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ONR GUIDE			
Supply Chain Management Arrangements for the Procurement of Nuclear Safety Related Items or Services			
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1. INTRODUCTION

- 1.1 ONR has established its Safety Assessment Principles (SAPs) which apply to the assessment by ONR specialist inspectors of safety cases for nuclear facilities that may be operated by potential licensees, existing licensees, or other duty holders. The principles presented in the SAPs are supported by a suite of guides to further assist ONR's inspectors in their technical assessment work in support of making regulatory judgements and decisions. This Technical Assessment Guide (TAG) is one of these guides.

2. PURPOSE

- 2.1 TAG's contain guidance to advise and inform ONR inspectors in the exercise of their regulatory judgment. They are also part of the demonstration on how ONR meets the Western European Nuclear Regulator's Association (WENRA) Reference Levels and how ONR links its guidance to that contained in the International Atomic Energy Agency (IAEA) safety standards. TAGs are not written for duty holders, and although they may be used as a source of guidance or good practice, they are not a prescriptive set of legal requirements.
- 2.2 The primary responsibility for safety of a nuclear installation rests with the Licensee. It is ONR's policy, promulgated through Nuclear Site Licence Condition 17 'Management Systems', that the Licensee makes and implements adequate quality management arrangements in all matters which may affect safety. A fundamental element of these arrangements is the Licensee's Supply Chain Management (SCM) arrangements. These arrangements, which include control of procurement of items or services and contract management activities, are fundamental to ensuring that the potential licensee, licensee or other dutyholder apply appropriate levels of control, oversight and assurance throughout all organisations within their supply chains.
- 2.3 This approach is designed to ensure that what is purchased complies with the purchaser's requirements, including contract specific requirements and the technical specification which, for certain nuclear safety related items or services, may have been assessed and considered adequate by the ONR.

3. SCOPE

- 3.1 This TAG applies to SCM arrangements and procurement activities for existing and new nuclear facilities. It also addresses the specific issues associated with procurement of items manufactured for the construction of a new civil reactor in advance of a nuclear site licence application, often termed long lead items (LLI).
- 3.2 The established and preferred model within the UK nuclear regulatory framework is that a UK nuclear licensee is the purchaser at the head of the supply chain. The Licensee is expected to establish effective SCM arrangements and carry out effective oversight, assurance and acceptance of items or services being supplied or undertaken on its behalf where their sub-standard delivery has the potential to impact on nuclear safety.
- 3.3 This TAG informs regulatory assessment of SCM arrangements and procurement activities for nuclear safety related items or services. It establishes ONR's expectations of the purchaser, as the organisation at the top of the supply chain.
- 3.4 Diagram 1 provides an overview of ONR's regulatory expectations of purchasers. The expectations also apply to any organisations in the purchaser's supply chain

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undertaking work with nuclear safety significance, with the exception of element 2 relating to 'Intelligent Customer' capability, which is a role for the licensee alone..

- 3.5 A future civil reactor operator may not be licensed until after orders have been placed for long lead items (LLI). If this happens, then the ONR would expect future civil reactor operators or potential future Licensees who have let the contract for long lead items to act as 'Intelligent Customer' until a licensed organisation is established. Further information can be found in appendix A3.
- 3.6 This TAG is structured to align to ONR's expectations defined in Diagram 1. Each chapter starts with the expectation summary then includes an explanation of the requirement. Inspectors are provided with guidance on activities they should consider during any enforcement activities with the purchaser or its supply chain.
- 3.7 Licensees frequently out-source delivery of products and services to specialist suppliers, many of which could be outside the UK. Therefore, the Licensees' extended enterprise can be complex and often international in nature. This can lead to increased risks, particularly at the interfaces between organisations in the Licensees' supply chain. If not effectively managed, these interfaces can represent a risk to safe and 'right first time' delivery of the Licensees' requirements. The potential risk factors for Inspectors to consider are summarised in diagram 2.

Diagram 1 - Summary of ONR expectations applied to a basic procurement cycle for work with nuclear safety significance

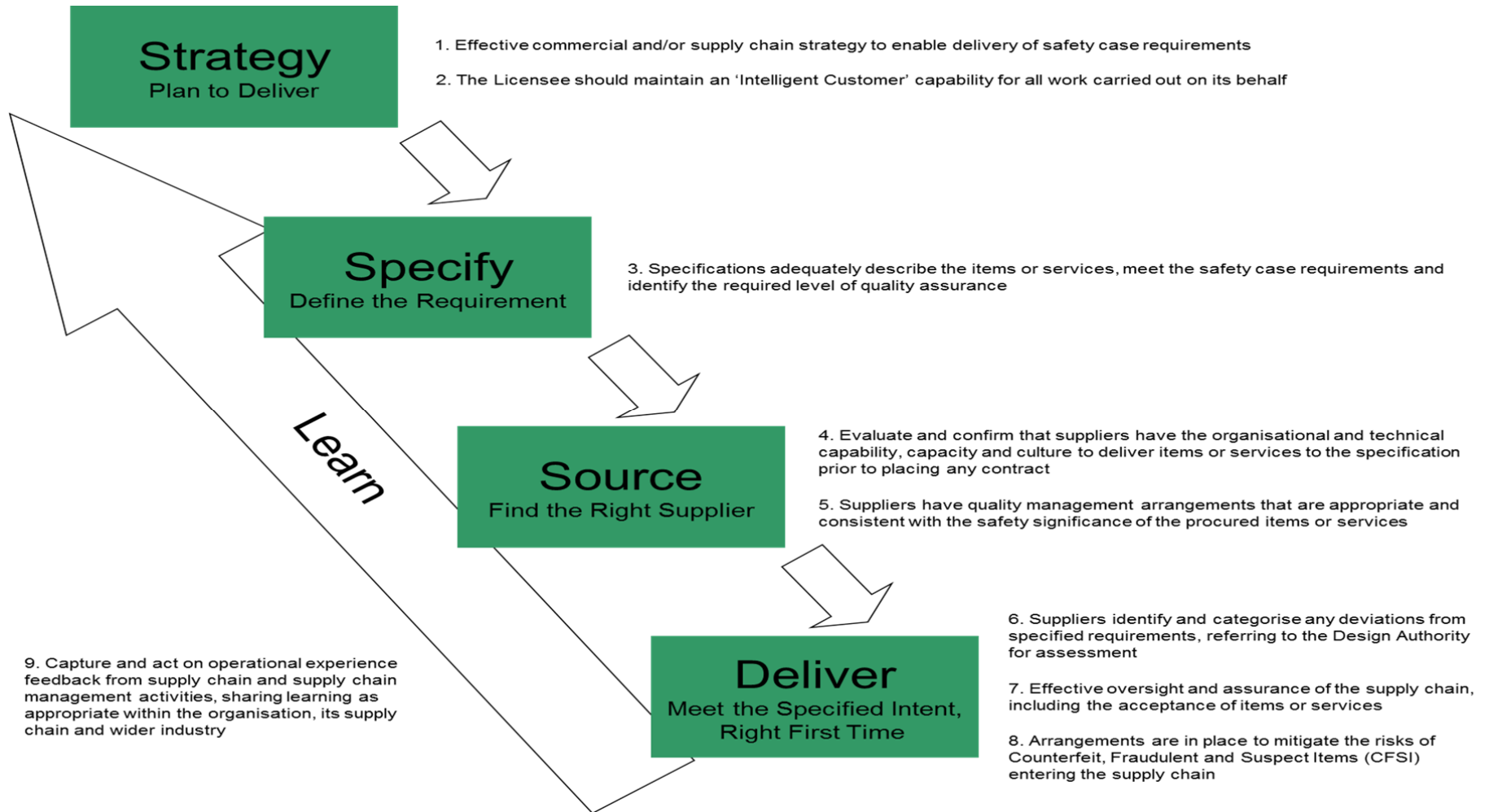


Diagram 2: Risk factors associated with organisational interfaces.



Risk factors to consider

- Capability
- Capacity
- Culture
- Cascade of requirements
- Oversight & Assurance
- Localisation
- Globalisation

4. RELATIONSHIP TO LICENCE AND OTHER RELEVANT LEGISLATION

The following UK legal and other requirements are applicable to procurement of items or services:

4.1 The Health and Safety at Work etc. Act (1974) – (HSWA74)

4.1.1 Section 2 requires every employer to provide and maintain plant and systems of work that are, so far as is reasonably practicable, safe and without risk to health.

4.1.2 Section 3 requires every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety.

4.1.3 Section 6 requires that any person who designs, manufactures imports or supplies any article for use at work:

- Must ensure, so far as is reasonably practicable, that the article is designed and constructed as to be safe and without risk to health when properly used;
- Must carry out or arrange for the carrying out of such testing and examination as may be necessary to comply with the above duty;
- Must provide adequate information about the use for which it is designed and has been tested to ensure that, when put to use it will be safe and without risk to health.

4.2 Management of Health and Safety at Work Regulations (1999)

4.2.1 Regulation 5 requires employers to have arrangements as appropriate for the effective planning, organisation, control, monitoring and review of the preventative and protective measures.

4.3 The Energy Act (2013) and the Health and Safety (Enforcing Authority) Regulations 1998.

4.3.1 Identifies the ONR as the enforcing authority for subsections 1, 2, 4 and 5 of section 6 of the HSWA74, but only in so far as those requirements relate to:

- Articles for use at work which are designed, manufactured, imported or supplied; or
- Substances which are manufactured, imported or supplied

Where the articles or substances are to be used exclusively or primarily in the installation, operation or decommissioning of a GB nuclear site or authorised defence site.

Appendix A4 explains how ONR will undertake this enforcement responsibility through inspection of suppliers to the GB nuclear industry.

