Chapter 6. Supply Chain Management

Governance	Assurance	Improvement
•2.3 Document Control •2.4 Records Mgmt •2.6 Customer facing quality documents •2.7 Establishes Quality Control regimes •2.9 Complies with a quality process	•3.1 Internal audit •3.2 External audit •3.4 Production process qualification •3.5 Quality Reporting •3.6 Verifies materials and supplied product •3.7 Certifies own product to customer •3.8 Supply chain quality •3.9 Project quality	•4.1 Quality Improvement •4.2 Customer satisfaction

Contents

6.1 Introduction

This chapter will provide an overview of key considerations to be applied to supply chain management within the Nuclear Industry. The content derives from experience relating to conventional nuclear licensed sites where there is an actual or prospective Licensee.

Few Licensees have the capabilities to undertake all their development, operation and support requirements from within their own organisation, so they seek support from specialist supply chain organisations. Developers and operators of nuclear facilities aim to deliver their objectives safely, securely, reliably and predictably. As such, they require their supply chain to deliver products and services safely, to schedule, of the correct Quality and to the agreed cost. Supply chain management is required to ensure effective delivery to the Licensee's specified intent.

Supply chain management in the nuclear industry requires effective arrangements to ensure control of the full acquisition cycle from specification of requirements, sourcing of suppliers, manufacture, delivery and installation or storage as appropriate. It will also include contract management arrangements to oversee and assure delivery.

A significant issue in the nuclear industry is the Licensee's absolute responsibility under the Nuclear Installations Act [1]. ONR's expectation is that the Licensee will be able to demonstrate an 'Intelligent Customer' Capability [2]. The Licensee should not solely rely on the specialist supply chain to deliver their requirements without oversight. They need to maintain sufficient knowledge and resources to ensure that they can manage the supply chain. This includes specifying and overseeing delivery in line with the nuclear facility design intent and safety case. ONR's expectations are described in the following two Technical Assessment Guides:

- NS-TAST-GD-049 Licensee Core Safety and Intelligent Customer Capabilities [3].
- NS-TAST-GD-077. Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services [4].

A UK industry guide on the Intelligent Customer Role [5] has been produced on behalf of the Nuclear Industry Safety Directors Forum (SDF).

6.1.1 Standards and Guides

ISO 9001:2015 [6] is the most commonly specified management system standard in the procurement of significant products and services. Major nuclear industry suppliers are normally certified to ISO 9001.

There is a growing interest in the use of ISO 19443:2018 [7] in the UK nuclear industry. This standard contains a number of additional requirements compared to ISO 9001:2015 specific to the nuclear industry, in particular:

- Giving adequate consideration to nuclear safety in the quality policy;
- Ensuring an appropriate nuclear safety culture is established;
- The determination of items important to nuclear safety (ITNS);
- The application of a Graded Approach to quality requirements commensurate with nuclear safety significance (see section 6.4 and Chapter 3);
- Effective management of changes and resources to ensure nuclear safety is not compromised;
- Training of persons involved in the provision of ITNS products or services on the importance of their tasks that includes the potential nuclear safety consequences of errors;
- Preventing counterfeit, fraudulent or suspect items (CFSI);
- Additional requirements relating to Design and development of products and services, Control of externally provided processes, products and services, Production and service provision, Release of products and services and Control of nonconforming outputs;
- Performance evaluation to include nuclear safety aspects;
- Internal audit to include evaluation of conformity to customer requirements;
- Management review to give attention to nuclear safety and consider lessons learned from nuclear experience as an input;
- Continual improvement to encompass nuclear safety culture.

Many licensees and major industry suppliers have developed their own specifications based on ISO 9001 but with additional requirements. The additional requirements reflect nuclear safety issues and the need for very high standards of safety, environmental and security management, when working on licensed sites. Additional requirements are normally specified on a graded basis with nuclear safety significance of the product or service being the major concern. The additional quality management requirements typically address topics such as:

- Arrangements for qualifying key personnel involved in important safety and quality related activities;
- The production and submission of contract specific Quality Plans;
- Document submission and approval requirements for important activities such as design, construction, manufacture, installation, commissioning and decommissioning;
- Inspection, surveillance and audit requirements;
- Records to be provided, stored and preserved by the supplier (Lifetime Records LTR).

