INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Holtec International 555 Lincoln Drive West Marlton, NJ 08053
Licensee/Certificate Holder contact and phone number	Mr. Mark Soler 1-856-797-0900, X-619
Docket No.	072-01014
Inspection Report No.	07201014/2007202
Inspection Date(s)	July 16-19, 2007
Inspection Location(s)	Marlton, NJ
Inspectors	Jim Pearson, Rob Temps, and John Nicholson
Summary of Findings and Actions	Holtec International performs Part 72 activities under NRC Docket 72-01014. This inspection involved a review of Holtec's QA Program, implementation for Part 72 activities at their office in Marlton, NJ. Inspection activities focused on management controls and design activities. Within these areas, the inspection consisted of selected examinations of procedures and representative records, observations of activities, and interviews with personnel. Holtec's activities were found to be in compliance with NRC Part 72 regulations and with their NRC approved QA Program. No significant adverse findings were noted.
Lead Inspector Signature/Date	Jim Pearson 08/02/2007
Inspector Notes Approval Section Chief Signature/Date	**/RA/** 08/03/2007

INSPECTOR NOTES:

IP 60851 AND 60857 WERE USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314 WITH INSPECTION RESULTS USING THE NUREG/CR 6314 FORMAT DOCUMENTED BELOW:

INSPECTION BACKGROUND:

Holtec was last inspected September 27 - October 1, 2004 (reference NRC IR 0720104-04-202). That inspection focused on the implementation of the NRC approved Holtec quality assurance program in regard to the requirements of 10 CFR Parts 21 and 72, the certificate of compliance, and the applicable safety analysis report.

INSPECTION RESULTS:

4.1.1 Quality Assurance Policy

The NRC inspection team (the team) reviewed the NRC-approved Quality Assurance Program (QAP) and other procedures that govern QA policy and administration at Holtec. The team noted that the NRC-approved QAP is applied at both the Holtec corporate offices located in Marlton, NJ and at the Holtec Manufacturing Division (HMD) near Pittsburgh, PA.

The Holtec quality procedures were reviewed, in whole or in part, by the team and determined to be fully implemented. The team interviewed various Holtec personnel and determined that the Holtec quality organization is independent from cost and scheduling pressures and that they have access to various levels of management to discuss any quality issues that arise.

Overall, no concerns regarding the quality assurance process were identified by the team.

4.1.2 Nonconformance Controls

The team reviewed the procedures controlling the problem identification and corrective action system used by Holtec. Discussions were held with QA personnel, and the team also reviewed selected deficiency reports. The team noted that Holtec uses a two-tiered corrective action system. All potential conditions adverse to quality are documented and entered into the corrective action system as Quality Program Violations (QPVs). During evaluation of QPVs in accordance with procedure HQP-16.0, “Conditions Adverse to Quality and Corrective Action,” a judgement based system is used to determine whether the issue is a significant condition adverse to quality (SCAQ). If the issue is determined to be an SCAQ, then a Corrective Action Request (CAR) is generated. CARS generally require a formal root cause analysis to be performed in accordance with HQP-16.1, “Root Cause Evaluations.” QPVs and CARs are all tracked and trended by the QA Manager and periodic reports issued to senior Holtec management. The team reviewed a sampling of QPVs and CARs and determined that Holtec’s resolution of issues documented in the QPVs and CARs was appropriate and they were closed in a time-frame commensurate with their importance. No concerns were identified by the team and the determination was made that Holtec’s implementation of the corrective action program was proper and adequate. It should be noted that Holtec also uses a non-conformance

reporting system; however, this system was not reviewed during this inspection as it is applicable only to fabrication activities and will be inspected during the September 2007 NRC inspection at the HMD.

The team also reviewed 10 CFR Part 21 controls and determined that Holtec is properly implementing regulatory requirements in this area. Specifically, Part 21 requirements were posted as required, a Part 21 evaluation procedure exists, and Part 21 requirements were imposed as required on certain types of purchase orders.

Overall, no concerns regarding the nonconformance control process were identified by the team.

4.1.3 Documentation Controls

The team reviewed procedure HQP-6.0, "Document Control," and its associated matrix in Exhibit 6.0.1 that shows the controlling procedures for the various types of documents subject to document control. The administrator for document control was interviewed regarding the distribution process for the various controlled documents, which is designed to ensure that approved and current procedures are available to individuals performing activities affecting quality. All documents are maintained electronically and appropriate controls are in place to ensure only current approved documents are accessed by document users. Controls are also in place for modification and revision of documents and notification, in some cases, to affected parties of a procedure or document revision.

The team reviewed the control of documents related to the development of the HI STORM and HI STAR cask systems and determined they were in accordance with relevant procedures. The team also determined that adequate procedures for the archiving of documents following the completion of projects have been developed and implemented. Through interviews with personnel and review of documents, the team verified that adequate controls have been applied to procedures, specifications, engineering change notices and drawings. No concerns were identified.

Overall, no concerns regarding the documentation control process were identified by the team.

4.1.4 Audit Program

The team reviewed the schedules for audits and surveillances for 2007. Both audits and surveillances were scheduled and conducted periodically, and covered all applicable aspects of the QA program. The team reviewed the most recently conducted internal audit (Jan/07). The team noted that all audit findings were documented as required by procedure.

