

**Office of Environment, Safety and Health
Process Guide for the Identification and Disposition of
Suspect/Counterfeit or Defective Items at
Department of Energy Facilities**



Prepared by
U.S. Department of Energy
Office of Environment, Safety and Health
Office of Corporate Performance Assessment

November 2004

Process Guide for the Identification and Disposition of S/CI or Defective Items

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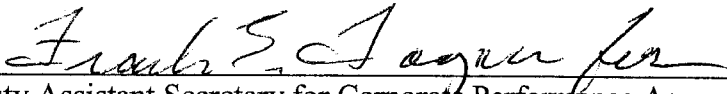
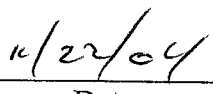

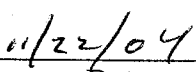
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ACRONYMS

DCS	Data Collection Sheet
DNFSB	Defense Nuclear Facilities Safety Board
DOE	Department of Energy
EH	Office of Environment, Safety and Health
EM	Office of Environmental Management
FE	Office of Fossil Energy
GC	Office of General Counsel
GIDEP	Government/Industry Data Exchange Program
HQ	Headquarters
IG	Inspector General
INPO	Institute of Nuclear Power Operations
LOI	Lines of Inquiry
NA	National Nuclear Security Administration
NE	Office of Nuclear Energy, Science and Technology
NRC	Nuclear Regulatory Commission
OA	Office of Independent Oversight and Performance Assurance
OE	Operating Experience Program
ORPS	Occurrence Reporting and Processing System
POC	Point of Contact
PSO	Program Secretarial Officer
QA	Quality Assurance
SC	Office of Science
S/CI	Suspect or Counterfeit Item

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Revision: 1	Effective Date: _____
Approved  Deputy Assistant Secretary for Corporate Performance Assessment	 Date
Recommended  Director, Office of Analytical Studies	 Date

1.0 INTRODUCTION

In the Deputy Secretary's March 18, 2003 letter to the Defense Nuclear Facilities Safety Board, the Assistant Secretary for the Office of Environment, Safety and Health (EH) was assigned responsibility for identifying, evaluating, monitoring, managing, and resolving crosscutting safety issues. As part of this effort, EH has assumed responsibility for activities associated with suspect/counterfeit items (S/CIs) or defective items from the Department of Energy (DOE) Quality Assurance Working Group (QAWG). This process guide and supporting manual provide direction to EH on implementing the S/CI and defective item process.

The Office of Corporate Performance Assessment (EH-3) will use the process guide and supporting manual to collect, screen, disposition, and communicate information on S/CI or defective items that could potentially impact operations at DOE facilities.

1.1 S/CI and Defective Item Terminology

The following sections define S/CI and defective item terminology as used in this process guide.

1.1.1 Defective Items

A defective item or material is any item or material that does not meet the commercial standard or procurement requirements as defined by catalogues, proposals, procurement specifications, design specifications, testing requirements, contracts, or the like. It does not include parts or services that fail or are otherwise found to be inadequate because of random failures or errors within the accepted reliability level (Reference: DOE M 231.1-2, *Occurrence Reporting and Processing of Operations Information*, August 2003).

Manufacturers generally notify their customers when defective items are identified through such mechanisms as recall notices. Such notices may be directly sent to customers, or may appear in Federal agency or industry databases.

1.1.2 Suspect Items

A suspect item is one in which there is an indication by visual inspection, testing, or other information that it may not conform to established Government- or industry-accepted specifications or national consensus standards. (Reference: DOE Guide 414.1-3, *Suspect and Counterfeit Item Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1B, Quality Assurance*).

Suspect items must be further investigated to determine whether they are counterfeit. When an item contains indications, but insufficient evidence, of irregularities such as noncompliance with agreed-upon specifications in the manufacturing process, it may be declared suspect.

1.1.3 Counterfeit Items

A counterfeit item is a suspect item that is a copy or substitute without legal right or authority to do so or one whose material, performance, or characteristics are knowingly misrepresented by the vendor, supplier, distributor, or manufacturer. An item that does not conform to established requirements is not normally considered an S/CI if the nonconformity results from one or more of the following conditions, which should be controlled by site procedures as nonconforming items: defects resulting from inadequate design or production quality control; damage during shipping, handling, or storage; improper installation; deterioration during service; degradation during removal; failure resulting from aging or misapplication; or other controllable causes. (Reference: DOE Guide 414.1-3, *Suspect and Counterfeit Item Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1B, Quality Assurance*).

