



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

EA-23-044

January 30, 2024

Jean Fleming, Vice President
of Licensing, Regulatory
and Probabilistic Safety Analysis
Holtec International, Inc.
Krishna P. Singh Technology Campus
1 Holtec Boulevard
Camden, NJ 08104

SUBJECT: HOLTEC INTERNATIONAL, INC. – NOTICE OF VIOLATION; THE U.S.
NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO.
07201014/2022-201

Dear Jean Fleming:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC, Commission) announced routine fabrication inspection conducted December 12-15, 2022, at Holtec Advanced Manufacturing Division (AMD) in Camden, New Jersey. The purpose of the inspection was to assess the adequacy of Holtec International, Inc.'s (Holtec) fabrication activities for spent fuel storage casks with regard to the applicable requirements of 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."

Based on the information developed during the inspection, three apparent violations were identified. Details regarding the apparent violations were provided in the NRC Inspection Report No. 07201014/2022-201, dated September 12, 2023. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession No. ML23145A175. ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the three apparent violations identified in the report by either: (1) attending a Pre-decisional Enforcement Conference (PEC), or (2) participating in an Alternative Dispute Resolution session before we made our final enforcement decision. In an email dated September 18, 2023, you requested a PEC with NRC staff to provide additional information for consideration prior to a final enforcement decision.

On October 26, 2023, a PEC was convened at the NRC Headquarters, with you and members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions. Additionally, post-PEC your staff submitted additional information in response to NRC requests made during the conference (ADAMS Accession No. ML23321A216).

During the PEC, your staff presented detailed technical information to support a position that enforcement actions were not necessary. The Holtec presentation (ADAMS Accession No. ML23297A261) included the following conclusionary points:

The modification from Friction Stir Welded to CBS basket variants improves the fabrication of the Fuel Baskets, enhanced the dimensional fidelity of the storage cells and meets existing FSAR design criteria;

Holtec modeled the accurate dimensional and physical changes that occurred with the CBS design change and did not change the calculational framework of the analysis;

[Revision] 17 of ANSYS used in the structural evaluation was appropriately validated in accordance with Holtec's long-established QA process; and

Holtec revised the four 72.48 evaluations and provided to the NRC via the audit-related SharePoint site on May 23, 2023

After considering all information developed during the inspection and provided as part of the PEC process, the staff concluded that Holec's engineering analyses for the design changes utilized new methods of evaluations (MOE) as well as 'changes in elements' of existing MOEs. As a result, Holec's design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants required prior NRC approval. In accordance with the NRC Enforcement Policy, the NRC has determined that three Severity Level IV violations of regulatory requirements occurred. The current Enforcement Policy is included on the NRC's website at: <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

These violations involved:

- A. Holtec's failure to obtain certificate of compliance (CoC) amendments prior to implementing proposed design changes to multi-purpose canister (MPC) continuous basket shims (CBS) for four spent fuel cask designs (i.e., MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants) that resulted in a departure from the method of evaluations described in the HI-STORM 100 and HI-STORM Flood/Wind (FW) final safety analysis reports (FSARs, as updated) used in establishing the design bases as required by 10 CFR 72.48(c)(2)(viii), "Changes, test, and experiments." The staff concluded that Holtec failed to consider the cumulative impacts from all the changes and made changes to more than one element of the method of evaluation (MOE) that were not consistent with the constraints and limitations of the fuel basket design's licensing basis and that Holtec adopted different aspects of different approved MOEs and did not apply these changes in the same manner as the original MOE. As such, without obtaining NRC approval, modifications were made to the CBS fuel basket variants using both new MOEs and existing MOEs (with changes to elements).
- B. Holtec's failure to maintain adequate records of changes that included written evaluations that provided an adequate bases for the determination that changes to the MPC CBS basket variants did not require CoC amendments pursuant to 10 CFR 72.48(c)(2), as required by 10 CFR 72.48(d)(1), "Changes, tests, and experiments." The staff concluded that Holtec maintained records of changes that did not clearly and thoroughly discuss the impacts on departures from elements of the methods of evaluation (MOEs) described in the FSARs for the original spent fuel storage cask designs made pursuant to paragraph (c) of 10 CFR 72.48. These written evaluations were the bases for Holec's incorrect determination that the changes did not require a CoC amendment pursuant to 10 CFR 72.48(c)(2); and

