






EDF Energy Nuclear Generation Supplier Quality Requirements Manual

EDF ENERGY

Contents

Introduction

EDF Energy Nuclear Generation Ltd, aim to support the delivery of excellence in all aspects of services of products and operating safely, securely, reliably and predictably.

To achieve this aim, EDF Energy Nuclear Generation Ltd requires its supply chain to procure / deliver products and services safely, to schedule, to the specified requirements and to the agreed cost.

The purpose of this document is to define the quality requirements to ensure that the activities, products and services provided by the supply chain support and maintain the integrity of EDF Energy Nuclear Generation Ltd (hereafter NGL) nuclear quality requirements specified within individual purchase orders.

This document does not replace any contractual requirements set out in any issued contract / purchase order terms and conditions.

The quality requirements confirmed in this document apply to all suppliers, contractors, sub-contractors and service providers in receipt of Purchase Order (PO), Contract or ITT / RFQ from NGL in relation to the provision of plant, equipment, products and services.

Graded Application to Quality Assurance

Plant systems on a Nuclear Power Station differ in their significance, hence controls applied to activities undertaken or items procured must be proportional to their significance. Differentiation is achieved by a graded approach derived from a risk assessment based upon risk to nuclear safety, people's health and safety, breach of nuclear site licence, environment or statutory requirements, cost penalty or loss of generation.

The requirements of each of the Quality Grade's are identified using the following as listed. Each individual PO / Contract will specify the QA grade as per BEG/SPEC/FENG/001 – Graded Application.

Quality Grade 1

- Uncontrolled release of radioactivity (e.g. a non-isolatable component in the pressure circuit).

Quality Grade 2

- Major risk of a radiological hazard.
- High risk of serious injury (e.g. bulk toxic chemical storage , large pressurised system, cranes).
- Non-compliance with Site Licence, environmental and / or Statutory requirements.
- Severe damage to major plant.

Quality Grade 3

- Minor risk of a radiological hazard.
- Lower risk of serious injury.
- Reduced integrity of plant.
- Minor loss of generation.
- Impact on business plan targets.

Supplier Request for Deviation from Contract Quality Requirements

If the supplier is unable to comply with any of the requirements defined within this document applicable to the quality grade requirements, the supplier shall apply to NGL to request agreement from NGL that it is acceptable to deviate from the contracted requirements, this would be contract or order specific.

Collaboration

NGL is committed to working together with its supply chain to deliver excellence in everything it does; this is achieved by having the right people, with the right skills in place to deliver products and services at the right time.

This requires NGL and its suppliers to develop a supportive relationship, working together to deliver to the required standards, identifying opportunities to improve performance and resolving issues promptly through:

- open and honest communication
  - at all levels and tiers, throughout the supply chain – raising queries and concerns as they become known
  - checking for understanding and compliance at all levels and tiers of the supply chain – ensuring that specifications, requirements, and identified processes are flowed down, understood, and met
- sharing learning
  - identifying and building on best practice
  - utilising operating experience (OPEX) to prevent issues and improve performance
  - documented process for lessons learnt to demonstrate improvement and repeat success
- focused improvement – step up to quality 6 Rs
  - right skills
  - right tools
  - right behaviours
  - right plant
  - right spares
  - right instructions
- structured problem solving
  - Basing decisions on data
  - Addressing the root cause
  - Implementing robust corrective and preventive actions.

Procedural Use and Adherence (PU&A)

The supplier will adhere to the NGL requirements for procedural use and adherence when working on NGL sites (BEG/SPEC/OPS/036A – Procedure Use and Adherence) available from the contract manager, or procurement specialist (see reference 2).

Business Continuity

The supplier shall have a Business Continuity process in place that identifies potential threats to the organisation and the impacts to business operations those threats, if realised, might cause. Suppliers are required to support the effective approach that safeguards the interests of its key stakeholders (with appropriate communication), reputation, brand and value-creating activities.

1 Nuclear Safety Requirements

Nuclear Safety Definition

The protection of workers, the public and the environment from undue radiological hazard by achievement of proper operating conditions, prevention of accidents and the mitigation of accident consequence.

1.1 NGL nuclear power stations are Nuclear Licensed Sites. The Nuclear Site Licences are granted by the Office for Nuclear Regulation (ONR) on behalf of the Health and Safety Executive (HSE). The Nuclear Site Licence is a legal document and is uniquely numbered for each nuclear installation.

The Nuclear Site Licence has two schedules attached to it:

Schedule 1

This is specific to each site. It specifies where the site is and defines the number and type of reactors and the fuel to be used in them.

Schedule 2

This is common to all nuclear licensed sites throughout the country and consists of 36 conditions, which cover design, construction, operation and decommissioning. These are available in the NGL Nuclear Site License Conditions Booklet.

