Counterfeit, Fraudulent, And Suspect Items (CFSI)

5th Public Meeting
Post-SECY 11-0154
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Public Meeting

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U.S.NRC
United States Nuclear Regulatory Commission
Protecting People and the Environment

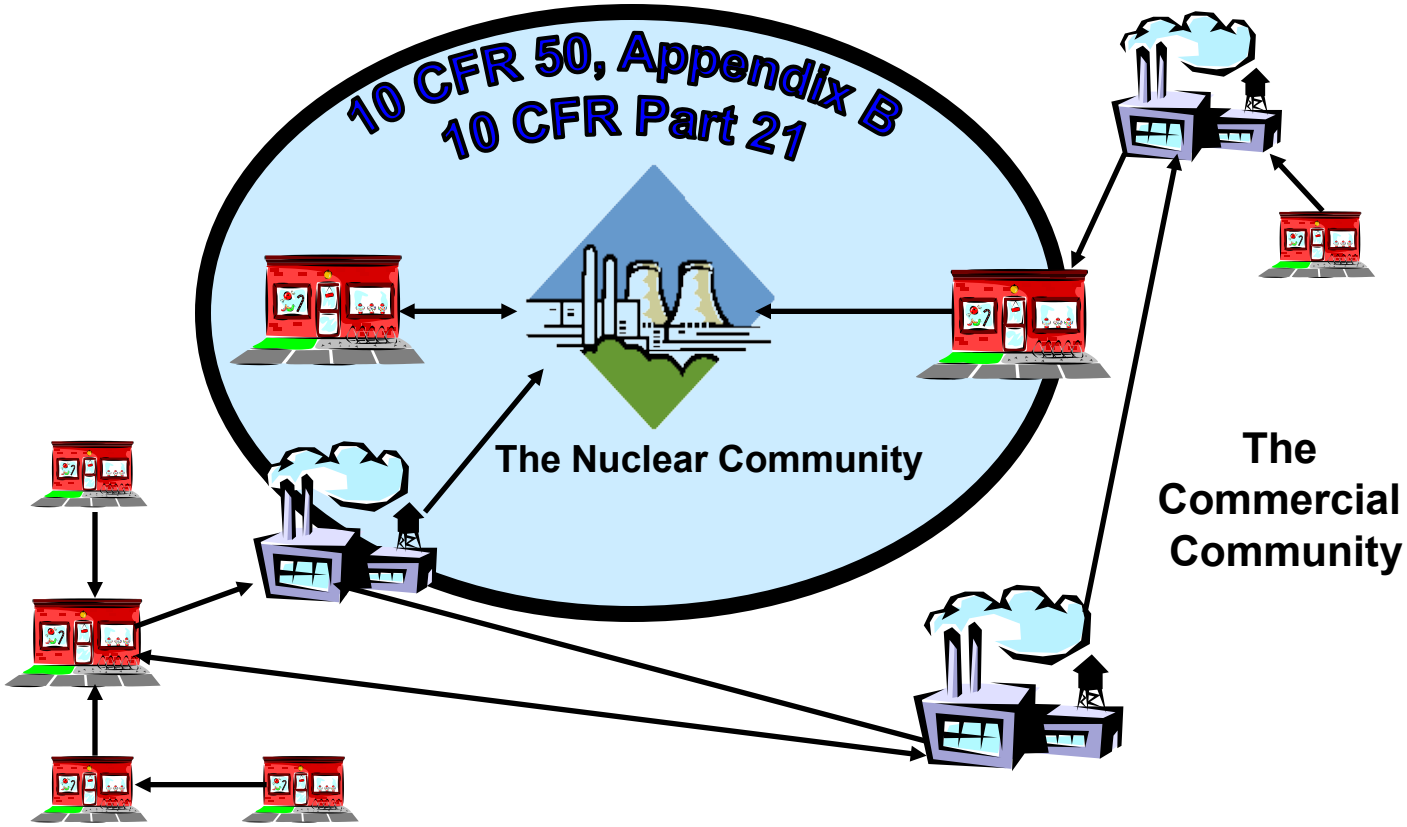
Acronyms

CFR	*Code of Federal Regulations*	USG
CFSI	*Counterfeit, Fraudulent, Suspect Item*	NRC
ConE	*Construction Experience Program*	NRC
DOE	*Department of Energy*	USG
ECD	*Estimated Completion Date*	General
EPRI	*Electric Power Research Institute*	EPRI
FAR	*Federal Acquisitions Regulations*	USG
FY	*Fiscal Year*	General
GIDEP	*Government Industry Data Exchange Program*	USG
IAEA	*International Atomic Energy Agency*	INT
IN	*Information Notice*	NRC
INPO	*Institute of Nuclear Plant Operators*	Industry
IPR	*Intellectual Property Rights*	USG
NEI	*Nuclear Energy Institute*	Industry
OI	*Office of Investigations*	NRC
OpE	*Operating Experience Program*	NRC
RG	*Regulatory Guide*	USG
ROP	*Reactor Oversight Program*	NRC
SECY	*Written issues papers the staff submits to the Commission*	NRC

Reporting Requirements
vs.
Proactive Initiative

Regulatory Requirement	Voluntary
• Prescribed process • Specific data requirements • Codified response times • Publicly available • Unrestricted usage • Broadcast publication • Full disclosure	• Process tailored to needs • Data tailored to needs • Arbitrary response times • Limited access • Ability to control usage • Targeted participation • Ability to establish “tear lines”

Basic Nuclear Supply Models



How far up the supply chain is sufficient to check for CFSI?

10 CFR 50, Appendix B[13] --*"quality assurance' comprises **all** those planned and systematic actions **necessary to provide adequate confidence** that a structure, system, or component **will perform satisfactorily in service**.*