4.4 The Construction (Design and Management) Regulations (2015)

4.4.1 These regulations place duties on clients, designers (including engineers), and principal contractors of construction projects of a certain duration and complexity. A purchaser should be able to demonstrate the ability to understand, monitor and direct the nuclear safety aspects of construction work.

4.5 Nuclear Site Licence Conditions, (Ref. 7.1):

4.5.1 The site licence conditions give a legal framework which can be drawn on in assessment and are, in general, set out in the form of requiring the Licensee to make adequate arrangements, in the interests of safety, to secure certain objectives. The principal licence conditions (LCs) relevant to SCM and procurement activities are:

- **LC 6** - Documents, records, authorities and certificates
- **LC 10** - Training
- **LC 12** - Duly authorised and other suitably qualified and experienced persons
- **LC 14** - Safety documentation
- **LC 17** - Management Systems
- **LC 19** - Construction or installation of new plant
- **LC 20** - Modification to design of plant under construction
- **LC 21** - Commissioning
- **LC 22** - Modification or experiment on existing plant
- **LC 25** - Operational records
- **LC 28** – Maintenance
- **LC 35** - Decommissioning

5. RELATIONSHIP TO SAPS, TAGS, WENRA REFERENCE LEVELS AND IAEA SAFETY STANDARDS ADDRESSED

5.1 Safety Assessment Principles (SAPs), (Ref. 7.2)

5.1.1 The Safety Assessment Principles for Nuclear Facilities (SAPs - 2014 Edition, Revision 0) provides a framework to guide regulatory decision-making in the nuclear permissioning process. It is supported by Technical Assessment Guides (TAGs) which further aid the decision-making process. The following principles are of relevance to this TAG:

- **MS.1 – Leadership** - Directors, managers and leaders at all levels should focus the organisation on achieving and sustaining high standards of safety and on delivering the characteristics of a high reliability organisation.
- **MS.2 – Capable Organisation** - The organisation should have the capability to secure and maintain the safety of its undertakings.
- **MS.4 – Learning from Experience** - Lessons should be learned from internal and external sources to continually improve leadership, organisational capability, the management system, safety decision making and safety performance.
- **EKP.4 – Safety Function** - The safety function(s) to be delivered within the facility should be identified by a structured analysis.
- **ECS.1 – Safety Categorisation** - The safety functions to be delivered within the facility, both during normal operation and in the event of a fault or accident, should be identified and then categorised based on their significance with regard to safety.
- **ECS.2 – Safety classification of structures, systems and components** - Structures, systems and components that have to deliver safety functions should be identified and classified on the basis of those functions and their significance to safety.
- **ECS.3 – Standards** - Structures, systems and components that are important to safety should be designed, manufactured, constructed, installed, commissioned, quality assured, maintained, tested and inspected to the appropriate codes and standards.
- **EQU.1 – Qualification procedures** – Qualification procedures should be applied to confirm that structures, systems and components will perform their allocated safety function(s) in all normal operational, fault and accident

conditions identified in the safety case and for the duration of their operational lives.

- **EAD.5 – Obsolescence** - A process for reviewing the obsolescence of structures, systems and components important to safety should be in place.
- **EMC.3 to 6, 13 to 16 & 18 to 20** – These SAPs identify the requirements to demonstrate the integrity of metal components and structures.

5.2 Technical Assessment and Inspection Guides (TAGs & TIGs), (Ref. 7.3)

5.2.1 The following Technical Assessment and Inspection Guides (TAGs & TIGs) are of relevance to this TAG and contain related guidance for inspectors on SCM and procurement of nuclear safety related items or services. The TAGs related to civil engineering, instrumentation, computer based systems, construction, integrity of components and structures make related references to the importance of effective specification of requirements, control of manufacturing processes, material traceability and inspection and test requirements.

- **NS-TAST-GD-016** – Integrity of Metal Components and Structures
- **NS-TAST-GD-017** – Civil Engineering
- **NS-TAST-GD-031** – Safety Related Instrumentation
- **NS-TAST-GD-033** – Licensee Management of Records
- **NS-TAST-GD-046** – Computer Based Safety Systems
- **NS-TAST-GD-049** – Licensee Core and Intelligent Customer Capabilities
- **NS-TAST-GD-057** – Design Safety Assurance
- **NS-TAST-GD-076** – Construction Assurance
- **NS-TAST-GD-079** – Licensee Design Authority Capability
- **NS-TAST-GD-098** – Asset Management
- **CNS-TAST-GD-4.3** – Oversight of Suppliers of Items or Services of Nuclear Security Significance
- **CNS-TAST-GD-4.1** – Procurement and intelligent customer capability
- **CNS-TAST-GD 4.2** – Supplier capability
- **CNS-TAST-GD-7.1** – Effective Cyber & Information Risk Management
- **CNS-TAST-GD-7.2** – Information Security
- **CNS-TAST-GD-7.4** – Physical Protection of Information
- **NS-INSP-GD-017** – Management Systems.
- **NS-INSP-GD-006** - Documents, Records, Authorities and Certificates.

5.3 WENRA Safety Reference Levels for Existing Reactors – 24th September 2014, (Ref. 7.4), (including update in relation to lessons learned from Tepco Fukushima Dai-ichi accident)

5.3.1 A principal aim of the Western European Nuclear Regulators' Association (WENRA) is to develop a harmonised approach to nuclear safety within the member countries. The Reference Levels (RLs) are agreed by the WENRA members. They reflect expected practices to be implemented in the WENRA countries. As the WENRA members have different responsibilities, the emphasis of the RLs has been on nuclear safety, primarily focussing on safety of the reactor core and spent fuel. The following RLs are relevant to this TAG and should be taken into account by the inspector. Each identified RL has an associated reference to TAG 077 section to demonstrate alignment:

- **Issue A: Safety Policy**
 - A1. Issuing and communication of a safety specification, (TAG 077, section 6.3).

- A1.5 Key elements of the safety policy shall be communicated to contractors, in such a way that licensee's expectations and requirements are understood and applied in their activities.
- **Issue B: Operating Organisation**
 - B2. Management of safety and quality, (TAG 077, section 6.5).
 - B2.6 The Licensee shall ensure that plant activities and processes are controlled through a documented management system covering all activities, including relevant activities of vendors and contractors, which may affect the safe operation of the plant.
 - B3. Sufficiency and competency of staff, (TAG 077, section 6.2)
 - B3.6 The Licensee shall maintain, in house, sufficient and competent staff and resources to specify, set standards, manage and evaluate safety work carried out by contractors.
- **Issue C: Management System**
 - C5. Process implementation
 - C5.5 The control of processes, or work performed within a process, contracted to external organisations shall be identified within the management system. The Licensee shall retain overall responsibility when contracting any processes or work performed within a process. (TAG 077, section 6.2).
 - C5.6 Suppliers of products and services shall be selected on the basis of specified criteria and their performance shall be evaluated. (TAG 077, section 6.4).
 - C5.7 Purchasing requirements shall be developed and specified in procurement documents. Evidence that products meet these requirements shall be available to the Licensee before the product is used. (TAG 077, section 6.4 & 6.7).
 - C5.8 It shall be confirmed that activities and their products meet the specified requirements and shall ensure that products perform satisfactorily in service. (TAG 077, section 6.7).
 - C7. Safety culture (TAG 077, section 6.7).
 - C7.1 Management, at all levels in the Licensee organisation, shall consistently demonstrate, support, and promote attitudes and behaviours that result in an enduring and strong safety culture. This shall include ensuring that their actions discourage complacency; encourage an open reporting culture as well as a questioning and learning attitude with a readiness to challenge acts or conditions adverse to safety.
 - C7.2 The management system shall provide the means to systematically develop, support, and promote desired and expected attitudes and behaviours that result in a strong safety culture. The adequacy and effectiveness of these means shall be assessed as part of self-assessments and management system reviews.
 - C7.3 The Licensee shall ensure that its suppliers and contractors whose operations may have a bearing on the safety of the nuclear facility comply with C7.1 and C7.2 to the appropriate extent.
- **Issue D: Training and Authorisation of NPP Staff (Jobs with Safety Importance)**
 - D2. Competence and qualification, (TAG 077, section 6.4).
 - D2.1 Only qualified persons that have the necessary knowledge, skills, and safety attitudes shall be allowed to carry out tasks important to safety. The licensee shall ensure that all personnel performing safety-related duties including contractors have been adequately trained and qualified.
 - D3. Training programmes and facilities, (TAG 077, section 6.4).

- D3.2 All technical staff including on-site contractors shall have a basic understanding of nuclear safety, radiation safety, fire safety, the on-site emergency arrangements and industrial safety.
 - D4. Authorisation (TAG 077, section 6.5 & 6.7).
 - D4.3 Work carried out by contractor personnel on structures, systems, or components that are important to safety shall be approved and monitored by a suitably competent member of licensee's staff.
- **Issue J: System for Investigation of Events and Operational Experience Feedback**
 - J4. Assessment and investigation of events, (TAG 077, section 6.9).
 - J4.4 The operating organisation shall maintain liaison as appropriate with the organisations (manufacturer, research organisation, designer) involved in design and construction, with the aims of feeding back information on operating experience and obtaining advice, if necessary, in case of equipment failures or abnormal events.

