



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

April 24, 2019

EA-18-151

Dr. K. P. Singh  
President and CEO  
Holtec International  
Krishna P. Singh Technology Campus  
1 Holtec Boulevard  
Camden, NJ 08104

SUBJECT: HOLTEC INTERNATIONAL – NOTICE OF VIOLATION; U.S. NUCLEAR  
REGULATORY COMMISSION INSPECTION REPORT NO. 07201014/2018-201  
DIVISION OF SPENT FUEL MANAGEMENT

Dear Dr. Singh:

This letter refers to the U.S. Nuclear Regulatory Commission (NRC) announced routine inspection at your Holtec International (Holtec) corporate office in Camden, New Jersey from May 14-18, 2018, with continued in-office review through November 26, 2018. The purpose of the inspection was to assess the adequacy of Holtec's activities with regard to the design of spent fuel storage casks with the 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, two apparent violations were identified. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with Mr. Mark Soler of your staff during an exit meeting on November 26, 2018. Details regarding the apparent violations were provided in NRC Inspection Report No. 07201014/2018-201, dated November 29, 2018. The inspection report can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at Accession Number ML18306A853. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

The letter transmitting the inspection report also provided you with the opportunity to address the 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 a letter dated December 3, 2018, (ADAMS Accession Number ML18341A126) you requested a pre-decisional enforcement conference.

A PEC was convened at the NRC Headquarters on January 9, 2019, with you and members of your staff to discuss the violations. Subsequent to the PEC, you submitted additional information for the NRC to consider as we proceeded with our enforcement decision process.

The NRC has determined that two violations of regulatory requirements occurred. This determination was based on information developed during the NRC inspection, information you provided in your responses to the inspection report, and information you provided during and after the PEC. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report (ML18306A853). These violations involved: (1) failure 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 as required by 10 CFR 72.146(a), and (2) failure to perform 10 CFR 72.48 evaluations prior to implementing proposed changes and failure to obtain certificate of compliance (CoC) amendments pursuant to 10 CFR 72.244 as required by 10 CFR 72.48.

The failure to establish adequate design control measures and obtain NRC approval prior to modifying multi-purpose canisters (MPC) with four-inch stainless steel stand-off pins, was deemed potentially safety significant. Holtec's design review process for the change did not adequately consider all potential impacts that could adversely affect the safety-related functions of the MPC shims. Impacts not adequately considered included, but are not limited to: MPC handling and manufacturing processes to include peening, lateral loads based on gaps within the MPCs, and conditions adverse to quality identified when personnel discovered defects with the shim stand-off pins during installation. The stand-off pins are essential to the function of the fuel basket to maintain support and ensure that the shims remain in place to allow helium to adequately circulate around the fuel assemblies within the canister.

The MPCs with the shim stand-off pins were not loaded to the full design basis heat load; however, the potential loss of multiple shim stand-off pins in an MPC loaded at the design-basis heat load configuration could have compromised the heat transfer characteristics of the MPC. This could have resulted in an increase in the peak cladding temperature beyond the allowable limit and potentially damage the fuel cladding. Holtec performed a thermal analysis to assess the consequences of the failure of multiple stand-off pins within a MPC and determined that, based on the assumptions used, all predicted results would remain below the described limits in the final safety analysis report with acceptable margin.

NRC staff reviewed the Holtec analysis and concluded that the heat transfer characteristics of the MPCs were adequate and that loaded MPCs would continue to be in a safe condition during the entire licensed period of storage as described in the respective CoC. As a result of this review, the NRC determined that Holtec's violation of 10 CFR 72.48 and 10 CFR 72.146 did not result in an actual significant safety concern. However, the NRC considers Violation 1 to be of moderate safety significance because Holtec's inadequate design control measures did not adequately assess a potentially credible accident and exposure scenario that had the potential for a significant consequence. The failure of multiple stand-off pins in an MPC could have resulted in inadequate heat transfer and the exceedance of peak clad temperature limits. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III, in part, because the design change was outside design specifications to the extent that a detailed evaluation was required to determine its operability. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Holtec has not been the subject of escalated traditional enforcement action within the last two years or two previous inspections. The NRC did not identify any aggravating circumstances through the course of its enforcement decision process. For mitigating circumstances, the NRC

considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy.

The NRC determined *Corrective Action* credit was warranted due to corrective actions initiated by Holtec. The following are the descriptions of short-term and long-term corrective actions taken. Short-term corrective actions and actions to prevent recurrence for violation 1 included: (1) a root cause evaluation; (2) an analysis of licensees loaded units to ensure they are in safe condition; (3) an analysis of basket shim stand-off for seismic and impact loading; (3) inspection of all non-loaded units to identify necessary actions on a case-by-case basis; (4) elimination of the shim stand-off design from MPC's licensing and fabrication drawings; and (5) notification to customers that have delivered or loaded systems.

