



U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

Protecting People and the Environment

Requirements and Guidance to Prevent the Intrusion of CFSI into the Nuclear Supply Chain

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Objectives

- Overview of the Nuclear Regulatory Commissions (NRC)'s regulatory requirements and guidance for Counterfeit, Fraudulent or Suspect Items (CFSI)
- Identify available CFSI training
- Raise awareness of CFSI and discuss means to prevent or mitigate CFSI in the nuclear supply chain

Background

- Continued concerns related to CFSI affecting NRC regulated entities prompted several NRC initiatives to support addressing CFSI concerns
- CFSI events both domestically and overseas resulted in:
 - Issuance of guidance to heighten awareness of the existing NRC regulations and how they apply to CFSI
 - Issuance of information notices on pertinent CFSI events
 - Creation of internal CFSI Technical Review Group to evaluate events to determine whether they involve CFSI and their applicability to NRC regulated facilities.
- NRC advocates a proactive approach to detect and prevent the intrusion of CFSI into structures, systems or components intended for use as a basic component.

CFSI is encompassed in NRC regulations: quality assurance and defect reporting

Appendix B to 10 CFR

Part 50 areas:

- 1) Design control
- 2) Procurement document control
- 3) Control of purchased materials, equipment, and services
- 4) Identification and control of material, parts, and components
- 5) Disposition of nonconforming materials, parts, or components
- 6) Corrective action and program effectiveness reviews



10 CFR Part 21 and 10 CFR 50.55(e)

- 1) Evaluation of deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazard
- 2) Notification to the NRC when there is information indicating a failure to comply or a defect

NRC Generic Communications

Regulatory Issue Summary (RIS)-15-08, “Oversight of Counterfeit, Fraudulent, and Suspect Items in Nuclear Industry” heightens awareness of the existing NRC regulations and how they apply to CFSI within the scope of NRC’s regulatory jurisdiction. (ADAMS Accession No. ML15008A191)

Generic Letter (GL) 89-02, “Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products” shares information regarding elements of programs that appear to be effective in providing the capability to detect counterfeit or fraudulently marked products. (ML031140060)

Information Notice (IN) 2018-11 Supplement 1: Kobe Steel Quality Assurance Record of Falsification (ML19357A138)

IN 2013-15 “Willful Misconduct/Record Falsification and Nuclear Safety Culture” (ML13142A437)

IN 2013-02 “Issues Potentially Affecting Nuclear Facility Fire Safety” (ML122840031)

IN 2008-04 “Counterfeit Parts Supplied to Nuclear Power Plants” (ML093620098)

NRC Bulletin 1988-10 “Nonconforming Molded-Case Circuit Breakers” (ML031220261) and Supplement 1 (ML031220271)

Other Sources of Guidance

Nuclear Industry Guidance

- Electric Power Research Institute (EPRI) Technical Report 3002002276, “Plant Support Engineering: Counterfeit and Fraudulent Items - Mitigating the Increasing Risk” (www.epri.com Free)
- Nuclear Energy Institute (NEI) 14-09, “Guidelines for Implementation of 10 CFR Part 21 Reporting of Defects and Noncompliance,” Rev 1 (ML16054A825) as endorsed in NRC Regulatory Guide (RG) 1.234 (ML17338A072)

International Guidance

- International Atomic Energy Agency (IAEA) Publication on “Managing Counterfeit and Fraudulent Items in the Nuclear Industry” (www.iaea.org Fee)
- Nuclear Energy Agency Multi-National Design Evaluation Program CP-VICWG-04, Common Position on Mitigating the Risks of Counterfeit, Fraudulent, and Suspect Items from the Vendor Inspection Co-operation Working Group (VICWG)

Resources from other Federal Agencies

- Department of Homeland Security National Intellectual Property Rights Coordination Center <https://www.iprcenter.gov>
- Department of Energy (DOE) Operating Experience Committee <https://www.energy.gov/ehss/doe-corporate-operating-experience-program>

Reporting Requirements

- 10 CFR 50.72, “Immediate Notification Requirements for Operating Nuclear Power Reactors”
- 10 CFR 50.73, “Licensee Event Report System”
- 10 CFR Part 21, “Reporting of Defects and Noncompliance”

Reporting Guidance

- NUREG-1022, “Event Report Guidelines: 10 CFR 50.72 and 50.73,” Rev 3 – contains guidance for making voluntary reports (ML13032A220)
- Regulatory Guide 1.234, “Evaluating Deviations and Reporting Defects and Noncompliance under 10 CFR Part 21” Rev 0 (ML17338A072)
- NEI 14-09, “Guidelines for Implementing 10 CFR Part 21 Reporting of Defects and Noncompliance,” Rev 1 (ML16054A825)

Additional Requirements

- **Completeness and Accuracy of Information**
 - 10 CFR 50.9
 - 10 CFR 52.6
 - 10 CFR 70.9
- **Deliberate Misconduct**
 - 10 CFR 50.5
 - 10 CFR 52.4
 - 10 CFR 70.10

NUREG/BR-0500

“Safety Culture Policy Statement”

May 2018 (ML18137A389)

“This policy statement applies to ...holders of quality assurance program approvals, vendors and suppliers of safety-related components...”

- **Problem Identification and Resolution**
Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.
- **Questioning Attitude**
Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

SAFETY CULTURE POLICY STATEMENT

The Safety Culture Policy Statement sets forth the U.S. Nuclear Regulatory Commission's (NRC's) expectation that individuals and organizations performing regulated activities establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions.

This policy statement applies to all licensees, certificate holders, permit holders, authorization holders, holders of quality assurance program approvals, vendors and suppliers of safety-related components, and applicants for a license, certificate, permit, authorization, or quality assurance program approval subject to NRC authority. In addition, the Commission encourages the Agreement States (States that assume regulatory authority over their own use of certain nuclear materials), their licensees, and other organizations interested in nuclear safety to support the development and maintenance of a positive safety culture within their regulated communities.



