

**POLICY ISSUE  
NOTATION VOTE**

SECY-00-0203

September 29, 2000

FOR: The Commissioners  
FROM: William D. Travers  
Executive Director for Operations  
SUBJECT: FINAL REGULATORY GUIDE ON IMPLEMENTATION OF 10 CFR 50.59 (CHANGES, TESTS, AND EXPERIMENTS)

**PURPOSE:**

To obtain the Commission's approval to publish Regulatory Guide (RG) 1.187, "Guidance for Implementation of [10 CFR 50.59](#), Changes, Tests, and Experiments" (formerly DG-1095) ([Attachment 1](#)).

**SUMMARY:**

The staff recommends that the Commission approve publication of RG 1.1.187, which endorses the industry guidance document developed by the Nuclear Energy Institute (NEI), NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation," Revision 1, dated September 2000 ([Attachment 2](#) )

**BACKGROUND:**

On October 4, 1999, the NRC published a final rule amending 10 CFR 50.59. The revisions to 10 CFR 50.59 become effective 90 days after approval of regulatory guidance. In [SECY-00-0071](#), dated March 24, 2000, the staff forwarded to the Commission the draft regulatory guide, DG-1095, before its publication for public comment. Following completion of the public comment process, the NEI revised their document such that the final guidance can be endorsed by the staff, as discussed in the final regulatory guide.

**DISCUSSION:**

DG-1095 was issued for a 45-day public comment period on April 25, 2000, ending June 9, 2000. Comments were received from 15 utilities, 1 alliance of utilities, 1 law firm, NEI, and 3 individuals. The comments were principally based upon NEI 96-07, Revision 1, dated February 22, 2000, and on the additional discussion in DG-1095. The comments were discussed with NEI during a public meeting on June 27, 2000. Subsequently, NEI submitted a final version of its guidance document, NEI 96-07, Revision 1, on September 22, 2000.

The comments primarily focused on the following areas.

**Change Affects Design Function**

NEI had proposed a definition of design function in the February 22 version of NEI 96-07 to be used in screening reviews as to whether particular changes required evaluation using the evaluation criteria. In the draft RG, the staff proposed certain clarifying discussion on this definition and how it would be used for screening as applied to particular functions, to ensure that appropriate changes receive evaluation and are not screened out. In its comments on the draft RG (as slightly modified in its final submittal of NEI 96-07), NEI revised its definition of "design function" and guidance on screening to incorporate much of the additional guidance from the draft RG.

The second major aspect of this screening guidance concerns whether changes, tests, or experiments *affect* design functions (and thus require evaluation). In Revision 1 to NEI 96-07, the concept of "adversely affect" as the basis for screening was introduced, in that a change that enhanced a function or was neutral would not lead to increases in initiation of accidents, increases in equipment failures, or increased consequences; therefore, performing an evaluation against the rule criteria would be unnecessary.

In the draft RG, the staff included some clarifications about how the NEI guidance was presented with respect to the full range of changes (facility, procedures, methods, and tests). In Revision 1 of NEI 96-07 (September 2000), NEI amplified the discussion to provide more specific information concerning how "adverse effects" would be determined for changes to the facility (design functions), procedures (means of performing or controlling SSC functions), and for evaluations (including methods). With the above-discussed revisions, the additional clarification provided in the draft RG on screening with respect to affecting design functions is no longer necessary.

Another clarification included in the draft RG concerned the use of engineering analyses or evaluations to screen out changes as not having adverse effects. Unless the results of such analyses are within the bounds of existing analyses or final safety analysis report information, the staff concluded that an evaluation (and not just a screen) would be necessary. In the revised

sections of NEI 96-07, NEI has included explicit discussion about this aspect that is consistent with the staff's position.

## Other Comments

Two commenters noted that the guidance concerning use of the license condition for fire protection plan changes is not consistent with the explicit wording of Paragraph 50.59(c)(4), since the license condition is not a "regulation." This issue was also discussed in a Differing Professional View (DPV) filed on June 16, 2000. This concern is being evaluated in accordance with NRC guidance for resolution of DPVs. Since the DPV concerned the NRC's proposed endorsement of the guidance in NEI 96-07 (that a Section 50.59 review is not required for changes to fire protection plans), the DPV resolution could affect the wording in the final RG. The staff will not issue the final RG until the DPV is resolved and will inform the Commission of any changes to the RG prior to issuance.

Other comments pertained to the guidance on the use of methods approved by NRC (for the intended application) for a specific plant. Changes were made in the latest revision of NEI 96-07 to explicitly state that if a licensee cannot establish a documented basis that a method has been approved, either through a topical report or a staff safety evaluation, the licensee could not conclude that it had been so approved.