The essential feature of the majority (21) of the 36 conditions is that they require NGL to implement adequate arrangements to ensure compliance. These arrangements therefore, affect everyone and it is important to remember that failure to follow these rules and procedures could put NGL in breach of its Nuclear Site Licence.

Arrangements include

Operating rules; operating instructions; work specifications and other documents; quality assurance; training and authorisations; maintenance schedule; plant modifications; nuclear safety committee; emergency preparedness; security; control of organisational change; requirement to report breaches etc.

1.2 In order to achieve this, NGL needs its supply chain to deliver goods and services to the agreed specified requirements. A key focus is ensuring that all supply chain personnel involved in design, manufacturing, fabrication, construction, inspection and testing understand how their role impacts upon Nuclear Safety and how the failure of a product or service can impact upon the associated plant and local community.

1.3 It is at the design stage where the biggest impact on Nuclear Safety can be made; therefore it is vital that any party undertaking design understand the impact of a failure. The design phase needs to concentrate on the four criteria of criticality (control conditions to prevent a criticality), control (prevent chemical reactions that could challenge containment), containment (keep nuclear inventory where it should be) and cooling (stop nuclear material overheating). Design is the first layer of defence.

1.4 The requirements of the design then need to be transmitted into the construction phase such that the design intent can be realised via the quality of workmanship. This will involve ensuring the manufacturing, fabrication and construction trades understand how the quality of their workmanship can impact on Nuclear Safety.

2 Quality Management Systems Requirements (QMS)

2.1 The suppliers of products and/or service providers shall have and provide evidence of, a documented and maintained QMS that conforms to the current edition of the BS EN ISO 9001 standard requirements or the relevant business sector variant, i.e. "TickIT" for software applications. The QMS shall cover all scope of supply, design, manufacture or provision of service, as applicable.

2.2 All suppliers shall maintain a QMS that is compliant to BS EN ISO 9001 standard or equivalent, certified by a United Kingdom Accredited Services (UKAS) accredited certification body or national equivalent accreditation body outside the UK.

2.3 Where the assessment body is not recognised by a national or international body the supplier shall support NGL in undertaking a full assessment of the supplier's QMS.

2.4 If assessed by a recognised third party body the certificate of registration and applicable scope of registration must be supplied to NGL.

2.5 The supplier shall submit any changes it considers necessary to its QMS to NGL for approval if such a change will impact upon or is likely to impact the quality of product or services or will lead (or is likely to lead) to the loss of the supplier's certification.

2.6 The supplier shall ensure that all personnel executing the contracted scope of work are aware of and understand the management systems arrangements and any special contractual requirements relevant to the scope of work.

2.7 The supplier shall ensure that documentation requiring submittal to NGL for information or for review and acceptance shall be submitted as detailed in this manual.

2.8 In addition to these requirements, suppliers engaged on nuclear projects may be subject to additional quality requirements. The suppliers will comply with NGL requirements and procedures whilst working on NGL sites.

3 Resource Management

3.1 The supplier shall ensure that all personnel they assign to undertaking work for NGL are suitably qualified and experienced to deliver the assigned work. There should be a clear auditable trail that demonstrates that supplier's employees are equally as 'Suitably Qualified and Experienced Person' (SQEP) as licensee staff would be for the same role. The supplier shall upon request, provide documented evidence of personnel competency to NGL.

3.2 The supplier shall determine and provide the appropriate number of SQEP resources required to deliver the contracted scope of work and where appropriate agree the level of resource with NGL.

3.3 The supplier shall implement and maintain a competency / training register supported by appropriate training and qualification records. The register shall identify:

- all personnel engaged on the works
- role Specification
- status of training received for each individual
- experience of each individual
- forward Plan to close out identified competency requirements and development plans
- task specific/specialised training; and
- perform documented reviews of personnel to maintain competency.

3.4 The supplier shall ensure that any personnel to be deployed on site work will receive all NGL site orientation and induction courses prior to commencing work on the contract. The basic requirements are as follows:

- CTC (Counter Terrorism Checks Vetting)
- DLA (Dynamic Learning Assessment)
- nuclear safety
- safety requirements
- security requirements
- overview of the works
- mandatory procedures
- standards and specifications requirements briefs.

3.5 The supplier shall notify NGL of any deficiencies identified with personnel competency that may affect the product or service provided. The supplier shall take corrective actions to eliminate personnel competency deficiencies.

3.6 The supplier shall define and implement appropriate arrangements to control any change to its organisational structure or resources, which may affect environmental, health and safety, security or quality performance. The supplier shall formally notify NGL of any organisational changes that could impact on environmental, health and safety, security and quality performance.

3.7 The supplier shall be able to demonstrate adequate arrangements of their sub-contractor's SQEPness when the product and services they provide to NGL have a direct impact on Nuclear Safety consequences.

