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EXTERNAL REFERENCE

MQP Detailed Policy

Requirements for Producing a Quality Plan

This document establishes the ITER requirements to be implemented by a Supplier/Contractor regarding the establishment of a Quality Plan which is mandatory for all entities supplying items and services to the ITER Organization.

Approval Process			
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Change Log			
Requirements for Producing a Quality Plan (22MFMW)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v4.0	Approved	16 Mar 2015	Changes according to MQP doc Request - QXRACN: - Title changed “Requirements for Producing a Quality Plan” - Doc type changed to MQP Detailed Policy - Template changed for MQP Detailed Policy - “should” changed to “shall” throughout the whole document - “approved” changed to “accepted” throughout the whole document - Facility for waiving the requirement for a Quality Plan added in the scope - Clarifications added for the update of a Quality Plan
v3.0	Approved	31 Mar 2009	
v2.0	Approved	22 Nov 2007	
v1.0	Signed	15 Dec 2005	

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1 Purpose

This document specifies ITER requirements to be implemented by a Performer regarding the establishment of a Quality Plan.

2 Scope

A dedicated Quality Plan must be prepared by all performers supplying items, services and activities to the ITER Organisation whether through cash procurement, in-kind procurement or task agreements. Where subcontractors are not performing Critical Quality Activities, this requirement may be waived in agreement with the IO Quality Officer.

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 operation that if not performed correctly would affect Safety, Performance or Reliability
Quality Plan	Document describing the operational quality system to ensure that: • Contract requirements will be met • Evidence of such compliance is maintained It covers the whole scope of the contract including work performed by suppliers/subcontractors and addresses all activities performed in connection with the contract.

4 References

ITER Procurement Quality Requirements (22MFG4)

5 Requirements

Each performer shall prepare a dedicated Quality Plan.

For contracts placed directly by the IO, this is sent to the IO for review and acceptance.

For Procurement Arrangements and Task Agreements, the DA submits a Quality Plan for IO review and acceptance however DA supplier/subcontractor Quality Plans are accepted by the DA, and then submitted to the IO for acceptance.

Quality Plans shall be submitted to the IO after suppliers/subcontractors are identified.

Quality Plans shall be brief and to the point, while giving sufficient visibility on the control of the activities to be carried out.

Quality Plans shall be revised, when appropriate, to reflect changes that have been made e.g.:

- to the requirements of the contract
- to the manner in which the contract is implemented

A revised Quality Plan shall be subject to the same acceptance procedure as the original Quality Plan. Work shall continue in accordance with the current approved Quality Plan until the revised Quality Plan is accepted.

6 Preparation and acceptance of the Quality Plan

DAs and IO direct contractors shall prepare a dedicated Quality Plan and submit it to the IO for acceptance.

The DA Suppliers/Subcontractors dedicated Quality Plans are accepted by the DA, and then submitted to the IO for acceptance.

Work shall not start until the relevant Quality Plan has been accepted by the IO.

Work shall be performed as directed in the Quality Plan. The performers shall monitor the implementation and effectiveness of the Quality Plan.

Documents referred to in the Quality Plan shall be made available to the IO.

IO acceptance of the Quality Plan shall not relieve the performer of any contractual obligations and responsibilities.

Quality Plans are living documents and shall be updated to identify any changes from the original e.g. change in design activities; the supply chain or surveillance management.

Revised Quality Plans must follow the same acceptance procedure as the original.

7 Template

7.1 Content

For the particular contract, the Quality Plan shall identify:

- the critical quality activities
- the specific allocation of resources, duties, responsibilities and authority
- details of all suppliers/subcontractors and how interfaces will be managed
- the specific procedures, methods and work instructions to be applied
- the specific methods of communication, both formal and informal, to be established between working groups

The level of detail in the plan shall be consistent with:

- the technical requirements of the contract
- the safety and operational importance of the items involved
- the complexity of the organizations, functions and activities involved
- the degree of design innovation
- the involvement of innovative processes
- the involvement of processes which cannot be fully verified by inspection or test
- the degree to which functional compliance can be demonstrated by inspection or test
- design, performance or manufacturing margins

Much of the generic documentation needed to prepare the Quality Plan will normally already exist as part of the performer’s quality documents and supporting procedures. The Quality Plan

need only refer to this documentation and show how it is to be applied to the particular contract.

The Quality Plan may be a single document that covers the whole scope of the contract, including work performed by subcontractors. The plan may also be the compilation of coordinated separate and well defined documents.