2.0 RESPONSIBILITIES

DOE is committed to establishing and implementing a process to ensure that S/CI or defective items are quickly identified and that actions are taken to ensure safety at DOE facilities. EH has assumed a corporate leadership role, and is responsible for ensuring the effective implementation of this process.

2.1 EH Responsibilities

The Assistant Secretary for the Office of Environment, Safety and Health (EH-1), reporting to the Deputy Secretary, is responsible for ensuring that Departmental crosscutting ES&H issues are addressed and resolved in a timely manner. These include Quality Assurance (QA) issues and S/CI or defective items that could potentially impact operations at DOE facilities.

EH will work closely with the Office General Counsel (GC) and the Office of Inspector General (IG) to ensure that sensitive or "Official Use Only" information is handled properly and that headquarters and field organizations get all relevant information in a timely manner to ensure an effective investigation.

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EH-3 has overall responsibility for implementing the EH S/CI process, including:

- Ensuring EH-3 staff are trained and qualified on the identification of S/CI and this Process Guide,
- Screening data sources to identify potential S/CI or defective items,
- Preparing and distributing Operating Experience Notifications for potential S/CI or defective items,
- Drafting memoranda from EH-1 and developing, in cooperation with subject matter experts, GC and IG lines of inquiry for crosscutting or high-priority S/CI or defective items, requesting that Program Secretarial Officers (PSOs) direct field element investigations and interface with other DOE offices as necessary,
- Evaluating the completeness of information provided to PSOs on the results of field element investigations of crosscutting or high-priority S/CI or defective items,
- Conducting trending and analysis for actions taken on S/CI or defective items,
- Preparing the annual S/CI Report to disseminate information regarding S/CI trends, analysis, and related quality assurance/procurement issues,
- Providing feedback and recommendations to EH-1 on S/CI process improvements.

2.2 PSO and Field Responsibilities

PSOs are expected to:

- Provide guidance to field elements on actions required for EH-3 Operating Experience Notifications,
- Direct field elements to investigate crosscutting or high priority S/CI or defective items in response to instruction from EH-1 via memorandum and lines of inquiry,
- Assess and document the results of investigations and actions taken by field elements and communicate those results to EH-1,
- Provide guidance to field elements on actions required as a result of investigations.

DOE field elements are expected to:

- Screen Operating Experience Notifications provided by EH-3 for S/CI or defective items and take appropriate action.
- Formally investigate crosscutting or high priority S/CI or defective items as requested by PSOs.
- Report to PSOs the results of investigations for high priority S/CI or defective items.
- Use the Occurrence Reporting and Processing System (ORPS) to report identified S/CI or defective items and take necessary corrective actions.
- Notify the IG at the local level upon identification of an S/CI that could impact DOE operations.

3.0 S/CI OR DEFECTIVE ITEM REVIEW PROCESS

Appendix A contains a flow chart of the EH process used to ensure that S/CI or defective items are quickly identified and that appropriate actions are taken, documented, and reported. Sections 3.1 through 3.7 describe the various actions within the flow chart.

3.1 Data Sources Reviewed for S/CI or Defective Items

EH-3 utilizes the following data sources to identify S/CI or defective items that could potentially impact DOE operations.

- DOE's ORPS database contains events reported across the DOE complex. Some of these events describe S/CI or defective items.
- The Government-Industry Data Exchange Program (GIDEP) database contains events reported by both Federal agencies and industry, some of which describe S/CI or defective items. Access to the GIDEP database is restricted. The Process Guide Support Manual includes access forms that users must submit to GIDEP. The Support Manual also describes the GIDEP access, data download, and reporting processes.
- The Institute of Nuclear Power Operations (INPO) database contains events reported by commercial nuclear power plants in the United States, some of which describe S/CI or defective items. Access to the INPO website is restricted. The Process Guide Support Manual describes the process for gaining access to the INPO website and instructions on downloading information.
- The IG website contains reports and other information, some of which address S/CI and defective items. Access to the IG website is available to the public and can be viewed at <http://www.ig.doe.gov>.
- Other data sources include notices issued by manufacturers that have not appeared in one of the above sources, DOE assessments, and field observations.