4 Supply Chain

A Graded Approach to Procurement

4.1 Nuclear Safety standards and safety case management drives a graded approach to the procurement of goods and services within the supply chain. This graded approach ensures that the appropriate levels of assurance and oversight are deployed, commensurate with the level of risk.

4.2 The supplier shall also apply a graded approach to procurement, deploying resources in consideration of:

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

Grading

4.3 The supplier shall be aware of the Graded Application requirements within BEG/SPEC/FENG/001- Graded Application and a flow down shall be implemented as a graded approach in accordance with the Nuclear Industry Standard Quality Requirements for the procurement of products and services to mitigate the risk of failure.

Purchasing Information

4.4 The supplier shall ensure that purchasing information provided by NGL accurately specifies the product and service to be purchased.

4.5 The supplier shall ensure that the requirements of the contract, NGL quality requirements manual, the appropriate standards, and necessary requirements to deliver the products and services specified are flowed to all tiers of the supplier's supply chain, and that understanding is tested.

4.6 The supplier shall ensure the purchasing information accurately specifies the requirements for acceptance of products and services, to include as applicable:

- reference to this document
- quality grade
- specification(s)
- drawing(s)
- material type
- quantity
- certification requirements
- inspection requirements, at vendor, on delivery or both
- functional testing requirements, at vendor, on delivery or both
- any special requirements such as packing, extra testing etc
- requirements for procured services.

4.7 A contract inaugural meeting must be held for all on site contracts immediately after the contract has been placed and before any work is peformed, as per the requirements as detailed in BEG/SPEC/PRO/019 – Contract Inaugural Meeting Minutes.

Supplier / Sub-contractor Management

4.8 Where the supplier has to or decides to sub-contract any or all of the order then they shall inform NGL as to whom the sub-tier supplier is prior to the sub-contract being placed. NGL reserves the right to then approve the use of the sub-tier supplier and associated processes prior to the commencement of any work.

4.9 The supplier shall ensure that all of the requirements of NGL are flowed down to the sub-tiers.

4.10 Where the supplier intends to use a sub-tier, the sub-tier operations shall be documented in the supplier's Quality Plan (QP) or Inspection Test Plan (ITP) and the QP or ITP for the sub-tier supplier.

4.10.1 In the instance the product is of the sub-tier suppliers own design, the supplier shall request and renew the sub-tier QP or ITP for adequacy.

4.11 The supplier shall have a process for sub-contractor selection through assessment and analysis of their competencies, facilities and equipment to ensure that they have the capability to conform to the contract requirements, delivering products and service safely, to schedule, of the correct quality and to the agreed cost.

4.12 Instruction from NGL to use a specific sub-contractor does not absolve the supplier from completing an evaluation of the sub-contractor's capabilities to meet the requirements and commitments of the contract prior, during and post the contract.

4.13 The supplier shall assess the sub-contractor's capability to plan and meet the required capacities and capabilities for new and existing contracts.

Review of Contract Requirements

4.14 The supplier shall have a process that covers contract review. This process shall pay attention to the supplier's ability to supply the product and service on time.

4.15 Where the supplier cannot supply exactly what the order / contract requires then the supplier shall contact NGL with any proposals for alternate methods of supply.

4.16 This contract review must be undertaken at both tender and order stages to take into account any changes that may impact delivery or any items not within the control of the supplier, e.g. material availability.

4.17 The supplier shall ensure that all contract requirements for the scope of work are reviewed, agreed and understood prior to the commencement of work both at site and in their supply chain. Any deviations from specifications will require the supplier to obtain written approval from NGL.

4.18 The supplier shall confirm their understanding of the works information package / purchase orders via the contract inaugural meetings held with their sub-contractors and explain each clause of the specification to ensure full understanding of the requirements. The supplier shall confirm that they understand and can meet NGL requirements.

4.19 Where the contract includes any of the following elements the review shall include:

- Project/Contract Management
- Commercial
- Health and Safety
- Quality (including Nuclear Safety and Specification Awareness Briefs)
- Environmental
- Project Controls (planning, programme and costs)
- Risk
- Product requirements
- Process requirements
- Engineering
- Construction
- Commissioning
- Operations and Maintenance
- Provision of product samples (when requested)
- Life Time Quality Records (here after LTQR).

4.20 The supplier shall have a process for ongoing contract review throughout the life of the contract.

4.21 Records of the ongoing reviews and the conclusion reached shall be retained and form part of the LTQR.

Sub-Contractor Control

4.22 The supplier shall ensure that the full extent of their supply chain has a clear understanding of all the contract technical and quality specified requirements.

4.23 The supplier's procedure for controlling documents between sub-contractors and NGL shall ensure documents are clearly identifiable to each sub-contractor. Configuration control of documents shall be appropriately managed.

