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U.S. Nuclear Regulatory Commission  
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Holtec International  
Docket No. 72-1014

Subject: Reply to a Notice of Violation; EA-23-044

Reference: Holtec International, Inc. – Notice of Violation; The U.S. Nuclear Regulatory Commission Inspection Report No. 07201014/2022-201 (ADAMS Accession No. ML24016A190), dated January 30, 2024

Ms. Helton:

Holtec International hereby submits the Reply to Violations identified in NRC Inspection Report No. 07201014/2022-201, Enforcement Action No. EA-23-044. As requested, the enclosure contains the following for the violations and Holtec's corrective actions: (1) the reason for the violations; (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.

If you have any questions, please contact me at 856-797-0900 ext. 3578.

Sincerely,

Jean A. Fleming  
Vice President of Licensing and Regulatory Affairs  
Holtec International

Enclosure: Reply to Notice of Violation EA-23-044

Document ID 5014979  
Page 1 of 8



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**ENCLOSURE**

**Reply to Notice of Violation**

**EA-23-044**



### **Notice of Violations**

NRC Notice of Violation related to Inspection Report 07201014/2022-201 (EA-23-044) dated January 30, 2024, cited three Severity Level IV violations as stated below. Pursuant to the provisions of 10 CFR 2.201, Holtec is required to submit a written response for Violation A. and Violation C.

#### 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.

#### 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 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.

### 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 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.

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

### Holtec Response

Holtec accepts these violations and has implemented comprehensive corrective actions to restore long-term sustained compliance.

### **Reason for Violation**

The root cause of the violations is less than adequate Holtec management oversight of the required 10 CFR 72.48 evaluation process for changes to spent fuel baskets resulting in changes being made to the conditions specified in the license without seeking prior NRC approval.

Contributing causes to the event and violations included the following:

- Holtec procedure HSP-321 Rev.10, Screening and Evaluation of Changes, Tests, and



Experiments Under 10 CFR 72.48, had weaknesses relative to the details and clarity in the evaluations to ensure a stand-alone document exists to support the evaluation's conclusions. In addition, the procedure lacks any peer approval and has no requirement for any increased management review and approval for complex modifications.

- The organization did not utilize effective communications and review processes to evaluate the 72.48 modeling and methodology questions during the 72.48 development process. Examples included a lack of an assigned 72.48 evaluation approver and no oversight review committee for complex 72.48 evaluations.
- Weaknesses in training and the number of qualified preparers/reviewers contributed to 10 CFR 72.48 evaluations that were not stand-alone documents.
- Management failure to identify early opportunities for enhanced oversight of 72.48 methodologies and modeling.

### **Corrective Steps and Results Achieved**

In response to the potential violations debriefed to Holtec in April 2023, Holtec performed the following prompt corrective actions:

- Completed a re-run of the qualification analyses of the CBS baskets using the elastic material model as in the original basket analyses. The results from these analyses resulted in essentially no change in the critical results. This supports the original conclusion that the change of the material model would be an acceptable change of an element of a methodology under 72.48 (i.e., no change in methodology).
- Increased communications with NRC staff regarding assumptions on methodology change documented in original 72.48 evaluations through drop-ins and white paper submittals to NRC staff. This action ensured the NRC staff was informed of the facts and assumptions on the methodology change documented in the 72.48 evaluation.
- Submitted white paper on May 23, 2023 responding to technical questions related to the non-mechanistic tipover analyses presented in the 72.48 evaluations. The results and conclusion of the white paper demonstrated to NRC staff the use of the CBS variants presented a very low safety significance.
- Revised four 72.48 evaluations (1446, 1498, 1502, and 1532) with additional information to expand the level of detail on the impacts on departures from elements 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 revised 72.48 evaluations arrived at the same conclusion as the original 72.48s evaluations. The revised 72.48 evaluations were provided to NRC staff for review on May 23, 2023.

- Drafted template exemption requests to provide users of potentially non-compliant casks.

