

<b>SUBJECT:</b>	Fermilab Assessment Manual – Chapter 4 Independent Assessment Procedure – Form 1	<b>NUMBER:</b>	3902.1004 FORM 1
<b>RESPONSIBILITY:</b>	Quality Assurance Manager	<b>REVISION:</b>	000 C1
<b>APPROVED BY:</b>	Head, Office of Quality and Best Practices	<b>EFFECTIVE:</b>	

### FERMILAB INDEPENDENT ASSESSMENT REPORT FORM

<b>Fermilab Independent Assessment Report</b>	
<b>Assessment Number &amp; Title:</b> 11-IA-QA-004-ESH Inspection and Acceptance Testing & Suspect/Counterfeit Items	<b>Version:</b> 001
<b>Date(s) of Assessment:</b> 2/14/11 – 2/17/11	
<b>Performing Organization:</b> Office of Quality and Best Practices	
<b>Assessed Organization(s):</b>	
Environment, Safety & Health (ESH) Departments: <ul style="list-style-type: none"> <li>• Instrumentation Team</li> <li>• Hazard Control Technology Team (HCTT)</li> <li>• Environmental Protection Group</li> </ul>	
<b>Report Content:</b>	
This report contains the following sections: <ul style="list-style-type: none"> <li>• Assessment Activities &amp; Scope</li> <li>• Scope Limitations</li> <li>• Activities Reviewed Within This Assessment</li> <li>• Description of Implementation &amp; Effectiveness of Observed Activities</li> <li>• Conclusions</li> <li>• Findings</li> <li>• Observations, &amp; Recommendations</li> </ul>	
<b>Assessment Activities &amp; Scope:</b>	
Implementation and effectiveness of controls for Inspection & Acceptance Test and Suspect/Counterfeit Items (S/CI) relative to the requirements of the Integrated Quality Assurance (IQA) program, Suspect/Counterfeit Item (S/CI) Program 1006, and Controlling Suspect/Counterfeit Items Procedure 1006.1001 were examined via interview, observation, and document review. These controls were examined across the ESH departments listed in the “Assessed Organization(s)” section of this report.	
<b>Scope Limitations:</b>	
IQA section 8.5 “Control of Measuring and Test Equipment (M&TE)” was not within the scope of this assessment.	
<b>Activities Reviewed Within this Assessment:</b>	
The following activities were reviewed during this assessment: <ul style="list-style-type: none"> <li>• Radiological tester production and testing</li> <li>• Chemical and radiological waste management</li> </ul>	

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- Environmental water sampling

**Description of Implementation & Effectiveness of Observed Activities:**

Inspection and Acceptance Testing:

IQA requirements for Inspection and Acceptance Testing are met and effectively implemented within the ESH departments assessed. Inspection and acceptance test practices are commensurate with the complexity of operations, the nature of the materials, and levels of risk perceived for noncompliance.

Corrective and preventive actions are handled with varying degrees of formality within the groups assessed. Within the HCTT, there is a formal procedure and form used for documenting waste handling procedure noncompliance incidents and corrective actions taken (File01 and File02). This form is distributed to the waste generator, the generating organization’s Chemical Waste Coordinator and HCTT management. This formal procedure has not been used recently and, according to interviewees, incidents regarding waste handling are usually handled on a more informal basis with the generator. Instrumentation Team problems are generally technical in nature and are resolved within the group by simple analysis of the problem and modifying specifications to resolve any deficiencies identified. According to team members, electronic component quality issues are rare, but would be referred through the Electrical Safety Subcommittee for consideration.

Controls for nonconforming materials to prevent their inadvertent use are informal and commensurate for the size and complexity of the operations. In both the HCTT and Instrumentation Team, only conforming materials proceed through the process. Nonconforming materials are dispositioned before proceeding. According to HCTT staff, nonconforming materials across site awaiting pickup are isolated by holding the documents required for pickup until nonconformances are corrected (required documentation is specified in File03). Within the Hazardous Waste Storage Facility (HWSF), incoming materials are physically isolated pending acceptance. The Instrumentation Team likewise uses an informal positive acceptance system for nonconforming materials due to low production volumes. Only components and materials meeting specifications move forward through assembly and rejected materials are rejected and dispositioned at the point of use. Interviewees indicated that because many of the component specifications they require exceed those of commercially available materials, components are “culled” to select those in the upper performance range.

All hazardous materials are characterized prior to approval for shipping in accordance with FESHM 8021 and completion of the specified testing is required for material transport, as indicated on the Radioactive and Chemical Waste Pickup Forms (File04 and File05). Primary receipts within the HCTT are various types of shipping containers, which are regulated by United Nations (UN) or Department of Transportation (DOT) certifications and bear a corresponding certification stamp or mark. Within the Instrumentation Team functions, acceptance testing is largely performance-based. Interviewees indicated that performance requirements are based on process knowledge and lessons learned from previous designs. Requirements are determined in the design phase and modified as needed throughout the prototyping process. Rejections are communicated informally within the group (File06). System technology and reliability drives the prioritization of inspection and acceptance test activities informally based on the knowledge and experience of team members.

