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INS QA Programme Requirements			

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1	**20/3/17**	**First Issue**

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Introduction

Contractors will have a generic (not contact specific) high level document describing their management system, as this is a requirement of ISO 9001. This is often described as an Integrated Management System Manual or simply a Management Manual. However, for goods and services that have an impact on nuclear safety, International Nuclear Services Ltd (INS) has a Contract requirement for the Contractor to provide specific details on the arrangements in place to ensure that the quality requirements of the Contract will be met. These details specific to the Contract shall be provided by the Contractor in the form of a Quality Assurance (QA) Programme.

This document is intended to specify in detail the requirements of the QA Programme that shall be issued to INS for acceptance. Where relevant, INS will request a draft QA Programme with the Tender and the formal QA Programme in accordance with the Schedule of Documents in Schedule 1 of the Contract.

The INS Contract Quality Requirements Manual (PROM 088 – S03, Reference 1) refers to Quality Grading of products and services. 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. Note that the requirement for a QA Programme applies to Quality Grades 1 and 2 only.

1. Guidance for the QA Programme

1.1. The required structure of the Quality Assurance (QA) Programme is specified in Appendix 1.

1.2. A draft QA Programme will be requested in the Request for Quotation (RFQ). The intention is that the QA Programme provided with the Tender includes a brief summary only of the topics in Appendix 1 that are relevant to the specific contract scope, and so how the Contractor intends managing the specific contract scope. However, it is for the Contractor to specify which of the topics are relevant to the Contract scope and hence which topics in Appendix 1 need to be completed.

1.3. The QA Programme provided post Contract award is intended to provide more detail on the topics in Appendix 1 that are relevant to the specific contract scope. Where appropriate, the more detailed information can be included in the QA Programme by reference to other Contractor documents, rather than by duplication of this information in the QA Programme. For the avoidance of doubt, the Contractor does not need to provide these references in the Tender. The Contract QA Programme should not therefore take significant resources to prepare, and indeed the offer price is expected to include this cost.

1.4. The QA Programme shall be provided to INS for acceptance in accordance with the Schedule of Documents in Schedule 1 of the Contract and Reference 1.

1.5. As an example, the Tender QA Programme may state that the Contractor has a suite of documents for Procurement Document Control, and indeed it may refer to the high level document describing their management system referred to in the Introduction if the latter includes this topic. The Contract QA Programme may then refer to the specific Contractor procedures/instructions/Quality Plans (as relevant) for this topic, with a brief description of what each referenced document addresses so that INS can have a high level understanding of how this topic is being managed.

2. References

1: PROM 088 – S03, INS Contract Quality Requirements Manual.

Appendix 1

Required structure of the QA Programme

The QA Programme shall provide control over activities affecting the quality of the identified structures, systems and components to an extent consistent with their importance to nuclear safety, and shall be structured as follows:

1. Introduction

2. Quality Policy
   Contractor's quality policy

3. Management Systems
   General description of the structure of the Quality/Management system and appropriate quality standards

4. General scope
   General description of the Contractor's work under the Contract

5. Contractor's organisation
   Contractor's organisation chart for delivery of Contract, including all key roles in the organisation, their job titles and reporting lines. Must include who is responsible for Quality and their level of authority for issues such as stopping work, holding shipment of product, etc. Key roles shall be held by full time Contractor employees only

6. Responsibility/authority/duty of each role in the organisation structure
   Detailed description of the responsibilities/authority/duties of each role in the Contractor's organisation chart

7. Contract review
   Arrangements in place to carry out and record a review of the technical and quality requirements of the Contract and confirm the Contractor's ability to comply with all INS's requirements

8. Quality system general description
   General description and references to key controlling documents

9. Design control, including management of external interfaces
   Measures in place to assure that the appropriate quality requirements are met or deviations from these requirements are controlled. Measures in place for the identification and control of design interfaces, including procedures for the review, approval, release, distribution and revision of documents involving design interfaces

10. Procurement document control
    Measures in place to assure that applicable standards and other requirements in the Contract which are necessary to assure adequate quality are suitably included or referenced in procurement documents for materials, equipment and services, whether purchased by the Contractor or Subcontractor

11. Instructions, procedures and drawings
Measures in place to assure that activities affecting quality are prescribed by documented instructions, procedures or drawings (appropriate to the circumstances) and shall be accomplished in accordance with these instructions, procedures or drawings. These shall include appropriate acceptance criteria for determining that key activities have been accomplished satisfactorily

12. Document control
Measures in place to control the issue of documents (both internal and external to the Contractor) in a timely manner such as instructions, procedures and drawings which prescribe all activities affecting quality. These measures shall assure that documents, including changes, are reviewed for adequacy and approved for release by authorised personnel and are distributed to, and used, at the locations where the prescribed activities are performed. Changes to documents shall be reviewed and approved by the same organisations that performed the original review and approval, unless otherwise specified formally

