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NUCLEAR ENERGY AGENCY
COMMITTEE ON NUCLEAR REGULATORY ACTIVITIES

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Regulatory oversight of Non-conforming, Counterfeit, Fraudulent and Suspect Items (NCFSI)

Final NCFSI Task Group Report

JT03334695

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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NUCLEAR ENERGY AGENCY

The OECD Nuclear Energy Agency (NEA) was established on 1 February 1958 under the name of the OEEC European Nuclear Energy Agency. It received its present designation on 20 April 1972, when Japan became its first non-European full member. NEA membership today consists of 28 OECD member countries: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Luxembourg, Mexico, the Netherlands, Norway, Portugal, Republic of Korea, the Slovak Republic, Spain, Sweden, Switzerland, Turkey, the United Kingdom and the United States. The Commission of the European Communities also takes part in the work of the Agency.

The mission of the NEA is:

- to assist its member countries in maintaining and further developing, through international co-operation, the scientific, technological and legal bases required for a safe, environmentally friendly and economical use of nuclear energy for peaceful purposes, as well as

- to provide authoritative assessments and to forge common understandings on key issues, as input to government decisions on nuclear energy policy and to broader OECD policy analyses in areas such as energy and sustainable development.

Specific areas of competence of the NEA include safety and regulation of nuclear activities, radioactive waste management, radiological protection, nuclear science, economic and technical analyses of the nuclear fuel cycle, nuclear law and liability, and public information.

The NEA Data Bank provides nuclear data and computer program services for participating countries. In these and related tasks, the NEA works in close collaboration with the International Atomic Energy Agency in Vienna, with which it has a Co-operation Agreement, as well as with other international organisations in the nuclear field.

FOREWORD

Programmes for the disposition of non-conforming items have been part of the regulatory framework, within the context of quality assurance programmes, for many years. Even with these programmes, there have been historical incidents where non-conforming, counterfeit, fraudulent, or suspect items (NCFSI) have been introduced into the supply chain for the nuclear power industry. While actions were taken within the nuclear power industry and by the regulatory authorities to address individual events as they occurred, there is a continued challenge with preventing the introduction of NCFSI into the supply chain for nuclear power plant construction, refurbishment, and maintenance. With the increased demand for high-quality parts and components to maintain the existing operating reactors while building a relatively large number of new reactors, the potential for NCFSI to be used in safety-related applications is greater than it has been in the past. Measures are needed to enhance the integrity of the supply chain by minimising the incidence of NCFSI. In assessing this issue emphasis should be placed on identifying commendable practices to detect and prevent the use of CFSI with the objective of enhancing nuclear safety. These measures may also cover aspects of malicious intent, but are not designed to explicitly address this aspect.

The NEA Committee on Nuclear Regulatory Activities (CNRA) authorised the formation of a task group in June 2011 to identify measures to enhance the integrity of the supply chain by minimising the incidence of NCFSI. The task group's work built upon relevant learning from international experience on NCFSI, including related Working Group on Operating Experience (WGOE) activities (Operating Experience Report: Counterfeit, Suspect and Fraudulent Items (NEA/CNRA/R(2011)9) and the June 2011 joint WGOE and Working Group on Inspection Practices (WGIP) Proceedings from the International Operating Experience Feedback Workshop.

The task group members participating in this review included:

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The general objectives of the task group review were to:

- Identify issues and challenges of NCFSI
- Acknowledge and build upon relevant learning from international experience on NCFSI.
- Identify commendable practices for the identification and disposition of NCFSI to prevent its introduction into the global nuclear supply chain. Such practices address:
  - Fostering informed and engaged supply chains with respect to NCFSI.
  - Implementing effective licensee processes and controls for addressing NCFSI
  - Ensuring regulatory oversight of licensees' approaches to managing NCFSI
  - Identifying mechanisms or approaches for collecting and sharing experience on NCFSI
- Document the results of its activities as a source of expert knowledge on the subject.

This report 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. Insights are provided on the background of the issue; what does NCFSI mean, what are the concerns; and the responsibilities of the regulator, the operator, and the suppliers. Causal factors and challenges faced are also discussed. These include insights on the root causes that may contribute to NCFSI, latent causal factors, increased incidence of NCFSI in the supply chain, issues with ageing and obsolescence, adequacy of laws and the regulatory framework in addressing CFSI, the lack of awareness of the issue and its impact on safety, difficulties in detecting CFSI, and issues with strong safety culture in the supply chain.

Information is also provided on the importance and practices that can develop an engaged and informed supply chain to address the issue of CFSI. The activities described include education and training practices, being intelligent customers and suppliers, and knowledge management.

In the section of the report on licensee process and controls, there are many suggestions on actions and controls that licensees and suppliers should consider to address the issue of CFSI as they go about procuring new and replacement items and services that are important to the safety of their nuclear facilities. The emphasis is on using the existing management or quality assurance programmes with enhancements as necessary to specifically address the issue of CFSI, beyond those just associated with non-conforming items. Insights are shared on what can be done with procurement and supply change management controls, and post procurement activities for addressing CFSI.

Finally, the task group shared insights on the role of the regulator in addressing CFSI. These included topics such as, what can be done to enhance the regulations and guidance to address CSFI, regulatory support for gathering and sharing information on CFSI, approaches to managing CFSI, international co-operation amongst regulators, and responses by other government organisations such as law enforcement officials.

1. BACKGROUND

Nuclear licensees ultimately have responsibility for the safety of their licensed facilities (sites) and activities. This includes ensuring that purchased and supplied products and services meet regulatory and design basis requirements. However, in an increasingly globalised world economy, with extended supply chains, there is increased opportunity for nonconforming, counterfeit, fraudulent and suspect items (NCFSI) to enter the supply chain. Such items can present a very real risk to nuclear safety[13] and it is important that regulators, licensees and their suppliers understand the potential for harm and the measures that may be taken to protect and assure the integrity of items that have a nuclear safety function.

This document considers the factors that may contribute to the incidence of NCFSI, and provides advice and guidance on the measures that may be taken to reduce the incidence of NCFSI occurring or entering service. Further, when appropriate it distinguishes factors associated with counterfeit, fraudulent, and suspect items (CFSI) from those primarily related to nonconforming items. It emphasises the benefits to be gained from promoting awareness of the potential nuclear safety impact of NCFSI throughout the supply chain, as well as reinforcing the need for robust licensee quality management arrangements that extend to embrace the whole of the supply chain. It also considers approaches that regulatory bodies can take to maintain oversight of licensee arrangements and to promote sharing of learning both within their countries and internationally.

Although international regulatory regimes differ in the extent to which they embody a prescriptive or non-prescriptive philosophy, they share a common basis, as set out in IAEA Safety Fundamental Principle 1, which is that the licensee is responsible for safety. It is incumbent upon the licensee, therefore, to take all reasonably practicable steps to ensure that the goods and service that it procures are fit for their intended purpose and meet the design specification and intent. If the licensee is able to promote and give assurance that it has a robust supply chain, where companies and individuals understand the need for quality, this reduces the potential for NCFSI items to enter and progress through the supply chain. It is therefore important for licensees to have quality management arrangements that:

- meet international standards
- meet their expectations
- promote education and training

1.1 What are NCFSI?

NCFSI are non-conforming (genuine or non genuine themselves), counterfeit, fraudulent or suspect items or ones that contain non genuine items as part of their construction. These items are described as follows:

N Non-conforming Items

Items that do not satisfy or meet with accepted standards, specifications and/or technical requirements such as those specified in a purchase order.

Non-conforming can be both genuine and non genuine items; they can emerge at any stage of the supply chain, including design, manufacturing, storage, and transportation. Non-conforming items can originate:

Unintentionally (genuine non-conforming items), due to random failures or errors within the accepted reliability level: a) deficiencies or ineffectiveness of quality management systems; b) inadequate quality/safety culture of personnel and managers participating in the supply chain; c) unavoidable stochastic deviations from desirable nominal combinations of parameters and/or characteristics of processes, materials and/or products. This type of non-conforming items could be delivered by any type of suppliers, including traditional certified nuclear-grade companies.

Intentionally (non-genuine - counterfeit or fraudulent items – CFI), which are fake copies or substitutes produced **deliberately** without legal right or authority or ones whose material, performance, or characteristics are knowingly misrepresented. CFI are mostly delivered from alternate sources due to economical reasons, or because of the lack of traditional certified nuclear-grade suppliers and/or manufacturers of original genuine items etc. Probability of non-conformance with applicable standards, specifications and/or technical requirements for this group of components usually is much higher.

C *Counterfeit Items*

Items that are intentionally manufactured or altered to imitate a legitimate product without legal right to do so.

F *Fraudulent Items*

Items that are intentionally misrepresented to be something they are not - whose material, performance, or characteristics are knowingly misrepresented.

Fraudulent items include items provided with incorrect identification or falsified/inaccurate certification, including the actual date of manufacture or estimated end-of-life values. Fraudulent items also include items 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 authorised and sell the excess as legitimate inventory.

S *Suspect Items*

Suspect items are items about which there is an indication by visual inspection, testing, or other preliminary information that they may not conform to the accepted standards, specifications and/or technical requirements and there is a suspicion that the item may be counterfeit or fraudulent. Additional information or investigation is needed to determine whether the suspect item is acceptable, non-conforming, counterfeit or fraudulent. It is possible for legitimate suppliers, unknowingly, to provide a suspect item due to the use of raw materials or sub parts from sub tier suppliers that for some reason did not meet the applicable specifications. After the adequate inspection and/or testing suspect items are attributed either to acceptable or to non-conforming, counterfeit or fraudulent components.

An item that does not conform to established requirements is not normally considered CFSI if the nonconformity results from one or more of the following conditions, which should be controlled by site procedures as nonconforming items [26, 27]:

- Defects resulting from inadequate design or production quality control;
- Damage during shipping, handling, or storage;
- Improper installation;
- Other controllable causes.