5.4 IAEA Safety Standards, (Ref. 7.5)

- 5.4.1 The International Atomic Energy Agency (IAEA) Safety Standards (Requirements and Guides) were the benchmark for the revision of the SAPs in 2006, and also the update in 2014, and are recognised by ONR as relevant good practice. They should therefore be consulted, where relevant, by the assessor, although it should be appreciated that they are design standards rather than regulatory standards. This TAG is broadly compatible with these standards as far as SCM arrangements for the procurement of nuclear safety related items or services is concerned.
- 5.4.2 The main IAEA Safety Standard of relevance is the Safety Requirements – **'Leadership and Management for Safety'**, Safety Standards Series No. **GSR PART 2**, IAEA, 2016; which defines the requirements for establishing, implementing, assessing and continually improving a management system. Section 6, Requirement 13: 'Measurement, Assessment and Improvement' The effectiveness of the management systems shall be measured, assessed and improved to enhance safety performance, including minimizing the occurrence of problems relating to safety, with which this TAG is consistent.
- 5.4.3 This requirement standard is supported by two relevant Safety Guides; **'Application of the Management System for Facilities and Activities'**, Safety Standards Series No. **GS-G-3.1**, IAEA, 2006 and **'The Management System for Nuclear Installations'**, Safety Standards Series No. **GS-G-3.5**, IAEA, 2009.

5.5 General Requirements

- 5.5.1 This TAG informs regulatory assessment of SCM arrangements and procurement activities for nuclear safety related items or services. It establishes ONR's expectations of the purchaser, as the organisation at the top of the supply chain. It also provides guidance for regulatory inspection during the manufacturing stages. It considers the following:
- Procurement of items or services for construction, manufacture, repair, replacement, modification of plant and equipment.
 - Procurement for new civil reactor build, where the reactor vendor may choose to place orders for long lead items in advance of an order from the future Licensee.

- 5.5.2 The level of ONR scrutiny is dependent on the nuclear safety significance of the items or services being procured (see Appendix A2). This scrutiny might include confirmation of the adequacy of the supplier's quality management arrangements and/or be part of the manufacturing or construction inspection activities identified via the supplier's quality planning arrangements.
- 5.5.3 Where the Licensee organisation is not in place or is not fully developed, some or all of the Licensee's responsibilities may be undertaken by the purchaser. This may be the case for procurements in support of new civil reactor build, where the reactor vendor may choose to place orders for long lead items, or for small modular reactors, in advance of an order from the future reactor operator/future Licensee. Where this is the case the ONR preferred approach is for the purchaser to organise the issue of a 'Licensee Certificate'.

5.6 Management System Certification – 'Licensee Certificate'

- 5.6.1 The 'Licensee Certificate' for implementation of management systems looks at the purchaser's management systems and assurance requirements for high risk long lead items appropriate to the project stage (see Appendix A3). An equivalent would be certification to an international management system requirement issued by a United Kingdom Accreditation Service (UKAS), (or equivalent international) accredited certification body.
- 5.6.2 Purchasers should clearly indicate which items or services they are procuring and detail what organisational and procedural arrangements will be applied to deliver the items or services.
- 5.6.3 The purchaser's management system arrangements must provide equivalent levels of assurance to those that a Licensee would apply if a nuclear site licence was in place.
- 5.6.4 Proposals should be fully discussed with the ONR prior to any procurement activity commencing.
- 5.6.5 The Inspector should consider:
- Whether they should consult, engage or share information with other UK regulators (i.e. Environment Agency, Defence Nuclear Safety Regulator) relevant to the purchaser's procurement of nuclear safety related items or services?
 - If the purchaser has identified any long lead items, or is procuring small modular reactors?
 - If the purchaser is working towards or has been awarded a Licensee Certificate (or certificate to other international management system requirements, for example; IAEA's GSR PART 2).
 - If the purchaser is implementing the approved management system?
 - If the purchaser is operating an adequate management system that combines safety, security, health, quality and environmental aspects?

6. SUPPLY CHAIN CYCLE

6.1 Supply Chain Strategy (Diagram 1, item 1)

- 6.1.1 **The purchaser should establish an effective commercial and/or supply chain strategy to enable delivery of safety case requirements.**
- 6.1.2 The purchaser's commercial and/or supply chain strategy will influence all arrangements associated with the procurement of nuclear safety related items or

services. Effective strategy, deployed through the organisation's business planning process should enable delivery of safety case requirements

6.1.3 The purchaser should plan to ensure their commercial and/or supply chain strategy addresses current and future safety case requirements over the lifetime of the facility including the decommissioning phase. The arrangements should be subject to routine review as they can be influenced by, for example:

- Changes in parent body organisation ownership; aggregation of contracts across multiple Licensees or organisations under parent group ownership, periodicity or stage of contract to operate facility, performance issues.
- Changes in the supply chain; such as mergers, acquisitions, insolvency, capability and performance issues.
- Security of supply; business continuity issues, strategic/critical suppliers, globalisation of suppliers.
- Make or buy policy; outsourcing and insourcing.
- Potential for tension between any drive to improve efficiency and competitiveness whilst enhancing quality and safety performance.

6.1.4 The purchaser's commercial and/or supply chain strategy, policy and arrangements should be appropriately resourced and include measures to reduce the risks from supply chain issues on safety case requirements. The arrangements should be subject to routine review as part of the organisations' business planning processes so that they remain effective and proportionate to the identified risks.

6.1.5 The Inspector should consider:

- If the purchaser has developed a commercial and/or supply chain strategy to address current and future safety case requirements?
- If the purchaser has effective arrangements to manage their supply chain including a clear strategy or policy and whether they are organised to deliver with roles and responsibilities clearly defined?
- If the purchaser has the organisational capability to manage supply chain delivery?
- If the purchaser's SCM arrangements are subject to routine review to ensure they remain effective in addressing safety case requirements?
- If the supply chain strategy has been developed mindful of the learning available from within the organisation, its suppliers, and wider industry?
- If the strategy encourages collaborative working with the suppliers sharing common safety aims, objectives and success criteria?
- If the purchaser's make or buy policy (i.e. outsourcing and insourcing) effectively considers current and future safety case requirements as part of the decision making criteria?

6.2 Intelligent Customer (Diagram 1, item 2)

6.2.1 The Licensee should maintain an 'Intelligent Customer' capability for all work carried out on its behalf by suppliers that may impact upon nuclear safety.

6.2.2 The primary responsibility for the safety of a nuclear installation rests with the Licensee. The Licensee must be able to demonstrate sufficient knowledge of the plant design and safety case for all plant and operations on the licensed site. The Licensee must be in control of activities on its site, understand the hazards associated with its activities and how to control them, and have sufficient competent resource within the licensee organisation to be an 'Intelligent Customer' (IC) for any work it commissions for its benefit. .

6.2.3 In the context of effective SCM the Licensee should maintain an 'Intelligent Customer' capability to know what is required, to fully understand the need for a contractor's services, at any level of the supply chain, to be capable of specifying requirements, and supervising the work and be able to technically review the output before, during and after implementation.

6.2.4 ONR's regulatory expectations for Licensee core and intelligent customer capability are defined in Technical Assessment Guide, NS-TAST-GD-049 (TAG 49) – 'Licensee Core and Intelligent Customer Capabilities'. Inspectors should review the document for detailed information that complements this TAG. TAG 49 highlights the following broad principles which underpin ONR's expectations of a licensee's arrangements for the use of contractors and for retaining control of nuclear safety and for discharging its other duties.

1. The licensee should maintain a core in-house staff to ensure effective control and management for nuclear safety;
2. The licensee should retain overall responsibility for, and control and oversight of, the nuclear and radiological safety and security of all of its business, including work carried out on its behalf by contractors;
3. Licensee choices between sourcing work in-house or from contractors should be informed by a company policy that takes into account the nuclear safety implications of those choices;
4. The licensee should maintain an intelligent customer capability for all work carried out on its behalf by contractors that may impact upon nuclear safety;
5. The licensee should ensure that it only lets contracts for work with nuclear safety significance to contractors with suitable competence, safety standards, management systems, culture and resources;
6. The licensee should ensure that all contractor staff are familiar with the nuclear safety implications of their work and interact in a well-co-ordinated manner with its own staff and those of other contractors;
7. The licensee should ensure that contractors' work is carried out to the required level of safety and quality in practice.

6.2.5 The Inspector should consider:

- If the Licensee has retained and maintains the core capability to understand, specify, oversee and accept nuclear safety related work undertaken on its behalf by contractors at any level of the supply chain?

- If the Licensee has given training and information on the subject of nuclear safety culture (refer also 6.4.1) to organisations within the supply chain and ensured flow down to all suppliers.

6.3 Specification (Diagram 1, item 3)

6.3.1 The purchaser should ensure that specifications adequately describe the items or services, meet the safety case requirements and identify the required level of quality assurance.

6.3.2 Establishing an effective specification could be considered the most important aspect of the procurement cycle. An ineffective specification mean that any contractor in the supply chain will find it difficult to deliver the purchaser's requirements right first time, regardless of its own capabilities and processes.

6.3.3 Given the importance of the specification it is essential that those writing specifications are trained and competent to perform the task and their work subject to the appropriate levels of verification and validation commensurate with the safety significance of the item or service being specified. At the pre-contract stage, the purchaser should ensure that prospective suppliers fully understand whether the items or services being procured are a principal means of ensuring nuclear safety. The Licensee or purchaser should develop specifications that benefit from the expertise of suppliers, particularly expertise in the manufacturability of the equipment.

6.3.4 The purchaser should detail any applicable design codes and standards and should prepare technical specifications that fully describe the items or services to be procured together with other generic contractual requirements. This combination of requirements should identify appropriate levels of quality assurance requirements to be applied. These should include, where applicable; assessment, audit, quality planning, quality control, inspection, surveillance, testing and release or handover of items and should fully detail the records package required to be supplied with the item or service.

6.3.5 For items or services which are important to ensuring nuclear safety, additional assurance and inspection arrangements may be required which go beyond basic compliance with established design codes and standards. ONR may wish to assess the technical specification used as the basis for procurement prior to the procurement action taking into account any additional requirements. Appendix A3, details the preferred model for procurement of primary circuit pressure boundary components which require the highest level of assurance.