In addition, in response to other comments, clarifications were made by NEI with respect to additional guidance on the substitution of manual action for an automatic action as not meeting the "minimal increase (in likelihood of malfunction)" criterion. Other revisions included in the latest version of NEI 96-07 were made in response to the remaining positions from the draft RG (on component malfunctions and on the interface with the maintenance rule).

In conclusion, with the revisions made by NEI to its document as a result of the draft RG and public comments, the staff finds the document acceptable for endorsement without exception.

## Inspection Guidance

Inspection guidance related to 10 CFR 50.59 has been revised to conform to the revised rule requirements. Within the revised baseline inspection program, the new procedure governing review of 10 CFR 50.59 evaluations is Inspection Procedure 71111.02, "Evaluations of Changes, Tests, or Experiments." Existing guidance in the inspection manual in Part 9900 for implementation of 10 CFR 50.59 has been revised and will be finalized shortly after completion of the final regulatory guide.

This guidance is attached for Commission information ([Attachment 3](#)). Training for the NRC staff will be provided. The staff plans to make the training material available through a web-based system that will allow self-paced study at the wide range of locations where resident and regional staff are located. In addition, the topic will be discussed during future counterpart meetings.

## Transition Issues

During the review of the draft RG, certain questions and comments arose concerning the process for transition from the "old" rule to the "new" rule. The staff plans to document the resolution of these issues in a regulatory issue summary. A draft of this document is also attached ([Attachment 4](#)). Of particular note is the discussion concerning the 90-day period for implementation. A number of licensees stated that more time was needed for training, or that due to outage schedules or the desire to synchronize the adjustment to the Section 50.59 program with their Section 72.48 program, they wished to continue following the "old" rule requirements for some limited period following the actual implementation date. Inasmuch as the "new" rule provides relaxations in requirements, the staff has no objection to allowing a period of transition since compliance with the "old" rule would bound the changes that would be allowed. The staff has suggested that in such instances, the licensee communicate with NRC about its intentions so that the NRC is clear about that licensee's activities.

## Guidance for Implementation of 10 CFR 72.48

As part of the FR notice of October 4, 1999, revisions were also made to Section 72.48 (changes, tests, and experiments for independent spent fuel storage facility licensees and cask storage certificate holders). The effective date of these requirements is April 5, 2001. NEI submitted a separate document, identified as Appendix B to NEI 96-07 on June 15, 2000, that provides guidance specifically for application to [10 CFR 72.48](#). The staff is presently reviewing this document and recently met with NEI to discuss comments on it. The staff will publish for public comment a separate draft regulatory guide proposing to endorse companion industry document Appendix B to NEI 96-07. The staff will subsequently provide to the Commission, for information, a final regulatory guide endorsing this companion industry document, as directed by the SRM to SECY-99-130, dated June 22, 1999.

## CONCLUSIONS:

The staff has concluded that NEI 96-07, Revision 1 dated September 2000, provides guidance and examples that are acceptable to the staff for implementation of the revision to 10 CFR 50.59, as discussed in the final regulatory guide. Therefore, the staff is seeking Commission approval to publish a notice in the Federal Register that announces availability of the final regulatory guide, and thus establishes the 90-day implementation period for the rule.

As noted above, the staff will inform the Commission of any changes to the RG resulting from the DPV resolution prior to

issuance of the final RG. The staff will also then issue the regulatory issue summary, and the inspection guidance.

## RESOURCES:

The resources necessary to complete the activities related to issuing the final guidance and conducting training are currently budgeted for Fiscal Year 2001. No additional staff resources are necessary.

## COORDINATION:

The Office of the General Counsel has no legal objection to this paper or to publication of the final regulatory guide. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections to its contents. The Committee To Review Generic Requirements was briefed on the final regulatory guide and on the inspection guidance on August 22, 2000. The Advisory Committee on Reactor Safeguards decided not to comment on the final regulatory guide.

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### Attachments:

1. [Regulatory Guide 1.187 "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments"](#)
2. [NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation," Revision 1, September 2000](#) 
3. [Inspection Guidance \(Part 9900\)](#) 
4. [Transition Guidance \(regulatory issue summary\)](#)

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ATTACHMENT 4

UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR REACTOR REGULATION  
WASHINGTON, D.C. 20555-0001

DATE

NRC REGULATORY ISSUE SUMMARY [NUMBER]  
CHANGES, TESTS, AND EXPERIMENTS

## Addressees

All holders of licenses for nuclear power reactors, including those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel. All holders of licenses for nonpower reactors, including those whose licenses have been modified for possession only.

