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

October 28, 2021

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

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1014/2021-201

Dear Dr. Singh:

On May 10, 2021, to May 13, 2021, the U.S. Nuclear Regulatory Commission (NRC) staff conducted an announced onsite inspection at the Holtec International (Holtec) corporate office in Camden, NJ. The staff continued the inspection activities with an in-office review and held two debrief meetings on May 24, and August 3, 2021, followed by an exit meeting on September 17, 2021 after further discussion on the violations. The purpose of the inspection was to verify and assess the adequacy of Holtec's activities with regards to the design control 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," and selected portions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The inspection scope included discussions and reviews of specific issues related to various design changes and evaluations of important-to-safety dry cask storage components. The NRC inspection team examined activities conducted under your NRC approved Quality Assurance (QA) program to determine whether Holtec implemented the requirements associated with the Commission's rules and regulations and with the conditions of the applicable certificate of compliance (CoC). The team reviewed selected procedures, records and interviewed specific personnel. Additionally, the team discussed the preliminary results of this inspection with you and other members of your staff on May 24, 2021, and the team leader conducted a final exit on September 17, 2021. The enclosed report presents the results of this inspection (Enclosure 1).

Based on the results of this inspection, the NRC inspection team determined that three Severity Level IV violations of NRC requirements occurred. The NRC is treating these violations as Non-Cited Violations (NCVs), consistent with Section 2.3.2 of the Enforcement Policy. The NRC inspection team described these NCVs in the subject inspection report.

If you contest these violations, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Director, Office of Nuclear Materials Safety and Safeguards; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Sincerely,

Francis Peduzzi

Francis Paul Peduzzi, Chief
Inspections and Operations Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 72-1014

Enclosure:
NRC Inspection Report No.
72-1014/2021201

SUBJECT: U.S. NUCLEAR REGULATORY COMMISSION INSPECTION REPORT NO. 72-1014/2021-201

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U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Management

Inspection Report

Docket:	72-1014
Report:	72-1014/2021-201
Certificate Holder:	Holtec International Krishna P. Singh Technology Campus 1 Holtec Boulevard Camden, NJ 08104
Inspection Dates:	May 10, through September 17, 2021
Inspection Team:	Marlone Davis, Senior Transportation and Storage Safety Inspector, Team Leader Earl Love, Senior Transportation and Storage Safety Inspector Jon Woodfield, Transportation and Storage Safety Inspector Matthew Learn, Transportation and Storage Safety Inspector Azmi Djapari, Transportation and Storage Inspector (In-Training) Patrick Koch, Structural Engineer JoAnn Ireland, Thermal Engineer
Approved By:	Francis Paul Peduzzi Inspections and Operations Branch Division of Fuel Management Office of Nuclear Material Safety and Safeguards

Enclosure

U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Fuel Management

EXECUTIVE SUMMARY

Holtec International
NRC Inspection Report 721014/2021-201

On May 10, to May 13, 2021, the U.S. Nuclear Regulatory Commission (NRC) inspection staff and technical reviewers (team) performed an inspection at Holtec International (Holtec) corporate office in Camden, NJ. The team continued the inspection activities with an in-office review of outstanding inspection questions and had a debrief on May 24 and August 3, 2021, and conducted a final exit on September 17, 2021, after further discussions on the violations. The purpose of the inspection was to assess Holtec's activities related to the design control of independent spent fuel storage installation (ISFSI) components 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," and 10 CFR Part 21, "Reporting of Defects and Noncompliance." The scope of the inspection activities was to determine whether Holtec's design control program met the requirements of their NRC approved quality assurance program for design development and design changes to applicable dry cask storage system certificate of compliances (CoCs) including technical specifications (TSs) and final safety analysis reports (FSARs).

Based on the results of this inspection, the NRC inspection team determined that the implementation of Holtec's QA program did not meet certain NRC requirements in the areas of design control and 10 CFR 72.48 evaluations. This resulted in three Severity Level IV violations of NRC requirements.

Design Controls

The team identified some general issues of concern and three violations of NRC requirements as described below in the areas of design control and 10 CFR 72.48 evaluations:

- Holtec did not correctly conclude that a change did not affect the technical specification incorporated in the CoC for specified requirements associated with one of the transfer casks the HI-TRAC 100G associated with the HI-STORM 100 cask system;
- Holtec did not include a complete written evaluation which provided the bases for the determination that the addition of a Girdle Beam Structure (GBS) on the HI-STORM 100 overpack, Version B, did not require a license or CoC amendment. Specifically, Holtec did not subject design changes to design control measures commensurate with those applied to the original design in that the written evaluation did not consider the critical stresses and strains that the GBS would place on the overpack, canister, and fuel basket; and
- Holtec did not include a complete written evaluation which provided the bases for the determination that the change that incorporated a new overpack and lid designated as the version (E) for HI-STORM Flood and Wind (FW) cask system did not determine require a CoC amendment, which may have met one or more of the 10 CFR 72.48 criteria, which may require prior NRC review and approval before the implementation.

(Other Inspection Areas)

The team determined that Holtec established its programs for management controls (i.e., nonconformance conditions, control of conditions adverse to quality, 10 CFR Part 21 reporting requirements, documentation controls and audit program) in accordance with the applicable regulatory requirements of their NRC approved quality assurance program. Based on the sample of documents reviewed, the NRC inspection team also determined that Holtec is implementing its policies and procedures associated with these programs. There were no findings of significance identified in these areas.