- C. Holtec's failure to subject design changes for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants to design control measures commensurate with those applied to the original design, as required by 10 CFR 72.146(c), "Design control." The staff concluded Holtec failed to perform adequate tip-over calculations and to model the basket shim bolts for the four CBS basket variants. In addition, material strength assumptions were different, the deflection design criteria of the fuel baskets were not demonstrated, and thermal expansion interference was not calculated in the CBS baskets

The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in the inspection report mentioned above. The violations are being cited in the Notice because Holtec has not demonstrated objective evidence of plans to restore compliance within a reasonable period of time.

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).

The NRC determined Corrective Action initiated by Holtec included the following short-term and long-term corrective actions: Short-term corrective actions for the violations included: (1) root cause/extent of condition evaluations and causal analyses, (2) safety significance determination, (3) revisions to applicable 72.48s, (4) submittal of HI-STORM FW CoC No. 1032, amendment No. 7 to the NRC for additional two other CBS designs, as well as acknowledged the possibility of submitting another HI-STORM 100 CoC amendment for the two existing CBS designs associated with that CoC based on the NRC's final determination of the violation, and (5) develop templates for use by general licensees should they opt to submit an exemption request for their non-compliant cask(s).

Long-term corrective actions included: (1) creation of a procedure and charter of a nuclear licensing board, (2) enhancement of the 10 CFR 72.48 implementing procedure to provide a graded approach for additional reviews of 72.48 screenings/evaluations (to include supervisory reviews/approvals, and review committee), (3) provide industry sponsored 72.48 training for 72.48 qualified personnel, supervisory/management, and leadership oversight reviews, (4) update 72.48s to better reference or include technical MOE information, (5) establish trending of 72.48 deficiencies, (6) update 72.48 writers guide to reinforce that is guidance is not intended to be used as boiler plate language but as guidance, and (7) establish a 72.48 review committee to perform an extent of condition reviews for previous 72.48s.

The staff noted Holtec's corrective actions contained specifics for restoring compliance with respect to Violation B and determined they provide adequate short and long-term corrective actions for preventing a future violation. As such, the staff is not requesting any additional response with respect to Violation B.

The staff has determined that the corrective actions are not complete with respect to addressing corrective actions for Violations A and C. The staff has determined that additional corrective actions are warranted concerning the amendment of the CoCs for the four basket variants


discussed in this enforcement action. As such, Holtec is requested to provide written responses to Violations A and C.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In addition, we will follow up your corrective actions during a future NRC inspection. Issuance of this Notice may subject you to increased inspection effort.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection in the NRC Public Document Room and in ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

If you have any questions concerning this matter, please contact Aida Rivera-Varona at (301) 415-4001 or email (Aida.Rivera-Varona@nrc.gov).

Sincerely,

 Signed by Helton, Shana
on 01/30/24

Shana Helton, Director
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket Nos. 72-1014 and 72-1032

Enclosure:
Notice of Violation

SUBJECT: HOLTEC INTERNATIONAL – NOTICE OF VIOLATION; THE U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 07201014/2022-201

DOCUMENT DATE: January 30, 2024

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NOTICE OF VIOLATION

Holtec International
Camden, NJ

Docket Nos. 72-1014 and 72-1032
EA-23-044

During an U.S. Nuclear Regulatory Commission (NRC) inspection conducted December 12-15, 2022, at Holtec Advanced Manufacturing Division (AMD) in Camden, New Jersey, three violations of the NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

Violation A:

Per Title 10 of the *Code of Federal Regulations* (10 CFR) Section 72.48(c)(2)(viii), "Changes, tests, and experiments," requires, in part, that "a certificate holder shall obtain a certificate of compliance (CoC) amendment pursuant to 10 CFR 72.244, prior to implementing a proposed change that would result in a departure from a method of evaluation described in the [Final Safety Analysis Report], (FSAR) as updated used in establishing the design bases or in the safety analyses."

