



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 3.XXX

(Draft was issued as DG-3020)

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 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

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>.

Regulatory guides are issued to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the NRC staff in its review of applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions different from those set out in the guides will be acceptable if they provide a basis for the findings requisite to the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Regulatory guides are issued in ten broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Single copies of regulatory guides (which may be reproduced) may be obtained free of charge by writing the Distribution Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to DISTRIBUTION@NRC.GOV. Electronic copies of this guide are available at NRC's home page at <WWW.NRC.GOV> in the Reference Library under Regulatory Guides. This guide is also in the Electronic Reading Room at NRC's home page, Accession Number ML003754825, along with other recently issued guides.

to clarify the requirements and to allow changes involving only “minimal increases” in probability or consequences to be made without prior NRC approval.

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.

The information collections contained in this 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 and CoC holders, 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. The letter from NEI, dated November 9, 2000, that forwarded the November 6, 2000, version of NEI 96-07, Appendix B also contained a list of the changes from the September 28, 2000, version.

In December 2000, the NRC issued for public comment Draft Regulatory Guide DG-3020, “GUIDANCE FOR IMPLEMENTATION OF 10 CFR 72.48, CHANGES, TESTS, AND EXPERIMENTS,” which endorsed Appendix B to NEI 96-07 with a number of clarifications. On January 22, 2001 NEI submitted proposed changes to Appendix B to NEI 96-07 to resolve the

Draft Regulatory Guide clarifications. On January 30, 2001 NEI submitted a revised final Appendix B to NEI 96-07, which was dated January 26, 2001.²

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 Revision 1 of NEI 96-07, which has been endorsed by the NRC in Regulatory Guide 1.187.

C. REGULATORY POSITION

1. APPENDIX B TO NEI 96-07

Appendix B, "Guidelines for 10 CFR 72.48 Evaluations,"² dated January 26, 2001, to NEI 96-07 provides methods that are acceptable to the NRC staff for complying with the provisions of 10 CFR 72.48.

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

For site-specific ISFSI licensees that obtain 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.

²Copies 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 ML010370087. 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>.

5. USE OF OTHER METHODS

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

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.

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 methods described in this guide 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 (as updated);

(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 as described in the FSAR (as updated) being exceeded or altered; 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.

ADAMS Accession Number of
RG-3.XXX: MLXXXXXXX

ADAMS Accession Number of
Appendix B to NEI 96-07:
ML010370087