REPORT DETAILS

1.0 Inspection Scope

On May 10 - 13, 2021, the NRC conducted an announced inspection at the corporate headquarters of Holtec in Camden, NJ with additional in-office reviews based on outstanding questions during the onsite week. The inspection focused on design control of independent spent fuel storage installation (ISFSI) components for Holtec's dry cask storage systems (DCSSs) listed in the Table below. The team reviewed design development and design changes implemented by Holtec and evaluated the impact of the design development and changes on the functionality of DCSS components used at ISFSIs.

Table
List of Holtec's Storage Design Models

Storage Design Model #	Docket / Certificate #	Amendment	FSAR (as updated)
HI-STAR 100	07201008	4	HI-STAR, Revision 3
HI-STORM 100	07201014	10 - 15	HI2002444, Various Revisions
HI-STORM FW	07201032	3 – 5	HI2114830, Various Revisions
HI-STORM UMAX	07201040	2 - 4	HI2115090, Various Revisions

1.1 Inspection Background

The NRC has conducted two fabrication inspections since the last corporate inspection at Holtec in Camden, New Jersey. This includes one at Holtec Orrvilon in Orrville, Ohio (ML 20262G981) in August 2020, and Holtec Manufacturing Division (HMD) at Turtle Creek, PA (ML20356A185) in November 2020. The inspection teams conducted these inspections to determine if Holtec performed fabrication activities in accordance with the requirements of 10 CFR Parts 21 and 72, the applicable CoC, FSAR, and Holtec's NRC-approved quality assurance program. Additionally, the staff performed a follow-up inspection associated with escalated enforcement actions for a design control issue in which the staff documented in a letter to Holtec, dated August 16, 2019 (ML19228A016).

2.0 Management Controls

2.1 General

The team assessed Holtec's management controls in the areas related to the implementation of their quality assurance program (QAP) and implementing procedures, nonconformance conditions, control of conditions adverse to quality, 10 CFR Part 21 reporting requirements, documentation controls and their audit program.

2.2 Quality Assurance Program Manual and Policy

The Holtec Quality Assurance Manual (QAM) and implementing procedures establish how Holtec controls and implements activities subject to 10 CFR Parts 71 and 72 regulatory requirements described in subparts H and G, respectively.

2.2.1 Scope

The team reviewed the Holtec QAM, Revision 14 and various Holtec implementing procedures designated as Holtec Quality Procedures (HQPs) and Holtec Standard Procedures (HSPs) to assess the effectiveness of their Quality Assurance (QA) program implementation. The team conducted reviews of Holtec's quality program, policies, and procedures, to determine whether Holtec adequately controlled and implemented activities under their NRC approved QA program and activities subject to 10 CFR Part 72 regulations. The team reviewed procedures to verify if Holtec clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group. The team also reviewed procedures for the use of a graded approached for identifying Important-to-Safety (ITS) components and whether Holtec applied this graded quality level to procurement documents. The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Additionally, the team reviewed training records of a random selection of employees in quality related positions to determine if they received the required QA indoctrination and QA program revision training. The team reviewed the following specific HQPs and HSPs:

- HQP-1.0, "Organization and Responsibilities," Revision 44
- HQP-2.0, "Quality Assurance Program," Revision 25
- HSP-100101, "Organization," Revision 3
- HSP-100201, "QA Manual and Procedures," Revision 2
- HSP-100203, "Training Program," Revision 1
- HSP-100204, "Measurement and Analysis of QA Program Effectiveness," Revision 1

2.1.1 Observations and Findings

The team assessed that Holtec had a QA program and implementing procedures in place that were effective in conducting activities in accordance with their DCSS CoCs as well as their NRC approved QA program. The team verified that the quality assurance program authorities and responsibilities were clearly defined and documented, and the quality assurance organization functioned as an independent group. The team also determined that for the sample of Holtec staff member training record's reviewed and selected that each staff member completed the required training and attained the applicable qualifications to perform their duties. Additionally, the team verified Holtec's quality assurance procedures discussed a graded approach for identifying ITS components for their DCSS components.

Additionally, the team evaluated the 2020 quality program status report number HI-2210443, which covers the work performed during the prior year. This report includes a summary of the results from internal audits, third party audits, trending of quality issues and nonconformance reports, summary and evaluation of any client report cards, trending of vendor nonconformance reports, and a summary of vendor audits performed from the previous year. The team noted that this report was an effective tool for the Holtec management to review the status and adequacy of the overall QA program.

2.1.2 Conclusions

The team concluded that Holtec had adequate quality assurance controls. The team determine that Holtec conducts its activities associated with their QA organization independence, QA

responsibilities and graded approach in accordance with their NRC approved QA program. There were no findings of significance identified.

2.2 Nonconformance Controls

2.2.1 Scope

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a nonconformance control program in accordance with their NRC approved QA Program, and the requirements of 10 CFR Parts 21 and 72. Specifically, the team reviewed Holtec's approved procedure HSP-101502, "Control of Nonconforming Conditions," Revision 0. The team selected several nonconformance reports (NCRs) associated with 10 CFR 72.48 screenings and evaluations to verify that the NCRs were identifiable, traceable, and the disposition of the nonconformance was adequate. The team reviewed NCRs since the previous 2018 inspection and concentrated on issues involving ITS structures, systems, and components (SSCs). The team reviewed these NCRs to evaluate if the disposition was appropriate, adequately performed as necessary, and properly closed out in accordance with the approved procedure, HSP-1010502. The team focused the review on accept-as-is and repair dispositions because generally these NCRs require a technical justification or engineering evaluation generally dispositioned with 10 CFR 72.48 requirements. This also included a review of supplier manufacturing deviation reports (SMDRs).