The Nuclear Industry Association (NIA) has produced a helpful introductory guide called the Essential Guide for the Nuclear New Build Supply Chain [8]. The NIA guide includes sections on “Quality Arrangements” and “Codes and Standards”.

The Nuclear Institutes Safety Directors Forum Supply Chain Quality Working Group has produced good practice guides on Supply Chain Quality [9] and Supply Chain Mapping [10].

6.1.2 Role of Quality Professionals in Procurement Activities

Quality professionals undertake a number of important activities in relation to procurement, such as:

- Ensuring that licensees and suppliers establish and implement robust procurement processes including mitigation of Counterfeit, Fraudulent or Suspect Items (CFSI) [11], [12], [13], [14];
- Assisting with the preparation and review of specifications, particularly in relation to Quality management requirements;
- Helping to establish suitable criteria for the assessment and selection of suppliers;
- Carrying out pre-contract supplier assessments;
- Producing Quality Plans and monitoring their implementation;
- Reviewing document and records submissions;
- Carrying out appropriate levels of assurance and oversight, including on-site and off-site inspections, surveillance visits and audits;
- Assisting with the management of non-conforming items and products;
- Document and records management including long-term preservation;
- Assisting the flow down of licensee requirements to all levels of the supply chain;
- The promotion of a proactive nuclear safety culture including encouraging a questioning attitude.

6.2 Globalisation

The globalisation of supply chains provides significant value opportunities as more companies compete for work in the global nuclear market. While globalisation provides value opportunities, it also has associated risks as vendors with little or no experience of the nuclear industry or its standards and requirements enter the markets to compete for work in the lucrative new build, operations and decommissioning sectors.

Supply chain management professionals in the nuclear industry need to be aware of both the opportunities available and associated risks to enable effective decision making and implementation of appropriate risk mitigation measures, including:

- Lack of nuclear awareness;
- Lack of knowledge of enhanced Quality requirements;
- Counterfeit Fraudulent & Suspect items (CFSI);
- Economic uncertainty;
- Data integrity & Quality;
- Political / Governments changes;

- Supplier consistency;
- Security requirements.

The cost-benefit analysis and justification of utilising global supply chains needs to consider and include not just the opportunities, but also the cost of risk mitigations.

One of the most significant risks of globalisation related to nuclear supply chain management is the opportunity for counterfeit, fraudulent or suspect items entering nuclear facilities. The risks can be increased as pressure is applied to the prime contractor to reduce costs, influencing the contractor to source cheaper suppliers, potentially without the required levels of controls or assurance arrangements that could be considered an unnecessary overhead by some suppliers.

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John Ruskin, 1819-1900, British philosopher, prominent social thinker and philanthropist

Nuclear developers and operators should have arrangements in place to effectively procure goods and services with the appropriate levels of controls to assure delivery to specified requirements. Traditionally designed to identify substandard product, these assurance arrangements now play a key part in the mitigation measures to prevent the procurement of counterfeit, fraudulent and suspect items (CFSI). Counterfeit, fraudulent and suspect items can be challenging to detect and may require more intrusive testing and controls such as material identification, product testing and traceability to original source.

The most important mitigation measure is to ensure that the supply chain are trained and competent to perform their roles.

Licensees and their contractors need to utilise suppliers with a proven track record of delivery or, if utilising a new supplier, carry out as assessment in advance of contract placement. The assessment needs to confirm that there are appropriate management systems in place that include adequate control of subcontractors and suppliers. Supply chain assurance arrangements, such as performance measures, inspection, surveillance and audits, need to test for substandard product and to examine the potential for CFSI.