10 CFR 21[14] -- *Commercial Grade Dedication (CGD) is "the acceptance process undertaken **to provide reasonable assurance** that a commercial-grade item to be used as a basic component will perform its intended safety function and, **in this respect, is deemed equivalent** to an item designed and manufactured under Appendix B …"*

IN 2008-04[12] -- *"It remains the **licensees' responsibility to ensure** that all suppliers use standards and processes that conform to US standards. **Effective oversight of suppliers** becomes increasingly more important as the nuclear industry begins construction of new nuclear power plants in the US."*

EPRI 1019163[1] **--** *Enhanced inspection criteria can be added for items …that are **procured via "at-risk" procurements**.*

EPRI 106439[11] **--** *The **more complex** the device, **the greater the effort to develop adequate confidence** it will meet the requirements of the application, particularly with regard to potential failure modes.*

How far up the supply chain is sufficient to check for CFSI?

EPRI NP-6406[10], "Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11) – Dec 1989:

- *For Items which are susceptible to counterfeiting or documentation falsification, **additional acceptance activities should be considered** to detect this type of anomaly.*

- ***Acceptance requirements imposed to detect counterfeit material** should be applied to those items which are **susceptible to counterfeiting**. These items include items **supplied by distributors**, high volume **"black box"** type electrical components, or items **purchased from distributors**.*

- *Additional acceptance requirements imposed to detect counterfeit items should be **separately maintained from those to provide the normal reasonable assurance**.*

Final Report, December 1989

What Should an Anti-CFSI Contract Clause Communicate?

