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| ONR Technical Assessment Guide  Supply chain management arrangements for the procurement of nuclear safety related items or services |



ONR Technical Assessment Guide (TAG)

Supply chain management arrangements for the procurement of nuclear safety related items or services

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| 6.3 | Comprehensive review of the content leading to minor revision of the text in line with updates to relevant good practice and learning from the use of the TAG. |

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# Introduction

1. ONR has established its [Safety Assessment Principles](http://www.onr.org.uk/saps/saps2014.pdf) (SAPs) [1] 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 dutyholders. 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.

# Purpose and scope

1. TAGs 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 dutyholders, and although they may be used as a source of guidance or good practice, they are not a prescriptive set of legal requirements.
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’ [2], that the licensee makes and implements adequate quality management arrangements in respect of 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 the control of procurement of items or services and contract management activities, are fundamental to ensuring that any potential licensee, licensee or other dutyholder applies appropriate levels of control, oversight and assurance over all organisations within their supply chains.
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 ONR.
4. This TAG applies to all SCM arrangements and procurement activities which relate to nuclear safety. The TAG also addresses the specific issues associated with procurement of items manufactured for the construction of any new civil reactor in advance of a nuclear site licence application, often termed long lead items (LLI).
5. 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 conduct effective oversight, assurance and acceptance of items or services being supplied or undertaken on its behalf where their delivery has the potential to impact on nuclear safety.
6. 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.
7. ONR’s expects purchasers to operate in line with Figure 1, which applies to any organisations in the purchaser’s supply chain undertaking work with nuclear safety significance, except for element two relating to ‘Intelligent Customer’ (IC) capability, which is a role for the licensee alone.
8. A future civil reactor operator may not be licensed until after orders need to be placed for long lead items (LLI). If this happens, then ONR would expect any future civil reactor operators or potential future licensees who have let the contract for long lead items to act as the IC until a licensed organisation is established. Further information can be found in [Appendix B](#_Appendix_B_–).
9. [Section 5.3](#_Supply_chain_cycle) of this TAG is structured to align to ONR’s expectations in   
   Figure 1. Each chapter starts with a summary of what ONR expects before giving guidance on activities inspectors should consider during any regulatory activities with the purchaser or its supply chain.
10. Licensees frequently out-source delivery of products and services to specialist suppliers, many of which perform activities outside the UK.   
    Hence, the licensees’ extended enterprise can be complex and often international in nature. This can lead to risks to nuclear safety, particularly at the interfaces between organisations in the licensees’ supply chain.   
    The potential risk factors for Inspectors to consider are summarised in   
    Figure 2.

An image summarising ONR expectations applied to a basic procurement cycle for work with nuclear safety significance.

These are - 

Heading 1 - Strategy - Plan to deliver - 
1. Effective commercial and/or supply chain strategy to enable delivery of safety case requirements. 
2. The Licensee should maintain an ‘Intelligent Customer’ capability for all work carried out on its behalf that may impact upon nuclear safety 

Heading 2 - Specify -Define the requirement - 
3. Specifications adequately describe the items or services, meet the safety case requirements and identify the required level of quality assurance.

Heading 3 - Source - Find the Right Supplier -
4. Evaluate and confirm the suppliers have the organisational and technical capability, capacity and culture to deliver items or services to the specification prior to placing any contract. 
5. Suppliers have quality management arrangements that are appropriate and consistent with the safety significance of the procured items or services.

Heading 4 - Deliver - Meet the Specified Intent, Right First Time -
6. Suppliers identify and categorise any deviations from specified requirements, referring to the Design Authority for assessment.
7. Effective oversight and assurance of the supply chain, including the acceptance of items or services.
8. Arrangements are in place to mitigate the risk of Counterfeit, Fraudulent and Suspect Items (CFSI) entering the supply chain. 
9. Capture and act on operational experience feedback from supply chain and supply chain management activities, sharing learning as appropriate within the organisation, its supply chain and wider industry.


Figure 1 - Summary of ONR expectations applied to a basic procurement cycle for work that may impact upon nuclear safety.

An image showing risk factors associated with organisational interfaces. These are displayed as a bubble diagram showing the interfaces between the various tiers of the supply chain, with the licensee organisation at the centre. 

Description automatically generated

Figure 2 – A diagram of a typical licensee’s supply chain to illustrate the licensee’s “extended enterprise” across all its tiers in the chain and organisational interfaces.

1. Risk factors to consider across the extended enterprise:

* Capability – the licensees’ or other dutyholders’ organisational and technical ability to secure delivery of items or services to the specification.
* Capacity – the licensees’ or other dutyholders’ ability to secure delivery of the specified volume of items or services to the specification.
* Organisational 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. For the purpose of this TAG this definition is inclusive of nuclear safety, nuclear site health and safety, security and quality.
* Cascade of requirements – the flow down of licensee requirements through the tiers of the supply chain and the associated communication between parties to understand the requirements.
* Oversight and assurance – the activities undertaken to oversee and assure performance throughout the tiers of the supply chain.
* Localisation – the restriction of trade to local markets.
* Globalisation – the increase in international trade.

# Relationship to licence and other relevant legislation

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

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

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.
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.
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.

## Management of Health and Safety at Work Regulations 1999

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.

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

1. Identifies 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.

1. 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.
2. [Appendix C](#_Appendix_C_–) explains how ONR undertake vendor (supplier) inspections as one of the means of discharging this enforcing authority responsibility.

## The Construction (Design and Management) Regulations 2015 (CDM 2015)

1. CDM 2015 places specific legal duties and requirements on organisations and individuals who undertake specific roles e.g. Clients, Designers, Principal Designers, Principal Contractors, Contractors and Workers etc.
2. CDM 2015 applies to all construction projects in Great Britain (GB), from concept to completion which includes, but is not limited to: design, new build, demolition, modifications, refurbishments, extensions, conversions, repair, and maintenance of a building and/or a civil structure. It also has implications for designs prepared outside of GB, which is an important consideration during the Generic Design Assessment (GDA) process for new nuclear power stations.
3. Those who hold roles under CDM 2015 may also hold roles of Design Authority (DA) or Intelligent Customer (IC). The responsibilities under CDM and Design Authority are often similar in intent with differing legal duties. Designers and principal designers under CDM 2015 must have the necessary skills, knowledge and experience, and if they are an organisation, the organisational capability to fulfil the duties under CDM 2015.   
   Further guidance is available in ONR inspection guide, NS-INSP-GD-074 [3].

