

U.S. NUCLEAR REGULATORY COMMISSION

REGULATORY GUIDE 3.72, REVISION 1



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

A. INTRODUCTION

Purpose

This regulatory guide (RG) describes an approach that is acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) to meet the regulatory requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) 72.48, “Changes, tests, and experiments.” Specifically, this RG provides guidance for addressing changes under 10 CFR 72.48 that affect an independent spent fuel storage installation (ISFSI), a spent fuel storage cask design, or a monitored retrievable storage (MRS) facility.

Applicability

This RG applies to certificate of compliance (CoC) holders and specific and general licensees subject to 10 CFR Part 72, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste” (Ref. 1).

Applicable Regulations

- 10 CFR Part 72 provides requirements, procedures, and criteria for the issuance of licenses to receive, transfer, and possess power reactor spent fuel, power reactor-related greater-than-Class-C waste, and other radioactive materials associated with spent fuel storage in an ISFSI and the terms and conditions under which the Commission will issue these licenses. The regulations in this part also establish requirements, procedures, and criteria for the issuance of CoCs approving spent fuel storage cask designs.
 - 10 CFR 72.48 describes the process under which licensees and CoC holders may make changes to an ISFSI facility, a spent fuel storage cask design, or an MRS installation and to related procedures, as described in the final safety analysis report (FSAR) (as updated), and may conduct tests or experiments not described in the FSAR (as updated), without prior NRC approval.

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Electronic copies of this RG, previous versions of RGs, and other recently issued guides are available through the NRC’s public Web site in the NRC Library at <https://nrcweb.nrc.gov/reading-rm/doc-collections/reg-guides/>, under Document Collections, in Regulatory Guides. The RG is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession Number (No.) ML20220A185. The regulatory analysis may be found in ADAMS under Accession No. ML19269B764. The associated draft guide DG-3054 may be found in ADAMS under Accession No. ML19269B763, and the staff responses to the public comments on DG-3054 may be found under ADAMS Accession No. ML20220A183.

- 10 CFR 72.146, “Design control”, requires that licensees, CoC holders, and applicants for CoCs establish measures to ensure that the license or CoC application specifies the applicable regulatory requirements and design bases.

Related Guidance

- RG 1.187, “Guidance for Implementation of 10 CFR 50.59, “Changes, tests, and experiments” (Ref. 2), provides guidance on the process by which licensees, under certain conditions, may make changes to their facilities and procedures as described in the FSAR.
 - The NRC endorsed Nuclear Energy Institute (NEI) 96-07, “Guidelines for 10 CFR 50.59 Implementation,” Revision 1, issued November 2000 (Ref. 3), in RG 1.187.
 - RG 1.187 references NEI 96-07, Appendix B, “Guidelines for 10 CFR 72.48 Implementation,” dated March 5, 2001 (Ref. 4).

Purpose of Regulatory Guides

The NRC issues RGs to describe methods that are acceptable to the staff for implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses. Regulatory guides are not NRC regulations and compliance with them is not required. Methods and solutions that differ from those set forth in RGs are acceptable if supported by a basis for the issuance or continuance of a permit or license by the Commission.

Paperwork Reduction Act

This RG provides voluntary guidance for implementing the mandatory information collections in 10 CFR Part 72 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval number 3150-0132. Send comments regarding this information collection to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

B. DISCUSSION

Reason for Revision

This revision of RG 3.72 (Revision 1) endorses NEI 12-04, Revision 2, “Guidelines for 10 CFR 72.48 Implementation,” issued September 2018 (Ref. 5), with exceptions and clarifications. NEI 12-04, Revision 2, updated and revised NEI 96-07, Appendix B, with information based on ISFSI operating experience and the NRC’s inspection findings. In addition, this revision modifies the NRC’s guidance for departures from a method of evaluation (MOE) and the NRC’s approval of an MOE.

Background

The NRC amended its regulations in 10 CFR 72.48 and 10 CFR 50.59 (Ref. 6), “Changes, tests and experiments,” in 1999 (Ref. 7). These regulations address the authority of licensees for nuclear reactors and ISFSIs, and of certificate holders for spent fuel storage casks, to make changes to the facility or procedures, or to conduct tests or experiments, without prior NRC approval. The objectives of 10 CFR 72.48 are to ensure that ISFSI licensees and holders of CoCs (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 (as updated), and (2) obtain prior NRC approval for changes that meet specified criteria in 10 CFR 72.48(c)(2) having a potential impact upon the basis of the license or CoC.