1.2 What are the concerns?

The infiltration of NCFSI into the supply chain introduces a number of serious concerns for the nuclear industry:

1.2.1 Impact on Safety

The selection of items for a nuclear installation is governed by the duty and function they are required to perform and the environment in which they are to perform it. This in turn will determine the standard(s) and codes used in their design, manufacture and construction. Items can be singular or be incorporated into systems and a number of these will be required to perform safety functions. These items will be called upon during normal operation, abnormal conditions, or accident conditions as described in the supporting safety analysis report or safety case which will assume that they perform in a predictable manner with set reliability. If these components or systems were to fail or be unavailable due to NCFSI then plant safety could be compromised because the assumed standard of manufacture and reliability may not be met. Failure could challenge correct safety system operation and in extreme cases, could lead to accident conditions developing.

Analysis of the reported events caused by non-conforming components at nuclear power plants shows, that their safety significance is relatively high [8, 9]. Up to 50% of such events resulted in some real undesirable consequences: unplanned reactor shutdown, unanticipated release of radioactive materials, damage of fuel, etc. The remaining part of the analysed events had no real identified consequences or no effect on the safe operation of a plant; however, most of these events had the potential to cause real, more serious consequences under other circumstances due to loss, degradation or weakening of safety functions or potential unavailability or inoperability of safety related systems or equipment. Most of the in-service failures related to non-conforming components took place while the reactor was at power (including power variations) – when the reactor was operated at full allowable or reduced power, raising or reducing power, starting up, or refuelling. In 32% of analysed events non-conforming items caused common cause failures (CCF) while multiple failures (including both independent and dependent multiple failures) amount to 38.3%.

1.2.2 Commercial Impacts

Plant availability is directly influenced by the ability of items to meet their design intent. The ability of items to meet the design intent relies on them performing the function for which they have been selected with the reliability that has been assumed in the overall design. The installation of non-conforming components can lead to unforeseen failures and plant outages that can be inconvenient and expensive. During the operational period of the plant, this could have adverse consequences on the operator as it may not be able to meet programmatic obligations for delivering electricity to the grid. Failures of components during construction or installation or the discovery of NCFSI items could lead to significant delays in the construction programme that would likely incur financial penalties and increased interest accrual. On these grounds, it seems that the deliberate use of NCFSI on economic or convenience grounds is a false economy that can lead to expensive consequences.

1.2.3 Loss of legitimate firms

The cost of a genuine item will take account of the research, design, production, certification, licensing, and inspection processes and facilities required to develop and produce them. Legitimate companies will invest in developing the required quality assurance programs, technical development, and infrastructure and will take a responsibility for the item they produce including customer support and product liability. A genuine part manufacturer also invests significant resources in establishing and maintaining the company's industry reputation and subsequent brand recognition, making the item even more susceptible to counterfeiting. Another, often overlooked cost for the legitimate company is the cost of implementing anti-counterfeiting policies and the legal expenses to defend their product. In order for a legitimate company to be economically viable they require an appropriate return on their investment: however, the existence of organisations that produce CFSI can result in a distorted pricing regime. The infiltration of CFSI can significantly undermine the partnership between operator and supplier because the demand for the genuine item can diminish threatening the economic viability of the supplier. In extreme cases this could threaten the continued existence of the supplier of the genuine items. CFSI by their nature are produced by suppliers who do not share the burden of investing in the design, development and production infrastructure required to produce the genuine product. Genuine suppliers delivering nonconforming items for short term expediency or because of a breakdown or inadequacy of their systems will potentially suffer adverse consequences later.

1.2.4 Loss of skilled jobs

Suppliers of genuine items will invest in the development of suitably qualified and experienced personnel who have the skills and abilities necessary to produce components of adequate quality. This is an economic investment which requires the supplier to allocate commensurate financial resources which ultimately will be paid back through the pricing structure of the company. Counterfeiters do not have the same concerns for their human resources and will tend to invest little in their development since they are supplying an inferior product at a reduced cost when compared with the genuine item. Ultimately, if CFSI become prevalent a loss of the skilled jobs necessary to deliver the genuine item could result because of a lack of demand.

1.2.5 Reputation

Nuclear power requires a consensual acceptance by the populous that it is safe and reliable. Reputation is a fragile commodity that takes a good deal of effort to acquire but which can be lost in an instant. Failures of a plant in service will not improve any reputation won but failures of plant caused by NCFSI are likely to be more damaging because of the suspicions aroused about the integrity of plants, and the fear that NCFSI may be prevalent in the industry, or that public health and safety is being sacrificed in exchange for increased profits.

1.2.6 Expansion of the Nuclear Industry

In response to growing energy demand a number of countries are considering developing or expanding existing nuclear energy programmes. This has created a large increase in-demand on the world supply chain. This creates opportunities for genuine suppliers to expand and invest. However at the same time providers of CFSI will also see this as an opportunity to increase their activities. The strain on the world supply chain may result in items being sourced from many countries and environments and opportunities for infiltrating NCFSI may arise throughout the supply chain from both legitimate suppliers and counterfeiting organisations.

1.3 What are the responsibilities?

The Licensee for the nuclear facility is primarily responsible for nuclear safety. This includes ensuring that the purchased and supplied products and services meet regulatory and design basis requirements. The infiltration of NCFSI into the supply chain will compromise the discharging of this responsibility. Although the Licensee has ultimate responsibility for nuclear safety of the plant there is a commensurate responsibility on vendors and suppliers throughout the supply chain to ensure that NCFSI are excluded from their own supply chains. As discussed later, regulatory authorities also have a responsibility in preventing the use of NCFSI in the nuclear supply chain.

2. Causal Factors and Challenges that May Contribute to Increase Incidence of NCFSI

Supply of products, components, systems, structures and complement items of every description originates during the design, manufacturing, construction and commissioning of nuclear power plants (NPPs) and subsequently continues during plant operation, outages and systems modernisation until decommissioning. An effectively functioning and properly managed nuclear supply chain is essential to ensure adequate quality of supplied products and subsequent safe and reliable operation of nuclear installations. Despite the general agreement about the need for, and numerous attempts towards, ensuring the integrity, reliability and fairness of the supply chain, incidence of NCFSI continue to occur. Some additional measures to enhance these characteristics of the supply chain may be prudent as there are a number of factors that indicate the NCFSI challenge, particularly CFSI, may be increasing. A few of those factors are described below.

2.1 Roots contributing to non-conforming items [8, 9]

The most frequent failures due to nonconformances identified in commercial nuclear power plants are from mechanical components, including hydraulic/pneumatic equipment. The second biggest group is composed of electrical components contributing to 30 - 37% of the total number of events. Failures as a result of non-conformances in NPPs related to instrumentation and controls parts or components, while prominent in non-nuclear industries, contribute less to the total number of events.

Among mechanical components, the following subgroup of valves is the biggest contributor to the reported events:

- safety/relief/check/solenoid valves
- pressure switches
- valve operators
- controllers
- dampers and fire breakers
- seals and packing

Among electrical elements three subgroups could be distinguished by their fault frequency:

- Circuit breakers, power breakers, and fuses (27 - 36%);
- Relays, connectors, hand switches, push buttons, contacts (19 - 27%);
- Wiring (14 - 18%).

The major contributors of the reported events are deficiencies in design and manufacturing. Most of them are the result of design or manufacturing errors such as inadequate selection or usage of material and/or heat treatment, inappropriate construction, systemic errors in calculations, low reliability/insufficient longevity, inadequate or not followed technological procedures, inappropriate assembling, wrong dimensions, and welding defects.

There are several latent causal factors, trends and potential challenges that have been identified that lay behind potential increased incidence of nonconforming items:

1. **Major changes in the nuclear supply chain** towards globalisation, relocation of manufacturing capacities and international consolidation together with increased complexity and length of supply chains. These general trends have a strong impact on the transformation of existing links between licensees, suppliers, and sub-suppliers that requires updating of management principles governing the nuclear supply chain.

2. **Growing economic pressure** challenging nuclear facilities to reduce production and operating costs due to the competition induced by the deregulation of private facilities or decreased funding for government-owned facilities. This changing operating environment can lead to outsourcing and changing approaches to procurement, such as a reduction of quantities in storage of spare parts for replacement, cutting resources and staff responsible for vendor qualification and receipt inspections. The remaining staff are doing more and are likely to have fewer opportunities for the training required to recognise non-conforming items. The lack of training and awareness, complacency or loosening of existing controls can exacerbate the difficulties of NCFSI.

3. **Unavailability of as-designed components.** Increasingly, spare parts from the original manufacturer are no longer available or the manufacturer is not willing to support the rigorous testing and documentation needed for some items. The number of items originating from new sources has increased. Engineering and procurement personnel often rely on commercial grade items being available from suppliers who obtain the items from a variety of sources. The open market of the industrial supply chain is of course, comprised of many different individuals with varying interests, strategies and ethics. Variations in product quality originating from other than legitimate manufacturing processes create a reason for concern for both the NPP and the Regulatory Body (RB). When an item is procured from a questionable source, much information about how the item was procured, manufactured, repaired, fabricated, assembled, handled, and stored is likely not available.

4. **New materials, design principles, manufacturing technologies and/or standards** are widely introduced to the nuclear industry. For example: digitalisation of control systems, implementation of modern instrumentation and control (I&C) devices, shortening the life cycle of components (especially digital devices and electronics), and “black box” based modular design. As a result, items that may appear to be the same in form, fit, and function but meet new standards that may not satisfy the design requirements of the part they replaced may become mixed with the inventory of items meeting old standards, even when they are not completely interchangeable. Additional difficulties are growing in specifying items correctly and completely in purchase documentation to ensure compliance with the original standard and to prevent the mixing of stock manufactured according to different standards.

5. **Sharp increase in demand for nuclear components** caused by aging and obsolescence of existing equipment, refurbishment, life extension and planned new builds. Based on operational experience[8.9] the number of events caused by nonconforming components increases considerably during construction, commissioning and the beginning of operation of new reactor types. Meeting the growing demand could be hindered by the limited global capacity for nuclear components production, lack of qualified suppliers of nuclear components, specialised equipment and machinery, shortage of skilled designers, workers, and engineering/technical consultancy.