4.24 If the supplier subcontracts work, the supplier is responsible for controlling the scope of work in accordance with the associated Quality Grade and the specified requirements.

4.25 The supplier shall implement a process for ongoing verification and monitoring of their sub-contractors to ensure that they are delivering products and services safely, to schedule, to the specified requirements and to the agreed cost.

4.26 When specified, contractors supplying products or services directly to NGL shall in accordance with the contract, provide for acceptance a schedule of intended sub-contractors. The supplier shall only sub-contract work in accordance with the agreed schedule submitted with the tender or in accordance with agreed changes following submission of a revised schedule.

4.27 The supplier shall provide to NGL details and justifications of any proposed increase or reduction in the control over its sub-contractors or replacement of any sub-contractors.

Primacy of Documents

4.28 To clarify which document issued from NGL has primacy with respect to the deliverable documents and contractual requirements, the primacy is:

i. contract / purchase order

ii. quality / inspection plan

iii. supplier quality requirements manual (this document).

Delivery / Delivery Notes

4.29 The supplier shall ensure that all delivery documentation, LTQR and other documents in accordance with the PO requirements and Quality Grade are enclosed with the goods.

4.30 A certificate of conformity (CofC) is the minimum documentation when delivering items to NGL. The CofC must include as a minimum the following:

- NGL order / contract number
- supplier reference number
- unique identification of the CofC
- identification of the item / items being certified
- date of issue
- identification of the QP or ITP where relevant which describes the process that ensures that the item / service conform to specification
- issue number and date of the plan
- the name of the person issuing the certificate
- job title of the person issuing the certificate
- the signature of the person issuing the certificate
- concessions / deviations applicable to the certificate.

5 Quality Assurance

NGL Oversight

5.1 NGL reserves the right to undertake oversight of the supplier's quality management system arrangements and all work being delivered within the contract scope including sub-contracted work activities. Oversight may be through qualification, inspection, verification, validation, commissioning and testing. Formal audits, assessments, surveillances and 3rd party inspections can be utilised to confirm that suppliers are meeting NGL's quality requirements. The supplier shall ensure that its sub-contractors are also informed of this requirement.

Supplier Oversight

5.2 The supplier shall document and establish sub-contractor assurance and oversight arrangements to ensure compliance with NGL specifications, standards and contract quality requirements. These arrangements shall be tailored to mitigate risk to Nuclear Safety where appropriate.

5.3 The supplier shall allow access for NGL to perform oversight inspection and audit activities; such right of access shall also be extended to all sub-tier suppliers. In addition, external representatives to NGL (e.g. 3rd party inspection services, regulatory authorities etc) shall similarly be allowed the right of access as needed, subject to mutual agreement.

5.4 Should, during the implementation of this activity, any deficiencies be observed the supplier, sub-tier supplier or service provider the supplier shall report to NGL these deficiencies identified from their assurance programme that will affect compliance with contractual requirements and shall be required to agree and implement corrective actions.

Production Realisation

5.5 The supplier shall have in place, or put in place a production planning and control system that ensures that the product is delivered right first time.

5.6 Should the supplier not be able to supply right first time / on time the suppliers system shall identify the reasons as to why and the supplier shall provide NGL with details of actions to correct the product or minimise the risk of late delivery.

5.7 Where contractually required or requested the supplier shall provide NGL with production plans that include all hold / witness points as detailed in the quality / inspection plan. This plan shall show a time line for delivery showing all stages within the product realisation process.

Management Review

5.8 The supplier shall notify NGL of any management review actions, which will affect compliance with contractual requirements. Management review output shall identify responsible persons and due dates for timely completion of agreed action.

Inspection

5.9 The supplier shall have suitable methods to ensure that the product or service can be inspected to sufficient accuracy as to ensure that the tolerances can be met in a repeatable manner.

5.10 All inspection and test quality personnel deployed on the works are suitably experienced and shall be in possession of nationally recognised qualifications. The supplier shall be able to demonstrate the qualification and independence of personnel verifying or inspecting work from those performing the work.

5.11 All inspection and test equipment is calibrated and traceable to national standards.

5.12 The supplier shall ensure that there is suitable inspection equipment available for NGL or a 3rd party to verify the supplier's results.

Identification and Traceability

5.13 The supplier shall:

- identify raw materials by suitable means (including sub-contract activities)
- ensure that full traceability of the raw material is available, if requested
- identify the product by suitable means throughout manufacturing / production and subcontract activities
- maintain the traceability for all products during production (including product quantities, split orders, non-conforming product)
- control the unique and serialised identification of the product when specified in NGL product definition and / or purchase order / contract.

Performance Measurement

5.14 The supplier shall in accordance with the contract requirements establish and agree a set of metrics to enable measurement of performance against contracted and sub-contracted work scopes. The metrics shall as a minimum measure the supplier's safety, schedule, quality and cost performance.

