

## **1. GENERAL QUALITY ASSURANCE (QA) REQUIREMENTS CQR01& CQR02**

1.1 The successful Contractor shall for all work covered by the contract: - establish and implement the quality assurance arrangements relevant to the scope of the contract and, which as a minimum, meets the requirements of ISO 9001:2015, “Quality Management Systems – Requirements”, or equivalent.

- **ISO 9001 : Clause 4 amendment (2024):** all parties must evidence climate change considerations, addressing risks and opportunities, noting UKNNL is committed to mitigating avoidable carbon emissions through all its activities, operations and services, this ISO amendment applies to the supply network. - establish a procedure for ongoing contract review through the life of the contract, which addresses any significant contract amendments. Records of the ongoing reviews and the conclusions reached shall be kept and form part of the lifetime quality records (LQR).

## **2. QUALITY PLANS**

2.1. In addition to the general QA requirements outlined in Section 1 above, the Contractor shall:

- Establish procedures for adequate planning and resourcing of all quality related
- activities including the preparation of quality plans. Quality plans shall be
- submitted to UKNNL for approval and work identified in the quality plan shall not
- commence prior to receipt of such approval.
- The UKNNL representative may identify hold points in the quality plan beyond
- which work must not proceed without UKNNL verification and / or permission

2.2. The quality plan shall conform to the following minimum standard:

- A quality plan shall be prepared listing the key/critical activities necessary to demonstrate compliance with the specified requirements to discharge the work.
- Those activities shall be listed in a logical sequence and broken down to a level of detail required to discharge the work e.g. phases associated with the contract lifecycle, different packages of work, etc.
- Where work covers design and manufacturing activities, separate quality plans shall be prepared (these will be referenced to the overarching Quality Plan for full accountability).
- The quality plan shall identify against activities all applicable procedures and associated records.
- The quality plan shall identify the records to be included in the lifetime quality records (LQRs).

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- To monitor the work, the quality plan shall facilitate the signing off of all activities against a defined coded schedule, this maybe a HOLD POINT, acting as an authorisation to proceed.
- The quality plan shall consist of three main parts: cover sheet, documentation sheet and activity sheet.

2.2.1 The cover sheet shall identify the following:

- a) Title
  - b) Reference number (UKNNL contract number and contractor' ref).
  - c) Scope of work the quality plan covers
  - d) Persons responsible for 'signing off' the quality plan activities (print/ sign)
  - e) Final 'sign off' for when the quality plan is complete (print/ sign)
  - f) Activity codes and description
  - g) Quality plan authorisation and approval - (names, signatures and dates)
- The documentation sheet shall identify all specifications applicable to the scope of work.
  - The activity sheet shall identify activities, controlling documents and generated records.
  - The following activity codes shall be used to identify the action required.

Action	Activity Code
100% Inspection	A1
Sample Inspection	A2 (#)
100% Witness	W1
Sample Witness	W2 (#)
100% Review	R1
Sample Review	R2 (#)
Hold Point	H
Approval	AP
Surveillance	S

- (#) Where "sample" is identified, the percentage (%) shall be defined with the code e.g. R2 (10) = 10% sample review.
- Quality plans shall be kept up to date to reflect current status i.e. signatures / dates recorded

2.3. Inspection / testing shall be by suitably qualified and experienced personnel independent of those having direct responsibility for the work being performed.

2.4. Before commencement of any manufacture and within 10 (ten) working days of receipt of the contract, or an instruction to proceed, the contractor shall submit the quality plan and an inspection and test schedule for approval.

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2.5. Quality plans, procedures, concession/ product permits, works test schedules and inspection schedules, etc. submitted by the Contractor for approval, and/or information, shall be addressed as follows:

For the attention of: - **The Demander (Nominated UKNNL technical representative)**

2.6. All the documents shall be marked with Contract Number and UKNNL Project Number (if applicable)

2.6.1 Documentation provided by the Contractor will be reviewed by UKNNL and marked as follows:

- Approved
- Approved with comments (this allows work to proceed, however, the document must be re-submitted incorporating the comments within 10 working days for formal approval)
- Rejected

\*Note: CQR grade 1/2 projects can be managed by QGM (Quality Governance module). Electronic links to relevant documents contained within the project file structure will be created as applicable.

### **3. CONTROL OF SUB-CONTRACTORS / SUPPLIERS**

3.1. The Contractor shall comply with all the requirements defined in this document and ensure they are flowed to all tiers of the Contractor's supply chain unless otherwise agreed with UKNNL. The Contractor shall be responsible for specifying relevant quality assurance requirements to his sub- contractors/suppliers and for approving where necessary the quality assurance arrangements of these and ensuring that they comply with such arrangements.

