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 One Holtec Drive Marlton, NJ 08053	Headquarters U. S. Nuclear Regulatory Commission Mail Stop TWFN 4B-34 Washington, DC 20555-0001
REPORT NUMBER(S) 072-1014/2015-201	

3. CERTIFICATE/QAP DOCKET NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
72-1014, 72-1032, 72-1040, 71-9325, 71-9367	1400 Dairy Lane Orrville, OH 44667	November 17-19, 2015

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	12/4/15
NRC INSPECTOR	Jon N. Woodfield	Jon N. Woodfield	12/14/15
BRANCH CHIEF	Patricia Silva		12/21/15

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	CoC Holder Location: Holtec International One Holtec Drive Marlton, New Jersey 08053	Inspection Location: Holtec Orrvilon 1400 Dairy Lane Orrville, Ohio 44667
Licensee/Certificate Holder contacts and phone number	Mark Soler, Holtec Corporate VP of Quality Assurance (856)-296-9224 extension 3619	
Docket No.	072-1014	
Inspection Report No.	72-1014/2015-201	
Inspection Date(s)	November 17-19, 2015	
Inspection Location(s)	Holtec Orrvilon, Orrville, Ohio	
Inspectors	Jon Woodfield, Team Leader, Safety Inspector Clyde Morell, Safety Inspector	
Summary of Findings and Actions	This inspection was the first of continuing routine periodic assessments of Holtec's Quality Assurance Program (QAP) implementation at their Holtec Orrvilon facility in Orrville, Ohio. The team assessed Orrvilon's management, design, and fabrication controls for compliance to 10 CFR Part 71, 10 CFR Part 72, 10 CFR Part 21, and Holtec's NRC approved QAP; as related to Holtec CoC's 72-1014 (HI-STORM 100), 72-1032 (HI-STORM FW), 72-1040 (HI-STORM UMAX), 71-9325 (HI-STAR 180), and 71-9367 (HI-STAR 180D). Overall, the team assessed that Holtec International through Orrvilon was adequately implementing their QA program with regard to QA, Management Controls, Design Controls, and Fabrication Controls. In this case, through Orrvilon, Holtec continues to effectively implement their NRC approved Quality Assurance Program for activities subject to 10 CFR Parts 71 and 72. The team noted some observations during the inspection while performing the review of calibration records for Measuring and Test Equipment. Holtec Orrvilon acknowledged the observations and captured them on a Quality Issue Form.	
Lead Inspector Signature/Date	Jon N. Woodfield Jon N. Woodfield 12/14/15	
Inspector Notes Approval Branch Chief Signature/Date	Patricia Silva 12/21/15	

Inspection History

The last official inspection of Holtec was a programmatic inspection June 23-27, 2014 (ML14218A813) at their headquarters office. The previous Holtec programmatic inspection was in October 2010 (ML1104500157). The NRC also conducted two fabrication inspections at the Holtec Manufacturing Division (HMD) in Turtle Creek, PA between these two programmatic inspections. The fabrication 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).

Since the Orrvilon inspection was a limited scope Multi-purpose Canister (MPC) and transportation packaging basket assembly fabrication inspection, only the history of the last two fabrication inspections is provided.

From March 10 through March 14, 2014, the NRC conducted the last fabrication inspection at the HMD in Turtle Creek, PA. The purpose of the inspection was to examine fabrication 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 NRC issued Certificate of Compliances (CoC), the applicable safety analysis reports (SAR), and the NRC-approved QAP. The team examined and witnessed selected fabrication, assembly, and test activities and reviewed numerous quality procedures, as well as quality records. Overall, as a result of the inspection, the team assessed that HMD's fabrication activities, and Holtec's oversight of the fabrication activities, were adequate in meeting their QA Program requirements as well as NRC QA requirements. No cited violations of NRC requirements were identified.

From December 6 through December 9, 2010, the NRC also conducted a fabrication inspection at the HMD in Turtle Creek, PA. The purpose of the inspection was the same as the 2014 inspection. Overall, HMD's fabrication activities and Holtec's oversight of the fabrication activities were assessed to be adequate in meeting their QAP requirements as well as NRC QA requirements. Overall, quality of welding and other fabrication activities were assessed to be good. No cited violations of NRC requirements were identified. Several observations with regard to fabrication activities were noted by the team and discussed with Holtec/HMD personnel for their consideration and action.