5.15 The supplier shall ensure specific, measurable, achievable, realistic and time bound (SMART) actions are taken if sub-contractor performance is not achieving the required standard or upon the identification of adverse trends.

Monitoring of Supplier performance / re-evaluation

5.16 NGL shall continually review and monitor suppler performance and will re-evaluate the supplier's capability if / when the scope of work changes to confirm that the supplier has the ability to provide processes, products and services that conform to NGL's requirements and applicable statutory and regulatory requirements. Records shall be retained by NGL of the results of the supplier's performance and re-evaluations. In addition suppliers need to be pro-active in monitoring and re-evaluating their sub-tier suppliers.

Control of Measure and Test Equipment

5.17 The supplier shall maintain a register of measurement and test equipment and ensure that it is calibrated and traceable to International or national standards for the duration of the contract.

5.18 The supplier shall notify NGL of any product that may be affected by the failure of measurement and test equipment or by the measurement and test equipment failing recalibration. The supplier shall evaluate the impact on product or service affected by such equipment; this product shall be treated as nonconforming product until demonstrated otherwise (see section 7).

6 Quality Plans

Quality Plans (QP) shall conform to the requirements detailed in BEG/SPEC/QUA/017- Quality Plans available from the contract manager, or procurement specialist.

6.1 The supplier will agree the use of QP and / or ITP and method statements with NGL.

6.2 The supplier shall provide documented QP and / or ITP when specified in the order and in accordance with the QA grade.

6.3 The QP and / or ITP identifies the supplier's control activities required to fulfil the order requirements. Each operation shall be signed off by a SQEP before commencing with the subsequent operation.

6.4 Where the QP and / or ITP calls for documents or procedures to be approved by NGL / 3rd party inspection body then no production shall be started or continue without such approval being given in a documented form.

6.5 Any hold / witness points shall be identified with in the QP and / or ITP.

6.6 The supplier shall provide advanced notification, a minimum of 72 hours, that a hold / witness point is due. Under no circumstances should production go past this point without written permission from NGL.

6.7 The distribution for review and approval of QP and / or ITP shall be agreed at the contract inaugural meeting for the contract, project, task specific purchase orders or operations.

6.8 The supplier shall ensure a QP and / or ITP is in place for the contracted scope of work. Where the work covers a number of phases for example design, manufacture, construction, installation and commissioning, a separate QP and / or ITP shall be prepared and submitted for each phase.

6.9 The supplier shall not commence work identified in the QP and / or ITP prior to confirmation of acceptance by NGL.

6.10 The supplier shall document in the QP and / or ITP the controls to be applied to its sub-contractors. Any change to an approved / accepted quality or inspection and test plans shall be resubmitted to NGL for approval and / or acceptance.

6.11 Specialist processes within the specification shall be identified within the QP and / or ITP and these will require approval by NGL. Typical special processes include but are not limited to welding, pipe work bending, heat treatment, non-destructive testing, material finishes and concrete mix design.

6.12 For products and services, the QP and / or ITP shall conform to the following criteria:

6.12.1 the QP and / or ITP shall be prepared listing the activities necessary to demonstrate compliance with the specified requirements and to discharge the work. The activities shall be listed in a logical sequence and be broken down into a level of detail required to discharge the work, for example, phases associated with the contract lifecycle and different packages of work

6.12.2 the QP and / or ITP shall identify against activities all applicable procedures, controlling arrangements, accountability for delivery and associated records. The wording and output of the activity shall be clear, concise and unambiguous

6.12.3 the QP and / or ITP shall identify the minimum records to be included in the LTQR. These records shall be reviewed, approved and accepted in accordance with the specification and contract requirements. NGL reserves the right to identify hold points in the QP and / or ITP. NGL representative may identify hold points in the QP and / or ITP beyond which work must not proceed without NGL verification and / or permission. If work commences prior to NGL acceptance of the QP and / or ITP, or work progresses past a hold point without the required sign off on the QP and / or ITP, NGL or supplier shall raise a non-conformance requiring corrective and preventative action.

6.13 When completed the QP and / or ITP should be able to act as a route map from the original scope of work, to the underpinning LTQR.

7 Deviation and Nonconforming Products or Process

7.1 No part of the work shall be repaired or spoiled work corrected without prior written approval of NGL.

7.2 Any deviation from specification shall be dealt with as a non-conformance request which shall be submitted to the key contact for the order / contract or as per the requirements as detailed in BEG/SPEC/PRO/36 – Change Control Process for Plant Spares (concession deviation process) available from the contract manager, or procurement specialist.

7.3 The supplier shall ensure that non-conforming items are clearly identified throughout the manufacturing process, are traceable and are kept separate from other items. All items with non-conformances shall clearly have the non-conformance recorded on the associated certificate of conformance to facilitate traceability and configuration control.

