



NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC-2025-0064]

Interim Enforcement Policy for Enforcement Discretion for General Licensee

Adoption of Certificate of Compliance Holder-Generated Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed policy revision; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comments a proposed Interim Enforcement Policy (IEP) titled, “Enforcement Discretion for General Licensee Adoption of CoC Holder-Generated Changes.” This proposed IEP would allow enforcement discretion for certain general licensee violations related to their adoption of a change generated by the Certificate of Compliance holder.

DATES: Submit comments by **[INSERT DATE 21 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the **Federal Rulemaking Website**:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0064. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- **Email comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time (ET), Federal workdays; telephone: 301-415-1677.

You can read a plain language description of this proposed rule at <https://www.regulations.gov/docket/NRC-2025-0064>. For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gerond A. George, Office of Nuclear Material Safety and Safeguards, telephone: 301-415-3882, email: Gerond.George@nrc.gov, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2025-0064 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2025-0064.
- **NRC’s Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please

contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. ET, Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the **Federal Rulemaking Website** (<https://www.regulations.gov>). Please include Docket ID NRC-2025-0064 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

The Certificate of Compliance (CoC or certificate) is the NRC approved design for each dry cask storage system. Section 72.48 of title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, tests, and experiments," establishes the conditions under which an Independent Spent Fuel Storage Installation (ISFSI) licensee, a

monitored retrievable storage installation (MRS) licensee, a general or specific licensee, or a spent fuel storage cask certificate holder may make changes to the ISFSI facility, MRS, spent fuel storage cask design, or procedures, and under which they may conduct tests or experiments, without prior NRC approval. In addition to the 10 CFR 72.48 change review process, paragraph (b)(7) of 10 CFR 72.212, "Conditions of general license issued under § 72.210," also requires the general licensee to evaluate any changes to written evaluations required by paragraphs (b)(5) and (6) of 10 CFR 72.212, using the requirements of 10 CFR 72.48(c). Moreover, there are various provisions in 10 CFR 72.212, such as paragraphs (a)(2), (b)(3), (b)(5)(i), and (b)(11), that require general licensees to ensure they use casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214.

Therefore, if a general licensee wishes to adopt a change initiated by the CoC holder under the CoC holder's 10 CFR 72.48 change authority, then a general licensee must perform a separate 10 CFR 72.48 review as required by the regulations. Additionally, if a general licensee adopts a CoC holder's change made under 10 CFR 72.48 and that change is later determined to be non-compliant, the general licensee would also be in noncompliance with provisions of 10 CFR 72.48 and 72.212.

The NRC seeks to implement a more efficient process in which the staff addresses CoC holders' apparent violations of the 10 CFR 72.48 change control process without pursuing an enforcement action against the general licensee for an apparent violation that is strictly due to the general licensee's adoption of a non-compliant change made under § 72.48 by the CoC holder. The NRC also seeks to implement a more efficient process for general licensees to review and adopt changes made by a CoC holder, pursuant to the CoC holder's § 72.48 change authority, as long as the general licensee does not need to make any site-specific technical changes. Accordingly, the staff is considering rulemaking, including potential interpretation of the applicable regulations, and revision of the implementation guidance.

III. Discussion

A. Rulemaking

The NRC published a final rule on October 4, 1999 (64 FR 53582), that revised 10 CFR 72.48 to clarify the specific types of changes, tests, and experiments conducted at a licensed facility or by a certificate holder that require evaluation, and revised the criteria that licensees and certificate holders must use to determine when NRC approval is needed before such changes, tests, or experiments can be implemented. The Commission approved the publication of the final rule in SECY-99-130, “Final Rule—Revisions to Requirements of 10 CFR Parts 50 and 72 Concerning Changes, Tests, and Experiments.”

The preamble to the final rule for 10 CFR 50.59 and 72.48 stated the following in Section O.1, “Part 72 Changes,” provided on page 53601: “The Commission envisioned that a general licensee who wants to adopt a change to the design of a spent fuel storage cask it possesses—which change was previously made to the generic design by the certificate holder under the provisions of § 72.48—would be required to perform a separate evaluation under the provisions of § 72.48 to determine the suitability of the change for itself.” As indicated by the rule and supported by the preamble, both the CoC holder and general licensee are required to perform an evaluation when implementing a change made by a CoC holder pursuant to § 72.48.

The NRC staff may request that the Commission revise its regulations or interpretation of existing regulations to establish that CoC holders and general licensees have different obligations. The NRC staff may seek this change because both entities have separate quality assurance programs, and the NRC staff performs inspections of each change control process on a regular basis, which would provide reasonable assurance of safety and increase regulatory efficiency. Specifically, the efficiency will be realized by streamlining the inspections associated with the evaluation of the changes to occur for (1) CoC holders and (2) general licensees only if additional changes are made.