6. **The pursuit of the increasing of profit margins**, which can lead to unsubstantiated organisational or technical decisions in design and manufacturing, e.g., selection of materials, production technologies etc.

The factors mentioned above can potentially lead to deterioration in the quality of nuclear components and increase incidence of non-conforming items supplied to NPPs.

2.2 Increased evidence of CFSI

An effective campaign to identify, quarantine, and eliminate an influx of fraudulent material was instituted in the late 1980's in response to a series of quality challenges. Many of the countermeasures introduced at that time to identify and control CFSI have been retained. The challenges that confront today's supply chain professionals however, are much less obvious and potentially more damaging than those of three decades ago. Today's counterfeiters are often more sophisticated than their predecessors. The overwhelming majority of today's threats originate from a number of diverse product families, buried deeply within the "black box" brains of electronic technology.

The U.S. Department of Defense (DOD) has been affected by occurrences of CFSI related to electronics. A U.S. Department of Commerce (DOC) study of DOD procurement practices released in January of 2010 indicated that 39% of all electronic distributors to the DOD encountered some form of counterfeiting[1]. Similarly, statistics published on 14 July 2011 by the European Commission show a significant upward trend in the number of shipments suspected of violating intellectual property rights (IPR). European Customs in 2010 registered around 80,000 cases, a figure that has almost doubled since 2009[2]. While these statistics are not specific to or necessarily representative of nuclear suppliers, they are indicative of the greater prevalence of CSFI in the larger supply chain.

2.3 Ageing and Obsolescence

Unlike consumer products that have life cycles measured in months, most items installed into industrial components, including those installed in NPPs, are expected to perform for several decades. As more and more "manufacturer specified" products are incorporated into "durable" components, the less rigorous commercially manufactured item becomes the limiting factor for assessing the parent component's ageing and obsolescence risks. This is particularly evident when electronic devices are used in parent components. The life cycle forecast of the embedded electronic component forces the parent component into a premature obsolescence classification. The potential for the introduction of NCSFI increases when replacement parts are no longer available from the original manufacturer.

The commercial nuclear power industry clearly understands and appreciates the impact of obsolescence to a reliable source of replacement parts. The traditional response has been to hoard large quantities of replacement parts that pose significant risks for unavailability due to obsolescence. The U.S. Electric Power Research Institute (EPRI) suggests that one of the reasons NCSFI has not been a more significant concern is that "the vintage of safety-related equipment in the current nuclear fleet has perhaps played a role in insulating the fleet from counterfeit and fraudulent items."(3) Several industry sponsored efforts exist to address this challenge including EPRI sponsored working groups on obsolescence, and commercial databases from companies such as PKMJ Technical Service's "Proactive Obsolescence Management System (POMS) and Curtiss-Wright/Scientech's Rapidly Available Parts Inform*a*tion Database (RAPIDS)[3].

Obsolescence has been credited many times in the past for making an item vulnerable to counterfeiting; however recent U.S. Department of Commerce (DOC) data suggests that obsolescence, although it is a growing trend, is still relatively minor compared with "in-process" components – those still being legitimately produced by the Original Equipment Manufacturers (OEMs). The survey reports that from 2005 through 2008, the percentage of incidents involving counterfeit microcircuits of obsolete items increased from 7% of the total counterfeit microcircuits incidents in 2005, to 32% in 2008, while 68% of counterfeit microcircuits were still being produced by the OEM. The same trend is evident in the number of incidents of counterfeited “discrete electronic components” (e.g., capacitors, resistors, transistors, and diodes)[4]. The report suggests that the larger vulnerability is in the demand for components incorporating the latest technologies. This is a relevant factor for NPPs considering the demand for multiple new NPP constructions simultaneously around the globe, as well as the migration of control systems for existing plants to digital I&C technology.

2.4 Adequacy of Laws, Industry Standards and Guidance for management of NCFSI

Taking into account the importance of an effectively functioning nuclear supply chain for safe and reliable operation of nuclear installations, the nuclear industry has established a quite comprehensive system for quality management of procured items. The general principles for management and quality assurance of supplied products and components are contained in the IAEA Safety Standards and Guides [6, 10, 11, 12, 14-17]. These principles are realised in obligatory procurement quality assurance requirements that should suffice to prevent the introduction of CSFI. As defined by the IAEA Safety Guide 50-SG-Q2 (14), all nonconforming items including suspect and counterfeit ones (S/CIs) should be addressed by the site procedures for non-conformance control and corrective actions.

The CFSI issue was broadly addressed in IAEA TECDOC-1169 [6] which stated, “S/CIs are potential non-conforming items and therefore their treatment can be integrated into the normal non-conformance process. New processes are not required. The identification and disposition of S/CIs can be conducted using the existing Quality Assurance Programme. The procedures and practices should include provisions for inspecting, identifying, reporting, evaluating, testing, removing, replacing, and the final disposition of S/CIs using a graded approach. The procedures should utilise the existing process for non-conforming items. An engineering evaluation should establish the disposition of installed S/CIs (reject, repair, rework, accept with conditions and accept without modification)”[6]. Due to the inherent uncertainty in the performance of a counterfeit or fraudulent item, these items should be removed from service and replaced with qualified and acceptable items as soon as practicable. Implementing procedures should address all areas of vulnerability within the organisation to ensure that the program is effectively implemented and individual roles and responsibilities are communicated clearly and consistently.

At this time, most manufacturers supporting the commercial nuclear power industry do not incorporate explicit anti-counterfeiting methods or technologies into their products, as they consider this issue to be covered by their quality assurance programmes[13]. Besides the need for licensees to remain vigilant and maintain effective quality assurance programmes, new information on how to reduce the potential for introduction of counterfeit parts into their supply chains is being developed that should be collected and incorporated into the licensees’ training programmes for procurement and quality assurance staff, and into its procurement procedures and processes. Many countries do not have laws or other requirements to specifically prevent and respond to the use or introduction of CSFI. There are no written policies or procedures for preventing, detecting, reporting and prosecuting confirmed counterfeit and fraudulent activity in any country(13). Only some countries like the USA or Finland have requirements in their national regulations which expressly address CSFI. Licensees do not generally incorporate anti-counterfeiting clauses in their procurement contracts or purchase order conditions specifically aimed at eliminating CSFI. Likewise, until recently, there has been no specific training for identifying CSFI within the nuclear industry[13].

The lack of standards and guidance specifically related to CFSI is an important contributing factor to the growing CFSI challenge. An effective CFSI program designed to perform consistently over a long period, requires clear and informative policy expectations driving both proactive and reactive solutions. Guidance that contains specific reference to CFSI will determine the subsequent quality of the licensee’s and supplier’s implementing procedures. Organisations that lack this level of guidance leave implementation up to the discretion of the end users. This is exactly the state in which the US Department of Defense (DOD) finds their anti-counterfeiting program. "In the absence of a department-wide policy, some DOD components and their contractors have supplemented existing procurement and quality-control practices to help mitigate the risk of counterfeit parts in the DOD supply chain"[5]. To date, there has been few if any consensus standards developed to address CSFI.

2.5 Lack of Awareness and Availability of Knowledgeable Resources

In general, CSFI currently is not considered as a growing challenge in most NEA member countries, with the exception of Finland, Canada, the UK, and the USA, which have experienced some events involving CSFI[13]. Up to now, no additional resources have been assigned to specifically inspect for CSFI. Poor oversight of CSFI could lead to an increase in safety risks.

In recent years, many vendors, with little or no experience in the nuclear industry have entered the market to supply parts and components for both safety and non-safety applications to nuclear power plants. Some vendors take advantage of poorly defined procurement documents/specifications, weak or absent contractors' and subcontractors' qualification processes, weak or absent receipt inspection programmes, and a lack of vendor information sharing among nuclear facility operators. The staff responsible for assembling and repairing equipment is not usually trained to identify counterfeit items[5].

CSFI training of both industry and regulatory staff is key to preventing and detecting counterfeit and fraudulent components that could affect NPP safety. "Perhaps the most important and effective means to avoid CFSIs is through training personnel and making them aware of the issue. The probability that CFSIs will be identified increases significantly when personnel are familiar with the types of items that are known to be counterfeited and the characteristics that indicate items or associated documentation may not be genuine. Training raises the level of awareness and communicates the potential impact that CFSIs can have on plant operations as well as nuclear and industrial safety"[3]. Training however, should not be restricted to just receiving dock personnel, or QA inspectors. Current information that provides an awareness of CFSI activity should be shared throughout all levels of the procurement process, from design through operations. CFSI training should address each individual's roles and responsibilities in identifying potential CFSI. Refresher training should be offered periodically and should include a review of the types of CFSI that have been recently reported. CFSI training should address the role that each individual within each discipline plays in identifying potential CFSI[3]. NEA/CNRA/R(2011)9[13] makes similar references: "Personnel should be trained within their respective areas of responsibility, to identify, prevent, and eliminate the introduction of S/CIs into the facility. Training should include the use of practical examples from the organisation and industry."[6] Specific training should be considered for:

- The detection of installed CFSI
- Identifying CFSI during receipt and inspection
- Using CFSI information within the procurement process
- Including the potential for CFSI as a factor in component failures

External sources of information from national agencies, law enforcement organisations and manufacturing trade organisations should be used to augment program training to include current advances in counterfeiting and anti-counterfeiting techniques. Training should include an emphasis to educate suppliers new to the commercial nuclear community to make them aware of the special requirements and nuances of supplying goods and services under unique nuclear industry requirements.