13. Control of purchased materials, equipment and services
Measures in place to assure that purchased materials, equipment or services, whether purchased directly or through Subcontractors, conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality provided by the Subcontractor, inspection at the Subcontractor and examination of products upon delivery. The effectiveness of the control of quality by Subcontractors shall be assessed by the Contractor at intervals consistent with the importance, complexity and quantity of the products and services

14. Identification and control of materials, parts and components
Measures in place to assure the identification and control of materials, parts and components, included partly fabricated packages. These measures to ensure the identification of the item is maintained by heat number, part number, serial number, batch number, Works Order number or other appropriate means, either on the item or on records traceable to the item, as required through fabrication. The identification and control measures shall be designed to prevent use of incorrect or defective material, parts or components

15. Control of special processes
Measures in place to assure that special processes including welding, heat treating and non-destructive testing are controlled and accomplished by qualified personnel using qualified procedures in accordance with the required standards

16. Manufacturing
Measures in place to assure that manufacturing activities are executed in a controlled manner in accordance with documented instructions, procedures, specifications and drawings. Manufacture to be performed by suitably qualified and experienced personnel. Measures in place to ensure that jigs or other equipment used are set up in a controlled manner and managed accordingly

17. Inspection
Measures in place to assure that inspections of activities affecting quality are executed to verify conformance with documented instructions, procedures, specifications and drawings. Inspections to be performed by persons other than those who performed the activity being inspected. Examinations, measurements or tests of material or products processed for each work operation where necessary to assure

quality. Both inspection and process monitoring to be provided when control is inadequate without both. Hold Points requiring witnessing or inspecting by INS to be specified in appropriate documents, and work beyond the Hold Point shall not proceed without written consent. Final verification of each finished product and associated fully completed records prior to preparation of quality release documentation

18. Test control
Measures in place to ensure that testing required to demonstrate conformance to requirements is executed in accordance with written test procedures, which shall incorporate the requirements and acceptance limits. Procedures shall also include provisions for assuring that all prerequisites are met, adequate test instrumentation is available and used and tests are performed under suitable environmental conditions. Test results to be documented and issued in a timely manner

19. Control of measuring and test equipment
Measures in place to ensure that tools, gauges, instruments and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted at specific periods to maintain accuracy within necessary limits

20. Handling, storage and shipping
Measures in place to control the handling, storage, shipping, cleaning and preservation of material and equipment to prevent damage or deterioration. This includes measures in place to manage component cleanliness during storage and manufacture

21. Inspection, test and operating status
Measures in place such as stamps, tags, labels, routing cards or other suitable means to assure the status of inspections, tests and fabrication performed upon individual items. Measures to include identification of items which have satisfactorily passed required inspections and tests to preclude inadvertent bypassing of such inspections and tests.

22. Nonconforming materials, parts, components, assemblies and services
Measures in place to control materials, parts, components, assemblies and services which do not conform to requirements in order to prevent their inadvertent use. Measures to include procedures for identification, documentation, segregation, disposition and notification to Purchaser in a timely manner. Nonconforming items to be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures

23. Corrective and preventive action
Measures in place to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances, are promptly identified and corrected. For significant conditions adverse to quality, measures to assure that the root cause is determined and preventive action taken to preclude repetition. Measures to include control actions to monitor the effectiveness of preventive actions. Identification, cause, corrective, preventive and control actions shall be documented and reported to appropriate levels of management

24. Quality Assurance records
Measures in place to assure that sufficient records are maintained to provide evidence of activities affecting quality and to provide necessary Lifetime Quality Records (LTQRs). Records to include as appropriate operating logs, results of

reviews, inspections, tests, audits, monitoring of work performance and materials analyses. Records also to include qualifications of personnel, procedures and equipment. Inspection and test records to identify the inspector or data recorder, type of observation, results, acceptability, and action taken in connection with noted deficiencies. Records to be identifiable and retrievable. Measures in place for records retention, such as duration, location and assigned responsibility

25. *Audits*
Measures to assure that a comprehensive system of planned and periodic audits (internal and external) is carried out to verify compliance with all aspects of the Quality Assurance Programme and determine the effectiveness of the Programme. Audits shall be performed in accordance with written procedures or checklists by suitable trained personnel not having direct responsibilities in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited and remedial actions including reaudits shall be taken where indicated

26. *Project management*
Measures to assure that a comprehensive system of project management processes and tools are used to manage the execution of the Contract and its detailed requirements, including all deliverables specified in the Contract. Measures to include suitable operational planning, change control and cost control processes

If specific sections are not relevant to the Contract scope of work, the QA Programme shall specify ‘Not applicable’ for that section(s).