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**GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48,
CHANGES, TESTS, AND EXPERIMENTS**

A. INTRODUCTION

In 10 CFR Part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste," Section 72.48, "Changes, Tests and Experiments," contains requirements for the process by which licensees and certificate holders may make changes to their facilities, independent spent fuel storage installations (ISFSIs), spent fuel storage cask designs, or monitored retrieval storage installations (MRSs) and procedures as described in the final safety analysis report (as updated), without prior NRC approval, under certain conditions. This regulation was originally promulgated in 1980 as 10 CFR 72.35, "Changes, Tests, and Experiments." It was subsequently designated as 10 CFR 72.48 and was recently revised (October 4, 1999, 64 FR 53582). The recent revision to the rule made comparable changes to 10 CFR 50.59, "Changes, Tests, and Experiments," that addresses the change process for reactor licensees.

As a result of lessons learned from operating experience and other initiatives related to control of conformance of reactor and ISFSI facilities with their final safety analysis report (FSAR) descriptions, the NRC determined that additional action was necessary to provide clarity and consistency in implementation of the rule. The NRC staff recommended specific actions in SECY-97-205, "Integration and Evaluation of Results from Recent Lessons-Learned Reviews,"¹ dated September 10, 1997. In a staff requirements memorandum dated March 24, 1998,¹ the Commission directed the staff to initiate rulemaking to revise the requirements of 10 CFR 50.59 and 10 CFR 72.48 to clarify the requirements and to allow changes involving only "minimal increases" in probability or consequences to be made without prior NRC approval.

¹Copies are available on the NRC's web site <WWW.NRC.GOV> in the Reference Library through Rulemaking, and for inspection or copying for a fee from the NRC Public Document at 11555 Rockville Pike, Rockville, MD 20852; the PDR's mailing address is Mail Stop 01-F-13, Washington, DC 20555; telephone (301-415-4737) or (800)397-4209; fax (301)415-3548; email <PDR@NRC.GOV>.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review or approval and does not represent an official NRC staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments may be submitted electronically or downloaded through the NRC's interactive web site at <WWW.NRC.GOV> through Rulemaking. Copies of comments received may be examined at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by **January 22, 2001.**

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On October 4, 1999, the NRC issued a revision to 10 CFR 72.48 that becomes effective on April 5, 2001. The text of this revised rule is contained in Appendix A to this regulatory guide for convenience.

Regulatory guides are issued to describe to the public methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in developing the regulatory positions. Draft regulatory guides have not received complete staff review; they therefore do not represent official NRC staff positions.

The information collections contained in this draft regulatory guide are covered by the requirements of 10 CFR Part 72, which were approved by the Office of Management and Budget, approval number 3150-0132. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

B. DISCUSSION

OBJECTIVE

The objectives of 10 CFR 72.48 are to ensure that licensees and holders of Certificates of Compliance (CoC) (1) evaluate proposed changes to their facilities or cask design for their effects on the licensing basis of the ISFSI, cask design, or MRS, as described in the FSAR, and (2) obtain prior NRC approval for changes that meet specified criteria as having a potential impact upon the basis for issuance of the license or certificate of compliance. This regulatory guide, through its endorsement of a guidance document for licensees, provides guidance on complying with the revised requirements of 10 CFR 72.48.

DEVELOPMENT OF INDUSTRY GUIDELINE, Appendix B to NEI 96-07

Following publication of the revised rule, the Nuclear Energy Institute (NEI) submitted a guidance document, NEI 96-07, "Guidelines for 10 CFR 50.59 Evaluations," for the implementation of 10 CFR 50.59 and requested NRC endorsement through a regulatory guide. The NRC endorsed Revision 1 of NEI-96-07 in Regulatory Guide 1.187, which was issued in November 2000. On June 15, 2000, NEI submitted to the NRC Appendix B, "Guidelines for 10 CFR 72.48 Implementation," to NEI 96-07. The NRC provided written comments on the document to NEI on August 18, 2000, and NEI provided to the NRC revisions dated September 28, 2000, and November 6, 2000.² (The November 9, 2000, letter from NEI that forwarded Appendix B also contains a list of the changes from the September 28, 2000, version.) NEI developed this guidance document by modifying appropriate language and sections in Revision 1 of NEI 96-07 to apply to Part 72 licensees and certificate holders. Thus, a significant portion of Appendix B includes text that is identical to that in

² Copies of Appendix B to NEI 96-07 are available through NRC's web site, <WWW.NRC.GOV> through Rulemaking, and through NRC's Electronic Reading Room at the same site, under Accession number ML003773698. Copies are available for inspection or copying for a fee from the NRC Public Document Room, telephone (301-415-4737) or (800)397-4209, fax (301)415-3548, email <PDR@NRC.GOV>.

Revision 1 of NEI 96-07, which has been endorsed by the NRC in Regulatory Guide 1.187. The guidance contained in Appendix B to NEI 96-07 is also generally applicable to 10 CFR 50.59 evaluations performed by reactor licensees.

C. REGULATORY POSITION

1. APPENDIX B TO NEI 96-07

Appendix B, "Guidelines for 10 CFR 72.48 Evaluations,"² dated November 6, 2000, to NEI 96-07 provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 72.48, with the clarifications noted below.

