NRC FORM 591S PART 1
(10-2013)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER:	2. NRC/REGIONAL OFFICE
Holtec International Holtec Center 555 Lincoln Drive West Marlton, NJ 08053	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 072-1014/2014-202	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
72-1008, 72-1014, 72-1032, 71-9261, 71-9325, 71-9336, 71-9261	555 Lincoln Drive West Marlton, NJ 08053	June 23-27, 2014

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☑ 1. Based on the inspection findings, no violations were identified.

☑ 2. Previous violation(s) closed.

☐ 3. The violations(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Mark Soler, VP of Quality Assurance	Mark Soler	6/27/14
NRC INSPECTOR	Jon N. Woodfield	Jon N. Woodfield	6/27/14
BRANCH CHIEF	Steve Koenick	Jon N. Woodfield for	6/6/14

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Holtec International 555 Lincoln Drive West Marlton, NJ 08053
Licensee/Certificate Holder contacts	Mark Soler, Holtec Corporate VP of Quality Assurance
Docket No.	72-1014
Inspection Report No.	72-1014/2014-202
Inspection Date(s)	June 23-27, 2014
Inspection Location(s)	Holtec International Headquarters, Marlton, NJ
Inspectors	Jon Woodfield, Team Leader, Safety Inspector Earl Love, Safety Inspection Engineer Jeremy Tapp, Safety Inspector Shadi Ghrayeb, Observer
Summary of Findings and Actions	This inspection was a routine periodic assessment of Holtec's Quality Assurance (QA) program implementation at their corporate office in Marlton, New Jersey. The team assessed Holtec's management, design, and fabrication controls for compliance to 10CFR71, 10CFR72, 10CFR Part 21, and Holtec's NRC approved QAP; as related to Holtec CoC s 72-1014 (HI-STORM), 72-1032 (HI-STORM FW), 72-1040 pending (HI-STORM UMAX), 71-9336 (HI-STAR 60), 71-9261 & 72-1008 (HI-STAR 100), 71-9325 (HI-STAR 180), and 71-9367 (HI-STAR 180D). The team noted one observation during the inspection. Holtec acknowledged the observation and captured it on a Quality Issue Form (QIF). No significant findings or concerns were identified during the inspection. Overall, the team assessed that Holtec was adequately implementing their QA program with regard to QA, Management Controls, Design Controls, and the associated fabrication interface. Holtec continues to effectively implement their NRC approved Quality Assurance Program for activities subject to 10 CFR Part 71 and 72.
Lead Inspector Signature/Date	Jon N. Woodfield Jon N. Woodfield 3/16/14
Inspector Notes Approval Branch Chief Signature/Date	Steve Koenick Jon N. Woodfield for 3/16/14

Inspection History

Since their last programmatic inspection in October 2010 (ML1104500157) the NRC has conducted two fabrication inspections at the Holtec Manufacturing Division in Turtle Creek, PA. The inspections were performed in December 2010 (ML103630482) and March 2014 (ML14108A473). The inspections were conducted to determine if fabrication activities were performed in accordance with the requirements of 10 CFR Parts 21, 71, and 72, the applicable Certificate of Compliance, Safety Analysis Report, and Holtec's NRC-approved Quality Assurance Program (QAP). Based on the inspection findings, no violations were found during either fabrication inspection.

From October 25, through October 29, 2010, the NRC conducted the last programmatic inspection at Holtec offices in Marlton, NJ. From October 29, 2010, through February 10, 2011, the inspection continued at NRC Headquarters in Rockville, MD, on two open items remaining from the on-site inspection. The purpose of the inspection was to examine design and quality assurance (QA) activities to determine if they were performed in accordance with the requirements of 10 CFR Part 21 and 10 CFR Part 72, the certificate of compliance (CoC) 1014, the applicable safety analysis report (SAR), and the NRC-approved QAP. The NRC noted two violations in Holtec's QAP implementation. Details of these violations are discussed in the inspection report (ML1104500157). Inspection follow-up actions were performed during the current programmatic inspection as described below.

Inspection Purpose

The purpose of the inspection was to assess Holtec's compliance with 10 CFR Parts 21, 71 & 72, and to verify that the transportation and storage systems for which Hotec is the holder of a CoC, comply with Part 71 & 72, respectively, in design, procurement, and fabrication requirements, as applicable. The focus of the inspection was to determine whether Holtec activities associated with the transportation and storage of radioactive materials are in accordance with their NRC-approved QA program requirements.

