



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

EGM 25-001

February 11, 2025

MEMORANDUM TO: Andrea L. Kock, Regional Administrator, Region I  
Laura Dudes, Regional Administrator, Region II  
John B. Giessner, Regional Administrator, Region III  
John D. Monninger, Regional Administrator, Region IV  
John W. Lubinski, Director,  
Office of Nuclear Material Safety and Safeguards  
Andrea D. Veil, Director,  
Office of Nuclear Reactor Regulation

FROM: David L. Pelton, Director  Signed by Pelton, David  
Office of Enforcement on 02/11/25

SUBJECT: ENFORCEMENT GUIDANCE MEMORANDUM 25-001,  
ENFORCEMENT GUIDANCE FOR DISPOSITIONING  
NONCOMPLIANCES RELATED TO A GENERAL LICENSEE'S  
USE OF CERTAIN NON-QUALIFIED SPENT FUEL CASKS

**PURPOSE:**

This enforcement guidance memorandum (EGM) provides guidance to U.S. Nuclear Regulatory Commission (NRC) staff when a general licensee does not comply with Title 10 of the *Code of Federal Regulations* (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." Specifically, this EGM provides guidance to the NRC staff to disposition violations of 10 CFR 72.48, "Changes, tests, and experiments," and 10 CFR 72.212, "Conditions of general license issued under 10 CFR 72.210," when a licensee has loaded spent fuel into certain non-qualified spent fuel canisters.

**BACKGROUND:**

Using the 10 CFR 72.48 change control process, Holtec International (Holtec) made a change to the design of its multi-purpose canisters (casks) that contain spent nuclear fuel inside of a honeycombed fuel basket. Holtec designated the basket design change as the "Continuous Basket Shim (CBS) variant," and assessed how the design change from a welded to a bolted

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shim design impacted the cask structural performance during a hypothetical cask tip-over event. Holtec failed to consider the cumulative impacts from changes made to multiple elements of the method of evaluation (MOE) that were not consistent with the licensing basis. Additionally, Holtec adopted aspects of several different approved MOEs and did not apply these evaluation aspects in the same manner as the original MOE. As such, NRC found Holtec in violation of 10 CFR 72.48 requirements and issued three Severity Level IV violations for: (1) implementation of design changes to NRC-approved spent fuel cask systems that resulted in departures from MOEs described in the final safety analysis report (FSAR); (2) failure to maintain adequate evaluations that provided the bases for determining that the design changes did not require a CoC amendment; and, (3) not subjecting the changes to design control measures that were commensurate with those applied to the original design.<sup>1</sup>

These violations affected 21 general licensees because they had already loaded the non-compliant casks with the CBS variant.<sup>2</sup>

### **GENERAL LICENSEE COMPLIANCE:**

In addition to applying to Holtec, the requirements of 10 CFR 72.48 also apply to the 21 general licensees who had purchased the casks discussed above. Specifically, pursuant to 10 CFR 72.48(c), a licensee or certificate holder may make changes to a spent fuel storage cask design without obtaining a CoC amendment so long as those changes meet certain criteria defined in 10 CFR 72.48(c). Under 10 CFR 72.48(c)(2)(viii), if the change would result in a departure from the method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses, a general licensee must request that the certificate holder obtain a CoC amendment prior to implementing the proposed change. Accordingly, a general licensee seeking to adopt a change that a CoC holder made to a cask design must perform an evaluation to determine the suitability of the change for itself.<sup>3</sup> Further, 10 CFR 72.48(d)(1) requires a general licensee to maintain records of a change in the cask design made pursuant to 10 CFR 72.48(c). These records must include a written evaluation that provides the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2).

Prior to loading the non-compliant casks obtained from Holtec, 21 general licensees did not identify that Holtec's cask modification (i.e., changing the basket shim from a welded to a bolted design) utilized MOEs that departed from the MOE described in the FSAR (as updated) that was used in establishing the design bases or in the safety analyses. Because of the non-compliant modification, the general licensees were required to request that the CoC holder submit an amendment request to the NRC to comply with 10 CFR 72.48(c)(2). Contrary to this requirement, none of the general licensees requested that the CoC holder submit an amendment request.

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<sup>1</sup> See Agencywide Documents Access and Management System [ADAMS] Accession Nos. ML23145A175 (inspection report), ML24016A190 (Notice of Violation) and ML24060A214 (Holtec's response to Notice of Violation).

<sup>2</sup> The CBS variant is used in two cask systems for which Holtec is the Certificate of Compliance (CoC) holder: the HI-STORM 100 (CoC 72-1014) and HI-STORM Flood/Wind (FW) (CoC 72-1032) as listed in 10 CFR 72.214.

<sup>3</sup> See 10 CFR 72.48(c)(2); Changes, Tests, and Experiments, 64 Fed. Reg. 53,601-02 (Oct. 4, 1999) (amending 10 CFR Parts 50 and 72).

Additionally, pursuant to 10 CFR 72.212(b)(3), a general licensee must also “ensure that each cask used by the general licensee conforms to the terms, conditions, and specifications of a CoC or an amended CoC listed in 72.214.” The casks with the CBS variant did not conform to the CoC due to the changes that the CoC holder made. Consequently, the 21 general licensees who used the casks did not comply with 10 CFR 72.212(b)(3), because the casks did not conform to a CoC or amended CoC when the general licensees loaded them.

