



### INSPECTOR NOTES COVER SHEET

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Docket No.	71-1031
Inspection Report No.	72-1031/2019-201
Inspection Date(s)	July 17-19, 2019
Inspection Location(s)	Hitachi Zosen Mechanical Corporation Ariake Works (HZA) Kumamoto, Japan
Inspectors	Jon Woodfield, Team Leader, Safety Inspector Marlone Davis, Senior Safety Inspector Jeremy Tapp, Safety Inspector
Summary of Findings and Actions	<p>This inspection was a routine periodic assessment of NAC's Quality Assurance Program (QAP) implementation at their Magnastor Transportable Storage Canister (TSC) steel fabricator HZA's facility in Kumamoto, Japan.</p> <p>The team assessed NAC's management controls, design interface controls, and fabrication controls for compliance to 10 CFR Parts 21 &amp; 72, and NAC's NRC approved QAP; as related to NAC Certificate of Compliance 1031 (Magnastor).</p> <p>Overall, the team assessed that NAC through HZA was adequately and effectively implementing their NRC approved QAP subject to 10 CFR Part 72 with regard to Quality Assurance, Management Controls, Design Interface Controls, and Fabrication Controls.</p> <p>There was one minor violation against regulation 10 CFR 72.150, "Instructions, procedures, and drawings," for HZA not having adequate procedures for providing extensions beyond three years for performing triennial external audits of their approved vendors. There were two observations also. One observation was that not all the required supporting documentation needed to write an annual QAP assessment report was documented in the report. The second observation was that the resolution of a corrective action report was lacking detailed justification. HZA captured the minor violation and observations in their corrective action program.</p>
Lead Inspector Signature/Date	Jon N. Woodfield <i>Jon N. Woodfield</i> 8/23/19
Inspector Notes Approval Branch Chief Signature/Date	Christian Araguas <i>Christian Araguas</i> 8/29/19

## **Inspection History**

In May of 2016 the NRC conducted the last fabrication inspection at NAC steel fabricator Hitachi Zosen Mechanical Corporation in Kumamoto, Japan. In inspection report 072-1031/2016-201 (ML16176A338) the inspection team assessed that fabrication activities were in compliance with NRC requirements and no violations of Part 72 regulatory requirements were identified.

In May of 2013 the NRC also conducted a fabrication inspection at NAC steel fabricator Hitachi Zosen Mechanical Corporation in Kumamoto, Japan. In inspection report 072-1031/2013-201 (ML13190A200) the inspection team assessed that fabrication activities were in compliance with NRC requirements and no violations of Part 72 regulatory requirements were identified.

Review ADAMS for inspection reports of fabrication inspections performed at other NAC steel fabricators.

## **Inspection Purpose**

The purpose of the inspection was to assess NAC's compliance with 10 CFR Parts 21 & 72 using Hitachi Zosen Mechanical Corporation Ariake Works (HZA) as a fabricator, and to verify that the storage system for which NAC is the holder of CoC 1031, could be verified to comply with Part 72 in design, procurement, and fabrication requirements, as applicable. The focus of the inspection was to determine whether NAC activities through HZA associated with the storage of radioactive materials were in accordance with NAC's NRC approved QA program requirements.

## **Primary Inspection Procedures/Guidance Documents**

IP-60852, "ISFSI Component Fabrication by Outside Fabricators"

NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"

NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers"

**INSPECTOR NOTES: APPLICABLE SECTIONS FROM IP 60852 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 sections of HZA Manual No. NQA-001, "Quality Assurance Manual for Nuclear Items," Eighteenth Revision, also referred to as the QAM. The team reviewed various sections of the QAM, as well as the implementing quality procedures referred to at HZA as the Standards for Nuclear Items and noted that the QAM implements the 18 Quality Assurance Criteria contained in 10 CFR Part 71 and 72, Subpart H and G, respectively. The team verified

that the QAM contained a statement of quality policy and authority, signed by the General Manager (GM) of HZA; that describes the expectations for all HZA personnel in complying with the requirements of the QAM. The team verified that the Quality Assurance Manager, as required by the QAM, provided an annual report in 2017 and 2018 to the GM containing a summary including, but not limited to, internal audits and corrective action reports (CARs). The annual report was also signed by the GM as required by the QAM. The team noted during the review of the 2017 annual report that the summary of CARs section was missing several CARs issued in the reporting period. In addition, the summary of external audits section was missing the triennial audit NAC performed of HZA. Therefore, the assessment performed didn't consider all applicable information during the reporting period. The team discussed this observation with HZA and NAC personnel and it was entered into HZA's corrective action program (CAP) as CAR Number C-19-C-06. No issues of significance were identified in the review of the QAM and associated Standards for Nuclear Items.