Inspection Purpose

The purpose of the Orrvilon 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 Holtec is the holder of a CoC, can be verified to comply with Part 71 & 72 in design, procurement, and fabrication requirements, as applicable. The focus of the inspection was to determine whether Holtec Orrvilon activities associated with the transportation and storage of radioactive materials are in accordance with their NRC-approved QA program requirements. The Orrvilon facility is a relatively new Dry Cask Storage System (DCSS) and transportation packaging Holtec manufacturing facility and this was the first inspection by the NRC. The Part 72 DCSS and Part 71 transportation packaging component manufacturing performed at the Orrvilon facility was primarily limited to the fabrication of MPC and packaging basket assemblies from metal Metamic-HT material. The only major production welding currently being performed was on the fabricated MPC and transportation packaging basket assemblies using the friction stir welding special process. Therefore, the scope of the inspection was essentially limited to the Holtec

Orrvilon management controls, design controls, and fabrication controls for the MPC and transportation packaging basket assemblies.

Primary Inspection Procedures/Guidance Documents

IP-60852, "ISFSI Component Fabrication by Outside Fabricators"
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"
NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"
Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

INSPECTOR NOTES: APPLICABLE SECTIONS FROM IPs 60852 & 86001 WERE PERFORMED DURING THE INSPECTION WITH RESULTS DOCUMENTED BELOW UNDER THE BASIC HEADINGS OUTLINED IN NUREG-6314

4.1 Management Controls

4.1.1 Quality Assurance Policy

The team reviewed Holtec's Quality Assurance Manual (HQAM) Revision 14 and implementing Holtec Quality Procedures (HQP) and assessed the effectiveness of the Quality Assurance (QA) program implementation at Orrvilon. The team conducted reviews of Holtec's quality manual, policies, and procedures, and discussed portions of the reviewed documents with selected Orrvilon 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 reviewed the Orrvilon quality organization chart and interviewed Holtec QA personnel to assess their organizational independence from cost, schedule, and production activities.

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 40, and HQP-2.4, "Training Program," Revision 13. 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 training records of 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 Orrvilon 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 32, and dedication plan QP-8079, dated October 23, 2015, for aluminum powder which is used in the production of Metamic-HT material. The team verified that the material dedication program/procedure included requirements for the identification, documentation, and implementation of important to safety levels in dedication plans. The procedure provided significant guidance on the identification of critical characteristics needed during the dedication process. The dedication report must provide the acceptance criteria for each critical characteristic and identification of the method of verification.

Guidance on the associated audits or approvals of the supplier or testing company commensurate with the safety rating of the part or material being procured is also provided in the HQP. The team determined that QP-8079 was performed adequately and in accordance with HQP-7.5. QP-8079 had received the proper QA signatures indicating that the dedication report and quality plan had been completed in accordance with HQP-7.5.

The team determined that quality assurance controls at Orrvilon 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 QAM and the following implementing procedures for its nonconformance program, corrective action program, and Part 21 reporting.

- HQP-4.1, "Purchase Requisitions," Revision 21
- HQP-15.1, "Reporting of Defects and Noncompliances per 10CFR21," Revision 13
- HQP-15.2, "Nonconformances," Revision 33
- HQP-16.0, "Conditions Adverse to Quality and Corrective Action," Revision 22
- HQP-16.1, "Root Cause Evaluations," Revision 7

The team reviewed Orrvilon's nonconformance program to assess the effectiveness of controls established for the processing of nonconforming materials, parts, or components. HQP-15.2 requires an Nonconformance Report (NCR) be issued whenever a nonconforming condition is identified on a material, item, component or equipment. The NCR is then reviewed by the Orrvilon QA department for completeness and procedure compliance. An electronic log is maintained for all NCRs. QC also marks nonconforming items with a Hold Tag that identifies the corresponding NCR number(s).

Orrvilon NCRs with a deposition of scrap or rework are controlled and processed completely in-house with an information copy being transmitted to Holtec headquarters, while Orrvilon NCRs with a disposition recommendation of use-as-is or repair must receive approval by Holtec headquarters.

No corrective action shall be performed on use-as-is or repair NCR items until Holtec headquarters provides final disposition in writing. Holtec headquarter's final disposition is provided to Orrvilon on a Supplier Manufacturing Deviation Report (SMDR) form. The team discussed the NCR process with Orrvilon QA personnel and found they were knowledgeable and understood the process as described in the HQP.