Contrary to the above, the certificate holder Holtec International, Inc. (Holtec) failed to obtain a CoC amendment pursuant to 10 CFR Section 72.244, prior to implementing proposed changes that would result in a departure from a method of evaluation (MOE) described in the FSAR used in establishing the design bases or in the safety analyses. Specifically, from November 6, 2020, to July 19, 2021, Holtec made design changes to four multi-purpose canister (MPC) fuel baskets from the standard MPC 68M, 32M, 89, and 37 baskets to the MPC 68M-continuous basket shims (CBS), MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS basket variants that resulted in a departure from methods of evaluation described in the FSARs (as updated) used in establishing the design bases and failed to submit CoC amendment applications prior to implementing the changes.

This is a Severity Level IV violation (NRC Enforcement Policy, section 6.2.d.2)

Violation B:

Per 10 CFR 72.48(d)(1), "Changes, tests, and experiments," requires, in part, that the licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and 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 does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, Holtec failed to maintain records of changes in the spent fuel storage cask design made pursuant to paragraph (c) of 10 CFR 72.48 that included a written evaluation which provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, for the MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS variants, as of February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec's written evaluations failed to provide an adequate bases for the determination that incorporation of the CBS design fuel basket variants did not require a CoC amendment. Holtec did not clearly and thoroughly discuss the impacts on departures from elements

Enclosure

of the methods of evaluation (MOEs) described in the FSARs for the original design (all-welded stainless steel fuel basket) that were affected by the changes to the CBS design fuel basket variants (MPC 68M-CBS, MPC 32M-CBS, MPC 89-CBS, and MPC 37-CBS). The impacted elements included the demonstration of the design criteria of the fuel basket; mathematical model associated with material performance and tip-over analysis; calculational framework on connections between fuel basket and shims; use of revised version of software; new assumptions, etc.

This is a Severity Level IV violation (NRC Enforcement Policy, section 6.2.d.2)

Violation C:

Per 10 CFR 72.146, "Design control," requires, in part, that a certificate holder shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the license or CoC require prior NRC approval.

Contrary to the above, Holtec failed to subject design changes, including field changes, to design control measures commensurate with those applied to the original basket design. Specifically, in four examples prior to February 17, 2021, July 19, 2021, May 13, 2020, and November 6, 2020, Holtec failed to subject design changes from the MPC 68M, 32M, 89, and 37 standard basket designs to the MPC 68M-CBS, 32M-CBS, 89-CBS, and 37-CBS basket variants to design control measures commensurate with those applied to the original design, and made changes in the conditions specified in the license that required prior NRC approval. Holtec failed to perform adequate tip-over calculations and to model the basket shim bolts for the four CBS basket variants. In addition, material strength assumptions were different, the deflection design criteria of the fuel baskets were not demonstrated, and thermal expansion interference was not calculated in the CBS baskets.

This is a Severity Level IV violation (NRC Enforcement Policy, section 6.1.d.2)

Pursuant to the provisions of 10 CFR 2.201, Holtec is hereby required to submit a written statement or explanation for Violation A. and Violation C. to the NRC, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to Shana Helton, Division Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738, within 30 days of the date of the letter transmitting this Notice of Violation (Notice or NOV). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-23-044" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary [NOTE: For NOV's to be issued to gaseous diffusion plants or any other facility likely to hold classified material, insert: classified,], or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. If Classified Information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR Part 95.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30th day of January 2024.