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INS Contractor Quality Requirements Manual			

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AMENDMENT RECORD

REPLACES: Issue 2		
Issue No.	**Date**	**Summary of Amendment**
1	**15/12/16**	First Issue
2	**20/3/17**	Second issue
3	**9/5/18**	Changes to Sections 2.14 and 2.15 to reflect circumstances for Quality Grades 1 and 2 when a QA Programme and Process Outline may be required. Changes to Section 2.11, Section 5 and Section 10.25 to clarify the Schedule of manufacturing and non-manufacturing Documents. Appendix 1 added to clarify hierarchy of supporting documents that apply to a contract.

Contents

Introduction

International Nuclear Services Ltd (INS) aims to support the delivery of excellence in all aspects of products and services and operating in a quality manner (namely safely, securely, reliably and predictably).

To achieve this aim, INS requires its supply chain to deliver products and services in a similar quality manner, particularly to the specified requirements, safely, to schedule and to the agreed cost.

The purpose of this document is to define generic quality requirements to ensure that the activities, products and services provided by the supply chain support and maintain the integrity of INS nuclear quality requirements specified within individual contract arrangements.

This document does not replace any contractual requirements set out in any issued contract terms and conditions. However, each contract will refer out to this document for the quality requirements and amend these quality requirements as necessary for each specific contract. Appendix 1 provides the hierarchical structure of the INS Technical, Quality and Manufacturing-related supporting documents that apply to a Contract.

Graded approach to Quality Assurance

Nuclear transport assets and associated equipment differ in their significance, hence the 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, the health and safety of INS personnel and the general public, breach of the licence conditions for nuclear transport assets, breach of environment or statutory requirements, cost penalties or public relations issues.

The requirements of each of the quality grades can be summarised as follows:

Quality Grade 1
- Failure is likely to result in uncontrolled release of radioactivity

Quality Grade 2
- Failure is likely to result in major risk of radiological hazard, and/or
- high risk of serious conventional injury

Quality Grade 3
- Failure is likely to result in minor risk of radiological hazard, and/or
- lower risk of serious conventional injury

There is also a Quality Grade 4 that applies where there is no safety significance (nuclear or conventional), but this Manual does not apply to this Quality Grade.

The requirements of each Quality Grade are identified using the key shown to the right of each heading or subheading as follows:

All clauses within the heading or subheading shall apply to these specified Quality Grades. The example above indicates that all clauses in that heading or subheading are applicable to Quality Grade 1, Quality Grade 2 and Quality Grade 3.

1. Nuclear Safety Requirements

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Nuclear Safety Definition

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

1.1. INS uses assets that are licensed by the Office for Nuclear Regulation (ONR) on behalf of the Health and Safety Executive (HSE). Licences include specific requirements to ensure that the assets are manufactured, operated and maintained in accordance with the safety case assessments that underpin the licence.

1.2. In order to achieve this, INS needs its supply chain to deliver products and services to the agreed specification. A key focus is ensuring that all supply chain personnel involved in design, manufacturing, inspection and testing understand how their role impacts upon nuclear safety and how the failure of a product or service can impact upon the public.

1.3. The first layer of defence is the design stage, which includes the associated safety case assessments of the design. This can have a significant impact on nuclear safety and so it is vital that any party undertaking design understands the impact of a failure. The design stage needs to concentrate on criticality, control, containment, shielding and cooling/thermal performance.

1.4. The requirements of the design then need to be transferred into the manufacturing stage such that the design intent can be realised by the quality of materials and workmanship. This will involve ensuring that the trades involved (such as manufacturing) understand how the quality of the materials and their workmanship can impact on nuclear safety.

1.5. The Contractor shall ensure that personnel are aware of the implications of suspect and counterfeit products being utilised in the products and/or services provided to INS.

1.6. The transition from design and manufacturing through to (if necessary) commissioning and operations shall be managed appropriately in order to ensure the necessary knowledge is passed over to the requisite personnel.

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1.7. The Contractor shall ensure that all personnel involved in the provision of work for INS understand any Nuclear Safety implications of failure of the product or service to meet the specified design intent. INS will provide the Contractor's personnel who will be carrying out work under the Contract with a familiarisation presentation prior to any work commencing.