The list of SMDRs reviewed and associated NCRs are as follows: SMDR Nos. 2516, 2762, 2786, and 2818.

In addition, the team reviewed Holtec's approved procedure HSP-101501, "Reporting of Defects per 10 CFR 21 or 10 CFR 50.55e," Revision 0, to determine if provisions were in place for reporting defects that could cause a substantial safety hazard from the NCRs and quality issues identified. This review also included, and assessment of NCRs and quality issues logs for compliance with 10 CFR 72.242(d).

2.2.2 Observations and Findings

The team assessed that Holtec adequately dispositioned and closed each selected NCR and SMDR in accordance with the requirements of procedure HSP-101502, as applicable. In addition, the team noted that there were no Part 21 or 10 CFR 72.242(d) reports issued for the past three years.

2.2.3 Conclusions

The team concluded that Holtec effectively implemented its nonconformance control program and has adequate procedures in place to ensure compliance with the applicable regulations and approved QA Program requirements. The team also concluded that Holtec has provisions in place for reporting defects that could cause a substantial safety hazard and design or fabrication deficiencies that could affect the DCSSs ITS SSCs to perform their intended safety function, as required by 10 CFR Parts 21 and 72.242(d), respectively. The Part 21 postings in the Holtec's Camden, NJ facility and corporate office met the approved implementing procedure and the applicable requirements of 10 CFR Part 21. There were no findings of significance identified.

2.3 Corrective Actions Controls

2.3.1 Scope

The team reviewed selected records and interviewed personnel to verify that Holtec effectively implemented a corrective action control program in accordance with the NRC approved QA Program and the requirements of 10 CFR Part 72. Specifically, the team reviewed Holtec's approved procedure HSP-101601, "Corrective Actions," Revision 2. The team reviewed quality issues (QIs) since the previous 2018 inspection and concentrated on issues involving ITS SSCs. The team reviewed selected records and interviewed selected personnel to verify that Holtec completed corrective actions for identified deficiencies in a technically sound and timely manner. Additionally, the team included a review of two QIs numbers 2937 and 2929 based on an incident that involved a crack weld near the water jacket shell structure on the HI-TRAC 100G, which occurred during a loading operation at a general licensee's facility.

2.3.2 Observations and Findings

HI-TRAC 100G Crack Weld

The team reviewed the QIs associated with a crack weld on the HI-TRAC 100G to determine if Holtec implemented the procedure guidance contained HSP-101601. Holtec identified a cause using a failure mode and effects analysis and performed an extent of condition and cause for the adverse to quality condition on the HI-TRAC 100G. Holtec identified that the original analysis used for the design did not consider the mechanical lifting loads and the additional stresses for all operating conditions. Holtec also identified that the cause of the crack weld was due to an improper weld technique doing the fabrication of the HI-TRAC 100G. The team assessed the design issues during this inspection and disposition the fabrication issues during the HMD inspection activities at Turtle Creek, PA in inspection report number 1014-2020-202 (ML20356A185).

The team noted that Holtec implemented their corrective actions in accordance with the QA implementing procedure HSP-101601.

2.3.3 Conclusions

Overall, the team assessed that Holtec had an adequate corrective action program in place to resolve conditions and significant conditions adverse to quality which include deficiencies. The team determined that Holtec, in general, completed corrective actions for identified deficiencies in a technically sound and timely manner. There were no findings of significance identified.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed Holtec's documentation control program and procedures to assess the effectiveness of controls established for the approval, issuance, revision and use of quality documents. The team reviewed a sample of Holtec documents (general procedures, records, drawings, and specifications) to verify that Holtec performed and controlled the quality activities

in accordance with implementing procedures and regulatory requirements. The team reviewed the following documents:

- HQP 6.0, “Document Control,” Revision 14,
- HQP 17.0, “Quality Assurance Records,” Revision 27,
- HSP 100201, “Quality Assurance Manual and Procedures,” Revision 1, and
- HSP 100502, “Standard and Project Procedures”, Revision 1

The team also interviewed QA personnel regarding documentation controls.

2.4.2 Observations and Findings

The Holtec document control procedures establish the processes for the preparation, approval, revision, distribution, and control of Holtec’s QAM. The team noted that the Vice President of Quality is responsible for writing some of the procedures and for reviewing and approving procedures developed through other QA staff members. The Vice President of Quality is also responsible for adding the new procedures or new version of a procedure in the appropriate folder in Holtec’s QA software and sending an email to the company with the information and location for the new procedure. Once this is done, previous versions of procedures are removed to an archive within the QA software. Currently, Holtec keeps all QA records electronically. The team noted that Holtec provided adequate guidance for record retention in the HQPs and HSPs.

2.4.3 Conclusions

The team concluded that Holtec conducts its activities associated with QA documentation controls in accordance with their NRC approved QA program. There were no findings of significance identified.

2.5 Procurement Controls

2.5.1 Scope

The team reviewed Holtec’s process of material procurement, which included the review of procurement documents, material traceability, drawings and procedures, and receipt inspection records to determine whether Holtec established an effective method for tracking, evaluating, and dispositioning changes or modifications to the DCSS component design. The team reviewed the following documents:

- HQP 4.0, “Procurement Document Control,” Revision 0,
- HQP 5.0, “Instructions, Procedures, and Drawings,” Revision 0
- HSP 100401, “Processing of Purchase Orders,” Revision 2,
- HSP 100402, “Purchase Specification,” Revision 2,
- HSP 100701, “Receipt Inspection,” Revision 1, and

2.5.2 Observations and Findings

The team verified that procurement of limited ITS, Category A and B (ITS-A and B) items and services were made to suppliers listed on Holtec’s approved suppliers list. The team reviewed a

sample of procurement documents. The team noted that Holtec does commercially dedicated some of their ITS components and maintained traceability from receipt of items until completion of commercial grade dedication and receipt inspection. The team assessed that Holtec provides layers of traceability as shown in the commercial grade dedication reports, quality plans, purchase specifications, material test and examination reports, and a final receipt inspection report.