Primary Inspection Procedures/Guidance Documents

IP-60851, "Design Control of ISFSI Components"
IP-60857, "Review of 10 CFR 72.48 Evaluations"
IP-86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers"

INSPECTOR NOTES: APPLICABLE SECTIONS FROM IP 60851, IP 60857 AND IP 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW UNDER THE BASIC HEADINGS OUTLINED IN NUREG-6314. A SECTION CALLED OTHER ADDRESSES ACTIONS TAKEN BY HOLTEC TO ADDRESS THE 2010-11 INSPECTION NOVs AND OTHER SPECIFIC ISSUES REVIEWED BY THE TEAM.

4.1 Management Controls

4.1.1 Quality Assurance Policy

The team reviewed Holtec's Quality Assurance (QA) Manual Revision 14 and implementing Holtec Quality Procedures (HQP) and assessed the effectiveness of the QA program

implementation. The team conducted reviews of Holtec's quality manual, policies, and procedures, and discussed portions of the reviewed documents with selected Holtec staff to determine whether activities subject to 10 CFR Part 71 and 72 were adequately controlled and implemented under Holtec's NRC approved QA program. Further, the team interviewed Holtec QA personnel and assessed their independence from cost, schedule, and production activities. The team noted that since the last inspection, Holtec added a new position to the QA organization titled: Vice President of Quality (VPQ). This position is in addition to the Corporate QA Manager and per the QA program; the VPQ may perform any of the required responsibilities of the Corporate QA Manager. Through interviews with the VPQ and Corporate QA Manager, the team determined that at the time of the inspection, they shared the Corporate QA Manager responsibilities based on workload and experience in performing the required duties.

The team reviewed procedures and documents regarding training, qualification, and certification of personnel involved in quality activities. Specifically, the team reviewed HQP-1.0, "Organization and Responsibilities," Revision 38, and HQP-2.4, "Training Program," Revision 12. The team reviewed the qualifications and training for selected Quality Managers and Quality Engineers to determine if they met the requirements stated in the QA program. In addition, the team reviewed a random selection of employees in quality related positions to determine if they received the required QA indoctrination and annual refresher training. The team found that for every Holtec QA staff member's records reviewed, each had completed the required training and attained the applicable qualifications to perform their duties.

The team also reviewed HQP-7.5, "Commercial Grade Dedication and Quality Plans," Revision 29, and dedication plan QP-7166, dated February 19, 2014, for a stainless steel plate. The team verified that the parts dedication program/procedure included requirements for the identification, documentation, and implementation of important to safety levels in dedication plans. Guidance on the associated audits or approvals of the supplier or testing company commensurate with the safety rating of the part being procured is also provided in the HQP. The team determined that QP-7166 was performed adequately and in accordance with HQP-7.5.

The team determined that quality assurance controls at Holtec were adequate and in accordance with their NRC approved QAP, with no concerns.

4.1.2 Nonconformance Controls and Corrective Action Controls

The team reviewed Holtec's Quality Program Violation (QPVF) Log and Quality Procedure, HQP-16, "Conditions Adverse to Quality and Corrective Action," Revision 22. HQP-16 establishes requirements for identifying, reporting, dispositioning conditions adverse to quality (including significant conditions adverse to quality), and implementing corrective action(s). This process uses a Quality Issue Form (QIF) to document conditions and corrective actions to be taken. The team noted that Conditions Adverse to Quality (CAQ) were appropriately documented on QIFs. The team noted Holtec uses a three-tier process for categorizing and documenting adverse conditions. The significance, risk, and level of uncertainties were noted as part of the evaluation process. Significance Levels ranged from 1 through 5 with 1-3 categorized as events or conditions that result in major, moderate, or minor impact; respectively. Significance level 4 is considered a low level problem and 5 only a concern or recommendation. The "Apparent Cause" of a quality issue is considered the most probable cause of a problem based on readily available information. The team noted the significance level provided a measurement to management of how effectively the organization is learning from lower level issues.