2. Quality Management System Requirements

2.1. The Contractor for products and/or services shall have, and provide evidence of, a documented and maintained Quality Management System (QMS) that conforms to the current edition of BS EN ISO 9001 standard requirements, certified by a United Kingdom Accredited Services (UKAS) accredited certification body or national equivalent accreditation body outside the UK, or the relevant business sector variant, for example, 'TickIT' for software applications. Where the Contract includes software design, development, supply and installation, modification or maintenance, the current revision of BS EN ISO 9001:2015 to Computer Software is applicable, together with BS ISO/IEC 12207 Systems and Software Engineering – Software Life Cycle Processes. The QMS shall cover the full scope of supply, including design, manufacture or the provision of a service (as applicable).

2.2. Where the assessment body is not recognised by a national or international body, the Contractor shall support INS in undertaking a full assessment of the Contractor's QMS.

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

2.4. The Contractor shall monitor, review and update its QMS as necessary to comply with Good Industry Practice and to ensure continued certification.

2.5. The Contractor shall appoint a suitably qualified and experienced Quality representative, supported by competent experienced personnel, to ensure effective implementation of the QMS. The Contractor shall advise INS of this person in writing.

2.6. The Contractor shall submit any changes to its QMS to INS for acceptance if such a change will impact upon, or is likely to impact upon, the quality of products or services.

2.7. When responding to any Contractor request for INS acceptance of changes to the Contractor's QMS, INS shall respond in writing and provide its reasons for determining that the Contractor's proposed changes to its QMS are unsuitable.

2.8. The Contractor shall provide evidence of compliance to the Contract Quality requirements to INS upon request.

2.9. The Contractor shall ensure that all personnel executing the contracted scope of work are aware of and understand any special contractual requirements or amendments thereof relevant to the scope of work.

2.10. Documents must be controlled and maintained throughout the duration of the Contract. Document reviewers/approvers shall have explicit guidance on what their signature on the document represents (for example, free from errors).

2.11. The Contractor shall ensure that documentation requiring submittal to INS for information or for review and acceptance shall be submitted as required in accordance with the Schedule of Documents. Note that for manufacturing documents, this will be included in the Manufacturing Specification, and for non-manufacturing documents, this will be specified in Schedule 1 of the Contract.

2.12. There shall be full independence of the Quality function from manufacturing, cost and schedule functions at Contractor and Subcontractor facilities.

2.13. The Contractor shall ensure that no Contractor personnel working on the Contract have targets that may encourage non-compliance with procedures.

2.14. A QA Programme may be required if the asset has novel features, is relatively complex to manufacture or is of medium to high value. This will be specified clearly in the Request For Tender. In these circumstances, the Contractor shall establish, implement and issue to INS for acceptance, a Contract specific QA Programme, which shall be structured as shown in Reference 13.1. After acceptance by INS, the QA Programme shall form an integral part of the Contract.

2.15. A Process Outline may be required if the asset has novel features, is relatively complex to manufacture or is of medium to high value. This will be specified clearly in the Request For Tender. In these circumstances, the Contractor shall establish, implement and issue to INS for acceptance, a high level description of the overall manufacturing process called a Process Outline. The requirements of the Process Outline are provided in Reference 13.2.

2.16. Organisation: The Contractor shall ensure that all personnel performing quality-related activities (including inspection and testing) shall have the authority to:
i) identify quality problems and, if necessary, suspend relevant manufacturing operations;
ii) initiate, recommend or provide solutions to such problems;
iii) to verify that solutions have been fully implemented.

2.17. Design control: Appropriate quality requirements shall be specified and included in design documents, and deviations from such requirements shall be controlled. The Contractor shall ensure that measures for the selection and review for suitability of application of materials, parts, equipment and processes that are essential to the safety-related functions of the structures, systems and components are established.

2.18. Instructions, procedures and drawings: The Contractor shall ensure that activities affecting quality shall be prescribed by documented instructions, procedures or drawings, of a type appropriate to the circumstances and shall be implemented in accordance with these instructions, procedures and drawings. Instructions, procedures and drawings shall include appropriate acceptance criteria for determining that important activities have been satisfactorily implemented.