The statement of considerations (SOC) for the final rule states that a departure from an MOE as described in the FSAR (as updated) used in establishing the design bases or in the safety analyses means (1) 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 (2) changing from a method described in the FSAR to another method unless that method has been approved by the NRC for the intended application.¹ The NRC defines the departure basics in 10 CFR 72.48(a)(2)(i) and (ii). The SOC states that “[a]pproval for intended application includes assuring that the approved method was approved for the type of analysis being conducted, generically approved for the type of facility using it, and that all terms and conditions for use of the method are satisfied.”² The guidance in NEI 12-04, Revision 2, clarifies, consistent with language in the SOC, that meeting all three factors is not required when determining whether an MOE was “approved for the intended application.” The SOC and the guidance provide a nonexhaustive list of factors that may be considered when making that determination.

Shortly following this rulemaking, NEI developed implementing guidance for ISFSIs in NEI 96-07, Appendix B. RG 3.72, Revision 0, issued March 2001 (Ref. 8), which endorsed NEI 96-07, Appendix B, with exceptions, provided guidance on the methods acceptable to the NRC staff for complying with the provisions of 10 CFR 72.48, including how to make changes to MOEs. With respect to MOEs, RG 3.72, Revision 0, limited MOEs “approved by NRC for the intended application” to the particular design being reviewed.

Subsequently, in August 2012, NEI submitted draft guidance for implementing a change control process, in accordance with 10 CFR 72.48, as NEI 12-04, Revision 0, issued August 2012 (Ref. 9). This RG endorses, with exceptions and clarifications, NEI 12-04, Revision 2. NEI 12-04, Revision 2, can be used to replace NEI 96-07, Appendix B.

1. Volume 64 of the *Federal Register* (FR), pages 53582-01 and 53598 (64 FR 53582-01, 53598), October 4, 1999 (Ref. 7).

2. 64 FR 53582-01, 53598, October 4, 1999, emphasis added (Ref. 7).

NEI 12-04, Revision 2, includes updates and revisions to NEI 96-07, which are based on operating experience and NRC lessons learned through inspections and enforcement. In addition, NEI 12-04, Revision 2, incorporates stakeholder input provided in a series of public meetings and in the NRC staff's written comments on both NEI 12-04, Revision 0, and NEI 12-04, Revision 1, issued September 2017 (Ref. 10). NEI 12-04, Revision 2, provides guidance for CoC holders and licensees in a separate document, rather than as an appendix to NEI 96-07. For the most part, a large portion of the current guidance in Appendix B to NEI 96-07 is unchanged in NEI 12-04, Revision 2. However, NEI has made some changes to the guidance on approvals and departures from MOEs under 10 CFR 72.48.

RG 3.72, Revision 1, provides guidance on which changes are permissible without prior NRC review and approval. Revision 1 increases regulatory effectiveness and efficiency by clarifying the NRC's licensing and oversight activities, bringing consistency to the guidance for implementing 10 CFR 72.48 and 10 CFR 50.59, and potentially reducing the number of amendment requests from specific licensees and certificate holders, with no reduction in safety.

NEI 12-04, Revision 2, states "approved by NRC for the intended application," including approval for the type of analysis being conducted across cask systems and amendments for a single vendor-design authority. Accordingly, when the NRC approves a CoC application or amendment that describes and analyzes an MOE in the FSAR (as updated), the NRC is approving the MOE. The approval of an MOE may be used to support the use of that MOE in another cask system in a separate licensing action if the MOE is used for the same type of analysis and is within a single vendor-design authority.

The guidance in NEI 12-04, Revision 2, includes guidance on MOEs, which is consistent with NEI 96-07, Revision 1, the current guidance for 10 CFR 50.59 changes for operating reactors. The NRC endorsed NEI 96-07, Revision 1, in RG 1.187. Specifically, the NRC's review and approval of a licensing action, documented in a safety evaluation report (SER), includes the review and approval of the MOEs for the intended application. The NRC's approval of a specific licensing action or method is not a generic approval for the use of the MOE by all licensees or CoC holders in making 10 CFR 72.48 changes. Licensees under 10 CFR Part 72 and CoC holders may extend the use of a previously approved MOE to other certificates when they (1) are the authorized design authority *and* (2) the NRC has approved the MOE for the intended application, provided the conditions and the limitations associated with the MOE are met.