Long-term corrective actions included: (1) conducting a lessons learned assessment to cover evaluation of design change from a manufacturing and licensing/analysis standpoint and to address issues within the corrective action program; (2) revising engineering change orders (ECO) and drawing review checklists to include questions on impacts to components during fabrication activities; (3) development of written instructions for process change risk evaluations; (4) development of on-the-job training to include shop tours and review of standard manufacturing processes; (5) evaluation of corrective actions initiated in 2018 for design changes that may not have been appropriately evaluated; (6) development of an ECO surveillance process for technical discipline managers to assess whether design changes were appropriately evaluated; (7) training shop personnel on reviewing travelers and other written instructions prior to performing work; (8) training shop personnel on issues identified with installation of the shims; and (9) evaluating the design change process within technical disciplines to determine areas for improvement.

A base civil penalty in the amount of \$36,250 was considered for this Severity Level III violation. However, the staff determined, in accordance with the Enforcement Policy, that a civil penalty for Violation 1 was not warranted. This determination is in recognition of no aggravating circumstances, Holtec's prompt and comprehensive correction of the violation, and the absence of recent escalated enforcement action. This enforcement action may be used in the evaluation of any future significant violations, which could result in a civil penalty. In addition, issuance of the Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>.

The NRC determined that Violation 2 is a Severity Level IV violation with three examples of failing to follow NRC's requirement to adequately perform a 10 CFR 72.48 evaluation prior to implementing proposed changes and failing to obtain CoC amendments pursuant to 10 CFR 72.244. The violation is described in the subject inspection report and was evaluated in accordance with the NRC Enforcement Policy and resulted in conditions as having very low safety significance. The NRC has determined that escalated enforcement was not warranted for this violation. The violation is cited in the enclosed Notice of Violation (Notice). There is no civil penalty associated with a Severity Level IV violation.

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 will use your response, in part, to 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.

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 Web site 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 Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Should you have any questions, please contact Mr. Christian Araguas at (301) 415-7210 or e-mail ([Christian.Araguas@nrc.gov](mailto:Christian.Araguas@nrc.gov)).

Sincerely,

*/RA/*

George Wilson, Director  
Office of Enforcement

Docket Nos. 72-1014, 72-1040,  
and 72-1032

Enclosure:  
Notice of Violation

SUBJECT: HOLTEC INTERNATIONAL – NOTICE OF VIOLATION; U.S. NUCLEAR  
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DOCUMENT DATE: April 24, 2019

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**ADAMS Accession No.: ML19072A128 \* see previous concurrence**

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## NOTICE OF VIOLATION

Holtec International  
Camden NJ

Docket Nos. 72-1014, 72-1040, 72-1032  
EA-18-151

Based on the results of an U.S. Nuclear Regulatory Commission (NRC) inspection conducted at Holtec International (hereafter referred to as Holtec), on May 14, 2018, through July 19, 2018, a team of inspectors identified violations of NRC requirements. In accordance with the NRC Enforcement Policy dated May 15, 2018, the violations are listed below:

### Violation 1

10 CFR 72.146(a), "Design control," requires, in part, that measures must be established for 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 helium to adequately circulate around the fuel assemblies within the canister.

This is a Severity Level III violation (NRC Enforcement Policy, Section 6.3.c.1 (b))

### Violation 2

- A. 10 CFR 72.48(c)(1)(ii)(A), requires, in part, that a certificate holder may make changes in the facility or spent fuel storage cask design as described in the final safety analysis report (FSAR) (as updated), make changes in the procedures as described in the FSAR (as updated), and conduct tests or experiments not described in the FSAR (as updated), without obtaining a CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if a change to the technical specifications incorporated in the specific license is not required.

Contrary to the above, 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

Enclosure

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. 10 CFR 72.48(c)(2)(v), "Changes, tests, and experiments," requires, in part, that a certificate holder shall obtain a CoC amendment pursuant to 10 CFR 72.244 prior to implementing a proposed change, test, or experiment if the change, test, or experiment would create a possibility for a malfunction of a different result than any previously evaluated in the FSAR (as updated).

Contrary to the above, 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. 10 CFR 72.48(d)(1) 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, 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.

This is 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 to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to Damaris Marcano, Acting Chief, Inspections and Operations Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" 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 to avoid further violations; (4) your plan and schedule for completing short and long term corrective actions and (5) 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 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.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/readingrm/adams.html>, to the extent possible, it 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, 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 24<sup>th</sup> day of April 2019.