1.1 Departure From a Method of Evaluation Described in the FSAR

In Appendix B in Section B3.4 in the paragraph, "Conservative vs. Non-Conservative Evaluation Results," NEI includes an example of a change in an element of a method of evaluation that changes the result of a cask peak pressure analysis from 45 to 48 psig. The NRC staff finds that the conclusion that this is a conservative change might not be correct in all cases. The validation of a new method element must show that the new element is conservative not only at the old design point, but also will be conservative at the new design point. The licensee should assess the effect of the new method element on the overall method as the design point moves from the old to the new. A trending or sensitivity analysis might be necessary in some cases. The NRC staff suggests that NEI expand the guidance in this section and in Section B4.3.8.

In Section B4.3.8, NEI lists examples in which the NRC, in its review of an FSAR, did not specifically approve a methodology either through review of a referenced topical report or by a statement of endorsement in the staff's safety evaluation report (SER). The second example deals with the NRC not endorsing a methodology described in the FSAR. NEI concludes that future use of the unendorsed methodology in this example would not "result in a departure from a method of evaluation described in the FSAR," and this would mean that no prior NRC approval would be needed to do so. The NRC staff suggests that NEI revise this example to remove the discussion of a methodology that is not endorsed by the NRC. This example is not relevant to NRC practice nor its record of approving designs. The NRC does not approve a design on the one hand and concurrently state that it does not endorse a method referenced in the FSAR that supports the design. The NRC suggests that NEI revise this example to discuss a case in which the NRC staff in its SER is silent on endorsing the methodology described in the FSAR and states that it has performed an independent confirmatory analysis using its own methodology. In such a revised example, use of the methodology described in the FSAR to support a subsequent design change would not require NRC approval.

It should be noted that the NRC staff, in reviewing dry cask storage designs, historically has not endorsed methodologies referenced in FSARs. Instead it has made statements in its SERs, following the guidance in the Standard Review Plan, that the design has been found to be acceptable in each review discipline area. If, however, vendors or licensees choose to submit methodologies to the NRC for review and approval as part of applications for design approval or as separate topical reports, the staff will document NRC endorsement or approval in appropriate SERs. Such endorsement or approval will enable

vendors and licensees to use the 10 CFR 72.48 process that deals with approved methodologies.

1.2 Design Basis Limit for a Fission Product Barrier

Section B4.3.7 lists examples of typical fission product barrier design basis limits, with an example in which the design uses a methodology for criticality control that credits partial burnup of fuel to be stored in a cask design. The NRC staff proposes revising this discussion to note that partial burnup credit may be utilized as in current NRC Interim Staff Guidance, ISG-8, "Limited Burnup Credit,"³ or in NUREG-1536, "Standard Review Plan for Dry Cask Storage Systems."³ This change is needed because the application of burnup credit in cask designs is an evolving technical issue based on work by both the industry and the NRC.

2. OTHER DOCUMENTS REFERENCED IN APPENDIX B TO NEI 96-07

Appendix B to NEI 96-07 references other documents, but NRC's endorsement of Appendix B should not be considered an endorsement of any referenced documents.

3. USE OF EXAMPLES IN APPENDIX B TO NEI 96-07

Appendix B to NEI 96-07 includes examples to supplement the guidance. While appropriate for illustrating and reinforcing the guidance in Appendix B, NRC's endorsement of Appendix B should not be considered a determination that the examples are applicable for all licensees and CoC holders. A licensee or certificate holder should ensure that an example is applicable to its particular circumstances before implementing the guidance as described in an example.

4. GUIDANCE FOR SITE-SPECIFIC ISFSI LICENSE RENEWAL

The guidance in Appendix B and in this regulatory guide is applicable to information added to the FSAR for summary descriptions of the programs, activities for managing the effects of aging, and evaluation of time-limited aging analyses that will support the bases for site-specific ISFSI license renewal. If necessary, the staff may provide further guidance or examples for use with respect to such programs and evaluations at a later date.

5. USE OF OTHER METHODS

Licensees and certificate holders may use methods other than those proposed in Appendix B to NEI 96-07, as clarified by this regulatory guide, to meet the requirements of 10 CFR 72.48. The NRC will determine the acceptability of other methods on a case-by-case basis.

³ Available electronically at <http://WWW.NRC.GOV/OPA/reports/cask.htm#licensing>.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees, certificate holders, and applicants regarding the NRC staff's plans for using this regulatory guide.

This draft regulatory guide has been released to encourage public participation in its development. Except in those cases in which a licensee or certificate holder proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the method to be described in the final version of this guide, reflecting public comments, will be used in the evaluation of licensee or certificate holder compliance with the requirements of 10 CFR 72.48.

APPENDIX A

TEXT OF 10 CFR 72.48

§ 72.48 Changes, Tests, and Experiments.

(a) Definitions for the purposes of this section:

(1) *Change* means a modification or addition to, or removal from, the facility or spent fuel storage cask design or procedures that affects a design function, method of performing or controlling the function, or an evaluation that demonstrates that intended functions will be accomplished.