Note: GIDEP and INPO user IDs and passwords remain active for 6 months and must be updated at the respective websites.

3.2 Database Searches to Identify S/CI or Defective Items

EH-3 staff routinely searches various databases to identify potential S/CI or defective items that require further review. Appendix B contains a list of keywords to assist in identifying potential S/CI and defective items.

3.2.1 ORPS Database Searches

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When field elements identify potential S/CI or defective items they report the items in ORPS. Historically, the majority of S/CI or defective items have been found in ORPS. EH-3 collects posted ORPS events and screens them for S/CI and defective items with potential impact to DOE operations. For each potential S/CI or defective item identified in ORPS, EH-3 prepares a Data Collection Sheet (DCS) and assigns a tracking number. The DCS is used to facilitate review of the S/CI or defective item and to document the actions that were taken to resolve the item. The Process Guide Support Manual contains a sample DCS.

3.2.2 GIDEP Database Searches

At least once per week, EH-3 searches the GIDEP database for potential S/CI or defective items. After the initial screening for potential S/CI or defective item identified in GIDEP, EH-3 downloads the information to its network "O" drive and prepares a DCS from the information.

3.2.3 INPO Database Searches

At least once per week, EH-3 searches the INPO database for potential S/CI or defective items. After the initial screening for potential S/CI or defective item identified in the INPO database, the EH-3 downloads the information to its "O" drive and prepares a DCS from the information.

Note: If S/CI or defective item information obtained from INPO is posted on the EH-3 S/CI website, reference to utility name, address, point of contact, and phone number must be omitted from the DCS.

3.2.4 Other Sources of S/CI or Defective Item Data

EH-3 reviews and screens other sources of data for potential S/CI or defective items. Occasionally, for example, manufacturers, vendors, or end users may distribute notices to DOE that describe items of a suspicious nature, such as recalled defective items or items under investigation by the Defense Criminal Investigative Service. Other sources that may provide useful data include DOE assessments generated from Headquarters organizations (including IG), field evaluations, and reports on field inspections and surveillances. For each potential S/CI or defective item identified through other sources, EH-3 prepares a DCS and assigns it a tracking number.

3.3 Data Collection Sheet Review

3.3.1 EH-3 Operating Experience Review

EH-3 typically reviews DCSs once a week following the morning Operating Experience (OE) meeting. S/CI or defective items identified through the various database searches are evaluated to determine what action should be taken. Appendix C provides screening

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criteria to assist this determination. The EH-3 decision regarding actions to be taken is recorded on the DCS.

If a DCS does not contain sufficient information to make a determination as to applicability of the S/CI or defective item to DOE, EH-3 may request additional information. This information is typically obtained from the point of contact listed on the DCS. EH-3 may also, on a case-by-case basis, obtain input from DOE subject matter experts to assist in deciding on the appropriate action to be taken for a S/CI or defective item. EH-3 maintains a list of subject matter experts (SME) by topic on the S/CI website. The Process Guide Support Manual contains a sample SME list.

An important aspect of determining the significance of ORPS related S/CI or defective items starts when the initial ORPS event is researched. Many times the initial report indicates that additional work is being conducted by any of a variety of organizations. This may have an impact on how EH-3 will disposition the item. Where such follow-up work is indicated, EH-3 will flag the item for follow-up. The *Non-Routine To-Do List* located on the "O" drive shall be updated to indicate that follow-up is needed.

In order to assure that significant events are acted upon in a timely manner, EH-3 shall conduct routine searches in ORPS to determine whether any final reports have been issued for items flagged for follow-up. The Process Guide Support Manual contains further instructions for final ORPS report follow-up.

3.3.2 Potential Actions Taken for S/CI or Defective Items

There are several possible actions that can result from the review of potential S/CI or defective item events. Appendix C provides more detail on criteria for determining actions to be taken.