The team reviewed a sampling of NCRs written within approximately the last year at Orrvilon that involved Important-to-Safety (ITS) items that had been dispositioned as use-as-is. The team confirmed that NCRs with this disposition received the required review and approval by Orrvilon Quality Assurance and Holtec headquarters as evidenced on the Orrvilon NCR form and associated Holtec headquarters SMDR form. All the NCRs reviewed by the team were found to be reviewed and electronically signed off by the required Holtec headquarters staff and Orrvilon QA representatives before the NCR was closed. NCRs become part of the final documentation package for the applicable basket assembly and the final applicable MPC. The team assessed that the NCRs reviewed had been appropriately dispositioned and closed. No concerns were identified by the team in the processing of NCRs by Orrvilon and through Holtec headquarters when required.

The team reviewed the Holtec/Orrvilon corrective action program to assess the effectiveness of controls established for the processing of conditions adverse to quality. Holtec/Orrvilon in HQP-16.0 uses a three-tier process for categorizing and documenting conditions adverse to quality (CAQ). All issues defined as potential CAQs are entered as a Quality Issue (QI) on a Quality Issue Form (QIF) except for manufacturing deviations which use the NCR process. During the evaluation of the QI, the significance of the CAQ is determined as well as the risk and level of uncertainty. Based on this evaluation, the investigation class is determined and the type of investigation (close to immediate action, apparent cause, or root cause) is performed and completed. Significance Levels range 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 team reviewed a sampling of five recent Quality Issue reports on QIFs for compliance to HQP-16. For all the QIFs reviewed, conditions adverse to quality were adequately documented. Each QI report included the determination and recording of the significance, risk, and uncertainty levels. The evaluation of the investigation class (A-D) was documented and the type of investigation was completed. The team found the evaluations satisfactorily performed as well as detailed cause analyses. The QIs reviewed included corrective actions and actions to prevent recurrence of the issue. The team found the actions taken appropriate and completed in a timeframe commensurate with the issue's importance.

Overall, no concerns were identified with the Holtec/Orrvilon corrective action program and the team assessed that CAQs were appropriately documented, evaluated, corrected, and closed.

The team also assessed how the requirements of 10 CFR Part 21 were being implemented for the fabrication activities being performed at Orrvilon. Orrvilon has responsibility for performing Part 21 assessments for work performed at Orrvilon. The QA department reviews NCRs for potential 10 CFR Part 21 reportability and shall also determine whether a QIF needs to be issued. Orrvilon stated that there had not been any 10 CFR Part 21 reports made by Orrvilon as of the time of the inspection.

The team reviewed the training records of two Orrvilon employees where they had signed off receiving general training in 10 CFR Part 21 per the requirements of HQP-15.1. In section 6.0 of HQP-4.1 it is stated that 10 CFR Part 21 shall be identified in the body of a purchase requisition as being applicable if either the vendor or Holtec (Orrvilon) is responsible for 10 CFR Part 21. Holtec/Orrvilon would be responsible for 10 CFR Part 21 when dedication activities are required for safety related or ITS Category A items or services. HQP-4.1 containes exhibit 4.1-2, which is a checklist to be attached to a purchase order (PO). The checklist has an item to check if 10 CFR Part 21 reporting applies to the PO. The team reviewed a PO for one of the materials used to manufacture the metal Metamic-HT. The vendor receiving the PO is on the Holtec/Orrvilon Approved Vendors List (AVL) and the team verified that the PO states the vendor is responsible for 10 CFR Part 21 reporting.

HQP-15.1 states that the QA Manager shall post a copy of HQP-15.1, a copy of 10 CFR Part 21, and Section 206 of the Energy Reorganization Act of 1974 in a conspicuous location on the Holtec (Orrvilon) premises. The three required 10 CFR Part 21 postings were posted on a bulletin board in the Orrvilon craft lunch room and on a bulletin board on one side of the shop. The team found the postings not to be the most current 10 CFR Part 21 issued regulations by a few months. Upon the team informing Orrvilon, the QA Manager replaced the 10 CFR Part 21

postings with the current regulations at both locations. No concerns were identified by the team regarding 10 CFR Part 21 assessment, reporting, or posting.