## Intent

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to advise addressees about certain issues concerning the transition to the revised requirements in Title 10 of the Code of Federal Regulations, Section 50.59, "Changes, Tests, and Experiments." This RIS requires no action or written response on the part of an addressee.

## Background Information

On October 4, 1999, changes were made to 10 CFR 50.59, the section of the Commission's regulations that includes requirements for licensees concerning changes to the facility that a licensee wishes to make without prior NRC approval. The revised requirements become effective 90 days after Commission approval of regulatory guidance on implementation. The NRC has issued a notice in the Federal Register on xxxxx, 2000, that announces availability of Regulatory Guide (RG) 1.187, "Guidance for Implementation of 10 CFR 50.59, Changes, Tests, and Experiments," dated October 2000. This RG provides NRC endorsement of NEI 96-07, "Guidelines for 10 CFR 50.59 Implementation," dated September 2000.

During the public comment process on the draft RG, some concerns were expressed that completing necessary procedural revisions and training during a 90-day period (from a to-be-determined) date, would pose difficulties for licensees because of planned outage schedules and other activities. It was also noted that revisions to Section 72.48 (similar requirements for changes to independent spent fuel storage facility licensees and certificate holders) become effective on April 5, 2001. Thus, questions were raised about how licensees were to best transition from the existing rule requirements to the new requirements.

This RIS informs licensees of NRC views on these issues, and provides guidance for consideration in making the transition.

RIS 2000-XX

Date

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## Summary of Issue

The basic issue is how will NRC view compliance for a licensee using the "old" rule requirements following the effective date (90-day period after publication of final regulatory guidance). Since the revised rule was issued on the basis of being a relaxation of existing requirements, as a general matter, if a licensee is in compliance with the "old" rule they would be satisfying the new rule requirements. More specific information, in the form of questions and answers, is provided in Attachment 1.

## Backfit Discussion

This RIS requires no action or written response. Consequently, the staff did not perform a backfit analysis.

## Federal Register Notification

The staff did not publish a notice of opportunity for public comment in the *Federal Register* because the RIS is informational and pertains to a staff position that does not represent a departure from current regulatory requirements and practice.

If there are any questions about this matter, please contact the person listed below.

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Attachments: 1. [Transition issues \(questions and answers\)](#)  
2. List of Recently Issued NRC Regulatory Issue Summaries

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ATTACHMENT

## GUIDANCE FOR TRANSITION FROM EXISTING 10 CFR 50.59 REQUIREMENTS TO REVISED 10 CFR 50.59 REQUIREMENTS

### Background

On October 4, 1999 (64 FR 53582), the NRC published a final rule revising 10 CFR 50.59 (and related requirements in Part 50 and in Part 72). The Part 50 requirements were to become effective 90 days after approval of regulatory guidance. During development of the industry guidance document that NRC is endorsing through a regulatory guide, certain questions arose concerning how the transition from the "old" rule to the "new" rule were to be accomplished. This document sets forth these issues and the applicable guidance.

### Discussion of Issues

A. Due to the expected timing of the 90-day implementation period, it may be difficult to schedule procedure revisions and training for all affected personnel in light of planned refueling outages or other activities. To ease transition to the new 10 CFR 50.59 rule, may a licensee opt to continue using the "old" rule for a period of time longer than the 90 days until the training can be completed? As another example, could a licensee arrange implementation such that the effective date for the revision to Section 50.59 coincides with implementation of the revised Section 72.48 (April 5, 2001). What licensee actions are needed to allow this?

**Response:** The Commission in promulgating the revision to Section 50.59 noted that the revised rule provisions provide greater flexibility than the existing rule requirements for licensees to make changes without prior NRC approval. Thus, if a licensee is appropriately implementing the "old" rule, they would be complying with the "new" requirements. Therefore, some delay beyond 90 days in implementation of the revised rule requirements is acceptable to NRC to allow for an orderly transition for personnel training and procedure preparation. However, to avoid confusion, it is expected that the additional implementation period would not exceed a few months (the April 2001 date would seem to be a logical break point for such implementation). While no formal notification or approval is needed for such licensee actions, it is recommended that the licensee clearly communicate with the NRC staff (in particular, the resident and regional staff) about their implementation schedule so that NRC understands what the licensee is doing and what procedures/process the licensee will be using.

B. Which version of 10 CFR 50.59 applies when evaluation of a change is begun before the effective date of the new rule, but the evaluation is not complete until after the new rule becomes effective?