2.19. Document control: The Contractor shall control the issuance of documents such as instructions, procedures and drawings, including changes thereto, which prescribe all activities affecting quality.

3. Resource Management

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3.1. The Contractor shall implement and maintain a competency/training register supported by appropriate training and qualification records.

3.2. The Contractor shall perform routine documented reviews of personnel to maintain competency.

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

3.4. The Contractor shall, upon request from INS, provide documentary evidence of personnel competency to INS.

3.5. INS reserves the right to interview personnel controlling quality related activities and, if necessary at the reasonable request of INS, the right to request a change of personnel.

3.6. The Contractor shall define and implement appropriate arrangements to control any change to its organisational structure or resources which may affect environment, health and safety, security and quality performance.

3.7. The Contractor shall notify INS formally of any organisational changes that could impact on environmental, health and safety, security and quality performance. The Contractor shall then update and issue the QA Programme to INS for acceptance.

3.8. The Contractor shall ensure that for critical inspections or tests affecting the manufacturing programme critical path, more than one inspector is suitably qualified and experienced to carry out said inspections or tests.

4. Supply Chain

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Quality Grading

4.1. The Contractor shall follow the INS approach by implementing a graded approach to the procurement of goods and services it intends to use in its delivery.

4.2. The Quality Grade to be applied (1, 2 or 3) will be advised by the drawings and/or specifications provided by INS. In the event that the Contractor is unsure of which grade to apply, advice shall be sought from the INS SO.

4.3. The factors which will influence the Quality Grade include:

i. the magnitude of the potential consequences if a product fails or an activity is carried out incorrectly;

ii. the significance and complexity of each product or activity;

iii. the hazards and the magnitude of the potential impact (risk) associated with the safety;

iv. health, environmental, security, quality and economic elements of each product or activity.

The Introduction also provides further information about Quality Grades.

Contractor selection of subcontractors

4.4. The Contractor shall have a process for subcontractor selection through assessment and analysis of their competencies, facilities and equipment to ensure that they have the capability to meet the Contract requirements, delivering products/services safely, to schedule, of the correct quality and to the agreed cost.

Flow down of information

4.5. The Contractor shall comply with all the requirements as applicable to the specified Quality Grade defined in this document and ensure that the requirements flow down to every applicable tier of the supply chain where the goods or services continue to be either a Quality Grade 1, 2 or 3.

4.6. The Contractor shall ensure that each subcontract articulates the necessary information to allow the subcontractor to supply the goods or service. In particular, the following should be included:

i. reference to this INS Contract Quality Requirements Manual;

ii. the Quality Grade applicable to the Contract and relevant products;

iii. specifications;

iv. drawings;

v. material type;

vi. quantity;

vii. certification requirements;

viii. inspection requirements at the subcontractor, on delivery to the Contractor, or both;

ix. functional testing requirements at the subcontractor, on delivery to the Contractor, or both;

x. any special requirements such as packing, additional testing, etc;

xi. requirements for procured services.

Subcontractor management

4.7. The Contractor shall ensure that each subcontractor fully understands their scope of supply.

4.8. The Contractor shall have a procedure for controlling documents issued between subcontractors and INS, and shall ensure documents are clearly identifiable to each subcontractor.

4.9. The Contractor shall implement a process for continuous review (verification and monitoring) of their subcontractors to ensure they are delivering products and services safely, to schedule, to the specification requirements and to the agreed cost.

4.10. Where the Contract includes any of the following elements, the continuous review process shall include:

i. organisation/resources;

ii. project/contract management;

iii. quality (including Nuclear Safety and Technical Specification awareness briefs);

iv. health and safety;

v. product requirements (including traceability);

vi. process requirements (including inspection and test);

vii. risk management (threats and opportunities);

viii. engineering;

ix. operations and maintenance;

x. provision of product samples (when required);

xi. Lifetime Quality Records (LTQRs).

4.11. Records of the continuous reviews, conclusions and any corrective actions shall be retained and form part of the LTQRs.

