

Multi-National Design Evaluation Programme (MDEP)
Vendor Inspection Co-operation Working Group (VICWG)

Common Position CP-VICWG-04

RELATED TO: VENDOR INSPECTION COOPERATION WORKING GROUP ACTIVITIES

Common Position on Mitigating the Risks of Counterfeit, Fraudulent, and Suspect Items

Participation

Regulators involved in the VICWG working group discussions:	ASN, CNSC, KINS, NRA, NNR, NRC, ONR, NDK, Rostechнадзор, STUK
Regulators which support the present common position	ASN, CNSC, KINS, NRA, NNR, NRC, ONR, NDK, Rostechнадзор, STUK
Regulators with no objection:	None
Regulators which disagree:	None
Compatible with existing related documents:	IAEA Nuclear Energy Series NP-T-3.26 NEA/CNRA/WGOE report R2011-9 NEA/CNRA report R2012-7 NEA/CNRA/WGOE Process for sharing of NCFSI-related information and associated template

Vendor Inspection Cooperation Working Group

**Common Position on Mitigating the Risks of
Counterfeit, Fraudulent, and Suspect Items**

Introduction

The international nuclear community has identified examples of documentation falsification and misrepresentation of materials in nuclear power plants, found not only within vendors' but also within the licensees' organizations. This type of systemic, quality issue affects a broad spectrum of users and suppliers in the nuclear field, particularly when the falsification has been ongoing and undetected for many years. Evidence of these recent events prompts a review of regulatory oversight and quality assurance practices of our international community.

In response to these recent events, the French Nuclear Safety Authority (ASN) surveyed its foreign counterparts, through the Nuclear Energy Agency (NEA) Working Group on Operating Experience (WGOE) and the Multinational Design Evaluation Program (MDEP) Vendor Inspection Cooperation Working Group (VICWG), in order to gather information on current practices and lessons learned in regard to counterfeit, fraudulent, and suspect items (CFSI). Specifically, the survey focused on the regulatory oversight system and reporting mechanisms related to CFSI.

MDEP VICWG prepared this Common Position (CP) to provide high-level guidance for regulators interested in developing a more robust reporting and information sharing system for minimizing the threats posed by CFSI in their country.

Regulators have a significant role in ensuring the safe operation of nuclear power plants, and irregularities could indicate a breach in the security of the nuclear supply chain. Further, recent events include a breakdown in the quality assurance programs for testing in some supply or manufacturing facilities, indicating that falsification in testing may be more wide spread than what appears on the surface.

The CP presented below offers guidance on how regulators may reinforce their oversight of nuclear power plant supply chains.

Definitions

Irregularities	Items that do not meet purchase or design specifications or their intended function
Counterfeit	Items that are intentionally manufactured or refurbished to pass as original equipment manufacturer products or parts, concentrating on physical attributes and without authorization to manufacture them
Fraudulent	Items that are misrepresented by false certifications or other falsified quality-related documentation with intent to deceive, including items that have been manufactured beyond a pre-authorized number of units
Suspect	Items that may not be genuine; but have not been verified yet as counterfeit or fraudulent
Commercial Grade Dedication	Commercial Grade Dedication (CGD) is an acceptance process whereby a commercial grade item is qualified through verification of its critical characteristics for dedicated nuclear use. This is achieved by verifying their acceptability by inspections, tests, or analyses by the purchaser or third-party dedicating entity. CGD is typically performed on items required for safety-related applications

The NEA CNRA WGOE Report on CFSI, NEA/CNRA/R(2011)9 (reference 1), emphasizes that using standardized terms and definitions for CFSI is advantageous in both national and international contexts. The NEA CNRA Report on CFSI, NEA/CNRA/R(2012)7 (reference 2) provides insights that should be useful to regulators and others in the nuclear safety community for addressing the issue of CFSI within the nuclear industry's supply chain.

Discussion

The common positions presented below follow the general topics of: (1) information and notification in the case of irregularities; (2) testing and materials; (3) inspection of licensees, (4) control of commercial products used in safety-related applications; and (5) enforcement.