1. Provide advance notification that the customer (& the commercial nuclear industry) is CFSI intolerant, and will report any illegal activities it encounters to authorities
2. That both parties value the significance of supplying only the highest quality parts
3. That both parties employ a meaningful testing/inspection process to screen for substandard and misrepresented items
4. Require solid CFSI practices from sub-suppliers
5. The customer does not approve of, or accept unauthorized part substitutions
6. The supplier is expected to receive authorization from the customer prior to altering any item associated with the contract
7. That both parties are exhibiting a questioning attitude regarding their supply sources, and use only authorized suppliers
8. That both parties will disposition identified CFSI in a responsible manner that is considerate of the industry as a whole (including quarantine of appropriate items)
9. The customer expects that they will be promptly notified by the supplier, if and when the supplier becomes aware that he has supplied misrepresented product to the customer
10. That motivations to try to pass off misrepresented goods have been effectively minimized

Standard CFSI Procurement Clause

Delivery of Suspect/Counterfeit Items

Seller is hereby notified that the delivery of suspect/counterfeit items is of **special concern**[1] to (Utility Name). If any items specified in this Order are described using a part or model number, a product description, and/or industry standard referenced in the Order, Seller shall assure that the items supplied by Seller **meet all requirements**[2] of the latest version of the applicable manufacturer data sheet, description, and/or industry standard unless otherwise specified. If the Seller is not the manufacturer of the goods, the Seller shall make **reasonable efforts**[3] to assure that the items supplied under this Order are made by the original manufacturer and **meet the applicable manufacturer data sheet or industry standard**[2]. Should Seller desire to supply an **alternate item**[5] that may not meet the requirements of this paragraph, Seller shall notify Purchaser of any exceptions and receive Purchaser's written **approval prior to shipment of the alternate items**[6] to Purchaser.

If suspect/counterfeit items are furnished under this order or are found in any of the goods delivered hereunder, such items will be dispositioned by (Utility Name) and / or the original manufacturer, and **may be returned to the Seller**[8] in accordance with the warranty provisions applicable to the Order. The Seller shall promptly replace such suspect/counterfeit items with items meeting the requirements of the Order. In the event the Seller **knowingly supplied suspect/counterfeit items, the Seller shall be liable for reasonable costs**[1] incurred by the Purchaser for the removal, replacement and reinstallation of said goods in accordance with the warranty provisions applicable to the Order.

- EPRI 1019163

The need to quarantine:

- is essential to the agency's ability to adequately conduct an effective inspection and/or investigation of a suspected counterfeit item. Possession of the item is necessary for investigators to address potential wrongdoing issues.

- protects investigatory evidence. Each suspected item is treated as potential evidence of a violation of NRC regulations or other U.S. law, and must be quarantined.

- is essential since each investigation is unique, and is conducted based on the facts/circumstances associated with the specific case. Once OI determines that the item is no longer needed, the item, will (if still in OI's possession) be returned to the licensee. This usually occurs fairly quickly, but some cases may take longer than others.

NOTE: Proper NRC protocols are currently being discussed internally as part of SECY 11-0154 implementation.

Key Terms Defined:

	NRC	EPRI	DOE	IAEA	FAR	
Counterfeit	✓	✓	✓	✓	✓	
Fraudulent	✓	✓	0	0	✓	
Suspect	0	✓	✓	✓	✓	
Substandard	0	✓	✓	0	0	
Authentication	✓	0	0	0	0	

Counterfeit

NRC	Items that are deliberately manufactured or altered in such a way as to misrepresent the actual quality of the item with intent to defraud or deceive the purchaser.	NRC-MC-2507[4]
EPRI	Counterfeit items are items that are intentionally manufactured or altered to imitate a legitimate product without the legal right to do so. A counterfeit item is one that has been fabricated in imitation of something else with the purpose to defraud by passing the false copy fro genuine or original or is an item copied without legal right or authority to do so.	1019163[1]
DOE	A suspect item that has been copied or substituted 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.	G 414.1-3[2]
IAEA	A counterfeit item 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. In this publication the terms suspect and counterfeit items (S/CIs) are combined and will be treated as such.	IAEA-TECDOC-1169[6]
FAR	An item that is an unauthorized copy or substitute that has been identified, marked, and/or altered by a source other than the item's legally authorized source or has been misrepresented to be an authorized item of the legally authorized source.	FAR Part 46[8]