## Nuclear Installations Act 1965 (NIA)

1. NIA requires ONR to attach conditions to nuclear site licences as necessary in the interests of safety. The site licence conditions [2] 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 – Examination, inspection, maintenance and testing
* LC 35 – Decommissioning
* LC 36 – Organisational Capability

# Relationship to Safety Assessment Principles, WENRA Reference Levels, and IAEA Safety Standards and Guides

## Safety Assessment Principles

1. The Safety Assessment Principles (SAPs) for Nuclear Facilities [1] provides a framework to guide regulatory decision-making in the nuclear permissioning process. It is supported by TAGs which further aid the decision-making process. The following principles are of most 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.

## Technical Assessment and Inspection Guides

1. The following TAGs and Technical Inspection Guides (TIGs) have a bearing on this TAG and contain related guidance for inspectors on SCM and procurement of nuclear safety related items or services:

* NS-TAST-GD-016 – Integrity of Metal Structures, Systems and Components
* NS-TAST-GD-017 – Civil Engineering
* NS-TAST-GD-027 – Training and Assuring Personnel Competence
* NS-TAST-GD-031 – Safety related Systems and Instrumentation
* NS-TAST-GD-033 – Dutyholder Management of Records
* NS-TAST-GD-046 – Computer Based Safety Systems
* NS-TAST-GD-049 – Licensee Core Safety and Intelligent Customer Capabilities
* NS-TAST-GD-057 – Design Safety Assurance
* NS-TAST-GD-079 – Licensee Design Authority Capability
* NS-TAST-GD-098 – Asset Management
* NS-TAST-GD-109 – Ageing and Degradation Management
* CNS-TAST-GD-4.1 – Procurement and Intelligent Customer Capability
* CNS-TAST-GD-4.2 – Supplier Capability
* CNS-TAST-GD-4.3 – Oversight of Suppliers
* 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-006 – LC6 – Documents, Records, Authorities and Certificates
* NS-INSP-GD-017 – LC17 – Management Systems
* NS-INSP-GD-074 – Construction (Design and Management) Regulations

1. The TAGs related to civil engineering, instrumentation, computer-based systems, construction, integrity of metal structures, systems and components make references similar to those in this TAG about the importance of effective specification of requirements, control of manufacturing processes, material traceability and inspection and test requirements.

## WENRA Safety Reference Levels for Existing Reactor

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 WENRA Safety Reference Levels (RLs) [4] 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 the respective section of this TAG to demonstrate alignment:

* Issue A: Safety Policy
  + A1. Issuing and communication of a safety policy (refer to Section ‎5.3.3 of this TAG for further information).
    - 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 (refer to Section ‎5.3.5 of this TAG for further information).
    - 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 (refer to Section ‎5.3.2 of this TAG for further information).
    - 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: Leadership and Management for Safety
  + C3. Management for safety
    - C3.17 Arrangements for qualification, selection, evaluation, procurement, and oversight of the supply of products and services important to safety shall be made on the basis of specified criteria. (refer to Section ‎5.3.4 of this TAG for further information).

**Note**: Important to safety products and services are defined by WENRA as “Products and services participating in the technical or organisational provisions on which the safety demonstration of the plant is based”.

Procurement procedures include specific instructions for preventing, detecting, reporting and disposing of counterfeit, fraudulent and suspect items.

* + - C3.18 Purchasing requirements shall be developed and specified in procurement documents. Evidence that products and services meet these requirements shall be available to the licensee before they are used (refer to sections ‎5.3.4 and ‎5.3.7 of this TAG for further information).
    - C3.19 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 safety responsibility when purchasing any products or contracting any services. It shall be ensured, that sufficient comprehension and knowledge about the product or service, that is being procured, are available within the licensee’s organisation (refer to Section ‎5.3.2 of this TAG for further information).
  + C4. Safety culture (refer to Section ‎5.3.7 of this TAG for further information).
    - C4.1 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.

* + - C4.2 The management system shall include provisions to systematically develop, support, and promote desired and expected attitudes and behaviours that result in a strong safety culture.
    - C4.3 The licensee organisation shall ensure that its suppliers and contractors whose operations may have a bearing on the plant safety comply with C4.1 and C4.2 in a way that ensures that the resulting interfaces with the plant support the standards and expectations.
* Issue D: Training and Authorisation of Nuclear Power Plant Staff   
  (Jobs with Safety Importance)
  + D2. Competence and qualification (refer to Section ‎5.3.4 of this TAG for further information).
    - 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 (refer to Section ‎5.3.4 of this TAG for further information).
    - 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.
    - D3.6 Maintenance and technical support staff including contractors shall have practical training on the required safety critical activities.
  + D4. Authorisation (refer to Sections ‎5.3.5 and ‎5.3.7 of this TAG for further information).
    - 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 (refer to Section ‎5.3.9 of this TAG for further information).
    - J4.4 The operating organisation shall maintain liaison as appropriate with the organizations (manufacturer, research organization, 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

## IAEA Safety Standards

1. The IAEA Safety Standards (Requirements and Guides) were the benchmark for the revision of the SAPs in 2006, 2014 and 2020 and are recognised by ONR as relevant good practice. They should be consulted, where relevant, by the assessor as complementary guidance, although written as design standards rather than regulatory standards. This TAG is broadly compatible with these standards for SCM arrangements for the procurement of nuclear safety related items or services.
2. The main IAEA Safety Standard of relevance is the Safety Requirements – **‘Leadership and Management for Safety**’, Safety Standards Series No. **GSR Part 2** [5]; 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 minimising the occurrence of problems relating to safety, with which this TAG is consistent.
3. This 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 [6] and ‘**The Management System for Nuclear Installations**’, Safety Standards Series No. GS-G-3.5 [7] .

## ISO Standards

1. ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). ISO standards in the field of nuclear safety are complementary technical documents and are recognised by ONR as relevant good practice.
2. This TAG does not include a full list of ISO standards that could apply to the field of supply chain management. However, the following have been highlighted due to each standards overarching scope -

* Management systems - BS EN ISO 9001 [8] and/or BS EN ISO 19443 [9].
* Testing laboratories, inspection bodies and certification of persons - BS EN ISO/IEC 17025 [10], BS EN ISO/IEC 17020 [11] and BS EN ISO/IEC 17024 [12].
* Guidance to understand, evaluate and improve organizational quality culture - BS ISO 10010 [13].

**Note**: Inspectors should reference most recently published version of the standard.

# Advice to inspectors

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 or decommissioning of plant and equipment.
* Procurement for new civil reactor build, where orders for long lead items may be placed before the purchaser is licensed.