#### 4.1.2 Nonconformance and Corrective Action Controls

The team reviewed the following sections of the HZA QAM and Standards that HZA uses to document, track and resolve nonconforming conditions and conditions adverse to quality.

- QAM Section M-31-1, Nonconformance Control, Revision 9
- QAM Section M-32-1, Corrective Action, Revision 10
- Standard Q-32-1, Corrective Action Standard, Revision 2

The team reviewed a representative sampling of HZA Nonconformance Reports (NCRs) and CARs since the last inspection in 2016. The reports documented various issues related to 10 CFR Part 72 activities performed by HZA for NAC. The team reviewed measures used to keep track of the status of nonconforming items and that HZA completed CARs for identified deficiencies in a technically sound and timely manner. The team also verified that the NCRs and CARs provided a connection to the 10 CFR Part 21 program.

The team sampled 5 NCRs which consisted of a variety of component types and suppliers and included a mix of rework and scrap component dispositions. The team determined that HZA appropriately dispositioned the nonconformances reviewed and closed them in a timely manner, in accordance with the QAM. The team sampled 8 CARs which included a review of fabrication process deficiencies and nonconformances that required a CAR. HZA classifies their CARs into either conditions adverse to quality or significant conditions adverse to quality depending on the significance of the issue. The sample chosen by the team only consisted of conditions adverse to quality as no significant conditions adverse to quality were selected. The team found that the corrective actions taken by HZA were adequate and closed out in a timeframe commensurate with the safety significance of the issue, when possible.

The team identified one observation during the review of CAR No. C-19-C-05 regarding the documentation provided in the extent of condition review. HZA justified a qualified calibration vendor of being able to meet the required 4:1 ratio of the reference standard to equipment being

calibrated by only stating that they were a qualified vendor with no supporting information. HZA entered this observation into their corrective action program and provided an appropriate justification in the extent of condition documentation.

Overall, the team concluded that HZA had an adequate nonconformance control and corrective action program in place to identify, track, and resolve quality related deficiencies and deviations.

The team reviewed QAM Sections M-31-1 and M-32-1 and both mention Part 21 reporting associated with NCRs and CARs. The team noted Q-32-1 provides basic direction to the HZA QA Manager to evaluate CAR issues for 10 CFR 21 reporting.

In addition, the team reviewed HZA Standard Q-20-2, "Reporting Standard of Defects and Noncompliance," Revision 4. This standard provides for customer notification of defects and noncompliance in shipped products. The Standard goes into great detail on how to do Part 21 reporting to customers or the NRC.

All NCR reports are also sent to NAC for final evaluation for Part 21 reporting applicability. The team assessed the procedures adequately implemented the requirements of 10 CFR Part 21. The team asked NAC/HZA if any Part 21 Reports had been written for the fabrication work performed for NAC since the last inspection and they stated that no Part 21 Reports had been written. HZA has four postings in its facility: QA office area, shop area, calibration shop, and weld wire shop area. The team verified the postings in all four areas and that they were current copies, which is compliant with Part 21.6, "Posting requirements." No issues were identified by the team regarding 10 CFR Part 21 program controls or implementation at HZA.

#### 4.1.3 Documentation Controls

The team reviewed the following sections of the HZA QAM and Standards that HZA uses to perform document control and quality records management.

- QAM Section M-15-1, Document Control, Revision 11
- QAM Section M-80-1, Quality Assurance Records, Revision 6
- Standard Q-80-1, Electronic Record Control Standard, Revision 2
- Standard Q-80-2, Quality Record Control Standard, Revision 0

HZA is traditional in that it issues hard copy controlled copies of their Quality Assurance Manual for Nuclear Items and Standards for Nuclear Items. The team requested a controlled copy master list for these documents from HZA and then performed a sample check of the controlled copies on the Design Engineering and Quality Assurance floor of the HZA office. The team determined that all the controlled copies sampled had correct control numbers and revisions in accordance with the master list.