Investigation

- An investigation is warranted if there is clear indication of a crosscutting or high-priority S/CI, if a criminal investigation is underway or expected to be initiated, or if a significant regulatory, environmental, health, or safety risk exists.
- EH-3's decision is documented on the DCS.
- An EH Safety Alert may also be sent out in advance of the formal investigation.
- EH-1 issues a memorandum within 30 days from the date the item is identified at the EH-3 OE meeting, requesting PSOs to conduct an investigation.
- Lines of inquiry are developed, and PSOs and field elements initiate an investigation.
- PSOs document results of the investigation and submit to EH-1.
- Issues identified as a result of an investigation are reported to the IG and in ORPS.

Operating Experience Notification

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The following are forms of Operating Experience Notifications used to distribute information on potential S/CI or defective items within DOE.

EH Safety Alert

- An EH Safety Alert is warranted if documentation clearly indicates that a S/CI or defective item may be involved, and a significant regulatory, environmental, health, or safety impact exists.
- EH-3's decision to issue an EH Safety Alert is documented on the DCS.
- An EH Safety Alert on S/CI or defective items will be distributed within 10 days after being discussed at the EH-3 OE meeting.
- EH Safety Alerts are distributed to DOE Headquarters and Field Element management.
- EH Safety Alerts shall request a response back to EH-3 whether or not S/CI or defective items are found.
- EH-3 shall maintain a record of responses to EH Safety Alerts.
- EH Safety Alerts are posted on the EH-3 S/CI website.
- Issues identified as a result of an EH Safety Alert are reported in ORPS.

POC Notification

- Points of contact notification are the most common form of Operating Experience Notification of potential S/CI or defective items. This is done when documentation indicates that the S/CI or defective item may be in use at DOE facilities.
- The DCS containing the potential S/CI or defective items shall be posted on the S/CI website within 10 days after the item was discussed at the EH-3 OE meeting.
- Points of contact are notified via the EH-3 S/CI website and list server distribution.
- EH-3 documents the points of contact notification on the DCS.
- The DCS shall be available on the S/CI website for a period of six months and then archived.
- S/CI or defective items identified by field element/contractor as a result of points of contact being notified are reported in ORPS.

OE Summary

- An article in the OE Summary is warranted if documentation indicates that the S/CI or defective item may be applicable to DOE facilities.
- EH-3 documents the OE Summary on the DCS.
- The article describing the S/CI or defective item shall appear in an OE Summary within 30 days after the item was discussed at the OE meeting.
- S/CI or defective items identified by field element/contractor as a result of an OE Summary article are reported in ORPS.

No further action

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- This is warranted if there is no clear indication that the event describes an S/CI or defective item or if the item does not apply to DOE facilities or operations.
- EH-3 documents the no further action on the DCS.

3.4 S/CI Website

DCSs selected for Operating Experience Notification are posted on the S/CI website as either S/CI or defective items. For potential S/CI, an e-mail notification with a one line description and link to the EH-3 S/CI website is sent to points of contact subscribing to the EH-3 S/CI website list server notification. Individuals can subscribe to the S/CI or defective item list server email notification on the S/CI website. DCSs shall be available on the EH-3 website for a period of six months and then archived.

3.5 Support Group and Lines of Inquiry

For S/CI items that are crosscutting or of a high priority, a support group of technical, legal, and investigative personnel will be convened as necessary to assist EH in developing lines of inquiry to support the investigation. The GC and the IG representatives in the support group will assist in dealing with sensitive (closely held) or “Official Use Only” information related to ongoing investigations. No information is to be withheld from DOE and the contractor community except whether a criminal investigation is planned or ongoing or who may have made the allegation. All other pertinent S/CI information will be provided. The Deputy Assistant Secretary for EH-3 or his designee will convene the support group within 10 days of the EH-3 OE meeting identifying the issue. EH-3 shall provide the support group with the necessary information to assist in developing lines of inquiry. The support group will be formed on an ad hoc basis and may consist of representatives from organizations such as:

- Environment, Safety and Health (EH) – Lead
- Inspector General (IG)
- General Counsel (GC)
- Environmental Management (EM)
- National Nuclear Security Administration (NA)
- Science (SC)
- Fossil Energy (FE)
- Nuclear Energy (NE)

3.5.1 Lines of Inquiry

Lines of inquiry are developed to ensure that the various organizations conducting the investigation gather consistent and defensible information. The lines of inquiry are developed by the support group discussed above, and typically include a set of questions to guide the investigation. (See the Process Guide Support Manual for sample lines of inquiry). The lines of inquiry typically specify the scope of the investigation, timeframe, what to do if S/CI are discovered, and the cost associated with conducting the investigation. The lines of inquiry are attached to the memoranda sent from EH-1 to PSOs for crosscutting or high-priority S/CI issues.