1. The level of ONR scrutiny is dependent on the nuclear safety significance of the items or services being procured (refer to [Appendix A](#_Appendix_A_–)). This scrutiny might include confirmation of the capability 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.

## Procurement for new civil reactor build, where orders for long lead items may be placed before the purchaser is licensed

1. Where the licensee organisation is not in place or is not yet fully developed, some or all 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 or prospective licensee may choose to place orders for long lead items prior to site licence award (or even prior to identification of the prospective licensee). Where this is the case the ONR preferred approach is for the purchaser to organise the issue of a ‘Licensee Certificate’.
2. The ‘Licensee Certificate’ for implementation of management systems looks at the purchaser’s management system arrangements and assurance requirements for high-risk long lead items appropriate to the project stage (refer to [Appendix B](#_Appendix_B_–)). Inspectors should be aware that an organisation may wish to establish other arrangements that are equivalent to a licensee certificate. This should be discussed with ONR as part of early engagement.
3. 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.
4. The purchaser’s management system arrangements should provide equivalent levels of assurance to those that a licensee would apply if a nuclear site licence were in place.
5. Proposals should be discussed with ONR prior to any procurement activity commencing. This is because the long-lead items may be subject to permissioning by ONR and understanding gained via early engagement will assist in any later permissioning decisions.
6. The Inspector should consider:

* Is the purchaser procuring high-risk long lead items prior to site licence award or identification of the prospective licensee?
* Can the purchaser demonstrate, either through a Licensee Certificate (preferred) or other means, that the purchasing organisation has adequate management system arrangements and adequate technical and organisational capability, capacity and organisational culture to manage the procurement of high-integrity long lead items?
* Whether there is a need to engage or share information with other UK regulators (i.e. Environment Agency, Defence Nuclear Safety Regulator (DNSR)) relevant to the purchaser’s procurement of nuclear safety related items or services?
* If the purchaser understands the risks associated with the procurement of long lead items, including the regulatory requirements for the permissioning process?

## Supply chain organisational culture

1. The NIA places the primary responsibility for the safety of a nuclear installation on the licensee. The NlA also places an absolute liability on the licensee as regards injury to persons or damage to property arising from a nuclear occurrence without proof of fault on the licensee's part. It is therefore essential that a licensee retains overall responsibility for control and oversight of, the nuclear and radiological safety and security of all its business. This includes work conducted on its behalf by its supply chain.
2. In its SAPs, ONR has established that:

“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” (SAP MS.1) [1].

1. ONR has provided supplementary guidance on this SAP which states:

“The value of safety as an integral part of good business and management practice should be reinforced through interactions between directors, managers, leaders, and staff, **including contractors**, to establish a common purpose and collective social responsibility. Consultation and involvement of all staff secures effective engagement and co-operation in the development, maintenance and improvement of safety and promotes a shared concern for achieving safety goals. As a result, people at all levels in the organisation should be engaged in a common purpose that recognises responsibility and accountability to each other and external stakeholders to ensure high standards of safety. **The licensee should ensure that this extends to contractors down the supply chain as required**.”

1. ONR therefore considers it important that a licensee develops and maintains a culture for safety and that the licensee ensures that this culture for safety extends to the contractors and suppliers in its supply chain.
2. Licensees and higher tier suppliers are likely to be familiar with the terms “safety culture,” “nuclear safety culture,” and/or “culture for safety,” and should be knowledgeable about their importance in securing good safety outcomes. However, further down the supply chain suppliers may have a lower level of understanding of these terms and instead the term “quality culture” may be more well understood. It is therefore important that licensees ensure that suppliers understand the relationship between the quality of the supplied goods or services and nuclear safety: in the context of a supply chain, a “quality culture” is a prerequisite for a “safety culture.”
3. ONR will set out its definition of “safety culture” in its publication Safety Culture: Definition and Model [14] which will be published later in 2024.   
   This document will also introduce ONR’s model of safety culture: a set of dimensions and attributes that ONR considers to be the crucial factors that organisations working in Great Britain’s nuclear industry should strive to understand and improve upon, so that they may continually improve their safety performance and outcomes. Licensees should ensure that they understand and improve on these dimensions and attributes in their own organisations and take measures to ensure that their contractors in the supply chain understand and improve on these too.
4. Integrated throughout relevant sections of this TAG is guidance for ONR inspectors relating to organisational culture within the supply chain. Inspectors can find further guidance on safety culture and quality culture in the following publications:

* BS EN ISO 19443 (nuclear safety culture) [9]; and,
* BS ISO 10010 (quality culture) [13].

1. A framework of indicators has been developed to support the collection of cultural insights during ONR activities (inspection, assessment, meetings, interventions, investigations) which can then be used to build up a picture and understanding of culture on site. Guidance for inspectors relating to this is set out within ONR’s TIG, NS-INSP-GD-070 [15], which is one component of ONR’s overall approach to regulating organisational culture. Its purpose is to support inspectors in gathering intelligence from their everyday interactions in a proportionate and a consistent manner.

## Supply chain cycle (Figure 1)

1. This section of the TAG is structured to align to ONR’s expectations in Figure 1. Each chapter starts with a summary of what ONR expects before giving guidance on activities inspectors should consider during any regulatory activities with the purchaser or its supply chain.

### Supply chain strategy (Figure 1, Item 1)

1. The purchaser should establish an effective commercial and/or supply chain strategy to enable delivery of safety case requirements (refer to Figure 1, Item 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.
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 part of the organisations’ business planning processes so that they remain effective and proportionate to the identified risks 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; mergers, acquisitions, insolvency, capability, risk and performance issues.
* Security of supply; business continuity issues, strategic/critical suppliers, globalisation or localisation of suppliers.
* “Make or buy” policy; delivering work internally (insourcing) or contracting work externally (outsourcing).
* Potential for tension between delivering quality and safety performance and any drive to improve efficiency and competitiveness commercially. 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 delivery of safety case requirements.

1. It should be noted that the NIA places a duty on the licensee to ensure that the conditions of the licence are complied with. The licensee is not able to delegate this overall responsibility to suppliers (contractors, service providers or others) who do work on its behalf.
2. The licensee therefore must retain overall responsibility and accountability for nuclear and radiological safety and security at all times, and ONR considers that in order to do this it must maintain a suitable level of control and oversight of those who are carrying out work on its behalf (refer to section 5.3.2).
3. Purchasers may develop and maintain supply chain maps as part of their graded approach to enable them to target their assurance activities at the areas of highest risk across its extended enterprise. The depth and breadth of the information gathered under supply chain mapping should be commensurate with the nuclear safety significance of the product or service being procured.
4. 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; delivering work in-house (insourcing) or contracting work externally (outsourcing), adequately considers current and future safety case requirements as part of the decision making criteria?
* If the purchaser proactively monitors and manages supply chain risks such as mergers, acquisitions, insolvency, capability and performance issues?
* If the purchaser maintains supply chain maps as part of their graded approach to assurance, commensurate to the nuclear safety significance of the product or service being procured?

