



May 23, 2019

Damaris Marciano, Acting Chief, Inspections and Operation Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to Notice of Violation EA-18-151

Reference(s): [1] "Holtec International 0 Notice of Violation; U.S. Nuclear Regulatory Commission Inspection Report No. 07201014/2018-201 Division of Spent Fuel Management

Dear Ms. Marciano:

As requested by the NRC in the letter to Holtec, the following responses are provided for each violation.

Violation 1: Design Control – "Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety.

Contrary to the above, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the structures, systems, and components which are important to safety. Specifically, on or after August of 2016, Holtec failed to establish adequate design control measures as a part of the selection and review for suitability of application for alternative four-inch stainless steel stand-off pins that were essential to the function of the fuel basket to maintain support and ensure that the shims stay upright to allow airflow to the fuel assemblies within the MPC."

- 1) The reason for the violation, or, if contested, the basis for disputing the violation or severity level

Holtec is not contesting this violation. Holtec previously submitted a Quality Issue (QI) document to the NRC as Attachment 3 to Letter 5014863 (ML19017A099). This



document includes a section entitled “Root Cause Determination,” which explains the reason for the violation, following a full root cause evaluation.

- 2) The corrective steps that have been taken and the results achieved

Similar to above, the QI and associated root cause evaluation already submitted to the NRC under letter 5014863 has a “Corrective Action Tracking Table,” which lists the corrective actions that have been taken.

- 3) The corrective steps that will be taken to avoid further violations

The QI information already submitted to the NRC as discussed above has a section that lists the “Actions to Prevent Recurrence,” which lists the corrective actions that are specifically aimed at preventing recurrence of similar issues.

- 4) Your plan and schedule for completing short and long term corrective actions

The table described in the response to question #2 has the dates for each of the corrective action and action to prevent recurrence.

- 5) The date when full compliance will be achieved

As noted in the referenced QI and root cause evaluation, there are four units at SONGS that require a license amendment to bring the canisters back into full compliance with the CoC. This amendment (HI-STORM UMAX Amendment 4) was submitted to the NRC, but requires review and approval prior to those canisters being in full compliance. This amendment request is still in the acceptance review phase and so no schedule has been yet set by the NRC staff. All other canisters with shim standoffs are already in full compliance with their licensing basis.

Violation 2: Design Control –

- A. “As of July 19, 2018, the certificate holder (Holtec) did not obtain a CoC amendment pursuant to § 72.244 for a storage cask design as described in the FSAR despite the fact that the new HI-TRAC VW, Version V design, required a change to the technical specification (TS) incorporated in the CoC. Specifically, Holtec made a change to the HI-TRAC VW design that required new operator actions with new dose rates that affected the FSAR design function and specifications. This change substituted a manual action for an automatic action for performing an FSAR described design function, which



would require prior NRC approval because it would result in more than a minimal increase in the likelihood of occurrence of a malfunction and a change to the TS.”

- B. “As of July 19, 2018, the certificate holder (Holtec) did not obtain a CoC amendment when implementing a proposed change that would create a possibility for a malfunction of a different result than any previously evaluated in the FSAR. Specifically, personnel were unable to remove a damaged lift cleat threaded stud from a lifting hole which resulted in three instead of four functional MPC lifting points. Holtec’s HI-STORM 100 FSAR analyzed lifting a fully loaded cask with four lifting lugs.”
- C. “As of July 19, 2018, the certificate holder (Holtec) failed to maintain records of changes that included a written evaluation that provided the bases for the determination that the change does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). Specifically, Holtec failed to perform a written evaluation to demonstrate that a design change for multi-purpose canister stainless steel standoff pins did not require a CoC amendment. Holtec completed a 10 CFR 72.48 screening and incorrectly determined that a written evaluation was not needed.”

- 1) The reason for the violation, or, if contested, the basis for disputing the violation or severity level

Holtec is not contesting this violation. Attached to this letter is Holtec’s QI-2471, which evaluates each of the above issues (along with some other concerns). The QI includes a section entitled “Cause,” which articulates the cause of this violation.

- 2) The corrective steps that have been taken and the results achieved

Holtec QI 2471, attached to this letter, contains a list of corrective actions that have been performed, including updating the affected documents.

- 3) The corrective steps that will be taken to avoid further violations

The same QI that is described above has a list of actions, including training and revised procedures which are intended to avoid further violations.

- 4) Your plan and schedule for completing short and long term corrective actions

The attached QI contains a table that outlines the dates that each corrective action was completed.

- 5) The date when full compliance will be achieved



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For item A on the ventilated HI-TRAC, this design change has been voided, and was not implemented anywhere, so there is no compliance issue.

For item B, on the lifting stud, this has been repaired, and the canister returned to full compliance as of October 2018.

For item C, on the shim standoff issue, the 72.48 documents that were screenings were updated to be full evaluations. These were already submitted to the NRC as attachments 5 and 6 to Holtec Letter 5014861 (ML19011A084). Therefore, the documents are now in compliance with NRC's expectations.

If you have any questions, please contact me at 856-797-0900 ext. 3951.

Sincerely,

Kimberly Manzione
Licensing Manager,
Holtec International

Attachments:

Attachment 1: Holtec QI #2471 (Proprietary)

Attachment 2: Affidavit in Accordance with 10CFR2.390