The team as a whole reviewed a sample of seventeen Quality Issue (QI) reports on QIFs for compliance to HQP-16. In all cases, conditions adverse to quality were adequately documented consistent with the HQP. The team noted the QI report included the determination and recording of the significance, risk, and uncertainty levels. Afterwards, the evaluation of the investigation class (A-D) was noted and the type of investigation (i.e., apparent, root cause, close to immediate action) was completed. The team noted satisfactory evaluations were performed, as well as detailed performance of apparent or root cause analyses. In addition, the QI's assessed included corrective actions (CA) and actions to prevent recurrence of the issue. The team found the required actions to be extensive and when possible, completed in a timely manner. A limited number of CAs were noted as open; however, these actions were assessed to be lengthy commitments (i.e., hiring of personnel, review extent of condition) and did not impact immediate CAs taken that addressed the primary apparent or root causes. Resolution of the issues documented was assessed to be appropriate, with the reports closed in a timeframe commensurate to their importance.

The team noted that the Quality Assurance Manager is required to perform tracking and trending of all issues on QIFs. The team discussed with the Corporate QA Manager how trending is performed and the results presented to management. The team reviewed Holtec's semi-annual Quality Assurance Program Status Report (dated April 2014). The report provided a summary and evaluation of the effectiveness and adequacy of implementation of the Holtec QA Program during the second half of 2013. Overall, no concerns were identified and the team assessed that quality issues were appropriately documented and evaluated.

4.1.3 Documentation Controls

Holtec's corporate headquarters in Marlton, New Jersey has the primary responsibility for document controls at Holtec. The Holtec Manufacturing Division (HMD) and Holtec Manufacturing Orrvilon (HMO) have access to controlled documents in the Holtec document control system through the Holtec corporate headquarters electronic computer system. The manufacturing facilities are responsible for entering quality records associated with the manufacturing of products into the Holtec document control system.

The team reviewed the document control section of the HQAM Revision 14 and the HQPs that address document controls to verify they are being properly implemented. The team specifically reviewed the following procedures associated with document control:

- HQP-2.1, "Quality Assurance Manual, Procedure Control, Program Implementation and Verification," Revision 26
- HQP-6.0, "Document Control," Revision 12
- HQP-6.1, "Project Document Transmittal and Control," Revision 9
- HQP-17.0, "Quality Assurance Records," Revision 22

The team reviewed a sample of documents issued and revised by Holtec to determine if the controls on those documents were adequate and performed in accordance with approved quality procedures. The team reviewed HQP-6.0 and discussed the document control process with QA and Project Management personnel. The team determined that adequate controls were in place to ensure that 1) document approval could only be performed by qualified personnel; 2) all technical departments reviewed the original issuance of a quality document for applicability to their discipline; 3) revisions must be approved by the original signatories; and 4) old document revisions are clearly separated from the current revision and a database is kept

up to date with the current revision number. New or revised document notification is sent out to Holtec staff by Holtec Project Managers when new or revised project documents are put in the database by the PMs. The distribution list is generally the individuals associated with the project for which the document applies. If the new or revised document is not project specific, such as a HQP procedure; it will be electronically distributed throughout all Holtec offices for staff reading and electronic acknowledgement back to headquarters. The team also reviewed a sample of documents transmitted to customers and Holtec fabrication facilities and determined the process was adequately controlled and performed as required by HQP-6.1.

In addition, the team reviewed HQP-2.1, to determine if document controls on the QA Manual and procedures were adequate and in accordance with the applicable regulations. The team noted that Step 6.1.7 of HQP-2.1 allowed for certain modifications to be made to the NRC approved QA Manual without requiring prior NRC approval before implementation. 10 CFR Part 71 and 72 regulations do not allow for changes to the NRC approved QA Manual to be implemented before approval by the NRC is granted. The team determined that although the procedure allowed modifications to be implemented prior to NRC approval, Holtec has not modified the QA Manual since the last revision was approved by the NRC in 2006. Holtec wrote QI Number 1628, dated June 25, 2014, to capture this observation in their corrective action program. Holtec stated they planned to revise the wording in Step 6.1.7 to remove the allowance for implementation of a modified Part 71 and 72 QA Manual before receiving NRC approval.

The team also discussed the requirements of HQP-17.0 with QA personnel and how the applicable regulatory and procedural requirements for quality record control were being implemented by Holtec's QA program. Specifically, the team discussed document retention requirements and toured the QA record storage facility with QA personnel. The Holtec document computer database is backed up by Holtec IT personnel in accordance with HQP-17.0. The team determined that Holtec quality record controls were adequate and met the requirements stated in HQP-17.0 and the applicable regulations.