4.1.3 Documentation Controls

Holtec's corporate headquarters in Marlton, New Jersey has the primary responsibility for document controls at Holtec International. The Holtec Manufacturing Division (HMD) and Orrvilon have access to controlled documents in the Holtec document control system through the Holtec corporate headquarters electronic computer system. The Orrvilon manufacturing facility is responsible for entering quality records associated with the products it manufactures 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-6.0, "Document Control," Revision 12
- HQP-6.1, "Project Document Transmittal and Control," Revision 9
- HQP-17.0, "Quality Assurance Records," Revision 24

The team reviewed a sample of documents issued and revised by Holtec headquarters 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 Orrvilon 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 Orrvilon staff Project Managers (PMs) by Holtec corporate headquarters PMs when new or revised project documents are put in the database by the headquarters 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 an Orrvilon MPC basket project PM and determined the process was adequately controlled and performed as required by HQP-6.1.

The team also briefly discussed the requirements of HQP-17.0 with Orrvilon QA personnel and how the applicable regulatory and procedural requirements for quality record control were being implemented by Holtec's QA program. Document retention requirements are primarily the responsibility of Holtec's corporate office. Holtec's corporate document computer database is backed up by Holtec headquarters IT personnel in accordance with HQP-17.0. The team determined that Orrvilon's quality record controls were adequate and met the requirements stated in HQP-17.0 and the applicable regulations.

The team also reviewed the MPC documentation requirements in Holtec specification PS-301, "Procurement Specification for the Fabrication of MPC-37/89 for the HI-STORM FW System," Revision 4. The specification makes reference to Holtec Standard Procedure HSP-173, "Procedure for the preparation of Document Packages for Dry Storage Equipment and Component," Revision 32 for preparation of the final MPC documentation package.

Exhibits 7.1 and 7.24 of HSP-173 provide lists of what shall be included in a MPC documentation package. The items from the lists that are applicable to a basket assembly documentation package are shown below:

1. Fabricator's Manufacturing Report
2. Shop Bill of Materials
3. Weld Records
4. Non-Destructive Examination Records
5. Basket Plate Gage Test Report
6. Dimensional Inspection Report
7. Supplier Manufacturing Deviation Reports (SMDRs) aka: NCRs
8. Material Test Reports

The team discussed with Orrvilon QA and PM personnel how all MPC basket assembly quality records are compiled into a sub-documentation package which is then added to the final MPC documentation package at HMD. Standard Orrvilon practices are used for quality records for each fabricated MPC basket assembly to make their way back to QA personnel for final review and approval or to the project PM. Once received by the PM or approved by QA personnel, the quality records are scanned electronically into the Holtec/Orrvilon computer system by the PM, QA personnel or administrative staff. The scanning of final quality records is within a few days. Each MPC basket assembly quality record becomes a separate file in the electronic folder assigned to each MPC basket.

The QA Manager receives a large quantity of quality records for each MPC basket purchase order and based on his experience knows when he has not received a required quality record and with the project PM's help, knows how to track down any missing records across the Orrvilon shop and office.

At the completion of each MPC basket's fabrication, the Orrvilon QA Manager assembles the basket document package using software that will combine all the individual quality record files into one large file which can be electronically retrieved by HMD for addition to the final MPC document package.

A Certificate of Conformance is produced by the Orrvilon QA Manager and included in each of the basket assembly document packages, although not required.

The team reviewed a totally completed basket assembly documentation package for a MPC-37 Basket (Serial No. 12306-880169-10, Project No. 12306) and had no concerns.

The team determined that adequate document control and quality records management exist at Orrvilon. No concerns were identified by the team in the Orrvilon documentation control area.

4.1.4 Audit Program

The team reviewed the HQAM and the following implementing procedures for performing external audits of Holtec/Orrvilon vendors on its AVL, internal audits of Holtec/Orrvilon, and performing Orrvilon internal QA surveillance.