5. Quality Plans

5.1. The Contractor shall use Quality Plans (QPs), Inspection and Test Plans (ITPs), Method Statements (MSs) or their equivalent. Note that with regard to this document, the term ‘Quality Plan’ or ‘QP’ shall be used to refer to QPs, ITPs, MSs or their equivalent.

5.2. QPs shall meet the requirements shown in Reference 13.3.

5.3. The Contractor shall submit the QP(s) to INS for acceptance in accordance with the Schedule of manufacturing Documents as shown in the Manufacturing Specification and in accordance with the required Quality Grade. The QP(s) shall be signed by the Contractor as appropriate before issue to INS.

5.4. A copy of the approved Quality Plan(s) may be forwarded by INS to the UK nuclear regulator for their review and for the possible inclusion of regulator Hold Points for ONR witness if required. The Quality Plan(s) will be returned to the Contractor for inclusion of any comments received from the regulator.

5.5. The QP(s) shall identify the Contractor’s control activities required to meet the Contract requirements. The activities shall be listed in a logical sequence to show all operations 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. The wording and output of the activity shall be clear, concise and unambiguous.

5.6. The Contractor shall not commence work identified in a QP prior to confirmation in writing of acceptance of the QP by INS. Additionally, where a QP calls for documents or procedures that need to be accepted by INS as specified in the Schedule of manufacturing Documents in the Manufacturing Specification, then no work shall commence without such written acceptance being given by INS.

5.7. INS Hold, Witness and Notification Points shall be identified in the QP(s).

5.8. The Contractor shall provide advanced notification in writing to INS that a hold or witness point is due. Under no circumstances shall production go beyond this point without written permission from INS.

5.9. The Contractor shall maintain a record of the written notifications it has provided for Notification, Witness and Hold Points.

5.10. The distribution for review and acceptance of QPs, together with the Contractor’s proposals for the number and scope of QPs to be prepared, shall be agreed at the Opening Up meeting for the Contract.

5.11. The Contractor shall ensure that QPs are in place for the entire scope of work in the Contract. Where work covers a number of phases, for example, design and manufacturing, separate QPs shall be prepared and submitted for each phase.

5.12. The Contractor shall document in QPs the controls to be applied to its subcontractors. Any change to a QP shall be resubmitted to INS for acceptance.

5.13. Special processes to be used by the Contractor or any subcontractor shall be identified in the relevant QP, and these will require specific and additional

acceptance by INS (see Section 10, Production and Services Provision). Typical special processes include but are not limited to welding, metal forming of critical components, heat treatment, non-destructive testing and material finishes.

5.14. The QPs shall identify the minimum records to be included in the LTQRs. These records shall be reviewed, approved and accepted in accordance with the Contract requirements.

5.15. If work commences prior to INS acceptance of the QP, INS acceptance of relevant documents referred to in the QP, or if work progresses past a Hold Point without the required signoff, INS or the Contractor shall raise a non-conformance requiring corrective and preventive action. INS also reserves the right to reject any product or service carried out in these circumstances.

5.16. When completed, the QPs should be able to act as a route map from the original scope of work to the underpinning LTQRs.

6. Quality Assurance and Quality Control

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INS oversight

6.1. INS reserves the right to undertake oversight of the Contractor's QMS arrangements and all work being delivered within the Contract scope (including subcontracted work). Oversight may be through qualification, inspection, verification, surveillance, formal audit or third party inspections/surveillances. The Contractor shall ensure that its Subcontractors are informed of, and agree to, this requirement.

6.2. INS shall not be refused reasonable access to the Contractor's or Subcontractor's premises to witness any stage of the Services and to examine relevant records.

Contractor oversight

6.3. The Contractor shall document, establish and maintain Subcontractor assurance and oversight arrangements to ensure compliance with INS specifications, standards and Contract quality requirements.

6.4. The Contractor shall develop, implement and maintain a risk-based quality assurance programme which aligns to the graded approach to procurement. This audit (oversight) programme shall address the scope of work to be undertaken by the Contractor and its Subcontractors during each financial year.

6.5. Upon request, the Contractor shall report progress against its audit (oversight) programme to INS. The Contractor shall also provide copies of specific audit reports (internal or external) to INS upon request.