2.6 Profitability of counterfeiting

One of the most important elements encouraging counterfeiting is the high potential for profit. Counterfeiting offers the possibility of avoiding most of the requirements associated with seeking nuclear accreditation or seeking to re-establish lapsed accreditations and can save considerable time, human and financial resources in order to achieve high profitability by circumventing these requirements. Counterfeiters can sell their products at prices equal to or lower than the price of genuine items without bearing the costs associated with research and development, correct materials and manufacturing, testing, liability, licensing, marketing and other expenses typically incurred by legitimate manufacturers. According to Daren Pogoda from the International Anti-Counterfeiting Coalition, "Counterfeiters have become more sophisticated as they've come to realise that counterfeiting is a good business to get into: it has very low risk of getting caught, very low risk of getting punished severely if you do get caught, and very high reward in terms of profit with low overhead"[25].

2.7 Difficulties in detecting CFSI

Detecting fraudulent or misrepresented products is difficult due to technical and organisational reasons. Technological capabilities of counterfeiters are improving. The rapid spread of modern manufacturing technologies enables quick and easy creation of counterfeit products that are difficult to distinguish from genuine products[3]. Most quality assurance programs are not designed to easily detect counterfeit or fraudulent practices. The criteria used to confirm the quality of products during receipt inspection and testing generally have assumed vendor integrity and are not focused on identifying an intent to deceive[18, 19]. The majority of licensees do not currently have either a policy or specific processes for detecting and preventing, or a consistent means of identifying instances of CFSI. Some of them do not even have a definition of the term 'counterfeit'. Established databases are not designed to track counterfeit parts. Once an item is suspect of being fraudulent or counterfeit, the organisation that identified the suspect item may not have the legal authority to investigate whether the item is in fact counterfeit or fraudulent, and may not want to incur the additional expense related to an investigation even if it did have the authority. Often, the investigation of fraudulent or counterfeiting is a criminal matter that is investigated by law enforcement organisations with support from the regulatory bodies and the organisation that identified the item as suspect of being fraudulent or counterfeit.

2.8 Lack of Effective Regulatory Oversight

Regulatory infrastructures have not always established clear requirements applicable to the prevention of NCFSI. Additionally, oversight by the regulator often focuses on the licensees and does not include lower levels of the supply chain. Various methods are being employed internationally for providing oversight of licensees and suppliers of regulated activities and components, but in the end, the ultimate responsibility rests with the licensee[7].The level of oversight a regulatory organisation should employ to assure that the licensees, suppliers, and sub-tier suppliers provide "the appropriate level of oversight" is however, a considerable challenge. The benefits of effective supply chain oversight cannot be over-emphasised, given the enormous uncertainties that could potentially exist in an unmonitored supply chain, comprised of multiple companies, residing in every corner of the globe. An additional reason for concern involves the new emerging sourcing models that have been gaining popularity since the advent of the internet. Any one of these factors can severely limit the regulator's or licensee's visibility of their sub-tier suppliers.

Effective regulatory oversight of NCFSI includes requirements for regular assessments of licensee and supplier internal processes ranging from access to product designs to manufacturing facility security. Some practices to consider also include instituting extra measures when purchasing from independent distributors such as internal and external validation and testing requirements, and part-authenticity documentation—such as certificates of conformance"[5]. EPRI guidance includes cautions regarding the use of supply sources determined to be "at-risk" for counterfeiting: "When alternate sources must be used due to obsolescence, schedule, or other reasons, the procurements should be flagged as "at-risk" so that appropriate precautions may be taken to ensure authenticity of items"[3].

Additionally, nuclear regulators need to assess the relevance of the existing regulatory framework to ensure that existing language is adequate to allow for the development and introduction of emerging innovation and technology in a cost effective and timely fashion. Regulations identified as presenting a barrier to modernisation may need to be modified to align with industry trends, address globalisation and electronic commerce concerns and incorporate clear anti-counterfeiting language.

2.9 Safety Culture

The International Nuclear Safety Advisory Group (INSAG) defines Safety Culture as the "assembly of characteristics and attitudes in organisations and individuals which establishes that, as an overriding priority, nuclear plant safety issues receive the attention warranted by their significance"[29]. The USNRC definition of safety culture provides that a company is said to have a positive nuclear safety culture when it possess "core values and behaviours resulting from a collective commitment by leaders and individuals to emphasise safety over competing goals to ensure protection of people and the environment"[28].

There are a number of key behavioural traits against which an organisation's underlying culture can be judged that include: Leadership Safety Values and Actions, Problem Identification and Resolution, Personal Accountability, Work Processes, Environment for Raising Concerns, Questioning Attitude, and others. Within the nuclear supply chain, the overwhelming majority of events seems to be caused by the same group of common fundamental root causes – inadequate quality/safety culture and deficiencies or ineffectiveness of management systems, quality management or quality assurance either of the supplier/vendor - designer, the manufacturer etc. - or of the customer[8,9]. Top management's commitment to safety, its safety culture, is often affected by the quality/safety versus production conflict in such a way that quality/safety requirements and practices may not always prevail in priority in favour of business interests.

A strong nuclear safety culture is an essential foundation stone for designing, building, operating and decommissioning a nuclear facility and new nuclear suppliers may not be familiar with or possess a strong safety culture. When a buyer chooses a supplier and they are uncertain whether that supplier possesses a strong safety culture, the level of risk associated with procuring NCFSI is greatly increased. Consequently, additional measures should be taken to offset this risk with additional levels of assurance that the item will perform its intended safety function. These additional measures should assure that the leadership, from senior management through to all strata of the organisation, have a demonstrable commitment to safety and that it creates a climate that fosters a strong safety culture. Further, decision making should reflect a safety first attitude at all levels; that all personnel within the organisation are educated on their personal responsibility for safety; and feel empowered to adopt a questioning attitude. The organisation as a whole should engender trust throughout and have effective means to capture and act on operational experience. Organisations should demonstrate that they recognise that nuclear facilities require special consideration and maintain a constant vigilance and focus on nuclear safety.

An outcome of a weak safety culture is that nonconforming or even CFSI may be produced, supplied, and used in safety-related applications at a nuclear facility. The licensee has responsibility for developing and promoting an appropriate nuclear safety culture within the licensee's organisation and also fostering a nuclear safety culture within the supply chain as a whole. This latter objective can be achieved through education, partnering and clear and unambiguous controlling documentation. The behavioural traits associated with a strong nuclear safety culture should be reflected in the attitudes towards controlling and eliminating the threat from NCFSI to their organisation.

3. AN INFORMED AND ENGAGED SUPPLY CHAIN

3.1 Education and Training

3.1.1 Acknowledge NCFSI as an issue

There should be recognition by the Licensee and throughout all levels of the supply chain that nonconforming items can be introduced at many points in the supply chain and further, that there are parties who would wish to substitute CFSI for genuine items for expediency or financial advantage.

The Licensee has responsibility for nuclear safety and must understand and acknowledge the threat posed by NCFSI. However in addition there must also be willingness on the part of all vendors and suppliers in the supply chain to acknowledge and understand the threat posed by NCFSI entering their products. The licensee, together with vendors and suppliers in the supply chain, must educate their staff to understand the threat from NCFSI and have appropriate training programmes in place. The Licensee and its suppliers must develop and implement processes and procedures which reflect vulnerabilities and the potential points of entry of NCFSI in order to eliminate the risk of NCFSI entering the supply chain.

3.1.2 Communication of the importance of understanding and complying with nuclear related technical and quality requirements to suppliers and sub tier suppliers (risks – safety, commercial, supply chain impact, etc)

The licensee when discharging the responsibility for nuclear safety should confirm that suppliers throughout the supply chain are aware of the importance of using and complying with appropriate technical and quality standards. Requirements of these standards should normally be specified in contract documentation throughout the supply chain from the licensee down. The approach is likely to be more robust at higher levels of the supply chain, but there is potential for dilution further down the supply chain when the appreciation and application of nuclear related standards may not be as well understood, especially when considering new suppliers. Use of organisations certified to a recognised quality standard will help to maintain consistency.

All suppliers should be made aware of their role in the supply chain and the responsibilities to supply genuine items that conform to specified requirements. In addition suppliers should have a general awareness of the specific technologies used in the nuclear industry and an appreciation of the associated risks and hazards, commensurate with their role in the supply chain. This should then enable them to have an informed appreciation of the industry they are supplying to and the potential consequences of failing to comply with the specified technical and quality requirements.

Suppliers need to have an appropriate awareness of the safety implication of NCFSI. By doing so they may better understand the importance of excluding NCFSI from the items they supply as there may be significant impacts on public safety and the environment. This also suggests that intelligent suppliers need to understand how and under what conditions the items they supply will be used in assuring the safe operation of nuclear facilities.

The licensee has a key role to play in informing suppliers of the context in which they are supplying, the importance of delivering to specified requirements and the potential consequences of incorporating NCFSI into the items they supply.

Communications of requirements need to be clear, concise and unambiguous between the licensee and suppliers and throughout the supply chain. There has to be a clear definition of requirements between the different links in the supply chain and each link must appreciate the importance of complying with the technical and quality requirements of the customer (licensee). Relationships and interfaces throughout the supply chain need to follow an appropriate due process in preventing the introduction of CFSI into the nuclear supply chain.

In order to combat the infiltration of CFSI into the supply chain there needs to be openness about experiences. A full disclosure of what happened, what the consequences were, how it was dealt with and what the lessons learnt were should be provided so that international efforts can be co-ordinated to effectively combat CFSI.

Co-operation needs to be established on an international basis and may be facilitated by active governmental oversight. The host government for suppliers must not tolerate malpractice and must have measures in place to stop it.

Industry forums should refer to and discuss the importance of eliminating CFSI from the supply chain.

3.1.3 Being an intelligent customer

Being an intelligent customer requires a sufficient depth of knowledge and understanding to appreciate what is required, what the specifications for procured items should be and whether the supplier has met those requirements. This is true for the licensee and its direct suppliers, as well as sub-tier suppliers. Acting as an intelligent customer in the nuclear industry requires oversight and often physical inspection to a greater depth than normal commercial practices to confirm compliance. This includes having a full appreciation of NCFSI and the negative impact these items can have on nuclear safety. An intelligent customer should first use well established manufacturers (name-brands) and distributors (certified) while contracting its suppliers. To the extent practical it is expected that an intelligent customer’s existing processes and procedures should provide adequate instructions and guidelines for dealing with NCFSI. However, as appropriate, processes and procedures should be developed that articulate how the intelligent customer role will be discharged, what the system requirements are, what the communication protocols are, and how responsibilities have been identified and apportioned.

