

How To

Quality Classification Determination

A quality classification is introduced to provide a basis for applying a graded approach to the management of structures, systems and components (SSC), spare parts and activities necessary for ITER operation or for supporting ITER operation. The document provides criteria for defining quality classes and the resulting general requirements, which are further implemented in IO Management and Quality Program and requirements for IO performers.

Approval Process			
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Change Log			
Quality Classification Determination (24VQES)			
Version	Latest Status	Issue Date	Description of Change
v1.0	Signed	24 Oct 2006	
v1.1	Approved	24 Oct 2006	
v1.2	Approved	22 Nov 2006	
v1.3	Signed	06 Jun 2007	
v1.4	Approved	22 Jan 2008	
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
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
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
v4.1	Approved	27 Jun 2012	Replaced attachments with appendixes in text Clarified Quality Class 4 criteria
v4.2	Revision Required	14 Feb 2017	New methodology for determination of quality class was included in the procedure. Improvement of Appendix 1 and Appendix 2 of procedure.
v4.3	Approved	03 Aug 2017	The new version was created to include the requirements related to construction, assembly and installation phase. The present version was not recirculated to DA's representatives taking into consideration that the new added requirements does not have impact on DA activities.
v5.0	In Work	07 May 2019	Chapter 6.2 - replace QAA Division with QMD Appendix 2: Quality classes application: - add note 6 for each referred procedure - responding to USIPO comments: Procedures versions: The procedures referred in the present document shall be applied at the latest version indicated in the PA Applicable Documents (PA AD) list - latest agreed version between IO and DA's. For the procedures not considered PA AD, the latest approved version shall be applied. Any modification of referred procedures, shall be applies following the requirements and workflow indicated in the MQP Document Change Control procedure (VDVFHY) - latest agreed version between IO and DA's. - add reference to Working Instruction for Construction Readiness Review (QXW4KQ) - quality audit section - for In kind - add clarifications regarding suppliers quality audits "unless otherwise agreed between IO / DA's. Alternative suppliers evaluation methods shall be applied in case audits are not performed." similar approach with In cash procurement. - close all the comments from previous version review cycle.
v5.1	Signed	07 May 2019	Technical issue, some spaces deleted for better view. The key changes are listed for the major version 5.0.
v5.2	Approved	04 Jul 2019	Revision to implement the USDA and JADA comments as following: - Appendix 2 - Design control section - clarification regarding application of ITER_D_R3KD8C - Design Verification and Validation Procedure (applicable for IO only)

			<ul style="list-style-type: none"> - Appendix 2 - Procurement / Documents and Records section - clarification regarding application of Working Instruction for Completion Dossier Preparation (UYUSEE) (applicable for IO only - not in the scope of PA) - Appendix 2 - NCR & DR control section - clarification regarding Minor NCR application as per USDA comments.
v6.0	Approved	25 Oct 2024	<p>As per decision CC4P3J, this document becomes non-MQP under responsibility of the process owner.</p> <p>In terms of content, it describes the calculation itself and expectations to the requirements to be developed in process and performer's documents.</p> <p>All requirements from the revision 5.2 moved to 22MFG4 v6.0 - Quality Requirements for IO Performers.</p>

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1 Purpose

A quality classification is introduced to provide a basis for applying a graded approach to the management of structures, systems and components (SSC), spare parts and activities necessary for ITER operation or for supporting ITER operation.

The document provides criteria for defining quality classes and the resulting general requirements, which are further implemented in IO Management and Quality Program and requirements for IO performers ([1] and other documents).

2 Definitions and acronyms

Term	Acronym	Definition
ITER Organization	IO	
Management and Quality Program	MQP	
Structures, systems and components	SSC	

3 References

[1]	Quality Requirements for IO Performers (22MFG4)
[2]	Safety Important Functions and Components Classification Criteria and Methodology (347SF3)

4 Factors influencing quality classification

	Factor (F) / Type of Risk	Class 1 Large impact	Class 2 Adverse impact	Class 3 Moderate impact
Consequence factors	F1: Functional and operational	Failure has potential for a loss of plasma operations for long period or has impact on machine operation activities /performances.	Failure has potential for loss of plasma operations for short period or leads to difficulties in machine operation activities.	Failure has no potential for loss of plasma operation or loss of data essential for machine operation.
	F2: Environment, industrial 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, or (2) Environmental damage that could exceed regulatory limits or involve	Failure has potential for: (1) injury or illness requiring hospitalization, temporary or partial disability, or (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, or