### Intelligent customer (Figure 1, Item 2)

1. The licensee should maintain an ‘Intelligent Customer’ (IC) capability for all work carried out on its behalf by suppliers that may impact upon nuclear safety (refer to Figure 1, Item 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.
3. 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 IC for any work it commissions for its benefit.
4. In the context of effective SCM the licensee should maintain an IC 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.
5. ONR’s regulatory expectations for licensee core safety and intelligent customer capabilities are defined in TAG, NS-TAST-GD-049 [16].   
   Inspectors should review the document for detailed information that complements this TAG. It 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:
6. The licensee should maintain a core safety capability to ensure effective control and oversight of nuclear safety.
7. The licensee shall retain overall accountability, control and oversight of the nuclear safety of all of its business, including work carried out on its behalf by contractors.
8. The licensee should be informed by a company policy that takes into account the nuclear safety implications of sourcing work in-house or from contractors.
9. The licensee should maintain an IC capability on the nuclear baseline for all work carried out on its behalf by contractors that may impact upon nuclear safety.
10. The licensee should ensure that it only lets contracts for work, with nuclear safety significance, to contractors who are suitably competent, with adequate resources, underpinned by a management system that promotes a positive safety culture, learning and safety standards.
11. The licensee should ensure that all relevant contractor staff adequately understand the nuclear safety significance of their work and the licensee should interface with contractor staff in a well co-ordinated manner.
12. The licensee shall implement adequate arrangements to ensure that contractors’ work is carried out to the required level of safety and quality in practice.
13. 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 evaluated the competence, standards, management system, organisational culture and resources of a supplier prior to contract award?
* If the licensee has given training and information on the subject of organisational culture (refer also to section ‎5.3.4) to organisations within the supply chain and ensured flow down to all suppliers?

### Specification (Figure 1, Item 3)

1. The purchaser should ensure that specifications adequately describe the items or services, meet any safety case requirements and identify the quality requirements (refer to Figure 1, Item 3).
2. One of the most important aspects of the procurement cycle is establishing an effective specification. An ineffective specification means that any supplier in the supply chain will find it difficult to deliver the purchaser’s requirements right first time, regardless of its own capabilities and processes.
3. Given the importance of the specification, it is essential that those writing them 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 their expertise in how to best manufacture the equipment.
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 specify appropriate quality requirements. These should include, where applicable; assessment, audit, quality planning, quality control, inspection, surveillance, testing and release or handover of items and set out the records that should be supplied with the item or service.
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 B](#_Appendix_B_–) details the preferred model for procurement of primary circuit pressure boundary components which require the highest level of assurance.
6. For new nuclear facilities, the technical requirements of the contract between the purchaser and supplier for items or services should, amongst other things, take into account the findings of any ONR technical assessment work.
7. The purchaser should undertake assurance activities to ensure the design meets their requirements and any applicable codes and standards or legal requirements throughout the design period.
8. Where technical specifications are prepared for nuclear safety significant items or services by suppliers on behalf of the purchaser these should be reviewed by staff from the purchaser’s organisation who are competent to confirm that the specifications reflect the design intent, meet any design codes and standards and as such meet safety case requirements.   
   This review should be carried out before contract placement.
9. On receipt of any purchase order, the supplier should conduct 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.
10. The purchaser should operate a change control process (refer also to section ‎5.3.6). The process should ensure that any changes to specification, design or contract are adequately 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 ONR.
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 because of changes in the supply chain (such as mergers, acquisitions) should be agreed by the licensee.
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 through early contractor involvement, engaged potential suppliers for advice as part of developing any specifications? This may include the ease of manufacture/construction/service provision.
* If specifications prepared by suppliers are reviewed by competent staff from the purchaser’s organisation?
* If appropriate quality management arrangements are applied to the procurement of items or services significant to nuclear safety?
* If the purchaser’s specification and assurance arrangements address 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?

### Supply chain organisation and technical capability (Figure 1, Item 4)

1. For work with nuclear safety significance, the purchaser should evaluate and confirm that suppliers have the organisational and technical capability, capacity and organisational culture to deliver items or services to the specification prior to placing any contract (refer to Figure 1, Item 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.
3. Purchasers are expected to ensure that suppliers 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 standards for quality, environment and safety management such as BS EN ISO 9001 [8] and/or BS EN ISO 19443 [9].
4. Any evaluation of a potential supplier should include their organisational culture (refer to section 5.2).
5. As part of the supplier selection process, the purchaser should confirm that suppliers have adequate oversight and assurance arrangements for their own suppliers (refer to section ‎5.3.7). 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. Purchasers should confirm that suppliers of high risk items and services have adequate arrangements to maintain sufficient competent personnel throughout the contract period. Purchasers should also verify that supplier personnel performing safety significant activities are competent prior to the work commencing, this may be controlled via a hold point in a quality plan. The judgement on competency should be based on qualifications, training and experience and any applicable design code requirements. Arrangements should include provisions to monitor suitably qualified and experienced persons (SQEP) performance and identify the corrective action to be taken when the required standard is not met.
7. In recent years, licensees have placed increasing emphasis on the use of contractors for work that may impact upon nuclear safety, often making use of novel commercial models, such as partnerships, joint ventures, or frameworks. Regardless of the commercial model, the licensee is still responsible for arranging that all personnel whose actions have the potential to affect safety are suitably qualified and experienced.
8. Both the contractor and the licensee are responsible for verifying the competence and qualification of contractor personnel. However, the ultimate responsibility for contractors, including ensuring the quality and safety of all work performed at the site rests with the licensee.
9. ONR’s regulatory expectations for training and assuring personnel competence are defined in TAG, NS-TAST-GD-027 [17]. For work on nuclear facilities 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.
10. 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 personnel throughout the contract period?
* If the supplier has the capacity to provide an enduring source of high risk items or services, to the specification, throughout the contract period?
* If the purchasing organisation have promulgated the required organisational culture with key suppliers?
* If the purchaser has evaluated the suppliers’ organisational culture?
* 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?