The implications of CFSI products being installed in nuclear applications and failing to meet design and safety case intent can have very significant implications for nuclear safety.

Case study

In South Korea in 2012, eight companies were accused of supplying 60 forged quality control certificates to Korea Hydro and Nuclear Power (KHNP) since 2002. The affected equipment comprised mainly fuses, switches and cooling fans. Another case discovered in 2013 involved false test certificates for safety-related cabling. One hundred people were indicted in 2013, including some senior management at KHNP. In a parallel case, prosecutors investigated KHNP's procurement functions and uncovered corruption among suppliers, brokers and company personnel. Over 7500 reactor parts were replaced at nuclear power plants on the orders of the Nuclear Safety and Security Commission at an additional cost of about $90 million. [*World Nuclear Association - Supply Chain Working Group: Countering Counterfeit, Fraudulent and Suspect Items in the Nuclear Supply Chain*]

6.3 Specifications

Effective specification of requirement is probably the most important aspect of the acquisition process. An ineffective specification will mean that the supply chain will find it difficult to deliver the Licensee's requirement right first time leading to delays, wastes and inevitable cost escalation. Equally, over-specification can lead to 'gold-plating' which increases complexity, adds production risks, increases lead-times and drives up cost without adding value. BS 7373-1:2001 [15] gives guidance on the layout and preparation of specifications.

Given the importance of the specification, it is key that those writing, reviewing and approving a specification are trained and competent to perform their task. The competence of specification authors will depend on the nature of the product being procured. Professional engineers are required for design activities relating to complex construction projects. This type of work could be subject to independent verification and validation. The procurement of replacement plant and equipment as part of operational maintenance does not usually require the same level of scrutiny. In the latter case, it is important that the person creating the demand ensures that requirements are effectively specified by consulting with competent professionals who understand the design and safety case requirements of the plant, equipment or service.

Specifications can be considered into two major categories:

6.3.1 Technical Specification

Describes the features, characteristics and properties of a product and gives all the information that is required to create it. Typically, procurement of physical assets will require a technical specification. Such a document would contain the defined functional requirements (performance, safety etc.) and the physical definition of the product within design documents, drawings and standards.

6.3.2 Functional Specification

Details the requirements in terms of features, characteristics, process conditions, limits and exclusions, defining the performance of the product. Typically, a functional specification will be used to specify work to deliver a study, design or project. A functional specification may be used for the supply of an asset, where performance is the prime objective, and its physical attributes are not.

6.4 Graded Approach

Nuclear Licensees and their supply chain are encouraged to apply a graded approach to procurement of goods and services. The graded approach ensures the effective use of resources through the deployment of appropriate levels of assurance and oversight, commensurate with the level of risk associated with failure of a procured item in use or service.

Higher levels of assurance, such as prequalification, auditing, inspection prior to product release, are deployed on higher risk products or services. Lower levels of assurance are deployed on activities with a lower measured risk such as receipt inspection of product and records.

Activities or products with little perceived risk or only minor commercial consequence if inadequately supplied may result in no implemented assurance measures other than for normal commercial transactions or receipt of stock.

When applying a graded approach, Licensees typically consider the following:

- The magnitude of the potential consequences if a product fails or an activity is carried out incorrectly;
- The significance and complexity of each product or activity;
- The hazards and the magnitude of the potential impact (risks) associated with the safety, health, environment, security, quality and economic elements of each product or activity.

For further information on the graded approach, see Chapter 3 (Leadership and Management).

6.5 Sourcing and Procurement

The sourcing of suitable suppliers or contractors in the nuclear industry follows common key principles but could be subject to certain legal constraints.

All suppliers, whether competing for significant Engineering, Procurement and Construction (EPC) contracts or less financially significant products and services, will be assessed on their ability to deliver against predefined criteria. The criteria will test the supplier's ability to

meet the specified requirements and may include the provision of information from the supplier that provides objective evidence of their capability to deliver the required product or service. IAEA GS-G-3.1 [16] includes general guidance on nuclear industry procurement practices.