Additionally, a root cause evaluation (RCE) was performed to provide long-term corrective actions that are comprehensive and effectively prevent recurrence of the violation. These actions include:

- Created HSP-524, “Change Review Committee” for the nuclear licensing review board, with responsibilities to review complex 72.48 evaluations.
- Revised HSP-321, “Screening and Evaluation of Changes, Tests, and Experiments Under 10CFR72.48,” to provide a graded approach for additional reviews of 72.48 screenings/evaluations. Include supervisory reviews/approvals, and review committee.
- Revised HSP-321, “Screening and Evaluation of Changes, Tests, and Experiments Under 10CFR72.48,” to include additional reviews of 72.48 documents, including an approval review and signature and implementation of the 72.48 review committee, and
- Revised HSP-321, “Screening and Evaluation of Changes, Tests, and Experiments Under 10CFR72.48,” to include that writer’s guide language shall be used as guidance only and that further evaluation and analysis is required in the 72.48 screening and evaluation process.
- Provided training to 72.48 qualified personnel and supervisory/management on leadership oversight reviews described in the updated procedures.
- Provided industry sponsored 72.48 training for 72.48 qualified personnel, supervisors/management, and leadership oversight reviews.

### **Corrective Steps that Will be Taken**

The RCE identified the following corrective actions that will be taken:

- Provide training for 72.48 technical disciplines on communicating MOE changes.
- Establish trending of 72.48 issues by nuclear review board and more detailed extent of condition for previously signed 72.48s for last 3 years.
- Document a ‘quality issue’ (QI) and revise any 72.48 evaluations identified in extent of condition review.
- Support a completed review of HI-STORM FW Amendment 7 to finalize approved methodology for FW CBS basket analysis.
- Submit an amendment to the HI-STORM 100 system to establish methodology for the HI-STORM 100 CBS basket analysis.
- Incorporate these methodologies once approved into revisions to the four 72.48 evaluations (1446, 1498, 1502, and 1532)



- Assess the number of qualified 72.48 preparers, reviewers, and approvers. Increase this number of personnel if determined to be required.
- Effectiveness review: Perform surveillances in the approximate months of June, September, and December to evaluate all 72.48s processed since the prior period. The first surveillance shall cover 72.48s initiated since 1/1/24. Verify the a) graded approach is being appropriately implemented per HSP-321, b) that licensing board review is being performed when required; and c) that appropriate communication with the NRC is being performed when complex issues exist.
- Revise HSP-524, “Change Review Committee” to include evaluation of regulatory engagement to solicit NRC staff feedback and establishment of communication with NRC on complex issues and specific 72.48 methodology topics.

### **Date of Full Compliance**

The violations state that amendments were required for the changes to the CBS basket variants. Therefore, both the HI-STORM FW canisters (MPC-37CBS and MPC-89CBS) and the HI-STORM 100 canisters (MPC-68MCBS and MPC-32MCBS) compliance will be restored when either the specific canisters or a method of evaluation for the CBS style canisters is approved by the NRC.

The Holtec HI-STORM FW System Amendment Number 7 (“Amendment 7”) is presently under NRC staff review and includes a methodology for evaluating Metamic-HT baskets, including the CBS variants. Once Amendment 7 is approved and issued by NRC, any Holtec user who intends to load fuel into either the MPC-37CBS and MPC-89CBS canisters under that amendment will be fully compliant, and, once approved, the method of evaluation will be applied to canisters loaded under earlier amendments with updated 72.48 evaluations. This amendment is expected to be approved by NRC later in 2024 and updated 72.48 evaluations will be completed within 2 weeks of the approval to bring all existing MPC-37CBS and MPC-89CBS canisters into full compliance.

Holtec will submit a license amendment request (LAR) to the NRC for the HI-STORM 100 system to restore compliance with the MPC-68MCBS and MPC-32MCBS basket variants. This LAR will utilize the same method of evaluation as HI-STORM FW Amendment 7 but demonstrate its applicability to the HI-STORM 100 system. The HI-STORM 100 LAR is expected to be submitted to the NRC for review in June 2024. Full compliance will be dependent on the NRC staff review of the amendment, however because the methodology is intended to be identical to the HI-STORM FW methodology, Holtec will request an expedited review time. Similar to the Amendment 7 process, once the HI-STORM 100 amendment is approved by the NRC, any site that loads to the new amendment will be in full compliance, and the existing loaded canisters under previous amendments will be brought into compliance with updated 72.48 evaluations. These evaluations will be completed within 2 weeks of amendment



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approval.

For both systems, affected Holtec storage cask users may pursue other actions to restore site-specific compliance, such as seeking exemption requests which will be submitted on a site-specific basis.