

General Technical Requirements
for
Quality Assurance
GTR-01

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Table of Contents

1	Introduction	3
1.1	Detailed Work Scope.....	3
2	References.....	3
2.1	Codes and standards	3
3	Quality Management System requirements	3
3.1	Quality Manual	3
3.2	Quality procedures	4
3.3	Quality plans.....	6
3.4	Method statements.....	7
3.5	Working procedures	7
3.6	Resources and tools.....	7
4	Quality control requirements.....	8
4.1	Design review	8
4.2	Design review package	8
4.3	Inspection and testing	8
5	Employer review and acceptance	11
5.1	Post-contract award QMS review and acceptance	11
5.2	General document requirements prior to Employer's review and acceptance	12
6	Employer audits	12
6.1	Audits and inspections	12

1 Introduction

This document specifies the general Quality Management System (QMS) requirements for the Contractors on the project.

The document defines the overall requirements for quality management on the project covering from the tender phases till expiration of the guarantee periode.

1.1 Detailed Work Scope

The Contractor shall develop, operate and maintain a QMS compliant with DS/EN ISO 9001 that shall apply through all project phases and applies to all supplied products, including services, design, construction, installed works, testing, trials and handover materials.

The Contractor shall:

- Comply with requirements for Contractors to prepare, operate and maintain a QMS
- Comply with requirements in relation to quality control
- Comply with requirements in relation to the Employer's review and acceptance.

2 References

2.1 Codes and standards

The following standards are relevant in relation to the requirements stated in this document:

- DS/EN ISO 9000 Quality management systems – Fundamentals and vocabulary
- DS/EN ISO 9001 Quality management systems – Requirements
- DS/EN ISO 10005 Quality management systems - Guidelines for quality plans
- DS/ISO/IEC 90003 Software engineering – Guidelines for application of ISO 9001 to computer software

3 Quality Management System requirements

The Contractor shall implement a single QMS based on the DS/EN ISO 9001 requirements and any additional specific project requirements defined in this document.

To demonstrate compliance, the Contractor's QMS shall include a detailed cross reference schedule showing correlation between the Contractor's QMS and the above requirements.

The Contractor shall plan and establish the quality management organisation and describe the responsibilities and authorities for staff performing quality assurance, quality control and document control.

Staff within the quality management organisation shall have the required competences and be properly instructed on how to perform and report results. These competences shall be documented by the Employer.

3.1 Quality Manual

The Contractor shall implement a Quality Manual (QM).

The Contractor may be a single company or a consortium (JV). A single company Contractor may use an already established QM. A JV shall establish a project specific QM.

The Contractor shall describe the policies, which are ruling for the Contractor's quality objectives and QMS.

A single company Contractor may use existing corporate directives, policies, and objectives whereas a JV shall develop policies and objectives specifically for the HOFOR project.

3.2 Quality procedures

The Contractor shall implement and maintain a set of general management procedures to control the overall QMS processes in relation to the contract and to ensure that project quality objectives are achieved.

A single company Contractor may use already established company procedures. A JV shall establish a project specific set of general management procedures, which may be based on procedures from one or more JV partners' QMS.

3.2.1 Mandatory procedures

Listed below are the mandatory ISO procedures, which shall comply with the DS/EN ISO 9001 standard:

- Control of documents (ISO 9001; 4.2.3)
- Control of records (ISO 9001; 4.2.4)
- Internal audits (ISO 9001; 8.2.2)
- Control of nonconforming product (ISO 9001; 8.3)
- Corrective action (ISO 9001; 8.5.2)
- Preventive action (ISO 9001; 8.5.3)

3.2.2 Additional procedures and requirements

Listed below are the supplementary requirements which shall be followed by the Contractor in addition to the mandatory procedures and general requirements in ISO 9001.

3.2.2.1 Document and data management

The Contractor shall prepare and maintain procedures for preparation and control of the documents listed below. The procedures shall include responsibility and authority for planning, preparation, check, approval, implementation, and follow-up activities:

- Method statements
- Working procedures (instructions)
- Inspection and test plans
- Document Control Plan (DCP)

The DCP shall show all planned documents and drawings to be produced on the project.

3.2.2.2 Configuration management

The Contractor shall develop and maintain procedures for the preparation and control of the following:

- A system and register for codes, standards, and regulations of relevance to the Contractor's Scope of Work shall be established and maintained.
- A system for complete control of the project basis shall be developed and maintained, ensuring that the project basis is up-to-date and known to all users.

- A system for traceability control to define which versions of documents are applicable at specific times during the project.
- Information regarding superseded and replaced documents shall be retained.