B. Summary

This IEP would allow staff to exercise enforcement discretion for certain general licensee violations of 10 CFR 72.48 and 72.212 related to the general licensee's adoption of a CoC holder generated modification. This proposed IEP would allow for better efficiency and reliability of spent fuel storage cask inspection oversight, while still providing adequate protection of public health and safety. The staff is proposing this IEP due to the NRC's operational experience with its inspection and oversight of general licensees' adoption of CoC holders' § 72.48 changes. Certificate holders are NRC-regulated entities that are required to 1) ensure their storage casks meet NRC requirements and the Certificate of Compliance and 2) perform design changes in accordance with § 72.48; the NRC inspects their processes. In addition, the staff recognizes that a general licensee who wants to adopt a change to the design of a spent fuel storage cask it possesses—where the change was previously made by the certificate holder under the provisions of § 72.48—must perform a review of that change for their site under a variety of other processes in addition to § 72.48, including those set forth in paragraphs (b)(5) and (6) of § 72.212, and in the general licensee quality assurance program. The combination of these review and oversight processes, together with other existing inspection and oversight processes, provide confidence that the general licensee has appropriately considered changes made by CoC holders and appropriately evaluated the potential safety implications of implementing those changes at its site. For these reasons, the staff determined that this proposed IEP continues to provide adequate protection of public health and safety while enabling the safe and secure use of civilian nuclear energy technologies. The staff believes this approach also aligns with the NRC's new mission statement and the Principles of Good Regulation.

The NRC staff plans to review the regulations in 10 CFR part 72 and guidance documents to determine if the NRC staff needs to consider rulemaking, including potential interpretation of the applicable regulations, and/or revising guidance to clarify the requirements in 10 CFR part 72.

IV. Paperwork Reduction Act

This proposed policy statement does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing collections of information were approved by the Office of Management and Budget (OMB), approval numbers 3150-0132 and 3150-0136.

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.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

DOCUMENT	ADAMS Accession No. / Federal Register Citation
Final Rule: "Changes, Tests, and Experiments," October 4, 1999.	64 FR 53582
SECY-99-130, "Revisions to Requirements of 10 CFR Parts 50 and 72 Concerning Changes, Tests, and Experiments," May 12, 1999.	ML992810140
Staff Requirements Affirmation Session, June 22, 1999.	ML003751724
NEI 12-04, "Guidelines for 10 CFR 72.48 Implementation," Revision 2, September 2018.	ML18250A255
Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, Changes, Tests, and Experiments," Revision 1, September 2020.	ML20220A185
NRC Enforcement Policy, August 23, 2024.	ML24205A249
Principles of Good Regulation, April 6, 1990.	ML15083A026

The text of the Interim Enforcement Policy is attached.

Dated at Rockville, Maryland, this 1st day of April 2025.

For the Nuclear Regulatory Commission.

David Pelton,
Director,
Office of Enforcement.

**Proposed Interim Enforcement Policy—Section 9.X, Enforcement Discretion for
General Licensee Adoption of CoC Holder-Generated Changes under
10 CFR 72.48**

9.X Enforcement Discretion for General Licensee Adoption of Certificate of
Compliance Holder-Generated Changes under 10 CFR 72.48

This section sets forth the Interim Enforcement Policy (IEP) that the NRC will use to exercise discretion for the disposition of violations involving a General Licensee's (GL's) adoption of a Certificate of Compliance (CoC) holder-generated change made under the CoC holder's change authority of Section 72.48 of title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, tests, and experiments." The current NRC regulations state:

- 10 CFR 72.212, in a number of regulatory provisions, such as 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), and 72.212(b)(11), requires a GL to ensure it uses casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214.
- 10 CFR 72.212(b)(5) requires that the GL, before use and before applying changes authorized by an amended CoC to a cask loaded under the initial CoC or an earlier amended CoC, perform written evaluations to establish that the storage cask, once loaded, will conform to terms and conditions of the CoC.
- 10 CFR 72.212(b)(6) requires that the GL review, and document the review of, the Safety Analysis Report referenced in the CoC or amended CoC and the related NRC

Safety Evaluation Report, to determine whether or not the reactor site parameters are enveloped by the cask design bases considered in these reports.

- 10 CFR 72.212(b)(7) requires the GL to evaluate any changes to written evaluations required by paragraphs (b)(5) and (6) of 10 CFR 72.212, using the requirements of 10 CFR 72.48(c).

- 10 CFR 72.48, as published on October 4, 1999 (64 FR 53582) and amended on February 26, 2001 (66 FR 11527), has provisions under which general and specific licensees and CoC holders may make changes to the facility or spent fuel storage cask design as described in the Final Safety Analysis Report without obtaining NRC review and approval. *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.