Fraudulent

NRC	Items that are deliberately manufactured or altered in such a way as to misrepresent the actual quality of the item with intent to defraud or deceive the purchaser.	NRC-MC-2507[4]
EPRI	Fraudulent items are items that are intentionally misrepresented with intent to deceive. Fraudulent items include items provided with incorrect identification or falsified/inaccurate certification. Fraudulent items also include manufacturing overages sold by entities that have acquired the legal right to manufacture a specified quantity of an item (such as an integrated circuit), but produce a larger quantity than authorized and sell the overage as legitimate inventory	1019163[1]
DOE	Used but not defined	G 414.1-3[2]
	Used but not defined	DOE O 221.1A[7]
IAEA	Not used	IAEA-TECDOC-1169[6]
FAR	Used but not defined: *A product whose source, identity, characteristics or composition is misrepresented, falsified or materially altered. Examples of fraudulently identified goods include:* *1) A product (end item, assembly or component) that is marked - or otherwise identified - as originating from a source (supplier, manufacturer or trademark holder, etc.) when it actually originates from a different source (including country of origin).* *2) A product that originates from the authentic source (supplier or manufacturer) that is not inherently defective, but does not meet the specifications for the intended use. Examples would be a lower quality rated product that is sold as a product of higher quality.* *3) A used, outdated or expired product that was legitimately manufactured, but is being sold as new.*	FAR Part 46[8]

Suspect

NRC	Not used	
EPRI	Items that are suspected of being counterfeit, fraudulent, or substandard.	1019163[1]
	Items that are suspected of being counterfeit, fraudulent, or substandard.	1021493[3]
DOE	One in which visual inspection, testing, or other means indicate that it may not conform to established Government or industry-accepted specifications or national consensus standards; or one whose documentation, appearance performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer.	G 414.1-3[2]
IAEA	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 industry-accepted specifications or national/international standards	IAEA-TECDOC-1169[6]
FAR	A product in which there is an indication by visual inspection, testing, or other information that it may have been misrepresented by the supplier or manufacturer and the part may meet the definition of either a counterfeit part or a fraudulently identified good or both. (i.e. Unconfirmed counterfeit or fraudulent item).	FAR Part 46[8]

Substandard

NRC	Not defined	
EPRI	Substandard items do not meet the intended product specification. It is possible for legitimate suppliers to unknowingly provide substandard items that were manufactured using raw materials or part-level items that were acquired from sub-tier suppliers and for some reason did not meet the applicable specifications.	1019163[1]
DOE	Substandard materials known as suspect/counterfeit items (S/CIs) pose immediate and potential threats to the safety of DOE/NNSA and contractor workers, the public, and the environment.	G 414.1-3[2]
IAEA	Not used	IAEA-TECDOC-1169[6]
FAR	Not used	FAR Part 46[8]

Authentication

NRC	Verifying the identity of a user and application acting as a user or verifying the origin of a data, messages, or commands. Authentication depends on four classes of data, generally summarized as "what you know," "what you have," "what you are," and "what you do."	NRC RG 5.71[5]
EPRI	Used but not defined	1019163[1]
	Used but not defined	1021493[3]
DOE	Not used	
IAEA	Not used	IAEA-TECDOC-1169[6]
FAR	Not used	FAR Part 46[8]
Proposed	*The process of determining whether an item is, in fact, genuine (what it is declared to be). This process may involve confirming the origins of the item by either tracing its' chain-of-custody back to the Original Equipment Manufacturer (O.E.M.), or through the use of positive identification methods, ensuring that the product is genuine. An effective authentication process involves verifying the validity of multiple identifying attributes unique to the item being authenticated.*	

CFSI Implementation

1. **Industry process enhancements & best practices**
   - (11) voluntary initiatives (In-Prog)
   - Possible Generic Communications (In-Prog)

2. **Regulatory guidance**
   - Addition of CFSI to Part 21 guidance (In-Prog)
   - Endorse Voluntary Initiatives ← **ECD 2013**
   - Proposed CFSI Rulemaking to 10 CFR 50 ← **Post -Effectiveness Review**