7.4 The supplier shall establish a documented process to identify record, clarify and resolve technical problems with respect to NGL and / or NGL requirements prior to or during the implementation of the contracted work scope.

7.5 The supplier shall establish a documented process to identify, clarify, resolve and close out non-conformances throughout the life of the contract.

7.6 An investigation into the root cause of the Non-Conformance Report (NCR) shall be undertaken and submitted to NGL for approval along with any corrective actions. Should this root cause investigation be deemed not to be sufficiently robust then NGL reserves the right to undertake a root cause investigation on the supplier's or sub-tier supplier's site.

7.7 The supplier shall establish a documented process to identify a request for deviation or a justification for the use of non-conforming product from NGL specified requirements, aligned with further guidance or processes where specified.

7.8 Upon identification of nonconforming product or service the supplier shall ensure the product is clearly identified, segregated, controlled, recorded, and reported to the appropriate level of management within the organisation and then reported onwards to NGL.

7.9 The supplier shall establish a process to review the cumulative effect of non-conformances, technical queries and concessions raised. The output of these reviews must be submitted to NGL.

Investigation Process

7.10 Non-conforming product or services identified by EDFE NGL will be recorded on the NGL Condition Reporting System and will be investigated in line with the requirements as detailed in BEG/SPEC/OPSV/CAP/002 – CAP Investigations (SACI, ACIN, MACI).

8 Design

Control of Design

8.1 The supplier shall ensure that all design activities and interfaces are clearly defined and controlled.

8.2 The supplier shall ensure that roles and responsibilities of appropriate design disciplines, for example, mechanical, electrical, process, safety and civil are clearly understood and communicated to NGL stakeholders to ensure their involvement at the appropriate stages.

8.3 The supplier shall ensure that all design documents and design changes issued to NGL are controlled by the documented management system process. Design changes shall be conducted at the same level as the original design review and verified accordingly.

8.4 The supplier shall ensure that IT software used in analysis and computation of high risk activities is acceptance tested, is validated, has a test plan and is not used beyond its life cycle without appropriate validation.

Design Review Requirements

8.5 When the design responsibility lies with the supplier as defined within the contract, the supplier shall identify and implement their proposed design reviews on the QP. This has to be approved by NGL prior to the commencement of work.

8.6 3rd party design verification activities shall be documented and included within the QP to ensure that responsibilities and communication interfaces are clearly defined.

8.7 The supplier shall submit all documents to be considered at design review to NGL in a fully approved state at least 10 working days prior to the design review.

8.8 NGL reserves the right to participate in supplier design reviews.

8.9 NGL reserves the right to identify any design activity, which requires confirmation or 3rd party design verification.

8.10 The supplier shall document the results of all design reviews and transmit the results to NGL. Actions resulting from design reviews shall be completed before final NGL approval of the design.

8.11 Verification reviews of design calculations and analyses performed by alternative means shall be controlled to determine when, by what method and by whom the calculations were performed and be traceable back to the original design.

Change management

8.12 Where any changes to the product or process occur after the product or process has been submitted to NGL then approval of these changes shall be obtained from NGL prior to continuation. Examples of these are, but not limited to:

a. change of design

b. change of manufacturing location

c. change of material

d. change of process parameters in relation to a special process

e. change of sub-tier supply

f. change in the organisation; and

g. change in QMS approval.

Design Output, Review, Checking and Approval

8.13 Review, checking and approval of design outputs shall be undertaken by SQEP who are independent of those having direct responsibility for the work being performed.

8.14 Design Output, whether in electronic or paper form, shall be considered at Lifetime Records and delivered in accordance with Section 10 Records.

Design & data configuration control

8.15 The supplier shall ensure that a Configuration Management process is documented, maintained and submitted to NGL for approval.

9 Production and Service Realisation

Product Traceability

9.1 The supplier shall have a documented process for identification and traceability of products during storage, manufacturing and delivery in accordance with relevant specified requirements.

9.2 The supplier shall, where required ensure stockists maintain a system that provides item traceability in accordance with the relevant specified requirements.

Management of Suspect and Counterfeit Products

9.3 The supplier shall ensure that processes are in place to mitigate the risk of suspect and counterfeit products being deployed to NGL. The processes shall include identification of Counterfeit, Suspect or Fraudulent items (CSFI), assurance of product source, selection of suppliers and verification that purchased products meet the specified requirements.

9.4 In the event of CSFI being found the supplier shall immediately notify NGL in case a similar item is in use and initiate the non-conformity process as described in section 7.

9.5 The supplier shall ensure that processes are in place to control and document the disposition of products identified as suspect. NGL shall be provided records of the dispositions of suspect products.