Overall, the team assessed that document and records management controls at Holtec were adequate.

4.1.4 Audit Program

The team reviewed Holtec's QAM and implementing procedures governing external audits and controls of vendors on its Approved Vendors List (AVL). The team noted as of January 1, 2014 there were a total of 119 vendors on Holtec's AVL of which 86 were qualified as safety significant suppliers. A total of 10 Holtec external audits of vendors were performed in 2013. In addition, there were 14 NIAC audits performed by NIAC members in 2013, which were used to maintain or add vendors to the Holtec AVL. A total of 21 commercial grade supplier (CGS) audits and 57 surveillances were performed in 2013. These surveillances included machine shops, concrete batch plants, test labs, and material distributors/manufacturers. The team reviewed a sample of vendor audits/surveillances performed by or for HMO for procured materials. All materials sampled were verified to have been procured from companies listed on Holtec's AVL, which is also used by HMO. All audit or surveillance reports reviewed were within their required periodicity for maintaining the subject companies on the AVL. Audit findings were documented in the reports along with corrective actions taken by those audited. No concerns were identified by the team in this review.

Consistent with its role in reactivity control, all Metamic-HT material procured for use in the

casks is qualified as important-to-safety (ITS). Manufacturing and in-process steps in the production of Metamic-HT are carried out using written procedures in Holtec's plant located in Orrville, Ohio. Holtec's corporate QA program is fully implemented at the Orrvilon facility. As required by Holtec's corporate quality program, the plant's QA implementation is subject to internal audits and ongoing assessment as set forth in applicable QA procedures to ensure that all extruded Metamic-HT plates meet the requirements appropriate for the cask systems.

Overall, no concerns were identified in the manner in which Holtec is performing vendor audits or in the manner in which vendors are added to and maintained on the Holtec AVL.

4.2 Design Controls

4.2.1 Design Development

The team reviewed the HQPs specifically related to design development/control and modification activities and held discussions with Holtec engineering analysis and design management staff. The team focused it review on Holtec design activities related to an amendment request under development for the Part 72 HI-STORM UMAX (UMAX) Holtec Dry Cask Storage System.

The team reviewed the design control section of the HQAM Revision 14 and specifically reviewed the following HQPs associated with design control to verify they are being properly implemented at Holtec headquarters:

- HQP-2.8, "Personnel Certification for Category A Computer Codes," Revision 9
- HQP-3.0, "Project Planning, Design Control, Product Realization and Project Execution," Revision 25
- HQP-3.1, "Design Input Requirements," Revision 10
- HQP-3.2, "Design Analysis," Revision 26
- HQP-3.3, "Design Verification," Revision 29
- HQP-3.4, "Design Specifications and Design Criteria Documents," Revision 4
- HQP-3.5, "Procedures and Practices for Streamlining Engineering Design and Analysis Activities," Revision 4
- HQP-5.1, "Engineering Drawings," Revision 36
- HQP-6.3, "Review of Vendor Documents," Revision 3
- HQP-11.0, "Computer Programs," Revision 21

The team noted that all the design development for the transportation packagings and dry cask storage systems sold by Holtec occurs at the Holtec corporate offices in New Jersey.

Holtec's system for the initiation, review, and approval of design documents is all electronic. Design documents are transmitted electronically during the design process from computer work station to computer work station of initiators, reviewers, and approvers. All signatures on design documents are electronic with user name and password protection.

The team reviewed two project plans associated with the UMAX. However, the first project plan was associated with the development of the UMAX design without a specific user of the system at that time. Holtec considered the project to be a developmental program and did not have an in-depth project plan. The second Project Plan associated with the UMAX design was to supply the system to Callaway Nuclear Power Plant as a user. The team found the Callaway Project Plan used the proper forms, was compliant with HQP-3.0 procedural requirements, was signed

off by the Project Manager, signed by an independent reviewer, and had received proper approval by a quality assurance representative.

