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EXTERNAL REFERENCE

MQP Detailed Policy

Quality Classification Determination

This document defines the quality classes, specifies the criteria for assigning quality classes and defines actions appropriate to quality classes. It details the graded application of the ITER QA Program requirements for safety/non safety items and/or services

<i>Approval Process</i>			
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<i>Change Log</i>				
<i>Title (Uid)</i>	<i>Version</i>	<i>Latest Status</i>	<i>Issue Date</i>	<i>Description of Change</i>
Quality Classification Determination (24VQES_v4_1)	v4.1	Approved	27 Jun 2012	Replaced attachments with appendixes in text Clarified Quality Class 4 criteria
Quality Classification Determination (24VQES_v4_0)	v4.0	In Work	27 Jun 2012	1) Document re-formatted to comply with detailed policy template 2) Attachments re-named as appendixes 3) Inspection Requirements in Appendix 2 relaxed
Quality Classification Determination (24VQES_v3_0)	v3.0	Approved	13 Oct 2010	General revision, incorporating safety classification as per document ITER_D_347SF3 Version 1.5 titled SAFETY IMPORTANT FUNCTIONS AND COMPONENTS CLASSIFICATION CRITERIA AND METHODOLOGY
Quality Classification Determination (24VQES_v2_0)	v2.0	Approved	22 Jun 2009	1)Classifications updated to remove terms “significant” and “major”; 2) Inspections requirements clarified; 3) Re-definition of Class 4; 4)The above incorporate comments from the Safety & Quality Working Group 5) Reviewers and approver changed to reflect MQP review
Quality Classification Determination (24VQES_v1_4)	v1.4	Approved	22 Jan 2008	
Quality Classification Determination (24VQES_v1_3)	v1.3	Signed	06 Jun 2007	
Quality Classification Determination (24VQES_v1_2)	v1.2	Approved	22 Nov 2006	
Quality Classification Determination (24VQES_v1_1)	v1.1	Approved	24 Oct 2006	
Quality Classification Determination (24VQES_v1_0)	v1.0	Signed	24 Oct 2006	

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1 Purpose

A Quality classification is introduced to provide a basis upon which a graded approach is used to implement the ITER Quality Program requirements.

This document:

- defines the quality classes,
- specifies the criteria for assigning quality classes
- defines actions appropriate to quality classes

Classification applies to structures, systems and components (SSC) necessary for ITER operation or for supporting ITER operation. These SSC may be safety relevant or non-safety related.

2 Scope

The requirements of this document apply to the ITER Project and all performers.

Specific technical and documentation requirements may be included in Contracts or in other contractual documents (i.e. Technical Specifications).

3 Definitions

IO	ITER Organization, sometimes referred to as ITER
DA	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
N.D.E.	Non-Destructive Examination

4 Reference

- [1] [ITER Quality Assurance Program \(22K4QX\)](#)
- [2] [Safety Important Functions and Components Classification Criteria and Methodology \(347SF3\)](#)
- [3] [ITER Procurement Quality Requirements \(22MFG4\)](#)

5 Basic principles

Defining ITER Quality Classes is a function of SSCs end use as items classified as Nuclear Safety Important (SIC), Safety Relevant (SR) and Non Safety Related (NSR) but affecting the performance, cost or reliability of the ITER facility. They are defined on the basis of:

- Safety Importance Class assigned to the item,
- Anticipated impact of item failure or malfunction on Machine availability,
- Maturity and complexity related to a risk of failure or malfunction.

Items may belong to one of four (4) Quality Classes, as defined in Appendix 1; however the following shall be noted:

- All SIC-1 systems and component parts shall be Quality Class 1
- SIC-2 systems and component parts can be Quality Class 1 or 2
- Commercial Grade or Proprietary Items (excluding base materials like pipes and plates), that are purchased using a manufacturer's catalogue or other commercially available documentation that have been assessed as Quality Class 1, 2 or 3, need only be supplied with a manufacturer's "Certificate of Conformity". Modified commercial or proprietary items shall conform to [3].
- For systems and component parts of Quality Class 4: no specific QA requirements apply.

Factors to be considered when assessing potential downtime duration would include:

- ease of replacement/repair,
- ease of fault/malfunction detection,
- ease of identification of defective part,
- availability of spare part,
- availability of qualified personnel.

Factors to be considered when assessing the risk of failure or malfunction would include:

- degree of design innovation,
- complexity or uniqueness of the item,
- design, performance and manufacturing margins,
- involvement of innovative processes,
- need for special controls and surveillance over processes and equipment,
- involvement of processes which cannot be fully verified by inspection or test,
- degree to which functional compliance can be demonstrated by inspection or test,
- quality history and degree of standardization of the item.