3. **Communication**
   - Expand OpE/ConE program for CFSI ← **In-Prog**
     - Program move from CEVB to CAEB ← **Complete**
     - CFSI Technical Review Group (TRG) ← **Complete**
   - Public meetings – **monthly, 1st on Feb. 13, 2013**
   - Add CFSI to CAP programs (Industry Voluntary Initiative (IVI))
   - Federal Agency Outreach: Joined DHS/ICE National IPR Center ← **Complete**
     - GIDEP (In-Prog)
     - Centralized clearinghouse/database (IVIs)
   - NEA Nonconforming /CFSI Task Group (NRC Chair) ← **Complete**
   - IAEA IRS & (CNS) Convention on Nuclear Safety ← **Complete 1st in 2013**

CFSI Implementation Overview

4. **Training**
   - CFSI awareness into Allegations training module ← **Complete**
   - Provided CFSI Overview to OI Inspectors ← **Complete**
   - Provided CFSI Awareness to NRC staff (Region I: In-Prog)
   - Issued IN 2012-21, CFSI Training Offerings ← **Complete**
   - Formal Inspector training module in development ← **ECD 2013**

5. **Industry oversight for detecting & preventing CFSI**
   - NRC inspections
     - Vendor inspections (in-Prog) ← **ECD 2013**
     - Licensee procurement, ROP/cROP (pilots) ← **ECD 2013**
     - Suppliers of CDAs (sample population) – Cyber (In-Prog)
   - Licensee audits of suppliers ← (In-Prog)
     - Manufacturers
     - Dedicating entities
     - Supplier-to-supplier audits
     - CFSI added to VIPP ← **Complete**

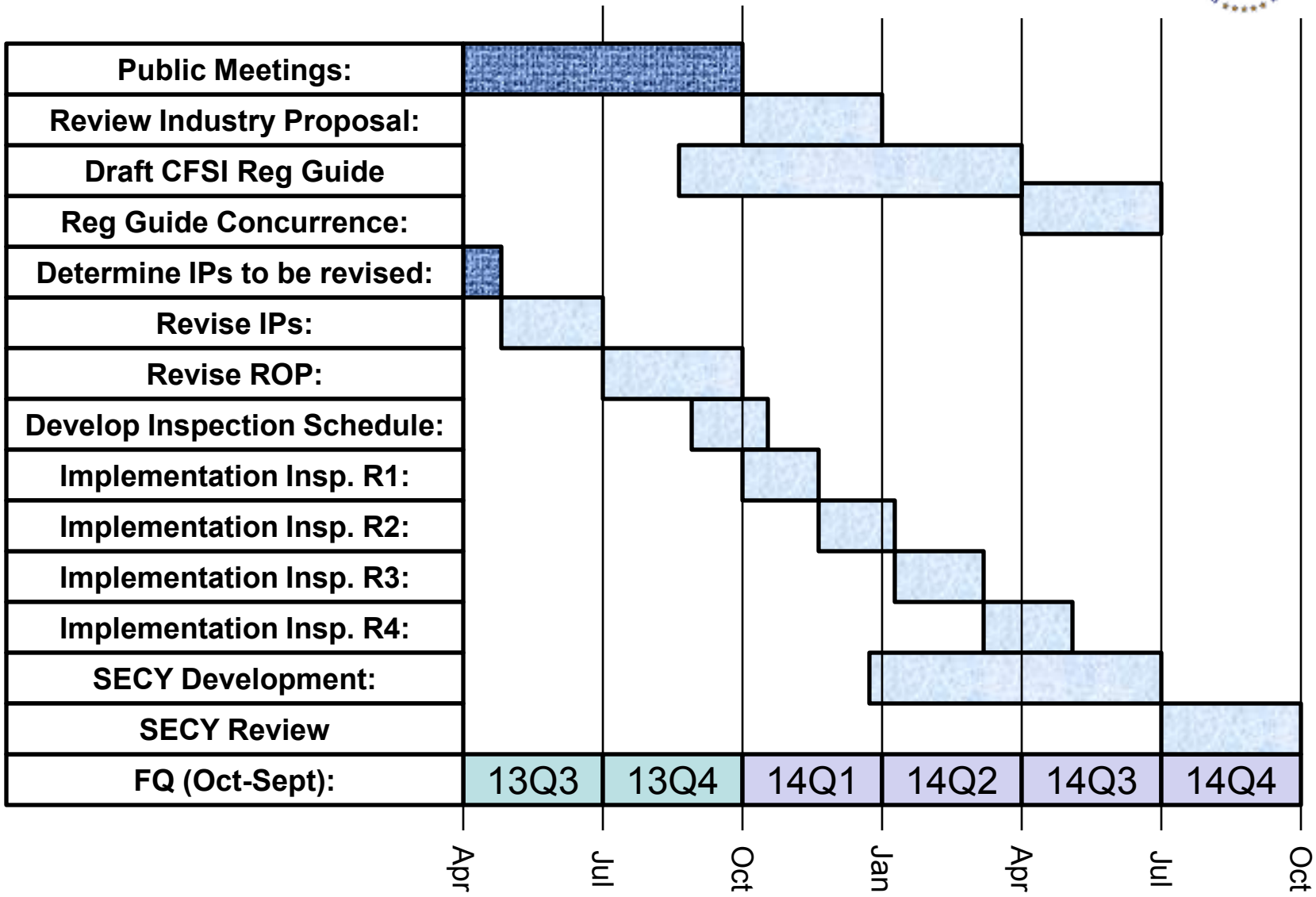
Voluntary Initiatives: Proposed Prioritization Sort by NUMBER