The team reviewed the following sampling of design calculations for the UMAX Program and Callaway Project for compliance with HQPs 2.8, 3.2, 3.3 and 11.0:

Holtec Report No. HI-2114807 Rev. 4, "Thermal-Hydraulic Evaluation of Hi-STORM UMAX"
Holtec Report No. HI-2125194 Rev. 3, "Shielding Analysis of the Hi-STORM UMAX"
Holtec Report No. HI-2125228 Rev. 2, "Structural Calculation Package for the Hi-STORM UMAX System"
Holtec Report No. HI-2125239 Rev. 0, "Structural Analysis of Hi-STORM UMAX ISFSI Structures"
Holtec Report No. HI-2146002 Rev. 1, "Structural Evaluation of Lift Yoke Extension at Callaway"

The team determined that the calculations used the proper forms, were detailed, and contained all the required format sections as required by HQP-3.2. Design Verification Checklists (DVC) showing the author, primary reviewer, and project manager (approver) names and the date of their electronic signatures were reviewed for the calculations. Verification Identification Record (VIR) Numbers, which are computer generated by Holtec's record database system to link each DVC to each calculation, were documented on each Document Issuance & Revision Status Log (coversheet) for each calculation. The team determined that all the forms, design verification requirements, electronic signature documentation, and revision tracking were in compliance with the requirements of HQP-3.3.

The team specifically focused its review of calculations on calculations that utilized commercially available computer software analytical programs. This lead the team to review the qualifications/certification of Holtec staff to utilize the programs. Holtec implements HQP-2.8 to document certification of its staff to utilize individual analytical software programs. The team reviewed the Holtec Approved Computer Program List (HACPL) (a matrix) which showed the various analytical software programs used at Holtec and the Holtec staff certified to use them. The team verified that the authors of the calculations were certified on the HACPL to use the analytical software used in the calculations. The team also reviewed the certification records (CR) which justified individual Holtec staff member software certification. A CR is developed for each staff member that uses a particular software program. An individual must achieve a specified point total to be certified for using a specific software package; with points awarded in different categories for levels of experience, training, education, etc. The team found all the documentation reviewed to be in compliance with HQP-2.8.

Documents associated with the actual QA validation of the software analytical programs on specific Holtec computer hardware platforms were also reviewed. HQP-11 establishes the development, control, validation and documentation of important to safety computer programs used at Holtec. The team reviewed Holtec Report No. HI-2012627 Revision 9, "QA Documentation Package for ANSYS (Versions 11.0 and Higher)," which qualified the use of ANSYS at Holtec on certain hardware platforms and operating systems. Holtec's evaluation and documentation of error reports received from the ANSYS software vendor were also reviewed. The HACPL was reviewed to verify that validation calculation HI-2012627, the computer operating system, and the approved computers for ANSYS use were shown in the HACPL matrix for ANSYS. The team found all the documentation reviewed for control and validation of the software to be in compliance with HQP-11.

Holtec's corporate office develops three drawings for 10 CFR Part 71 and 72 projects; licensing, design, and fabrication. HQP-5.1 is the procedure used to control all three types of drawings and Engineering Change Orders (ECOs). The team focused its review of drawing controls on the UMAX design. The team reviewed UMAX Licensing Drawing 8446 Revision 5, Sheets 1 through 7. The Holtec engineering drawing process is all electronic; which required the team to have extensive discussions with Holtec engineering management as they demonstrated the process on computer screens. All Holtec drawing identification numbers are generated by the Holtec database. Most drawings are prepared as drawing packages whereby each drawing sheet has the same drawing number with a separate sheet number. The electronic copy of all drawings is the authoritative record. All superseded drawing revisions are retained on the Holtec computer database. When using a drawing hardcopy, Holtec staff must verify the database revision to ensure the latest revision is being used. For 10 CFR Part 71 and 72 projects, the drawings must show in the parts list the individual parts important to safety classification.

A Drawing and Bill-of-Materials Review and Approval Log (DBMRAL) and Review and Approval Checklist (RAC) are associated with the initial issue and every revision to a drawing. The DBMRAL lists the names of the designer, checker, required technical discipline reviewers, Holtec Manufacturing Division reviewer (fabrication drawings only), other reviewers, approvers and the date of their electronic signature. As for calculations, all signatures on the drawings are password controlled electronic entries. All relevant technical discipline reviews of drawings are documented with their concurrence in the applicable portions of the RAC. Once final approval is received by the project manager, the project manager at Holtec headquarters releases the drawings into the electronic system. At release, the fabrication drawings have a watermark added to them stating "For Analysis", "For Procurement" or "Released for Fabrication." Also at release, a VIR number is added to the drawing revision. The DBMRAL for drawings is tied to the VIR number. From the unique drawing number and VIR, the DBMRAL for that revision can be retrieved. All three types of drawings are available to all Holtec employees with computer system access; however, notification by email of a new drawing or revision release is sent to individuals associated with the drawing's project.

