

CRITERIA REVIEW AND APPROACH DOCUMENT (CRAD)

Suspect/Counterfeit Items Program

Date of Issue: 01/20/2022

FUNCTIONAL AREA GOAL:

Suspect/Counterfeit Items (S/CI) programs are being effectively implemented and assessed by DOE/NNSA Headquarters, field organizations, and their contractors.

REQUIREMENTS:

- DOE Order 414.1(current version), *Quality Assurance*
- DOE Order 221.1, *Reporting Fraud, Waste, and Abuse to the Office of Inspector General*
- DOE Order 232.2A, *Occurrence Reporting and Processing of Operations Information*
- DOE Order 210.2A, *DOE Corporate Operating Experience Program*
- FAR 52.246-26, *Reporting Nonconforming Items*

GUIDANCE:

- DOE-HDBK-1221-2016, *Suspect/Counterfeit Items Handbook*
- DOE G 414.1-2B, *Quality Assurance Program Guide*
- IAEA-TECDOC-1169, *Managing suspect and counterfeit items in the nuclear industry*

PERFORMANCE OBJECTIVE:

Organization (i.e., Contractor/Subcontractor) has a formal system to adequately identify, define, and implement controls that: identify and preclude S/CI from being introduced into the DOE/NNSA supply chain that may create potential hazards; ensure oversight of the S/CI program; verify identified S/CIs are controlled and segregated and not placed back into the supply chain; and effectively communicate S/CI and defective items/products to other organizations. The “*Objectives, Criteria, and Suggested Lines of Inquiry*” section can be broken down into three main categories or performance objectives for the S/CI assessment process: oversight, controls, and reporting.

The “*Approach*” section of this document provides document review suggestions, observations, and potential interviews that may be conducted during an S/CI assessment.

OBJECTIVES, CRITERIA, AND SUGGESTED LINES OF INQUIRY:**PERFORMANCE OBJECTIVE 1: OVERSIGHT***Organization has processes for providing oversight of the S/CI program*

#	REQUIREMENT REFERENCE	CRITERIA	SUGGESTED LINE(S) OF INQUIRY: OVERSIGHT
1	DOE O 414.1D, Att. 3, para. 2.a.	The organization has a formal S/CI oversight and prevention process commensurate with the facility/activity hazards, and mission impact.	How does the organization conduct S/CI oversight and prevention processes? Are processes commensurate with the facility /activity hazards or mission impact?
2	DOE O 414.1D, Att. 3, para. 2.b	The organization has identified the position responsible for S/CI activities and for serving as a point of contact with the Office of Environment, Health, Safety, and Security.	What is the position responsible for S/CI activities and for serving as the point of contact with the Office of Environment Health Safety and Security? How is this documented or conveyed?
3	DOE O 414.1D, Att. 3, para. 2.c.	The organization has a training program that ensures managers, supervisors, and workers of S/CI controls are being trained and informed on prevention, detection, and disposition of S/CIs.	What training is provided for informing managers, supervisors, and workers about S/CI processes and controls?
4	DOE O 414.1D, Att. 3, para. 2.d.(1)	The organization involves engineering in the development of procurement specifications; during inspection and testing; and when maintaining, replacing, or modifying equipment.	How does your organization involve Engineering and Procurement in processes to prevent the introduction of S/CI?
5	DOE O 414.1D, Att. 3, para. 2.j.	The organization has a process to conduct trend analyses for improving the S/CI prevention process.	What data is tracked to aid in improving the S/CI prevention process?
6	DOE O 414.1D, Att. 3, para. 2.i.	The organization has a process to collect, maintain, disseminate, and use the most accurate, up to date information on S/CIs and suppliers.	How does your organization collect, maintain, disseminate, and use the most accurate/up to date information on S/CIs and suppliers?
5	FAR 52.246-26	The organization screens Government Industry Data Exchange Program (GIDEP) reports to avoid the use and delivery of S/CIs.	What processes does your organization have for GIDEP screening?

PERFORMANCE OBJECTIVE 2: CONTROLS

Organization has a formal system to adequately identify, define, and implement controls that: identify and preclude S/CI from being introduced into the DOE/NNSA supply chain that may create potential hazards.