The NRC has determined that this guidance is one acceptable way of meeting the requirements in 10 CFR 72.48 because it continues to ensure adequate protection of public health and safety. Licensees and certificate holders continue to be responsible for evaluating whether a proposed change constitutes a departure from an MOE under 10 CFR 72.48(a)(2) and whether the change is permissible without prior approval by the NRC under 10 CFR 72.48(c). Additionally, 10 CFR 72.48(d)(2) requires the specific licensee or certificate holder making changes to submit a report summarizing the changes, tests, and experiments, and the evaluation performed for each, at intervals not to exceed 24 months. Through its oversight function, the NRC may inspect the licensee's or certificate holder's evaluation.

Harmonization with International Standards

The NRC has a goal of harmonizing its regulatory guides with documents issued by the International Atomic Energy Agency (IAEA) to the extent practical. The NRC staff has reviewed the IAEA standards and guides and did not identify any documents with relevant information related to the topics in this RG.

Documents Discussed in Staff Regulatory Guidance

This RG endorses the use of one or more codes or standards developed by external organizations, and other third party guidance documents. These codes, standards and third party guidance documents may contain references to other codes, standards or third party guidance documents (“secondary references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a requirement, then licensees and applicants must comply with that standard as set forth in the regulation. If the secondary reference has been endorsed in a RG as an acceptable approach for meeting an NRC requirement, then the standard constitutes a method acceptable to the NRC staff for meeting that regulatory requirement as described in the specific RG. If the secondary reference has neither been incorporated by reference into NRC regulations nor endorsed in a RG, then the secondary reference is neither a legally-binding requirement nor a “generic” NRC approved acceptable approach for meeting an NRC requirement. However, licensees and applicants may consider and use the information in the secondary reference, if appropriately justified, consistent with current regulatory practice, and consistent with applicable NRC requirements.

C. STAFF REGULATORY GUIDANCE

The NRC staff endorses NEI 12-04, Revision 2, as generally acceptable for use in complying with the requirements in 10 CFR 72.48. However, the NRC staff provides exceptions and clarifications to specific statements in NEI 12-04, Revision 2, as described below.

1. NEI 12-04, Revision 2, Section 6.8, provides the following as one of several examples of changes that “are not considered departures from a method of evaluation”:

Use of a methodology revision that is documented as providing results that are essentially the same as or more conservative than either the previous revision of the same methodology or with another methodology previously accepted by NRC through issuance of an SER.

Exception—The regulation allows licensees to document a methodology revision either (1) as a change to any of the elements of the methodology described in the FSAR (as updated) (i.e., 10 CFR 72.48(a)(2)(i) of the departure definition), *or* (2) as a change from the methodology described in the FSAR (as updated) to another method (i.e., 10 CFR 72.48(a)(2)(ii) of the departure definition). If a methodology revision is documented as a change from the methodology described in the FSAR to another method using 10 CFR 72.48(a)(2)(ii) of the departure definition, then 10 CFR 72.48(a)(2)(i) of the departure definition (i.e., “the results of the analysis are conservative or essentially the same”) is not applicable.

2. NEI 12-04, Revision 2, Section 6.5, states, in part, the following:

Certain accidents are not discussed in the UFSAR because their effects are bounded by other related events that are analyzed. For example, a postulated cask drop of a certain distance may not be specifically evaluated in the UFSAR because it has been determined to be less limiting than the evaluated cask drop. Therefore, if a proposed design change would introduce a cask drop of a distance less than the evaluated cask drop, the postulated cask drop need not be considered an accident of a different type.

The last sentence of Section 6.5 of NEI 12-04, Revision 2, states: “The types of credible accidents that the proposed activity could create that are not bounded by UFSAR-evaluated accidents are accidents of a different type.”

Exception—An accident of a different type is any new accident, distinct from any previously evaluated in the updated final safety analysis report (UFSAR) but of similar frequency and significance. A different accident analysis, not simply a revision of an existing analysis, would be needed for this different type of accident.

3. NEI 12-04, Revision 2, Section 6.8.1, as it relates to uncertainty in method of evaluation.

Regarding the use of uncertainty in evaluation methods, NEI 12-04, Revision 2, Section 6.8.1, provides language that addresses the use of uncertainty as an element of a method when documenting a change under 10 CFR 72.48.

Clarification—The statement on uncertainty in Section 6.8.1 of NEI 12-04, Revision 2, could limit the use of uncertainty in an MOE to be considered only as an element. The NRC staff’s

position is that uncertainty in an MOE could either be an element or an input parameter, depending on the circumstances of specified factors to account for uncertainty in measurements or data. The NRC staff also notes that in some situations, an input parameter in an MOE can be considered an element of an MOE, if it meets the criteria for an input parameter being an element of an MOE. Sections 2.15 and 2.17 of NEI 12-04, Revision 2, provide additional guidance on those particular circumstances.