3.2. The Contractor shall ensure that all relevant technical information is extracted from the Contract documentation and passed to the sub-contractor / supplier.

3.3. The contractor shall only place work in accordance with the agreed schedule submitted with the tender or in accordance with agreed changes following submission of a revised schedule.

### **4. MONITORING OF CONTRACT WORK**

4.1. During the course of the Contract, UKNNL reserve the right to monitor the implementation of the Contractor's quality assurance arrangements. Monitoring will be by means of surveillance of activities at the work locations and, where appropriate, through formal auditing.

Representatives of UKNNL shall be afforded unrestricted access and facilities at all reasonable times to carry out this work (within the specified work area) in accordance with UKNNL Standard Conditions of Contract.

4.2. UKNNL reserve the right to monitor any sub-contractors' activities and the Contractor shall ensure that sub-contractors are informed of this requirement (see 4.1 above).

4.3. No part of the work shall be repaired or, spoilt work corrected, without the prior written approval of UKNNL. Any deviation from specification shall be dealt with as a concession request, which shall be submitted for UKNNL approval. Copies of the forms will be supplied to the Contractor.

4.4. A minimum of 3 (three) working days' notice of a hold point requiring UKNNL inspection or witness shall be given for UK manufacture and a minimum of 10 (ten) days' notice outside the UK.

## **5. CERTIFICATION RECORDS - COMPILATION AND REFERENCING**

5.1. All records shall be compiled concurrently with the activity to which they relate. All records including those generated by sub-contractors / suppliers shall be compiled, indexed and uniquely identified to the Contract and specific work activity.

5.2. The contents of the Lifetime Quality Records (LQRs) shall be in accordance with either the specification or as stated in the contract documentation.

5.3. LQRs shall be supplied in A4 files.

5.4. All sections within the file shall be separated using file section dividers and suitably ordered either numerically or alphabetically.

5.5. The first page of the LQRs shall state:

- Contract number
- Contractor's name, address and telephone number
- Contractor's Reference
- Plant Item Number
- Plant System Number and Title (if applicable)
- Equipment Titles

5.6. The second page shall list the sections included in the LQR file.

5.7. Where appropriate, the records shall be cross referenced in a clear and understandable manner, e.g. material certificates, where appropriate, shall be cross referenced to the drawing number (s) of the components (s) which have been manufactured from that material.

5.8. The pages within each section shall be numbered in the manner page x of y, so that completeness of the section can be verified.

5.9. A test/ inspection certificate shall as a minimum contain the following information:

- UKNNL Contract Number
- Supplier Reference Number
- Title (e.g. Test Report or Calibration Certificate)
- Name of laboratory or test facility
- Address of laboratory or test facility
- Unique identification of the report
- Name of client
- Identification of the method used
- Identification of the item(s) tested
- Test date
- Result including where appropriate the unit of measure and degree of accuracy
- The name of the person authorising the report
- Job title of person authorising the report
- The signature of the person authorising the report
- and in addition, for calibration certificates:
  - Confirmation that the result is traceable to National Standards

5.10. A certificate of conformity shall as a minimum contain the following information:

- UKNNL Contract Number
- Supplier Reference Number
- Title
- Unique identification of the certificate
- Identification of the item/service being certified
- Date of issue
- Identification of the control document (quality plan/procedure etc.) which describes
- the process that ensures that the item/service conforms to specification
- a clear statement that the goods comply with specific criteria or standards
- Issue number and date of Quality plan or procedure
- The name of the person authorising the certificate
- Job title of person authorising the certificate
- The signature of the person authorising the report

5.11. Original material test certificates, will be inspected and MUST meet the requirements of BS EN 10204 Type 3.1 or Type 3.2, or equivalent depending on contract

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requirements, this requirement is to mitigate counterfeit goods or substandard materials, entering into the infrastructure of a Nuclear Facility

\*Note (BS EN 10204 is the standard for inspection documents for steel [and other] products, **to mitigate counterfeit materials/goods or/& substandard materials/workmanship entering into the infrastructure of a Nuclear Facility**).

5.12. Records defined in the Contract as being required by UKNNL shall be collated and be available at contract completion; the satisfactory review of the records by UKNNL shall constitute an element of the acceptance procedure.

5.13. The retention times for records shall be agreed with UKNNL in writing and retained in accordance with UKNNL approved record retention procedures (IMS-PRJ-RRDS-001).

5.14. No item shall be despatched unless all associated documentation is available and authorisation has been obtained from a competent person e.g. a sub contracted Inspector.

