



# NRC Vendor Workshop 2016

## Counterfeit, Fraudulent, and Suspect Items (CFSI)

# CFSI Remains High-Priority

- ▶ Indications of CFSI in the non-nuclear industrial supply chain
- ▶ No recent evidence of significant counterfeit activity at U.S. nuclear facilities
- ▶ Implementation of appropriate response protocols
- ▶ Continued cooperation and information sharing

# Initiatives to Address CFSI



- **International**

- Nuclear Energy Agency (NEA)
- International Atomic Energy Agency (IAEA)

- **Domestic**

- U.S. Government Agencies
- Industry Organizations
- Key Nuclear Suppliers
- Public Outreach



## National Intellectual Property Rights (IPR) Coordination Center

Protection is Our Trademark - The IPR Center manages and supports the ICE commercial fraud program. Successful cases have produced significant seizures, civil penalties and criminal prosecutions.

## Latest News

**Tijuana man charged with importing counterfeit pain pills containing potentially deadly chemical**

Sergio Linyuntang Mendoza Bohon, 19, was arrested in February after he attempted to smuggle nearly 1,200 counterfeit oxycodone pills into the U.S. through the pedestrian lane at the Otay Mesa port of entry. During a secondary inspection and pat down, U.S. Customs and Border Protection (CBP) officers found the tablets along with a package containing several grams of white powder in Mendoza's...

**Rhode Island man sentenced for trafficking in counterfeit Viagra**

A Pawtucket, R.I. man was sentenced Thursday in U.S. District Court in Boston for trafficking in counterfeit prescription medications following a joint investigation led by (ICE) Homeland Security Investigations (HSI), and the U.S. Postal Inspection Service.

## Consumer Alerts

**Pirated Software May Contain Malware**

Software bought on the cheap from unknown sellers may contain hidden dangers.

**Counterfeit Auto Parts**

PSA for counterfeit auto parts.

## Quick Links

- [National Crime Prevention Council \(NCPC\)](#)
- [Office of Intellectual Property Enforcement Coordinator \(IPEC\)](#)
- [Law-Enforcement Online \(For Law-Enforcement Only\)](#)
- [Acquisition Professional Training](#)
- [STOPfakes.gov](#)

## Report IP Theft

To report violations of intellectual property rights, including counterfeiting and piracy, to the National IPR Coordination Center, [click here](#)...



## Civil Anti-Counterfeiting and Piracy Banner

For more information or to request permission to use and place the official seizure banner on your website, please [click here](#).



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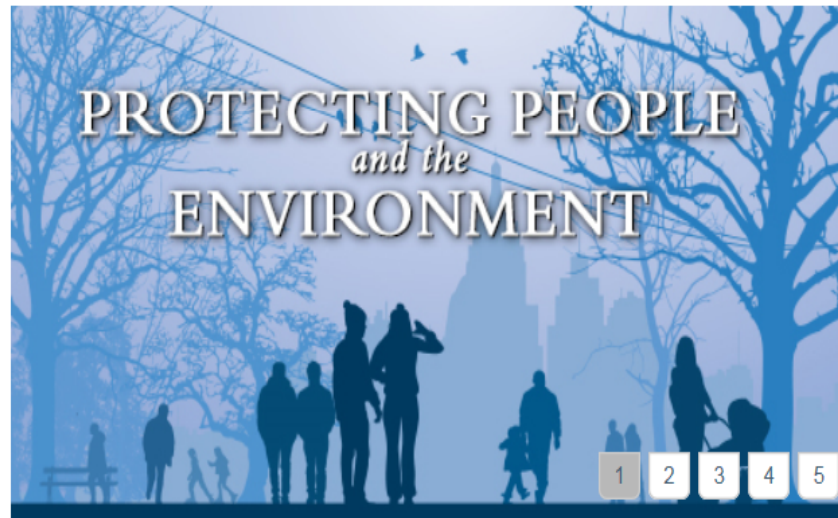
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#### Commission Meeting Webcasts

Next Commission Webcast  
[April 19, 2016 at 9:30 a.m.]

#### Event Reports



Reports  
Associated with  
Events  
[Read more »](#)

#### ADAMS Public Documents



Search and view  
NRC's public  
documents  
[Read more »](#)

#### Spotlight

Open-Phase Electrical Issue

Additional NRC Oversight at Pilgrim  
Nuclear Power Plant

Project Aim

Watts Bar Nuclear Plant Unit 2

#### News & Speeches

April 20, 2016



NRC to Hold Open House on April 27  
in Berwick, Pa., to Discuss 2015  
Performance of Susquehanna Nuclear  
Plant

#### Public Meetings

April 21 2016

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#### Open Government



NRC Approach to  
Open/Digital  
Government  
[Read more »](#)

#### The Student Corner

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## About NRC

The U.S. Nuclear Regulatory Commission (NRC) was created as an independent agency by Congress in 1974 to ensure the safe use of radioactive materials for beneficial civilian purposes while protecting people and the environment. The NRC regulates commercial nuclear power plants and other uses of nuclear materials, such as in nuclear medicine, through licensing, inspection and enforcement of its requirements.