4. NEI 12-04, Revision 2, Section 3.1.5.2, states the following:

Licensees and CoC holders are required to report certain defects or deficiencies in any spent fuel storage structure, system, or component to the NRC in accordance with the reporting requirements in 10 CFR 72.75, and 10 CFR 21.

Clarification—Section 3.1.5.2 of NEI 12-04, Revision 2, does not include all applicable reporting requirements for CoC holders. The NRC’s regulations at 10 CFR 72.242(d) also require that CoC holders submit a written report to the NRC within 30 days of the discovery of a design or fabrication deficiency in any spent fuel storage cask that has been delivered to a licensee if the design or fabrication deficiency affects the ability of structures, systems, and components important to safety to perform their intended safety function.

5. Guidance for FSAR supplements for license renewal.

Clarification—The guidance in NEI 12-04 and RG 3.72 is applicable to information added to the FSAR (as updated) and submitted as part of ISFSI license renewals, in accordance with 10 CFR 72.42(a) and 10 CFR 72.240(c). The summary descriptions of the aging management programs, activities for managing the effects of aging, and the evaluation of time-limited aging analyses in the UFSAR that supports the bases for renewals of specific licenses and CoCs.

D. IMPLEMENTATION

The NRC staff may use this regulatory guide as a reference in its regulatory processes, such as licensing, inspection, or enforcement. However, the NRC staff does not intend to use the guidance in this regulatory guide to support NRC staff actions in a manner that would constitute backfitting as that term is defined in 10 CFR 72.62, “Backfitting,” and as described in NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests” (Ref. 11). The staff also does not intend to use the guidance to support NRC staff actions in a manner that constitutes forward fitting as that term is defined and described in Management Directive 8.4.

The backfitting and forward fitting considerations in 10 CFR 72.62 and NRC Management Directive 8.4 apply to holders of general and specific licenses for ISFSIs and MRSs issued under 10 CFR Part 72. However, the backfitting and forward fitting considerations in 10 CFR 72.62 and NRC Management Directive 8.4 do not apply to CoC holders. If a licensee believes that the NRC is using this regulatory guide in a manner inconsistent with the discussion in this Implementation section, then the licensee may file a backfitting or forward fitting appeal with the NRC in accordance with the process in Management Directive 8.4.

REFERENCES³

1. *U.S. Code of Federal Regulations*, “Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste,” Part 72, Chapter 1, Title 10, “Energy” (10 CFR Part 72).
2. U.S. Nuclear Regulatory Commission, Regulatory Guide 1.187, “Guidance for Implementation of 10 CFR 50.59, Changes, tests, and experiments.”
3. Nuclear Energy Institute, “Guidelines for 10 CFR 50.59 Implementation,” NEI 96-07, Revision 1, Washington, DC, November 2000, ADAMS Accession No. ML003771157.
4. Nuclear Energy Institute, “Guidelines for 10 CFR 72.48 Implementation,” Appendix B to NEI 96-07, Washington, DC, March 5, 2001, ADAMS Accession No. ML010670023.⁴
5. Nuclear Energy Institute, “Guidelines for 10 CFR 72.48 Implementation,” NEI 12-04, Revision 2, Washington, DC, September 2018, ADAMS Accession No. ML18250A255.
6. *U.S. Code of Federal Regulations*, “Domestic Licensing of Production and Utilization Facilities,” Part 50, Chapter 1, Title 10, “Energy” (10 CFR Part 50).
7. U.S. Nuclear Regulatory Commission, “10 CFR Parts 50 and 72, Changes, Tests, and Experiments, Final Rule,” *Federal Register*, Vol. 64, No. October 4, 1999, p. 53582-01.⁵
8. U.S. Nuclear Regulatory Commission, Regulatory Guide 3.72, Revision 0, “Guidance for Implementation of 10 CFR 72.48, Changes, tests, and experiments,” March 2001, ADAMS Accession No. ML010710153.
9. Nuclear Energy Institute, “Guidelines for 10 CFR 72.48 Implementation,” NEI 12-04, Revision 0, Washington, DC, August 2012, ADAMS Accession No. ML12258A356.
10. Nuclear Energy Institute, “Guidelines for 10 CFR 72.48 Implementation,” NEI 12-04, Revision 1, Washington, DC, September 2017, ADAMS Accession No. ML17249A095.
11. NRC Management Directive 8.4, “Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,” Washington, DC.