#	INITIATIVE	PRIORITY	LEVEL
1.	Develop a **plan** for implementing "proactive" CFSI strategies	XI	LOW
2.	Develop a method for sharing CFSI Information, including issues identified during receipt inspection and during commercial grade dedication	VI	MEDIUM
3.	Develop an industry accepted practice for using the corrective action program and nonconformance programs for entering CFSI related to safety related components	I	HIGH
4.	Develop an industry accepted practice for using the corrective action program to enter non-safety related CFSI into the corrective action program	V	MEDIUM
5.	Establish an industry CFSI database	VII	MEDIUM
6.	Incorporate industry best practices for quarantining CFSI items and removing them from the supply chain without returning them to the supplier	III	HIGH
7.	Incorporate industry best practices for identifying and informing the industry of CFSI trends	X	LOW
8.	Incorporate industry best practices for enhancing commercial-grade dedication, and receipt inspection practices to account for CFSI	IV	HIGH
9.	Incorporate industry best practices for product authentication of complex items that will provide additional assurance for preventing CFSI	VIII	LOW
10.	Incorporate industry best practices for using batch sampling with authentication testing	IX	LOW
11.	Incorporate industry best practices for the use of standardized anti-CFSI language in procurement documents	II	HIGH

Voluntary Initiatives: Proposed Prioritization Sort by PRIORITY

#	INITIATIVE	PRIORITY	LEVEL
3.	Develop an industry accepted practice for using the corrective action program and nonconformance programs for entering CFSI related to safety related components	I	HIGH
11.	Incorporate industry best practices for the use of standardized anti-CFSI language in procurement documents	II	HIGH
6.	Incorporate industry best practices for quarantining CFSI items and removing them from the supply chain without returning them to the supplier	III	HIGH
8.	Incorporate industry best practices for enhancing commercial-grade dedication, and receipt inspection practices to account for CFSI	IV	HIGH
4.	Develop an industry accepted practice for using the corrective action program to enter non-safety related CFSI into the corrective action program	V	MEDIUM
2.	Develop a method for sharing CFSI Information, including issues identified during receipt inspection and during commercial grade dedication	VI	MEDIUM
5.	Establish an industry CFSI database	VII	MEDIUM
9.	Incorporate industry best practices for product authentication of complex items that will provide additional assurance for preventing CFSI	VIII	LOW
10.	Incorporate industry best practices for using batch sampling with authentication testing	IX	LOW
7.	Incorporate industry best practices for identifying and informing the industry of CFSI trends	X	LOW
1.	Develop a **plan** for implementing “proactive” CFSI strategies	XI	LOW