### **SIGNIFICANCE AND ENFORCEMENT DISCRETION:**

A general licensee’s loading of a non-compliant Holtec cask (i.e., MPC 37-CBS, MPC 89-CBS, MPC 68M-CBS, and MPC 32M-CBS) under the circumstances presented here has been designated as having very low safety significance. The NRC performed an Immediate Safety Determination<sup>4</sup> to confirm that general licensee use of the CBS basket design does not pose a risk to public health and safety, which stated:

*A potential consequence of the unapproved design change is a cask tip-over event that results in damaged fuel assemblies. The staff assigned a significance of Severity Level IV (i.e., violations that are less serious, but are of more than minor concern) because Holtec’s failure to obtain an amendment is deemed as having very low safety significance (see Section 6.1.d.2 of the Enforcement Policy). The staff’s safety significance determination is summarized in memorandum, “Safety Determination of a Potential Structural Failure of the Fuel Basket During Accident Conditions for the HI-STORM 100 and HI-STORM Flood/Wind Dry Cask Storage Systems” (ADAMS Accession No. ML24018A085).*

In accordance with the NRC Enforcement Policy, Section 3.5, “Violations Involving Special Circumstances,” the NRC may refrain from issuing a violation based on the merits of the case after considering factors such as the clarity of the requirement and associated guidance, as well as other relevant circumstances. The NRC-endorsed industry guidance<sup>5</sup> lacks clarity concerning the level of review required by general licensees of changes made by CoC holders pursuant to 10 CFR 72.48 that include a modified, new, or different MOE. The significant number of general licensees that failed to comply with the applicable regulations in this instance also indicates a lack of clarity. Accordingly, the staff will exercise enforcement discretion for general licensee’s violations of 10 CFR 72.48 and 10 CFR 72.212 because of the lack of clarity in the guidance.

There is a need for additional engagement with the industry concerning the adequacy of NRC-endorsed guidance for how a general licensee should perform 10 CFR 72.48 evaluations for changes made by a CoC holder.

### **CONDITIONS:**

Enforcement discretion may be granted in accordance with Section 3.5, “Violations Involving Special Circumstances,” of the Enforcement Policy, if a general licensee meets condition A as well as either condition B or C (as applicable to the type of cask the general licensee loaded):

- A. The general licensee has entered the concern into their corrective action program (e.g., the site did not ensure that spent fuel cask conformed to the terms, conditions, and

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<sup>4</sup> ADAMS Accession No. ML23145A175.

<sup>5</sup> Regulatory Guide 3.72, “Guidance for Implementation of 10 CFR 72.48, ‘Changes, Tests, and Experiments,’” endorsed NEI 12-04, Revision 2, “Guidelines for 10 CFR 72.48 Implementation.”

specifications of a CoC or an amended CoC listed in 72.214, and did not maintain [or perform] a written evaluation that provided the bases for determining that Holtec's change to the HI-STORM FW [HI-STORM 100] system did not require a CoC amendment).

B. For sites that loaded the HI-STORM FW system (MPC 37-CBS and MPC 89-CBS), the general licensee's corrective action program includes actions to perform a Part 72.48 evaluation to:

- 1) apply changes (e.g., method of evaluation) authorized by Holtec HI-STORM FW System Amendment Number 7 (ML24199A236), by demonstrating through a written evaluation in accordance with 10 CFR 72.212(b), that the cask meets the terms and conditions of its CoC amendment; or
- 2) adopt Amendment 7, by performing a written evaluation in accordance with 10 CFR 72.212(b), that demonstrates the cask conforms to the terms, conditions, and specifications of Amendment 7.

C. For sites that loaded the HI-STORM 100 system (MPC 68M-CBS and MPC 32M-CBS):

- 1) movement of the spent fuel storage casks has been restricted until the cask non-compliance is resolved; and
- 2) the licensee's corrective action program includes actions to actively pursue restoring compliance via a 72.212(b) and 72.48 evaluation, license amendment request,<sup>6</sup> or an exemption request.

#### **DOCUMENTATION:**

Upon determining that the conditions stated in this EGM are satisfied, NRC staff will document the following in the cover letter to the inspection report:

*The NRC (or licensee) identified a violation of 10 CFR 72.48 and 72.212 associated with (general licensee name)'s use of the Holtec [HI-STORM 100 (or FW) spent fuel storage cask]. Enforcement discretion is being granted as authorized by Enforcement Guidance Memorandum 25-001, ENFORCEMENT GUIDANCE FOR DISPOSITIONING NONCOMPLIANCES RELATED TO A GENERAL LICENSEE'S USE OF CERTAIN NON-QUALIFIED SPENT FUEL CASKS (see ADAMS Accession No. ML24303A436). The NRC will take additional enforcement action if compliance is not restored following the expiration date of this EGM.*

The NRC staff will assign an enforcement action (EA) tracking number to any inspection report that documents using this EGM as the basis for exercising enforcement discretion. An enforcement panel is not required unless a site-specific issue warrants further evaluation. A new EA tracking number is required for each use of this EGM (i.e., subsequent inspections at a facility).

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<sup>6</sup> Holtec submitted an amendment request for Amendment No. 19 to the HI-STORM 100 storage system on August 9, 2024 (ML24222A858).

**EXPIRATION:**

This EGM will remain in effect until December 31, 2027.