1. Information and notification in the case of irregularities

Irregularities are an inevitable occurrence for a nuclear power plant's extended supply chain. There should be pre-established methods for informing stakeholders and regulatory counterparts after the discovery of such an event.

An irregularity should prompt a licensee to evaluate the item as a suspect counterfeit or fraudulent item. In the case of a confirmed CFSI, the regulator may require notification from the licensee through pre-established reporting methods and general information sharing between the regulator and the licensee. In some countries, specific reporting methods related to CFSI are implemented. Others use specific conditions and requirements included in supply contracts, such as purchase orders, requiring notification to the regulator. Regulators may consider requiring the licensee to further evaluate the event.

The MDEP VICWG concludes that a regulatory framework should include specific notification criteria for CFSI related to nuclear safety equipment or activity. Such criteria should include an evaluation of the known safety-related deviations or failures, datelines, and discovery of CFSI. The need and the timing of the notification submittal to the regulator should be commensurate with the safety significance of the issue. Operating experience provisions are another efficient and established method of disseminating information.

Generally, countries have regulations and provisions in place for considering anonymous reports or declarations of activity inconsistent with regulations, for which its validity has not been determined. These reports and declarations should first be investigated before initiating any regulatory action. Careful consideration should be provided during the investigation to protect the identity of whistle-blowers. Ideally, the provisions for protection of whistle-blowers should be clearly covered by legislation or as a minimum by the regulatory framework.

In addition, VICWG endorses the process developed by the WGOE, Appendix A and B, 'Instruction on the process to be used by Regulatory Bodies for the prompt Sharing of Non-conformance, Counterfeit, Fraudulent, and Suspect Items (NCFSI) related information', and the associated form or template to be used by regulatory bodies for sharing of NCFSI-related information with their international counterparts. These documents are not available to the public and therefore will not be included in this CP. However, these documents (Appendix A and B) are intended for the use of MDEP VICWG members and will be made available to the VICWG in the MDEP Library.

2. Testing and materials

Testing

Regarding test result records management for equipment important to safety, all member countries underline that test result recording is managed according to an approved quality assurance program

required by regulation or by codes and standards such as AFCEN or ASME. Licensees should develop appropriate quality assurance programs which also includes oversight of vendor and supplier activities. This function, primarily, pertains to equipment important to safety. Currently, there are no explicit regulatory requirements for integrating CFSI-specific detection into approved QA programs. For regulators, a comprehensive review and verification of an adequate sampling of testing records should promote detection of apparent irregularities by licensees and vendors, which would also promote the detection of CFSI as well.

Regulators commonly witness inspections and audits of material and equipment testing. Procedures implemented for testing and inspection of materials are carried out directly by the licensee, vendor, sub-contractors, or by third parties. Regulators may witness testing but do not directly test and inspect materials. The number of inspections and the scope of the inspections are not prescribed. Accreditation of third-party inspectors and auditors is mandated in some countries.

Preservation of source materials

The regulatory framework should endorse and mandate long-term storage of key materials for availability, if future analysis is required. Standards and codes, such as RCC-M and ASME, currently require the licensee to establish appropriate requirements regarding record retention and preservation of significant materials.

3. Maintenance of Records

Today's use of databases for records retention is an invaluable tool that should be accessible to regulators. If an industry-managed database is available, regulators should request access to it. The NEA CNRA WGOE report on CFSI (reference 1) recognizes that sharing CFSI-related information among regulatory bodies and use of a common database is preferred. The benefit of a single common database is that a more comprehensive view of the issues becomes available for analysis and trending reports. These reports and related intelligence should be generated from the database and communicated to other regulators, relevant agencies and companies. Data and information in the database should be confidential and access to the database should be controlled.

The International Atomic Energy Agency's (IAEA) International Reporting System (IRS) database includes a specific reporting code for CFSI-related events.

Inspection of licensees, suppliers, and external parties

Inspection framework

A robust safety culture within an organization involves core values and behaviors that regularly put safety in front of profit and production schedules. Through inspection or auditing, regulators should be aware of a licensee's managerial organization and how safety-related issues are communicated and dispositioned. At a minimum, countries should have guidance or inspections tools to evaluate the safety culture of licensees and vendors.