		significant cleanup costs		(2) a negligible impact on the environment.
	F3: Cost or schedule impacts	Failure has potential for a financial loss of 1000K Euro or more.	Failure has potential for: (1) a financial loss of 500K Euro or more or (2) Impact on ITER construction schedule	Failure has potential for a financial loss less than 500K Euro and no impact on construction schedule.
	F4: Compliance	Failure has potential for noncompliance with state, federal or international laws, regulations or requirements	Failure has potential for noncompliance with established IO management practices and procedures.	Failure has potential for minor non-compliance with established management practices.
Probability factors	F5: Other classifications	The SSC has other classifications: PIC/ SIC 1 or PIC/ SIC 2 or SR/ seismic class 1/ vacuum class 1/tritium class 1	The SSC has other classifications: PIC /SIC 2 or SR / seismic class 2 / vacuum class 2 / tritium class 2	The SSC has other classifications: SR / seismic class 3 / vacuum class 3 / tritium class 3.
	F6: Design complexity	The design requires multiple discipline, interfaces, complex verifications, independent validation of the design and special software and models.	The design efforts is normal, it involves different disciplines and independent validation of the design.	The design efforts are minimal.
	F7: Complexity of manufacturing process	The product has multiple critical characteristics and fabrication requires multiple number of manufacturing processes, special process, complex technologies and high qualified personnel that is involved in manufacturing process	The product has critical characteristics and the fabrication requires normal processes, normal fabrication technologies and qualified personnel that are involved in manufacturing process.	The product has characteristics easy to be realised and the product fabrication does not requires a multiple number of manufacturing processes

A quality class shall be defined for each factor, resulting in seven values of FxQC (F1QC, F2QC, etc.) that can be equal to 1, 2, or 3.

If the description of a factor's quality class is not relevant, the factor's quality class shall be assigned as 4. In particular, this may pertain to certain factors of the SSC used for research and development.

5 Assignment of quality class

The final quality class (FQC) is the weighted arithmetic mean of the seven factors:

$$FQC = (1.5 \times (F1QC + F2QC + F3QC) + 0.75 \times (F4QC + F5QC) + 0.5 \times (F6QC + F7QC)) / 7$$

with the associated weights provided in the following table:

Factor	Weight
F1	1.5
F2	1.5
F3	1.5
F4	0.75
F5	0.75
F6	0.5
F7	0.5

Unless otherwise specified by the special conditions below, the assigned quality class shall be taken as outlined in the following table:

FQC	Quality Class
$FQC < 2$	1
$2 \leq FQC \leq 2.5$	2
$2.5 < FQC \leq 3$	3
$3 < FQC$	4

Special conditions:

For all PIC/SIC-1 (see [2]), the quality shall be assigned as 1.

For all PIC/SIC-2, the quality class shall not be assigned lower than 2.

For buildings, the quality class shall correspond to that of the main component located within the building.

6 General requirements for quality classes

The requirements outlined below are primarily intended for those developing IO process documents or IO performer requirements. Detailed requirements for end users can be found accordingly.

Area	Requirement with IO involvement	Class 1	Class 2	Class 3	Class 4
Quality management	Established quality management system	●	●	●	●
	Quality plan	●	●	●	○
	Management of nonconformities				
	- Major nonconformities	●	●	●	●
	- Minor nonconformities	●	●	○	○
	Deviations				
	- Agreement	●	●	●	●
	- Implementation	●	●	○	○
	Mandatory audit or alternative checks	●	●	○	○
	Optional audit or alternative checks	○	○	●	○
	Risk management	●	●	○	○
Engineering	Independent verification of design, including design review	●	●	○	○
	Selection of software and models	●	●	○	○
Manufacturing	Manufacturing and inspection plan (MIP)	●	●	○	○
	Procedures used in inspection plans	●	●	○	○
	Qualification of special processes	●	●	○	○
	Manufacturing readiness review (MRR)	●	●	○	○
	Material certificates	●	●	●	○
	Manufacturing dossier	●	●	○	○
	Contractor release note (CRN)	●	●	○	○
Assembly and Installation	Inspection and test plan for assembly and installation (ITP)	●	●	●	○
	Procedures used in inspection plans	●	●	●	○
	Qualification of special processes	●	●	●	○
	Construction readiness review (CRR)	●	●	●	○
	Mechanical completion dossier (MCD)	●	●	●	○
	Contractor release note (CRN)	●	●	●	○
Storage and Shipping	Shipping notification	●	●	●	○
	Storage specifications	●	●	○	○
	Transportation specifications	●	●	○	○