The team reviewed Holtec's external audit program to determine if Holtec scheduled and performed supplier audits and annual evaluations in accordance with approved quality procedures as discussed in Section 2.6 of this report.

Overall, the team identified no concerns with Holtec's supplier survey, audit, and supplier evaluation program. The team verified that for the audits sampled, Holtec conducted the audit and survey with qualified and certified personnel, scheduled and evaluated applicable elements of the QA program, and resolved findings and observations in a timely manner.

2.5.3 Conclusions

The team assessed that Holtec procurement control for design changes were comprehensive and effective when tracking, evaluating, and dispositioning changes or modifications to the DCSS component design. There were no findings of significance identified.

2.6 Audit Program

2.6.1 Scope

The team reviewed Holtec's audit program to determine whether audit plans, schedules, and other audit records met the requirements described in the Holtec QAM and implementing procedures. The team also reviewed the following implementing procedures for performing internal and external audits of Holtec vendors on their AVL.

- HQP-18.0, "Audits," Revision 0
- HSP-101801, "Certification of Audit Personnel," Revision 0
- HSP-101802, "Audits," Revision 5
- HSP-101803, "Internal QA Surveillance and Document Reviews," Revision 0

The team reviewed the qualifications, training records, and annual evaluations for Holtec's Lead Auditors to determine if they met the requirements stated in HSP-101801.

The team reviewed the audits of two vendors on the Holtec AVL. The two vendors were on the Holtec AVL for: 1) Supplier of Safety-Related Computer Program Structural Modeling, Analysis, and Design Software, 2) Provider of ITS-A welding material. The second audit reviewed by the team was a quality assurance program audit performed by Holtec for itself and NIAC members of an ITS-A weld material supplier.

The team reviewed the 2019, 2020, and 2021 Holtec internal audits. The team requested and reviewed the 2020 and 2021 Holtec internal surveillance schedules for compliance with HSP-101803.

2.6.2 Observations and Findings

The team noted the audit included both corporate (design, project management, procurement, etc.) and the manufacturing facility. The team reviewed the audit results to determine if Holtec identified deficiencies and addressed the deficiencies with their corrective action program. The team noted that the auditors identified twelve QIs during the audit and that all the issues were captured on QI reports. The team noted the status of the QI's in that six were closed and evidence provided included appropriate corrective actions and that the additional six QI's were open in which the majority were pending QA verification of implementation of corrective actions. The team determined the Nuclear Industry Assessment Committee (NIAC) audit package to be thorough with the use of the NIAC checklists and detailed documentation. Holtec followed it procedures by performing an audit review checklist to accept the audit as its own. and assessed them to be very thorough with the use of checklists and documented evidence for determinations. All findings each year were placed in the Holtec corrective action program for resolution.

The team assessed if each auditor had completed the required training and attained the applicable qualifications to perform their duties as lead auditor. The first audit reviewed by the team was a quality assurance program audit performed by the NIAC where Holtec received a copy of the audit and performed an audit review checklist to accept the audit for its purposes. The team assessed the audit package to be thorough with detailed documentation. The team assessed the sampled vendor audit results to be very detailed and well documented with the findings, audit checklists, supporting audit documentation reviewed, and vendor written responses all recorded and retrievable. All the requirements of the audit procedures were found to be implemented appropriately. No concerns were identified by the team in the review of AVL audits.

The team noted that Holtec performs internal audits on a yearly basis and audits all eighteen QA program elements and develops audit plans in accordance with approved procedures. The team noted that the audit plans identify the organization being audited, audit scope, requirements, audit team, activities for audit, applicable documents, schedule of the audit, and identification of audit checklists that audit personnel would use to prepare and conduct the audit. As stated in the Holtec audit procedure, the audit team shall consist of one or more auditors, one being designated as the lead auditor. The team noted that Holtec provided objective evidence, documentation, and examined to the depth necessary to determine that auditors effectively implemented the applicable criteria. The team noted that a Holtec lead auditor issues and signs all audit reports. The corporate quality assurance manager is responsible for the development of the internal surveillance schedules for random surveillances. In addition, the QA manager is responsible for assigning personnel to perform the random surveillances, providing surveillance training, determining the surveillance methods, and reviewing the results.

2.6.3 Conclusions

Overall, the team determined that Holtec conducted the audit with qualified and certified auditors, and provided sufficient objective evidence satisfying all the elements of Holtec's QA program.

The team assessed that Holtec scheduled and performed internal audits and internal surveillances in accordance with their implementing procedures. There were no findings of significance identified.

3.0 Design Controls

3.1 General

The team reviewed the design control program described in Holtec's QAM and governing procedures to determine whether Holtec implemented design controls and design changes to their DCSS for use at independent spent fuel storage installations. The team reviewed selected design change packages, including engineering change orders (ECOs), 10 CFR 72.48 evaluations, and interviewed Holtec personnel involved in their engineering design control process.