» **Video: NRC & Your Community**  
» **NRC: Who We Are and What We Do**   
» **Video: Inside the NRC**  
(Flash/Mobile/HTML5 | Windows Media)

- **The Commission**
- Our Organization & Functions
- Our Governing Legislation
- Our Plans, Budget, & Performance
- Our Locations
- Our History
- Our Values

### Regulatory Activities

- Commission Direction-Setting and Policymaking Activities
- Radiation Protection
- Fire Protection
- Safety Culture
- How We Regulate
- Emergency Preparedness and Response
- Counterfeit, Fraudulent, and Suspect Items

### NRC MISSION

The NRC licenses and regulates the Nation's civilian use of radioactive materials to protect public health and safety, promote the common defense and security, and protect the environment.

#### NRC's regulatory mission covers three main areas:

**Reactors** - Commercial reactors for generating electric power and research and test reactors used for research, testing, and training

**Materials** - Uses of nuclear materials in medical, industrial, and academic settings and facilities that produce nuclear fuel

**Waste** - Transportation, storage, and disposal of nuclear materials and waste, and decommissioning of nuclear facilities from service

### RELATED INFORMATION

Strategic Plan



## ABOUT NRC

- The Commission
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## Counterfeit, Fraudulent, and Suspect Items

The NRC requires U.S. nuclear power plants to use only those products and services exhibiting the highest quality in agency-regulated activities. This has always been a cornerstone in the NRC's mission of protecting public health and safety, promoting the common defense and security, and protecting the environment during the civilian use of radioactive materials. Vendors, suppliers and nuclear power plants must verify the quality of items destined for safety-related functions in NRC-regulated activities. Verification includes extensive inspections of an item's critical physical characteristics, combined with rigorous performance testing, to provide reasonable assurance that parts will perform their intended safety functions when required to do so.

Each of the various NRC-regulated industry sectors use similar regulatory language to meet the highest quality assurance standards for the products and services employed in NRC-regulated activities. The NRC advocates a proactive approach to detect and prevent the intrusion of counterfeit, fraudulent, and suspect items (CFSI) into agency-regulated equipment, components, systems, and structures. The NRC routinely interacts with regulated companies, other federal agencies, international organizations, industry trade associations (nuclear & industrial), and academia to stay abreast of emerging CFSI trends.

The NRC inspection staff works with these outside organizations in order to evaluate vulnerabilities in procurement processes and to share best practices for the prevention of CFSI in the supply chain. The NRC holds periodic public workshops to provide information and updates on CFSI issues and to solicit industry feedback and lessons learned. Finally, the NRC participates in [Nuclear Energy Agency \(NEA\)](#) [\(EXIT\)](#) and [International Atomic Energy Agency \(IAEA\)](#) [\(EXIT\)](#) meetings to share CFSI information and lessons learned with foreign regulators.

- [Guidance Documents and Background Information](#)
- [Safety Culture Policy Statement](#)
- [Public Presentations](#)

The [National Intellectual Property Rights Coordination Center](#) [\(EXIT\)](#) (IPR Center) stands at the forefront of the United States Government's response to global intellectual property (IP) theft and enforcement of its international trade laws. The mission of the IPR Center is to ensure national security by protecting the public's health and safety, the U.S. economy, and our war fighters, and to stop predatory and unfair trade practices that threaten the global economy. To accomplish this goal, the IPR Center brings together 23 partner agencies, including the NRC, in a task-force setting. The task force structure enables the IPR Center to effectively leverage the resources, skills, and authorities of each partner and provide a comprehensive response to IP theft.

To report violations of intellectual property rights, including counterfeiting and piracy, to the National IPR Coordination Center, [visit the IPR website.](#) [\(EXIT\)](#)

[\(EXIT\)](#)

 COUNTERFEIT, FRAUDULENT, AND  
SUSPECT ITEMSGuidance Documents and Background  
Information

## Safety Culture Policy Statement

## Public Presentations

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## Guidance Documents and Background Information for Counterfeit, Fraudulent, and Suspect Items (CFSI)

Generic communications are the NRC's primary method of communicating a common need for information or resolution approach regarding an issue, or communicating NRC's position and information on issues pertaining to a matter of regulatory interest. Generic communications also allow the NRC to communicate and share industry experiences and send information to specific classes of licensees and interested stakeholders. CFSI-related generic communications and other documents are listed below:

Descriptions of the various types of generic communications and their applications can be found on the NRC public website.