(2) *Departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses* means: (i) changing any of the elements of the method described in the FSAR (as updated) unless the results of the analysis are conservative or essentially the same; or (ii) changing from a method described in the FSAR to another method unless that method has been approved by NRC for the intended application.

(3) *Facility* means either an independent spent fuel storage installation (ISFSI) or a Monitored Retrievable Storage facility(MRS).

(4) The *facility or spent fuel storage cask design as described in the Final Safety Analysis Report (FSAR) (as updated)* means:

(i) The structures, systems, and components (SSC) that are described in the FSAR (as updated),

(ii) The design and performance requirements for such SSCs described in the FSAR (as updated), and

(iii) The evaluations or methods of evaluation included in the FSAR (as updated) for such SSCs which demonstrate that their intended function(s) will be accomplished.

(5) *Final Safety Analysis Report (as updated)* means:

(i) For specific licensees, the Safety Analysis Report for a facility submitted and updated in accordance with § 72.70;

(ii) For general licensees, the Safety Analysis Report for a spent fuel storage cask design, as amended and supplemented; and

(iii) For certificate holders, the Safety Analysis Report for a spent fuel storage cask design submitted and updated in accordance with § 72.248.

(6) *Procedures as described in the Final Safety Analysis Report (as updated)* means those procedures that contain information described in the FSAR (as updated) such as how SSCs are operated and controlled (including assumed operator actions and response times).

(7) *Tests or experiments not described in the Final Safety Analysis Report (as updated)* means any activity where any SSC is utilized or controlled in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the FSAR (as updated) or

(ii) Inconsistent with the analyses or descriptions in the FSAR (as updated).

(b) This section applies to:

(1) Each holder of a general or specific license issued under this part, and

(2) Each holder of a Certificate of Compliance (CoC) issued under this part.

(c)(1) A licensee or certificate holder may make changes in the facility or spent fuel storage cask design as described in the FSAR (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining either: (i) A license amendment pursuant to § 72.56 (for specific licensees) or (ii) A CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if:

(A) A change to the technical specifications incorporated in the specific license is not required; or

(B) A change in the terms, conditions, or specifications incorporated in the CoC is not required; and

(C) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

(2) A specific licensee shall obtain a license amendment pursuant to § 72.56, a certificate holder shall obtain a CoC amendment pursuant to § 72.244, and a general licensee shall request that the certificate holder obtain a CoC amendment pursuant to § 72.244, prior to implementing a proposed change, test, or experiment if the change, test, or experiment would:

(i) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the FSAR (as updated);

(ii) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a system, structure, or component (SSC) important to safety previously evaluated in the FSAR (as updated);

(iii) Result in more than a minimal increase in the consequences of an accident previously evaluated in the FSAR;

(iv) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the FSAR (as updated);

(v) Create a possibility for an accident of a different type than any previously evaluated in the FSAR (as updated);

(vi) Create a possibility for a malfunction of an SSC important to safety with a different result than any previously evaluated in the FSAR (as updated);

(vii) Result in a design basis limit for a fission product barrier being exceeded or altered as described in the FSAR (as updated); or

(viii) Result 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.

(3) In implementing this paragraph, the FSAR (as updated) is considered to include FSAR changes resulting from evaluations performed pursuant to this section and analyses performed pursuant to §§ 72.56 or 72.244 since the last update of the FSAR pursuant to § 72.70, or § 72.248 of this part.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(d)(1) The licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license or CoC amendment pursuant to paragraph (c)(2) of this section.

(2) The licensee and certificate holder shall submit, as specified in § 72.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the evaluation of each. A report shall be submitted at intervals not to exceed 24 months.

(3) The records of changes in the facility or spent fuel storage cask design shall be maintained until:

(i) Spent fuel is no longer stored in the facility or the spent fuel storage cask design is no longer being used, or

(ii) The Commission terminates the license or CoC issued pursuant to this part.

(4) The records of changes in procedures and of tests and experiments shall be maintained for a period of 5 years.

(5) The holder of a spent fuel storage cask design CoC, who permanently ceases operation, shall provide the records of changes to the new certificate holder or to the Commission, as appropriate, in accordance with § 72.234(d)(3).

(6)(i) A general licensee shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(ii) A specific licensee using a spent fuel storage cask design, approved pursuant to subpart L of this part, shall provide a copy of the record for any changes to a spent fuel storage cask design to the applicable certificate holder within 60 days of implementing the change.

(iii) A certificate holder shall provide a copy of the record for any changes to a spent fuel storage cask design to any general or specific licensee using the cask design within 60 days of implementing the change.

VALUE/IMPACT STATEMENT

A separate Value/Impact Statement was not prepared for this regulatory guide. The Value/Impact Statement that was prepared as part of the Regulatory Analysis for the rulemaking in May 1999 is still applicable. Copies of the Regulatory Analysis are available for inspection or copying for a fee in the NRC's Public Document Room at 11555 Rockville Pike, Rockville, MD, Washington, DC, as part of SECY-99-130, dated May 12, 1999. The PDR may be reached by telephone at (301)415-4737 or fax at (301)415-3548.

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