**Response:** Implementation of the 10 CFR 50.59 requirements occurs at the time that the licensee completes the evaluation (in whatever form that the licensee concludes that an evaluation is complete, as for example, when approved by the safety review committee). Thus, it is at this time that the requirements of whichever rule is currently in effect should be met (see also question A). For evaluations started after the implementation date, the revised rule should be followed. Since as noted above, the revised rule is a relaxation of the existing rule, completing an acceptable evaluation (begun under the "old" rule using a licensee's procedures for the "old" rule) after the implementation date would also be considered to comply with the revised rule during this transition.

C. If new information is discovered after the revised rule takes effect that necessitates revision of a 10 CFR 50.59 evaluation that was completed using the "old" rule, should the "new" or the "old" rule be used to revise the evaluation?

**Response:** The licensee would need to comply with the rule requirements that are in effect at the time the evaluation is revised. However, as previously noted, since the new rule largely represents a relaxation from the "old" rule, if the licensee used the "old" rule requirements for purposes of completing the revision, they would be expected to also comply with the new rule. Therefore, it would be acceptable to assess the revision against the "old" rule requirements. Only the portions of the evaluation affected by the new information would need to be revised. If the effect of the new information is that one or more of the new rule criteria are met, the licensee should seek approval for the change.

D. The revised maintenance rule requirements, including implementation of new Paragraph 50.65(a)(4), go into effect on November 28, 2000, which is before the effective date of the revised Section 50.59. During the period between the effective dates of the two rules, are licensees required to perform both Section 50.65(a)(4) assessments as well as Section 50.59 reviews for temporary alterations in support of maintenance?

**Response:** The maintenance rule guidance in RG 1.182 states that maintenance activities, including associated temporary alterations are to be assessed in accordance with Paragraph 50.65(a)(4) and that a Section 50.59 evaluation is not required (provided the temporary alteration is to be in effect for less than 90 days at power). This guidance is also reflected in the guidance for implementation of Section 50.59. The explicit language that a Section 50.59 evaluation is not needed when another regulation establishes the control process for such activities appears in the revised rule. However, the Commission, in approving the final regulatory guide for Section 50.65, supported that licensees could begin use of the guidance in RG 1.182 before the effective date of (revised) Section 50.59. Thus, if a licensee performs the assessments in accordance with Paragraph 50.65(a)(4), a Section 50.59 review is not needed for such temporary alterations.

E. If an evaluation has been performed before the effective date of the revised rule, but the change has not yet been implemented, what action (if any) is required?

**Response:** No action would be required with respect to the new rule for changes already evaluated, whether or not already implemented. The licensee does have the option of performing a new evaluation under the revised rule requirements for certain changes that might have required prior approval under the "old" rule, but which would satisfy the "new" rule. Such an evaluation would then provide the basis for not seeking NRC approval for that change.

F. May a licensee continue to reference Section 50.59 evaluations performed under the old rule/guidance when making a similar change in the future?

**Response.** Past evaluations will continue to be a valuable resource when performing Section 50.59 screening and evaluation of similar future changes. However, for reviews of proposed changes that are begun after the new/revised rule takes effect (except as noted in item A above), screening and evaluation should be performed in term of the definitions and criteria reflected in the new rule and approved guidance.

G. How should previous NRC documents that discuss 10 CFR 50.59 be viewed in light of the revised rule. In some instances, the discussion therein appears to be in conflict with the revised rule or the new regulatory guidance. Examples include Generic Letter (GL) 95-02 (on digital instrumentation) and Bulletin 96-02 (Heavy Loads).

**Response:** NRC documents such as those noted were written to be used with the "old" rule. To the extent that the rule requirements that led to particular statements or conclusions have been revised, the impact of the rule revisions on those statements must be taken into account. Thus, for example in GL 95-02, the part of the guidance that discusses the evaluation criterion of "malfunction of a different type" would no longer apply because that criterion has been revised to be "malfunction with a different result." However, other aspects of the guidance, as for instance how the change to the system in which the digital instrumentation is used is to be viewed in performing the evaluation, would remain applicable. In the case of the

Bulletin on heavy loads, it is noted that if the heavy load were being accomplished as part of a maintenance activity, there is no Section 50.59 evaluation being performed, and thus, no expectation that the heavy load lift would require prior NRC approval. The fact that the load is larger or is moving in a different load path than previously evaluated would factor into the risk assessment and thus the determination as to under what plant conditions the load lift should occur. If the heavy load lift is not maintenance-related, such that a Section 50.59 evaluation is being performed, the determination as to whether prior NRC approval is needed would be made in accordance with the revised rule requirements, as for instance, whether there would be a more than minimal increase in the consequences of an accident previously evaluated (or if the change creates an accident of a different type).