Engineering Change Orders are only written at Holtec Headquarters. The team reviewed ECO-5201-03 for the UMAX Program and ECO-105-01 for the UMAX Callaway Project. The team found the ECOs to: use the proper forms, provide details of the proposed changes, provide justification for the proposed changes, provide affected drawings/documents, have the proper electronic signatures from the preparer, reviewer, and technical disciplines; have the fields pertaining to Part 71 and 72.48 completed, and be closed by the PM with their electronic signature. The team found all the drawings reviewed, ECOs reviewed, and the drawing: initiation, review, approval, transmittal, revision, and revision tracking processes demonstrated by Holtec engineering managers on computer screens to be in compliance with HQP-5.1.

The team assessed that Holtec was effectively implementing its design control procedures. The team found that calculations, design/licensing/fabrication drawings, and ECOs were developed and processed in accordance with the applicable procedures and received the proper independent verification reviews and approvals. Overall, no concerns were identified by the team in the design control area.

4.2.2 Modifications

Section 4.2.1 provides some discussion of the team's review of ECOs for modifications to designs. As part of the design change process (modification) for 10 CFR Part 72 designs,

Holtec performs 72.48 screenings and evaluations. The team reviewed 72.48 screenings and evaluations performed to determine if NRC approval was required prior to implementing a proposed change to or deviation from a Part 72 system FSAR. The team noted that typically 72.48 evaluations originate from a source document [e.g., ECO, Supplier Manufacturing Deviation Report (SMDR), and Project Procedures] and that the source documents were incorporated in the 72.48 document by reference. The team noted that evaluations were performed in accordance with various level Quality Procedures as part of design control and verification activities. The team reviewed a sample of six 72.48s, including two applicable to UMAX. The team noted that the NRC has yet to issue the UMAX CoC/SER and that final approval of the evaluations is pending. Overall, 72.48 evaluations were satisfactorily prepared and reviewed as specified in Holtec Standard Procedure (HSP) HSP-321, Revision 2, "Screening and Evaluation of Changes, Tests, and Experiments under 10 CFR 72.48."

Specific to the UMAX as part of the team's 72.48 process review; the team reviewed Engineering Change Order Nos. 105-1 & 2; both provided a comprehensive description of the proposed changes to the UMAX FSAR (HI-2115090R1) and Licensing Drawing 8446. In certain instances, changes were determined to be editorial; however, in others a more extensive and detailed technical evaluation was performed. The team noted that changes were appropriately evaluated through a multi-discipline technical and administrative review using the appropriate design control process. In addition to the ECOs, the team reviewed UMAX 72.48 Evaluation Nos. 1012 and 1058. The team noted that the baseline revision of the UMAX FSAR, including licensing drawings, is currently under NRC review and that a preliminary SER/CoC has been issued. Holtec has currently manufactured several cask systems "at-risk." The team noted additional changes to the FSAR that are tracked under the 72.48 process described above. Because of this, the team recognized the need for deferred approval of ECOs and 72.48s until CoC final rulemaking and issuance of the CoC/SER. This process was evaluated for conformance to Holtec procedure HSP-322, Revision 3 dated 5/13/2011, "Dry Storage and Transportation SAR Control and CoC Amendment Requests," and determined to be acceptable with no concerns.

Based on a review of Holtec staff training records the team verified that 72.48 screenings/evaluations were performed and reviewed by qualified personnel. The team determined the process of training and recertification to be acceptable and identified no concerns with the overall Holtec 72.48 processes in evaluating changes to its Part 72 designs and design documents.