- [Bulletins](#)
- [Generic Letters](#)
- [Regulatory Issue Summaries](#)
- [Information Notices](#)
- [Policy Issues and Support Documents](#)
- [Cyber Security Information](#)
- [International CFSI](#)

**Bulletins**

Date	NRC Bulletin No.	Description
12/22/88	NRC Bulletin 1988-010	Nonconforming Molded-Case Circuit Breakers
08/03/88	NRC Bulletin 1988-005, Supplement 2	Nonconforming Materials Supplied by Piping Supplies, Inc. at Folsom, New Jersey and West Jersey Manufacturing Co. at Williamstown, New Jersey
06/15/88	NRC Bulletin 1988-005, Supplement 1	Nonconforming Materials Supplied by Piping Supplies, Inc. At Folsom, New Jersey and West Jersey Manufacturing Co. at Williamstown, New Jersey
06/10/88	NRC Bulletin	Fastener Testing to Determine Conformance With Applicable



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## Public Presentations for Counterfeit, Fraudulent, and Suspect Items (CFSI)

The NRC considers public involvement in, and information about, our activities to be a cornerstone of strong, fair regulation of the nuclear industry. We recognize the public's interest in the proper regulation of nuclear activities and provide opportunities for citizens to be heard. Additional information about previous public meetings, presentations, and speeches related to CFSI is listed below:

- [Commissioners' Speeches](#)
- [Public Meetings](#)
- [NRC Presentations at Industry Conferences](#)

*This page includes links to files in non-HTML format. See [Plugins](#), [Viewers](#), and [Other Tools](#) for more information.*

### Commissioners' Speeches

The following is a listing of presentations given by NRC Commissioners over the years on the topic of CFSI.

Date	Document Number	Description
11/19/13	S-13-012	"Ensuring Safety in Dynamic Times: A Regulatory Perspective" Prepared Remarks of NRC Chairman Allison M. Macfarlane, Institute for Nuclear Power Operations (INPO) CEO Conference, November 19, 2013, Atlanta, Georgia
11/11/13	S-13-011	Prepared Remarks of NRC Chairman Allison M. Macfarlane, American Nuclear Society Winter Meeting, November 11, 2013 - Washington, DC
11/05/13	S-13-010	Prepared Remarks of NRC Chairman Allison M. Macfarlane, State Liaison Officers Conference, Nov. 5, 2013, Rockville, Md
05/14/13	S-13-008	Life after Fukushima: "The New Normal," Prepared Remarks of NRC Chairman Allison M. Macfarlane at the Nuclear Energy Institute (NEI) Nuclear Energy Assembly, May 14, 2013 - Washington, D.C.
06/28/12		Commissioner William C. Ostendorf, USNRC at the 3rd NRC Workshop

# NRC's CFSI Initiatives

- ▶ Remain proactive and ahead of events or threats
- ▶ NRC is engaged with other Government agencies to gain knowledge and experience
- ▶ NRC has a formal agency-wide strategy to monitor and evaluate CFSI
- ▶ Operating Experience Program updated to include CFSI as a Technical Review Group

# NRC Documents



- ▶ **Generic Letter 89-02**, “Actions To Improve the Detection of Counterfeit and Fraudulently Marketed Products”
- ▶ **Information Notice 2008-04**, “Counterfeit Parts Supplied to Nuclear Power Plants”
- ▶ **Information Notice 2012-22**, “Counterfeit, Fraudulent, Suspect Items (CFSI) Training Offerings”
- ▶ **Information Notice 2013-02**, “Issues Potentially Affecting Nuclear Facility Fire Safety”
- ▶ **Information Notice 2013-15**, “Willful Misconduct/Record Falsification and Nuclear Safety Culture”

# SECY-11-0154 “An Agencywide Approach to Counterfeit, Fraudulent, and Suspect Items”

► 19 actions were identified to respond to challenges associated with CFSI, categorized in the following areas:

- Endorsement of Industry Process Enhancements and Best Practices
- Developing or Clarifying Regulatory Guidance
- Communication
- Training
- Inspecting for Effective Industry Oversight for Detecting and Preventing CFSI

# SECY-15-0003, “Staff Activities Related to Counterfeit, Fraudulent, and Suspect Items”

- ▶ 16 of 19 actions are complete
- ▶ Vendor inspection procedures provide additional guidance for verifying cyber security requirements
- ▶ Extensive outreach with other Federal agencies and international organizations (IAEA, NEA)
- ▶ Future outreach efforts will continue to emphasize the importance of information sharing

# Regulatory Issue Summary 2015-08, “Oversight of Counterfeit, Fraudulent, and Suspect Items in the Nuclear Industry”

- ▶ Issued to heighten awareness of existing regulations and how they apply to CFSI
- ▶ Three areas –
  - ▶ Nuclear Reactors
  - ▶ Nuclear Materials
  - ▶ Radioactive Waste
- ▶ Focuses on codified QA and reporting requirements

# Regulatory Issue Summary 2015-08

## Nuclear Reactors

Appendix B areas:

- 1) design control
- 2) procurement document control
- 3) control of purchased material, 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

Nuclear Materials  
Part 32 for sealed source devices

Parts 40, 70, and 76 for fuel cycle facilities

Radioactive Waste includes transportation, storage, and disposal

Parts 71 and 72, both similar to App B QA



Part 21 reporting

# Questions and Comments