The licensee, as the intelligent customer with prime responsibility for nuclear safety, should communicate with essential elements of its supply chain (i.e., through its contract language or during periodic audits of suppliers) to ensure that a similar appreciation of what being an intelligent customer means pervades the whole supply chain. A commendable practice used in some countries is that several licensees act together as intelligent customers sharing parts of procurement activity such as: audits and oversight of suppliers, receipt inspections and tests, NCFSI data bases, etc. In this way, there is a larger resource available to more effectively and consistently oversee the supply chain and facilitate the sharing of experiences with NCFSI.

3.1.4 Being an intelligent supplier

An intelligent supplier must demonstrate that there is a full understanding and appreciation of what the requirements are for the items to be supplied and of the consequences of failing to deliver to those requirements. New suppliers in particular need to be made aware of the context of the nuclear industry and the need for compliance with specified requirements and relevant nuclear codes and standards. All suppliers in the supply chain need to be aware of the importance of preventing NCFSI infiltrating the supply chain. They need to specify clearly their requirements to their own suppliers and share with them their experiences and insights on the importance of complying with procurement specifications and the safety implications of NCFSI being used in nuclear facilities.

3.1.5 Training to identify and prevent the use of NCFSI

Personnel at all levels need to be aware of the importance of preventing NCFSI entering the supply chain and they need to be trained to recognise them. This includes, for example, training of personnel responsible for specifying the technical and quality requirements of a item, or for the selection of appropriate suppliers to fill the orders, or individuals that install the items, inspect receipt of purchased material, provide quality control and inspect work activities, including managers, supervisors, and regulatory authority, personnel responsible for overseeing onsite activities at nuclear facilities Training should include methods for preventing the introduction of NCFSI into safety related application and also dealing with items that have already entered into the supply chain. Early detection of NCFSI has both safety and cost benefits and can help prevent programme delays.

Personnel need to be made aware of the ways in which NCFSI can enter the supply chain for the product they are dealing with. Knowing where the vulnerable points are in procuring items can inform the development of appropriate processes and procedures to help eliminate them. The supply chain is likely to be more vulnerable the further away the suppliers are from the original source requirement. Suppliers may have their own supply chain and they need to be vigilant in preventing NCFSI from entering their overall deliveries and be insistent on having robust processes and procedures which are strictly adhered to.

Organisations which receive products must be increasingly more knowledgeable and familiar with the expected characteristics and appearance of their purchases and be insistent that items are supported by authentic documentation. Quality Control Receipt Inspectors in particular need to be trained in spotting NCFSI.

The organisation needs to have a process for dealing with NCFSI once they have been identified. This will involve not only the immediate steps to be taken, such as quarantine and replacement, but may also include an analysis and further investigation to determine the extent and root cause for the introduction of the NCFSI into the supply chain.

3.1.6 Translate education and training into practices and procedures

The Licensee and suppliers should identify existing processes and procedures (such as procurement process, maintenance process, etc) that will be effective at excluding NCFSI. Often these are part of the licensee’s existing quality programme. Further, they must have the capability and capacity to implement these processes and procedures to recognise and avoid the potential threats from NCFSI. Ensuring that the training provided to their personnel and the processes and procedures it has in place are consistent and emphasise the potential threats from NCFSI is a method for providing the capability to implement an effective programme. To be effective, they must also allocate sufficient resources to implement these practices and procedures. Implementing these practices and procedures will have an impact on procurement; however, the concept of preventing NCFSI entering the plant should be a consideration when developing all processes related to construction, maintenance, and repair of nuclear facilities.

3.2 Knowledge Management

3.2.1 Understanding why things are used and how they are done

Although there are many hazardous industries the nuclear industry has a number of unique hazards from exposure to radioactive materials that have the potential to result in significant and long lived societal impacts. As a result the industry has developed standards and methods of working that reflect the nature and consequences of these hazards. These are typically captured in regulatory requirements and guidance; industry or national consensus codes and standards; and licensee practices and procedures. Often these standards and practices are viewed as un-necessarily complex and rigorous by those new to the nuclear industry. However, due to the potential for adverse impacts to the public and the environment from the peaceful use of nuclear power, strict adherence to them is demanded by the international nuclear safety community.

It is important that organisations and personnel who work in the nuclear industry have knowledge of these hazards which is commensurate with the role and activities they are going to undertake. This reinforces the need for adherence to specifications, processes and procedures. Further, it helps to understand why it is necessary to have rigorous processes and procedures that are controlled in a way that provides high confidence of the quality of the parts provided for safety related uses. This awareness and understanding helps to understand why there is a strong emphasis on eliminating NCFSI.

Bringing in new organisations and individuals (licensees, regulators, and suppliers) is a double-edged sword; fresh minds can bring a new perspective to things but there is the danger that the experiences that have forged the way things are done is not appreciated and changes are made that potentially undo advances that have been made to minimise the potential for NCFSI to be introduced into the nuclear supply system.

3.2.2 Partner with other industries on NCFSI

The nuclear industry is not unique when considering a problem such as NCSFI that can easily afflict other high hazard/high integrity industries. The fact that it is of concern to other industries means that they are likely to want to develop approaches based on their own experiences. There is likely to be some commonality and some variations that would be of interest to all. Forums to discuss the problem with different industries participating, both nationally and internationally, would help to illuminate NCSFI and would help to facilitate shared experiences and solutions. Partnering arrangements with other industries may provide opportunities for a more intimate exchange of information and views.

3.2.3 Capturing and sharing knowledge and experiences

Knowledge is the essence of what makes an organisation effective. An organisation's knowledge exists in diverse areas: it is reflected in its procedures, the products it supplies, the project work it undertakes, its operations and the technical papers it produces. Most importantly, however, a good deal of knowledge and 'know how' can be locked in the experience and abilities of the people who make up the organisation's workforce. This aspect of knowledge management is particularly vulnerable to the mobility of staff and the gradually ageing and retirement of members of the workforce. Personnel who have been engaged in an organisation's undertakings build up experience and knowledge that can be lost by the organisation if these people leave, unless there are systems in place to routinely capture it.

The organisation needs to develop a knowledge management system that captures the knowledge and experience of individuals, analyses it, develops it into a usable form and places it on a system for communal benefit. The specific knowledge individuals may have with regard to the elimination and management of NCFSI should be retained in a specific element of the knowledge management system. To assure that new employees, of regulatory bodies, licensee, and suppliers understand the issues and challenges in dealing with NCFSI, knowledge management processes should integrate the knowledge and insights from more experienced personnel related to NCFSI. Partnership arrangements between the licensee and major suppliers in the supply chain are potentially a means of sharing values, knowledge and concerns about problems such as NCFSI and developing a co-ordinated approach to managing and eliminating them. The International Atomic Energy Agency (IAEA) has well established programmes and guidance on knowledge management practices and approaches[1] that should be used to capture and share knowledge and experiences on NCFSI.

4. Licensee Processes and Controls

A robust Quality Assurance Program or Management System provides several barriers to prevent items being purchased, supplied and installed that are not in accordance with applicable regulatory requirements and the design basis. While these programmes and systems provide a substantial barrier to identify non-conforming items, the increased opportunity for supplying and the enhanced capabilities to produce counterfeit and fraudulent items that are difficult to detect may require additional measures to be taken to reinforce these barriers. By implementing these additional barriers, the nuclear industry will be better prepared to prevent counterfeit and fraudulent items impacting on nuclear installations safety. These measures should be designed to:

- Prevent CFSI from entering the qualified supply chain of the nuclear installations.
- Detect CFSI inside of the qualified supply chain
- Prevent installation of CFSI in safety related applications
- Detect CFSI installed in safety related applications
- Detect incidents in safety systems caused by CFSI
- Provide feedback into the licensee systems and broader operating experience to industry.
- Eliminate identified CFSI from the supply chain
- Support the investigation of CFSI incidents
- Respond effectively as a community to CFSI threats and incidents

As discussed previously, training programs for staff involved in design, procurement, and maintenance processes should include the nature of NCSFI, the importance of preventing its use in safety related applications, and techniques that have been found effective at its detection.

4.1 Procurement and Supply Chain Management – Detection of CFSI, placed within context of NCFSI

A critical aspect for controlling NCSFI begins with adequate controls being placed in the procurement programme. A traditional procurement programme is designed to identify and manage nonconforming parts and services. However, CFSI represent an active attempt to hide non-conformances. As a result, a procurement programme should consider additional controls designed to identify CFSI.

4.1.1 <u>Procedures</u>

The procurement management procedures intended to identify and control purchased items and services, including the management of non-conformances should include specific instructions for preventing, detecting, reporting and disposing of CFSI.

4.1.2 <u>Procurement Controls</u>

The procurement process includes a number of steps that are critical to assuring that the introduction of NCFSI into the supply chain is minimised, detected if introduced, or eliminated if possible. Procurement contracts and supporting documents need to be reviewed by the responsible engineers within the procurement organisations and any technical changes confirmed by the responsible design engineer within the organisation responsible for maintaining design control. The review should consider possible impacts or consequences of NCSFI on nuclear safety.