4.3 Fabrication Controls

The team determined that most fabrication NCRs are dispositioned at Holtec's two manufacturing divisions; however, some less routine NCRs are sent to Holtec headquarters in New Jersey for disposition where a Supplier Manufacturing Deviation Report is generated. SMDRs are controlled at headquarters but a copy is sent back to the manufacturing divisions. SMDR numbers 2305 and 2355 for the UMAX Callaway Project were reviewed by the team. With the creation of SMDRs, fabrication deviations receive a thorough headquarters evaluation against the design basis approved by the NRC CoC for the affected Part 71 or 72 component. SMDRs are reviewed by the required design engineering disciplines and a determination made if the deviation affects the Part 71 or 72 licensing basis. 72.48s are performed for Part 72 deviations after evaluation, if required. The team found the two SMDRs reviewed used the proper forms, had the proper electronic signatures, and were written & evaluated in accordance with applicable HQPs. In addition, the team found Holtec's Headquarters involvement in the fabrication control process adequate, with no concerns.

OTHER ISSUES REVIEWED BY THE INSPECTION TEAM

Corrective Action Follow-up to 2010-11 Inspection Notice of Violations

The team reviewed Holtec's corrective actions and root cause evaluation associated with the first violation identified during the 2010 inspection (72-1014/2010-201). Specifically, the 2010 inspection noted that 72.48 evaluation No. 923 resulted in a change that departed from a method of evaluation described in the CoC 72-1014 FSAR used to establish the safety analysis for cladding integrity during a drop accident event of the HI-STORM 100 while being transported to the ISFSI pad. The team noted that Holtec determined that the cause of the violation was an inadequate 72.48 procedure and that actions to prevent recurrence were initiated. The team reviewed implementation of Holtec corrective actions documented in CAR 177, Root Cause Evaluation 2011-1, and Holtec's NRC response letter dated March 24, 2011. Actions verified as implemented included: a revision to HSP-321 on processing 72.48's to provide additional clarifications, update to 72.48 screening/evaluation checklists to provide additional questions to eliminate potential issues, and training of personnel on updated 72.48 process. In addition, as part of extent of condition, the team verified that Holtec performed a review of the previous two years of ECOs (19) and confirmed that none of the ECOs added, removed, or altered the methodologies presented in the FSAR. Lastly, the team verified the removal of text from the HI-STORM 100 FSAR per an ECO (193). Specifically, the discussion on the performance of the cladding during a design basis accident was removed from the FSAR.

The team verified procedure HSP-321 provides additional clarification in the screening and evaluation questions regarding change in methodology and that additional training was provided to personnel qualified to author or review 72.48 documents. In addition, based on a review of corrective actions, the team verified that additional text was added to the 72.48 in question as described in the Holtec NRC letter response and the corresponding engineering change order was revised. The team reviewed Holtec's extent of condition evaluation documentation and verified that the four year review of ECO's that added FSAR text was adequately performed.

The second violation cited measures that did not ensure thermal evaluations during vacuum drying conditions were adequate and that could have resulted in FSAR peak cladding temperature allowable limits potentially being exceeded. The violation pertained to the use of a two-dimensional (2-D) axisymmetric FLUENT thermal model to simulate vacuum drying in comparison to FSAR, Table 4.5.9, "Peak Cladding Temperature in Vacuum" and FSAR Appendix I (which states in order to avoid excessive conservatism in the computed 2-D FLUENT solution, partial recognition for higher axial heat dissipation is adopted in peak cladding calculations). Specifically, the maximum calculated temperatures obtained from the 2-D analysis did not match FSAR Table 4.5.9, Peak Cladding Temperature in Vacuum and the approach described in Appendix I was incorrect. The team determined that Holtec had performed additional calculations that simulated vacuum drying using both 2-D and 3-D FLUENT models without inclusion of methods described in FSAR Appendix I for loaded canisters. The results indicate compliance to ISG-11 Revision 3 limits for short term operations at any Holtec system loaded site.

The violation also cited measures that did not specify vacuum drying time and heat load limits in Amendment 1 through 4 technical specifications. The team verified that Holtec issued an information notice (HIB-48, Revision 1, dated March 21, 2011 and May 18, 2011) to its users

advising them of modified heat load limits during vacuum drying and that if loading canisters greater than 23kW, they shall institute a 40 hour drying time consistent with CoC Amendment 5.

The violation also cited that measures did not provide required actions commensurate with the supporting thermal-hydraulic analysis in the technical specifications when the vacuum drying 40-hour limit is exceeded before achieving dryness criteria and before restarting vacuum. The NRC had cited that Holtec did not consider the 40 hour limit to be a timeframe that would occur since actual times were significantly less than 40 hours and the increase in heat loads reduce drying times. The team verified that HIB-48 includes a statement to users that they must have operational procedures in place to initiate fuel cooling and perform additional vacuum drying cycles within the guidance of ISG-11, Revision 3. The team verified Holtec performed a comprehensive review of Technical Specification LCOs for CoC 72-1004 that confirmed no other unanalyzed conditions exist.

