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 Inc. 2500 Broadway, One Holtec Boulevard Camden, NJ 08104	Headquarters U. S. Nuclear Regulatory Commission Mail Stop 3WFN 14C-28 Washington, DC 20555-0001
REPORT NUMBER(S) 72-1014/2017-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
07201014	Holtec Manufacturing Division (HMD) Turtle Creek, PA	September 26-28, 2017

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.

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

10 CFR 72.120 "Nonconforming materials, parts, or components," states in part, "The licensee, applicant for a license, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures."

☐ 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 Vice President of Quality	Mark Soler	11/6/17
NRC INSPECTOR	Earl C. Love	Earl C. Love	11/6/2017
BRANCH CHIEF	Patricia Silva		11/14/17

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Holtec International Inc. 2500 Broadway, One Holtec Boulevard Camden, NJ 08104
Licensee/Certificate Holder contacts	Mark Soler, Vice President of Quality Assurance
Docket No.	72-1014
Inspection Report No.	72-1014/2017-201
Inspection Date(s)	September 26-28, 2017
Inspection Location(s)	Holtec Manufacturing Division, Turtle Creek, PA
Inspectors	Earl Love, Sr. Transportation & Storage Safety Inspector Marlone Davis, Sr. Transportation & Storage Safety Inspector Jon Woodfield, Transportation and Storage Safety Inspector Darrell Dunn, Sr. Materials Engineer, SFM, Renewals & Materials Branch
Summary of Findings and Actions	The inspection assessed fabrication, assembly, and testing activities for compliance to 10CFR72, Part 21, HOLTEC CoC 72-1014 (HI-STORM), 1032 (HI-STORM FW), 72-1040 (HI-STORM UMAX) and Holtec's quality assurance program as approved by NRC. No significant findings or concerns were identified during the inspection. The team conducted the final exit meeting on September 28, 2017. The team did not identify any violations of significance related to NRC requirements. However, the team identified one Severity Level IV Non-cited violation (NCV) of NRC requirements in that Holtec did not disposition and properly accept a nonconforming condition that affected multiple MPC baskets in accordance with documented procedures. Specifically, Holtec did not perform a 72.48 screening/evaluation to provide the technical justification to accept a deviation dispositioned "use-as-is" in accordance with a quality procedure requirement. The Non-cited violation is described in NRC Form 591S and the circumstances surrounding it is described in detail in the inspector notes Section 2.07 and is consistent with Section 2.3.2 of the NRC Enforcement Policy. With exception of the NCV, Holtec continues to effectively implement their NRC approved Quality Assurance Program Manual for those activities that were subject to the scope of this inspection.
Lead Inspector Signature/Date	Earl C. Love 11/06/2017 Earl C. Love
Inspector Notes Approval Branch Chief Signature/Date	Patricia Silva 11/14/17

INSPECTOR NOTES: APPLICABLE PORTIONS OF 02.01 THROUGH 02.08 OF IP 60852 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW

02.01 Determine whether the fabrication specifications are consistent with the design commitments and requirements documented in the SAR, and, as applicable, the CoC or the site-specific license and TS.

The team reviewed the design control section of the Holtec Quality Assurance Program Manual (HQAPM) and the Holtec Quality Procedures (HQP) that address design controls to verify they are being properly implemented at the Holtec Manufacturing Division (HMD). The team specifically reviewed the following procedures associated with design control:

- HQP-3.0, "Project Planning, Design Control, Product Realization and Project Execution," Revision 28
- HQP-3.1, "Design Input Requirements," Revision 11
- HQP-3.2, "Preparation of Analysis Documentation (Design Analysis)," Revision 29
- HQP-3.3, "Design Verification," Revision 31
- HQP-3.4, "Design Specifications and Design Criteria Documents," Revision 5
- HQP-3.5, "Procedures and Practices for Streamlining Engineering Design and Analysis Activities," Revision 5
- HQP-5.1, "Engineering Drawings," Revision 40
- HSP-321, "Screening and Evaluation of Changes," Revision 5

The team noted that all the design development for the systems manufactured at HMD occurs at the Holtec corporate offices in New Jersey and that the initiation, review, approval and associated changes of design documents is performed electronically. HMD has access to all design documents (such as specifications, calculations, design criteria documents, project plans, and design drawings) through the Holtec computer system, however, HMD is primarily concerned with the fabrication drawings for a project. Fabrication drawings are available to all Holtec employees with computer system access and any changes to fabrication drawings are processed by corporate headquarters. Notification to HMD by email of a new drawing or revision release is sent to individuals associated with the drawing's project. At release, fabrication drawings state "Released for Fabrication" along with the addition of a unique verification identification record (VIR) number to the drawing revision for retrievability.

