IDM UID
22MFG4
VERSION CREATED ON / VERSION / STATUS
11 May 2018 / 5.1 / Approved
EXTERNAL REFERENCE / VERSION

MQP Procedure

ITER Procurement Quality Requirements

This document establishes the ITER Procurement Quality requirements to be implemented regarding the procurement of items, services and IOproject activities.These requirements apply to all activities performed for the IO by Domestic Agencies and outside organisations.

Approval Process			
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Document Security: Internal Use *RO: Fabre Nadine*			
Read Access	**LG: Quality Control Group, AD: ITER, AD: External Collaborators, AD: IO_Director-General, AD: EMAB, AD: OBS - Quality Management Division (QMD) - EXT, AD: OBS - Quality Management Division (QMD), AD: Auditors, AD: ITER Management Assessor, project administrator, RO, LG: 5th working group, LG: [CCS] ...**		

Change Log			
ITER Procurement Quality Requirements (22MFG4)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	In Work	14 Dec 2005	
v2.0	Signed	14 Dec 2005	
v2.1	Signed	14 Jun 2007	
v3.0	Signed	20 Nov 2007	
v3.1	Approved	23 Nov 2007	
v4.0	Approved	31 Mar 2009	
v5.0	Approved	17 Mar 2015	Changes according to MQP doc Request - QX8F5H: - Abstract changed - Template changed for MQP Detailed Policy - “should” changed to “shall” throughout the whole document - General Revision incorporating the definition of a Critical Quality Activity and definitions of approval, acceptance and for information. - The requirements for PAs and Cash Procurements are now separated and requirements for R & D activities clarified
v5.1	Approved	11 May 2018	As per MQP doc Request - WK7APM Includes Module H needs

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1 Purpose

This document specifies IO Procurement Quality requirements to be implemented regarding the procurement of items, services and IO project activities. These IO Procurement Quality requirements are referred to in this document as IO Procurement Quality Clauses.

2 Scope

These requirements apply to all activities performed for the IO by Domestic Agencies and outside organisations.

NOTE: Methods and solutions other than those set out in this document:

- may be acceptable provided they result in at least the same level of quality
- shall be subject to IO Quality Assurance Division written acceptance prior to implementation.

3 Definitions and acronyms

IO	ITER Organization sometimes referred to as ITER
Domestic Agency	An organization set up under the ITER Framework Agreement to provide goods or services to the ITER Organisation through Procurement Arrangements (PA) and Task Agreements (TA)
Supplier	Any entity that provides goods or services to the ITER Organisation
Subcontractor	An entity that performs work for the Supplier
Performer	An all-inclusive term used to cover Domestic Agencies, Suppliers and Subcontractors
Contract	An all-inclusive term used to cover Procurement Arrangements, Task Agreements and Contracts placed directly by the IO
Critical Quality Activity	Any activity or operation that if not performed correctly may affect safety, functionality or reliability
Approval	Formal agreement for the use or application of a product or document. The approver takes responsibility for the use
Acceptance	Acknowledgement that a product or document is in compliance with the contractual requirements
For Information	Documents sent for information require no further decision i.e. they require neither acceptance nor approval
Equipment	In this document Pressure Equipment and Nuclear pressure Equipment are so called Equipment
Manufacturer	Any natural or legal person who manufactures an equipment or has an equipment designed or manufactured and markets under his name or trademark
Pressure Equipment / Nuclear Pressure Equipment	Vessels, piping, pressure accessories and safety accessories, including where applicable element permanently attached to pressure parts in the scope of PED or French ESPN Order
PED	Pressure Equipment Directive
ESPN Order	French Regulation for Nuclear Pressure Equipment

4 References

ITER Quality Assurance Program (QAP) (22K4QX)

5 ITER Procurement Quality Clauses

5.1 Quality Management System

The performers of IO project activities shall establish and implement a quality system capable of ensuring that:

- contract requirements are met
- evidence of such compliance is maintained

The quality assurance system implemented by these various performers shall:

- be based on a recognized quality standard meeting the ITER Quality Assurance Program requirements
- encompass all activities performed in connection with the IO project activities
- be described in a document to be accepted for use by the IO or DAs as appropriate (see paragraph 7)

All performers shall establish a dedicated Quality Plan [1] for managing each IO project activity and shall ensure that each supplier/subcontractor implements an effective quality system. The performers shall undertake all necessary actions to establish and maintain quality in locations within suppliers/subcontractor's premises where IO related work is conducted.

A Responsible Point of Contact shall be appointed to:

- coordinate the planning and performance of the work, including work assigned to subcontractors
- keep time schedules and issue monthly progress reports
- verify that the quality systems are consistently followed during the performance of the contract
- assess and oversee quality in subcontractors premises
- monitor the implementation of ITER Procurement Quality Requirements
- provide IO with periodic assessment of quality performance

5.2 R&D Activities

For R&D work, unless otherwise specified, only the DA (for Task Agreements) or Main Supplier (for Direct Procurements) is required to submit a Quality Plan, however where R&D prototypes are used to qualify manufacturing processes or produce equipment that may be used in ITER, the full Procurement Quality Requirements will apply.