For most regulatory bodies, safety culture is not directly addressed in training programs. However, those training programs have to be sufficient and appropriate for staff performing activities affecting safety and quality. Most regulators require that training programs are suitable and inclusive for employees to successfully, and safely, carry out their work. Most regulatory frameworks require the implementation of an approved quality assurance program by licensees, which includes activities and items provided by suppliers.

Normally, regulators do not require a licensee to identify suppliers or external parties that have been prone to CFSI (e.g., a distributor that may not have a rigorous screening process for where it receives its supply).

As previously discussed, since specialized communications dedicated to CFSI are not regularly implemented, if a CFSI issue is detected and confirmed, regular reporting mechanisms may be used as routine practice to notify the regulatory body. It is highly recommended that regulators have access to lists or databases that contains vendor information, such as CFSI events and issues. It is important to identify who the counterfeiters are in order to fully assess their impact on the global supply chain and prevent CFSI issues from recurring or expanding further.

It should be required that the regulator be notified of confirmed, safety-significant irregularities, with actions expected from the licensee to appropriately address the issue.

Suppliers

Regulators should consider implementing inspections of suppliers, where enabled under country specific legislation. The scope of the inspections may be commensurate with the safety level of the equipment. Where inspections are not carried out by the regulator; for instance, in the case of not having the personnel to conduct the inspections, third parties or authorized inspectors/auditors have been successfully used.

If regulators do inspect the implementation of the quality assurance programs, licensee oversight of its suppliers should also be considered. The primary responsibility for safety is on the licensees, and therefore, they have the primary responsibility for oversight of their supply chain. A country's regulator should consider inspecting the quality assurance programs of suppliers to their country's nuclear power plants, in addition to the oversight completed by the licensees. Such inspections are a good tool to verify the licensees are providing adequate oversight.

- When establishing an inspection programme of suppliers, a regulator should consider the following items, related to CFSI, in addition to the stakes already considered to prioritise which suppliers are to be inspected: The supplier was reported in a report of safety concern by a whistleblower
- The supplier depends on a parent company where other suppliers are known to have committed CFSI
- Known financial difficulties
- Already known for CFSI

Inspection

Normally, regulators do not schedule dedicated inspections for CFSI issues. Dedicated inspections of licensees and suppliers should be possible on an as-needed basis, particularly when an investigation regarding declarations sent to the regulator shows a safety significant consideration. Where dedicated CFSI inspections are not used or scheduled, CFSI should be a sub-topic on regularly scheduled regulatory vendor inspections for areas; such as, acceptance of components (i.e. non-destructive examination, qualification certificate), and during manufacturers and vendor inspections.

Safety culture and organizational factors should be considered part of the scope of inspections in general. The results may lead to insights on an organization's propensity to raise quality concerns and report issues.

Normally, inspectors do not undergo training specific for CFSI, but rather are trained in general quality assurance. Since the topic is closely related to quality assurance, specialized CFSI-trained inspection staff is generally not a requirement. Regulators should determine if inspector training needs to include specific areas to cover fraudulent and counterfeiting activities as part of regular inspections. A small, dedicated CFSI inspection team may be warranted when fraud or counterfeiting issues are anticipated; such as, when a significant alert is received by the regulator. Both the NEA CNRA reports on CFSI and the IAEA Nuclear

Energy Series NP-T-3.26 (references 1, 2 and 3, respectively) cite training for regulators and industry as a key element for preventing CFSI in nuclear supply chains.

The VICWG recommends that regulators consider the topics listed below when assessing the vendor's or supplier's procedures in order to gauge the robustness of their processes to protect against CFSI events. These topics are consistent with a number of key elements recommended for operators of nuclear power plants to provide a robust defense against CFSI events, as explained in IAEA Nuclear Energy Series NP-T-3.26 (reference 3). Although the VICWG agrees with the IAEA recommendations in reference 3, with regards to the topic of "zero tolerance" to vendor's CFSI events, it is important to clarify that zero tolerance policies may prove difficult to enforce and may not always be appropriate in all circumstances. Therefore, it is recommended that regulators consider a graded approach to CFSI events, as appropriate.