The team reviewed fabrication drawing Nos. 10079 revision 5, "Hi-Storm FW VER, XL Cask Body Assembly" and 8728 revision 14, "MPC-89 Enclosure Vessel Assembly", along with their associated VIRs to verify manufacturing's review and electronic signature. The team assessed that HMD was effectively implementing its design control procedures. The team determined that fabrication engineering drawings were receiving the proper independent verification reviews and approvals. Overall, no concerns were identified by the team in the design control area.

02.02 Determine whether corrective actions for identified fabrication deficiencies have been implemented in a time frame commensurate with their significance, and whether nonconformance reports documenting the deficiencies have been initiated and resolved.

The team verified that the HMD completed corrective actions for identified deficiencies and nonconformance reports in a technically sound and timely manner. The team reviewed a sample of quality issues (QIs) and nonconformance reports (NCRs). Specifically, the team reviewed the following quality procedures:

- HQP – 15.2, "Nonconformances", Revision 37; and

- HQP – 16.0, “Conditions Adverse to Quality and Corrective Action”, Revision 23

The team interviewed selected personnel to verify that HMD effectively implemented their corrective action and nonconformance control programs. The team reviewed a sample of nonconformance reports and QIs for the previous three years. The team also discussed the nonconformance reports with the HMD staff.

Based on the review, the team evaluated nonconformance reports (NCRs) that did not provide adequate technical justifications for “use-as-is” dispositions in accordance with implementing quality procedures. This was contrary to Section 6.2.3.3 of HQP-15.2, which states, in part, that for “accept-as-is” and “repair” dispositions, appropriate technical justification must be provided. The team identified this issue during a review of NCR 9905-6, Revision 0 in that personnel did not measure the overall length of the MPC basket following fabrication on a number of 32 and 68 MPCs. The team noted that HMD dispositioned the NCR as “accept-as-is” and determined that Holtec needed to perform a 72.48 screening/evaluation as described in Section 6.2.3.4 of HQP-15.2. However, Holtec personnel did not perform the 72.48 screening/evaluation to provide the technical justification to accept the use-as-is disposition in accordance with written procedures. The team assessed that this was a violation of NRC requirements 10 CFR 72.170.

10 CFR 72.170 requires, in part, that certificate holder shall establish measures to control materials, parts, or components that do not conform to their requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification. Nonconforming items must be reviewed and accepted, rejected, repaired, or re-worked in accordance with documented procedures. Contrary to, as of September 26, 2017, Holtec did not disposition and properly accept the nonconforming condition that affected multiple MPC baskets in accordance with documented procedures. Specifically, Holtec did not perform the 72.48 screening/evaluation to provide the technical justification to accept the use-as-is disposition in accordance with HQP-15.2, Revision 37. The team dispositioned the violation in accordance with Section 2.3 of the NRC Enforcement Policy. The team characterized the finding as a non-cited Severity Level IV violation since it was more than minor and Holtec entered the condition in their corrective action program. Holtec captured this issue in their corrective action program as QI No. 2307.

02.03 Determine whether individuals performing quality-related activities are trained and certified where required.

The NRC inspection team reviewed HQAM, policies, and HQPs to verify how Holtec conducted activities in accordance with their NRC-approved HQAM commitments and requirements. The team reviewed HQPs used to implement the HQAM. The team verified that Holtec clearly defined and documented the quality program authorities and responsibilities and that the quality assurance organization functioned as an independent group.

The team assessed that HMD had programs and procedures in place to conduct quality-related activities in accordance with HQAM, and 10CFR Parts 21 and 72 requirements. The team reviewed a sample of personnel qualifications and training records and determined that individuals performing quality-related activities at HMD were trained and certified.

02.05 Determine whether: a) Materials, components, and other equipment received by the fabricator meet DCSS design procurement specifications; and b) The procurement specifications conform to the design commitments and requirements contained in the SAR and, as applicable, the CoC or the site-specific license and TS.