#	REQUIREMENT REFERENCE	CRITERIA	SUGGESTED LINE(S) OF INQUIRY: CONTROLS
1	DOE O 414.1D, Att. 3, para. 2.d.(2)	The organization identifies and places technical and Quality Assurance (QA) requirements in procurement specifications.	What processes or procedures are in place to verify that the organization places technical and QA requirements in procurement specifications?
2	DOE O 414.1D, Att. 3, para. 2.d.(3)	The organization accepts only those items that comply with procurement specifications, consensus standards, and commonly accepted industry practices.	What are your organization's item acceptance processes or procedures?
3	DOE O 414.1D, Att. 3, para. 2.d.(4)	The organization inspects inventory and storage areas to identify, control, and disposition for S/CIs.	What are the processes for inventory and storage area inspections to identify, control, and disposition for S/CIs?
4	DOE O 414.1D, Att. 3, para. 2.e.	The organization includes processes for inspection, identification, evaluation, and disposition of S/CIs that have been installed in safety applications and other applications that create potential hazards.	What is your process for inspecting, identifying, evaluating, and dispositioning installed S/CIs?
5	DOE O 414.1D, Att. 3, para. 2.e.	The organization addresses the use of supporting engineering evaluations for acceptance of installed S/CI as well as marking to prevent future reuse.	How do you determine how to mark installed S/CIs to prevent future use? How do you determine if an installed S/CI is acceptable for continued use?
6	DOE O 414.1D, Att. 3, para. 2.f.	The organization conducts engineering evaluations to be used in the disposition of identified S/CIs installed in safety applications/systems or in applications that create potential hazards.	How are items dispositioned to prevent future use in these applications?
7	DOE O 414.1D, Att. 3, para. 2.f.	The organizations evaluations consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required).	How do you ensure evaluations consider potential risks to the environment, the public and workers along with a cost/benefit impact, and a schedule for replacement (if required)?

#	REQUIREMENT REFERENCE	CRITERIA	SUGGESTED LINE(S) OF INQUIRY: CONTROLS
8	DOE O 414.1D, Att. 3, para. 2.g	The organization performs evaluations to determine whether S/CIs installed in non-safety applications pose potential safety hazards or may remain in place.	What are the engineering evaluation processes conducted on S/CIs identified in safety applications and non-safety applications?
9	DOE O 414.1D, Att. 3, para. 2.g.	The organization disposes S/CIs identified during routine maintenance and/or inspections to prevent future use in these applications.	How do you dispose S/CIs identified during routine maintenance and/or inspections to prevent future use?

PERFORMANCE OBJECTIVE 3: REPORTING

Organization has processes for communicating and reporting S/CI and defective items

#	REQUIREMENT REFERENCE	CRITERIA	SUGGESTED LINE(S) OF INQUIRY: REPORTING
1	DOE O 414.1D, Att. 3, para. 2.h.	The organization has a process to report S/CIs to the DOE Inspector General in accordance with DOE Order 221.1B, Reporting Fraud, Waste, and Abuse to the Office of Inspector General (current version).	What are your organization's reporting processes for S/CIs?
2	DOE O 414.1D, Att. 3, para. 3. also references DOE O 221.1B	The organization has a process for notifying the DOE Inspector General before destroying or disposing of S/CIs and corresponding documentation.	What is the process once items are released by the DOE Inspector General and is this documented?
3	DOE O 414.1D, Att. 3, para. 4 also references DOE O 232.2A, Subgroup C	The organization has a process for reporting S/CIs which meet the requirements for reporting into the DOE Occurrence Reporting and Processing System (ORPS) in accordance with DOE Order 232.2, <i>Occurrence Reporting and Processing of Operations Information</i> (current version).	What is the process for reporting S/CIs to ORPS?
4	DOE O 414.1D, Att. 3, para. 2. NOTE (DOE O 210.2A)	The organization reviews existing Operating Experience lessons learned reports and submits new lessons learned reports for use in improving the S/CI prevention process.	What process is in place to monitor OPEX lessons learned as they may apply to your organization? What process/procedure does your organization follow for reporting S/CI events to OPEX as a lessons learned?
5	FAR 52.246-26, <i>Reporting Nonconforming Items</i>	The organization submits S/CI reports to the Government Industry Data Exchange Program (GIDEP).	What processes does your organization have for GIDEP reporting?

APPROACH:

Document Review suggestions:

- Procedures
- Test documents and plans concerning S/CIs
- Occurrence reports on S/CIs
- Inspector General correspondence
- GIDEP submissions
- Approved training plans
- Training records
- Trending analyses
- Procurement Documentation (contracts, terms & conditions, etc.)
- Inspection Records
- Documentation used to gather information, evaluate, and disposition S/CIs

Observations:

- Selected work processes such as testing, inspection, quality, or training being performed e.g., processes for procurement, receiving, testing, maintenance, nonconformance, engineering involvement, etc.
- Controlled areas for identified S/CIs
- Inventory, warehouse, and/or storage areas

Interviews:

- Site Suspect/Counterfeit Point of Contact
- Management/ Project Managers
- Maintenance/Facilities/Fleet/Logistics
- Trainers/Training Coordinators
- Procurement
- Quality Assurance/Quality Control (Inspection)
- Engineering
- General Technicians/Site Personnel