The team verified the document control of fabrication drawings for the NAC transportable storage canisters (TSC) for the just started Three Mile Island (TMI) Project. Each HZA

fabrication drawing has a table on it showing the required distribution of the drawings to various locations on the HZA site. It also provides the number of drawings to be provided at each location. The fabrication drawings showed that the fabrication shop was to get three sets of each fabrication drawing. The team verified that the fabrication shop had all three controlled fabrication drawing sets at the latest revisions and that all the drawings were stamped "for fabrication."

The team also reviewed the HZA Document Control Sheets for the TMI Project and verified per procedure that the accounting of all controlled copies of fabrication drawings and their revisions had been accounted for and superseded revisions closed out on the sheets. Only active drawings were still open on the TMI Project Document Control Sheets.

The team reviewed Final Documentation Packages (FDP) for the just completed Magnastor TSCs to be used by Duke Energy at their Catawba Nuclear Station. The team verified that the as-built fabrication drawings were included in each FDP per procedure. The revision level of the as-built fabrication drawings in the FDPs reviewed were specific to each TSC. The TSC associated with each document package was certified by HZA to be fabricated to the drawing revisions in the FDP.

The team verified per procedure the isolation of two separate copies of quality records for completed NAC projects. The quality records for fabricated TSCs for all NAC projects have been put on digital versatile discs (DVDs) and are stored in a file cabinet in the QA office area and at another location on site that is far enough away that it must be driven to. The team verified the project DVDs at each location and determined they were properly stored and labeled. In place are access controls to the quality records in accordance with the procedures also. It should be noted that the procedures require verification every few years that the data stored on the DVDs is retrievable and that the data be transferred to new DVDs at that time.

The team determined the document control and QA record procedures were adequate and being followed by HZA personnel. No concerns were identified by the team in the documentation control and records management areas.

#### 4.1.4 Audit Program

The team reviewed both the internal and external audit programs implemented at HZA. The internal audit schedules for 2017 and 2018 were reviewed and the team noted that audits of all the organizations and the appropriate quality functions of each were planned on an annual basis as required by the QAM. Four internal audits from 2017 and 2018 were reviewed; the audits were of the Procurement Department, Machining Section, Nuclear Section, and Nuclear Equipment Quality Assurance Section. The audits were planned as required and performed to the appropriate checklists. All the audits identified findings, which were entered into HZA's CAP as appropriate. The team also sampled four internal surveillances that were performed of quality related activities per Standard Q-40-1, "Internal Surveillance Standard," Revision 5. The

team noted that issues were being identified during the performance of internal surveillances. Overall, the internal audits performed by HZA were assessed to be adequate.

The team reviewed HZA's qualified vendor list (QVL) to verify it was current. The team selected a sample of 3 external audits to review of HZA's qualified vendors. For the external audits reviewed, the team determine that all applicable quality areas were assessed for the material or services provided by the vendor. In general, the audit reports were written with enough detail to provide the necessary objective evidence that the vendor met the applicable quality requirements. No issues of significance were identified for the external audits that HZA performed.

However, the team identified during the review of the QVL, Revision 32, that approved vendor TD FORGE Italia was qualified only until July 21, 2019, but the due date for the next planned triennial audit was extended until the week of September 9, 2019. The team reviewed HZA's QAM and Standards for Nuclear Items and performed interviews of cognizant personnel to determine if a vendor due date extension process was documented and followed. The team found that there was no due date extension process documented or followed for TD FOREG Italia. Specifically, QAM Section M-20-1, "Purchase Control," Revision 12, Step 5.11 only states that a vendor is qualified for 3 years after audit. The team determined that this failure to have a documented due date extension process for qualified vendors was a violation of 10 CFR 72.150, "Instructions, procedures, and drawings," for inadequate procedures. The violation was assessed to be of minor safety significance and not subject to formal enforcement action because the due date had not been passed yet for the triennial audit at the time of the inspection and HZA entered this issue into their CAP as CAR Number C-19-C-07.