The team reviewed HQPs that address procurement, traceability, and receipt inspection to verify they are being properly implemented at HMD. The team specifically reviewed the following procedures:

- HQP-4.1, "Purchase Requisitions," Revision 24
- HQP-4.2, "Purchase Specifications," Revision 7
- HQP-7.0, "Receipt Inspection," Revision 20
- HQP-7.5, "Commercial Grade Dedication and Quality Plans," Revision 33
- HQP-8.0, "Material and Item Identification and Control," Revision 8

The team verified that Holtec used a graded approached for identifying ITS components and applied this graded quality level to design procurement documents. Specifically, the team reviewed procurement, traceability and receipt inspection of canister stainless steel plate, stainless steel weld consumables including flux. The team noted that Material Identification and Control (MIC) numbers were assigned to materials in use on the shop floor. Each MIC number for those components observed was traced back to a Material Inspection & Release Form (MIR). The MIR for each item showed the purchase order number for the item. The vendor certification documents that were supplied with each item at receipt inspection as required by the respective purchase orders were reviewed and all contained reference to the Holtec purchase order. The team determined that Holtec's material traceability, procurement, and receipt Inspection controls were adequate with no concerns.

02.06 Determine whether DCSS components are being fabricated per approved quality assurance (QA) and 10 CFR Part 21 implementing procedures and fabrication specifications.

The team reviewed implementing procedures and fabrication specifications that address fabrication, assembly and test controls to verify they are being properly implemented at HMD. The team specifically reviewed the following procedures:

- PS-301, "Procurement Specification for the Fabrication of MPC-37/89 for the HI-STORM FW System," Revision 8
- HSP-108, "Containment/Confinement Boundary Grinding Control," Revision 11
- HSP-320, "Standard Remedial Work Practices in Fabrication of Safety Significant Components," Revision 33
- HSP-701, "In-process & Final Inspection Procedure for the Fabrication of MPC-37/89," Revision 17

The team noted that MIC numbers were identified on ITS-A materials located throughout the shop (e.g., shell sub-assemblies, closure ring, and lower split lid). The team noted acceptable storage and tagging for status and traceability to applicable purchase orders and specifications. The team reviewed vendor certification documentation for items against the respective purchase orders and applicable procurement specifications and noted that 10 CFR Part 21 requirements were included, when required, on the purchase orders reviewed.

The team, witnessed helium leak test of confinement boundary welds on SONGS MPC-37, Shell identification No. 61. The team noted that the test was performed in accordance with Industrial Testing Laboratory Services, LLC (ITLS), Procedure No. 949, revision 0, "Helium Leak Testing," for conformance to ANSI N14.5 (1977), Method A5.3, gas filled envelope. The team verified ITLS's Nondestructive Examination (NDE) technician qualification and certification records according to ITLS procedure IP-101, revision 9, "Qualification and Certification of NDE

Personnel," and noted certification records conformed to the requirements of American Society for Nondestructive Testing (ASNT), recommended practice No. SNT-TC-1A, 2006 Edition. The team verified equipment was appropriately calibrated by reviewing certificates of calibration of a thermometer, helium leak standard, and oxygen analyzer, used to conduct the test. The team noted equipment was appropriately calibrated as prescribed by ITLS procedure No. 102, revision 9, "Calibration of Equipment," used within required frequency (due date), and that records were traceable to nationally recognized standards. Overall, no leak test concerns were noted.

The team witnessed fit-up and longitudinal tack welding of MPC shell plates specific to Hatch (Project No. 9925), Unit No. 27. The team noted that tack welding was conducted according to fabrication drawing No. 4838, revision 1, "MPC-Shell Weldment," and weld procedure specification (WPS) No. 47HC, revision 5, "Manual GTAW on Stainless Steel Base Metals." The team witnessed longitudinal seam welding of a Hatch MPC shell, Unit No. 26 for conformance to WPS No. WS227HC, revision 4, "Machine SAW on Stainless Steel Base Metals." In addition, the team reviewed a sample of welding operator qualification and proficiency records. Overall, no concerns were noted.