### Quality management systems (Figure 1, Item 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 (refer to Figure 1, Item 5).
2. These quality management arrangements 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. Suppliers undertaking specialist activities may also be certified to additional specialist standards such as those for welding and Non-Destructive Testing (NDT).
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 factors 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 TIG, NS-INSP-GD-017 [18].

#### Quality plans

1. 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.
2. 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, ONR, to insert inspection points, witness points, review points or hold points into the manufacturing sequence. The wording and output of the activity should be clear, concise, and unambiguous.
3. 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.
4. 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 wet signatures used in quality plans should be identified by an accompanying printed name and position, this can be done each time or provided in a summary table at the front of the document. Equivalent arrangements should be in place for electronic signatures.
5. Quality plans should facilitate the signing off of all activities against the agreed inspection and verification activities identified. Quality plans should be completed in accordance with the purchasers’ requirements concurrently with the activity to which they relate.
6. 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, and should be able to function as a route map from the original scope of work to the underpinning records. These records should be collected progressively.
7. 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.
8. 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).
9. 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.
10. The evidence and records resulting from the quality plan inspection and verification activities should be unambiguous and traceable at all times, including all the links to personnel performing inspection and verification, criteria for inspection and verification, notifications, related non-conformities and concessions, open points including records of inspection and verification non-attendance and/or waiver, and regulator’s decisions.

#### Records

1. Identification and retention of design, procurement, manufacturing, fabrication and inspection records are required to support the case for operations (the safety case) and is necessary for compliance with the nuclear site licence. They provide evidence of assurance activities including those carried out by the supplier, sub-suppliers and the purchaser.   
   Guidance for inspectors on records can be found in TIGs, NS-INSP-GD-006 [19] and NS-TAST-GD-033 [20]. Records also provide 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.
2. 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.
3. 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, and any strategy to create records concurrently with the activity to which they relate.
4. 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 and is an important aspect of future verification and maintenance. The purchaser should develop the lifetime record package tracking process and ensure supplier’s contract arrangements identify this process and the supplier’s role within that process. The purchaser should ensure that all Lifetime Records (LTRs) are compiled concurrently with the work being undertaken and in accordance with the specification.
5. All records shall be readable, complete, unambiguous, identifiable with the product or process involved, and easily retrievable at all times.
6. All quality records generated as a result of conducting the inspection and verification activities shall include details of the authorised competent individual(s). All signatures, including electronic signatures should consist of a printed name, legible signature and date. Electronic systems should provide equivalent controls.
7. 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 there is adequate traceability in quality plans and records to plant item and/or component unique reference numbers?
* 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 there is adequate traceability to records for non-attendance and/or waiver of inspection and verification activities, non-conformities, concessions and open points?
* 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 (refer to TAG, NS-TAST-GD-033 [20] for further information)?
* If identified records are sufficient to satisfy the requirements of relevant LCs such as LC 6, 19, 20, 22, 25 and 28?
* If for construction projects involving more than one contractor, a health and safety file, has been produced to satisfy the requirement of CDM 2015?

### Deviations from specified requirements (Figure 1, item 6)

1. The purchaser should ensure that suppliers identify and categorise any deviations from specified requirements, referring to the Design Authority for assessment (refer to Figure 1, Item 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.
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. The purchaser should consider the cumulative effect of deviations from the specification.
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 (or sentencing) of deviations.
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 within the licensee or dutyholder for the deviation in the form of a concession or procedure for re-work. They should inform the ultimate purchaser and potentially ONR (via the purchaser at the head of the supply chain) for deviations that are significant to nuclear safety.
6. Technical queries (TQs) 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. TQs 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.
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.
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 dutyholder and ONR if appropriate, via the purchaser at the head of the supply chain?
* If the cumulative effect of deviations, including concessions and technical queries have been considered?
* 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?

### Supply chain oversight and assurance (Figure 1, Item 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 (refer to Figure 1, Item 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. These oversight and assurance activities are an important demonstration that the purchaser is acting as an intelligent customer for work which may impact on nuclear safety.
3. The purchaser’s oversight and assurance arrangements should continue to review the supplier’s organisational culture, ensuring that after the contract is awarded, 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. Assurance activities should include the inspection, test, release, acceptance and storage of high-risk items and services.
4. 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 the supplier’s works to receipt inspection at the purchaser’s facility).

#### Oversight

1. The purchaser should set the level of oversight 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 inadequate performance. Purchasers are likely to deploy some or all 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.

1. 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

1. 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 proportionate to the nuclear safety significance of the item or service being supplied.
2. The purchaser may specify that items or services should be verified or independently assessed by other organisations. This should be planned and executed, in part; by the application of quality plans (refer to section ‎5.3.5 for more detail on quality plan requirements). Verification and independent assessment provides enhanced levels of assurance beyond that provided through the supplier’s quality arrangements and may be required by certain pieces of legislation.
3. 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, whether the procurement is “at-risk” (refer to section ‎5.3.8), the code/standard requirements and the difficulty of inspection and testing post manufacture or installation.
4. The purchaser’s assurance arrangements should consider the use of accredited testing laboratories, in GB this is often via accreditation to   
   BS EN ISO/IEC 17025 [10]. The standard specifies the general requirements for the competence, impartiality and consistent operation of laboratories and is applicable to all organisations performing laboratory activities.
5. The purchaser’s assurance arrangements should consider the use of accredited inspection bodies, in GB this is often via accreditation to   
   BS EN ISO/IEC 17020 [11]. The standard specifies requirements for the competence of bodies performing inspection and for the impartiality and consistency of their inspection activities.
6. The licensee should permit regulatory access to its supply chain through its contractual arrangements. This will enable ONR, or other regulators as appropriate, to consider the adequacy of its supply chain management arrangements for high risk items or services regardless of the supplier location. This expectation is detailed within Licensing Nuclear Installations [21] .
7. 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.
8. 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 continued to monitor and review the supplier’s organisational culture post contract award?
* 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?
* If the inspection body or testing laboratory is competent to provide assurance and verification of items or services significant to nuclear safety?
* If the purchaser has verified whether there are any shortfalls or performance issues raised with the accreditation body (UKAS or equivalent )?
* Whether the purchaser is considering the use of third party/independent inspection bodies or testing laboratories for high risk procurements?
* If the purchaser’s storage arrangements for supplied items are sufficient to maintain item traceability and prevent damage, loss, deterioration or inadvertent use?