6.6. The Contractor shall report to INS within two working days any deficiencies identified from its audit (oversight) programme that may or will affect compliance with the requirements of the Contract. The Contractor shall provide to INS corrective actions to address the specific deficiency and preventive actions to avoid a recurrence.

Management Review

6.7. Upon request, the Contractor shall provide INS with copies of its Management Review records relevant to the Contract scope.

6.8. The Contractor shall notify INS of any Management Review actions which may affect compliance with the requirements of the Contract. The Management Review records shall identify responsible persons and due dates for completion of agreed actions.

Product realisation

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

Inspection and Test, Inspection and Test Status

6.10. The Contractor shall have suitable methods to ensure that the product(s) and/or service(s) can be inspected to sufficient accuracy to ensure that the tolerances can be met in a repeatable manner. These methods shall be specified in the relevant QP.

6.11. All personnel verifying, inspecting or testing product(s) and/or service(s) as part of the Contract scope shall be included in the Quality function and shall be independent from those performing the work. The Contractor shall demonstrate this independence if requested by INS.

6.12. The Contractor or Subcontractor shall ensure that there is suitable inspection equipment available for INS or its appointed third party to verify the Contractor's results.

6.13. Measures shall be established to assure, by the use of markings such as stamps, tags, labels, routing cards or other suitable means, the status of inspections, tests and fabrication performed upon individual items. These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests.

6.14. The Contractor shall provide to INS for acceptance copies of any templates used by the Contractor or Subcontractor for recording the inspection and test results specified in Quality Plans.

Identification and traceability

6.15. The Contractor and Subcontractors shall have a documented process to:

i. identify raw materials used by the Contractor and Subcontractors by suitable means;

ii. ensure the full traceability of raw materials and provide evidence that these raw materials meet the appropriate specification;

iii. identify all products (including parts) by suitable means throughout storage, manufacture, inspection, test and delivery activities at Contractor and Subcontractor facilities (for example, by heat number, part number, serial number, batch number);

iv. maintain the traceability of all products (including parts) throughout storage, manufacture, inspection, test and delivery activities at Contractor and Subcontractor facilities (including product quantities, split orders, non-conforming product);

v. maintain the inspection and test status of all products (including parts) throughout storage, manufacture, inspection, test and delivery activities at Contractor and Subcontractor facilities;

vi. control the unique and serialised identification of the product when specified in INS product definition and/or purchase order/Contract.

6.16. The Contractor shall ensure that during the manufacture of metallic components, the traceability of such components during the manufacturing process shall meet the relevant requirements of BS EN 10204:2004.

Change management

6.17. Where any changes to the product or process occur after the product or process has been submitted to INS, acceptance of these changes shall be obtained from INS prior to continuation. Examples of such changes include, but are not limited to:

i. change of design;
ii. change of manufacturing location;
iii. change of material;
iv. change of process parameters in relation to a special process;
v. change of Subcontractor supply;
vi. change in the organisation in the Contractor or Subcontractor;
vii. change in QMS acceptance.

7. Deviation and Non-conforming Products or Processes

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7.1. The Contractor shall establish, implement and maintain a documented process to identify, record, clarify and resolve each of the following:

i. technical questions with respect to INS requirements prior to and for the duration of the Contract (Technical Query (TQ));

ii. proposals prior to manufacture for a permanent change to an INS specification requirement associated with a production process or product feature for the duration of the Contract (Production Permit (PP));

iii. non-conformances to applicable drawings, specifications, procedures, standards, Codes, regulations, criteria or any Contract requirement which the Contractor proposes to use. This non-conformance process, using a Contractor Non-Conformance Report (NCR), shall include the option for the Contractor to request INS acceptance to use non-conforming product manufactured by the Contractor or Subcontractor via a concession as part of the NCR.

7.2. The Contractor shall use the INS Manufacturing Deviation Form (Reference 13.5) to apply to INS for TQs, PPs and concessions.

7.3. When a NCR is raised, there shall be a documented investigation into the root cause of the non-conformance, together with any corrective and preventive actions, and shall be submitted to INS for acceptance. Should the root cause investigation be deemed by INS not to be sufficiently robust, then INS reserves the right to undertake a root cause investigation at the Contractor's or Subcontractor's facilities.