The procurement specifications must be clearly defined with input from the design organisation (Design Engineering or Design Authority) responsible for understanding the intended use of the item being procured. This is a critical step to identify the risk significance, tolerances, legal, administrative, and technical requirements for procured items. These specifications, as a minimum, must:

- Clearly specify the design requirements critical for nuclear safety (technical and administrative) from the original design and require that these requirements are preserved and noting that any changes require customer approval.
- Specify that quality controls and oversight are consistent with nuclear safety significance. Procurement contracts should include controls specifically for CSFI once a supplier has been selected,
- The supplier's non-conformance programme or controls may provide an acceptable method for addressing CFSI. This aspect of the supplier's controls should be within the scope of the qualification process.
- Specify no substitutions without customer approval and should caution the supplier that substitutions have been known to occur in sub-components by sub-tier suppliers. This control should be applied down the supply chain to all sub-tier suppliers.
- Request that the supplier provide information about known incidents of CFSI involving items it provided.
- Provide access for customer procurement engineering and quality control inspections and audit to verify the proper execution of supplier inspection and test plans and procedures. If sub-suppliers are used, this control should be required in the contracts with sub-tier suppliers.
- Include a requirement that the suppliers' procurement specifications to any sub-tier suppliers that may be used to provide the item or any part of the item with an impact on nuclear safety include the relevant technical and administrative specifications of the original procurement documents of the licensee. This provision should be implemented throughout the entire supply chain, from the licensee's original procurement documentation through the procurement documentation to the sub-supplier of the most basic subpart of any item supplied that has an impact on nuclear safety.

4.1.3 Selection and Qualification of Suppliers

Licensees should have established controls for the selection and qualification of suppliers. These controls should be such that the licensee avoids selecting suppliers who may provide CFSI; such as suppliers with poor control over their own supply chain. Further, the selection processes and procedures should assure the qualification of the suppliers to provide the specific parts and services (including calibration, non-destructive examination and testing, analyses, and other service), in accordance with nationally or internationally recognised codes or standards. Also during the selection process CFSI aspects should be included in the supplier's evaluation, for example, by verifying whether the supplier's quality assurance personnel are trained to identify and control CFSI.

Selected suppliers should also be required by contract provisions to have programmes and procedures in place to detect and preclude the use of NCFSI; provide notifications up and down the supply chain of the detection of CFSI in order to identify other potential CSFI and allow the effectiveness of the controls to be assessed; provide needed access to facilities and staff to allow the evaluation of the supplier and sub-tier suppliers like Purchasing Agents by audit or inspection; and verify if suppliers are aware and have provisions to avoid CFSI.

The licensee’s procurement programme should provide control and oversight of suppliers and assure control and oversight of sub-tier suppliers either directly or through the supplier. Control can be provided by several means, such as the right to audit suppliers and sub-tier suppliers within the supply chain, including Parts Agents, warehouse suppliers, and brokers of spare parts. Control and oversight of suppliers and sub-tier suppliers should be consistent with the experience of these suppliers and sub tier suppliers in the nuclear industry.

4.1.4 Evaluation of Suppliers Tenders

The evaluation of suppliers’ tenders provides a critical opportunity to identify and control NCSFI. This is of particular concern when the procurement effort is directed towards a “one off” purchase of something not available in the existing acceptable supply chains. Factors to consider when evaluating suppliers’ tenders include:

- Whether the procurement is an "at-risk" or a “one off” procurement, or an unusual item or service.
- Experiences associated with the continual interface with the suppliers both in the regular supply chain and in “one off” purchases.
- Whether concerns about CFSI are being communicated to every supplier.
- Does the supplier have established anti-CFSI policies and program specified in the QA program
- Look for signs of whether the suppliers may be providing CFSI, such as bids that are significantly lower than other bids or that the item's average unit cost is low. Similarly, significantly faster supply times that other bidders can indicate an increased threat of CSFI.
- Identification of deviations to Technical Specification by the supplier via effective non-conformance processes also provides an indication of an increased potential for NCFSI and may require extra attention by design and procurement engineering to assure the procured item will meet specifications.
- Buyers, purchasing agents, and contract negotiators should be familiar with the issue of CFSI.
- Check existing operating experience or data on CFSI as part of the selection process. Develop and use of the history on operational behaviour of procured components in maintaining supplier’s qualification.

4.1.5 In-Process and Receipt Inspections and Tests, Including Services

Quality control and receipt inspectors, whether in the licensee’s, the supplier’s, or in the sub-supplier’s organisation, perform a critical role in identifying NCSFI through source inspection and receiving inspections. These inspections represent a systematic opportunity to prevent NCSFI from being used in a safety related system. When implementing these inspections, it is important to assure:

- Documentation and traceability of source materials has been established to help identify potential sources of NCSFI
- Inspection and Test Plans include specific checks for NCSFI

- If commercial items are used the inspection and oversight should verify that there is a well defined process being implemented to demonstrate that the components are capable of performing their intended safety functions under the environmental conditions they are expected to perform under (dedicating them for use in nuclear safety applications).
- Receipt Inspection failures include awareness of the potential of a possible CFSI.

4.1.6 *Control of Identified NCFSI*

Controls must be in place to manage NCFSI once it is identified as having entered the procurement process or used in a safety related system. Typically, the controls applied at this point are little different than would be applied to any nonconforming part or service. However, some additional factors that should be considered for control of CFSI include:

- An understanding and knowledge of where and how CFSI or items suspected of being CFSI are reported (such as the plant corrective action system, a national database, or an international database).
- Following a consistent plan of action every time items suspected of being CFSI are identified, including quarantining and controlling items, discretely contacting the supplier and Original Equipment Manufacturer (O.E.M..) to gather additional information about the item within the context of root cause evaluations, and carefully deciding if the suspect items should be returned to the supplier.
- Confirmed CFSI should be segregated and quarantined and not returned to the supplier.
- A sensitivity that known CSFI may be subject to other requirements within the national legislative framework that may require the involvement of police or other judicial processes and procedures.
- Having controls in place such that when a CFSI is installed in a safety related application and is detected, immediate action is taken to assure the safety function is not degraded by replacement with a qualified item or taking actions required consistent with licensing requirements for the affected plant (such as entry into a limiting condition for operation or other technical specification required actions). An operability analysis should be accomplished to justify continued operation. Compensatory measures should be taken until the item is replaced. Design engineering must be involved in any review.
- Consistent with the quality assurance or management programme the degraded condition must be documented.
- Programmatic controls should include provisions for providing a warning to the rest of the industry.

4.2 *Post procurement identification, assessment, and disposition (receipt inspection completed)*

4.2.1 *Control and Supervision of Maintenance Work*

When NCSFI is not identified during the procurement process and is physically onsite (i.e. in stores) or installed in a system, the maintenance staff provides an additional opportunity to identify and remove NCSFI. Training should be conducted for the maintenance personnel such that they are knowledgeable regarding how to effectively compare replacement parts to the installed parts so they can identify unusual deviations or failures of components that are used in safety related applications. Other controls should be developed to improve the contribution that maintenance workers can make identifying NCFSI during their work activities. Items to consider include:

- Including CFSI precautions in pre-job briefings when the work involves items that are identified as obsolete or when CFSI items similar to those being used to complete the work have been identified in the past.
- Emphasising that any discrepancies between installed and replacement items in orientation, labelling, configuration, or other characteristics should be identified and dispositioned before work begins. This includes identification during installation of differences in form or fit of a component.
- Acknowledging the important role that maintenance practices contribute to identifying NCFSI
- Encouraging maintenance staff to inspect replaced or failed components, in particular early or premature failures, for potential problems and additional follow up (i.e. unusual wear or cracking) potentially due to NCSFI.

4.2.2 Reliability and Testing (Surveillance) Programmes

Another opportunity to detect and remove NCSFI by the licensee is through the reliability and testing programmes. Personnel responsible for reliability and testing programmes need to be aware of the potential for NCSFI. Problems with NCSFI may initially appear as a minor reliability issues. Issues to consider in the development and implementation of these programmes include:

- Trending of component performance and failures
- Involving design engineers (design authority) in the evaluation of non-conformances
- Evaluating functional capability (operability analysis) and the need to replace obsolete components
- Considering the extent of condition
- Conducting a thorough root cause analyses of the failure, including the potential for CSFI
- Collaborating with suppliers and/or the O.E.M. when assessing in-service failures (especially early failures) as necessary to determine whether the suspect items are nonconforming, counterfeit or fraudulent.
- Interfacing with operating experience and organisational learning programmes
- Notifying external organisations within the industry and appropriate government agencies that an item is potentially CFSI and of NCFSI issues with safety significance.

5. The Regulators’ Role

NEA/CNRA/R(2011)4 defines distinctions between the regulator’s role and responsibilities and the licensee’s role and responsibilities regarding supplier oversight. “The licensee shall retain primary responsibility for the safety of its licensed facility, including responsibility for those activities of contractors and subcontractors which might affect safety. The regulatory body should, through its regulatory activities, provide assurance that the licensee meets its responsibilities for the safety of its facility. This includes assuring that the licensee provides the appropriate level of oversight of all contractors and subcontractors, commensurate with the safety significance of the activity.”(7)

The regulator, in exercising its responsibilities, needs to proactively assess the licensee's processes to effectively control the supply chain. This should include periodic CFSI process implementation inspections or reviews by the regulator at licensees' facilities. The purposes of these reviews are to:

- sample implementation of the CFSI process in the field;
- communicate regulatory expectations for the CFSI process implementation by the licensee;
- gather feedback on issues encountered in CFSI process implementation;
- solicit improvements in the overall CFSI process

The results of the CFSI process reviews should be discussed with site management prior to departure of the review team[27].

These efforts should include extensive co-operation with other regulators, international authorities, appropriate law enforcement agencies and representatives from relevant industries to gather and share current information on advances in quality improvements and anti-counterfeiting techniques. Countermeasures that should be encouraged at the regulator level include: 1) enhancing regulations and guidance to explicitly address CFSI, 2) assuring the licensees effectively implement their programmes for CFSI, 3) assure appropriate actions are taken by the licensee and its suppliers to prevent recurrence, 4) information gathering, storing and sharing with internal and external stakeholders, 5) having defined expectations and protocols for managing CFSI, and 6) international co-operation.