The team assessed control, issuance, use, return and storage of consumable welding electrodes, filler metal, and flux used in fabrication. The team assessed HSP-1110, revision 1, "Control and Issuance of Weld Filler Metal," the team noted a well-defined ticketing issuance process such that a tool room attendant issues materials and controls the return into storage and that welders control weld materials until completion of work and are responsible for return to storage. The team noted release of filler metals and fluxes are controlled by initiation of a weld wire release form and that a filler metal issue (FMI) ticket and log supports the release of material for use. Spools of welding electrodes in continuous use are left on the welding machine until completely used and follow FMI protocol. The team reviewed a sample of FMI tickets and logs and assessed appropriate controls and adequate traceability (e.g., welder identification, date, project number, WPS number, and quantity of materials issued). The team noted adequate storage of weld filler materials and spools in that materials were stored in original containers in a segregated controlled storage area. In addition, submerged-arc welding flux was controlled, recycled, and adequately stored in storage ovens to prevent contamination. The team reviewed the manufacturer (Lincoln Electric Company), certified material test reports (CMTR's) for traceability and compliance to ASME Section III NB-2000 and Section II (as applicable). In addition, the team noted CMTR's to include a statement of the vendor's quality assurance program for conformance to 10CFR 50 Appendix B and 10CFR Part21. Overall, no concerns were identified with the control, issuance and storage of weld filler material.

The team witnessed visual and liquid penetrant examination of a MPC-37 Split Lid. The team noted the examination was adequately performed in accordance with HSP-1105, revision 3, "Liquid Penetrant Examination" and fabrication drawing 9986, revision 10, "MPC-37 Enclosure Vessel Assembly." The team reviewed NDE personnel training and certification records, including eye exams. Overall, no concerns were identified.

<u>Fabrication Special Process for Canister Laser Peening</u>

The team reviewed a number of documents related to the special process for laser peening the MPC at the HMD fabrication facility. The documents are as follows but not limited to:

- PS-510, "Procurement Specification for MPC Laser Peening Services," Revision 4.
- 72.48 Evaluation Number (#) 1238 for CoCs 71-1032 and 72-1040
- Engineering Change Order (ECO) #69, Revision 0

- Holtec Position Paper DS-418, “Peening of MPC Welds to Mitigate Residual Stress,” Revision 1
- HI-2177584, “Peening of MPC Welds Sourcebook,” Revision 6

The team observed portions of the laser peening special process on a HI-STORM UMAX MPC. The team witness multiple aspects of the MPC peening setup and operation. The team reviewed the work instructions, approved procedures and observed a portion of the following tasks:

- MPC positioning and alignment checks,
- Laser spot size and laser power measurements,
- Testing of the Almen strips to check laser peening parameters,
- Laser peening of circumferential baseplate and longitudinal welds, and
- Laser peened areas on the MPC.

Additionally, the team interviewed and discussed the laser peening special process with members of the Holtec technical staff along with their subcontractor. These discussions included system operations, process controls, interlocks and automatic shutdowns, and real time information displayed to the staff conducting the peening operation. The team also reviewed personnel qualifications and training records to verify whether trained and certified individuals performed quality-related activities.

Overall, the team assessed that the procedures and operational controls were sufficient to maintain the safety function of the MPC welds and base metal adjacent to the welds throughout the laser peening process. The team noted that the laser peening sourcebook provided adequate information to describe and demonstrate that the peening process and selected parameters would accomplish the desired results of compressive residual stresses in the MPC welds and base metal. The team also noted that the Holtec technical staff and subcontractor were knowable of the special process and information presented in the laser peening sourcebook. The team assessed that Holtec had qualified personnel performing laser-peening activities based on a review of qualifications and training records.

Measuring & Test Equipment

The team verified that appropriate procedures were implemented for control of Measuring and Test Equipment (M&TE). HMD has approximately 500 active devices in its M&TE program. The team specifically reviewed the following documents/procedures associated with M&TE:

- HQP-12.0, “Equipment Calibration and Control of Measuring and Test Equipment Document Control,” Revision 28
- HSP-13, “Calibration of Measure and Test Equipment,” Revision 19

The team interviewed the quality inspector responsible for administrating and updating the computer database of the devices in HMD’s M&TE program. The team also verified the certifications of the inspector and found them current and procedure compliant. The database contains a unique serial number and description of each item in the M&TE program. The database also provides the location of the device in the shop facility, standard for calibration, calibration tolerance, and range check points as applicable, frequency of calibration, applicable procedure, and current status of each M&TE device. The M&TE quality inspector can perform database queries to identify M&TE that is soon due for re-calibration.