### Counterfeit, fraudulent and suspect items (Figure 1, Item 8)

1. The purchaser should have arrangements to mitigate the risks of Counterfeit, Fraudulent and Suspect Items (CFSI) entering their supply chain   
   (refer to Figure 1, Item 8).
2. All licensees and other dutyholders should recognise that there are parties who 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 ‎4.2.
3. Management of CFSIs by any supplier includes managing the risks from, and thereby reducing the likelihood of:

* Dishonesty and malpractice within that supplier’s own organisation; and,
* “Importing” sub-standard items, or receiving unsatisfactory services, from other organisations in relation to that supplier’s final products.

1. 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. The purchaser should also consider the procurement source or availability of the item on the market. To consider this, staff need training in recognising at-risk procurement scenarios.   
   IAEA guidance, NP-T-3.26 [22] defines at-risk procurements in as “…such scenarios are those known to have a higher than normal risk of receiving CFSI from a vendor”. Examples of at-risk procurements include the procurement of difficult to source or obsolete items from non-approved distributors or equipment resellers, or the procurement of items known to be susceptible to CFSI. **Note**: The use of non-approved distributors or equipment re-sellers is commonly known as the “grey market”.
2. The purchaser should determine whether the procurement is “at-risk” and accordingly consider the use of enhanced assurance. This may include enhanced verification, validation and qualification.
3. The following list represents appropriate mitigating measures that should be deployed as part of a purchaser or supplier’s management system, as levels of defence against CFSI for high-risk items or services:

* Robust SCM and procurement process arrangements including effective supply chain oversight and assurance, including inspection and testing.
* A healthy organisational culture and a questioning attitude.
* Competent and honest staff involved in the acquisition processes from specification of requirement through inspection, 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.
* The use of Original Equipment Manufacturers (OEM) and their Authorised Distributors.
* The use of enhanced assurance arrangements for the procurement of items from non-approved distributors or equipment resellers (“at-risk” procurements). This may include enhanced verification, validation and qualification.
* Use of positive material identification and destructive testing methods during product inspection, testing and receipt as part of assurance sampling of high risk proprietary items (i.e. bolts and fasteners).
* Product samples of known precision and authenticity available for comparison with purchased items.
* Training and awareness within purchasing organisation SCM teams (i.e., Engineering, Procurement, Audit & Inspection), partners and suppliers. Staff should be aware of the risks of CFSI and be trained in mitigation, detection methods and identifying “at-risk” procurements as appropriate.
* Processes and procedures to identify, quarantine, 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.
* Arrangements for handling employee concerns relating to product safety, quality (including CFSI) or other matters.

1. The use of an accredited testing laboratory can assist in mitigating CFSI risks, BS EN ISO/IEC 17025 [10] contains requirements for impartiality. If a supplier requests the use of an in-house testing laboratory the purchaser should assure itself that appropriate controls are in place. For the highest risk items, the use of an independent testing laboratory may be proportionate.
2. The use of an accredited inspection body can assist in mitigating CFSI risks, BS EN ISO/IEC 17020 [11] requires the inspection body to be independent to the extent that is required with regard to the conditions under which it performs its services. For the highest risk items, the use of an independent (third-party) inspection body may be appropriate or required by law.
3. 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 decide whether the item is conforming,   
   non-conforming, counterfeit or fraudulent; and to examine the consequences of a suspect service.
4. Examples of counterfeit or fraudulent items or services should be shared within the purchaser and the licensee or other dutyholder organisation, supply chain and wider industry as appropriate to support learning, prevent use and encourage remedial measures in other impacted facilities.
5. Reporting of significant CFSI occurrences to ONR should normally be via the incident notification (INF1) process NS12 categorisation for licensees.   
   ONR expects that licensees should, through an appropriate means, routinely inform ONR of all examples of CFSI confirmed within their supply chain (including those that do not meet INF1 reporting thresholds). This may be done via routine level 4 engagements or other appropriate means agreed with ONR.
6. Suppliers should inform the relevant licensee or purchaser of all examples of CFSI confirmed within their SC in the first instance, for onward reporting to ONR (through the most appropriate means). ONR will consider the appropriateness of sharing CFSI events more widely amongst national and international regulatory colleagues, for example through the CNRA Working Group on Operational Experience (WGOE) and/or Working Group on Supply Chain (WGSUP).
7. Arrangements should be in place for handling employee concerns, these may relate to product safety, quality (including CFSI) or other matters. Where appropriate, concerns, whistleblowing (protected disclosures), or complaints about the nuclear industry, can be raised directly with ONR. Refer to the [ONR website](https://www.onr.org.uk/complaints-concerns-whistleblowing.htm) for more information.
8. The licensee should consider giving explicit permission in contracts for suppliers to interact directly (and independently of the licensee) with ONR about any safety concerns, without penalty.
9. 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.
10. 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 the purchaser is procuring from the OEM, or its authorised distributors?
* If the purchaser is undertaking enhanced assurance for “at-risk” procurement scenarios? 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, and its suppliers have displayed the traits of a healthy organisational culture and a questioning attitude?
* If the purchaser has appropriate arrangements for handling employee concerns, these may relate to product safety, quality (including CFSI) or other matters?
* If the dutyholder understands that, where appropriate, the ONR concerns, whistleblowing (protected disclosures), or complaints processes is available for the reporting of concerns?
* 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 ONR and the sharing of learning through their operational experience (OPEX) arrangements?
* If the purchaser has examples of malicious intent to introduce weaknesses into safety or security arrangements and has taken appropriate actions including notifying the relevant licensee or other dutyholder?
* If the purchaser is using an accredited testing laboratory   
  (BS EN ISO/IEC 17025 [10]) or accredited inspection body   
  (BS EN ISO/IEC 17020 [11])?
* If the purchaser is using an independent testing laboratory or independent (third party) inspection body for procurements of the highest safety significance?

### Supply chain operational experience (Figure 1, Item 9)

1. The purchaser should have arrangements to capture and act on OPEX feedback from its supply chain and SCM activities, sharing learning as appropriate within the organisation, its supply chain and wider industry   
   (refer to Figure 1, Item 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.
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.
4. The purchaser should recognise that key suppliers (such as niche products or construction contractors) in the nuclear industry could supply items or services to multiple licensees or dutyholders 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 dutyholders.
5. The purchaser’s OPEX processes should enable the wider sharing of relevant supplier and SCM experience with other licensees or dutyholders and wider industry as appropriate. Arrangements should be in place to evaluate OPEX shared by other licensees or dutyholders, and wider related industry, for implications within the purchaser’s organisation and management system arrangements.
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 dutyholders.
7. The Inspector should consider:

* If the purchaser’s OPEX process is established and is capturing and acting upon sub-standard performance issues?
* 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 dutyholders, purchasers and supplier organisations, nationally and internationally as appropriate?
* If the purchaser shares learning with its supply chain and wider industry as appropriate?