3.5.2 EH-1 Memorandum to PSOs

EH-3 will prepare the memorandum identifying high-priority S/CI issues and requesting assistance from PSOs in formally investigating the event based on the lines of inquiry developed by the support group. The Process Guide Support Manual contains a sample EH-1 memorandum. The memorandum shall be prepared within 30 days of identifying the issue and is forwarded to EH-1 for signature and distribution. The memorandum with lines of inquiry, will request that PSOs respond to EH-1 with a plan and schedule for completing the investigation. Distribution of the EH-1 memorandum is determined on a case-by-case basis.

3.6 Investigation of Crosscutting or High-Priority S/CI Items

PSOs will direct their field elements to conduct an investigation of the crosscutting or high-priority S/CI issue. PSOs will notify EH-1 of their plan and schedule for conducting the investigation. PSOs will document the results of their investigation, whether or not an S/CI is identified, and evaluate any impact. If an S/CI is identified, an Occurrence Report is submitted to ORPS, and the IG is notified in accordance with the requirements in DOE O 221.1, *Reporting Fraud, Waste, and Abuse to the Office of the Inspector General*. The PSOs will also develop the appropriate corrective actions to address the S/CI issue and collect the cost associated with this effort. The documented results of the investigation, including any corrective actions, are forwarded to EH-1.

3.7 EH Review, Consolidation of Results and Inquiry Closeout

EH will consolidate the results of the PSO investigation reports and review them for completeness. EH may make recommendations to the PSOs regarding the report results. EH will forward consolidated information such as cost data and other information to the IG or other organizations as appropriate to closeout the investigation. EH-3 will use the results of investigations as input to the annual S/CI report. A sample investigation closeout package is contained in the Process Guide Support Manual.

4.0 ENTERING S/CI OR DEFECTIVE ITEM INFORMATION IN GIDEP

The Office of Management and Budget (OMB) Policy Letter 91-3, requires agencies to establish policies and procedures for using GIDEP to exchange information, examine GIDEP information and promptly disseminate safety-related information, conduct assessments of the effectiveness of their programs, and establish procedures for involving the IG in S/CI issues, including receipt and dissemination of sensitive information.

EH-3 shall review S/CI ORPS entries and ensure that appropriate information is entered into GIDEP as required by OMB Policy Letter 91-1. The Process Guide Support Manual contains instructions about entering S/CI information into GIDEP.

5.0 PREPARATION OF THE ANNUAL S/CI REPORT

EH-3 shall prepare an annual S/CI report that documents S/CI and defective items that were identified and their disposition. This includes both high-priority and lower-priority S/CI items that were contained in Operating Experience Notifications and investigations. The report will characterize the current status of the S/CI process, corrective actions taken, and recommendations for improvement.

Lessons learned and training issues will also be included. The annual S/CI report provides historical data and trend information regarding discovery and disposition of S/CI in the DOE complex.

The intent of the annual S/CI report is to disseminate information regarding S/CI and defective item trends, analyses, and related procurement/quality assurance issues. The report is provided to DOE management to relay information on progress within the Department on S/CI and defective item issues. The Process Guide Support Manual contains portions of a previous annual S/CI report as a guideline.

6.0 TRAINING

EH-3 staff shall be trained on identifying S/CI or defective items and on the EH S/CI process.

7.0 S/CI PROCESS IMPLEMENTATION REVIEWS

EH-3 shall periodically conduct S/CI process implementation reviews at selected DOE facilities. The purpose of these reviews is to:

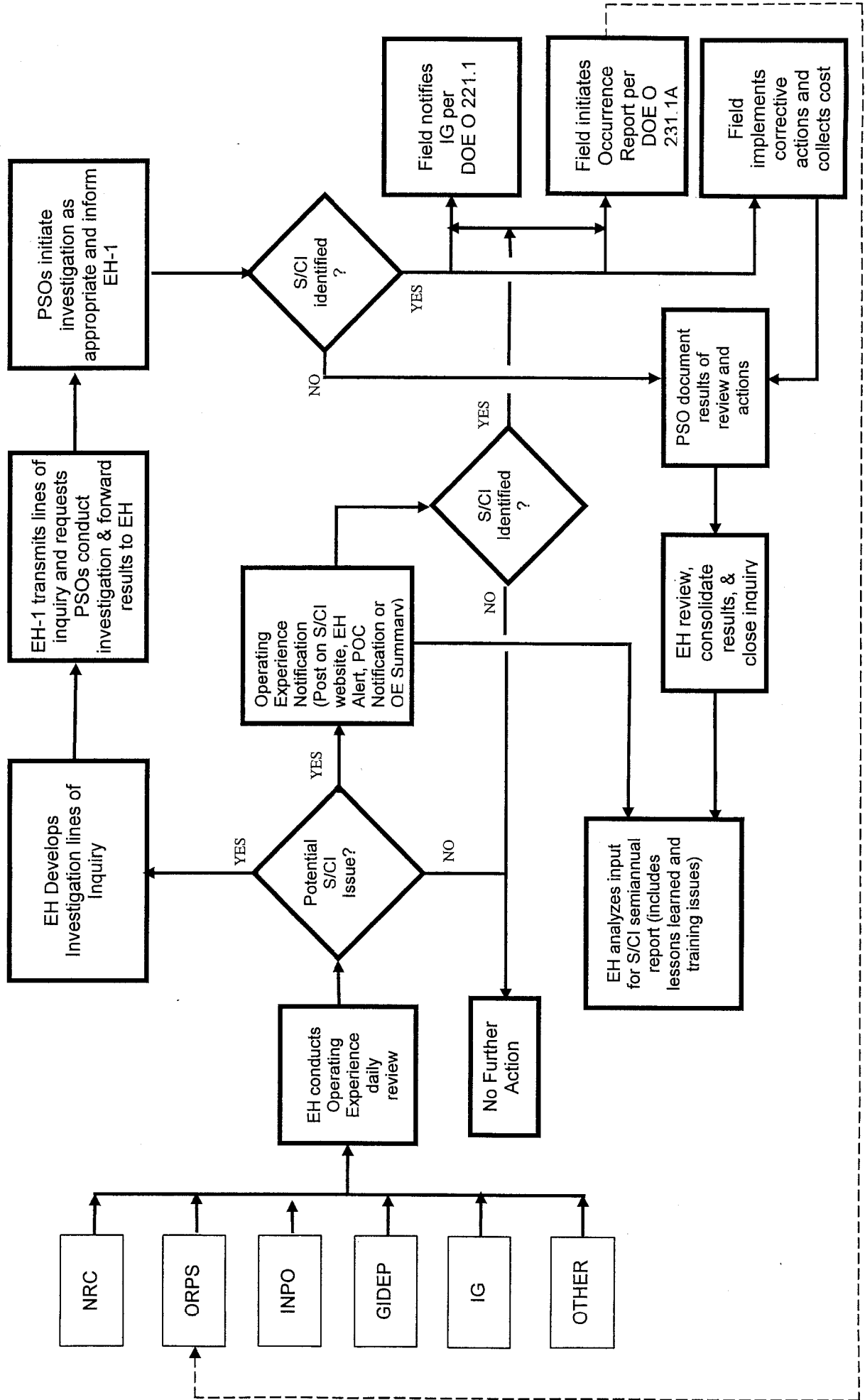
- sample implementation of the S/CI and defective item process in the field
- communicate expectations for the S/CI and defective item process implementation
- gather feedback on issues encountered in S/CI and defective item process implementation
- solicit improvements in the S/CI and defective item process

The S/CI process reviews should be conducted by a team with representatives from EH-3, the Headquarters PSO and the site. The process review should be in the form of a self-assessment that determines the effectiveness of S/CI process implementation by sampling. Tracing the response to Safety Alerts is one example of sampling. Other samplings could be site specific. The results of the S/CI process reviews will be discussed with site management prior to departure.

8.0 RECORDKEEPING

DCSs, the annual S/CI report, and other EH-3 reports detailing activities associated with S/CI or defective items shall be maintained electronically, on the EH-3 S/CI website and in a location accessible to EH-3 personnel. The records shall be maintained for at least five years.