For R&D activities, where performers do not have an established quality system (typically Institutions/Universities), they must provide a Quality Plan to IO detailing how the activities will be managed and how the results will be validated.

5.3 Design

Where design is done by performers, acceptance of the final design must be given by IO prior to commencement of manufacture unless otherwise agreed in the contract.

When IO acts as manufacturer of equipment final design including design done by performer shall be approved by IO.

The preparation, review, and approval of design documents for the assigned tasks shall be accomplished through controlled procedures that establish the approval authorities and responsibilities.

5.4 Qualification of Special Processes

Proposals for qualification of Special Processes such as welding, heat treatment, brazing etc. must be submitted for IO review.

IO reserves the right to witness the qualification and testing of Special Processes.

Records of approval verifying process parameters, materials and test results must be reviewed and accepted by IO prior to use in manufacturing.

When IO acts as manufacturer of equipment qualification of special processes shall be carried out according to the requirements of "*Implementation plan for design & manufacture of PE/NPE in accordance with applicable regulation. (VE2DSP)*"

5.5 Manufacturing, Inspection and Testing

Suppliers and Subcontractors shall not start work on any contract without a Quality Plan in place that has been accepted by the IO (see paragraph 7). It is DA responsibility to ensure this in the case of Procurement Arrangements.

Suppliers and Subcontractors shall not start manufacturing operations on any contract without a Manufacturing and Inspection Plan (MIP) in place that has been accepted by the IO (see paragraph 7). It is DA responsibility to ensure this in the case of Procurement Arrangements.

Manufacture, inspection and testing shall be carried out:

- following pre-established lists of operations in accordance with the 'Manufacturing and Inspection Plan' document [2]
- using approved and up-to-date drawings, procedures, instructions, standards or other documents directly accessible to those carrying out the work

Processes that cannot be adequately inspected after completion shall be performed according to qualified procedures implemented by qualified personnel. Evidence of qualification shall be available for IO review prior to use.

Inspection and testing status of items and services shall be readily identified.

Evidence of validation of computers and automated machining and inspection programs and software shall be maintained.

5.6 Measuring and Test Equipment

Equipment used for process monitoring, data collection, inspections and tests shall be of the proper range, type, accuracy and precision.

Calibration of measuring and test equipment used for process monitoring, data collection, inspections and tests shall be maintained in accordance with:

- manufacturer's recommendations
- a calibration program based on a recognized standard

Calibration records shall be kept and current calibration status shall be readily identified.

5.7 Handling, Storage and Shipping

Where specific handling, storage or shipping conditions are required, documented procedures shall be submitted and accepted by the IO.

When IO acts as manufacturer of equipment handling, storage or shipping procedures shall be approved by IO.

5.8 Deviations and Non-Conformances

Deviations and non-conformances shall be processed in accordance with the 'Deviations and Non-Conformances' document [3]:

- Technical changes that may be necessary or advisable in the course of a contract must be agreed with IO prior to implementation. Records of this agreement must be available at the performer's premises.
- Conditions adverse to quality, which may occur during manufacture, inspection or testing, must be reported to the IO, resolved and documented.

5.9 Acceptance and Delivery

Prior to acceptance, delivery or payment, a review of items and services status with respect to contract requirements and regulatory requirements when applicable shall be made and documented. This review will be done in accordance with the 'Release Note' document [4].

5.10 Personnel Training and Qualification

Personnel performing activities affecting quality shall have appropriate competence:

- to perform their assigned work
- to understand the quality consequences of their activities

Standard of Qualification of each item and service shall be in accordance with specifications supplied by the IO.

When IO acts as manufacturer of equipment qualification of personnel shall be carried out according to the requirements of "*Implementation plan for design & manufacture of PE/NPE in accordance with applicable regulation. (VE2DSP)*"

Records of training, qualification and experience shall be available for IO review.

5.11 Access

Performers shall arrange for IO representatives to have access to the premises, including those of suppliers/subcontractors, where work is performed for IO activities.

Mandatory and optional inspections shall be carried out in accordance with the 'Manufacturing and Inspection Plan'. In addition, access must be available to IO representatives throughout the manufacturing stage to perform unscheduled visits at any location where ITER related work is being performed. This would normally be to verify compliance with procedures and manufacturing requirements. Where DAs are involved, these visits will be coordinated through the DA and justification will be given by IO on a case by case basis.

Planned and documented audits will be performed by IO, and regulatory body representatives in France, to verify compliance with the technical and quality requirements of the contract. Auditors must have access to perform unscheduled visits

to the performer's facilities for the duration of the audit in order to pursue any audit trails.