The team also reviewed the most recent triennial audit of HZA by NAC, 17-E-03, performed in 2017. The team found the audit to be comprehensive, review all 18 QA criteria, and identified both findings and observations. The team noted that the NAC audit also reviewed commercial grade dedication activities and the counterfeit and fraudulent materials program at HZA. HZA was verified to be on NAC's QVL, dated July 11, 2019, and current. In addition, the team also reviewed NAC Surveillance Reports 19-S-33 and 19-S-27, conducted May 30 – June 5, 2019 and May 27 – June 7, 2019, respectively. The NAC surveillances were assessed to be comprehensive, documented adequately with an appropriate level of objective evidence provided, and performed per the requirements of NAC quality procedure QP 10-2, "Quality Source Surveillance," Revision 10. Overall, no concerns were identified in the area of quality assurance audits of HZA by NAC.

The team also reviewed applicable procedures and records to determine if individuals performing quality-related activities were trained and certified where required. The team sampled training and qualification records for quality assurance auditors and lead auditors. The team selected random audit personnel records to determine if they were qualified and certified in accordance with the requirements in Standard Q-01-3, "Audit Personnel Qualification Standard," Revision 1, and no issues or concerns were identified.

## 4.2 Design Control

### 4.2.1 Design Development

The team reviewed the following sections of the HZA QAM and Standards that HZA uses to ensure that fabrication specifications and drawings are consistent with NAC design drawings and NRC approved licensing drawings.

- QAM Section M-10-2, Design Control, Revision 3
- QAM Section M-15-1, Document Control, Revision 11
- Standard Q-30-2, Standard for Control of Request for Design Change, Specification Change and Material Utilization, Revision 1

The team addressed this inspection element by reviewing the design control process between the Dry Cask Storage System (DCSS) designer NAC and fabricator HZA. Specifically, the team reviewed the process for HZA to develop fabrication drawings from NAC design drawings and the transmittal and approval of fabrication drawing revisions between the two.

The team initially reviewed purchase order (PO) 845964 and change order 1 from NAC to HZA dated 3/28/2019 for 10 TSCs for NAC's client TMI. All eight NAC TSC design drawings were listed in the PO. HZA is part of NAC's controlled document distribution system and received the most current revisions of the design drawings electronically. The team also reviewed NAC's specification 71160-S-05, "Procurement Specification Magnastor TSC," which was listed in the PO and sent to HZA through NAC's controlled document distribution system. The specification contained the minimum quality records and fabrication procedure documentation requirements and submittal requirements of those documents for NAC review and approval prior to actual HZA fabrication. From the official NAC design drawings HZA received, HZA developed the TMI Project fabrication drawings.

Procedure M-15-1 contains table 4.1 "Document Authorization Procedure" which shows the required signatures and reviews required on HZA fabrication drawings. All the fabrication drawings reviewed by the team for the TMI Project had the proper reviews and signatures in accordance with the table.

The team also verified that HZA had records of the transmittal of the fabrication drawings to NAC's corporate office in Georgia for approval prior to issuing the drawings for fabrication. The team then reviewed a sampling of NAC "Supplier Documentation Review Reports" approving/accepting the HZA fabrication drawing revisions. In some instances, NAC rejected the fabrication drawing revision with resolution of the reason for rejection required. HZA would then have to submit to NAC another revision to the fabrication drawing due to the resolution of the rejection reason. NAC would then issue another supplier documentation review report providing approval.

Based on its review, the team determined that HZA was following its procedures to ensure that

fabrication drawings and specifications were consistent with the NAC design drawings, NRC approved licensing drawings, and design requirements/commitments as documented in the CoC for the DCSS. Overall, no concerns were identified with the development, HZA approval, transmittal, NAC approval, control, and record keeping of fabrication drawings and specifications at HZA.

#### 4.2.2 Modifications

HZA has no design authority and does not use their own design change record (DCR) process to revise the fabrication drawings developed for NAC projects. Any need to revise the HZA fabrication drawings comes through NAC by a design change to the NAC design drawings. In this process, NAC would revise its TSC design drawing and issue the revised drawing to HZA through its electronic controlled document system. HZA would then review the revised TSC design drawing against the fabrication drawings to determine if they also needed to be revised. If a fabrication drawing was needed to be revised, it would be revised due to the revised NAC design drawing without using a DCR. The fabrication drawing would be revised with five HZA reviews and signatures.

