SUBJECT:	Suspect/Counterfeit Items Program	NUMBER:	1006
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	03/19/2010

QA

1006

Suspect/Counterfeit Item (S/CI) Program

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1.0 Purpose

The purpose of this procedure is to describe the activities required to prohibit or control the use of Suspect/Counterfeit Items (S/CI) at Fermilab.

2.0 Scope

All new and existing items, equipment, products or parts at Fermilab are within the scope of this document.

3.0 Applicability

This procedure applies to Fermilab line management, division/section/center (D/S/C) S/CI Coordinators, employees, subcontractors, and users, Senior Safety Officers (SSO's), Laboratory ES&H Committee Chair, Procurement Department, and the Office of Quality and Best Practices (OQBP).

4.0 Responsibilities

4.1 The Fermilab Director

- Approves the S/CI policy as part of Director's Policy #10, Quality Assurance
- Holds management accountable for implementation of, and compliance with, this program and its implementing procedures
- Appoints OQBP as the Fermilab site S/CI Coordinator

4.2 Heads of Divisions/Sections/Centers

- Ensure compliance with this procedure for their areas of responsibility including flow down of requirements and awareness
- Provide personnel as appropriate to implement this procedure
- Ensure individuals within their D/S/C are trained in S/CI where required
- Appoint S/CI Coordinators for each D/S/C

4.3 The Office of Quality and Best Practices

- Oversees the Fermilab S/CI Program and serves as the site S/CI Coordinator
- Provides support to line management and S/CI Coordinators in resolving open S/CI issues
- Recommends what notification to the DOE Office of the Inspector General and the DOE Site Office is required
- Forwards requests for subject matter expert (SME) guidance to the relevant laboratory safety subcommittee chairs when S/CI discoveries or reports require a laboratory response.
- Provides periodic status reports to the Fermilab Assurance Council, the Laboratory Director, line managers, and others as appropriate
- Maintains training materials and works with ES&H and D/S/C training to provide training

4.4 Employees, Subcontractors and Users

- Receive training in S/CI awareness as it pertains to their work
- Notify their immediate supervisor when a potential S/CI is discovered
- Follow applicable FESHM policies and procedures

4.5 Supervisors, Construction Coordinators, and Task Managers

- Notify appropriate line management and S/CI Coordinator of potential S/CI

- Refer to 1006.1001 Controlling Suspect/Counterfeit Items Procedure when a potential S/CI is discovered
- Determine training requirements
- Ensure that S/CI-related information is flowed down to all employees , subcontractors and users working under their direction as appropriate, either through formal training or transfer of information (with records maintained) by an S/CI-trained Fermilab employee

4.6 Division/Section/Center S/CI Coordinators
- Work with the supervisor, engineering, OQBP, Procurement or other subject matter expert, to document and resolve reported S/CI
- Maintain an S/CI log

4.7 Senior Safety Officer for Division/Section/Center
- Respond to requests for safety related evaluation of S/CI
- Inform local S/CI Coordinator and OQBP when the result of a safety related evaluation of S/CI identifies a safety risk

4.8 Fermilab ES&H Committee (FESHCOM) Chair
- Bring requests from OQBP for SME guidance on S/CI to the relevant subcommittee for review and response
- Provide the laboratory's response to requested S/CI reviews
- Elevate to other ES&H subcommittees or the laboratory ES&H committee if necessary

4.9 Procurement
- Incorporate technical requirements that are a part of or attached to the relevant requisition into the subcontract
- Contact subcontractor and ensure that Fermilab's S/CI concerns are documented in Fermilab's subcontract file

5.0 Requirements
The suspect/counterfeit item program prevents or controls use of suspect items via:
- Director's Policy #10, Quality Assurance
- Training
- Reference resources on websites (OQBP, DOE, others)
- S/CI alerts from a variety of sources including DOE, subject matter experts, other laboratories, and industry lessons learned
- Identification, reporting and disposition of S/CI discovered at Fermilab

5.1 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.

5.2 Procurement of products and services are made in compliance with the Fermilab Procurement Policy and Procedure Manual that includes safeguards against procuring, of suspect/counterfeit parts.

5.2.1 To reduce the likelihood of receiving suspect/counterfeit items, the requestor/requisitioner may include information on suspect parts with a purchase requisition or subcontract to ensure supplier and subcontractor awareness.

5.2.2 The requestor may include S/CI procurement controls including, but are not limited to:
- Imposing observation or inspection hold points
- Specifying inspections and/or tests to be witnessed by or performed by Fermilab personnel or others on behalf of Fermilab
- Specifying the manufacturer or authorized distributor for items (ie: non-competitive justification)
- Requiring a pre-award survey
- Performing post award audits
- Additional provisions

5.2.3 Procurement notifies the suppliers of requirements including supplier S/CI program management via the subcontract.

5.3 All not yet in-service equipment, products or parts shall be inspected prior to installation or use to ensure that they are not S/CI.