Mill Certification

9.6 The supplier shall supply to NGL Original Material Mill Certificates listing the mechanical and chemical properties as required by the contract specification. Where this is not possible copies should be taken and endorsed by authorised personnel in red ink as "verified true certified copies of the original".

9.7 Where specified and where a product has been manufactured from a previously certified material the supplier shall provide endorsed certificates of both material products produced by one manufacturer and reworked by another manufacturer, for example fittings made from pipe or plate, flanges made from a forging or plate.

9.8 The supplier shall review and endorse the Original Material Mill Certificates or certified copies to verify conformance with the contract specification prior to the commencement of work.

9.9 Stockist certificates are not acceptable when Original Material Mill Certificates or certified copies are specified within the contract specification.

9.10 The supplier's authorised personnel reviewing Original Material Mill Certificates for conformity shall be SQEPed to perform such reviews.

Verification and Inspection of Products and Services by NGL

9.11 Acceptance of any aspect of a product or service by NGL does not absolve the supplier of his responsibility to ensure conformity to product and service requirements.

9.12 The supplier shall establish a process for goods inward inspection. The process shall ensure the following:

- plant and materials are received with a copy of the relevant certificate(s). Certification shall be traceable to relevant purchase orders and / or contracts
- plant and materials shall be accompanied by a manufacturer's delivery note and should be checked for quantities and any damage or defects
- plant, materials and associated certification are be booked into an approved storage or lay down area and allocated with a unique identification number / GRN
- plant and materials that are found to be damaged or considered to be outside of specified requirements are immediately quarantined.

Release of Goods

9.13 The supplier shall not dispatch products identified as requiring an interim release note until authorisation has been obtained from NGL by the issue of appropriate written certification. Products and services must not be released to NGL until all the planned activities, tests and checks have been satisfactorily completed; unless a relevant authority approves their early release. Approval for such early release shall be obtained in writing.

Preservation of Product

9.14 The supplier shall ensure the preservation of product and its constituent parts during internal processing, storage and delivery to NGL.

Special processes and approvals

9.15 Where the supplier uses a special process, they shall submit the controlling documentation for the process and qualification samples (if applicable) to NGL for approval prior to the starting of any work. No work shall commence until such time that NGL has approved these processes.

Manufacturing data and instructions

9.16 The supplier shall ensure that the manufacturing process is documented to show each operation and all inspection / hold / witness points.

9.17 This shall be in the form of the associated QP and any route card that is used to show that each operation has been done and the records verified that they evident compliance plus completeness by a SQEP.

Material Handling / Segregation / Storage / Transportation

9.18 The supplier shall have documented and maintained processes for the methods that will ensure that damage does not occur to the product. Material shall be subject to FME when finished / despatched (free from contamination or debris).

9.19 Where the material to be processed is free issue from NGL the supplier shall detail how this shall be segregated from all other raw material.

9.20 The supplier shall ensure that all materials were applicable are segregated to prevent cross contamination.

9.21 The supplier shall ensure that all materials are stored in such a manner as to prevent / minimise degradation due to time or environment.

9.22 Stored material shall be identifiable and traceable to their incoming release documentation.

9.23 The supplier shall document how they will deal with items that have a shelf life.

9.24 If the supplier has specific handling / storage or transportation instructions then these shall be provided to NGL.

10 Records

Life Time Quality Records

10.1 LTQR are considered to be one of the principle forms of objective evidence of quality assurance. It should be unequivocally understood that generation and compilation of quality records shall commence following QP approval, acceptance and commencement of contract.

10.2 The supplier shall ensure that all Lifetime Quality Records (LTQR) including those generated by sub-contractors are compiled in accordance with the contract and the requirements detailed in BEG/ICP/QUA/006 – Records Management.

10.3 LTQR will be supplied in line with the requirements of the contract by NGL.

10.4 Products will not fitted be to plant without acceptable LTQR and supporting documentation.

10.5 No items of equipment will be deemed acceptable without submission or demonstration of critical documents as defined within contractual requirements and / or legislative requirements to support their integrity and fit for purpose criteria.

10.6 It is the responsibility of the supplier to continually monitor the development, quality and status of the essential documents. The quality records will form part of the handover of documents. To enable clear provenance all documentation must be legible, dated, clean, readily identifiable, retrievable and maintained in an orderly manner.

10.7 Documents must be controlled and maintained throughout the life cycle of the contract.

10.8 Typically, but not exclusively, the LTQR for non-standard product / plant & equipment will include the following as applicable:

- LTQR shall be provided in accordance with the quality assurance requirements as stated in the accompanying contract / purchase order documentation. LTQR shall be collated and presented in a format specified by the particular project document controller
- at the front of the LTQR, the first page should state the following:
  - **i.** project description
  - **ii.** contract number
  - **iii.** contractors / sub-contractors name address and telephone number.
  - **iv.** plant item numbers
  - **v.** plant system number and title
  - **vi.** equipment titles.