The Instrumentation Team has turnkey responsibility for design, production, and inspection activities for radiation monitoring equipment. Acceptance testing is conducted appropriately by staff with knowledge of

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performance requirements. There is no indication of conflicts of interest in determining inspection disposition. The HCTT is responsible for the categorization, packaging, documentation, and disposition of hazardous materials. Material testing is performed by the generators and the HCTT serves in an independent oversight role of the hazardous waste accumulation processes from across the lab.

Within the HCTT, forms and procedures exist for most standard operations, as demonstrated for dumpster surveillance (File07 and File08). Numerous other examples were provided for review. In some cases, forms serve as checklists for acceptance testing activities as indicated in the Packaging Acceptance Inspection Form (File09). Results are indicated on the forms as records of the inspections. The Instrumentation Team also utilizes checklists for standard test procedures as indicated in File10 and File 11. Completed checklists are retained as records of the inspections. In other cases, graphs or other formats are used to record test results (File12).

Suspect/Counterfeit Items:

The requirements of the Fermilab S/CI program, as specified in IQA Chapter 10, the Suspect/ Counterfeit Item (S/CI) Program 1006, and Controlling Suspect/ Counterfeit Items Procedure 1006.1001 have not been fully implemented across the ESH groups assessed.

All interviewees had some knowledge of S/CI issues in general. They knew the identity of the section’s S/CI Coordinator and knew of some typically at-risk items. None of the interviewees indicated specific knowledge of the Fermilab S/CI program documents and specific requirements of the program. Four of the five interviewees assessed indicated that their primary control against S/CI was the selection of reputable suppliers. Within the HCTT and Environmental Protection groups, none of the three interviewees had S/CI training or training requirements assigned. Because of the nature of their work and lesser S/CI-related risks involved, it was not clear that S/CI training would be required for these personnel.

According to both interviewees within the Instrumentation Team, electronic components are specified, purchased, and installed as a part of the radiation tester manufacturing process. Interviewees were aware of recent bulletins distributed via OQBP regarding recent suspect electronic components and indicated there had been no personal experience with S/CI materials within their area of responsibility. It was related that, although they attempt to use only reputable vendors, they are sometimes obligated to seek secondary or surplus sources to purchase discontinued components for older testers. Neither interviewee on the Instrumentation Team had either of the S/CI training courses listed as Individual Training Needs Assessment (ITNA) requirements, nor had either taken any Fermilab S/CI training. Likewise, none of the four other HCTT members indicated on an ESH organization chart dated 2/10/11 had any S/CI requirements in their ITNA’s or S/CI training completed.

**Conclusions:**

Inspection and Acceptance Testing requirements are met and effectively implemented where applicable within the three ESH organizations assessed. Where not specifically mandated by policy or regulation, testing is commensurate to the nature and scale of the operations and the risks associated with the materials involved.

The Fermilab S/CI program has not been fully implemented within the assessed organizations. Training requirements for personnel interviewed involved in design, procurement, receipt, inspection, and installation of S/CI-sensitive materials have not been met. Awareness of the specific isolation,

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investigation, status determination, and reporting requirements for S/CI is low.

**Finding:**

The requirements of the Fermilab S/CI program, as specified in IQA Chapter 10, the Suspect/ Counterfeit Item (S/CI) Program 1006, and Controlling Suspect/ Counterfeit Items Procedure 1006.1001 have not been effectively implemented across the ESH groups assessed.

Section 10.2 of the Integrated Quality Assurance Manual states that: “Line management is responsible for identifying individuals requiring S/CI training, ensuring they receive this training, and providing necessary resources for implementing the S/CI program.” Section 5.1 of the Suspect/ Counterfeit Item (S/CI) Program 1006 states “Personnel specifying, receiving, inspecting, or installing mechanical or electrical items that are susceptible to counterfeiting shall receive S/CI Items Awareness Training. Where required for specific positions, training is indicated on the Individual Training Needs Assessment (ITNA) and tracked in the laboratory’s central training database.” The Individual Training Needs Assessment (ITNA) questionnaire, asks managers: “Will individual be involved in engineering design and specification, procurement of materials & supplies IAW engineering requirements, review of material requirements, or receipt & inspection of materials?” A positive response indicates the need for S/CI Program training.

Neither interviewee on the Instrumentation Team had either of the S/CI training courses listed as Individual Training Needs Assessment (ITNA) requirements, nor had either taken any Fermilab S/CI training. Likewise, none of the four other Instrumentation Team members indicated on an ESH organization chart dated 2/10/11 had any S/CI requirements in their ITNA’s or S/CI training completed.

**Observations and Recommendations:**

1. **Observation:** None of the interviewees within the assessed organizations indicated specific knowledge of the Fermilab S/CI program documents and specific requirements of the program. Within the HCTT and Environmental Protection groups, none of the three interviewees had S/CI training or training requirements assigned. Because of the nature of their work and lesser S/CI-related risks involved, it was not clear that S/CI training would be required for these personnel.