Under the current NRC regulations, if a GL chooses to adopt a change the CoC holder made pursuant to a CoC holder's change authority under 10 CFR 72.48 (referred to herein as a "CoC holder-generated change"), a GL must perform a separate review using the requirements of 10 CFR 72.48(c). This is in addition to the requirement that the GL evaluate any additional resulting site-specific, technical changes the GL makes to written evaluations required by paragraphs (b)(5) and (6) of 10 CFR 72.212 using the requirements of 10 CFR 72.48(c), when adopting the CoC holder's change. Further, the GL is required, by various provisions of 10 CFR 72.212, to only use casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214.

Accordingly, when a GL chooses to adopt a CoC holder-generated change, and that change results in a non-conforming cask, there is a violation of 10 CFR 72.48 and certain provisions of 10 CFR 72.212 by the GL, in addition to a CoC holder violation of 10 CFR 72.48. And, when a GL chooses to adopt a CoC holder-generated change

without performing a separate 10 CFR 72.48 analysis, the GL is in violation of 10 CFR 72.48.

These requirements have led to enforcement actions issued against both the GL's 10 CFR 72.48 program (as well as certain 10 CFR 72.212 violations) and CoC holder's 10 CFR 72.48 program for changes that originated with the CoC holder. The NRC has concluded that this enforcement approach is inconsistent with efficiency, which is one of the NRC's Principles of Good Regulation, and NRC's mission of efficient and reliable oversight.

The NRC staff will review the regulations in 10 CFR Part 72 and guidance documents to determine what changes are needed to focus requirements on the entity that initiated the change. Until such time as regulatory changes are developed, the Interim Enforcement Policy will be:

(1) The NRC will exercise enforcement discretion and not issue an enforcement action to a GL, for a noncompliance with the requirements of paragraphs (c)(1) and (2) and (d)(1) of 10 CFR 72.48 and with provisions of 10 CFR 72.212 that require GLs to ensure use of casks that conform to the terms, conditions and specifications of a CoC listed in 10 CFR 72.214, when the noncompliance results from a CoC holder's failure to comply with 10 CFR 72.48 for a CoC holder-generated change. In granting this discretion, the GL will be expected to come into compliance with the 72.212 provisions that require each cask to conform to the terms, conditions, and specifications of a CoC or an amended CoC listed in § 72.214 using established processes. The NRC staff will monitor the GL's actions to determine if additional regulatory actions will be necessary.

(2) The NRC will exercise enforcement discretion and not issue an enforcement action to the GL for failure to perform a 10 CFR 72.48 screening and/or evaluation when

the GL adopts a CoC holder-generated change that does not result in the GL making a change to the site-specific, technical aspects of the GL's 10 CFR 72.212 report.

(3) When the GL adopts a CoC holder-generated change and the accompanying 10 CFR 72.48 screening and/or evaluation that was performed by the CoC holder, the GL does not have to perform a separate 10 CFR 72.48 evaluation of CoC holder-generated changes. The GL only needs to review the CoC holder's change for applicability to their spent fuel storage cask and for impact on the site-specific, technical evaluations and analyses described in the 10 CFR 72.212 report, and site programs and procedures. The NRC's inspections of the GL and enforcement actions against the GL will focus on the GL's assessment for the site-specific applicability of the CoC holder-generated change to its spent fuel storage cask.

(4) The GL is responsible for performing written evaluations to establish that the storage cask conforms to terms and conditions of the CoC, in accordance with paragraphs (b)(5) and (6) of 10 CFR 72.212. If the GL chooses to adopt a CoC holder-generated change, the GL does not need to follow the requirements of 10 CFR 72.212(b)(7) unless the GL determines that GL-initiated site-specific, technical changes are needed to the GL's written evaluations required by paragraphs (b)(5) and (b)(6) of 10 CFR 72.212. Additionally, the GL is responsible for ensuring compliance with applicable requirements of Appendix B to 10 CFR Part 50, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and Subpart G to 10 CFR Part 72, "Quality Assurance."

(5) NRC enforcement actions will focus on the entity that initiated the change. The CoC holder will be accountable for a noncompliance identified within CoC holder-generated 10 CFR 72.48 screenings and/or evaluations of a change made pursuant to

the CoC holder's 10 CFR 72.48 change authority. The GL will be accountable for any noncompliance identified within GL-initiated changes.

An enforcement panel is not required to disposition a noncompliance using this discretion; however, each time discretion is granted, an enforcement action number will be assigned to document the use of discretion under this IEP.

This IEP will remain in place until the underlying regulatory issue is dispositioned through rulemaking or other regulatory action.

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