CONSIDERATION OF SAFETY AND SECURITY

Because safety and security are the primary pillars of the NRC's regulatory mission, consideration of both is an underlying principle of the Safety Culture Policy Statement. Organizations should ensure that personnel in the safety and security sectors appreciate the importance of each, emphasizing the

need for integration and balance to achieve both safety and security in their activities.



DEFINITION OF NUCLEAR SAFETY CULTURE

Nuclear safety culture is the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.

TRAITS OF A POSITIVE NUCLEAR SAFETY CULTURE

Experience has shown that certain personal and organizational traits are present in a positive safety culture. The following are traits of a positive safety culture:

Leadership Safety Values and Actions

Leaders demonstrate a commitment to safety in their decisions and behaviors.

Problem Identification and Resolution

Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance.

Personal Accountability

All individuals take personal responsibility for safety.

Work Processes

The process of planning and controlling work activities is implemented so that safety is maintained.

Continuous Learning

Opportunities to learn about ways to ensure safety are sought out and implemented.

Environment for Raising Concerns

A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination.

Effective Safety Communication

Communications maintain a focus on safety.

Respectful Work Environment

Trust and respect permeate the organization.

Questioning Attitude

Individuals avoid complacency and continuously challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action.

Additional traits not included here may also be important in a positive safety culture. For example, decision-making is included as a trait in the safety culture common language for the nuclear power industry (NUREG-2165, "Safety Culture Common Language," issued March 2014).

BACKGROUND

The 1986 nuclear accident at the Chernobyl nuclear power plant in Ukraine revealed the impact that weaknesses in safety culture can have on safety. Since then, a number of significant events in the United States and internationally have further demonstrated the influence of safety culture. Assessments of these events revealed that safety culture weaknesses were an underlying cause or increased the severity of problems.



The NRC addressed aspects of safety culture in two previously issued policy statements. The "Policy Statement on the Conduct of Nuclear Power Plant Operations" (published in 1989) states the NRC's expectations that licensed operators and managers of nuclear power plants conduct themselves professionally to ensure safety. In 1996, the NRC published "Freedom of Employees in the Nuclear Industry To Raise Safety Concerns without Fear of



Retaliation," a policy statement that applies to the regulated activities of all NRC licensees and their contractors. It provides the expectation that licensees and employers subject to NRC authority establish and maintain work environments where employees feel free to raise safety concerns without fear of retaliation (referred to as a "safety conscious work environment").

IMPORTANCE FOR REGULATED ENTITIES

Industry experience has shown the value of establishing and maintaining a positive safety culture. It is important to remember that individuals and organizations performing regulated activities bear the primary responsibility for safety and security. The Safety Culture Policy Statement is not a regulation; therefore, it is the regulated entities' responsibility to consider how to apply this policy statement to its regulated activities.

CFSI Training

- IN 2012-22, “Counterfeit, Fraudulent, Suspect Item Training Offerings,” Rev 1, November 20, 2019 (ML19017A118 and ML19017A117)
- NRC continues to engage stakeholders to enhance awareness on CFSI and disseminate information on CFSI-related events in the nuclear industry

OIG Audit and Special Inquiry

- February 2022 – OIG issued report OIG-22-A-06 documenting its audit findings and recommendations on the NRC’s oversight of CFSI at nuclear plants
 - NRC should improve its oversight CFSI
 - Clarify and communicate how the NRC collects, assesses, and disseminates information regarding CFSI
 - Improve staff awareness of CFSI
- February 2022 – OIG issued Special Inquiry Case No. 20-022

Staff Responses to OIG Audit and Special Inquiry

- In response to these reports, the staff conducted a risk-informed review of the OIG's findings and determined that there were no immediate safety concerns to nuclear power facilities and other nuclear facilities regulated by the NRC
- The staff proposed actions to address the recommendations within the 2022 OIG audit report.
- The staff assessed the NRC's overall approach for oversight related to CFSI at NRC regulated entities and proposed additional recommendations aimed at strengthening knowledge and awareness of the risks posed by CFSI.

Improvements to NRC's Oversight Process based on Office of the Inspector General (OIG) Audit and Special Inquiry

- Strengthen awareness of reporting requirements within the agency and external stakeholders
- Perform outreach during industry meetings with vendors of nuclear power plants, spent fuel storage systems, and radioactive material transportation packages to enhance supplier awareness of risks posed by CFSI and available guidance
- Engage with other Federal agencies that perform regulatory oversight of safety critical industries and international regulatory counterparts

Prevent the Introduction of CFSI into the Nuclear Supply Chain

- Incorporate processes to verify that products are authentic using receipt inspection, procurement controls, and vendor authentication tools
- Maintain traceability of products within the supply chain and reduce risk of counterfeit products by procuring from authorized distributors or sellers
- Increase awareness of CFSI through training and coordination with industry and government organizations involved in preventing and mitigating CFSI

Key Points

- The NRC oversight of CFSI is addressed CFSI-related guidance, development of processes to evaluate potential CFSI events and performance of outreach activities
- OIG recent audit and special inquiry reports on the NRC's oversight of CFSI at nuclear power plants and recommended the NRC improve its oversight
- The NRC recognizes the opportunity to make improvements to the current process for oversight of risks related to CFSI and identified actions to implement improvements
- The NRC reviewed the OIG reports and concluded - no evidence to substantiate that NRC regulated facilities have been adversely impacted by CFSI
- The NRC staff performed an assessment of its oversight of risks posed by CFSI to its regulated facilities - determined that the current regulatory framework adequately mitigates the risk posed by CFSI

QUESTIONS