3.2.2.3 Change management

The Contractor shall develop and maintain a system for managing the contract requirements and ensuring that any changes to existing agreements or specifications are agreed, documented and informed to all affected parties.

For clarification of contract requirements from the Employer, queries or information requests shall be used.

For proposed changes to the Employer's contract requirements a change request form shall be used.

Information regarding any superseded and replaced contract basis shall be retained.

3.2.2.4 Risk management

The Contractor shall describe how risk will be managed on the project defining all phases from identification to mitigation and barriers.

3.2.2.5 Interface management

The Contractor shall establish and maintain a procedure for interface management and describe how internal and external interfaces to other Contractors, subcontractors and suppliers, Authorities and third parties shall be managed.

3.2.2.6 QMS requirements for subcontractors and suppliers

The Contractor shall develop and maintain a procedure for grading, selecting and appointing subcontractors and suppliers, including independent test laboratories.

The procedure shall define:

- General quality selection criteria
- Which QMS requirements the subcontractor or supplier shall fulfil in relation to service and risk on the HOFOR project
- How the grading will be performed, and how compliance is verified

The Contractor shall prepare and maintain a schedule showing each subcontractor's and supplier's grading, qualifications, certifications and associated documentation, performed audits or inspections.

3.2.2.7 Traceability and preservation of parts and products

The Contractor shall introduce a system, which enables tracing of a part or product from when it is received (or manufactured) by the Contractor until it is installed. The system shall be described in a procedure and shall take into account product withdrawal and delivery errors.

The Contractor shall document and maintain a system to ensure that parts and products are protected correctly from the time of receipt (or manufacture), during transportation and storage, until final installation and hand-over.

3.2.2.8 Contractor's audit plan

The Contractor shall establish and maintain an audit plan for internal and external audits.

The external audits shall include all major subcontractors and major suppliers. The audit plan shall be kept updated and forwarded to the Employer on a regular basis to be agreed with the Employer.

3.3 Quality plans

This section deals with the set-up of quality plans.

3.3.1 Project Quality Plan

The Contractor shall within the framework of the contract and QMS prepare, follow, monitor, and maintain an overall Project Quality Plan (PQP), which is specific to the project.

The overall PQP shall apply to all parties managed by the Contractor.

The overall PQP shall be used by the Contractor to control all tasks including temporary construction and equipment, which influence the quality of the final work or may have fundamental impact on the progress of the work.

The overall PQP shall describe the project organisation including the quality management organisation, responsibilities and authorities.

In the overall PQP the Contractor shall state all identified tasks relevant to the contract under his responsibility and which task specific quality plans shall be applied by whom and when.

3.3.2 Task specific quality plans

Based on the overall PQP the Contractor can produce task specific quality plans defining the tasks and their interfaces.

Where possible, the task specific quality plans may refer to the quality procedures (for example subcontractor and supplier grading, document control, review, verification & validation, use of measuring equipment).

The Contractor shall, based on the task specific quality plans, plan and produce method statements and working procedures (instructions) needed to perform the actual work, and the inspection and test plans which document quality control.

3.3.3 Subcontractors' and suppliers' quality plans

The Contractor shall pass all relevant QMS requirements on to the selected subcontractors and suppliers and verify compliance in accordance with the chosen grading described in the Contractor's procedure for grading of QMS requirements towards subcontractors and suppliers.

The Contractor shall ensure that the subcontractors' and suppliers' own QMS and the overall PQP are suitable for the planned work and followed.

Task specific quality plans, DCPs, method statements, working procedures etc. prepared by the subcontractor or supplier shall follow the quality procedures and carry the approval of the Contractor.

3.4 Method statements

The Contractor shall prepare method statements for work, which requires an overall description of one or more technical solutions.

Method statements shall follow a systematic approach and format to ensure that technical specifications and requirements are obtained, traceable and verifiable.

Preparation and content requirements shall be described in a procedure for preparation of method statements. Method statements shall include requirements for inspection and testing, acceptance criteria and records.

Method statements shall address project risks and shall be consistent with the Contractor's risk and hazard register.

3.5 Working procedures

Working procedures (instructions) shall be prepared for all work, where the lack of instruction may result in poor or uneven performance. Working procedures shall ensure that work is carried out correctly and that all participating parties understand their responsibilities and role.

The preparation and content requirements shall be described in a procedure for preparation of working procedures. Working procedures shall identify required materials, include list of tools, define responsibility, instruct on how to perform work, instruct on how to perform required inspection and test, list acceptance criteria, and list required verification documentation, reporting and filing.

Working procedures shall be directed towards the staff performing the work in respect of language, wording, requirements for instruction, and location accessibility.