5.15. One set of the records after acceptance by UKNNL shall be sent:

For the attention of: - **The Demander**

### **6. QUALITY RELATED INFORMATION TO BE SUPPLIED**

As part of the contract management and following the award of the tender; The Contractor shall provide the following:

6.1. Confirmation by written statement that the Quality Assurance Programme (Management System) for the work will as a minimum meet the requirements set out in the contract for:

- the Quality Assurance Conditions, and
- the Environmental Requirements

6.2. Where a Quality Assurance Programme is to be a Contract requirement, an outline of the proposed Quality Assurance Programme indicating how the Contractor intends to comply with the specified quality assurance requirements with respect to those activities is to be carried out by the Contractor and his Sub-Contractors. The submitted Quality Assurance Programme is to be a composite document:

6.2.1 containing the "Policy Statement";

6.2.2 describing the scope of work;

- ❖ describing the overall organisation;
- ❖ identifying key positions;
- ❖ defining specific responsibilities;
- ❖ identifying the applicable management procedures; and

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- ❖ confirming the procedures compliance with the relevant quality assurance standard (possibly by matrix).

6.3. Job profiles and Curricula Vitae (CVs) of quality personnel.

6.4. Copies of any 'Quality System' certificates.

6.5. A schedule of proposed sub-contractors on UKNNL Form IMS-F-6200 'Notice of Intention to Use Sub-Contractors' defining the type of work or service to be subcontracted and the quality assurance standard applicable.

### 7. PROGRAMMABLE ELECTRONIC SYSTEMS (PES)

7.1. Where a contract includes development, supply, installation or maintenance of PES that performs a safety or safety related function then BS EN 61508 'Functional safety of electrical/electronic/ programmable electronic safety-related systems' applies. In addition, for all work covered by the contract, the contractor shall establish and implement quality assurance arrangements that, as a minimum, meet the requirements set out in the current releases of:

- **BS ISO/IEC/IEEE 12207:** Systems and software engineering. Software life cycle processes or equivalent;
- **BS ISO/IEC/IEEE 90003:2018:** Guidelines for the application of ISO 9001 to computer software, or equivalent.

7.2. If delivery and installation to the contract specified location is sub-contracted to a third party, the contractor shall ensure that the quality assurance requirements, herewith specified, are complied with fully.

### 8. RADIOACTIVE MATERIALS INCLUDING SOURCES (SEALED AND UNSEALED) AND GENERATORS CONTAINING RADIOACTIVE SOURCES

8.1. The Contractor must demonstrate compliance with statutory legislation appropriate to the identification, packaging, handling and transportation of radioactive material.

8.2. Packages must be identified with the contract and/or purchase order number and with the UKNNL Demanding Officer (Name, Dept, Building Number and Tel Number).

8.3. In addition to the requirements of ISO 9001:2015, or equivalent the contractor shall provide source lot traceability with all products supplied.

8.4. All certification and documentation as specified by the demanding officer and identified in the contract/Purchase Order This shall include where applicable:-

- a) Sealed sources certificate in compliance with BS EN ISO 2919, **or equivalent**
- b) A leak test certificate
- c) Wipe test certificate or certificate of non-contamination

- d) Calibration certificate
- e) Consignment certificate conforming with the requirements of the transportation regulations.
- f) Exchange of declarations for members of the European Union organised by the Site Movement Liaison Office (SMLO) at the request of the customer.

### **8.5. SELLAFIELD and WINDSCALE**

8.5.1 The Contractor must give 3 days' notice by fax to the Sellafield Movement Liaison Officer (SMLO) of pending delivery to UKNNL and must include as a minimum the following information (form SLF2.07.04: Notice of an Inbound Movement should be used):

- Purchase Order Number or Contract Number
- Name of Demanding Officer
- Despatch Date
- Package Number
- Material
- Activity
- U.N Number
- Carrier
- Consignee

**Acceptance must be received from the SMLO before despatch.**

**The information must be faxed to the following:**

- Sellafield Site Movements Liaison Officer (SMLO). Contact Consignee for fax no.
- Health Physics Instrument Centre (HPIC). Contact Consignee for fax no.
- Consignee

### **8.6. SPRINGFIELDS**

8.6.1 The Contractor must give sufficient (try to give the SMLO 5 days) notice by fax to the

Springfields Site Movements Liaison Officer (SMLO) of pending delivery to UKNNL and must include as a minimum the following information (appropriate SFL form is to be used to record this information):

- Name of Demanding Officer
- Despatch Date
- Package Number
- Material
- Activity
- Principle Isotopes

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- Radiation readings
- U.N Number
- Carrier
- Consignee

**Acceptance must be received from the SMLO before despatch.**

**The information must be faxed/**emailed to both of the following:

- Springfields Site Movements Liaison Officer (SMLO). Contact Consignee for fax no.
- Consignee