**Recommendation:** The need for S/CI program or identification training should be reevaluated by management relative to the specific job responsibilities of those within the assessed organizations to ensure that those involved in work where S/CI risks may be significant receive the appropriate training and that basic program knowledge exists within these organizations.

**Names of Person Interviewed:**

- Billy Arnold, Hazard Control Technology Team Leader
- Dave Hockin-Hazardous Waste Storage Facilities Supervisor
- Butch Hartman, Co-Supervisor, Instrumentation Team
- John Larson, Co-Supervisor, Instrumentation Team
- Geoff Eargle, Environmental Protection

**Documents Reviewed:** See Appendix 1

**Requirements Applied:**

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- Fermilab Integrated Quality Assurance (IQA), Document 1001  
Chapter 8 – Inspection and Acceptance Testing  
Chapter 10 – Suspect/Counterfeit Items
- Suspect/Counterfeit Item (S/CI) Program, Document 1006
- Controlling Suspect/Counterfeit Items Procedure, Document 1006.1001

**Describe or List Any Other Assessment Methods Used:** None

**Corrective Action Plan Issued:**

ESH-20110405-01: Requirements of the “Suspect/ Counterfeit Item (S/CI) Program”, (Document 1006) and “Controlling Suspect/ Counterfeit Items Procedure” (Document 1006.1001) are not fully implemented

**Assessors’ Names (asterisk indicates team leader):**

Frank Cesarano  
Kurt Mohr\*

**Submitted by:** Kurt Mohr

**Date:** 4/27/2011

**Distribution:**

Billy Arnold	Frank Cesarano
Don Cossairt	Bob Grant
John Dawson	Jed Heyes
Geoff Eargle	Ed Vokoun
Nancy Grossman	
Butch Hartman	
Dave Hockin	
John Larson	
Eric Mieland	
Tim Miller	

**Attachments:**

- File01-#08 Waste Incident Form.pdf
- File02-#20 Waste Incident Procedure.pdf
- File03-#22 Pre-shipment Documentation.pdf
- File04-#31- Rad Waste Pickup.pdf
- File05-#10 Chem Waste Pickup.pdf
- File06-CageFrameRejection.pdf
- File07-#06 Dumpster Survey Procedure.pdf
- File08-#05 Dumpster Survey form.pdf
- File09-#06 Package Acceptance.pdf
- File10-Ludlum\_14C 2009\_2.pdf
- File11-Fox Ion Chamber Parts InspectionJL.pdf

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- File12-P2 linearity 20071031BH\_fk\_update .pdf

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**Appendix 1: Documents Reviewed** (Does not include attachments)

- FESHM 8021 Chemical and Radioactive Waste Management
- FESHM 8011 Monitoring Wells.pdf
- #01 HCTT Writing Procedure.docx
- #02 Sling Inspection.docx
- #03 Bicron Analyst Survey.docx
- #04 Frisker.docx
- #05 Ludlum 14C-1 Dose Rate Meter Survey.docx
- #07 Snoop Survey.docx
- #08 Performing Wipe Survey.docx
- HCTT Blank Procedure.docx
- #01 Compositing Waste.doc
- #02 Empty Containers.doc
- #03 Unknowns.doc
- #04 Waste Staging.doc
- #05 Waste Pickups and Transport.doc
- #07 Fire Protection.doc
- #08 Mixed Waste.doc
- #09 PCBs.doc
- #10 Hydrofluoric Acid Waste PickupandTransport.doc
- #11 Waste Sampling.doc
- #13 Transfer and OverpackWaste.doc
- #14 Safety Kleen.doc
- #15 Emergency Evac.doc
- #16 Lead Battery Shipment.doc
- #17 Inspections.doc
- #18 Compliance Inq.doc
- #21 Chem Compatibility.doc
- #24 Bond Ground Test.doc
- #25 Draining Rad Batteries.doc
- #26 Respirator Use.doc
- #27 Inspection Cert Issuing Containers.doc
- #28 PPE.doc
- #30 Screening Verification WS-3.doc
- #31 Used Oil Disposal.doc
- Blue Box Wiring for Fox.pdf
- Fox Blue Box Wiring Check.pdf
- Fox P2\_Ener\_Resp\_Hor\_20071020\_grf updat.pdf
- Fox Post Cal 2011\_1.pdf
- Fox Pre Cal 2011\_1.pdf
- Fox Source Installation.pdf
- FOX001 TempChart.pdf
- FOX001TempPass-Fail.pdf
- FOX5B\_ExposureRateVsPlateauKnee.pdf
- FOX5B\_PlateauKneeVsExposureRate.pdf
- FoxP2\_Ener\_Resp\_Vert\_20071029\_grf\_update.pdf
- IonChamberAssemblyProcedureV02.pdf
- RP330 HV Board Modifications for Fox.pdf
- RP84 Board Modificationsfor Fox.pdf
- X-Ray Cage Assembly Pictures.pdf
- xray\_chmbr5b\_plat\_series\_update.pdf