3.6 Resources and tools

The Contractor shall document the management of resources and tools (IT programmes, survey and measuring equipment, templates). General resource and tool management shall, as a minimum, include:

- IT-registration and use
- Calibration and use of survey and measuring equipment
- Programme for QHSE training of staff
- Registration of training and competences

Within the scope of the task specific quality plans the Contractor shall ensure that the resources and tools (including qualified staff, facilities, equipment, and templates for internal document check and review) under each task are available within the project organisation.

All tools used during the performance of the work, including tools for development, design and planning, testing and maintenance, as well as software tools, shall be identified and documented.

The Contractor shall supply and utilise all necessary measurement- and test equipment for the verification and validation of specified requirements.

All measurement and test equipment shall be calibrated and have valid independent third party certification available, if required.

The Employer can require the use of common project templates to ensure that the content and records contained in the templates are consistent and conform to the Employer's and third-party requirements.

Templates for inspection and testing forms and checklists shall be prepared and presented to the Employer for acceptance prior to use.

4 Quality control requirements

This section describes the requirements for the design review process and inspection and testing system that shall be followed on the project.

4.1 Design review

Beside the ongoing verification and validation work performed by the Contractor a number of Design reviews packages are required. A Design review package contains a signed document confirming the validation and validation, with reference to all documents and drawings (plus issue numbers) that are associated with the design work package.

The verification requires that at each design stage, or in relation to design modification, a verification shall take place to the same level of detail (or more detailed) than earlier stages of design.

4.2 Design review package

At certain stages of design all the parties responsible for design and verification are required to provide signatures on a certificate. The certificate contains reference to all documents and drawings (plus issue numbers) that are associated with the design work package.

Certificates shall be produced for the following design stages/ submissions:

- Preliminary design submissions - "Approved for design" (AFD)
- Detailed design submissions also signed by the Safety Assessor when applicable (to enable construction of the work package to commence) - "Approved for construction" (AFC)
- The end of as-built - "Ready for commissioning" (RFC)

For each element of the works, the design submissions shall be fully verified and the Design review package shall exist prior to submission for acceptance to the Employer.

Certification at the as-built design stage shall take place after completion of construction.

4.3 Inspection and testing

4.3.1 General

Each Contractor shall define his planning, specification, scheduling and reporting of inspections and tests to be carried out during the course of the project according to the minimum requirements in the following.

When used in the contract specifications the term Site Acceptance Test (SAT) shall be understood to cover all site acceptance activities related to supplies within one contract, including integration among subsystems, within that contract.

When used within the contract specifications the term Site Integration Test (SIT) shall be understood to cover integration activities involving more than one contract.

The sequence of inspection and test activities shall be planned in such a manner to gradually build up confidence that contract requirements are being fulfilled.

All standard materials and products purchased for HOFOR shall be delivered with a certificate of production from the original supplier.

All materials, components and systems produced to meet specific HOFOR requirements shall be subject to inspection and test at the production site to verify compliance with requirements (Factory Acceptance Test, FAT).

Shipping to, and installation on HOFOR premises, and subsequent site inspections and tests shall not take place unless certificates of production and report of completed FAT are available with the Contractor and can be presented to the Employer.

Inspection and testing of a composite system or construction shall not be considered completed unless all relevant reports of the completed inspections and tests of the constituent parts (components, subsystems, locations) are available with the Contractor (and can be presented to the Employer).

For each contract the logical sequence of inspection and test activities of the supplies from production in the factory until completion at site shall be identified in the working schedule (including activity start and completion dates) according to the Work Breakdown Structure (WBS).

The completion of individual inspections and tests shall serve as intermediate check points of the verification and validation process.

4.3.2 Planning of inspection and testing

Each Contractor shall develop and maintain a master inspection and test plan that specifies the Contractor's overall strategy and approach to conducting of test on:

- Materials
- Component
- Subsystem
- System
- Factory
- Site installation
- Site integration
- Commissioning

This shall lead to fulfilment of any specific completion milestone or any intermediate check point prior to such milestone.

The Contractor shall further develop individual inspection and test plans subordinate to the master plan. The individual plans shall be structured and subdivided according to the WBS of the project and the contractual works. The plans shall be further subdivided to identify the relevant stage of inspection and test during the course of the contract.