6.3.6 For new nuclear facilities, the technical requirements of the contract between the purchaser and supplier for items or services must, amongst other things, take into account the findings of any ONR technical assessment work.

6.3.7 Throughout the design process, significant assurance activities should be undertaken to ensure that the design meets the requirements of the purchaser and applicable codes or standards in addition to any regulatory requirements.

6.3.8 Where technical specifications are prepared for nuclear safety significant items or services by contractors on behalf of the purchaser these should be reviewed by staff from the purchaser's organisation who are competent to confirm that the specifications properly reflect the design intent, meet any design codes and standards and as such meet safety case requirements. This review must be carried out before contract placement.

6.3.9 On receipt of the purchase order, the supplier should carry out a review of the contract documentation to ensure that it can fulfil all the technical, procedural and commercial

requirements of the contract. For complex and high capital value plant, discussions between the supplier (and sub-suppliers) and purchaser should normally have covered these aspects prior to contract placement. The supplier should advise the purchaser of any changes to its (or its sub-suppliers) ability to fulfil the contract as such changes arise.

6.3.10 The purchaser should operate a change control process. Refer also to section 6.6 'Deviation from Specified Requirements'. The process should ensure that any changes to specification, design or contract are properly controlled and authorised prior to the implementation of the change. There should be full consideration of the implications for nuclear safety and the manufacturing or delivery processes, including any changes to documentation (particularly process quality related, e.g. quality plans). Where these changes impact on the safety case, this may require further assessment by the ONR.

6.3.11 The purchaser should ensure that specific requirements of the safety case (such as diversity, redundancy etc.) are reflected in the specification and maintained throughout procurement and manufacture. Impacts on the safety case as a result of changes in the supply chain (such as mergers, acquisitions) should be agreed by the licensee.

6.3.12 The Inspector should consider:

- If specifications reflect the design intent, design codes and standards and meet safety case requirements?
- If the Licensee or purchaser has consider early supplier or manufacturer involvement in developing specifications to ensure the manufacturability of the specified items.
- If specifications prepared by contractors are reviewed by competent staff from the purchaser's organisation?
- If appropriate levels of quality assurance are applied to the procurement of items or services significant to nuclear safety?
- If the purchaser's specification and assurance arrangement address any specific regulatory requirements?
- If suppliers fully understand whether the items or services being procured are the principal means of ensuring nuclear safety?
- If variations to specification, design or contract are properly conceived, communicated, implemented and assessed for nuclear safety implications and authorised?
- If suppliers have notified the purchaser of proposed changes and that they are properly assessed, controlled and authorised by the purchaser?
- If supplier documents e.g. quality plans and manufacturing instructions have been re-approved before a change is implemented?
- If safety case requirements for diversity and redundancy in light of supplier mergers and acquisitions are reviewed and agreed by the purchaser.

6.4 Supply Chain Organisation and Technical Capability (Diagram 1, item 4)

- 6.4.1 For work with nuclear safety significance, the purchaser should evaluate and confirm that suppliers have the organisational and technical capability, capacity and culture to deliver items or services to the specification prior to placing any contract.**
- 6.4.2 Suppliers should be selected by the purchaser after evaluation against predefined criteria appropriate to the contract. The criteria will test the supplier's ability to meet the specified intent and should include the provision of information from the supplier that provides objective evidence of their capability and capacity to deliver the required item or service. The criteria for selection should be appropriately weighted to evaluate the supplier's ability to meet the required safety performance and deliver the safety case requirements of the contract.
- 6.4.3 Purchasers are expected to ensure that supply organisations have the organisational and technical capabilities to deliver items or services, including site construction, in line with their requirements. Suppliers' organisational arrangements should include documented management system arrangements appropriate to the items or services being supplied. These systems should be implemented and be able to meet the requirements of a relevant national or international management system standard for quality, environment and safety management, an example is, BS ISO 19443: 2018 "Quality Management Systems – Specific requirements for the application of ISO 9001: 2015 by organisations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety" An evaluation of a potential supplier should include the potential supplier's nuclear safety culture, ensuring that the organisation and its leaders understand, or have the potential to understand, the importance of nuclear safety and the contribution of any high risk item or service they would supply to achieving the safety case requirements of the purchaser.
- 6.4.4 As part of the supplier selection process, the purchaser should confirm that suppliers have adequate oversight and assurance arrangements for their own suppliers (see section 6.7 for more detail on supply chain oversight and assurance requirements). The purchaser and suppliers should hold certification to recognised management system requirements, issued by a UKAS or international equivalent accredited organisation, to ensure that appropriate quality management arrangements are in place and are being applied throughout the supply chain. This approach should not preclude purchasers from directly evaluating any level of the supply chain or carrying out oversight and assurance when work is in progress. All contracts should detail this right of access by the purchaser.
- 6.4.5 Purchasers should assure themselves that suppliers have competent staff, particularly those carrying out key functions such as contract review, fabrication and inspection. The judgement on competency should be based on qualifications, training and experience using the supplier organisations own criteria and any applicable design code requirements for selection, employment and training of employees. A responsible officer within the supplier organisation should review post profiles against the suitably qualified and experienced persons (SQEP) records for each person and record acceptance and/or limitations identifying how the latter will be addressed.
- 6.4.6 Arrangements should include provisions to monitor SQEP performance and identify the corrective action to be taken when the required standard is not met. For work on nuclear plants the following posts are typically monitored for quality of the work; welders, Non Destructive Testing (NDT) operators and inspectors, note this list is not exhaustive.

6.4.7 The Inspector should consider:

- If the purchaser's process for evaluation of suppliers of high risk items and services is appropriately weighted to consider the quality and safety requirements as a key part of the contract selection and award criteria?
- If the suppliers of high risk items and services currently have, and have established arrangements to maintain, sufficient competent staff throughout the contract period?
- If the supplier has the capacity to provide an enduring source of high risk items or services throughout the contract period?
- If the purchasing organisation have promulgated the required nuclear safety culture with key suppliers?
- If suppliers of high risk items or services understand the role of their products in achieving the safety case requirements of the Licensee and interact in a well-coordinated manner with the purchasers' staff?
- If the purchasing organisation and/or suppliers monitor the performance of key individuals in the provision of high risk items or services?

6.5 Supply Chain Management Systems (Diagram 1, item 5)

6.5.1 The purchaser should ensure that suppliers have quality management arrangements that are appropriate and consistent with the safety significance of the procured items or services.

6.5.2 Purchasers should ensure that supply organisations have management system arrangements appropriate to the items or services being supplied. These systems should be implemented and be able to meet relevant national or international; quality, environment and safety management system requirements and be certified by a UKAS or equivalent international accredited organisation.

6.5.3 The purchaser's management system arrangements should ensure that effective SCM, procurement, oversight and assurance arrangements are applied proportionate to the nuclear safety significance of the items or services being procured. Arrangements should include comprehensive measures for the generation and control of quality plans and records, detailed further below, as key requirements in the effective procurement, manufacture and/or delivery of high risk items and services. Management system and quality management guidance for inspectors can be found in Technical Inspection Guide (TIG) reference: NS-INSP-GD-017 – 'Management Systems'.

Quality Plans

6.5.4 The purchaser should make clear in the contract the extent to which quality plans will be used. Quality plans should be agreed with the purchaser prior to their use. The use of quality plans, developed by the supplier and agreed with the purchaser, is essential to ensure that items are fabricated, manufactured, erected, tested and inspected in a planned and controlled manner and that the required levels of integrity are achieved and can be demonstrated within the required record/evidence package.

6.5.5 Quality plans allow the purchaser to check in advance that the supplier has fully understood the detailed requirements of the technical specification, and that the supplier has in place the necessary assurance activities to deliver items that will meet the technical specification and applicable codes and standards. Quality plans also allow the purchaser, second party (supplier), independent third party inspection personnel and, in some instances, the ONR, to insert inspection points, witness points, review points or hold points into the manufacturing sequence.

- 6.5.6 Quality plans should show the entire sequence of steps to realise the item or service and give details of hold point release. These need to be available for review by involved parties, before work commences and in sufficient time to allow these parties to review and annotate them with hold, inspection, witness and review points and/or to question the sequence or referenced documents.
- 6.5.7 Quality plans, in identifying the sequence of activities required to satisfy the requirements of the contract, should reference process or fabrication instructions, tests, inspections and clearly identify the records required to be generated and provided to the purchaser. They should provide the facility for signatures and the date to be entered on all stages and final completion of the work covered at each element of the plan. Proposed changes to quality plans before and during work commencement should be formally controlled and agreed by all the inspecting parties. All signatures used, in the quality plan including electronic signatures to be identified by, printed name and position at least once in each document they are used in.
- 6.5.8 A completed quality plan should provide the demonstration that all appropriate steps have been taken to deliver items or services to purchaser requirements, including details of the organisations involved and references to control documents and appropriate records.
- 6.5.9 For complex items that are fabricated, manufactured or erected in stages, there may be several quality plans which support a top level quality plan. Quality plan operations which are carried out by different organisations should make reference to release from one to the other and the quality plans that control the ongoing work.
- 6.5.10 A quality plan should identify or reference all those documents which form the purchaser's document package and include such aspects as qualification of personnel, fabrication procedures, material certification and traceability, consumable specification, concessions and rework, manufacture, fabrication instructions, heat treatment records, inspection and test results (including those from the purchaser, second, and third party inspection organisations).
- 6.5.11 Quality plans should identify steps for release, transport or handover and the process that will control the interfaces between organisations. The release process to the purchaser from the supplier should identify and record any approved deviations from contract requirements, specified intent and any outstanding actions.

