. On May 10, 1999, the Committee provided a letter recommending going forward with the amendments.

The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objection.

The Office of the Chief Information Officer has reviewed the proposed rule for information technology and information management implications and notes that the final rule amends information collection requirements. The staff had submitted its estimate of the information collection burden to the Office of Management and Budget (OMB) for the proposed rule. OMB stated that because of the probability of changes in the information collection at the final rule stage, NRC should resubmit the information collection request when it takes final action. This step will necessitate NRC's seeking OMB's approval for the information collection associated with the final rule as it is approved by the Commission before the rule can be published in the *Federal Register*.

RECOMMENDATIONS:

That the Commission:

1. Approve the publication of the enclosed *Federal Register* notice that promulgates the final rule;
2. Certify that this rule, if issued, would not have a significant economic impact on a substantial number of small entities to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).
3. Authorize the Executive Director for Operations to sign the attached letter (with the approved *Federal Register* notice) to Ms. Fawn Shillinglaw closing out action on PRM-72-3.
4. Note that:
 - (a) The staff plans to issue regulatory guidance and revised inspection guidance following approval of the final rule. The staff 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.
 - (b) The Regulatory Analysis ([Attachment 2](#)) will be available in the Public Document Room.
 - (c) This rule amends information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) The information collection requirements for this rulemaking will be submitted to OMB as soon as the Commission approves the final rule. Publication of the rule will proceed as expeditiously as possible once OMB approval is obtained.
 - (d) The appropriate congressional committees will be informed of this action ([Attachment 4](#)).
 - (e) A press release will be issued ([Attachment 5](#)).
 - (f) The Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification regarding the economic impact on small entities and the reason for it as required by the Regulatory Flexibility Act.
 - (g) The NRC has determined that this action is not a major rule under the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) and has confirmed this determination with OMB. This determination is reflected in correspondence to the President of the Senate, the Speaker of the House, and the General Counsel of the General Accounting Office ([Attachment 6](#)).

CONTACT: Eileen McKenna, NRR
301-415-2189

Attachments:

1. *Federal Register* notice with final rule
2. Regulatory Analysis
3. Letter to Ms.F.Shillinglaw
4. Letters to congressional committees
5. Public announcement
6. Congressional Review Act Forms