6 Responsibilities

Technical Responsible Officers are required to indicate the Quality Classes relevant to the systems placed under their responsibility. The selection of Quality Classes and the grading of the QA requirements shall be in accordance with Appendixes 1 and 2. Assistance from IO QA Division shall be sought if any clarification is needed.

Rationale and adequacy of the assigned class shall be reviewed as part of the item design review and recorded by Technical Responsible Officers.

Performers may grade the quality classification down to the component levels (some of which may be lower than the related system classification), however they will be responsible for ensuring the correct classification is applied.

Appendix 1: Determination of Quality Class

Risk Type	Quality Class 1 Large Impact	Quality Class 2 Adverse Impact	Quality Class 3 Moderate Impact
Functional	Failure has potential for a loss of plasma operations for more than 3 weeks	Failure has potential for: (1) loss of plasma operations for less than 3 weeks <u>OR</u> (2) a loss of data essential for machine operation	Failure has no potential for loss of plasma operation or loss of data essential for machine operation
Environment, safety, and health	Failure has potential for: (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, <u>OR</u> (2) environmental damage that could exceed regulatory limits or involve significant cleanup costs.	Failure has potential for: (1) injury or illness requiring hospitalization, temporary or partial disability, <u>OR</u> (2) moderately adverse impact on the environment or health or safety of a worker or the public.	Failure has potential for: (1) minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization, <u>OR</u> (2) a negligible impact on the environment.
Compliance	Failure has potential for non-compliance with state, federal or international laws, regulations or requirements	Failure has potential for non-compliance with established management practices and procedures.	Failure has potential for minor non-compliance with established management practices.
Cost/Schedule Impacts		Failure has potential for: (1) a financial loss of 500K Euro or more <u>OR</u> (2) major Impact of ITER construction schedule	Failure has potential for a financial loss less than 500K Euros.

Class 4: for items whose failure has no safety, operational, significant cost or schedule impact:
No QA Program applicability or specific quality requirements.

Note: Permanent lifting attachments shall be designated as Quality Class 1 items

Appendix 2: Actions applicable to Quality Classes

Quality Classification ⁽¹⁾	Class 1	Class 2		Class 3	
Allowed Nuclear Safety classes	SIC-1 / SIC-2 / SR / NSR	SIC-2	SR / NSR	SR	NSR
Design	Design controls including design reviews and <i>independent</i> ⁽²⁾ verifications		Design controls including design reviews and verifications		No design review required, unless otherwise agreed between the parties
Software	Acceptance of Software used for Design and Operation, including life cycle management		Identify and validate software usage		No requirement, unless otherwise agreed
Minimum Documents and Records to be delivered	Quality Plans, Manufacturing & Inspection Plans, Procedures, calculation note (where design is involved), working instructions, Special Process Qualifications (if applicable), Operator Qualifications, 'As Built drawings', Release Note, Certificate of Conformity. Material certification and inspection documents according to EN 10204 Type 3.1 (or equivalent) traceable to the component part and equipment.		Quality Plans, Manufacturing & Inspection Plans, Release Note, 'As Built drawings', material certification and inspection documents acc. to EN 10204 Type 3.1 (or equivalent) traceable to the component part/equipment.		Certificate of Conformity according to to EN 10204 Type 2.1 (or equivalent)
Monitoring of performers	Audit of performers including qualification and surveillance		Limited on-site reviews		No Monitoring, unless otherwise agreed between the parties
Measurements and Test Equipments	Controlled Calibrated measuring and test equipment (M&TE)				Controlled Calibrated M&TE for validation processes
Inspection ^(3,4,5)	100% visual, surface and volumetric inspection	100% visual, 20% surface and volumetric inspection	100% visual, 10% surface and volumetric inspection		
Special processes Personnel Qualifications and Training (i.e. welding, brazing, N.D.E.)	Documented personnel qualifications and training				
QA requirements	QA representative approvals of documents related to special processes and inspections are required	QA representative consultations on special processes and inspections are required		QA consultations on as-needed basis	

Notes:

(1) For systems and component parts of **class 4**: no specific QA requirements.

- (2) *'Independent' means individual, groups, divisions, departments who were not involved in the original design. 'Independent' can also mean a Third Party organization.*
- (3) *These requirements only apply where no construction code or other IO approved document is specified in the Contract Technical Requirements.*
- (4) *When joining processes are used and the required volumetric inspection is not practicable, Production Proof Sampling shall be used and the implementation agreed with the IO TRO.*
- (5) *Permanent lifting attachments if welded must be 100% inspected using N.D.E. before and after lifts*