

March 24, 2000

SECY-00-0071

FOR: The Commissioners

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

SUBJECT: DRAFT REGULATORY GUIDE (DG-1095), "GUIDANCE FOR IMPLEMENTATION OF 10 CFR 50.59 (CHANGES, TESTS, AND EXPERIMENTS)" (WITS 1997000191 and 200000038)

PURPOSE:

To provide for the Commission's information Draft Regulatory Guide DG-1095, "Guidance for Implementation of 10 CFR 50.59 (Changes, Tests, and Experiments)" (Attachment 1), which the staff is planning to publish for public comment.

BACKGROUND:

The rulemaking to revise the 10 CFR 50.59 requirements was published as a final rule on October 4, 1999 (64 FR 53582). The revisions to 10 CFR 50.59 become effective 90 days after approval of regulatory guidance. As part of its efforts to finalize this regulatory guidance, the staff plans to issue the attached draft regulatory guide for public comment. Upon resolution of the comments, the staff will forward a final regulatory guide to the Commission for approval by September 30, 2000.

DISCUSSION:

Development of Industry Guideline NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations"

Following issuance of the revised rule, the Nuclear Energy Institute (NEI) submitted a guidance document for implementation of 10 CFR 50.59 and requested NRC endorsement through a regulatory guide. Following a series of public meetings between NEI and the NRC, and written comments from the staff provided in letters dated November 4, 1999, and February 4, 2000, NEI submitted a revised version of the document on February 22, 2000 (Attachment 2).

Draft Regulatory Guide

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The staff has prepared the attached draft regulatory guide that proposes to endorse the NEI guideline document as an acceptable means of meeting the rule, with certain exceptions and clarifications as discussed below.

In the draft regulatory guide, the staff is proposing clarifications in four areas: the screening process on changes that affect design function; the relationship between the 10 CFR 50.59 process and the maintenance rule 10 CFR 50.65(a)(4) assessments; increases in the likelihood of malfunction of systems, structures, or components (SSCs); and licensee use of a different method and considering it as being approved by the NRC for the intended application.

#### A. CHANGE AFFECTS DESIGN FUNCTION

The NEI guidance discusses screening out of changes from further evaluation on the basis of a proposed definition of “design function<sup>1</sup>” that focuses upon the safety analyses. The staff believes that the NEI definition was somewhat vague as to its breadth and therefore might not be applied consistently. Design function in the staff’s view is broad in extent such that changes that have the potential to meet any of the 10 CFR 50.59 evaluation criteria are evaluated rather than screened out from further review. Since the criteria include both the initiation and response to previously postulated events (including equipment performance), as well as introduction of new events, “design function” extends beyond safety-related SSCs and specific mitigation systems, the performance of which is explicitly modeled and discussed in the safety analyses. Thus, the staff’s understanding of design function is broader than what the definition proposed by NEI appears to include.

The staff also believes that the rule revision did not intend to screen out changes to SSCs from further evaluation on the basis of what functions are performed (by an SSC), but rather on the basis of whether or not a particular change affects a function. Thus, for SSC functions described in the FSAR, the staff concludes that “design function” should not be used as a means of excluding changes from further evaluation because the described function does not fit the definition in the NEI guidance, without consideration of the effects of the change.

The staff believes the concept of “design function” can be used as a means of determining whether particular changes to the facility or procedures are of such a nature as to require evaluation because they affect a “design function,” if the definition is viewed in a broader sense than might be applied using just the NEI guidance. Thus, the staff has proposed certain clarifying discussion with respect to the meaning of “design function” as proposed by NEI. Finally, the staff is specifically requesting comments about the impact of the above-described staff guidance (such as seeking examples of functions that would be described in the FSAR, but would not be design functions).

The staff notes that Section 4.2.1 of NEI 96-07 provides guidance as to whether a change may (adversely) affect a design function. In the draft regulatory guide, the staff is relocating some discussion from Section 4.2.1 to Section 4.2.1.1 about changes affecting design functions, as being a more appropriate location for that guidance. The staff is also adding guidance stating

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<sup>1</sup> Design function, as used in 10 CFR 50.59 as part of the definition of “change,” should not be confused with the definition of “design bases” in 10 CFR 50.2 that involves in part functions. Design bases functions as discussed in SECY-00-0047 (Draft Regulatory Guide Providing Guidance and Examples for Identifying 10 CFR 50.2 Design Bases) are a subset of “design function” as used in the implementation guidance for 10 CFR 50.59.

that in deciding if a function is affected, when the change involves some characteristic or value (response time, capacity) of an SSC, the decision as to whether it affects the function is with respect to whether the result is within the bounds of existing analyses or FSAR information. If the nature of the change is such that an engineering assessment or revised analyses is needed to determine whether an effect is adverse, the staff concludes that a 10 CFR 50.59 evaluation is required rather than a screening.