5.3.1 All not yet in-service equipment products or parts that are inspected and considered potential S/CI shall be segregated, properly identified using an S/CI Tag or paint (or other means agreed to by OQBP if the tag or paint cannot be used), and documented in the SCI log.

5.3.2 Items determined to be S/CI shall not be allowed to be used or installed.

5.3.2.1 Subcontractors and suppliers in violation may be subject to investigation by the DOE.

5.4 Existing equipment, products or parts which are in use or installed shall be inspected for S/CI by the persons responsible for the operation and/or maintenance of the system. Additional controls which may be applied to indentify S/CI already installed or in use include:
- Independent Inspections
- Management walkthroughs
- Assessments

5.4.1 Existing equipment, products or parts which are in use or installed and considered to be S/CI shall be quarantined where practicable and tagged with an S/CI Tag or paint to prevent unauthorized use. An S/CI log is maintained to record pertinent information about each S/CI and record the status from discovery to closure.

Disposition of S/CI shall be made by engineering or other subject matter experts based on evaluation of the likelihood of injury to personnel, damage to the environment, damage to other equipment, and other technical and operational considerations. Results of dispositions shall be recorded.

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5.5 Procedure 1006.1001 Controlling Suspect/Counterfeit Items Procedure describes the detailed actions necessary to manage S/CI from discovery to closure.

6.0 Records
S/CI Log
Records of destruction

7.0 Review Cycle
This procedure shall be reviewed for accuracy and relevance on at least a three year cycle

7.1 Document Owner
OQBP QA Manager

7.2 Reviewers
OQBP Head
Division/section/center S/CI Coordinators
Fermilab site SSO
Procurement Manager
BSS Property & Inventory Control Manager

7.3 Approver
OQBP Head

8.0 Policy and Program Documents
Directors Policy #10, Quality Assurance
1001 Fermilab Integrated Quality Assurance (IQA) Chapter 10, Suspect/Counterfeit Items
1006.1001 Controlling Suspect/Counterfeit Items Procedure
1006.1002 Suspect/Counterfeit Items OQBP Procedure
Fermilab Environment Safety & Health Manual (FESHM) Chapter 3010, Significant and Reportable Occurrences

9.0 Definitions

Counterfeit items are items whose documentation, appearance, performance, material, or other characteristics **are** knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Nonconforming items are items that do not meet specified requirements.

Suspect items are items whose documentation, appearance, performance, material, or other characteristics **may have been** knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Note: By definition, for an item to be considered S/CI officially it must first be nonconforming to specified requirements. Therefore all confirmed S/CI are nonconforming items but all nonconforming items are not necessarily S/CI.

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10.0 References

DOE O 414.1C *Quality Assurance* – Contractor Requirements Document, Attachment 2 Section 4 – DOE-Wide Suspect/Counterfeit Item Prevention Process

DOE G 414.1-3- *Suspect Counterfeit Items Guide*

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Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft A5 to A6 with updated document schema. Separated Lab-wide step by step procedure & flowchart for discovered S/CI. Most formatting changes accepted. A6 to A7 reconciled OQBP comments	000 A7	07/16/08
Jed Heyes	Final reconciliation & promotion	000 B	07/23/08
Jed Heyes	Updated to reference the role of the laboratory safety subcommittees	000 B1	0817/08
Jed Heyes, Kurt Mohr	Updated based on formatting comments from Business Services Section & Jeff Cotton. Separated 5.2.2 from end of 5.2.1 & consistency with S/CI Program.	000 B2	11/07/08
Kurt Mohr	Changed Sect. 8 (Policy and Program) reference to "FIQMP" to "IQA"	000 B3	11/13/08
S/CI Coordinators/Trainers	Input during first review meeting	000 B4	11/24/08
Jed Heyes	Input to section 5.2 from Joe Collins & Greg Mitchell to comments from S/CI team	000 B5	12/02/08
Kurt Mohr	Minor revisions based on S/CI Coordinator reviews 12/09	000 B6	1/26/10
Kurt Mohr	Minor revisions based on S/CI Coordinator Meeting 1/27/10 and: Revised list of those with program responsibilities in 3.0 Applicability. Clarified supervisory role for program flowdown and expanded application to Construction Coordinators and Task Managers in 4.5. Eliminated training requirements for employees "ordering" (administratively only) materials in 5.1. Clarified requirement for supplier S/CI program in 5.2.3	000 B7	3/3/10
Jed Heyes	Added reference to paint to 5.3.1 and 5.4.1.	000 C	3/15/2010
Jed Heyes	Incorporated additional comments from Fermilab site safety officer.	001	3/18/2010