Lastly, the violation cited that even though operating procedures allow the use of nitrogen, FSAR Chapter 4, "Thermal Evaluation," does not prescribe nor analyze for the use of nitrogen during the Multi-purpose canister (MPC) blow down operation. The team verified Holtec has addressed this by reviewing Holtec ECO (5014-192), the associated 72.48 (No. 956), and the technical basis that now allows bulk water removal from a MPC using the helium or nitrogen blow down processes.

Verify Corrective Actions Taken to Address Error in Holtec Fire Hazards Analysis Found During Waterford ISFSI 72.212 Review

The team reviewed Quality Issue (QI) 1108, dated October 7, 2011, which evaluated an error identified by the NRC in Holtec calculation HI-2094371, "Evaluation of Fire and Explosion Hazards at Waterford 3," relating to the Fire Hazards Analysis (FHA) for the Waterford Independent Spent Fuel Storage Installation (ISFSI). The team reviewed the corrective actions performed to determine if they were adequate and appropriate in scope and timeliness. The team determined that the error was adequately corrected in the FHA calculation; an appropriate extent of condition was performed, and the corrective actions were completed as stated in the QIF in a timely manner. In addition, the team verified that the revised calculation was transmitted to Waterford as required by the applicable procedure.

Verify a Holtec Information Bulletin (HIB) Has Been Issued Addressing the Opening or Removal of the HI-STORM Mating Device after Stackup

During the HI-STORM Stackup loading operation, the MPC is downloaded onto the HI-STORM overpack, which is followed by closure of the mating device drawer and subsequent removal of the HI-TRAC and mating device from the loaded HI-STORM. One NRC HI-STORM licensee had asked Holtec what are the limitations for leaving the mating device on the loaded HI-STORM overpack for an extended period of time. Holtec has evaluated this issue and discussed its evaluation and resolution with its Holtec (systems) User Group (HUG). At the time of the inspection Holtec had drafted HIB 65 and distributed it to the HUG members for comments. The team reviewed the draft HIB for compliance with HSP-1003, "Preparation and Issuance of Holtec Information Bulletins," Revision 4. The team found the draft HIB to be compliant with the procedure, addressed the issue, and provided direction to the HUG members. The team was shown a transmittal email to the HUG members providing the draft HIB and containing a deadline to receive comments back to Holtec. The team found that Holtec was adequately addressing the issue with a draft HIB that had a schedule to be formally completed and issued in the near future, with no concerns.

Review Holtec's Evaluation and Actions Concerning Exelon/Dresden Questioning the MPC Lift Cleat Analysis

ECO-5014-131 was written in 2006 to remove the torque requirement on the MPC lift cleat stud nuts from the HI-STORM 100 FSAR. The analysis (HI-992234) which qualified this change was later revised to consider boundary conditions for the cleat as an average of simply supported and clamped (fixed) at the stud locations. Exelon/Dresden had questioned the applicability of Holtec's methodology and whether the increased safety factors of ANSI N14.6 are met with a wrench tight lift cleat stud nut. The team reviewed the following documents associated with this issue.

- QIF 1561 documenting this issue and the corrective actions to resolve it
- Drawing 2511 sheets 1 and 2, Revision 18, MPC Cleat
- Exelon/Dresden Owner Acceptance Review comments on Holtec Calculation HI-2146010
- HUG Project Punch List showing actions and dates for closeout of this issue
- Holtec calculation HI-2146080 revision 1 addressing this issue, associated correspondence emails, and the transmittal for calculation distribution
- Power Point slide presentation on this issue showing draft of a new cleat design, presented at HUG meeting

The team had extensive discussions with Holtec staff on this issue and the above documents. The team determined that the Exelon/Dresden (E/D) concern had been addressed to adequate E/D satisfaction and the concern is being addressed generically for all Holtec Dry Spent Fuel Storage Systems where a cleat is used. To resolve this issue generically, Holtec might change the cleat design. The team found that the long term resolution of the generic issue was not complete, but the immediate concern of E/D had been adequately addressed, with no concerns.