Records

- 6.5.12 The importance of identification and retention of design, procurement, manufacturing, fabrication and inspection records cannot be overstated as these ultimately support the safety case. They provide evidence of assurance activities including those carried out by the supplier, sub-suppliers and the purchaser. Guidance for inspector on records requirements can be found in TIG reference: **NS-INSP-GD-006** - Documents, Records, Authorities and Certificates. Records also provide the ONR with evidence of the application of assurance arrangements and are used to demonstrate compliance with the requirements of LC 19 when a nuclear site licence is granted to a nuclear site operator/duty-holder.
- 6.5.13 Records form part of the demonstration that plant and equipment meet the design intent and safety requirements. The identification, generation, timely completion, handover and retention of records associated with the supply of items or services should form part of the contractual arrangements between purchaser and supplier at all levels of the supply chain.

- 6.5.14 The purchaser should identify all the records required to be delivered to the purchaser during or on completion of the contract. Particular attention should be given to material traceability and inspection, test and surveillance activities.
- 6.5.15 Tracking of record packages by unique reference and to plant item unique numbers will aid part and full system sign off prior to pre and post commissioning testing. The Purchaser should develop the life time record package tracking process and ensure supplier's contract arrangements identify this process and the supplier's role within that process.

6.5.16 The Inspector should consider:

- If the supplier's management system arrangements are appropriate to the risks of the items of services being supplied?
- If quality plans are comprehensive and inclusive of the full sequence of steps required to deliver the item or service including references to assurance activities and applicable codes and standards?
- If quality plans identify inspection/witness/review and hold points for all the required inspection parties?
- If quality plans are being adhered to and are fully signed off after each step has been completed?
- If the purchaser has put adequate contractual arrangements in place to ensure that relevant records are identified and provided by the supply chain in the correct form and to the required timescale (see T/AST/033 – Records Storage)?
- If identified records are sufficient to satisfy the requirements of LC19.

6.6 Deviations from Specified Requirements (Diagram 1, item 6)

6.6.1 The purchaser should ensure that suppliers identify and categorise any deviations from specified requirements, referring to the Design Authority for assessment

- 6.6.2 Deviations (non-conformances) are unplanned departures from the purchaser's requirements and can be identified through a number of devices including inspection, audit or surveillance. They can occur at any level within the supply chain. Deviations can be associated with an item or service or be the result of the inadequate implementation of the approved process.
- 6.6.3 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.
- 6.6.4 All organisations within the supply chain should, as part of their quality management arrangements, operate consistent arrangements, overseen by the purchaser, for the categorisation and sentencing of deviations.
- 6.6.5 Purchasers at each level of the supply chain should ensure that their suppliers have adequate arrangements for the identification, categorisation and sentencing of deviations for items or services. These should include obtaining the approval of the purchaser, or Design Authority (DA) within the Licensee or duty holder for the deviation in the form of a concession or procedure for re-work. They should inform the ultimate purchaser and potentially the ONR (via the purchaser at the head of the supply chain) for deviations that are significant to nuclear safety.

6.6.6 Technical queries (TQ's) are slightly different to non-conformances. For TQs the supplier is asking a question for approval prior to doing the work and for non-conformances the work has started and is found to be outside the acceptance criteria for product, or the process has not been implemented as approved. TQ's are raised in the work planning stage and help inform or clarify the contract requirements. Once the purchaser agrees to a TQ that requires a change in the design or other process then the purchaser will track a modification to completion with contract changes through formal change control being communicated to the supplier. The purchaser's management arrangements should ensure that both types of deviation from the originally specified requirements are appropriately controlled and documented.

6.6.7 There should be an audit trail from work control documents to all approved deviations as well as systematic overarching deviation tracking logs showing the status of each deviation. Approved deviations should be used to update drawings to reflect 'as built' status to aid configuration control for future modifications.

6.6.8 The Inspector should consider:

- If deviations are identified, characterised and formally sanctioned by competent staff with the appropriate delegated authority?
- If suppliers bring all deviations of nuclear safety significance to the attention of the purchaser, design authority within the Licensee or duty holder and the ONR if appropriate, via the purchaser at the head of the supply chain?
- If an audit trail is evident for all deviations approved from the work control document to logs showing status of each deviation raised, approved, rejected or reworked with links to required document changes?

6.7 Supply Chain Oversight and Assurance (Diagram 1, item 7)

6.7.1 The purchaser should conduct effective oversight and assurance of the supply chain, including the acceptance of items or services for work with nuclear safety significance.

6.7.2 The purchaser should establish effective arrangements for the oversight of supplier performance throughout the contract period and assurance to ensure that items or services meet the specified intent. The purchaser should ensure that it has sufficient capability to oversee and assure performance throughout the tiers of the supply chain. Assurance activities should include the inspection, test, release, acceptance and storage of high risk items and services.

6.7.3 ONR's expectation is that the purchaser retains sufficient intelligent customer capability to specify, conduct oversight and assurance, monitor manufacturing, fabrication and testing, and accept for technical adequacy the items or services being purchased.

6.7.4 The purchaser's oversight and assurance arrangements should continue to review the supplier's nuclear safety culture, ensuring that post contract award, the supplier organisations and their leaders continue to understand and promote the importance of nuclear safety and the contribution of any high risk item or service they supply to achieving the safety case requirements of the purchaser.

6.7.5 The level of oversight and assurance deployed by the purchaser should be guided by the performance of the supplier or supply chain. If performance is below expectation then the purchaser should increase the level of engagement, oversight and assurance controls until supplier performance meets expectations or until completion or termination of the contract. Conversely, if a supplier demonstrates routine delivery

to the specified requirements, right first time, every time, the purchaser may consider a change to the method of oversight and assurance as appropriate (for example, from release inspection at manufacturer's works to receipt inspection at the purchaser's facility).

Oversight

- 6.7.6 The level of oversight deployed by the purchaser should be commensurate with the risk of the item or service failing to meet the specified intent. The purchaser's approach should be influenced by the type of contract, the performance of the supplier and the nuclear safety risks of poor performance. Purchasers are likely to deploy some or all of the following approaches:
- **Contract Review** – Meetings between the supplier and purchaser that should review performance and delivery issues including safety requirements.
 - **Supplier Relationship Management** – Used to maintain effective relationships between the supplier and purchaser throughout the contract period ensuring achievement of common objectives. Effective relationship management should support a collaborative approach between the purchaser and supplier.
 - **Vendor Analysis** – Performance analysis throughout the contract period with data collated on contract success criteria, often delivery to correct quality, schedule and cost. Vendor analysis may be utilised to target and demonstrate improvements, rank and rate suppliers and maintain a purchaser's preferred suppliers listing.
- 6.7.7 The purchaser's supply chain oversight arrangements should generate quantitative and qualitative performance data to demonstrate the performance of suppliers of high risk items or services against specified target levels. Purchasers should instigate remedial measures as appropriate, which may include withdrawal of contract, to address sub-standard performance that may impact nuclear safety.

Assurance

- 6.7.8 The purchaser should carry out adequate assurance and acceptance of items or services being supplied or undertaken by others on its behalf. The level of assurance, inspection and test deployed on item or service completion should be dependent on the nuclear safety significance of the item or service being supplied.
- 6.7.9 Acceptance of items or services may include verification or independent assessment using second or independent third party organisations. This should be planned and executed, in part; by the application of quality plans (see section 6.5 for more detail on quality plan requirements). This approach provides essential levels of assurance which are in addition to that provided through the suppliers' own quality arrangements.
- 6.7.10 In deciding on the levels of assurance, in addition to the safety significance of the item or service, the purchaser should consider the level of assurance normally applied to the item or service for its intended use, the code/standard requirements and the difficulty of inspection and testing post manufacture or installation. It is important that the ONR has access to all parties that are carrying out quality related activities if required. Access will normally be arranged via the purchaser.
- 6.7.11 The purchaser's assurance activities should examine the effectiveness of arrangements for the transport, receipt and storage of items or assembly sub-components within the purchaser's facilities prior to delivery from the supplier. The storage arrangements should be sufficient to maintain item traceability and prevent damage, loss, deterioration or inadvertent use.

6.7.12 The Inspector should consider:

- If the purchaser is in control of their supply chain management and procurement process arrangements for high risk items from specification of requirement, sourcing a supplier including contract award, through to manufacture of item, construction of facility or provision of item or service?
- If the purchaser's expectations for a supplier to the nuclear industry are understood, cascaded throughout the supply chain and routinely reviewed to ensure that suppliers have appropriate understanding of the nuclear safety application of their high risk items or services?
- If the purchaser has sufficient capability to oversee and assess performance throughout the supply chain and if the level of oversight and assurance deployed by the purchaser post contract award is commensurate with the risk of the item or service failing to meet the specified intent?
- If the purchaser utilises qualitative and quantitative data to demonstrate supplier performance during contract execution and instigate remedial measures where appropriate?
- If the purchaser is carrying out adequate and appropriate assurance and acceptance of items or services being supplied or undertaken by others on its behalf?
- The competence of any Inspection Agency to provide third party assurance and verification of items or services significant to nuclear safety?
- If the purchaser's storage arrangements for supplied items are sufficient to maintain item traceability and prevent damage, loss, deterioration or inadvertent use?

6.8 Counterfeit, Fraudulent and Suspect Items (CFSI) (Diagram 1, item 8).

6.8.1 The purchaser should have arrangements to mitigate the risks of Counterfeit, Fraudulent and Suspect Items (CFSI) entering their supply chain.

6.8.2 There should be recognition throughout all levels of the supply chain that there are parties who might wish to substitute CFSI for genuine items or services for reasons of commercial gain. All purchasers should be aware of the risks and hazards of CFSI entering the nuclear industry supply chain and understand their role in mitigating the risks. The security aspects are covered in the references in section 5.2.