# References

|  |  |
| --- | --- |
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| [11] | BS ISO, “BS EN ISO/IEC 17020 Conformity assessment. Requirements for the operation of various types of bodies performing inspection”. |
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| [22] | IAEA, “IAEA NP-T-3.26 Managing Counterfeit and Fraudulent Items in the Nuclear Industry,” 2019. |
| [23] | ONR, “ONR-INSP-GD-064 - General Inspection Guide”. |
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# Glossary and abbreviations

## Abbreviations

CDM 2015 Construction (Design and Management) Regulations 2015

CFSI Counterfeit, Fraudulent & Suspect Items

CNRA Committee on Nuclear Regulatory Activities

DA Design Authority

HSWA74 The Health and Safety at Work etc Act 1974

IB Inspection Body

IAEA International Atomic Energy Agency

IC Intelligent Customer

NDT Non-Destructive Testing

NEA Nuclear Energy Agency

NIA 1965 Nuclear Installations Act 1965

ONR Office for Nuclear Regulation

OPEX Operational Experience

SAP Safety Assessment Principle(s)

SC Supply Chain

SCM Supply Chain Management

SQEP Suitably qualified and experienced persons

TAG Technical Assessment Guide(s)

TIG Technical Inspection Guide(s)

TQ Technical Query

UKAS United Kingdom Accreditation Service

WENRA Western European Nuclear Regulators’ Association

WGSUP Working Group on Supply Chain

## Glossary

The SAPs [1] 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:

* **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.
* **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.
* **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.

**Note**: 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.

* **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.
* **Dutyholder** - A person or corporate body who has a duty in law.
* **Extended Enterprise** – The totality of the supply to chain to ensure the licensee or dutyholder can deliver its objectives.
* **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.
* **Inspection Body (IB)** - The independent body or organisation that verifies that items or services have been designed, constructed and tested in accordance with the technical specification. The IB should have suitable competencies.
* **Intelligent Customer** **(IC)** - IC enables the organisation to maintain a clear line of sight to the safety case and underpinning justification for products or services bought on its behalf. IC is 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.
* **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.
* **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).
* **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.
* **Long Lead Items (LLI)** - In the context of this TAG, means items manufactured for the construction of a new nuclear facility in advance of a nuclear site licence being granted to the procuring organisation.
* **Manufacturer/Contractor/Vendor** - Any organisation or individual person that provides a product or service for a licensee under a commercial contract that is: not in the licensee’s direct employment or formally seconded to the licensee from the licensee’s parent company, are subject to licensee's IC oversight and are employed by companies external to the licensee/licensee's parent company.

**Note:** 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.

* **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.
* **Nuclear Safety** - The achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks.
* **Organisational 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. For the purpose of this TAG this definition is inclusive of Nuclear Safety, Conventional Safety, Security and Quality.
* **Purchaser** - In the context of this TAG, the organisation or person procuring an item or service. The purchaser may be the licensee or dutyholder 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 dutyholder’s SC.
* **Quality Culture** - Integrated shared values, beliefs, history, ethics, attitudes and observed behaviours supporting the achievement of a quality policy and objectives, and the delivery of products and services that meet the needs and expectations of customers and other relevant interested parties.
* **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 IB and 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.

* **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.
* **Safety Case** - In this document, ‘safety case’ refers to the totality of a licensee’s (or dutyholder’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.

* **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). See organisational culture definition above for the wider term.
* **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.
* **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.
* **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. It is illustrated in Figure 1. It 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 (i.e. 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.
* **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 no-conforming. Additional information or investigation is needed to determine whether the suspect item is acceptable, non-conforming, counterfeit or fraudulent.
* **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.
* **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.
* **Validation** - The process of confirming, e.g. by use of objective evidence, that the outputs from an activity will meet the objectives and requirements set for that activity.
* **Verification** - The process of confirming, e.g. by use of objective evidence, that an activity was carried out as intended, specified or stated.

# Appendix A – Examples of items requiring high-levels of ONR involvement with the supply chain

## Introduction

1. This appendix 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 ONR.

## Structural integrity

1. Structural Integrity of materials or processes carried out to improve material functionality and reliability.
   1. 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)
   2. Class 1 components (including those that fall under (a) above)
   3. A sample of Class 2 components (the sample to include any Class 2 components that fall under (a) above)
   4. 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)

## Electrical, control and instrumentation

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

## Civil engineering

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

## Mechanical engineering

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

## Notes

1. The following notes are applicable to the sub-sections 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.

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# Appendix B – Preferred model for the procurement of high-integrity long lead items.

## Introduction

1. The preferred model for the procurement of high-integrity items in support of new build is for the licensee to be the head of the supply chain. However, where the licensee organisation is not in place or is not fully developed, some or all the licensee’s responsibilities may be undertaken by the purchaser. In all cases, the licensee/purchaser should commence early engagement with ONR.
2. This appendix provides examples of organisational roles and responsibilities for the specification, design, manufacture, testing and installation of high integrity components (including primary circuit pressure boundary components) which represent the highest risk and level of assurance.
3. The main organisations involved are:

* licensee/purchaser (where licensee organisation is not in place or fully developed)
* Manufacturer/Contractor
* Inspection Body
* Accredited organisation that issues the licensee’s Certificate or certification to international management system requirements.

1. The responsibilities of these organisations are as follows:

## Licensee/Purchaser

1. The responsibilities of the licensee/purchaser are to:

* Document the management systems arrangements in accordance with national/international standards, e.g., GSR Part 2 [5].
* Obtain a licensee’s Certificate or the equivalent certification to management systems requirements to confirm the licensee’s/purchaser’s capability to execute its responsibilities. The organisation that issues this certificate to the licensee/purchaser should be communicated to ONR. Ideally the Certificate should be issued by an organisation engaged by the licensee/purchaser for this sole purpose.
* Engage one or more inspection bodies to fulfil the role described in Appendix B.
* Certify that the completed installation complies with the design code/technical specifications for the various components/systems.
* 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:
  + Identification of the records to be retained by the licensee/purchaser and the contractor.
  + Arrangements to safeguard and maintain records to be retained by the licensee/purchaser and the contractor.
  + 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.
* 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.
* Establish the design code version to be used and define this in the design specification.
* Prepare, review and certify the technical specifications, design reports and certification forms and designate authorised personnel to carry out those duties.
* 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.
* Designate overpressure protection requirements and location for each component or system.
* Provide a report that explains and justifies the overpressure protection arrangements.
* Provide adequate structures, foundations and auxiliary systems for pressure equipment.
* Permit regulatory access to its supply chain through its contractual arrangements.
* Make available to ONR those documents which the inspection body are required to endorse and such documentation as is necessary for the inspection body to fulfil its responsibilities.
* If not required by the design code, agree with the Contractor and inspection body a suitable means of physical identification of components and items.