3.2 Design Development

3.2.1 Scope

The team reviewed the design control section of the Holtec's QAM Revision 14 and reviewed the following Holtec quality and standard procedures associated with design development to verify that Holtec properly implemented proper controls in accordance with implementing procedures. The team reviewed the following procedures:

- HQP-2.0, "Quality Assurance Program," Revision 25
- HQP-3.0, "Project Planning, Design Control, Product Realization and Project Execution," Revision 29,
- HSP-100202, "Project Planning, Product Realization and Project Execution," Revision 0
- HSP-100301, "Design Specifications and Design Criteria Documents," Revision 0
- HSP-100302, "Design Control," Revision 0
- HSP-100303, "Design and Analysis Personnel Qualifications," Revision 1
- HSP-101101, "Computer Programs," Revision 0

The team reviewed selected drawings, calculation packages, design verification checklists, design specifications, purchasing specifications and other design control records to verify that materials, equipment, and engineering services met design requirements. The team reviewed Holtec's HI-STORM 100 Cask System CoC No. 1014, Amendments 10 - 15, FSAR No. HI-2002444, various revisions; HI-STORM FW CoC No. 1032, Amendments 3 - 5, FSAR No. HI-2004830, various revisions, and HI-STORM UMAX CoC No. 1040, Amendments 2 - 4, FSAR No. HI2115090, various revisions, to assure compliance with approved methods, procedures, and specifications.

The team reviewed design changes that the licensee (as applicable) and Holtec initiated to determine whether a method existed to ensure that both the licensee and Holtec communicated design changes in a timely manner, minimize production or operational impacts, and if the design changes received the necessary approvals.

3.2.2 Observations and Findings

The team verified that Holtec assigned design responsibilities appropriately and verified that the responsible parties either Holtec or the general licensee performed acceptance and formal

reviews. The team also noted that Holtec uses a network database that organizes information needed to maintain configuration control for licensing and design basis documentation. This included the use of approved computer codes on the network in that Holtec had methods in place to development, control, verification, validation, and documentation of computer programs used for ITS activities.

3.2.3 Conclusions

Overall, the team concluded that Holtec had methods in place for each project and design development contained the necessary information to enable the project team to execute the project in a controlled manner and to assure that products and services met customer specifications requirements. Additionally, the team determined that Holtec maintained configuration control for licensing and design basis documentation. There were no findings of significance identified.

3.3 Design Changes

3.3.1 Scope

The team reviewed selected records and interviewed personnel to determine whether Holtec implemented and evaluated design changes for their impact on the functionality of DCSS components. The team focused its review on the complete and accurate documentation and appropriate evaluation of ECOs and 10 CFR 72.48 screenings and evaluations. The team reviewed Holtec's procedures related to the implementation instructions for 10 CFR 72.48 evaluations and control of modification activities. Specifically, the team reviewed Holtec's approved procedure HSP-321, "Screening and Evaluation of Changes," Revision 6.

The team reviewed a list of ECOs, screenings and evaluations performed by Holtec to meet the regulatory requirements associated with 10 CFR 72.48 based on the last corporate inspection in May 2018. The team selected a representative sample of screenings and evaluations from the biennial summary reports and a more recent list provided by Holtec using the guidance in IP 60857, "Review of 10 CFR 72.48 Evaluations," and Appendix E to IMC 2690, "Guidance for Risk-Informed Review of 72.48 Evaluations." The team reviewed biennial reports from 2018 and 2020, titled 10 CFR 72.48(d)(2) reports, "Biennial Summaries of Changes, Tests, and Experiments," pertaining to the HI-STAR 100, HI-STORM 100, HI-STORM FW, and HI-STORM UMAX Dry Cask Storage Systems (NRC Docket Nos. 72-1008, 72-1014, 72-1032, and 72-1040).

The team used the guidance in NRC Inspection Manal Chapter (IMC) 0335, "Changes, Tests, Experiments," Nuclear Energy Institute (NEI) 12-04, Revision 2 and NEI 96-07, Appendix B, "Guidelines for 10 CFR 72.48 Evaluations," dated September 2018 and March 5, 2001, respectively to evaluate the screenings and evaluations. The NRC endorsed both NEI documents in Regulatory Guide 3.72, "Guidance for Implementation of 10 CFR 72.48, "Changes, Tests, and Experiments". The team also reviewed the NRC safety evaluation reports (SERs) associated with each DCSS.

3.3.2 Observations and Findings

10 CFR 72.48 Screenings and Evaluations

The team selected a sample of approximately thirty-five 10 CFR 72.48 screenings (15) and evaluations (20) to verify that Holtec appropriately concluded that the change did not require prior NRC review and approval or a full evaluation if Holtec personnel determined that the change screened out during the screening process in accordance with NRC requirements and Holtec procedures, respectively. Based on the team's assessment, the team identified some general issues of concern and three violations of NRC requirements. The team describes the details of the violations below.

HI-STORM 100 HI-TRAC 100G

The team reviewed the HI-STORM 100 Cask System FSAR, HI-2002444, Revisions 18 – 20, and evaluated the 72.48 evaluation number 1439 and ECO 5014-292 related to the design change that incorporated a new transfer cask HI-TRAC 100G for the CoC No. 1014. The new or alternate HI-TRAC had a few differences compared to the other HI-TRAC transfer cask designs.

In reviewing the FSAR related to the 72.48 evaluation change that incorporated the HI-TRAC transfer cask, the team noted that Section 2.0.3 of the HI-STORM 100 Cask System FSAR described the design criteria for all the HI-TRAC transfer cask. Section 2.0.3 states, in part, that the HI-TRAC transfer cask is designed for all normal, off-normal, and design basis accident condition loadings, as defined in Section 2.2. At a minimum, the HI-TRAC transfer cask must protect the MPC from deformation, provide continued adequate performance, and allow the retrieval of the MPC under all conditions. These design loadings include a side drop from the maximum allowable handling height, consistent with the technical specifications (Not applicable for HI-TRAC 100G).