7.4. Any materials, products or parts thereof manufactured with unapproved documentation shall be subject to a Contractor NCR. If the Contractor proposes to use such materials, products or parts, the Contractor shall use the INS Manufacturing Deviation Form (Reference 13.5) to apply to INS for a concession.

7.5. INS's acceptance of the proposed disposition of each concession shall be obtained by the Contractor prior to the item being used in the next manufacturing stage or prior to shipping.

7.6. A concession will be considered unacceptable until accepted in writing by INS.

7.7. No part of the work shall be repaired, or spoiled work corrected, by the Contractor or Subcontractors without the prior written acceptance of INS.

7.8. Upon identification of a non-conforming product or service, the Contractor shall ensure that the non-conforming product is clearly identified as such, segregated, controlled, recorded and then reported to INS.

7.9. All items with non-conformances or concessions shall clearly have the non-conformance or concession recorded on the relevant manufacturing certification and Quality Release documentation.

7.10. The Contractor shall establish a process to review the cumulative effect of non-conformances, TQs, PPs and concessions raised. The output of these reviews must be submitted to the INS Design Authority.

7.11. In the event that INS identifies any deficiency, finding or non-conformance at the Contractor or Subcontractor, INS will issue its own NCR to the Contractor or Subcontractor as appropriate.

8. Control of Measurement and Test Equipment

8.1. The Contractor and its Subcontractors shall document, establish and maintain a register of measurement and test equipment and its calibration status in accordance with the requirements of BS EN ISO/IEC 17025.

8.2. The Contractor and its Subcontractors shall maintain all measurement and test equipment calibrated and traceable to national or international standards for the duration of the Contract.

8.3. The Contractor shall notify INS of any product at the Contractor's or Subcontractor's facilities that may be or is affected by the failure of measurement and test equipment or by the measurement and test equipment failing recalibration. The Contractor shall evaluate the impact on the products affected, and shall be treated as non-conforming product until demonstrated otherwise (see Section 7, Deviation and Non-conforming Products or Processes).

8.4. The Contractor shall ensure that all calibration certificates for measurement and test equipment subject to calibration are available for inspection by INS at all reasonable times.

9. Design

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Control of design

9.1. The Contractor shall ensure that all design activities and interfaces are clearly defined and controlled.

9.2. The Contractor shall ensure that roles and responsibilities of appropriate design disciplines (for example, mechanical, electrical, process, safety) are clearly understood and communicated to INS to ensure its involvement at the appropriate stages.

9.3. The Contractor shall ensure that all design documents and design changes issued to INS are controlled by the documented management system processes. Design changes shall be conducted at the same level as the original design review and verified accordingly.

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

Design review requirements

9.5. When the design responsibility lies with the Contractor as defined in the Contract, the Contractor shall identify and implement its proposed design reviews in a QP that shall be accepted by INS prior to the commencement of work.

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

9.7. The Contractor shall submit all documents to be considered at design review to INS in a fully approved state at least 10 working days prior to the design review.

9.8. INS reserves the right to participate in Contractor design reviews, and in this respect the Contractor shall advise INS of the date of a design review as soon as this is known.

9.9. INS reserves the right to identify any design activity which requires confirmation or third party verification.

9.10. The Contractor shall document the results of all design reviews and submit the results to INS. Actions resulting from design reviews shall be completed before final INS acceptance of the design.

9.11. 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.

Design output, review, checking and approval

9.12. 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.

9.13. Design output, whether in electronic or paper form, shall be considered as LTQRs and delivered in accordance with Section 11 (Records (including LTQRs)).

Design and data configuration control

9.14. The Contractor shall ensure that a configuration management process is documented, established, maintained and submitted to INS for acceptance.

10. Production and Service Provision

Management of counterfeit, suspect or fraudulent items 1 2 3

10.1. The Contractor shall ensure that processes are in place to mitigate the risk of counterfeit, suspect or fraudulent items (CSFI) being deployed to INS. The processes shall include identification of CSFI, assurance of product source, selection of suppliers and verification that procured products meet the specified requirements.