Effectiveness Review Timeline



Plan for Going Forward

Prioritize the (11) Industry Voluntary Initiatives:

- Highest net gain to prevent CFSI ← **Complete**
- Ready for implementation

Develop Plans for Highest Priority Items:

- Include Estimated Completion Dates [ECD]
- Include any requests for support resources [ECD]

Schedule Monthly (Category 3) Public Meetings

- Working sessions to fully develop highest priority items ← **1st 05/08/13**
- Including focus topic discussions & general CFSI discussions ← **1st 05/08/13**

Implementation Commitment:

- Plan submittal to staff [ECD]
- Staff endorsement [ECD] ← **Reg Guide**
- Industry commitment [ECD] ← **How?**
- Change Management [ECD]

NRC Effectiveness Reviews:

- Determine characteristics of "effective" and sample population
- Develop a schedule to perform the reviews
- Issue Temporary Instruction (internal)
- Assess the results of the reviews & formulate SECY
- Issue follow-up SECY to Commissioners…… **< FY 2014>**

References:

1	EPRI 1019163	"Plant Support Engineering: Counterfeit, Substandard and Fraudulent Items, Mitigating the Increasing Risk"
2	DOE G 414.1-3	"Suspect/Counterfeit Items Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1B, Quality Assurance"
3	EPRI TR-1021493	"Plant Support Engineering: Counterfeit and Fraudulent Items A Self-Assessment Checklist"
4	NRC-MC-2507	"Construction Inspection Program: Vendor Inspections"
5	NRC RG 5.71	US NRC Regulatory Guide. "Cyber Security Programs for Nuclear Facilities"
6	IAEA-TECDOC-1169	"Managing suspect and counterfeit items in the nuclear industry"
7	DOE O 221.1A	"Reporting Fraud, Waste And Abuse To The Office Of Inspector General"
8	FAR Part 46	"Quality Assurance"
9	EPRI NP-5652	"Guideline for the Utilization of Commercial Grade Items In Nuclear Safety Related Applications (NCIG-07)"
10	EPRI NP-6406	"Guidelines for the Technical Evaluation of Replacement Items in Nuclear Power Plants (NCIG-11)"

References:

11	EPRI TR-106439	"Guideline on Evaluation and Acceptance of Commercial Grade Digital Equipment for Nuclear Safety Applications"
12	IN 2008-04	"Counterfeit Parts Supplied to Nuclear Power Plants" (Information Notice)
13	10 CFR 50,Appendix B	"Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"
14	10 CFR 21	"Reporting of Defects and Noncompliance"
15	SECY-11-0154	"An Agency Wide Approach to Counterfeit, Fraudulent, and Suspect Items"
16	NUREG/BR-0500	"Safety Culture Policy Statement" (ML11165A021)
17	GL 89-02:	"Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products (Generic Letter)

NUREG/BR-0500
"Safety Culture Policy Statement" [Rev. 1]
Dec 2012 (ML12355A122)

"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.

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.

There may be additional traits not included here that are also important in a positive safety culture. These traits were not developed for inspection purposes.

NRC MISSION

The mission of the NRC is to license and regulate the Nation's civilian use of byproduct, source, and special nuclear materials in order to protect public health and safety, promote the common defense and security, and protect the environment.

Photo Courtesy PPL

NUREG/BR-0500, Rev. 1
December 2012

TO GET MORE INFORMATION

www.nrc.gov
www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html

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SAFETY CULTURE
Policy Statement

Photo Courtesy Nanotech

QUESTIONS ?

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