Implementation stages shall include:

- Manufacturing – FAT (factory acceptance inspection and test)
- Construction – SAT (site acceptance inspection and test – covering supplies within one Contract)
- System integration – SIT (site integration inspection and test – covering supplies from several contracts)

The plans shall provide the information detailed as relevant for the subject in question and the stage of the project. As a minimum they shall specify:

- Scope and objective
- Organisation and administration
- Strategy and approach for the inspection and/or test
- General requirements relating to:
 - Involved works and their base-lining
 - Principles of inspection and test methods, reproducibility, data collection and analysis, conditions for re-inspection or re-test
 - Acceptance (pass/fail criteria)
 - Human and other resource requirements
 - Environment and configuration of object under test/inspection
 - Use of tools, instruments, simulators
 - Manuals, drawings and other necessary documentation
- Reference to inspection/test schedule
- Reference to inspection/test specifications
- Reference to inspection/test reports

4.3.3 Specification requirements

For each of the above plans, specifications or procedures shall provide details of how inspection and test shall be conducted in a sequential manner for a specific item. A collection of inspection/test specifications shall be referred to by the governing plan and they, together, constitute the process supporting the realisation of the plan.

The specifications shall provide the following detailed information relevant for the actual inspection/test and the subject item:

- Scope and objective
- Summary description
- Detailed specification of
 - Affected works and their base-lining
 - Inspection and test methods, reproducibility, data collection and analysis, conditions for re-inspection or retest
 - Inspection/test steps with actions, responses and associated acceptance (pass/fail criteria)
 - Human and other resources
 - Environment and configuration of object under test/inspection
 - Use of tools, instruments, simulators
 - Manuals drawings and other necessary documentation

- The proposed test report template

4.3.4 Schedule level

Schedules shall be developed to specify the Contractor's proposed date, time and place of inspection and test activities according to each individual inspection and test plan. The schedule shall form the basis for the practical arrangement of participation for witnessing of the progress of the activities and of the results by the Employer and Contractor.

The Employer shall be entitled to attend and witness all planned inspections and tests and will inform the Contractor, in each case, of his intentions to actually participate.

The schedule shall be submitted to the Employer, for review, not later than one month prior to the scheduled start of the activities.

4.3.5 Reporting requirements

Reports shall be prepared for each inspection and test according to individual inspection and test specifications.

The reports shall collect the actual results of each individual inspection and test and identify any deviations observed from the expected outcome.

4.3.6 Purchased product

The Contractor shall verify that purchased products fulfil the Contract requirements and specifications.

The Contractor shall do so by inspecting all products upon arrival at the site. The Contractor shall confirm that the delivered products are in accordance with the requirements and that items tested previously in a plant or factory are identical to these items actually received on site.

The Contractor shall plan and implement how products, which do not fulfill the requirements, are identified and quarantined from use.

Where the product is a service, which shall fulfill contract requirements, the same verification requirements apply.

5 Employer review and acceptance

5.1 Post-contract award QMS review and acceptance

The Contractor's QMS shall be subject to review and/or acceptance by the Employer.

The Contractor shall forward the QMS documentation defined below to demonstrate the preparation and implementation of a QMS on the project.

Within 20 working days after signing the contract, the Contractor shall submit a detailed time schedule for preparation of the QM, general management procedures, and the overall PQP for the Employer's acceptance.

The time schedule shall include 20 working days for the Employer's review and acceptance of the included documents.

The Contractor shall submit any existing QM and general management procedures, which will be implemented directly on the project for the Employer's review.

In accordance with the accepted time schedule the Contractor shall submit the agreed QMS documents and an outline of the overall PQP for the Employer's review and/or acceptance.

Task specific quality plans shall be submitted for acceptance at least two month before commence of the specific task.

Whether comments are received from the Employer or not the Contractor shall submit the overall PQP for acceptance taking proper account of the Employer's comments (if any) to the outline.

After acceptance of the QM, general management procedures, and the overall PQP, the quality procedures shall be prepared in accordance with the accepted time schedule and submitted for the Employer's acceptance.

5.2 General document requirements prior to Employer's review and acceptance

It is the Employer's privilege, during the contract period, to decide which documents will be reviewed and/or accepted, as the Employer's acceptance shall not in any way relieve the Contractor of the Contractor's duties or responsibility according to the contract.

All QMS documents, which are sent for the Employer's review and/or acceptance shall be checked and approved prior to submittal by the Contractor. Check and approval shall appear on the documents. If the submitted documents deviate from given requirements, the deviations shall be presented to the Employer in writing upon submittal.

All QMS documents shall be maintained during execution of the Contract. Updates and changes shall be presented to the Employer for review and/or acceptance. Changes can be rejected if these are not in accordance with the contract.

6 Employer audits

6.1 Audits and inspections

The Employer shall be entitled to inspect and audit the Contractor's, subcontractors', and suppliers' QMS and implementation.

The Contractor shall assist the Employer in every way necessary.

The Contractor shall invite and permit the Employer to examine and witness the construction, inspection and testing, stored materials and equipment on the Contractor's premises whether at construction sites, plants or factories.