3 Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD 20852. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail pdr.resource@nrc.gov.

4 Publications from the Nuclear Energy Institute (NEI) are available at its Web site: <http://www.nei.org/> or by contacting the headquarters at Nuclear Energy Institute, 1776 I Street, NW, Washington DC 20006-3708, telephone 202-739-800, fax 202-785-4019.

5 Printed copies of *Federal Register* notices are available for a fee from the U.S. Government Publishing Office, 732 N. Capitol Street, NW, Washington, DC 20401, telephone 866-521-1800, or they may be downloaded for free from the Government Publishing Office Web site: <http://www.gpo.gov/fdsys/>.

BIBLIOGRAPHY

The following documents are listed to provide additional general reference information on issues related to 10 CFR 72.48.

NRC Guidance

NRC, “Computational Fluid Dynamics Best Practices Guidelines for Dry Cask Applications,” NUREG-2152, Washington, DC, March 2013. (ADAMS Accession No. ML13086A202)

NRC, Information Notice (IN) 2000-11, “Licensee Responsibility for Quality Assurance Oversight of Contractor Activities Regarding Fabrication and Use of Spent Fuel Storage Cask Systems,” Washington, DC, August 7, 2000. (ADAMS Accession No. ML003734271)

NRC, IN 2011-10, “Thermal Issues Identified During Loading of Spent Fuel Storage Casks,” Washington, DC, May 2, 2011. (ADAMS Accession No. ML111090200)

NRC, IN 2014-09, “Spent Fuel Storage or Transportation System Misloading,” Washington, DC, June 20, 2014. (ADAMS Accession No. ML14121A469)

NRC, IN 2015-03, “Improper Operation of Spent Fuel Transfer Cask Neutron Shield Equipment Leading to Elevated Radiation Levels Adjacent to Spent Fuel Transfer Cask,” Washington, DC, February 9, 2015. (ADAMS Accession No. ML14213A477)

NRC, Regulatory Issue Summary (RIS) 2001-03, “Changes, Tests, and Experiments,” Washington, DC, January 23, 2001. (ADAMS Accession No. ML010040446)

NRC, RIS 2004-20, “Lessons Learned from Review of 10 CFR Parts 71 and 72 Applications,” Washington, DC, December 16, 2004. (ADAMS Accession No. ML043510074)

NRC, RIS 2006-22, “Lessons Learned from Recent 10 CFR Part 72 Dry Cask Storage Campaign,” Washington, DC, November 15, 2006. (ADAMS Accession No. ML062930034)

NRC, RIS 2007-09, “Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications,” Washington, DC, May 4, 2007. (ADAMS Accession No. ML062550133)

NRC, RIS 2012-05, “Clarifying the Relationship Between 10 CFR 72.212 and 10 CFR 72.48 Evaluations,” Washington, DC, April 20, 2012. (ADAMS Accession No. ML113050537)

NRC, RIS 2015-13, “Seismic Stability Analysis Methodologies for Spent Fuel Dry Cask Loading Stack-Up Configuration,” Washington, DC, November 12, 2015. (ADAMS Accession No. ML15132A122)

NRC, RIS 2016-03, “10 CFR 50.59 Issues Identified in NRC’s San Onofre Steam Generator Tube Degradation Lessons Learned Report,” Washington, DC, April 13, 2016. (ADAMS Accession No. ML15196A575)

NRC, Inspection Manual Chapter 2690, “Inspection Program for Dry Storage of Spent Reactor Fuel at Independent Spent Fuel Storage Installations and for 10 CFR Part 71 Transportation Packagings,” Washington, DC, March 9, 2012. (ADAMS Accession No. ML120390415)

NRC, Inspection Manual, Inspection Procedure 60857, “Review of 10 CFR 72.48 Evaluations,” Washington, DC, October 24, 2007. (ADAMS Accession No. ML072681099)

NRC, Spent Fuel Project Office Interim Staff Guidance-21, “Use of Computational Modeling Software,” Washington, DC, April 5, 2006. (ADAMS Accession No. ML061080669)

Other Guidance

American Society of Mechanical Engineers, Standard V&V 20, “Standard for Verification and Validation in Computational Fluid Dynamics and Heat Transfer,” New York, NY, 2009.⁶

⁶ Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Two Park Avenue, New York, New York 10016-5990; telephone (800) 843-2763. Purchase information is available through the ASME Web-based store at <http://www.asme.org/Codes/Publications/>.