7.2 Structure

It is not essential for the Quality Plan to follow the structure outlined below which is given for guidance.

The elements listed in the following sections are neither prescriptive nor exhaustive and shall be addressed only where relevant:

7.2.1 Quality Management

The plan shall:

- identify all critical quality activities
- identify the different organizations involved
- detail the breakdown of responsibilities
- identify within the different organizations involved the key individuals responsible for:
    - ensuring that the activities performed in connection with the particular contract are planned, implemented and controlled and their progress monitored
    - communicating requirements peculiar to the specific contract to all affected organizations
    - resolving problems that may arise at interfaces between the organisations involved

An organization flow chart could facilitate the understanding.

7.2.2 Contract Review

The plan shall indicate how, when and by whom contract requirements are to be reviewed and the review recorded.

7.2.3 Document

The plan shall show how, when and by whom documents will be controlled.

7.2.4 Design

The plan shall show how, when and by whom design will be controlled, including:

- when, how and by whom the design process is to be carried out, controlled and documented
- the arrangements for the review, verification and validation of design output conformity to design inputs requirements

Where applicable, the plan shall indicate the extent to which the IO will be involved in design activities, such as participation in design reviews and design verification.

The plan shall reference applicable codes, standards and regulatory requirements.

The plan shall:

- list the computer programs to be used
- indicate how, when and by whom they will be controlled

7.2.5 Procurement

The plan shall show how, when and by whom procurements will be controlled, including:

- any important items or activities that are to be purchased or subcontracted
- the relevant quality assurance requirements
- the proposed suppliers or subcontractors
- the methods to be used to evaluate, select and control suppliers and subcontractors
- the methods to be used to satisfy regulatory requirements, which apply to, purchased or subcontracted products

7.2.6 Identification and Control of items

Where traceability is a requirement or necessary for the adequate control of the work, the plan shall define its scope and extent, including:

- how affected items are to be identified
- how contractual and regulatory traceability requirements are identified and incorporated into working documents
- what records relating to such traceability are to be generated and how and by whom they are to be controlled

7.2.7 Manufacture

The plan shall indicate how processes, manufacture, assembly, inspections and tests will be controlled.

Where appropriate, the plan shall introduce or refer to:

- relevant documented procedures and work instructions
- the methods to be used to monitor and control processes
- criteria for workmanship
- use of special and qualified processes and associated personnel
- tools, techniques and methods to be used

7.2.8 Inspection and Test

The plan shall show how, when and by whom inspection and test would be controlled, including:

- any inspection and test plan to be used, and how and by whom they are reviewed and approved
- how and by whom inspection and test reports are reviewed and approved
- acceptance criteria to be applied
- acceptance of purchased or subcontracted items
- any specific requirements for the identification of inspections and tests status
- the extent to which the IO and (Agreed) Notified Bodies will be involved, such as witnessing inspection and test

7.2.9 Measuring and Test equipment

The plan shall indicate the control system to be used for measuring and test equipment specifically used in connection with the particular contract, including:

- identification of such equipment
- method of calibration
- method of indicating and recording calibration status

7.2.10 Handling, Storage, Packing, Shipping and Delivery

The plan shall show how, when and by whom handling, storage, packing, shipping and delivery will be controlled:

- how contract requirements for handling, storage, packaging and shipping are to be met
- how the item will be delivered to the specified site in a manner that will ensure that its required characteristics are not degraded

7.2.11 Records

The plan shall indicate:

- how records are to be controlled, including how legibility, storage and retrievability will be satisfied
- what records are to be kept
- what records are to be supplied to the IO, when and by what means
- how and by whom the records are reviewed and approved prior to inclusion in the deliverables handed over to the IO
- what form the records will take (such as paper, microfilm, tape, disc or other medium) and in what language the records will be provided

7.2.12 Deviations and Non-Conformances

The plan shall indicate how, when and by whom deviations and non-conformances will be processed including those originating from suppliers and subcontractors.

7.2.13 Training and Qualification

The plan shall address:

- any specific training requirement for personnel
- how such training is accomplished and recorded

7.2.14 Statistical Techniques

Where statistical techniques are relevant for establishing, controlling and verifying process capability and item characteristics, they shall be indicated in the plan.

7.2.15 Assessment

The plan shall indicate how, when and by whom the implementation and effectiveness of the Quality Plan will be monitored.

8 Records

The Quality Plan is an integral part of the contract. Upon completion of the work, the Quality Plan shall be included in the data package handed over to the IO.