
INSPECTION PROCEDURE 60857 APPENDIX A

INSPECTION GUIDANCE FOR IMPLEMENTATION OF INTERIM ENFORCEMENT POLICY 9.4, ENFORCEMENT DISCRETION FOR GENERAL LICENSEE ADOPTION OF CERTIFICATE OF COMPLIANCE HOLDER-GENERATED CHANGES UNDER TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* SECTION 72.48

Effective Date: 11/20/2025

PROGRAM APPLICABILITY: IMC 2690

60857.01-01 INSPECTION OBJECTIVE

01.01 Determine whether the Interim Enforcement Policy (IEP) 9.4, "Enforcement Discretion for General Licensee Adoption of Certificate of Compliance (CoC) Holder Generated Changes under 10 CFR 72.48," applies to general licensees (GLs) in order to provide enforcement discretion for the disposition of certain violations involving a GL's adoption of a CoC holder-generated change made under the change authority of Section 72.48 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, tests, and experiments."

60857.01-02 BACKGROUND

The U.S. Nuclear Regulatory Commission (NRC) published a final rule on October 4, 1999 (64 FR 53582), that revised 10 CFR 72.48 to conform with those made to 10 CFR 50.59 and expanded the scope of 10 CFR 72.48 to CoC holders. 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." Prior to this rule change, the Commission had only allowed GLs the authority to make design changes to their independent spent fuel storage installation facility, the spent fuel storage cask design in use at the site, their site procedures, and conduct tests or experiments without seeking prior NRC approval, if the proposed activities satisfied the criteria described in the rule.

When the NRC added the CoC holders, the Commission envisioned that if a GL wanted to adopt a change to the design of a spent fuel storage cask that it possessed and the change was made to the generic design by the CoC holder under the provisions of 10 CFR 72.48, then the GL would be required to perform a separate evaluation under the provisions of 10 CFR 72.48 to determine the suitability of the change for their facility. Additionally, the Commission revised the provisions in 10 CFR 72.212(b) to require that the GL evaluate any changes made to the written evaluations described in 10 CFR 72.212 by using the requirements of 10 CFR 72.48. The NRC also endorsed industry guidance, as part of implementing the new revised rule, with additional provisions.

The NRC staff recognized after over 20 years of lessons-learned and operating experience that additional clarifying guidance and potential changes or interpretation of the rule may be needed regarding GLs adopting CoC holders generated changes to the generic design. The NRC may

make changes to guidance or seek changes to interpretation of the rule since both entities have separate quality assurance programs, and the NRC staff perform inspections of each change control process on a regular basis, which provides reasonable assurance of safety and increase regulatory efficiency. Specifically, efficiency will be realized by streamlining the inspections associated with the evaluation of the changes to focus on (1) CoC holders and (2) GLs, only to the extent when a GL adopts a generic design that may also need a site-specific, technical change. The NRC wanted to provide a consistent approach in applying enforcement actions when the inspection staff identifies apparent violations of 10 CFR 72.48 that may impact both the CoC holder and the GLs. However, prior to the NRC staff developing these regulatory changes, the inspection staff expects to use the IEP 9.4 to resolve inspection related issues when GLs adopt generic design changes generated by the CoC holders.

60857.01-03 INSPECTION REQUIREMENTS

As described in the IEP 9.4, the NRC will exercise enforcement discretion and not issue an enforcement action to a GL, for a noncompliance, pursuant to 10 CFR 72.48, paragraphs (c)(1), (c)(2), and (d)(1), and certain provisions of 72.212, that resulted in a failure of the CoC holder to comply with 10 CFR 72.48 regulations when the CoC holder makes a generic change and no site-specific technical changes were made to the GL's 10 CFR 72.212 evaluation report. Below are pertinent IEP Conditions to be met when exercising enforcement discretion.

03.01 IEP Conditions

- a. 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 10 CFR 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, after the NRC disposition of the noncompliance for a CoC holder-generated change. The NRC staff will monitor GLs actions to determine if additional regulatory actions are necessary.
- b. 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. Enforcement discretion does not apply to CoC holder-generated changes that result in the GL making a change to the site-specific, technical aspects of the GL's 10 CFR 72.212 report.
- c. When a 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 for impact on their 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 of the site-specific applicability for the CoC holder-generated change to its spent fuel storage cask.

- d. 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 (b)(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 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 the applicable Quality Assurance Program as described in 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". The GL is responsible for ensuring compliance with 10 CFR 72.48 when making GL-initiated changes.
- e. The 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 either with GL-initiated changes made under 10 CFR 72.48 or with any site-specific, technical changes required by paragraphs (b)(5) and (b)(6) of 10 CFR 72.212.

03.02 Enforcement Process

As stated in IEP 9.4, an enforcement panel will not be necessary to resolve a noncompliance using the discretion provided in IEP 9.4. However, each time the staff grants discretion, the staff will assign an enforcement action number to the inspection report in accordance with applicable processes and procedures. This will include coordination with the appropriate enforcement staff (see Section 60857.01-05).

60857.01-04 INSPECTION GUIDANCE

04.01 General Guidance

This IP provides inspector guidance in implementing IEP 9.4. For inspection planning, the inspection staff should review previous inspection reports and enforcement actions (Reactor Program System or Allegations, Resolution, Investigation, and Enforcement System) related to 10 CFR 72.48 violations, as necessary.