5.1 Enhancing Regulations and Guidance to Explicitly Address CSFI

The principal role of the regulator is oversight of nuclear safety including the elimination (minimisation) of all types of non-conforming items that can lead to degradation of safety. To achieve this, the regulator needs to have proper legal tools. The regulatory framework typically includes requirements for Quality Management Systems that require measures to identify and correct nonconforming conditions. This regulatory basis is generally broad and has traditionally been considered sufficient to also address measures for CSFI. However, the changing situation in the nuclear supply chain and emerging new challenges suggest the need to do more.

To address the existing dynamics in the supply chain for nuclear facilities, consideration should be given to the development of additional quality assurance regulations or guidance to more explicitly address the CFSI issue. Areas to be considered in such an effort may include:

- Developing a consensus definition of CFSI
- Detailed requirements on avoiding CFSI including the clear responsibility of licensees for verification of new or replacement parts focused on revealing potential CFSI
- Guidance on an appropriate level of oversight an organisation must employ for suppliers and sub-tier suppliers
- Development of unified criteria on recording and reporting requirements for CFSI
- Guidance on actions to be taken to eliminate the detected CFSI.

The Regulatory Body should make arrangements to assess the existing regulatory framework to ensure that existing requirements are adequate to allow the development and introduction of emerging innovation and technology and not serve as a barrier to modernisation. Finally, Regulators may wish to convey expectations that individuals and organisations performing regulated activities establish and maintain a positive safety culture, ensuring that quality and safety have higher priority than costs and schedule, commensurate with the safety and security significance of their activities and the nature and complexity of their organisation's function.

5.2 Information gathering, storing and sharing

The International Atomic Energy Agency's TECDOC-1169[6] provides some guidance on how to apply existing quality assurance programmes to gather and share information on the control of NCFSI. It states: "Significant benefits can be realised by sharing all instances of S/CIs [suspect or counterfeit items] with outside organisations in the nuclear industry. Use of shared S/CI information saves both personnel and financial resources. For instance, learning of S/CIs from a shared information source can assist the facility operator to identify any possible instances and their locations at the nuclear facility. This example would save inspection time and the time to rectify any performance problems should the S/CI fail in-service. Engineering evaluation time and effort can also be reduced through shared testing or analytical results. There are currently a number of organisations that maintain systems with information on operational events, receipt inspection, and other problems that could be useful for S/CI identification"[6].

A review of existing practices has identified some commendable activities that should be considered by regulators as they look to enhance their regulatory framework with regard to NCFSI. These include:

1. Gathering of CFSI–related information. Capturing of CFSI-related information is a topical problem, because many countries do not have laws or other requirements for detecting, reporting and responding to the introduction or use of CSFI. Unlike most other countries, the legal system of the US contains requirements addressed to all entities acting in the nuclear supply chain (including designers, manufacturers and distributors) to inform the NRC and end users (NPPs) about any defects or non-compliances discovered in the components supplied to nuclear facilities. Such a good practice seems to be useful for gathering CFSI-related information in any country.

2. Storing and processing of gathered information. Since the amount of information related to non-conforming items is vast and is continuously growing, only a small part of it can be used practically. Raw operational experience related data should be properly prepared, screened, classified, catalogued, and formatted in a user-friendly shape allowing the relevant data to be easily found, retrieved and used. Established operating experience exchange repositories such as Joint IAEA/NEA International Reporting System for Operating Experience (IRS) and Database of European Clearinghouse for Operational Experience Feedback should be used for this purpose. For example, internet-based repositories of information allowing collecting, maintaining, dissemination, and use the most accurate, up-to-date information on CFSI and suppliers. Some of them are already available (e.g., DOE Suspect/Counterfeit web site (http://hss.energy.gov/csa/csp/sci) or being developed (e. g., Automated CFSI Data Sharing and Processing System designed by EPRI) [3, 13, 26].

3. Sharing of experiences collected with the international community. The Incident Reporting System (IRS) is a worldwide system designed to complement national schemes for reporting, assessing, analysing and providing feedback on information about safety significant unusual events to operators to prevent similar occurrences. If effectively populated, this system should be an important forum for information sharing and organisational learning on CFSI. Unfortunately, as insightful as this system has proven to be, currently there are only a few instances of counterfeit items, confirmed or suspected, entered into the IRS database. NEA and IAEA worked together to add a code, 5.7.6 "CSFI – Counterfeit, Suspect, Fraudulent Items," specifically identifying CSFI to facilitate reporting and the international nuclear community should be encouraged to utilise this resource to its full potential. This code will be included in the next

update to the IRS coding guideline[20]. Additionally, regulators should periodically review available CSFI information to respond to emerging CFSI occurrences and trends. There is also benefit to working internationally to review relevant CFSI experience, and share lessons learned from responding to these events. Periodic discussions targeting CSFI by the NEA's WGOE will be useful in sharing international experience on NCFSI issues.

5.3 Approaches to Managing CFSI

Monitoring and utilising the global supply chain is an enormous and complex task that requires transparent exchanges of information, close connections to industry experts, and co-operation between government agencies and law enforcement officials. The historic reactive approaches towards CFSI occurrences simply may not be sufficient to combat the challenges this industry may be facing from a highly technological, fully modernised supply chain. Regulators may wish to respond to the challenges of a global supply chain by leveraging the advantages of the technologies at our disposal and draw from collective resources and capabilities as well as learning from other industries. In general, the best CFSI prevention practices include implementing institutional counterfeit avoidance policies and procedures, counterfeit part detection training programs, and internal and external communication processes [1].

An EU founded project, SToP (Stop Tampering of Products), that is aimed at developing intelligence-based and network-oriented systems for the efficient and secure authentication of products is an example of a good practice for managing NCFSI [21]. Using auto-identification technologies (such as RFID - Radio Frequency Identification), the project suggests applicable standards and proposes a secure RFID method and guidelines to prevent counterfeiting in different areas, especially in the aviation industry [22]. This helps to detect counterfeit products as early as possible or even prevent them from entering the supply chain in the first place. As a network-based solution, it supports the alignment and sharing of information of with stakeholders. It encourages information sharing on counterfeiting related problems and promotes closer co-operation. It also improves communication with consumers, providing them with better ways of risk mitigation and education.

Another example is the AIA Counterfeit Parts-Integrated Project Team (CP-IPT) that developed a report with specific recommendations to be used by both the aerospace and defence industry and the U.S. government. This report covers procurement, reporting, disposition, obsolescence and electronic waste [23].

Aiming to provide uniform requirements, practices and methods to mitigate the risks of receiving and installing counterfeit electronic parts the SAE standard AS5553 was developed [24]. This document is intended for use in aviation, space, defence, and other high performance/reliability electronic equipment applications by all contracting organisations that procure electronic parts, whether such parts are procured directly or integrated into electronic assemblies or equipment. The requirements of this standard are generic and intended to be applied and flowed down to all organisations that procure electronic parts, regardless of type, size, and product provided.

5.4 International Co-operation

NEA/CNRA/R(2011)4 states: "As contracted services change and licensees modify their oversight and procurement practices, regulatory bodies must also continually adapt to maintain their effectiveness in the assessment of the licensee's contracting practices in an increasingly international supply market. Such improvements in the oversight process facilitate the ongoing multinational work to evaluate and eventually increase harmonisation in designs, regulations, standards and quality requirements that is now being supported by many of the regulatory bodies and by industry. Continued and increased international co-ordination and co-operation among regulatory bodies through the collection and dissemination of inspection findings, operating and construction experience, lessons learnt, and information related to substandard contractor products and services, including the timely identification and communication of information on counterfeit, fraudulent and substandard parts, is paramount. These efforts enhance regulatory effectiveness and efficiency in all countries without diminishing regulatory independence”[7].

The resources of the Multi-National Design Evaluation Programme (MDEP), Vendor Inspection Co-operation Working Group (VICWG) needs to be leveraged so that regulators can work together to improve the quality and effectiveness of global supplier inspections, and to identify and resolve international barriers to performing these inspections. Based on the work so far, regulators can review the results of vendor inspections to help understand the scope of regulatory oversight, issues identified at the vendors, and potential vulnerabilities that could impact their licensees. Regulators are encouraged to actively participate in this working group.

5.5 Established Response Protocols

Efficient co-operation between organisations needs to be extended to responsible investigative and law enforcement organisations, to ensure that these essential activities are not encumbered by external influences or international legal frameworks that could detract from the regulators’ mission to ensure adequate protection of public health and safety. Regulators should proactively review established treaties, agreements and protocols to understand how co-operation and co-ordination amongst nuclear regulators and investigation/law enforcement personnel can be utilised to pursue and prosecute counterfeiters. The establishment of communication chains and protocols within each country will greatly facilitate the actions necessary to accomplish this goal.

6. Conclusions and Recommendations

The term ‘‘quality assurance’ when applied to the commercial nuclear industry, encompasses a wide array of planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily, during both routine service conditions, and under postulated accident scenarios. Achieving such a level of confidence can be an exceptionally daunting task given the levels of risk introduced by the complexity of an item and/or the source from where it was obtained. These risks can usually be appropriately managed through effective supplier selection, supplier performance, and effective supplier oversight programs, passed down through the nuclear supply chain. Each tier of the supply chain relies on the preceding supplier to verify and document the quality of the item before it is passed along. Each tier in-turn performs a receipt inspection to assure the item meets their technical and quality requirements. The accompanying documentation plays a vital role in these decisions, but the quality of the supplied item can only be achieved through verification. The more the validity and capabilities of the supply chain is verified, the more trust can be given to the documentation. When any of these processes are violated, as is the case with counterfeit or fraudulent items, that developed trust that has become inherent to the program is lost, and the risk the item will not perform its intended functions, either in-service or during a postulated event is also lost.

Unquestionably, a distinction exists between poor performance from a conscientious supplier and a willful intent to deceive the purchaser from an unscrupulous one. It is precisely for this reason that the nonconformance process must take two equally distinct resolution paths. Managing a supplier’s poor performance, including development, implementation and verification of these processes, should continue to be activities essential to address conventional quality issues. Effective anti-CFSI techniques however, will require quick and accurate identification attained through heightened awareness, enhanced skill sets, improved detection tools and close co-ordination amongst stakeholders.