- Employee training on recognizing counterfeit parts
- Engineering involvement in procurement and product acceptance
- Design rules and practices that emphasize diversity of supply
- Detailed knowledge of suppliers, including reducing use of independent distributors and parts brokers, and effective supplier audits
- Questions regarding CFSI identification methods and programs within supplier audit checklists
- Bid evaluation processes accounting for CFSI concerns
- Identification of 'at-risk' procurement
- Clear and complete procurement requirements
- Procurement clauses and standard contract language addressing CFSI
- Safeguarding of protection of intellectual property
- Sensitive scrap and disposal policies to protect against inappropriate reuse
- Human performance tools
- Use of difficult to counterfeit, positive ID tools
- Thorough receipt inspections
- Contractual arrangements for independent testing
- Procedures for addressing suspected CFSI incidents, which include engagement of original equipment manufacturers (OEM)
- Mandatory reporting to regulators of discovered CFSI events
- Reporting to industry or governmental databases of incident data
- Participation in industry peer groups
- Whistle-blowing system and whistle-blower protection
- Arrangements ensuring data integrity

Participating countries may consider how to share the results of their inspections. For instance, inspection reports shared with VICWG members in the MDEP Library and inspection reports that are publicly available could also be posted on the regulator's public website.

4. Control of commercial products used in safety-related applications

To promote control of commercial grade products for use in nuclear applications, regulators should require, at a minimum, that licensees have responsibilities for overseeing the testing and dedication of commercial grade equipment. Most of the regulators included in the survey do not have an established framework for inspecting commercial equipment dedicated for use in safety-related applications. However, many countries do have regulations and guidance for the dedication, or use, of commercial equipment in safety-related applications. Normally, the licensees or vendors develop inspection, test, and witnessing methods for verifying their use.

Regulators should have an available inspection program to sample commercial grade dedication activities at the licensee or supplier locations for at least safety-related equipment. Regulators should select locations through a risk-informed and/or deterministic process for inspections, which should include aspects of commercial grade dedication.

5. Enforcement

If a CFSI is confirmed, regulators should have specific enforcement actions available to use. Such enforcement actions are regularly matched with subsequent penalties that can be implemented. Since licensees are regularly on the receiving end of a CFSI issue, they normally would not be punished, unless, of course, they were found negligent in identifying the CFSI parts or materials. Although vendors and suppliers normally do not hold licenses, a regulator could impose additional requirement or restrictions on them from further supplying to nuclear power plants in their country.

Regulators may also want to coordinate with the country's justice system and law enforcement agencies that could assist them when investigating CFSI. Since pre-set limits regarding enforcement actions to be implemented in case of CFSI may not be practical due to the unique situations that may be encountered, regulators should consult with their court and judicial systems for guidance on recommended fines, where they are relied on for determining adequate penalties. Cases of CFSI events, such as persons knowingly producing counterfeit parts that could fail in service, may warrant close coordination with law enforcement and justice departments. Minor cases, such as those involving human error and not having significant safety impacts, would likely not justify such actions. Significant CFSI events may be considered similar to other occurring events that courts and justice have experience for determining adequate penalties.

References

1. Nuclear Energy Agency, Committee on Nuclear Regulatory Activities, "Operating Experience Report: Counterfeit, Suspect and Fraudulent Items NEA/CNRA/R(2011)9", October 2011.
2. Nuclear Energy Agency, Committee on Nuclear Regulatory Activities, "Regulatory oversight of Non-conforming, Counterfeit, Fraudulent, and Suspect Items (NCFSI), Final NCFSI Task Group Report, NEA/CNRA/R(2012)7," February 2013.
3. International Atomic Energy Agency, "Managing Counterfeit and Fraudulent Items in the Nuclear Industry", Nuclear Energy Series No. NP-T-3.26, IAEA, Vienna (2019).

Appendix

- A. Instruction on the process to be used by Regulatory Bodies for the prompt Sharing of NCFSI-related information, NEA/WGOE Report (Non-Public)
- B. Notice of Potential NCFSI, NEA/WGOE Form (Non-Public)