Any supplier evaluation would examine a series of factors such as the following:

- Cost;
- Supplier's management systems controlling their quality, safety, environmental and security systems;
- Quality performance and technical capability;
- Nuclear safety culture;
- The supplier's past achievements;
- References supporting work carried out which is similar to the intended scope;
- Supplier's legal and financial status.

The initial assessment of a supplier should be a desktop exercise which focuses on the needs of the particular project package and be proportionate to the risks, size and complexity of the work.

This initial assessment should assist in determining the extent of any further evaluation required. The likelihood of a potential supplier failing to fulfil requirements is dependent not only on the nature of the product or service to be provided, but also on the circumstances under which they are expected to provide them. The risks to the purchaser of suppliers failing to meet requirements will depend on the criticality of the requirements. It may be necessary to identify the potential for things to go wrong, the likelihood of them doing so and the impact of the failure.

The options available for evaluation might be one or a combination of the following:

- Questionnaire/feedback data;
- External references;
- Interview with buyer/project team;
- Technical appraisal;
- Commercial appraisal;
- Full systems and capability audit.

Many companies will maintain relationship with a group of suppliers with which they routinely do business. The suppliers would be subject to ongoing performance review after initial selection and evaluation to ensure they continue to deliver in line with the customer's success criteria. This grouping of suppliers is often referred to as a 'Preferred Suppliers'

listing. Many suppliers will inquire with potential customers as to how they can be evaluated to become a preferred supplier.

Maintaining a preferred supplier listing is an effective way of managing a restricted group of suppliers for future procurements. Preferred Suppliers have the benefit of reducing supply chain risks as a result of a proven track record of supply, however their use reduces competition and innovation. The use of Preferred Suppliers is also not an option available to all Licensees in the Nuclear Sector as many will have to compete contracts above a certain value, in line with the requirements of the national legislation and policy [17].

6.6 Contract Management

The level of post contract management deployed by the Licensee or supplier should be commensurate with the graded approach to procurement and risk if the product or service failed to meet the intent. The higher the identified risk the more intrusive or more frequent the methods of contract management and oversight.

Contract management of the supply chain will also be impacted by the performance of the supplier or supply chain. If a supplier can demonstrate delivery to requirements right first time, every time then the Licensee or sub-supplier may adjust the level of oversight as appropriate. This can often be the case with manufacturing suppliers who may make large volumes of key components or equipment and have good control of their processes, demonstrating compliance using statistical techniques. In such instances the purchaser may rely on records to demonstrate compliance and resort to sampling methods to monitor effective delivery of requirements, rather than deploying intrusive audit and inspection at the manufacturer's facilities.

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The Licensee has the responsibility for defining the overall supply chain Quality arrangements. A key challenge is to ensure that the arrangements for the higher risk products and services flow down in a transparent manner through the supply chain.

At the top of the supply chain, it is the Licensee who will define the Quality requirements in their tier-1 contracts. It then becomes the responsibility of the tier-1 supplier and below to ensure that they flow or cascade these arrangements, as appropriate, down the supply chain to tier- 'n'. Each tier within the supply chain should be made aware of, and understand, the nuclear safety significance of the work they are performing or the product

and service they are delivering. The Licensee will deploy appropriate oversight to ensure this happens effectively.

6.6.1 Methods of Oversight

There are many methods of performing supply chain oversight and assurance when the contract has been placed and during delivery or manufacture of the product or service. Organisations are likely to deploy a combination of approaches dependent on the scope of supply that could include:

- **Contract Review**. Meetings between the supplier and purchaser that would review quality, cost and schedule issues specific to the contract. They could consider technical matters such as: specification changes; approvals of design and engineering outputs or approval of manufacturing and test requirements; discussions on deviations and concessions; performance against key performance indicators etc.
- **Supplier Relationship Management.** Used to ensure effective relationship between the supplier and purchaser throughout any contract period. Many large suppliers provide multiple products and services to Licensees and often discussions only take place on a contract-by-contract basis. Relationship management is often deployed at a more strategic level to ensure that both supplier and purchaser are aware of each other's organizational issues (capacity, expansion, profitability etc.) and work in a collaborative way throughout the lifetime of multiple contracts to ensure that potential issues are resolved prior to creating any impact on product or service delivery.
- **Quality Plans**. May be used to control manufacture, design, fabrication or service delivery stages requiring the identification and agreement of hold points that the supplier may not progress beyond without independent or purchaser witnessing, inspection or approval.
  Quality plans allow the purchaser to check in advance that the supplier has fully understood the detailed requirements of the specification, and that the supplier has in place the necessary assurance activities to deliver items that will meet the specification.
- **Assessment/Audit**. An organisation's management system may have been subject to review during the sourcing phase. The ongoing effective deployment of these arrangements may be subject to routine assessment by the Licensee, purchaser or by independent third-party organisations performing audits on the purchaser's behalf. The audits would assess compliance with best practice management system standards and / or contract specific requirements.
  Suppliers working on Nuclear Licensed sites would expect to be subject to increased scrutiny, audit and assessment to ensure compliance with specific health and safety requirements associated with working within the Licensee's facility.
- **Vendor Analysis**. Throughout the contract period, performance data can be collated on suppliers against contract success criteria, often dominated by delivery to the

correct quality, on schedule and at the correct cost. Qualitative and quantitative data is utilised to demonstrate the required performance or when remedial measures are required. Vendor analysis is often used to rank and rate suppliers and maintain preferred status if applicable.

6.7 Product and Service Completion

6.7.1 Inspection and Test

The level of inspection and test deployed on product or service completion will be defined dependent on the nuclear safety significance and the graded approach to procurement.

For products with a high impact on nuclear safety this final review may include verification or independent assessment by the Licensee, customer or a third-party assessor.

For the product or service release process to be managed effectively, it is essential that suppliers carry out their activities in a controlled manner utilising quality plans as appropriate and verify that all specified procurement requirements or technical characteristics have been satisfied before offering an item or service for acceptance and release. It is important to ensure that the purchaser states clearly the intended inspection and verification requirements and method of product release in the purchasing information to ensure that the supplier and purchaser are appropriately prepared prior to contract placement.

The supplier and purchaser must ensure that those involved in the release of products and services are trained and competent to perform their role and have available training records to demonstrate the currency of their qualifications (e.g., non-destructive testing qualifications).

6.7.2 Concession and Open Reporting of Failure

It is important to develop a culture where suppliers are encouraged to identify non-conformance or failures. The alternative, the hiding of errors and uncontrolled repairs, could have an impact on nuclear safety. While the objective of the purchaser and supplier needs to be on right first-time delivery, it is important to recognise that people can make mistakes and when this happens, appropriate corrective action takes place.

The identification, reporting and resolution of deviations should not be seen as negative but as an indication that the achievement of the purchaser's requirements is of prime importance. The control of any deviation from the technical specification is fundamental to the achievement of Quality and therefore the integrity of the item.

Purchasers at each level of the supply chain should ensure that their suppliers have adequate arrangements for the identification, categorisation and disposition of deviations for items or services. These should include obtaining the approval of the purchaser for the

deviation in the form of a Concession, Production Permit or procedure for re-work, and informing the ultimate Licensee / Regulator for deviations that are significant to nuclear safety.

Production Permits are typically proactive and are used when a contactor requests permission to deviate from what has been originally specified. This may be due to availability of materials, manpower, cost, or innovations, new methods or technology etc. If the client approves, then the work can continue as stated in the Production Permit.

A Concession typically results from a non-conformance and is reactive. Concessions are used when an activity has already been carried out but has produced a result not compliant with the specification. In this case, the contractor would put forward a Concession to the client explaining the detail of the work. This would then be assessed by the client as to whether the work can be accepted, taking into consideration nuclear safety and the function of the equipment/item being supplied. The nuclear industry should strive for zero Concessions.