The team observed that Holtec revised this section of the FSAR as a part of the design change so that it would not apply to the HI-TRAC 100G and further discussed the basis for this change in FSAR Section 3.1.2.1.1.2. Section 3.1.2.1.1.2 states, in part, that a handling accident of a loaded HI-TRAC 100G is not credible as the HI-TRAC 100G will always be handled by a single failure-proof lifting equipment. Subsequently, Holtec did not analyze the HI-TRAC 100G for a side drop accident as Holtec previously performed for all the other HI-TRAC models and captured within the design and licensing basis.

The team reviewed the technical specifications (TSs) associated with the CoC No. 1014, Amendments 13 - 14. The team noted that Holtec did not update or incorporate the new administrative controls specified in the FSAR into the CoC TSs. Specifically, TS section 5.5, "Cask Transport Evaluation Program," of Appendix A and TS section 3.5, "Cask Transfer Facility," of Appendix B for CoC No. 1014 Amendments 13 and 14. Both TS sections discusses the "Transfer Cask" generically without distinguishing between the different types contained in the HI-STORM FSAR. The team noted that without the new administrative controls for the transfer cask, HI-TRAC 100G, the TSs would allow lifts without a single failure proof lifting equipment and had the potential to create a possibility for a malfunction since there was no drop analysis associated with this transfer cask. The team identified that section 1.4 of Holtec evaluation screening for 72.48-1439, "Evaluation of the eligibility of the proposed change for the 72.48 process," question 2, states, in part, "does the propose change conflict with any provisions in the TS?" However, Holtec answered "No" instead of "Yes" to the question. The team determined that Holtec should have answered yes because the proposed change conflicted with the provisions in the TS. The team identified that Holtec did not update the TSs

to provide the new administrative controls to ensure that licensees would manage the new transfer cask in a safe and reliable manner.

The team assessed that this was a violation of NRC requirements related to 10 CFR 72.48(c). Specifically, 10 CFR 72.48(c)(1), requires, in part, that a certificate holder may make changes in the facility or spent fuel storage cask design as described in the 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 either…

> (ii) A CoC amendment submitted by the certificate holder pursuant to § 72.244 (for general licensees and certificate holders) if:
> (A) A change to the technical specifications incorporated in the specific license is not required; or
> (B) A change in the terms, conditions, or specifications incorporated in the CoC is not required; and
> (C) The change, test, or experiment does not meet any of the criteria in paragraph (c)(2) of this section.

Contrary to the above, on April 24, 2020, the certificate holder (Holtec) made changes to the spent fuel storage cask design as described in the FSAR (as updated) without obtaining a CoC amendment pursuant to 10 CFR 72.244 for a change required the in terms, conditions, or specifications incorporated in the CoC. Specifically, Holtec made changes in the HI-STORM 100 cask system design that incorporated a new transfer cask HI-TRAC 100G into the FSAR without obtaining a CoC amendment pursuant to 10 CFR 72.244 for a change in the TS, which required incorporation of additional administrative controls specific to the HI-TRAC 100G transfer cask in the specifications of the CoC.

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The inspectors determined that the violation impacted the ability of the NRC to perform its regulatory oversight function because the licensee did not receive prior NRC approval for changes in licensed activities. The team determined that the violation was more than minor because the change would require NRC approval. The team characterized the violation as a Severity Level IV violation because the change resulted in a condition having low safety significance. Holtec plans to enter this issue into their corrective action program (CAP). The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and being entered in the Holtec's CAP, the team is treating this issue as a Non-Cited Violation (NCV), consistent with Section 2.3.2.a of the Enforcement Policy.

HI-STORM 100S Overpack Version B, Optional Structural Attachment

The team reviewed the HI-STORM 100 Cask System FSAR, the 72.48 evaluation number 1389, Holtec Engineering Report HI-2188381, and ECOs 1024-162 and 5014-291 related to the design change that incorporated an optional attachment for the HI-STORM 100S Version B overpack called the Girdle Beam Structure (GBS). The GBS is a welded hollow steel component added to the outside top of the overpack shell body below the outlet vents. Holtec added the GBS to absorb some of the impact energy following a non-mechanistic tip-over accident. The tip-over accident is a design basis event considered in the HI-STORM 100 FSAR accident analysis. Holtec had performed a site-specific tip-over analysis with the optional GBS attachment to the 100S Version B overpack and with the increase in compressive strength for the site-specific ISFSI pad and subgrade design parameters. The team reviewed the impact

that the GBS had on the cask design and the non-mechanistic tip-over accident as characterized in the HI-STORM 100 FSAR.

The team identified that the tip-over analysis performed for the addition of the GBS did not address the stresses that the GBS would apply on the overpack, canister, and fuel basket. As discussed in the HI-STORM 100 FSAR Section 3.4.10, the structural integrity of the components of the overpack following the tip-over accident relies on an examination of the stresses and strains in the overpack for the multi-purpose canister and fuel basket. In the FSAR, Holtec determined these stresses and strains from a finite element model with a non-rigid overpack, separate from the model for determining maximum decelerations at the top of the fuel basket. The 72.48 evaluation for the addition of the GBS did not address changes to theses stresses and strains observed in the overpack or the structural integrity of the overpack shielding components based on the addition of the GBS.