## **9. DESIGN REQUIREMENT**

### **9.1. CONTROL OF DESIGN**

9.1.1 The Contractor shall ensure that all design interfaces are clearly defined by:

- I. Ensuring the responsibilities of appropriate disciplines eg. mechanical, electrical, civils are clearly understood and communication controls established to ensure their involvement when appropriate
- II. Ensuring that when design organisations are used the interfaces are adequately controlled.
- III. Ensuring that all design documents and design changes issued to UKNNL are adequately controlled (numbered including versions controls).
- IV. Ensuring that, In accordance with ISO 50001:2018 Clause

8.2 (Design), performance over the planned or expected operating lifetime shall be looked at when considering energy improvement opportunities and operational control in the design of new, modified and renovated facilities, equipment etc. that can have a significant impact on its energy performance.

### **9.2. DESIGN REVIEW REQUIREMENTS**

9.2.1. When the design responsibility lies with the Contractor, the Contractor shall implement and identify on the quality plan, any proposed design reviews which shall be conducted in accordance with BS EN 61160:2005, or equivalent.

9.2.2. UKNNL reserve the right to participate in the design reviews.

9.2.3. UKNNL will identify any design activity which requires confirmation or third party verification.

9.2.4. The design reviews, at a minimum shall include the following:

- Appropriate disciplines; and documented check lists of factors considered.

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- The results of all design reviews shall be documented, and information communicated to all interested parties.
- Actions resulting from design reviews shall be completed, in a timely manner and MUST be closed, before final approval of the design.
- Checks of design calculations and analyses (manual or computer) performed by alternate means shall be adequately controlled to determine when, by what method and by whom, the calculations were performed and be traceable back to the original design (full traceability requirements).
- Third party design verification activities (when carried out) shall be documented to ensure that responsibilities and communication interfaces are clearly defined.

### **9.3. DESIGN OUTPUT, REVIEW, CHECKING AND APPROVAL**

9.3.1. Review, checking and approval of design outputs shall be by suitably qualified and experienced personnel independent of those having direct responsibility for the work being performed.

## **10. SITE CONSTRUCTION, INSTALLATION, TESTING & COMMISSIONING**

### **REQUIREMENTS**

10.1. The Contractor's Quality Assurance Programme shall define those systems and procedures he intends to implement for controlling all construction / installation / testing / commissioning activities. Prior to commencement of the work the Contractor shall prepare contract specific quality assurance procedures for agreement with UKNNL.

10.2. The system shall demonstrate effective control of construction / installation / testing / commissioning activities by the implementation of control documents such as quality plans specific to the activities, method statements, installation / inspection / test schedules.

10.3. These documents shall be provided to the Demander for review and appropriate endorsement at least four weeks prior to the start date of the specific activity. (Note: Unless notified to the contrary, by the Demander, documents produced by subcontractors will be reviewed and appropriately endorsed by the main Contractor).

10.4. The Contractor shall establish procedures defining the methods of identifying, recording and resolving / clarifying technical problems with respect to drawing / specification information prior to implementation.

10.5. No part of the work shall be repaired or, spoilt work corrected, without the prior written approval of UKNNL. Any deviation from specification shall be dealt with as a concession request, which shall be submitted for UKNNL approval. Copies of the forms will be supplied to the Contractor.

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10.6. Acceptance of any aspect of work by UKNNL or their representative shall in no way absolve the Contractor of his responsibility to complete the works in accordance with the specified requirements.

10.7. UKNNL reserves the right to interview personnel controlling quality related activities. Personnel proposed shall be to the satisfaction of the Demander.

10.8. Inspection and tests shall be performed by individuals other than those responsible for the activity or item subject to inspection or test.

10.9. The Contractor shall submit to the Demander for approval within four weeks of Contract placement a schedule of audits on his own activities. Audits shall be carried out annually as a minimum on all elements of the quality system relevant to the Contract. Progress in implementing the schedule shall be reported to the Demander.

10.10. The Contractor shall submit and agree a procedure for the compilation of Lifetime Quality Records for the site-work, with the Demander.

### **11. SUB-CONTRACTOR INFORMATION**

Prior to the placement of orders the Contractor shall submit additional information on UKNNL Form IMS-F-6200. The submission shall define which parts of the work is intended for subcontract to any other party.

### **12. R&D REQUIREMENTS/ ADDITIONAL ACCREDITATION**

Where the contract includes Research & Development (R&D) and/or Laboratory Testing in addition to compliance with ISO 9001 or equivalent, the UKNNL Ltd contract can stipulate valid accreditation with ISO 17025, to ensure robust chain of command, impartiality and consistent operation of laboratories.