HZA would also remove the previously issued fabrication drawing(s) as controlled copies from the outstanding controlled copies on the shop floor and at other locations and replace them with the next revision issued when all reviews and approvals were completed.

The team assessed that the process for revising and controlling revisions to HZA fabrication drawings due to NAC design changes was adequate with no concerns.

### 4.3 Fabrication Controls

#### 4.3.1 Material Procurement

The team reviewed HZA processes and procedures that addressed procurement, traceability, and receipt inspection of all material used in the fabrication of the MAGNASTOR DCSS. The team reviewed selected drawings, records and interviewed personnel to verify that the specifications for the procurement of materials, fabrication, inspection, and services performed at HZA met the design and procurement requirements of the MAGNASTOR TSCs, internal basket assembly, damaged fuel cans (DFCs), and fuel spacers. The team reviewed the following design documents, PO specifications and HZA quality procedures:

- NAC Specification 71160-S-01, MAGNASTOR Transport and Storage Cask System Design Specification, Revision 5
- NAC Specification 71160-S-05, Procurement/Fabrication Specification for the MAGNASTOR TSCs, Basket Assemblies, DFCs, and Fuel Spacers, Revision 2
- NAC Specification 71160-S-08, Procurement/Fabrication Specification for the MAGNASTOR Transfer Cask, Revision 1
- NAC to HZA Purchase Orders 845964 and 845593

- QAM Section M-20-1, Purchase Control, Revision 12
- QAM Section M-20-2, Control of Purchased Items, Revision 6
- QAM Section M-25-1, Material Identification and Verification, Revision 4

The team reviewed the completed Catawba Project (an 11 Magnastor TSC order) final documentation package for procurement of the TSC shell plates, closure lid, closure ring, and DFC components (lid plates, lid bottom, and tube body). The team also reviewed commercial grade dedication items such as the anchor post and weld post.

Overall, the team assessed that HZA had adequate control of the procurement process for the important to safety (ITS) Category A and B components reviewed. The team determined that HZA procured ITS components consistent with design and procurement requirements and their implementing procedures. The team assessed that HZA had adequate controls for material procurement, traceability, and receipt inspection. The team also determined that the material purchase orders were adequate and specified the applicable criteria and requirements including Part 21. For the commercial grade dedication items, the team assessed that HZA received and accepted the material in accordance with the critical characteristics selected as a part of the procurement process. Additionally, the team determined that HZA purchased the components from vendors currently on the HZA's Qualified Vendors List (QVL). The team concluded that HZA procured each in accordance with a PO or through their commercial grade dedication process.

#### 4.3.2 Fabrication and Assembly

The team conducted personnel interviews and reviewed selective HZA fabrication and assembly procedures used in the fabrication of the MAGNASTOR DCSS. The procedures are as follows:

- QAM Section M-30-1, Process Control, Revision 6
- Standard F-30-1, Fabrication Sequence Diagram Standard, Revision 2
- Standard F-30-2, Check Sheet Standard, Revision 2

Additionally, the team reviewed fabrication sequence diagrams (FSDs) and associated check sheets to evaluate applicable steps within the assembly of the TSCs. Specifically, the team reviewed the fabrication and assembly packages for MAG-TSC-418, MAG-TSC-111, and MAG-TSC-121 for the just completed Catawba Project.

The team assessed that HZA identified and implemented the appropriate codes, standards, and fabrication drawings. The team noted that HZA translated the design drawings and specification information into FSD and fabrication drawings. The FSD and the check sheets contained the appropriate hold points for quality control inspectors to witness and gather information (take verification measurements and perform nondestructive examinations) prior to proceeding on in the fabrication process. The team assessed that HZA practiced and implemented high standards of fabrication and assembly.

The team reviewed selected records to evaluate if trained and certified individuals were performing quality related activities in cleaning and special processes as required. Specifically, the team reviewed completed document packages and procedures to determine how individuals controlled production welding, obtained the correct weld procedure specification (WPS) for fabrication use, assigned qualified welders, and tracked welder qualifications. The team reviewed the following procedures:

- QAM Section M-40-1, Heat Treatment Control, Revision 5
- QAM Section M-41-1, Welding Control, Revision 7
- Standard F-10-1, Welding Materials Control Standard, Revision 3
- Standard F-40-7, Cleaning Standard, Revision 2
- Standard W-01-1, Weld Record Form Usage Control Standard, Revision 2

The team reviewed welding qualification records and reviewed the heat treatment control process that HZA used for certain fabrication activities. The team selected one of the welding processes, gas tungsten arc welding, to verify the controls HZA had in place for the process and the storage of the weld filler material.