The team reviewed the calibration records for various M&TE being used in the fabrication shops to assess the control and traceability of measuring and test equipment for compliance with the procedures. Specifically, the team reviewed the calibration records for a 24 inch caliper, 750 in-lb torque wrench, 600 ft-lb torque wrench, sub arc welding machine, and a pressure gauge. The records documented: date of calibration, item description, serial number, due date for next calibration, "As-found" and "As-Left" condition at each calibration or check point, reference procedure used, test standard identification, and allowable tolerance; as applicable for each device. The team initially located each device in the fabrication facility to verify calibration labeling in accordance with the procedures. The team noted appropriate labeling, proper identification of the M&TE, initials of the person who performed the latest calibration, date of calibration, and next calibration due date.

The 750 in-lb torque wrench was found by the team in an in-service tool cabinet without a current calibration sticker. The M&TE database listed the torque wrench as out-of-service and therefore it should have been in the out-of-service tool cabinet. The HMD quality inspector stated that the torque wrench probably could not be found at the time of its required calibration and placed out-of- service in the database. The wrench was probably found, calibrated, and then placed in the in-service cabinet without updating the database to in-service. Since the data base was never updated, the torque wrench never showed up as needing future calibration. HMD wrote a condition report (CR No. 09143-337) and QI 2310 to address the issue and investigate it. There was no safety concern as the torque wrench was listed as out-of-service in the database and the calibration sticker on it was out of date. Other than the issue with the out-of-service torque wrench being in the in-service tool cabinet, no M&TE program concerns were identified by the team.

02.07 With regard to fabrication activities, determine whether: a) They are conducted under an NRC-approved QAP (10 CFR 72.140); b) The provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance," for reporting defects that could cause a substantial safety hazard have been implemented; c) The fabricator's personnel are familiar with the reporting requirements of 10 CFR Part 21; and d) the fabricator has complied with 10 CFR 21.6, "Posting requirements."

The team reviewed HQP-15.1, "Reporting of Defects and Noncompliances per 10CFR21," Revision 14, to verify if provisions were in place for reporting defects that could cause a substantial safety hazard and complete the required notification. The inspectors requested a list of Part 21 evaluations and notifications associated with the Holtec's CoCs. The team interviewed personnel to verify if they were familiar with the implementing procedure HQP-15.1. The team also verified that Holtec complied with the 10 CFR 21.6, "Posting requirements".

The team assessed that provisions were in place for reporting defects that could cause a substantial safety hazard, as required by 10 CFR Part 21. The inspectors noted that there were no defects or Part 21 noncompliance reports identified during previous three years and Holtec posted the latest Part 21 requirements in multiple accessible locations throughout the fabrication facility.

02.08 With regard to QA activities, determine whether: a) The fabricator has been audited by either the licensee or CoC holder; b) for selected audits and inspection findings from (as applicable) QA audit or surveillance and/or inspection reports issued in the previous 2 years, the findings were appropriately handled with corrective actions implemented in a time frame commensurate with their safety significance; and c) Supervision and QC/QA personnel perform appropriate oversight during fabrication activities.

The team reviewed Holtec's internal audits to verify whether the program covered all applicable aspects of the QA program. The team reviewed procedures, schedules, plans and records associated with the internal audit program. The team verified whether Holtec scheduled and performed audits in accordance with approved procedures periodically. The team reviewed internal audit reports from the previous three years. The team also reviewed corrective actions associated with audit findings as applicable. Additionally, the team reviewed auditor qualification and certification records. The team reviewed the following procedures:

- HQP-18.1, “Certification of Audit Personnel,” Revision 19
- HQP-18.2, "Audits," Revision 23, and
- HQP-18.4, “Evaluation of Significant Audit Findings and Deficiencies,” Revision 5, and
- HPQ-18.5, “Internal QA Surveillance and Document Reviews,” Revision 5.

Overall, the team assessed that Holtec adequately implemented their internal audit program as described in HQP-18.2. The team noted that Holtec conducted the audit program in accordance with NRC-approved QAP requirements.

In addition, the team noted routine oversight occurs during key fabrication and functional testing activities. With respect to oversight, the team noted an adequate level of oversight when it comes to assessing the effectiveness of the control of quality at the HMD facility at intervals consistent with the importance, complexity, and quantity of the fabrication assembly and testing of the cask systems.