6.8.3 The purchaser or supplier should deploy mitigating measures as appropriate to prevent CFSI impacting their supply chain depending on the scale, complexity, international nature of their supply chain or nuclear safety application of their items or services.

6.8.4 The following non-exhaustive list represents appropriate mitigating measures that should be deployed as part of a purchaser or supplier's management system, as levels of defence against CFSIs for high risk items or services:

- Robust SCM and procurement process arrangements including effective supply chain oversight and assurance, including inspection and testing.
- Competent and honest staff involved in the acquisition processes from specification of requirement through to inspection and receipt of items and services and review of associated records.
- Material or component traceability back to source supplier, including verification testing by third party specialist organisations for high risk items.
- Use of positive material identification and destructive testing methods during product inspection, testing and receipt and as part of assurance sampling of high risk proprietary items (ie bolts and fasteners).
- Product samples of known precision and authenticity available for comparison with purchased items.
- Training and awareness within purchasing organisation SCM teams (ie Engineering, Procurement, Audit & Inspection), partners and suppliers. Staff should be aware of the risks of CFSI and be trained in mitigation and detection methods as appropriate.
- Processes and procedures to identify, investigate, record incidences of CFSI and share lessons learnt.
- Benchmarking and collaboration with other purchasers and suppliers.
- Requirements clearly defined in contract terms and conditions.
- The destruction of non-conforming items to prevent re-entry into the supply chain as genuine items.

6.8.5 The purchaser should have arrangements in place to quarantine a suspect item or suspend a service. Further investigation will be required by the purchaser or supplier to sentence the item as conforming, non-conforming, counterfeit or fraudulent; and to examine the consequences of a suspect service.

6.8.6 Examples of counterfeit or fraudulent items or services should be shared within the purchaser and the Licensee or duty holder organisation, supply chain and wider industry as appropriate to support learning, prevent use and encourage remedial measures in other impacted facilities, but only when the purchaser has conducted a sufficient investigation to disposition the item.

6.8.7 The ONR should be informed of all examples of counterfeit or fraudulent items or services confirmed within the purchaser's supply chain relating to high risk items or services or to shortfalls in the purchaser's SCM or procurement arrangements.

6.8.8 The ONR security should be informed of all suspected incidents of malicious intent to introduce weaknesses or defects into goods or services for nuclear security significant items or services within the purchasers supply chain.

6.8.9 The Inspector should consider:

- If the purchaser has effective processes in place to prevent against CFSI entering their supply chain at any level?
- If the purchaser is deploying positive material identification and destructive testing methods during its assurance arrangements, including sample testing of proprietary high risk items (such as bolts and fasteners)?
- If staff involved in the purchaser's acquisition processes are competent to perform their role, are aware of the risks of CFSI, understand and support the organisation's mitigation methods?
- If the purchaser has appropriate arrangements in place, to quarantine, investigate and sentence suspect items as conforming, non-conforming, counterfeit or fraudulent, and to examine the consequences of a suspect service?
- If the purchaser has established arrangements to raise awareness of CFSI within their supply chain and is encouraging the open reporting of CFSI examples to maximise learning and mitigate risks to related industry?
- If the purchaser has examples of identified CFSI and has taken appropriate remedial measures including the notification of the ONR and the sharing of learning through their Operational Experience (OPEX) arrangements?
- If the purchaser has examples of malicious intent to introduce weaknesses into security arrangements and has taken appropriate actions including notifying Licensees and ONR security?

6.9 Supply Chain Operational Experience (OPEX) (Diagram 1, item 9)

6.9.1 The purchaser should have arrangements to capture and act on operational experience feedback from its supply chain and SCM activities, sharing learning as appropriate within the organisation, its supply chain and wider industry.

6.9.2 The purchaser should have effective operational experience processes that capture and act upon cross discipline (i.e. engineering, commercial, quality, inspection and test, safety & security etc.) SCM issues associated with the sub-standard procurement of high risk items or services from specification of requirements, sourcing of suppliers, oversight of delivery, inspection, test and installation or use.

6.9.3 The purchaser should ensure that relevant learning is captured and acted upon from their supply chain, related to the provision of high risk items and services. This could include incidences of CFSI in their supply chain tiers or sub-standard supplier performance issues that could impact the purchaser at the top of the chain and could influence future commercial and/or supply chain strategy.

6.9.4 The purchaser should recognise that key suppliers (such as niche products or construction contractors) in the nuclear industry could provide items or services to multiple Licensees or duty holders and as such, sub-standard performance from a key industry supplier could have an impact on the nuclear safety related activities of multiple Licensees or duty holders.

6.9.5 The purchaser's OPEX processes should enable the wider sharing of relevant supplier and SCM experience with other Licensees or duty holders and wider industry as appropriate. Arrangements should be in place to evaluate OPEX shared by other

Licensees or duty holders, and wider related industry, for implications within the purchaser's organisation and management system arrangements.

6.9.6 ONR should be informed of confirmed instances of sub-standard supply chain performance in the provision of high risk items or services, particularly where the supplier is likely to form part of the supply chain for other Licensees or duty holders or future Licensees.

6.9.7 The Inspector should consider:

- If the purchaser's OPEX process is established and is capturing and acting upon sub-standard performance issues associated with their SCM arrangements?
- If the purchaser's OPEX process is capturing and acting upon issues occurring within their supply chain tiers?
- If the OPEX arrangements are generating improvements in the purchaser's SCM arrangements and influencing commercial and/or supply chain strategy?
- If the purchaser evaluates relevant learning briefs from other Licensees or duty holders, purchasers and supplier organisations, nationally and internationally as appropriate?
- If the purchaser shares learning with its supply chain and wider industry as appropriate?

7. REFERENCES

- 7.1 Licence condition handbook. Office for Nuclear Regulation. October 2014.
<http://www.onr.org.uk/silicon.pdf>
- 7.2 Safety Assessment Principles for Nuclear Facilities. 2014, Revision 0.
<http://www.onr.org.uk/saps/index.htm>
- 7.3 Security Assessment Principles for the Civil Nuclear Industry
<http://www.onr.org.uk/syaps/>
- 7.4 Nuclear Industry Association: Cyber security in the nuclear supply chain.
https://www.niauk.org/wp-content/uploads/2018/10/NIA_BP_Cyber-Security_180911.pdf
- 7.5 ONR How2 Business Management System. Technical Assessment and Inspection Guides (TAGs & TIGs). http://www.onr.org.uk/operational/tech_asst_guides/index.htm
- 7.6 Western European Nuclear Regulators' Association. Reactor Harmonization Group. WENRA Reactor Reference Safety Levels. WENRA. September 2014.
http://www.wenra.org/media/filer_public/2014/09/19/wenra_safety_reference_level_for_existing_reactors_september_2014.pdf
- 7.7 The Leadership and Management for Safety, Safety Standards Series No. GSR PART 2 - IAEA, 2016, and Management Systems for Facilities and Activities, Safety Standard Series, GS-G-3.1 IAEA, 2006, GS-G-3.5, IAEA, 2009. <http://www-ns.iaea.org/standards/documents/pubdoc-list.asp?s=11&l=83>
- 7.8 BS-EN-ISO 17020:2012 Conformity assessment. Requirements for the operation of various types of bodies performing inspection.
- 7.9 IAEA Specific Safety Guide (SSG) – 38 Construction of Nuclear Installations.
<https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1693Web-54107132.pdf>

Note: ONR staff should access the above internal ONR references via the How2 Business Management System.

8. ABBREVIATIONS

CFSI	Counterfeit, Fraudulent & Suspect Items
DA	Design Authority
HSWA74	The Health and Safety at Work etc Act 1974
IA	Inspection Agency
IAEA	International Atomic Energy Agency
IC	Intelligent Customer
NDT	Non Destructive Testing
ONR	Office for Nuclear Regulation
OPEX	Operational Experience
SAP	Safety Assessment Principle(s)
SCM	Supply Chain Management
SQEP	Suitably qualified and experienced persons
TAG	Technical Assessment Guide(s)
TQ	Technical Query
UKAS	United Kingdom Accreditation Service
WENRA	Western European Nuclear Regulators' Association

9. APPENDICES

APPENDIX A1: GLOSSARY

A1.1. The SAPs (Ref. 2) include a glossary of terms used in the SAPs and TAGs. The following specific definitions will support the wider understanding of terms used in this TAG.

A1.2. Counterfeit

Items intentionally manufactured, or altered to imitate a legitimate product in order to pass themselves off as genuine. Counterfeit product can be deficient materially or in ability to reliably function within the specified conditions.

A1.3. Design Code

A standard with industry, national or international status, that defines the technical and possibly organisational rules by which an item or process can be described and realised.

A1.4. Design Report

The Design Report includes the stress calculations and other data and information in sufficient detail to demonstrate compliance with the appropriate codes and standards. This is done by showing that the applicable stress and other limits and requirements of the chosen design code are met when the system, component or item is subjected to the loading conditions defined in the design specification.

The Design Report should be reconciled with all design changes, including deviations, which occur prior to the completion and acceptance of the items described in the Design Report.

A1.5. Deviations

Deviations are unplanned departures from the intended requirements. Deviations can emerge at any stage of the supply chain, including design, manufacturing, storage and transportation.

A1.6. Duty-holder

A person or corporate body who has a duty in law.

A1.7. Fraudulent

Fraudulent items are misrepresented with intent to deceive, including items with incorrect identification or false certifications. They may also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but produce a larger quantity than authorised and sell the excess as legitimate inventory.

A1.8. Inspection Agency (IA)

The independent body or organisation that verifies that items or services have been designed, constructed and tested in accordance with the technical specification. The IA should have suitable competencies.