Appendix A Suspect/Counterfeit and Defective Item Process Flow Chart



Appendix B Suspect/Counterfeit and Defective Item Keywords

The following list contains keywords and phrases related to the S/CI and defective item process. This is a sample of keywords and should be considered red flags to help assist in the identification of potential S/CI and defective items during searches of the INPO, GIDEP, ORPS, and other databases. By themselves, some of the words and phrases may not be indicative of an S/CI or defective item, but combinations may point toward the need for closer evaluation to make the appropriate decision.

Defective Items	Suspect/Counterfeit Items
<ul style="list-style-type: none"> - non-conformance with specifications - investigation - further investigation - enforcement action - defect - component failure - returned to supplier - unexpected failure - new... failed - returned to supplier 	<ul style="list-style-type: none"> - alleged falsification - falsification - potentially fraudulent - problems with testing - fraudulent data or certification - complaint - under seal - litigation - <i>qui tam</i> - improper certification - improper marking - invalid data - unapproved parts (Federal Aviation Administration term related to S/CI) - Defense Criminal Investigative Service (DCIS) - Inspector General (IG) - held for IG - suspect - counterfeit - returned to supplier - investigation - further investigation - identical data or certifications

An extensive list of terms and phrases related to actual S/CI and defective items such as:

- improper weld
- missing or improper manufacturer's standard markings
- evidence of tampering
- document not traceable to the item procured

can be found in *Suspect Indications List* of the *Suspect/Counterfeit Awareness Training* document found on the EH S/CI website at <https://info.eh.doe.gov/sci/refdocs/>.

Appendix C
Criteria for Determining Level of Action for Potential S/CI or Defective Items

Screening Criteria for Operating Experience Notifications		Potential EH-3 Action				
Question	No	Yes	Include in OE Summary	POC Notification	EH Safety Alert Issued	Investigation
Does the issue require any EH-3 involvement to obtain additional information?	See additional screening criteria.	Additional information on the issue will be obtained from Headquarters or field SMEs and/or the DCS point of contact. No action required until additional information is evaluated.				
Is this a repeat occurrence?	See additional screening criteria.	Previous occurrences should be reviewed to help determine action to take.	X	X		
Does the issue affect more than one site or have the potential to affect more than one site?	Scope of S/CI or defective item implications may be limited and can be addressed by the respective site.	Scope of S/CI or defective item may be crosscutting with complex-wide applicability. OE notification required based on applicability to DOE facilities and operations.	X	X		
Has the issue been declared S/CI or defective, or does it have the potential to be declared S/CI?	See additional screening criteria.	S/CI has already been declared. OE notification required based on applicability to DOE.	X	X	X	X
Is an investigation underway or about to be initiated regarding potential criminal activities?	See additional screening criteria.	An investigation is in progress. OE notification required based on input from IG and GC and applicability to DOE facilities and operations.			X	X
Does the issue have any immediate or potential regulatory, environmental, health, or safety impact?	See additional screening criteria.	Scope of S/CI or defective item may be crosscutting with complex-wide applicability. OE notification required.	X	X	X	
Could other organizations address the issue more appropriately?	See additional screening criteria.	EH transfers action to appropriate organization. No further action required.				
Does the issue have any complex-wide procurement implication?	See additional screening criteria.	Scope of S/CI or defective item is crosscutting with complex-wide applicability. OE notification required.	X	X	X	X

Note: EH-3 staff will use professional judgment in determining the potential actions to be taken using the above criteria.

Appendix D
References

1. DOE Order 221.1, Reporting Fraud, Waste, and Abuse to The Office of Inspector General, March 2001
2. DOE Order 231.1A, Environment, Safety and Health Reporting, August 2003
3. DOE Manual 231.1-2, Occurrence Reporting and Processing of Operations Information, August 2003
4. DOE Order 414.1B, Quality Assurance, April 2004
5. DOE Guide 414.1-3, Suspect and Counterfeit Item Guide for use with 10 CFR 830 Subpart A, Quality Assurance Requirements and DOE O 414.1B, Quality Assurance
6. Office of Environment, Safety and Health Support Manual to the Process Guide for the identification and Disposition of Suspect/Counterfeit of Defective Items
7. IAEA-TECDOC-1169, Managing suspect and counterfeit items in the nuclear industry, August 2000