- HQP-7.4, "Approved Vendor List," Revision 20
- HQP-18.1, "Certification of Audit Personnel," Revision 18

- HQP-18.2, "Audits," Revision 22
- HQP-18.4, "Evaluation of Significant Audit Findings and Deficiencies," Revision 4
- HQP-18.5, "Internal QA Surveillance and Document Reviews," Revision 4

The team focused its review on the audits performed by Holtec/Orrvilon of the vendors on the AVL which supply raw materials used in the manufacturing of the metal Metamic-HT plates. Only one supplier of the various raw materials used in the production of metal Metamic-HT plates is on the AVL. Orrvilon performs its own commercial grade dedication of the raw materials it receives from commercial material suppliers. The team reviewed the latest 2014 audit of the AVL material supplier. The material supplier procures its materials from several suppliers for which it performs its own commercial grade dedication through testing and/or survey. The AVL material supplier then performs further processing of the raw materials to Orrvilon's required specifications. The Holtec/Orrvilon audit identified three findings and two observations against the vendor. The vendor had to provide a written response within two months of the audit report addressing the findings and how they would be corrected. The team reviewed the vendor's responses to the findings and Holtec/Orrvilon's acceptance of the vendor's corrective actions. The team found the 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 procedure HQP-18.2 were found to be adhered to. No concerns were identified by the team in the review of AVL audits.

The team reviewed the latest Holtec International internal audit report from 2015, which covered all Holtec corporate entities and thus included an audit of Orrvilon's implementation of the HQAM and program. Internal audits are performed by Holtec on a yearly basis. The audit team consisted of Holtec personnel, but the auditors only evaluated areas that they were not responsible for in their normal work assignments. There was an audit plan per the HQP procedures and the audit was performed using standard Nuclear Industry Assessment Committee (NIAC) audit checklists. The team reviewed the audit findings specific to Orrvilon. The internal audit report discussed all the Orrvilon 2015 issues and identified the QIF numbers assigned to track the issues through corrective action closure. The 2015 Internal Audit Report also addressed closure of issues found during the 2014 Internal Audit and if similar issues were still occurring in 2015. One 2014 Orrvilon audit issue was still occurring during the 2015 audit. To address the reoccurring issue from 2014 to 2015, an internal surveillance was added to the corporate internal surveillance schedule in 2015. The team found the audit results to be very detailed and the findings, audit checklists, and supporting audit documentation reviewed well documented; along with QIFs assigned to resolve issues identified. The continuity of any issues between the prior 2014 internal audit and 2015 audit results was well organized and documented. The team determined that the internal audit was very effective in its structured approach for finding issues affecting quality at Orrvilon. All the requirements of procedure HQP-18.2 were found to be adhered to. No concerns were identified by the team in the internal audit review.

The team discussed with the Orrvilon QA Manger the Internal QA Surveillance program at Orrvilon. Internal surveillance is a second self-assessment program used at Orrvilon besides internal audits. Surveillances are performed to provide an evaluation of the implementation of a particular part of the Orrvilon QA program; to verify adequacy of corrective actions; or to determine compliance to program or project requirements. Random surveillances are performed on prescribed intervals via an internal surveillance schedule. The surveillances are performed using checklists that identify the criteria and requirements to be evaluated. The QA manager at Orrvilon is responsible for the surveillance program at Orrvilon. The QA manager

reviews the surveillances and confirmed issues are documented on a QIF. The team reviewed several completed surveillance checklists and found them filled out and processed in compliance with HQP-18.5 with no concerns. The team found the internal surveillance program to be an effective second self-assessment program that focused on the quality activities performed at Orrvilon.

Overall, no concerns were identified with the performance of Holtec/Orrvilon AVL audits, internal audits, and Orrvilon internal QA surveillance.

4.2 Design Controls

4.2.1 Design Development

The team noted that all the design development for the MPC basket assemblies fabricated at Orrvilon occurs at the Holtec International corporate offices in New Jersey. The Holtec corporate office usually develops three drawings for 10 CFR Part 71 and 72 projects: licensing, design, and fabrication. Although Orrvilon has access to all design documents (such as specifications, calculations, design criteria documents, project plans, and design drawings) through the Holtec computer system; Orrvilon during the time of this inspection was primarily concerned with the fabrication drawings for MPC basket assembly projects.

The team reviewed the design control section of the HQAM and the HQPs that address design controls to verify they are being properly implemented at Orrvilon. The team specifically reviewed the following procedures associated with design control as it applies to fabrication:

- HQP-3.0, "Project Planning, Design Control, Product Realization and Project Execution," Revision 26
- HQP-3.4, "Design Specifications and Design Criteria Documents," Revision 4
- HQP-5.1, "Engineering Drawings," Revision 39

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.