10.2. In the event of CSFI being found, the Contractor shall immediately notify INS (in case a similar item is in use), and initiate the NCR process as described in Section 7 (Deviation and Non-conforming Products or Processes).

10.3. The Contractor shall ensure that processes are in place to control and document the disposition of products identified as CSFI. INS shall be provided with records of the disposition of CSFI as agreed at the opening up meeting.

Mill certification 1 2 3

10.4. The Contractor shall supply to INS original material mill certificates listing the mechanical and chemical properties as required by the Contract specification. Where this is not possible, copies shall be taken and endorsed by authorised Quality personnel in red ink as “verified true certified copies of the original”.

10.5. Where a product has been manufactured from a previously certified material, the Contractor 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.

10.6. The Contractor 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.

10.7. Stockist certificates are not acceptable when original material mill certificates or certified copies are specified within the Contract specification.

Certificate of Conformance 1 2 3

10.8. Where required, the Contractor shall supply a document certified by a competent authority that the supplied products and/or services meet the required specifications. This is also referred to as a Certificate of Compliance or a Certificate of Conformity. Details that need to be identified on the Certificate of Conformance shall include as a minimum:

i. Contract/Purchase Order number (unique identifier);

ii. compliance to referenced Specification (BS EN 10204 certificate);

iii. drawing number (if appropriate);

iv. item identification and number of items covered under the Certificate of Conformance.

Verification and inspection of products and services by INS 1 2

10.9. The Contractor shall establish a process for goods inward inspection. The process shall ensure the following:

i. plant and materials are received with a copy of the relevant certificate(s). Certification shall be traceable to relevant purchase orders or contracts;

ii. plant and materials shall be accompanied by a manufacturer's delivery note and should be checked for quantities and any damage or defects;

iii. plant, materials and associated certification are to be booked into an approved storage or lay down area that meets the storage conditions of the Contract and allocated with an unique identification number;

iv. plant and materials that are found to be damaged, or considered to be outside of specified requirements, shall be quarantined immediately.

Release of products from the Contractor to INS 1 2†

10.10. The Contractor shall not dispatch product(s) identified as requiring an INS quality release until authorisation for Delivery has been obtained from INS by the issue of a signed INS Quality Release Form (QRF).

10.11. This quality release shall be a mandatory Hold Point for INS on the relevant Quality Plan.

10.12. The Lifetime Quality Records (LTQRs) for the associated product shall be completed, reviewed and accepted by both the Contractor and INS, and shall accompany the relevant product, prior to INS signing the QRF.

Release of materials, products or parts thereof from store 1 2 3

10.13. A QP and associated inspection checklists shall be used to control the release of materials, products or parts thereof from the Contractor's or Subcontractor's store.

Preservation of product (handling, segregation, storage, transport) 1 2 3

10.14. The Contractor shall ensure the security of product and its constituent parts during internal processing, storage and delivery to INS.

10.15. The Contractor shall document, establish and maintain processes for ensuring that damage does not occur to the product. Material shall be subject to Foreign Material Exclusion (FME) inspections as necessary when completed and dispatched (that is, free from contamination or debris).

10.16. The Contractor shall establish a specified storage area for products and parts thereof. This storage area shall satisfy the relevant Contract specification requirements and must be maintained to the required standards. The specified storage area shall contain a secure quarantine area clearly marked and segregated as such.

10.17. Any reject materials, components or finished products shall be marked and segregated accordingly.

10.18. The Contractor shall ensure that all materials where applicable are segregated to prevent cross contamination.

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

10.20. The Contractor shall document how it will manage items that have a shelf life.

10.21. If the Contractor has specific handling, storage or transportation instructions, then these shall be provided to INS.

10.22. The Contractor shall establish and maintain a plant and materials schedule containing the following as a minimum for each item of plant and material:

i. Quality grading;
ii. relevant specifications from the Contract;
iii. supplier and location;
iv. resource requirements;
v. QP requirements;
vi. factory acceptance test requirements;
vii. functional test requirements;
viii. certification requirements;
ix. release requirements;
x. anticipated delivery dates.