In addition, the 72.48 evaluation did not address changes to the stresses observed in the overpack lid due to the addition of the GBS. Holtec evaluated stresses in the HI-STORM 100S Version B lid from the tip-over accident in FSAR Subsection 3.4.4.3.2.2. In a discussion with Holtec staff during the inspection, Holtec stated that the previous tip-over evaluation of the HI-STORM 100S Version B lid considered a higher acceleration than would be experienced by the lid of an overpack with GBS, and thus Holtec concluded that the FSAR tip-over evaluation of the HI-STORM 100S Version B lid would be bounding for an overpack with the GBS attached. The staff notes that this evaluation of the lid for an overpack with GBS was not documented in the 72.48 evaluation or the supplementary engineering report, HI-2188381. The team also noted that this evaluation was not consistent with the methodology for evaluating the HI-STORM 100S Version B lid for the tip-over accident described in FSAR Subsection 3.4.4.3.2.2.

The team also discussed the non-mechanistic tip-over analyses performed for the general licensees (i.e., the site-specific analysis) because of the increase in compressive strength and ISFSI pad thickness, which fell outside design parameters identified in the FSAR. The team noted that both parameters were limiting design parameters for the ISFSI pad characterized in the HI-STORM 100 FSAR and were conservatively chosen inputs as described in FSAR Subsection 2.2.3.2 and Table 2.2.9. The team also noted that Holtec stated that the tip-over analyses is heavily dependent on the compressive strength of the reinforced concrete for the ISFSI pad and the GBS made those secondary parameters. The team determined that these assumptions and conservative input values made the compressive strength and ISFSI pad thickness elements of the tip-over analysis (i.e., method of evaluation) and the results of the site-specific analyses with the GBS were non-conservative in that the maximum deceleration results gain margin. However, the 72.48 evaluation did not capture the bases for the changes in stresses, elements, or methodologies for the addition of the GBS.

The team determined that this was a violation of NRC requirements related to 10 CFR 72.48(d)(1).

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 May 24, 2021, the certificate holder (Holtec) did not 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 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 did not include a written evaluation which provided the bases for the determination that the addition of the GBS on the HI-STORM 100S Version B overpack does not require a CoC amendment pursuant to 10 CFR 72.48 (c)(2).

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team determined that the violation had the potential for impacting the NRC's ability to perform its regulatory oversight function because Holtec did not perform an adequate 10 CFR 72.48 evaluation that provided the bases for the determination that the addition of the GBS does not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). The team determined that the violation was more than minor because there was a reasonable likelihood that the change would require NRC review and approval. The inspectors characterized the violation as a Severity Level IV violation because the change resulted in a condition having low safety significance. Holtec plans to enter this issue into their CAP as QI-3045. The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and Holtec entered the issue into their CAP, the team is treating this issue as an NCV, consistent with Section 2.3.2.a of the Enforcement Policy.

HI-STORM FW Overpack Version E

The team reviewed the 72.48 evaluation number 1399R1, various sections of the HI-STORM FW FSAR, Holtec Engineering Reports HI-2200503 and HI-2094353, and ECO 518-96R1. The team also discussed the design change related to HI-STORM FW overpack with Holtec personnel. The team noted that Holtec made a design change to add a new version of the overpack and lid to the HI-STORM FW cask system. The new overpack and lid, called the Version E, included differences from the standard overpack and lid but not limited to the following, an increase in the concrete thickness, height, weight, and code allowable temperature. Holtec also modified the outlet vent configuration and the canister pedestal height within the overpack.

As a part of the review of the 72.48 evaluation 1399R1, the team observed that Holtec changed the allowable limits in several analyses for the Version E overpack. Table 2.2.12 of the HI-STORM FW FSAR lists allowable stress limits for the steel structure of the HI-STORM FW overpack to meet the stress limits of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code as applicable. Tables 3.4.3 through 3.4.6 and 3.4.10 of the HI-STORM FW FSAR list the allowable limits for the normal handling of the overpack and lid, tornado missile, and snow load conditions, respectively. In the case of the normal lifting conditions, Holtec changed the allowable limits from those taken at a temperature of 350 degrees Fahrenheit (°F) as described in the HI-STORM FW FSAR to those taken at a temperature of 500°F as discussed in ECO 5018-96R1. However, there was no explanation of using a different temperature that altered or exceeded allowable limits contained in the 72.48 evaluation and ECO for the overpack and lid. The change in temperature altered or exceeded the allowable limits and resulted in increases in the factors of safety in some cases and decreases in others as compared to the standard overpack and lid. Additionally, based on a review of the method of evaluation as described in the HI-STORM FW FSAR and the information provided in the ECO, the team could not determine if the change in the temperature was a change in an element of the method of evaluation use to calculate the allowable limits for the load conditions.

Another example was the flood load case, where the maximum acceptable water velocity change from 30.8 foot per second to 30.5 foot per second. The value of 30.8 foot per second was in the NRC safety evaluation report, used in calculating the maximum acceptable water velocity of a moving flood water scenario for the controlling event of sliding. The team noted that Holtec did not consider all the direct and indirect effects of the change or provide an appropriate justification that clearly explain that the fission product barriers were not affected (i.e., altered or exceeded).

The team determined that this was another example of a violation of NRC requirements related to 10 CFR 72.48(d)(1).