A1.9. Intelligent Customer

The capability of an organisation to understand where and when work is needed; specify what needs to be done; understand and set suitable standards; supervise and control the work; and review, evaluate and accept the work carried out on its behalf.

A1.10. Items or Services

Items or services referred to in this guidance are those that contribute to nuclear safety including those that provide the principal means of ensuring safety. Items include components, assemblies, vessels and civil structural components, structures and facilities whilst services include design, inspection, technical support and peer review.

A1.11. Licensee

The body corporate that has been granted a Nuclear Site Licence under the Nuclear Installations Act 1965 (as amended), which permits it to carry out a defined scope of activities on a delineated site (NIA).

A1.11A Licensee Certificate.

For pre licence grant organisations only, typically for new build projects who wish to procure long lead items. Licensee certificate certification is awarded following successful assessment by a third party, on the prospective licensee. The assessment objective is to confirm, for items and services being procured, that the prospective licensee organisation has the capability, capacity and understanding of their responsibilities for design, manufacture, inspection and oversight and is implementing them. This also includes activities undertaken by sub contractors.

A1.12. Long Lead Items (LLI)

In the context of this TAG, items manufactured for the construction of a new nuclear facility in advance of a nuclear site licence application.

A1.13. Manufacturer/Contractor/Vendor

The supplier organisation that designs, constructs and tests items or services in accordance with a purchaser's order. This term includes the main manufacturer and any sub-contractors in the supply chain. It also encompasses the scenario where design, manufacture, and installation might be carried out by different organisations.

A1.14. Non-conforming

Items or services that do not meet their intended requirements. Non-conformances can emerge at any stage of the supply chain, including design, manufacturing, storage and transportation.

A1.15. Nuclear Safety

The achievement of proper operating conditions, prevention of accident or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation hazards. In this document safety means nuclear safety unless otherwise stated.

A1.16. Purchaser

In the context of this TAG, the organisation or person procuring an item or service. The purchaser may be the Licensee or duty holder where a site is already licensed or other dutyholder such as a future civil reactor operator/eventual Licensee in the case of new civil reactor build. The purchaser may also be part of a Licensee's or duty holder's SC.

A1.17. Quality Plan

A document or set of documents setting out the specific quality practices, resources and sequence of activities relevant to realisation of a particular item or service. A quality plan is

useful for formalising and co-ordinating the interactions of various organisations, including the IA and the ONR, through the identification of witness and hold points.

Note: Quality Plans are called many different names within industry. The purchaser should identify in their contract their requirements and expectations for workface Inspection and test documents, including defining the meaning of inspection codes to be marked up in those documents.

A1.18. Quality Management System

A management system to direct a unit and control an organisation with regard to quality; a combination of resources and means with which quality is realised.

A1.19. Safety Case

In this document, 'safety case' refers to the totality of a licensee's (or duty holder's) documentation to demonstrate safety, and any sub-set of this documentation that is submitted to ONR.

Note: Licence Condition 1 defines 'safety case' as the document or documents produced by the licensee in accordance with Licence Condition 14.

A1.20. Safety Culture

The assembly of characteristics and attitudes in organisations and individuals, which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance (IAEA Safety Glossary).

A1.21. Supplier

An organisation that provides items or services in accordance with a purchaser's order. The supplier may provide the item or service directly to the purchaser or form part of the purchaser's supply chain. See also Manufacturer/Contractor/Vendor.

A1.22. Supply Chain

The network of organisations that are involved in the different processes and activities that contribute to the provision of items or services to the purchaser.

A1.23. Supply Chain Management

In the context of this TAG, SCM refers to the 'end to end' SC processes managing the flow of items and services from the supplier to the ultimate customer. This includes the effective specification of requirements by the purchaser as 'Intelligent Customer'; sourcing of suppliers; procurement of items or services; installation, operation or use, and associated supporting activities (ie logistics, relationship & performance management etc.). In the context of this TAG, an efficient procurement process is only one part of effective SCM arrangements for nuclear safety related items or services.

A1.24. Suspect Item

An item about which there is an indication by visual inspection, testing, or other preliminary information that it may not conform to accepted standards, specifications and/or technical requirements and there is a suspicion that the item may be counterfeit, fraudulent or non-conforming. Additional information or investigation is needed to determine whether the suspect item is acceptable, non-conforming, counterfeit or fraudulent.

A1.25. Technical Query

A question for approval prior to work stage commencement. Clarification of requirements. Care should be taken as some responses to TQ's may require a change to the specification or requirements and thus controlled as deviations to ensure the as built condition is captured.

A1.26. Technical Specification

The Technical Specification defines the system, components and items, as applicable, in sufficient detail to provide a complete basis for the design, manufacture, testing and installation.

APPENDIX A2: EXAMPLES OF ITEMS REQUIRING HIGH LEVELS OF ONR INVOLVEMENT WITH THE SUPPLY CHAIN

A2.1. Introduction

This annex provides a summary of items and services that warrant high levels of ONR involvement, such as agreement of the technical specification prior to contract placement and intervention activity associated with the purchaser's supply chain management arrangements and procurement processes. In each case, the purchaser should commence early engagement with the ONR.

A2.2. Structural Integrity

Structural Integrity of materials or processes carried out to improve material functionality and reliability.

- a) Pressure system components where the nuclear safety claim is that the likelihood of gross failure is so low it can be discounted (gross failure cannot be tolerated within design provisions),
- b) Class 1 components (including those that fall under (a) above),
- c) A sample of Class 2 components (the sample to include any Class 2 components that fall under (a) above),
- d) A sample of Class 3 components. The sample is expected to be smaller than for Class 2 components (the sample to include any Class 3 components that fall under (a) above).

A2.3. Electrical, Control and Instrumentation

Class 1 systems and components and a sample of Class 2 systems and components.

A2.4. Civil Engineering

Class 1 structures and a sample of Class 2 structures and systems.

A2.5. Mechanical Engineering

Class 1 systems and components and a sample of Class 2 systems and components.

A2.6. The following notes are applicable to paragraphs A2.2, A2.3, A2.4 and A2.5 above:

Note 1 - ONR SAP, EKP.4 defines safety function. SAPs references ECS.1 to ECS.3 deal with categorisation of safety functions, identification of structures, systems and components that deliver safety functions and selection of appropriate codes and standards.

Note 2 - Class 1, 2 and 3 structures, systems or components are defined within the SAPs as:

- Class 1 – any structure, system or component that forms a principal means of fulfilling a Category A safety function.
- Class 2 – any structure, system or component that makes a significant contribution to fulfilling a Category A safety function, or forms a principle means of ensuring a Category B safety function.
- Class 3 any other structure, system or component contributing to a categorised safety function.

Note 3 - Category A, B and C functions are defined within the SAPs as:

- Category A – any function that plays a principal role in ensuring nuclear safety.
- Category B – any function that makes a significant contribution to nuclear safety.
- Category C – any other safety function contributing to nuclear safety.

APPENDIX A3: PREFERRED MODEL FOR THE PRIMARY CIRCUIT PRESSURE BOUNDARY COMPONENTS

A3.1. Introduction

A3.1.1 The preferred model for procurement of high risk items in support of new build or development or maintenance of existing facilities positions the Licensee at the head of the supply chain. However, where the Licensee organisation is not in place or is not fully developed, some or all of the Licensee's responsibilities may be undertaken by the purchaser. In all cases, the Licensee/purchaser should commence early engagement with the ONR.

A3.1.2 This annex provides examples of organisational roles and responsibilities for the specification, design, manufacture, testing and installation of primary circuit pressure boundary components which represents the highest risk and level of assurance.

A3.1.3 The main organisations involved are:

- Licensee/Purchaser (where Licensee organisation is not in place or fully developed)
- Manufacturer/Contractor
- Inspection Agency
- Accredited organisation that issues the Licensee's Certificate or certification to international management system requirements.

The responsibilities of these organisations are as follows:

A3.2. Licensee/Purchaser

The responsibilities of the Licensee/purchaser are to:

A3.2.1. Document the management systems arrangements in accordance with national/international standards, e.g. IAEA GSR PART 2 'Leadership and Management for Safety'.

A3.2.2. Obtain a Licensee's Certificate or the equivalent certification to management systems requirements to confirm the Licensee's capability to execute its responsibilities. The organisation that issues this certificate to the Licensee/Purchaser should be agreed with the ONR. Ideally the Certificate should be issued by an organisation engaged by the Licensee/purchaser for this sole purpose.

A3.2.3. Engage one or more Inspection Agencies to fulfil the role described in Section A3.4 of this appendix.

A3.2.4 Certify that the completed installation complies with the design code/technical specifications for the various components/systems.

A3.2.5. Define in the technical specification, those records that are to be included in the lifetime records for the installation and the associated records management arrangements. These will include:

- a) Identification of the records to be retained by the Licensee/purchaser and the contractor.
- b) Arrangements to safeguard and maintain records to be retained by the Licensee/purchaser and the contractor.

- c) Arrangements which ensure that contractor's records are transferred to the Licensee/purchaser if the contractor is no longer willing or able to retain the records.

A3.2.6. Evaluate and audit the management systems quality arrangements employed by contractors (and where appropriate, including sub-contractors) for design, manufacture and installation of nuclear safety related pressure equipment.

A3.2.7. Establish the design code version to be used and define this in the design specification.

A3.2.8. Prepare, review and certify the technical specifications, design reports and certification forms and designate authorised personnel to carry out those duties.

A3.2.9 Classify equipment in accordance with applicable safety criteria, define the resulting applicable design code, and define the acceptance criteria to be applied to load/design limit combinations.

A3.2.10. Designate overpressure protection requirements and location for each component or system.

A3.2.11. Provide a report that explains and justifies the overpressure protection arrangements.