The commercial nuclear industry is not currently seeing CFSI occurrences in safety related applications however, in recognition of the potential implications of adverse trends in global supply chains, combined with anticipated increases in procurement activities associated with new reactors, we feel it is both prudent and warranted at this time to take deliberate efforts at understanding how both the regulator and industry would address any new challenges from CFSI.

Key Messages:

1. NCFSI is a serious threat to nuclear safety.

2. The regulatory bodies and operators need to be informed of the nature of CFSI.

3. Existing operator quality and management system controls for procurement and nonconforming material control may need to be enhanced to address the deliberate deception involved in CFSI and the advances in counterfeiting technology. As such, additional controls may need to be put in place throughout the supply chain and internal to the operator's management system to identify and remove CFSI in the nuclear industry supply chain. These controls include not only procurement and material management, but also operations, maintenance, and engineering processes.

4. Regulators need to be aware of the risk of NCSFI to nuclear safety and review and update their regulatory requirements accordingly.

5. Exchange of NCFSI information between regulators and operators should include information exchange with organisations outside of the nuclear industry.

Recommendations:

1. The regulatory body should consider the impact of NCFSI on their current regulatory requirements, and revise them if necessary.

2. The regulatory body's inspection programs should consider methods for inspecting for NCFSI controls.

3. The Vendor Inspection Co-operation Working Group (VICWG) of the Multinational Design Evaluation Program (MDEP) should consider how to address the issue of CFSI within the context of its activities.

4. The NEA CNRA Working Group on Inspection Practices (WGIP) and the Working Group on Operating Experience (WGOE) should consider including within the scope of their mandates the periodic reviews on how the international nuclear safety community is addressing the issues with CFSI in the nuclear industry's supply chain.

5. The NEA CNRA WGOE should consider developing criteria for reporting CFSI within the context of operating experience databases (both national and international databases).

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ANNEX: COMMENDABLE PRACTICES

1. Due to the inherent uncertainty in the performance of a counterfeit or fraudulent item, these items should be removed from service and replaced with qualified and acceptable items as soon as practicable.

2. New information on how to reduce the potential for introduction of counterfeit parts into the nuclear industry supply chains that is continually being developed should be collected and incorporated into licensees' training programmes for procurement and quality assurance staff, and into their procurement procedures and processes. External sources of information from national agencies, law enforcement organisations and manufacturing trade organisations should be used to augment program training to include current advances in counterfeiting and anti-counterfeiting techniques. Partnering arrangements with other industries may provide opportunities for a more intimate exchange of information and views.

3. CSFI training of both industry and regulatory staff is key to preventing and detecting counterfeit and fraudulent components that could affect NPP safety. Training however, should not be restricted to just receiving dock personnel, or QA inspectors, but should be shared throughout all levels of the procurement process, from design through operations and maintenance. Training should include an emphasis to educate suppliers new to the commercial nuclear community to make them aware of the special requirements and nuances of supplying goods and services under unique nuclear industry requirements. CFSI training should address each individual's roles and responsibilities in identifying potential CFSI. Specific training should be considered for:

    - The detection of installed CFSI
    - Identifying CFSI during receipt and inspection
    - Using CFSI information within the procurement process
    - Including the potential for CFSI as a factor in component failures

4. Effective regulatory oversight of NCFSI includes requirements for regular assessments of licensee and supplier internal processes ranging from access to product designs to manufacturing facility security. CFSI–related information should be gathered, stored and processed, then shared with the international community. This can be accomplished using the International Reporting System for Operating Experience (IRS), that now includes a code, 5.7.6 "CSFI – Counterfeit, Suspect, Fraudulent Items," specifically identifying CFSI to facilitate reporting and the international nuclear community should be encouraged to utilise this resource to its full potential. Countermeasures that should be encouraged at the regulator level include: 1) enhancing regulations and guidance to explicitly address CFSI, 2) assuring the licensees effectively implement their programmes for CFSI, 3) assure appropriate actions are taken by the licensee and its suppliers to prevent recurrence, 4) information gathering, storing and sharing with internal and external stakeholders, 5) having defined expectations and protocols for managing CFSI, and 6) international co-operation. To address the existing dynamics in the supply chain for nuclear facilities, consideration should be given to the development of additional quality assurance regulations or guidance to more explicitly address the CFSI issue. Areas to be considered in such an effort may include:

    - Developing a consensus definition of CFSI

- Detailed requirements on avoiding CFSI including the clear responsibility of licensees for verification of new or replacement parts focused on revealing potential CFSI
- Guidance on an appropriate level of oversight an organisation must employ for suppliers and sub-tier suppliers
- Development of unified criteria on recording and reporting requirements for CFSI
- Guidance on actions to be taken to eliminate the detected CFSI.

5. During the supplier selection process CFSI aspects should be included in the evaluation of the supplier, for example, by verifying whether the supplier’s quality assurance personnel are trained to identify and control CFSI. Selected suppliers should also be required by contract provisions to have programmes and procedures in place to detect and preclude the use of NCFSI; provide notifications up and down the supply chain of the detection of CFSI in order to identify other potential CSFI and allow the effectiveness of the controls to be assessed; provide needed access to facilities and staff to allow the evaluation of the supplier and sub-tier suppliers like Purchasing Agents by audit or inspection; and verify if suppliers are aware and have provisions to avoid CFSI. Some practices to consider also include instituting extra measures when purchasing from independent distributors such as internal and external validation and testing requirements, and part-authenticity documentation—such as certificates of conformance. When alternate sources must be used due to obsolescence, schedule, or other reasons, the procurements should be flagged as “at-risk” so that appropriate precautions may be taken to ensure authenticity of items. Use of organisations certified to a recognised quality standard will help to maintain consistency. A commendable practice used in some countries is that several licensees act together as intelligent customers sharing parts of procurement activity such as: audits and oversight of suppliers, receipt inspections and tests, NCFSI data bases, etc. In this way, there is a larger resource available to more effectively and consistently oversee the supply chain and facilitate the sharing of experiences with NCFSI.

6. Factors to consider when evaluating suppliers’ tenders include:

- Whether the procurement is an "at-risk" or a “one off” procurement, or an unusual item or service.
- Experiences associated with the continual interface with the suppliers both in the regular supply chain and in “one off” purchases.
- Whether concerns about CFSI are being communicated to every supplier.
- Does the supplier have established anti-CFSI policies and program specified in the QA program
- Look for signs of whether the suppliers may be providing CFSI, such as bids that are significantly lower than other bids or that the item's average unit cost is low. Similarly, significantly faster supply times that other bidders can indicate an increased threat of CSFI.
- Identification of deviations to Technical Specification by the supplier via an effective non-conformance process also provides an indication of an increased potential for NCFSI and may require extra attention by design and procurement engineering to assure the procured item will meet specifications.
- Buyers, purchasing agents, and contract negotiators should be familiar with the issue of CFSI.

- Check existing operating experience or data on CFSI as part of the selection process. Develop and use of the history on operational behaviour of procured components in maintaining supplier's qualification.

7. The licensee has responsibility for developing and promoting an appropriate nuclear safety culture within the licensee's organisation and also fostering a nuclear safety culture within the supply chain as a whole.

8. Being an intelligent customer requires a sufficient depth of knowledge and understanding to appreciate what is required, what the specifications for procured items should be and whether the supplier has met those requirements. The licensee, as the intelligent customer with prime responsibility for nuclear safety, should communicate with essential elements of its supply chain (i.e., through its contract language or during periodic audits of suppliers) to ensure that a similar appreciation of what being an intelligent customer means pervades the whole supply chain. The licensee when discharging the responsibility for nuclear safety should confirm that suppliers throughout the supply chain are aware of the importance of using and complying with appropriate technical and quality standards. The licensee, together with vendors and suppliers in the supply chain, must educate their staff to understand the threat from NCFSI and have appropriate training programmes in place.

9. An intelligent supplier must demonstrate that there is a full understanding and appreciation of what the requirements are for the items to be supplied and of the consequences of failing to deliver to those requirements.

10. Suppliers may have their own supply chain and they need to be vigilant in preventing NCFSI from entering their overall deliveries and be insistent on having robust processes and procedures which are strictly adhered to.

11. The specific knowledge individuals may have with regard to the elimination and management of NCFSI should be retained in a specific element of the knowledge management system. The International Atomic Energy Agency (IAEA) has well established programmes and guidance on knowledge management practices and approaches[1] that should be used to capture and share knowledge and experiences on NCFSI.

12. Additional factors that should be considered for control of CFSI include:

    - An understanding and knowledge of where and how CFSI or items suspected of being CFSI are reported (such as the plant corrective action system, a national database, or an international database).
    - Following a consistent plan of action every time items suspected of being CFSI are identified, including quarantining and controlling items, discretely contacting the supplier and Original Equipment Manufacturer (O.E.M.) to gather additional information about the item within the context of root cause evaluations, and carefully deciding if the suspect items should be returned to the supplier.
    - Confirmed CFSI should be segregated and quarantined and not returned to the supplier.

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[1] http://www.iaea.org/nuclearenergy/nuclearknowledge/AboutNKM.html provides a link to the IAEA Knowledge Management Section's webpage.

- A sensitivity that known CSFI may be subject to other requirements within the national legislative framework that may require the involvement of police or other judicial processes and procedures.
- Having controls in place such that when a CFSI is installed in a safety related application and is detected, immediate action is taken to assure the safety function is not degraded by replacement with a qualified item or taking actions required consistent with licensing requirements for the affected plant (such as entry into a limiting condition for operation or other technical specification required actions). An operability analysis should be accomplished to justify continued operation. Compensatory measures should be taken until the item is replaced. Design engineering must be involved in any review.
- Consistent with the quality assurance or management programme the degraded condition must be documented.
- Programmatic controls should include provisions for providing a warning to the rest of the industry.