## Manufacturer/contractor

1. The responsibilities of the manufacturer/contractor are to:

* 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 body as necessary.
* Designate authorised personnel to carry out the certification duties required. Such personnel should not be in the employment of the inspection body.   
  The Contractor should be prepared to justify their arrangements for designation to the licensee/purchaser.
* Obtain approval from the licensee/purchaser for the management system arrangements.
* 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 body 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 body of approval or audit activities so that participation by their nominated representatives may be agreed in advance of the activity.
* Ensure compliance with the technical specification and design code.
* Ensure that applicable requirements are effectively applied throughout the supply chain. This shall include, but not be limited to, procurement from its suppliers of technical specifications, design reports, certification certificates and other applicable documents.
* Prepare records packages for items being procured including manufacturer/contractor certification certificates and those provided by sub-contractors. These records should be safeguarded and maintained.
* Review material and other test reports for compliance with the relevant code, standard or specification.
* Submit the following items to the licensee/purchaser for approval:
  + Any proposed deviation from the chosen technical specification including design code;
  + 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;
  + Any other proposed deviation from the technical requirements of the technical specification or agreed Quality or management systems arrangements.

## Inspection body

1. In the UK, accreditation meeting the requirements of ISO 17020 [11], implies the inspection body 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.
2. An inspection department maintained by the manufacturer does not satisfy the requirement of an independent inspection body. The categorisation of inspection bodies as type A, B or C within ISO 17020 [11] is a measure of their independence. Demonstrable independence of an inspection body can strengthen the confidence of the inspection body's clients with respect to the body's ability to carry out inspection work with impartiality.
3. The responsibilities of the inspection body are to:

* Maintain access to Surveyors who are suitably trained and qualified to perform the duties required, including familiarisation with the requirements of the design code.
* 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.
* 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.
* 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.
* Endorse Certification Forms and other documents requiring inspection body certification.
* Review and comment on drawings and process procedures, designate hold and notification points on Quality Plans and inspect against them.

## Accredited organisation that issues the licensee’s certificate

1. The responsibilities of the organisation that issues the licensee’s Certificate are to:

* Verify that the licensee/purchaser understands its Quality Assurance responsibilities specifically with regard to items or services significant to nuclear safety.
* Verify the licensee/purchaser’s agreement to meet its responsibilities.
* 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 C – Supplement to the general inspection guide covering vendor (supplier) inspections

## Introduction

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.
2. ONR’s inspections of such vendors (suppliers) should be conducted to the same professional and procedural standards as other types of inspection undertaken by ONR.
3. This appendix gives information that will allow Inspectors to tailor ONR’s inspection approach to accommodate the features that are unique to inspection of vendors.

## Purpose and scope

1. ONR’s inspection guide, ONR-INSP-GD-064 [23], sets out ONR’s expectations for all inspection activities, including those of vendors.
2. ONR’s guidance for inspection strategy planning and recording   
   (ONR-INSP-GD-059) [24], acknowledges that vendor inspections are a type of integrated specialism inspection and gives advice on the categories of vendor inspection that may be carried out. These are:

* Inspection of the licensee’s own arrangements to oversee its suppliers; and
* Direct inspection of suppliers, called vendor (supplier) inspections.

1. 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 ONR inspection guides, ONR-INSP-GD-064 [23] and ONR-INSP-GD-059 [24]. For both types of inspection, the regulatory expectations are defined in this document.

## General objectives for vendor inspections

* Focus on the risks associated with the supplied items or services and the adequacy of the vendor’s or the licensee’s arrangements to control the risks.
* Establish the governance arrangements for developing maintaining and sustaining the supply chain for nuclear safety related items and services within the vendor and their own supply chain.
* Establish the vendor’s approach to licensee strategic partnerships and how these relationships are managed.
* Identify who the key sub-contractors are and the arrangements vendors have to manage and oversee these relationships, and control changes in their own supply chain.
* Establish how the vendor engages with licensees and analyses any issues in procurement to identify lessons to be learnt and any measures required to prevent recurrence.
* Overview by the vendor 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.

## Tailored advice on vendor inspections

1. ONR’s inspection guide, ONR-INSP-GD-064 [23], 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. Tailored advice is given against each of the five phases, as follows.

### Planning phase

* The Supply Chain Specialism Lead will arrange for an annual vendor inspection programme to be developed and determine which vendors should be targeted in it.
* The vendor inspection programme should be planned and implemented, in line with the advice in ONR-INSP-GD-064 [23] and ONR-INSP-GD-059 [24]. The programme should be kept under review.
* The programme may include vendor inspections under international regulatory protocols such as the Nuclear Energy Agency (NEA) Committee on Nuclear Regulatory Activities (CNRA) Working Group on Supply Chain Regulation (WGSUP). As such, other national Regulators may be invited to conduct joint or witnessed inspections of GB vendors. Similarly, ONR may conduct vendor inspections with other national regulators outside GB.

### Preparation phase

* The Inspector should consider whether it is appropriate to inspect the vendor directly or accompanied by the licensee.
* The Inspector should hold a pre-meeting with the vendor, particularly if it is a vendor that has not had interactions with ONR before. The pre-meeting should explain ONR’s vires, the inspection process and address any vendor concerns. ONR’s vires within the supply chain is outlined in this document. 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

* The inspection should be conducted in line with ONR’s inspection guide, ONR-INSP-GD-064 [23]. Normally, there are two phases to the inspection: an assessment of the vendor’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

* Reports and contact records should be in line with ONR’s inspection guide, ONR-INSP-GD-064 [23]. It is important to confirm findings and corrective actions directly with the vendor and confirm them in writing.

### Follow up phase

* 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 vendor actions.
* The ONR Regulatory Issues database should be used for vendor issues, and entries should be made against dutyholders.The process for managing regulatory issues in ONR is described in ONR-RIO-PROC-001 [25].
* Inspectors should consider sharing any relevant learning with specialism colleagues, relevant site inspectors and the Safety Director’s Forum, Supply Chain & Quality working group.   
  Vendors 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.