Orrvilon is involved in the design process for fabrication drawings only. Generally, in the development of new and revised fabrication drawings, the Project Manager at Orrvilon for a fabrication contract/project will be an official reviewer of the drawings; especially at initial issue. A Drawing and Bill-of-Materials Review and Approval Log (DBMRAL) is associated with the initial issue and every revision to a fabrication drawing. The DBMRAL lists the names of the designer, checker, required technical discipline reviewers, Orrvilon fabricator reviewer (usually the Orrvilon PM), other reviewers, approvers and the date of their electronic signature. Once final approval is received, the PM in New Jersey releases the fabrication drawing into the electronic system. At release, the fabrication drawings have a watermark added to them stating "Released for Fabrication." Also at release, a unique verification identification record (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. Fabrication 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 not written at Orrvilon. Orrvilon can ask for changes to fabrication drawings by sending emails to the New Jersey Headquarters. Orrvilon only has the Non-conformance Report (NCR) process available. Some NCR's can be dispositioned at Orrvilon due to a standard "cook book" method of evaluation. More involved NCRs have to be sent to Holtec headquarters for final disposition. Generally, a dispositioned NCR does not require a fabrication drawing change. The NCRs generally only apply to one fabricated component or assembly. MPC basket NCRs are engineering documents that will be a part of the documentation package for a particular MPC basket and not shown or noted on the fabrication drawings. See Section 4.1.2 above for more information on NCRs.

The team reviewed the following drawings:

- 6506 Sht. 1 of 1, "Assembly, MPC 37 Fuel Basket Licensing Drawing – General Arrangement," Revision 12
- 6507 Sht. 1 of 1, "Assembly, MPC 89 Fuel Basket Licensing Drawing – General Arrangement," Revision 11
- 8689 Sht. 1 of 12, "Assembly, MPC 89 Fuel Basket Fabrication Drawing," Revision 6
- 8801 Sht. 1 of 20, "Assembly, MPC 37 Fuel Basket Fabrication Drawing," Revision 8
- 9220 Sht. 1 of 13, "Assembly, MPC 68M89 Fuel Basket Fabrication Drawing," Revision 6

The team assessed that Orrivilon was effectively implementing its design control procedures. The team found 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.

4.2.2 Modifications

Holtec International is responsible for all MPC basket assembly design modifications and any analysis justifying the changes. Orrvilon would only be concerned when receiving design changes to Holtec fabrication drawings. However, as discussed in 4.2.1 above, the Orrvilon PM would know the revision was coming since they would be one of the drawing revision approvers. Orrvilon then reviews the fabrication drawing changes for effects on existing travelers in the field. Travelers would be revised if required. Orrvilon craft have to verify the most current revision of the fabrication drawing they are working with at computer stations in the facility prior to every shift. The craft are locked out from charging the project until the revision check is made. The craft would also have access to the revised fabrication drawing itself at the computer station. The craft have read only access to the computer system to check revisions. If there are no required changes to travelers, nothing would have to be removed from the field as the craft would use the latest fabrication drawing in the computer system.

The team identified no concerns with the Orrvilon process for placing Holtec basket assembly fabrication modifications into production.

4.3 Fabrication Controls

4.3.1 Material Procurement

The Metamic-HT material is a metal composite material of proprietary specifications manufactured at the Orrvilon fabrication facility using raw powdered materials. The raw

powdered materials have either been purchased commercial grade and dedicated to ITS Category A quality or purchased ITS Category A from a vendor on the Holtec/Orrvilon AVL.

The team reviewed procedures, selected drawings and records, and interviewed selected Orrvilon personnel associated with the in-house manufacturing of the Metamic-HT material, to verify that the procurement specifications for the raw powdered materials met the Metamic-HT design requirements. The team reviewed selected manufacturing travelers for critical shop operations used in the manufacturing of the Metamic-HT metal plate sheets to be used in the assembly of the MPC baskets; including documentation to verify Metamic-HT material traceability from powder to basket assembled piece parts. For all basket assembly cases reviewed at Orrvilon, the team determined that the in-house manufactured Metamic-HT material met the design specifications and the formed plates were traceable to the serial number of the specific Utility Customer MPC CoC model in which it was to be used.