10.23. The Contractor shall have a Foreign Material Exclusion (FME) process. The process shall include but not limited to the following:

i. identification as to whether FME principles apply to the Contract scope of work and, if so, when (for example, final vessel closures, works testing, dismantling, packing and dispatch);
ii. identification, segregation and management of FME areas;
iii. identification and use of materials, equipment, processes and systems demonstrating their status (for example, 5S, shadow boards, lanyards, work management, materials control including items to be removed or added such as bolts, washers, items in or items out, management of waste arising such as swarf);
iv. training and awareness information, including good housekeeping for personnel involved in such activities.

1 2

10.24. The Contractor and Subcontractor shall have a documented process for determining approved or prohibited materials for contact with product (or parts thereof). This process shall include a documented and controlled list of materials that are either approved or prohibited for contact with product (and parts thereof).

Special processes

1 2 3

10.25. Where the Contractor or Subcontractor uses a special process (see Section 5, Quality Plans), the Contractor or Subcontractor shall submit the controlling documentation for the process qualification test plan, testing and results to INS for acceptance prior to the starting of any work and in accordance with the Schedule of manufacturing Documents identified in the Manufacturing Specification. No process qualification work shall commence until such time that INS has accepted these processes.

10.26. Upon request from INS, the Contractor or Subcontractor shall make available to INS for inspection the qualification certificates for personnel carrying out special processes.

10.27. The Contractor shall provide weld repair or rework procedures for the Contractor and Subcontractor to INS for acceptance.

† Note: these clauses may be applicable to Quality Grade 3 if specified by the Contract.

11. Records (including LTQRs)

11.1. The requirements for records (LTQRs and Contractor internal) are specified in Reference 13.4.

12. Definitions

The INS Contract Quality Requirements have been written using the standard management system vocabulary as defined in BS EN ISO9000:2005 – "Quality Management Systems – Fundamentals and Vocabulary" with additional terms defined where required.

Audit
Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

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 to confirm that arrangements comply with required legislation, standards and customer requirements.

Certification
Carried out to ensure that customers 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
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
Binding agreement between INS and a Contractor.

Contract review
Process used by an organisation to review that contract supplied documentation (works information pack) is adequate to enable successful delivery of a specific scope of work.

Contractor
Supplier or individual who provides products or services in accordance with the INS contract requirements. Contractor is an all-inclusive term used in place of supplier, contractor, subcontractor or consultant.

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.

Customer
A customer is the organisation receiving the product or service. In using this document, a customer may be INS or the next tier up in the supply chain from the contractor in question.

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.

Hold Point
A stage in the overall manufacturing process beyond which work shall not proceed without the documented acceptance of INS. Failure by the Contractor or Subcontractor to obtain such INS acceptance may result in rejection by INS at INS's sole discretion of any product subjected to manufacturing processes beyond the Hold Point.

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

Inspection and 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.

Lifetime Quality Records (LTQRs)
Record(s) that provide documentary evidence of the research and 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 quality management system.

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 and 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.

Notification Point
A stage in the overall manufacturing process for which INS requires suitable advanced notice in writing.

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.

Organisational change
A structured and cascading approach to transitioning individuals, teams, suppliers and subcontractors from a current state to a future state when change becomes necessary.

Preventive action
Action to eliminate the cause of a potential nonconformity or other undesirable potential situation.

Production Permit (PP)
A written authorisation from INS 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
A document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

Suspect
Indicated by inspection, testing or documentation that the product may not conform to specified requirements.

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. The response should provide clarification, but must not in its own right change design intent.

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.

Witness Point
A stage in the overall manufacturing process where INS has identified a requirement for INS to witness an operation or inspection and requires suitable advanced notice in writing.

Work information pack
Contract documentation supplied by INS or a contractor to their supply chain, relevant to the specific requirements of a project/contract that enables successful delivery.

13. References

13.1. PROM 088 – S04: INS QA Programme requirements

13.2. PROM 088 – S05: INS Process Outline requirements

13.3. PROM 088 – S06: INS Quality Plan requirements

13.4. PROM 088 – S07: INS Records requirements (including LTQRs)

13.5. PROM 088 – F06: Manufacturing Deviation Form

Appendix 1

Generic Hierarchy of INS Technical, Quality and Manufacturing-Related Supporting Documents