The above clarifications are documented in Section 1.1 of Attachment 1.

## B. RELATIONSHIP TO THE MAINTENANCE RULE

The staff is proposing minor clarifications in the draft regulatory guide on the respective requirements of 10 CFR 50.59 and 50.65 for design modifications and for temporary changes needed to support maintenance activities (see Section 1.2 of Attachment 1).

## C. INCREASE IN LIKELIHOOD OF MALFUNCTION

The staff is proposing minor clarifications in the draft regulatory guide concerning the guidance on increases in likelihood of malfunction of SSCs (see Section 1.3 of Attachment 1).

## D. METHODS

The NEI guidance discusses changes from one method to another method that has been approved by the NRC for the intended application. In the Statement of Considerations (SOC) for the rule (64 FR 53598), such changes (without NRC approval) were discussed as being limited to use of methods that were explicitly “generically approved.” (Note, however, that the definition of “departure” in the revised rule did not have this explicit qualifier). The staff is proposing that with additional guidance and limitations contained in NEI 96-07 (and in the draft regulatory guide) concerning departures from a method of evaluation, the limitation to “generic approval” is not necessary. The Federal Register notice of availability notes that the guidance differs from the SOC as stated above.

The staff is proposing two modifications to the NEI guidance concerning changes from one method to another (approved) method, in particular where the other approval was not on a generic basis. These clarifications relate to changes made to “approved” methods, and that such changes need to be assessed with respect to whether results are “conservative or essentially the same,” not on the basis of NRC approval of the (unchanged) method.

These clarifications are documented in Section 1.4 of Attachment 1.

## Guidance for Implementation of 10 CFR 72.48

As part of the same rulemaking, 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. Although the guidance in the draft regulatory guide is also generally applicable for implementation of Section 72.48, the staff in the Spent Fuel Project Office plans to provide a separate regulatory guide specific to implementation of these requirements at a later date. NEI has stated that it will provide supplemental guidance and examples applicable to Section 72.48 (which is expected to be an appendix to NEI 96-07) for the staff’s consideration.

### Final Regulatory Guide Review Process

In a Staff Requirements Memorandum dated March 8, 2000, the Commission stated that the staff should review the need for Advisory Committee on Reactor Safeguards (ACRS) and Committee to Review Generic Requirements (CRGR) review of the final regulatory guide in the August time frame. Such reviews are part of NRC normal practice for final regulatory guides (as specified in the Charter for the CRGR, and in the NRR Office Letter on Coordination with the ACRS). Under the staff's current schedule, the staff anticipates being in a position to request such reviews in the August time frame. The staff notes that no ACRS meeting is scheduled for August 2000. Therefore, the staff proposes to seek CRGR review of the final regulatory guide in August 2000 and ACRS review in September 2000.

### CONCLUSIONS:

The staff has concluded that the version of NEI 96-07 dated February 22, 2000, provides guidance acceptable to the staff for implementation of the revision to 10 CFR 50.59, with the clarifications noted in the draft regulatory guide. Therefore, the staff is issuing a notice of availability in the Federal Register with a 45-day public comment period for the draft regulatory guide that endorses the NEI document with staff clarifications. The staff will evaluate public comments to determine whether it is appropriate to endorse the NEI document in its current form or whether other clarifications or comments are appropriate. As discussed during the Commission briefing on February 29, 2000, the staff proposes that the Commission promptly release this paper to facilitate dialogue with stakeholders such as during the forthcoming industry workshop scheduled for April 10, 2000.

### RESOURCES:

The resources necessary to complete the activities related to issuing the draft regulatory guide, resolving public comments, and issuing a final regulatory guide are currently budgeted for Fiscal Year 2000. 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 draft regulatory guide. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. The Committee To Review Generic Requirements has deferred its review until the final regulatory guide is written reflecting public comments. The staff briefed the Advisory Committee on Reactor Safeguards on the status of this regulatory guide and on the issues for which the staff was considering positions in the regulatory guide on February 3, 2000.

*/RA/*

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Attachments: 1. Draft Regulatory Guide DG-1095  
2. NEI 96-07, "Guidelines for 10 CFR 50.59  
Evaluations," Revision 1

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 2. NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," Revision 1

\*SEE PREVIOUS CONCURRENCES

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