10.9 The LTQR pack should be presented to NGL as early as possible to permit endorsement at the time of final Inspections and Plant & Equipment acceptance and release. Following acceptance, the document pack should be forwarded to the Project Document Controller.

10.10 The supplier shall compile the LTQR during the project to facilitate the timely compiling of the LTQR and the subsequent NGL approval / endorsement or comment as applicable.

11 Definitions

The UK Nuclear Industry Standard Quality Requirements have been written using the standard management system vocabulary as defined in BS EN ISO9000:2005 – "QMSs – Fundamentals and Vocabulary" with additional terms defined where required.

Authorised individual
An individual with documented permission to undertake the activity.

Assurance
A systematic approach to confirm activities are being completed as per the requirements, to the appropriate standard and confirm that arrangements comply with required legislation, standards and customer requirements.

Certification
Carried out to ensure that NGL receive what they have specified in their contract documents, and to formalise the transfer of acceptance information.

Certified
Authoritatively or officially attested or confirmed as being genuine or true as represented, or as complying or meeting specified requirements or standards.

Certificate of Conformance/ Certificate of Compliance (CofC)
A document certified by a competent authority that the supplied good or service meets the required specifications.

Concession
Permission to use or release of product or service that does not conform to requirements.

Contract Review
Process used by an organisation to review that contract supplied documentation is adequate to enable successful delivery of a specific scope of work.

Corrective action
Action to eliminate the cause of a detected nonconformity or other undesirable situation.

Counterfeit
A copy or substitute product whose material, performance or characteristics are knowingly misrepresented by the supplier.

Deviation
Departure from the originally specified requirements of a product prior to realisation.

Foreign Material
Material that is not part of the system or component as designed, such as dirt, debris, broken or missing parts, oil, slag, tools, rags, chemicals, lapping compounds, grinding particles and PVC bags/sheets, and any other items that could affect the intended operation of the system or component.

Inspection
Conformity evaluation by observation and judgment accompanied as appropriate by measurement, testing or gauging.

Inspection & Test Plan (ITP)
Document which defines the sequential quality control, testing activities and associated arrangements that are to be applied to a specific scope of work or individual piece of plant and equipment.

Life Time Quality Records (LTQR)
Record(s) that provide documentary evidence of the research & development, design, build, construction, commissioning, decommissioning and demolition of/on a nuclear installation.

Management Review
Regular documented systematic reviews by top management to evaluate the suitability, adequacy, effectiveness and efficiency of the QMS.

Material Mill Certificate (Original)
Issued by the material manufacturer with a coloured letterhead, original authorised signature, embossed mark, watermark etc. to prove it is an original. The certificate shall meet the requirements of the most current edition of BS EN 10204, certificate type 3.1.

Material Mill Certificate (Copy)
A photocopy of an Original Material Mill Certificate endorsed in red ink by an authorised individual, inspector, third party inspector or QA representative by the manufacturer's approved representative declaring the document as a "true certified copy of the original mill certificate".

Measurement and Test Equipment
Tools, gauges, instruments, other measuring and test equipment used for activities affecting quality that are required to be controlled, calibrated at specific periods, adjusted by approved personnel or approved calibration laboratories, and maintained to required accuracy limits.

Nonconformity
Non-fulfilment of a requirement.

Nuclear Safety Culture
An organisation's values and behaviours, modelled by its leaders and internalised by its members, that serve to make nuclear safety the overriding priority at all times.

Production Permit
Is a written authorisation from NGL prior to production, to deviate from specified requirements.

Quality Grade
A grade indicating the extent that quality assurance and control shall be applied to a product or service based on the level of risk associated with failure.

Quality Plan (QP)
Is a document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

SQEP
Suitably Qualified and Experienced Person.

Technical Query (TQ)
A Technical Query is a request for clarification of technical or engineering information typically contained in drawings, specifications and contract documents.

Verification
Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Validation
Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

12 References

EDF Energy

1 **BEG/SPEC/SHE/010/002** Nuclear site licence conditions

2 **BEG/SPEC/OPS/036A** Procedure Use and Adherence

3 **BEG/SPEC/FENG/001** Graded Application

4 **BEG/SPEC/QUA/017** Quality Plans

5 **BEG/SPEC/PRO/036** Change Control Process for Plant Spares (Concession deviation process)

6 **BEG/SPEC/OPSV/CAP/002** CAP Investigations

7 **BEG/ICP/QUA/006** Records Managements

National Standards

8 **ISO9001:2008** Quality Management Systems Requirements

9 **GS-R-3 IAEA** The Management System for Facilities and Activities

Tender and Contract Specific Documents

10 **AGS** Acquired Goods and Services

11 **BEG/SPEC/PRO/019** Contract Inaugural Meeting Minutes