A3.2.12. Provide adequate structures, foundations and auxiliary systems for pressure equipment.

A3.2.13. Make available to the ONR those documents which the Inspection Agency are required to endorse and such documentation as is necessary for the Inspection Agency to fulfil its responsibilities.

A3.2.14. If not required by the design code, agree with the contractor and inspection agency a suitable means of physical identification of components and items.

A3.3. Manufacturer/Contractor

The responsibilities of the manufacturer/contractor are to:

A3.3.1. Prepare, review, approve and certify the Technical Specification, Design Report and Certification Forms, where these responsibilities have been delegated by the Licensee/purchaser, and to submit the certified documents to the Licensee/purchaser and Inspection Agency as necessary.

A3.3.2. Designate authorised personnel to carry out the certification duties required. Such personnel should not be in the employment of the Inspection Agency. The Contractor must be prepared to justify his arrangements for designation to the Licensee/purchaser.

A3.3.3. Obtain approval from the Licensee/purchaser for the management system arrangements.

A3.3.4. Specify appropriate management system and quality arrangements requirements to be met by its sub-contractors, and to approve its sub-contractors arrangements against these requirements. The Licensee/purchaser and Inspection Agency shall have the right to participate in the management system approval process and its subsequent audit activities at any level of supply. It is the responsibility of the contractor to advise the Licensee/purchaser and the Inspection Agency of approval or audit activities so that participation by their nominated representatives may be agreed in advance of the activity.

A3.3.5. Ensure compliance with the technical specification and design code.

A3.3.6. Ensure that applicable requirements are effectively applied throughout the SC. This shall include, but not be limited to, procurement from its suppliers of technical specifications, design reports, certification certificates and other applicable documents.

A3.3.7. Prepare records packages for items being procured including manufacturer/contractor certification certificates and those provided by sub-contractors. These records must be safeguarded and maintained.

A3.3.8. Review material and other test reports for compliance with the relevant code, standard or specification.

A3.3.9. Submit the following items to the Licensee/purchaser for approval:

- a) Any proposed deviation from the chosen technical specification including design code;
- b) Any proposed concessions, for example to use materials which do not comply in full with the chemical and mechanical properties of the materials defined in the technical specification or applicable design code;
- c) Any other proposed deviation from the technical requirements of the technical specification or agreed Quality or management systems arrangements.

A3.4 Inspection Agency

A3.4.1 In the UK, accreditation meeting the requirements of ISO 17020:2012, (Ref. 7.6), implies the inspection agency is accredited through the UK accreditation service (UKAS) or another recognised equivalent international accreditation body that is a signatory to an appropriate international multi-lateral agreement for mutual recognition.

A3.4.2 An inspection department maintained by the manufacturer does not satisfy the requirement of an independent Inspection Agency.

A3.4.3 The responsibilities of the Inspection Agency are to:

- a) Maintain access to Surveyors who are suitably trained and qualified to perform the duties required, including familiarisation with the requirements of the design code.
- b) Assess and monitor the Quality Assurance Programme activities of the Contractor, its Sub-Contractors and suppliers. This responsibility will generally be carried out in participation with the Licensee/purchaser and/or its Contractor, but may be supplemented by independent monitoring as necessary.
- c) Verify that all materials used comply with the applicable requirements by witnessing examinations or carrying out inspection as it considers necessary. Such inspections shall include verification of methods of identification and traceability of materials, items and components.

A3.4.4. Witness or verify in-process fabrication and erection, non-destructive examination and tests as necessary, and witness final pressure tests. Such verification shall include the review of welder qualification and welding procedure qualification records, the endorsement of witnessed test results, and the review of non-destructive examination personnel qualification records.

A3.4.5. Endorse Certification Forms and other documents requiring Inspection Agency certification.

A3.4.6. Review and comment on drawings and process procedures, designate hold and notification points on Quality Plans and inspect against them.

A3.5 Accredited Organisation that issues the Licensee's Certificate

The responsibilities of the organisation that issues the Licensee's Certificate are to:

A3.5.1. Verify that the Licensee/purchaser understands its Quality Assurance responsibilities specifically with regard to items or services significant to nuclear safety.

A3.5.2. Verify the Licensee/purchaser's agreement to meet its responsibilities.

A3.5.3. Ensure that the Licensee/purchaser's Quality Assurance Programme is sufficient to discharge its responsibilities, including activities undertaken by sub-contracting organisations on behalf of the Licensee/purchaser.

**APPENDIX A4: SUPPLEMENT TO THE GENERAL INSPECTION GUIDE (TAG-064)
COVERING SUPPLIER (VENDOR) INSPECTIONS.**

A4.1. INTRODUCTION

- A4.1.1 ONR is the enforcing authority for HSW Act section 6 for suppliers of products and services primarily intended for GB nuclear sites and authorised defence sites.
- A4.1.2 ONR's inspections of such suppliers must be conducted to the same professional and procedural standards as other types of inspection undertaken by ONR.
- A4.1.3 This appendix gives information that will permit Inspectors to tailor ONR's inspection approach to accommodate the features that are unique to inspection of suppliers.

A4.2. PURPOSE AND SCOPE

- A4.2.1. General Inspection Guide (ONR-INSP-GD-064 Rev 2) sets out ONR's expectations for all inspection activities, including those of suppliers.
- A4.2.2. ONR Guidance on Intervention Planning and Reporting (ONR-INSP-GD-059 Rev 6), acknowledges that supply chain and quality inspections are a type of integrated specialism inspection and gives advice (in para 9.14 et seq.) on the categories of supply chain inspection that may be carried out. These are:
 - Inspection of the Licensee's own arrangements to oversee its suppliers; and
 - Direct inspection of key suppliers, called vendor inspections.
- A4.2.3. The purpose of this appendix is to give tailored advice on how to conduct vendor inspections most effectively. Tailored advice is not needed for inspection of the Licensee's own arrangements, which can be conducted wholly in accordance with GD-064 and GD-059. For both types of inspection, the regulatory expectations are defined in the ONR Nuclear Safety Technical Assessment Guide TAG 077.

A4.3 GENERAL OBJECTIVES FOR VENDOR INSPECTIONS

- A4.3.1. Focus on the risks associated with the supplied items or services and the adequacy of the supplier's or the Licensee's arrangements to control the risks. See diagrams 1 & 2.
- A4.3.2. Establish the governance arrangements for developing maintaining and sustaining the supply chain for nuclear safety related items and services within the supplier and their own supply chain.
- A4.3.3. Establish the supplier's approach to licensee strategic partnerships and how these relationships are managed.
- A4.3.4. Identify who the key sub-contractors are and the arrangements suppliers have to manage and oversee these relationships, and control changes in their own supply chain.

- A4.3.5. Establish how the supplier engages with licensees and analyses any issues in procurement to identify lessons to be learnt and any measures required to prevent recurrence. See diagram 1 item 9.
- A4.3.6. Overview by the supplier of their organisation including position in any wider corporate body. Overview of what the company supplies to the nuclear industry and their locations. For example: project management, design, manufacture, inspection, installation, commissioning, outages, maintenance, de-commissioning and any role in industry working groups aimed at shared learning and improvements.

A4.4 TAILORED ADVICE ON VENDOR INSPECTIONS

- A4.4.1 The General Inspection Guide (ONR-INSP-GD-064) covers the five phases of any ONR inspection from planning through preparation, delivery, write up and follow up. These five phases apply to vendor inspections and the information in the Guide is also applicable to them. Particular tailored advice is given against each of the five phases, as follows.

Planning phase

- A4.4.2 The Professional Lead will arrange for an annual vendor inspection programme to be developed and determine which suppliers should be targeted in it.
- A4.4.3 The vendor inspection programme should be planned and implemented in line with the advice in GD-064 and GD-059. The programme should be kept under review.
- A4.4.4 The programme may include vendor inspections under international regulatory protocols such as the MDEP VICWG (Multi-national design evaluation programme, vendor inspection co-operation working group). As such, other national Regulators may be invited to conduct joint or witnessed inspections of GB suppliers. Similarly, ONR may conduct supplier inspections with other national regulators outside GB.

Preparation phase

- A4.4.5 The Inspector should consider whether it is appropriate to inspect the vendor directly or accompanied by the Licensee.
- A4.4.6 The Inspector should hold a pre-meeting with the supplier, particularly if it is a supplier that has not had interactions with ONR before. The pre-meeting should explain ONR's vires, the inspection process and address any supplier concerns. ONR's vires within the supply chain is outlined in TAG-077. The pre-meeting should discuss practicalities, including whether a Licensee will observe the vendor inspection and which projects may be sampled by the Inspection.

Delivery phase

- A4.4.7 The inspection should be conducted in line with GD-064. Normally, there are two phases to the inspection: an assessment of the supplier's general supply chain and quality management arrangements and an inspection of the effective deployment of the arrangements into a sample of at least one project, product or service.

Write up phase

A4.4.8 Reports and contact records should be in line with GD-064. It is important to confirm findings and corrective actions directly with the supplier and confirm them in writing.

Follow up phase

A4.4.9 Corrective actions should be monitored to closure in a proportionate manner. Licensees may be involved in this activity, and Inspectors should be alert to opportunities to involve Licensees in follow up to supplier actions.

A4.4.10 The ONR Regulatory Issues database should be used for supplier issues, and entries should be made against suppliers. Guidance is in ONR-RI-GD-003 "Management of Regulatory Issues".

A4.4.11 Inspectors should consider sharing any relevant learning with specialism colleagues, relevant site inspectors and the Safety Director's Forum, Supply Chain & Quality working group. Suppliers should be encouraged to engage with the Licensees that they support and let them know the outcome of ONR's inspections and share relevant learning where applicable.