An effective method of recording Concessions and Production Permits is essential to ensure that any deviations to specified intent are captured and traceable back to the specification and competent authority who can give permission to proceed.

It is imperative that the Operator of nuclear equipment has a full and transparent record of the 'as-built' condition of equipment, and as such, all records of deviations must be fully traceable and included in the records handed over to the purchaser on completion.

6.7.3 Storage

For many new nuclear facilities, the period from procurement to operation can be several years. Despite efforts to build off site, many components will need to be stored and assembled on site and therefore items should be controlled from receipt to storage, handling and use, preventing their abuse, misuse, damage, deterioration or loss of identification.

Where possible, items that arrive at the purchaser facility should be visually inspected before unloading to verify that there is no damage.

Clean conditions are required and is often a term used to define locations or activities where rigorous material controls are necessary. Examples of controls are :

- Protection from material incompatibility, e.g., storage of stainless steel piping on carbon steel shelving with a segregation layer of inert material;
- Storage in controlled or inert atmospheres to prevent materials degradation;
- Avoidance of in-core debris by control of what goes in and out of the reactor housing, e.g. 100% component inventory, including assay of fixings such as nuts, bolts and consumables.

Storage should be provided to segregate and protect items prior to their installation and use. Guidance is provided in IAEA GS-G-3.5 [18]. The methods and conditions of storage to prevent corrosion, contamination, deterioration and physical damage should be established and controlled, with account taken of aspects such as:

- Access;
- Cleanliness and housekeeping practices;
- Requirements for fire protection;
- Identification and marking of items;
- Protective requirements relating to coatings, preservatives, covers and sleeves;
- Prevention of physical damage;
- Removal from and return to storage;
- Environmental control (such as temperature and humidity);
- Preventive maintenance;
- Security;
- Items that have limited shelf life or service life;
- Physical and chemical characteristics of items;
- Safety grades;
- Segregation.

6.8 Records

Manufacturers of safety related plant and equipment will be required to provide adequate records to demonstrate compliance to specified requirements. This requirement is not unique to the Nuclear Industry; however, the industry does have specific record requirements related to products that require enhanced focus. Many products, particularly associated with radioactive wastes, will not be subject to any future handling when subject to long term disposal. As such, the record forms the only part of the plant or equipment that will be available throughout the lifetime of the product. It is therefore important to ensure that product records are supplied in the correct state and effectively controlled by the Licensee to ensure that the information is available as required during storage, to support disposal of the product or decommissioning of the facility at the end of its design life.

Records form part of the demonstration that plant and equipment meet the design intent and safety requirements and therefore the identification, generation, completion and retention of records associated with the supply of products or services should form part of the contractual arrangements between purchaser and supplier at all levels of the supply chain. Particular attention should be given to material traceability and inspection, test and surveillance activities.

Pressure often exists, particularly in project activities, for products to be delivered in advance of their associated records. While there are exceptional circumstances where this risk may be considered acceptable (e.g., to meet a shipping window), as a general rule it is important to ensure that all lifetime records, including those generated by subcontractors, are compiled concurrently with the activity to which they relate. This minimises the risks of failure and prevents the use or installation of products that may prove to be substandard on record review and requiring considerable rework, if feasible. To prevent any poor practice, clear instructions should be given to suppliers regarding the times when the necessary documents and records should be submitted prior to the planned use or installation of the product or service.

Requirements on records and on material samples should be made clear to the supplier prior to commencing the contract. This could best be achieved by providing or requiring a record schedule that details all record requirements to be submitted by the supplier. Instructions for the retention by, or transfer of records from the supplier and subcontractors should be specified. These should include the records that are requested by the organisation to ensure that the products or services have met or will meet the requirements. Retention periods and responsibilities for the maintenance of records by the supplier should also be specified.

For more general guidance on the importance of record keeping in the nuclear industry see Chapter 8 (Knowledge and Information Management).

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Revisions

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