

<b>SUSPECT/COUNTERFEIT ITEMS</b>		Identifier: PRD-5095	
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Companywide	Program Requirements Document	For Additional Info: <a href="http://EDMS">http://EDMS</a>	Effective Date: 12/06/12

Manual: 13—Quality Assurance Program

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\*The current revision can be verified on EDMS.

## 1. PURPOSE

This program requirements document (PRD) identifies requirements and responsibilities for identifying, investigating and controlling *suspect/counterfeit items* (S/CI; see def.).

The requirements identified are contained in Department of Energy (DOE) Order 414.1D, “Quality Assurance.”

## 2. APPLICABILITY

This PRD applies to the development of procurement documents; acquisition of material or equipment; inventory and storage; receipt inspection; inspection and testing; replacement, maintenance, or modification of equipment; and the inspection, identification, evaluation, and disposition of S/CI installed in all systems, structures or components and other applications that create potential for S/CI.

## 3. RESPONSIBILITIES

### 3.1 Quality Assurance

3.1.1 The quality assurance organization is responsible for providing direction and assessment of the company S/CI program which includes, but is not limited, to the following:

- A. Support the resolution of conditions not in compliance with the PRD requirements to ensure that the conditions are corrected in an appropriate and timely manner
- B. Support the establishment of company policy and procedures in compliance with the PRD
- C. Providing independent oversight of the S/CI program implementation to ensure compliance with the requirements of the PRD.

### 3.2 Line Organizations and Subcontractors

3.2.1 Line organizations and subcontractors are responsible for the following:

- A. Implementing the S/CI program as defined in company policy and procedures.

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- B. Resolving S/CI issues and implementing timely *corrective action* (see def.)

## 4. REQUIREMENTS

### 4.1 Companywide Applications

- 4.1.1 The requirements identified in this subsection meet the requirements in DOE Order 414.1D, and apply to the entire company as defined by FWD-7, “Foreword.”

### 4.2 Basic

- 4.2.1 A S/CI prevention process shall be developed and implemented as part of the Quality Assurance Program (QAP).
- 4.2.2 The S/CI prevention process shall be commensurate with the facility/activity hazards and mission impact.
- 4.2.3 The QAP shall be applied to identification, analysis, and removal of S/CIs and prevention of S/CI materials being supplied to DOE contractors.

### 4.3 Management System Requirements

- 4.3.1 The QAP shall address the following elements for S/CI prevention:
- 4.3.1.1 Preventing the introduction and use of S/CI through engineering involvement, design, procurement, testing, inspection maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls.
  - 4.3.1.2 Training and informing managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CI).
  - 4.3.1.3 Identifying and disposing of S/CI on site.
  - 4.3.1.4 Restricting S/CI use to only those *items* (see def.) that have been found acceptable through *engineering analysis* (see def.) and formal disposition process.
  - 4.3.1.5 Collecting, maintaining, disseminating and using the most accurate, up-to-date information on S/CI and associated suppliers using all available sources. S/CI information sources include the following:

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- A. Government-Industry Data Exchange Program
- B. Institute of Nuclear Power Operations
- C. DOE Occurrence Reporting and Processing System, and
- D. DOE S/CI website (<http://www.eh.doe.gov/S/CI/>).

4.3.1.6 Identifying the management point of contact responsible for those activities to ensure that the DOE Office of Environment, Safety, and Health has a viable recipient for S/CI information notices.

#### 4.4 Work Process Controls

4.4.1 Work processes shall be developed and implemented using available S/CI information and shall include the following elements:

- 4.4.1.1 Engineering involvement in the development of procurement specifications; during inspection and testing; and when replacing, maintaining, or modifying equipment.
- 4.4.1.2 Procurement processes to prevent introducing S/CI by:
  - A. Identifying technical and QA requirements in procurement specifications
  - B. Accepting only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices
  - C. Inspecting inventory and storage areas to identify, control, and disposition S/CI.
- 4.4.1.3 Inspection, identification, evaluation, and disposition of S/CI installed in all safety applications and other applications that create potential hazards.
- 4.4.1.4 *Engineering evaluations* (see def.) and disposition of S/CI installed in safety applications/systems or in applications that create potential hazards. The evaluations must consider potential risks to the public and worker and cost/benefit impact, and include a schedule for replacement (if required).

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- 4.4.1.5 Ensuring that S/CI identified in non-safety applications during routine maintenance and/or inspection are reported, evaluated, and dispositioned to prevent future use in safety applications.
- 4.4.1.6 Contacting the DOE Inspector General (IG) before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.
- 4.4.1.7 Testing procured or installed S/CI as necessary using approved engineering methods.
- 4.4.1.8 Reporting S/CI to responsible DOE/NNSA line management offices; the Office of Environment, Safety and Health; and the Inspector General.
- 4.4.1.9 Conducting trend analysis and issuing lessons learned reports for use in improving the S/CI prevention process.

## 5. RECORDS

All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) will be controlled in accordance with PRD-5088, “Quality Assurance Records.”

## 6. Definitions

Refer to LST-199, “Quality Assurance Program Requirements Document Definitions,” for the definitions of the following terms:

*corrective action*

*engineering analysis/evaluation*

*item*

*quality assurance records*

*suspect/counterfeit items (S/CI)*

## 7. REFERENCES

DOE Order 414.1D, “Quality Assurance”

FWD-7, “Foreword”

LST-199, “Quality Assurance Program Requirements Document Definitions”

PRD-5088, “Quality Assurance Records”