Overall, the team noted that the WPS provided for each weld required during fabrication contained appropriate essential and nonessential variables as appropriate. The team noted welder performance qualifications and welder continuities conformed to Section IX of the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code. Additionally, the storage control for the weld filler material met all procedure requirements. There were no issues identified with the cleaning and welding processes used for the fabrication of the MAGNASTOR TSCs packages reviewed.

#### 4.3.3. Test and Inspection

##### Test and Inspection

The team reviewed applicable procedures and records to evaluate how HZA implemented controls for tests and inspections related to fabrication activities for the MAGNASTOR TSC and if the personnel conducting these tests and inspections were trained and qualified. The team reviewed the following documents:

- QAM Section M-06-01, Indoctrination and Training, Revision 10
- QAM Section M-50-1, Examination, Inspection and Test, Revision 6
- Standard Q-01-2, Qualification Standard for Inspector and Test Personnel, Revision 4
- Standard Q-01-4, NDE Personnel Qualification and Certification Standard, Revision 8

The team also reviewed completed check sheets to evaluate the type of Nondestructive Examinations (NDE) conducted during the fabrication process. The team reviewed NDE results associated with radiography, visual, and magnetic particle testing.

The team assessed that HZA personnel performed and documented NDE in accordance with approved procedures. The team noted that HZA used qualified and certified personnel to conduct fabrication activities for each of the selected and completed NDE documentation reviewed. The team noted that the selected examiners identified in the check sheets were qualified according to the American Society for Nondestructive Testing (ASNT) Recommended Practice No. SNT-TC-1A. The team assessed that the training records reviewed included the experience, medical testing, and education for all qualified examiners selected from the check sheets. There were no issues discovered during the documentation review.

Overall, the team determined that all the test and inspection activities observed were adequately performed by knowledgeable and qualified inspectors and no significant concerns were identified.

#### 4.3.4 Tools and Equipment

The team reviewed the following sections of the HZA QAM and Standards for the quality assurance requirements for calibration and maintenance of measuring and test equipment (M&TE) and to verify that they were being properly implemented.

- QAM Section M-60-1, Measuring and Test Equipment Control, Revision 8
- QAM Section M-60-2, Gauge Control, Revision 3
- Standard Q-10-1, Calibration Standard for Measuring and Test Equipment, Revision 11
- Standard Q-10-2, Calibration Standard for Master and Standard Equipment, Revision 7

Since during the inspection there was no actual fabrication of NAC TSCs going on, the team selected M&TE from the most recent common FDP for NAC TSCs to review calibration records. The team chose from the common FDP to review calibration records for an oxygen monitor, micro meter, slide caliper, scale (ruler), torque wrench, and load cell. The team reviewed the calibration records for each of these devices at the HZA calibration lab. The team determined that all the calibration records were current and the calibration documents all in order and in accordance with the procedures. The team had the calibration lab personnel demonstrate HZA's M&TE computer data base by finding the current calibration data for each device sampled and searching the database for M&TE requiring calibration in the next three weeks. In addition, the team verified that the actual calibration room had instruments to measure temperature and humidity as required by procedure. The team also verified that the torque wrench and load cell had identification numbers, last calibration date, and next calibration due date on stickers attached to them. M-60-1 states that the Manager of Manufacturing Equipment Maintenance and System Management Section is responsible for indoctrination, training, and qualification of calibration personnel. The team requested these records for the lead person working in the calibration lab. The team reviewed all the records for the individual and determined the records were thorough and adequate to demonstrate his competence for performing his calibration lab duties. The procedures provided guidance on actions to be taken if any M&TE was found to be out of calibration during recalibration.

The calibration of each M&TE instrument sampled was current and traceable to a recognized standard. The team determined that HZA was controlling M&TE calibration activities and records in accordance with its procedures with no concerns.