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 June 2, 2020, the certificate holder (Holtec) did not 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 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 did not include a written evaluation which provided the bases for the determination that the new Version E overpack and lid does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

The team assessed the significance of the violation using the NRC Enforcement Policy and Enforcement Manual. The team determined that the violation had the potential for impacting the NRC's ability to perform its regulatory oversight function because Holtec did not perform an adequate 10 CFR 72.48 evaluation that provided the bases for the determination that the new Version E overpack and lid did not require a CoC amendment pursuant to 10 CFR 72.48(c)(2). The team determined that the violation was more than minor because there was a reasonable likelihood that the change would require NRC review and approval. The inspectors characterized the violation as a Severity Level IV violation because the change resulted in a condition having low safety significance. Holtec plans to enter this issue into their CAP as QI-3045. The team determined that because the violation was of very low safety significance, the issue was not repetitive or willful, and Holtec entered the issue into their, the team is treating this issue as an NCV, consistent with Section 2.3.2.a of the Enforcement Policy.

72.48 Screenings and Evaluations Generic Review

The team also noted that Holtec used canned responses to evaluate the eight criteria questions under 10 CFR 72.48(c)(2), which sometime did not address or capture the specific design change. For example, the canned response for criterion seven related to design basis limits for a fission product barrier sometimes focused only on the maximum peak cladding temperature design basis limit. However, there are other parameters that may impact the fission product barrier such as decay heat, and the number of thermal cycles. Additionally, the team noted that the confinement barrier may also be impacted such as allowable stresses, or max deceleration or g-loads on the canister or fuel basket. The team noted that the canned response may limit the evaluator responses to the actual design change.

3.3.3 Conclusions

The team identified some issues in the design control area related to the implementation of the 10 CFR 72.48 evaluation process. This resulted in three Severity Level IV NCVs of NRC requirements.

4.0 Exit Meeting

On May 12, 2021, the NRC inspection team discussed the scope of the inspection during an entrance meeting with Mr. Mark Soler, Vice President of Quality Assurance, and other members of the Holtec staff. On May 24, 2021, the NRC inspection team presented the inspection results and observations during a preliminary exit meeting with you and other members of your staff. During that preliminary exit meeting, Holtec wanted to provide additional information on items discussed in the meeting. On September 17, 2021, the NRC inspection team leader conducted a final Microsoft TEAMS exit with Mr. Mark Soler and other members from the Holtec staff. The table in the Attachment to this report shows the attendance for all entrance and exit meetings.

ATTACHMENT

LIST OF ATTENDEES FOR ENTRANCE AND EXIT MEETINGS

The team held an entrance meeting with Holtec personnel on May 10, 2021, to present the purpose and scope of the NRC inspection activities. On May 13, 24, and August 3, 2021, the team held these briefings to discuss the primarily results of the inspection based on additional information Holtec provided related to the team's questions. On September 17, 2021, the team conducted the final exit meeting with Mark Soler, Director of Quality Assurance, and other members from the Holtec staff. The table below documents the individuals present at the entrance and exit meetings.

Table
Entrance and Exit Meetings Attendees

NAME	AFFILIATION	ENTRANCE	TEAMS (Debrief)	TEAMS (Debrief)	TEAMS (Debrief)	TEAMS (Exit)
Marlone Davis	NRC/DFM	X	X	X	X	X
Earl Love	NRC/DFM	X	X			
Jon Woodfield	NRC/DFM	X	X	X		
Matthew Learn	NRC/DFM	X	X			
Azmi Djapari	NRC/DFM	X	X	X		
JoAnn Ireland	NRC/DFM	X	X	X		
Patrick Koch	NRC/DFM	X	X	X		X
Dr. Kris Singh	Holtec			X		
Mark Soler	Holtec	X	X	X	X	X
Stefan Anton	Holtec	X		X		
Kimberly Manzione	Holtec	X	X	X		
Chuck Bullard	Holtec	X	X	X		X
Shea Rader	Holtec	X	X			
Pankaj Chaudhary	Holtec	X		X		
Robert Tindal	Holtec	X		X		
Andrew Fecht	Holtec	X	X	X		
Abrar Mohammad	Holtec	X	X	X		
Debu Mitra Majumdar	Holtec	X	X	X		X
Brad Williams	Holtec	X				
Chris O' Mullane	Holtec	X	X			
John Griffiths	Holtec	X	X			

LIST INSPECTION PROCEDURES USED

1. Inspection Procedure 60851, "Design Control of ISFSI Components," dated 1/16/08
2. Inspection Procedure 60857, "Review of 10 CFR 72.48 Evaluations," dated 10/20/20

3. Appendix E to Inspection Manual Chapter (IMC) 2690, “Risk-Informed Selection Criteria for 72.48 Screenings and Evaluations,” dated 12/15/20
4. NUREG/CR-6407, “Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety”
5. NUREG/CR 6314, “Quality Assurance Inspections for Shipping and Storage Containers”

LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

Item Number	Status	Type	Description
72-01014/2021-201-01	Opened	NCV	72.48 Evaluation
72-01014/2021-201-02	Opened	NCV	72.48 Evaluation
72-01014/2021-201-03	Opened	NCV	72.48 Evaluation

LIST OF ACRONYMS USED

AVL	Approved Vendor List
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
ECO	Engineering Change Order
FSAR	Final Safety Analysis Report
HQP	Holtec Quality Procedure
HSP	Holtec Standard Procedure
IMC	Inspection Manual Chapter
IP	Inspection Procedure
ITS	Important-to-Safety
ISFSI	Independent Spent Fuel Storage Installation
MPC	Multi-purpose canister
NRC	Nuclear Regulatory Commission
QA	Quality Assurance
QAM	Quality Assurance Manual
QI	Quality Issue
SER	Safety Evaluation Report
SMDR	Supplier Manufacturing Deviation Reports
SSCs	Structures, Systems, and Components
UFSAR	Updated Final Safety Analysis Report

LIST OF DOCUMENTS REVIEWED

The team identified the documents reviewed during the inspection in the report details above.