The team reviewed Holtec procedures and records for indoctrination, training, qualification, and certification of personnel performing audits and evaluations. Included in the review were lead auditor qualifications, annual assessments of lead auditor activities, lead auditor participation records. These documents adequately supported the qualifications of the lead audit personnel.

The team reviewed the procedure for control of the Holtec Approved Vendor List (AVL), which is maintained as an electronic database and used for the purchase of certain materials and services. The team reviewed a sample of vendor surveillances for companies on the AVL that supply materials and services to Holtec. The Holtec audits and surveillances were thorough and well-documented, and corrective actions were appropriately followed up. The audit and surveillance reports reviewed by the team were adequate.

Overall, no concerns regarding the audit process were identified by the team.

4.2.1 Design Development

The team interviewed Holtec engineering and QA personnel responsible for the preparation and approval of design documents. All personnel were able to provide descriptions of the control and review processes for design control activities. Included in the discussions with these individuals was the role that Holtec procedures 3.0 through 3.5 covering design control, input, analysis, and verification and Holtec procedure 5.1 Engineering Drawings, play in the control of design documents used to specify requirements. Engineering personnel - described the development, issuance, and control of Safety Analysis Report (SAR) drawings and the process whereby Engineering Change Orders (ECOs) are reviewed and approved under the requirements of Holtec procedure 5.1 Engineering Drawings.

Overall, no concerns regarding the design control process were identified by the team.

4.2.2 Design Changes

The team reviewed controls for the design modification processes that are used to ensure that design changes are controlled, and that any changes made to an original design are reflected in design documents. Holtec personnel were interviewed by the team, and selected drawings, procedures, records, ECOs, and calculations related to design modifications were reviewed. A sample of revisions to drawings resulting from approved ECOs were verified for accuracy in translation of the ECO specifics to the affected drawings. The team verified that design checking, review, and approval were performed and documented properly as required by the Holtec procedures.

The team reviewed several applications of 72.48 design changes. Most involved only screening, but several needed a full evaluation. The 72.48 packages reviewed involved criticality, shielding, and thermal issues, although the majority involved structural issues. Holtec personnel use the NEI 96-07 guidance for the 72.48 process. The team also reviewed the training given for personnel involved with the 72.48 process.

Inspectors spoke with the licensing manager regarding the licensing amendment request (LAR) process. Specifically team members looked over the document packages for the Indian Point Unit 1 multi-purpose canister (MPC) and the storage overpack (HI-STORM). These are shorter than the standard MPC and HI-STORM. These design changes involved changes to the CoC and the FSAR and involved submitting a license amendment. As part of the LAR process review nonconformance reports (NCRs) were reviewed, all were minor in nature and had been closed.

Overall, no concerns regarding the design modification process were identified by the team.

A partial listing of documents reviewed during the inspection follows:

HQP-1.0, Organization and Responsibilities, Revision 23
HQP-2.0, Quality Assurance Program, Revision 16
HQP-2.1, Quality Assurance Manual, Procedure Control, Program Implementation & Verification, Revision 20
HQP-2.2, Execution of HQAM and Extension to a fabricator's Facility, Revision 12
HQP-2.4, Training program, Revision 6
HQP-2.6, Execution of Quality Requirements and Extension to a Suppler's Facility for Important-to-Safety Categories B Items, Revision 6
HQP-3.0, Project planning, Design Control, Product Realization and Project Execution, Revision 18
HQP-3.1, Design Input Requirements, Revision 8
HQP-3.2, Design Analysis, Revision 20
HQP-3.3, Design Verification, Revision 22
HQP-3.4, Design Specification and Design Criteria Documents, Revision 4
HQP-4.1, Purchase Requisitions, Revision 17
HQP-4.2, Material Purchase Specifications, Revision 3
HQP-5.1, Engineering Drawings, Revision 26
HQP-5.3, Standard and Project Procedures, Revision 7
HQP-6.0, Document Control, Revision 9
HQP-6.1, Project Document Transmittal and Control, Revision 7
HQP-6.2, Document Classification, Revision 3
HQP-6.3, Review of Vendor Documents, Revision 3
HQP-7.2, Supplier Surveillance, Revision 8
HQP-7.4, Approved Vendor List, Revision 17
HQP-7.5, Commercial Grade Dedication and Quality Plans, Revision 16
HQP-15.1, Reporting of Defects and Noncompliances per 10 CFR21, Revision 11
HQP-15.2, Nonconformances, Revision 19
HQP-16.0, Conditions Adverse to Quality and Corrective Action, Revision 16
HQP-17.0, Quality Assurance Records, Revision 19
HQP-18.1, Certification of Audit Personnel, Revision 14
HQP-18.2, Audits, Revision 15
HQP-18.4, Evaluation of Significant Audit Findings and Deficiencies, Revision 4
HQP-18.5, Internal QA Surveillances and Document Reviews, Revision 3
HSP-322, Dry Storage & Transportation SAR Control and CoC Amendment Requests
Document package for IP HI-STORM 100S version B dated 04/11/2007
Document package for IP MPC-32 assembly dated 02/09/2007
Engineering Change Order 1023-42, and associated drawings 3923, and 3753
Engineering Change Order 1021-77, and associated drawing 3923
Engineering Change Order 1021-89, and associated drawings 1402, and 3928
72.48 Screening/Evaluation documents 5014-36, 1021-42, 1024-63, 1022-9, and 1024-37
LAR 1014-5