In addition, the team observed quality activities associated with material control in the processing of the Metamic-HT material into plate form. The team reviewed associated process control inspection reports, materials records for the in-process cutting to the required pattern of the stock Metamic-HT plate, and verified that the materials were controlled, verifiable, and traceable from the time of powder purchase through final basket fabrication. No concerns were identified by the team.

4.3.2 Fabrication and Assembly

The team interviewed Orrvilon personnel and reviewed documentation of fabrication activities affecting safety aspects of MPC basket assemblies to verify that the activities were performed in accordance with approved methods, procedures, specifications, and purchase order requirements. The team reviewed documentation associated with forming of the Metamic-HT billets, extrusion of the billets into plate, in-process fabrication/waterjet cutting, and assembly operations.

The team noted that a Holtec/Orrvilon approved traveler was initiated for each Metamic-HT plate configuration to ensure high standards of fabrication and assembly control. Travelers were sufficiently detailed to include recording latest fabrication drawing revisions, latest specification revisions, hold points and witness points, recording Metamic-HT batch ticket number, recording Metamic-HT mix identification number, mix design report, recording plate sample testing information, recording plate sample mechanical strength test results, and steps for performing fabrication work and recording inspection results. Each step of the travelers were signed off by a QC technician when the step was satisfactorily completed.

The team reviewed a sampling of records of completed MPC baskets and observed work in progress of assembling individual Metamic-HT plates into MPC baskets to verify that the process was adequately controlled.

The team observed the friction stir welding of two MPC baskets. The team determined that the friction stir welding operators were trained, certified, or qualified to perform this fabrication activity based upon review of each individual's training records or certifications.

The team determined Orrvilon's implementation of fabrication practices, assembly processes, and material storage controls to be adequate with no concerns identified.

4.3.3 Test and Inspection

The team reviewed the following Holtec/Orrvilon procedures specifically related to testing and inspections at Orrvilon:

- HSP-101, "In-Process and Final Inspection Procedure for Fabrications of MPC's," Revision 43
- HSP-638, "Visual & Dimensional Inspection," Revision 7
- HSP-214, "Marking Components and Assemblies for Inspection and Traceability," Revision 0
- HSP-314, "Cleaning of Fabricated Components and Finished Products," Revision 10

The team observed a selected sampling of fabrication activities for the Metamic-HT plate into MPC baskets; which included, in process and final visual examinations as well as in process material storage controls. The team verified that all phases of the fabrication, inspection, and storage processes were properly controlled and implemented. The team's observations of fabrication testing and inspection activities included extruding of Metamic-HT billet into plate, waterjet cutting of the plate, MPC basket assembly, friction stir welding of the MPC basket assembly, MPC basket plate mechanical testing, and final basket visual and dimension inspection.

The team toured the Orrvilon facility's testing laboratory and observed a lab technician perform a chemical analysis of the Metamic-HT powder mixture to assure that the composite material met the Holtec/Orrvilon proprietary design requirements.

The team reviewed the certifications of selected QC personnel and verified that they were qualified and certified. For observed fabrication activities, the team determined that Orrvilon personnel were trained, certified, or qualified to perform those fabrication activities based upon review of each individual's training records or certifications.

The team determined that Orrvilon's testing and inspections were structured, controlled, verifiable, well documented, and retrievable from the beginning of the metal Metamic-HT manufacturing phase through final fabrication and acceptance of the MPC basket assemblies with no concerns identified.

4.3.4 Tools and Equipment

The team reviewed the Holtec International MPC fabrication procurement specification PS-301 for any Measuring and Test Equipment (M&TE) requirements and found none. The team reviewed Holtec quality procedure HQP-12.0, "Equipment Calibration and Control of Measuring and Test Equipment," Revision 25, to verify that it was being properly implemented on the Orrvilon MPC basket projects. HQP-12.0 states that M&TE calibration may be performed by Orrvilon or an approved outside service vendor.

HQP-12.0 further states that all tools to be calibrated are scheduled for calibration per the M&TE Calibration Frequency Table (Exhibit 12.0.1). Actual scheduling is through the Orrvilon Tool and Equipment computer Database Calibration Schedule. All Orrvilon M&TE is in a computer database which tracks all M&TE information and can print a calibration due schedule; which will include the M&TE identification description, serial numbers, calibration due date, and department assigned location. HQP-12.0 also states a calibration sticker shall be attached to each M&TE or its container listing the identification number, initials of the person performing the

calibration, date calibrated, and due date for re-calibration. Each QC inspector is required to document the Orrvilon calibration serial number of the measuring and test equipment used for an item acceptance inspection on a fabrication Traveler.