IO overseeing of the performance of the contract shall not relieve the performer of any contractual obligations and responsibilities.

6 Applicable ITER Quality Documents

The requirements specified in the following ITER quality documents are an integral part of the requirements of the present specification:

[1] Requirements for Producing a Quality Plan (22MFMW)

[2] Requirements for Producing a Manufacturing and Inspection Plan (22MDZD)

[3] Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities (22F53X)

[4] Requirements for Producing a Contractors Release Note (22F52F)

For R&D activities or supply of services, Manufacturing and Inspection Plans and Release Notes are not normally required.

7 Summary of Quality Requirements Actions

The following tables give an overview of the ITER quality requirements specified in the applicable ITER Procurement Documents for Procurement Arrangements and for Direct IO procurements.

Procurement Document Submittal Requirements for Procurement Arrangements	
Prior to contract implementation	DA to submit a description of the successful Tender's Quality Assurance system for IO information
Prior to contract implementation	Obtain IO acceptance of DA and Suppliers/Subcontractors dedicated Quality Plans
Prior to start of manufacturing	Obtain IO acceptance and mark-up of Suppliers/Subcontractors Manufacturing and Inspection Plan (MIP)
During manufacture	• Update Quality Plans and MIPs as necessary and seek IO re-acceptance • Notify IO representatives of any pending Inspection points as marked up on the MIP • Complete the relevant entries in the MIP as work progresses.
During contract implementation	Issue Deviation Requests and Non-Conformance Reports as necessary
Prior to delivery	Complete the Release Note

Notes summarizing actions related to Procurement Arrangements

1. Each DA has a QA Program that is reviewed and approved for compliance with the IO QA Program.
2. Each DA Tenderer shall supply the DA with a description of their Quality Assurance System identifying compliance standards and accreditations and specifying the elements they plan to use for the contract.

3. After award of the contract, the DA shall send the above description from the successful tenderer to the IO for information.
4. Quality Plans are produced by the DAs, Suppliers and Subcontractors (unless otherwise agreed between the parties) describing how they will implement the ITER Procurement Quality Requirements. DA approved Quality Plans are accepted by the IO; approved Supplier Quality Plans are accepted by the DA and then accepted by IO; approved Subcontractor Quality Plans are accepted by the Supplier, then accepted by the DA, then sent to IO for acceptance.
5. Manufacturing and Inspection Plans (MIPs) are produced and approved by each Supplier and Subcontractor, unless otherwise agreed between the parties. The DA marks up its intended intervention points on the Supplier's MIP, accepts the plan and sends it to IO for acceptance and mark-up of any IO interventions. The Supplier marks up its intended intervention points on the Subcontractor's MIP, accepts the plan and sends it to the DA. The DA marks up its intended intervention points on the Subcontractor's MIP, accepts the plan and sends it to IO for acceptance and mark-up of any IO interventions.

Procurement Document Submittal Requirements for Direct IO procurement	
Prior to Tender (pre-qualification)	Potential Tenderers shall submit a description of the Quality Assurance system for IO acceptance
With Tender Reply	Potential Suppliers shall submit to IO a provisional Quality Plan for IO information
Prior to contract implementation	Obtain IO acceptance of a Supplier dedicated Quality Plan and IO acceptance of Subcontractors dedicated Quality Plan
Prior to start of manufacturing	Obtain IO acceptance and mark-up of Supplier Manufacturing and Inspection Plan (MIP) and IO acceptance / mark-up of Subcontractors MIP
During manufacture	• Update Quality Plans and MIPs as necessary and seek IO re-acceptance • Notify IO representatives of any pending Inspection points as marked up on the MIP • Complete the relevant entries in the MIP as work progresses.
During contract implementation	Issue Deviation Requests and Non-Conformance Reports as necessary
Prior to delivery	Complete the Release Note

Notes summarizing actions related to Direct IO procurement

1. Prior to the Tender, each potential Tenderer shall submit a description of the Quality Assurance system for IO acceptance.
2. Each Tenderer shall supply to IO a provisional Quality Plan identifying how they intend to implement the ITER Procurement Quality Requirements.
3. Quality Plans are produced by Suppliers and Subcontractors (unless otherwise agreed between the parties) describing how they will implement the ITER Procurement Quality Requirements. Supplier approved Quality Plans are accepted by the IO, Subcontractors approved Quality Plans are accepted by the Supplier, then sent to IO for acceptance.
4. Manufacturing and Inspection Plans (MIPs) are produced and approved by each Supplier and Subcontractor, unless otherwise agreed between the parties. The IO marks up its intended intervention points on the Supplier's MIP and accepts the plan. The Supplier marks up its intended intervention points on the Subcontractor's MIP, accepts the plan and sends it to the IO. The IO marks up its intended intervention points on the Subcontractor's MIP and accepts the plan.