04.02 Specific Guidance

When the inspection staff identifies a noncompliance after performing a review of a CoC holder change or when the GL adopts a CoC holder-generated change and the inspection staff determines that the accompanying 10 CFR 72.48 screening and/or evaluation is in violation of the 10 CFR 72.48 provisions then the inspection staff should review the IEP conditions for applicability.

If the inspection staff determines that the IEP conditions may be applicable to a noncompliance identified during ongoing inspection activities, the inspection staff should initiate a counterpart call with the applicable staff in the program office and subject matter experts to discuss the IEP conditions and the noncompliance identified. The purpose of this call is to determine a path forward and to gather sufficient information to assist the inspection staff with applying IEP conditions for the GL users, and to

determine if additional oversight of the CoC holder is necessary. During the call, the inspection staff should discuss the identified noncompliance including the extent of condition, initial safety significance assessment, the bases for the determination, what IEP condition applies, and if possible, discuss any proposed resolutions.

The extent of condition review should identify whether this is an isolated condition or whether the noncompliance impacts multiple sites. The inspection staff should consider the safety significance of the noncompliance to support prioritization and potential follow-up actions for the proposed resolution. The inspection staff should discuss options that include but are not limited to the following: (1) An option to perform a problem identification and resolution inspection sample, as part of a vendor inspection; or (2) perform a supplemental or reactive inspection in accordance with Inspection Manual Chapter 2690.

If it is determined that enforcement discretion is not warranted per IEP 9.4, then the inspection staff should close the inspection activity using the normal process. The inspection staff should determine what follow-up action, if any, is necessary as a part of the inspection closeout.

If it is determined that enforcement discretion is warranted per IEP 9.4, then the inspector should document the use of enforcement discretion in the inspection report as described in Section 60857.01-05. The inspection staff should determine what follow-up action, if any, is necessary as a part of the inspection closeout.

On a case-by-case basis, if a previously identified noncompliance that has not been resolved and falls within the scope of this IEP, then the inspection staff should consider using the guidance provided in IEP 9.4 to disposition the noncompliance.

The program office inspection staff should consider issuing generic communication (i.e., Information Notice) after documentation of the generic issues that are given enforcement discretion using IEP 9.4. Based on the CoC holder's and GL's quality assurance programs, the inspection staff should expect that the CoC holders and the GLs will communicate the noncompliance to other stakeholders and take appropriate corrective actions, as applicable. The inspection staff may monitor these actions to determine if additional regulatory actions are deemed necessary.

60857.01-05 REPORTING REQUIREMENTS

The inspection staff should provide the draft inspection report to the program office inspection staff prior to completing the final enforcement action to ensure consistent application of the IEP 9.4 and the reporting requirements related to these inspection activities.

05.01 Documentation Requirements

The inspection staff should use existing inspection documentation guidance to document the use of the enforcement discretion.

When the decision is made to use enforcement discretion related to a CoC holder generated generic design change, the case should be tracked under an enforcement action number (EA#) from NMSS (EA-NMSS-XXXX-XXXX). For example, the format should be as follows: EA-NMSS-2024-0001.

Under that EA#, an enforcement action facility number (EAF#) should be used to track each facility affected by the issue. Note: If a site-specific issue warrants further evaluation for a facility, then a separate EA# would be required if the IEP 9.4 is not applicable.

The EA# and the EAF# should be placed at the top of the cover letter documenting the issue in an inspection report. Consequently, both the CoC holder and the GL would be able to identify the EA# and the EAF#. The cover letter to the inspection report that discusses the violation should include the following or similar language:

“The NRC [or licensee] identified a violation of [insert provision of 10 CFR 72.48, paragraphs (c)(1), (c)(2), and (d)(1), and/or provisions of 10 CFR 72.212] that resulted from a CoC holder’s failure to comply with 10 CFR 72.48 for a CoC holder-generated change for [insert brief change description here]. However, an Interim Enforcement Policy (IEP) issued in August 2025 is applicable to this violation. Specifically, Enforcement Policy section 9.4, “Enforcement Discretion for General Licensee Adoption of Certificate of Compliance (CoC) Holder-Generated Modifications under 10 CFR Part 72.48,” provides enforcement discretion to not issue an enforcement action for this violation. The licensee will be expected to comply with 10 CFR 72.212 provisions after the NRC dispositions the noncompliance for a CoC holder-generated change that affects the General Licensee.

60857.01-06 RESOURCE ESTIMATE

No additional inspection hours are expected as these activities will be managed within the hours of the existing inspection procedure.

Attachment 1: Revision History for IP 60857 Appendix A

Commitment Tracking Number	Accession Number Issue Date Change Notice	Description of Change	Description of Training Required and Completion Date	Comment Resolution and Closed Feedback Form Accession Number (Pre-Decisional Non-Public Information)
N/A	ML25234A169 11/20/25 CN 25-033	New Appendix to provide specific guidance to inspectors applying Interim Enforcement Policy 9.4 as part of this IP.	August ISFSI Inspector Counterpart Call (training) August 28, 2025	N/A