When a M&TE device is found discrepant during calibration, all items checked using the particular M&TE shall be considered unacceptable and an evaluation of the impact of the out of calibration condition shall be completed. The evaluation shall be documented and when it is determined that no adverse impact on items exists, the evaluation shall be attached to the calibration record or documented on a Condition Report. Condition Reports are used to document conditions that are not CAQs at Orrvilon.

When an M&TE is found unacceptable during a periodic check, all items measured since the last periodic check shall be re-inspected or a Condition or Nonconformance Report shall be issued to evaluate the impact on previously inspected items.

The team interviewed the Quality Control individual responsible for administrating the Orrvilon M&TE program and maintaining the M&TE database through the Orrvilon computer software. The QC individual provided on a computer screen using the database a listing of all the M&TE requiring near term calibration. The list included the device's description, department assigned to, its serial number, and next calibration due date. For some of the generic M&TE devices in the database, for example a gage, there were several units and models listed with unique serial numbers. The QC individual demonstrated how calibration documentation from outside vendors could be scanned into the computer database system and associated with an M&TE device. The QC individual also demonstrated how queries could be made from the database for various M&TE information.

The team reviewed Holtec/Orrvilon procedure HSP-13, "Calibration of Measure and Test Equipment," Revision 14, which provided instructions to Orrvilon QA/QC personnel on how to perform all generic M&TE calibrations performed in-house. The team also reviewed purchase specification PS-501, "Purchase specification for Calibration of ITS and Safety Related M&TE," Revision 2, which is used to procure outside vendor calibration services.

The team reviewed the current calibration documentation/records for the following six M&TE devices that were actually used on MPC basket assembly projects:

12" Dial Caliper	Serial Number 13534321
Friction Stir Welding Machine	Serial Number 426-6-73
12" Dial Caliper	Serial Number C111226003
Pin Gage	Serial Number HOH 2054
Coordinate Measuring Machine	Serial Number 921152
Mixing Scale	Serial Number FM84139

The team visually inspected the two 12 inch dial calipers, pin gage, and coordinate measuring machine to verify that calibration stickers were attached showing component identification information and calibration dates. The team found the stickers to be in compliance with HQP-12.0 requirements. For the pin gage and coordinate measuring machine, the latest calibration and calibration documentation was provided by an outside vender that the team verified to be on the Holtec/Orrvilon AVL. The team noted that lab temperature and relative humidity were recorded by the calibration vendor on the certificate of calibration for these two items.

The team visually inspected the friction stir welding machine to verify that a calibration sticker was attached showing component identification information and calibration dates. The team found the sticker to be in compliance with HQP-12.0 requirements, but found the in-house calibration records to provide only a single tolerance with no units when two tolerances with units should have been provided for travel speed and rotation. There was no safety issue as this was only a documentation error and the machine was still within calibration tolerance. Orrvilon corrected the calibration record to show the correct travel speed and rotational speed tolerances.

The team visually inspected the mixing scale to verify that a calibration sticker was attached showing component identification information and calibration dates. The team found the sticker to be in compliance with HQP-12.0 requirements, but found the in-house calibration record to show an incorrect tolerance with no units. There was no safety issue as this was only a documentation error and the mixing scale was still within the correct calibration tolerance. Orrvilon corrected the calibration record to show the correct weight tolerance in pounds. However, while the team found the mixing scale with the proper calibration sticker, the scale had a broken wire which took it out of service. Since it was removed from service, the QC person responsible for the calibration program should have been notified so that the mixing scale could have been tagged out of service. This was not a significant safety issue, but the QC calibration person should have been notified so that when the scale was fixed, he would know to recalibrate it prior to use. Since it was a broken wire, the scale itself would probably have remained in calibration so this was not a significant issue. Orrvilon wrote Quality Issue Form 1926 to document the calibration record tolerance errors for the friction stir welding machine and the mixing scale and also not tagging the mixing scale out of service.

Overall, the team found the M&TE program to be adequate even with the minor concerns identified by the team during the inspection. The resolution of QIF 1926 will be reviewed and evaluated for appropriate actions and closure during the next NRC Orrvilon inspection.