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Quality Document

SOP-01.29 Quality Class Determination and Implementation (QA-010)

This document describes the quality classification process being applied in Fusion for Energy projects. In particular it covers the procedures to be followed for determining a graded application of the QA Program.

Approval Process			
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Change Log			
SOP-01.29 Quality Class Determination and Implementation (QA-010) (22MD99)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	In Work	11 May 2010	
v1.1	Signed	17 June 2010	Updated reference to idm@F4E system and the correct version This version has been approved by the DIRECTOR
v1.2	Signed	03 February 2011	Updated to new IO Quality Classification Determination (division of SIC into SIC1 and SIC2)
v1.3	Approved	04 February 2011	Adopted comments of previous version (by F. Casci) Added SRA's and QA-013 as reference document.
v2.0	Approved	20 July 2012	Updated to reflect IO Procedure Update: - Format update with cover page // - Clarified Quality Class criteria // - Inspection Requirements in Table2 relaxed
v3.0	Approved	20 November 2020	Updated to comply with "Quality Classification Determination" ITER_24VQES_v5.2 (PA Applicable Document). This document supersedes F4E documents F4E-QA-100 Quality Graded application (F4E_22EPT2) and PM-09 Quality Classification (F4E_22DSEF). The document passed the pre-review: https://idm.f4e.europa.eu/?uid=2LX2GZ "

FUSION FOR ENERGY

STANDARD OPERATING PROCEDURE

Control Page

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Document title:	QUALITY CLASS DETERMINATION AND IMPLEMENTATION (QA-010) (SOP-01.29)

Areas and functions	
Version Responsible:	J. Ilves (QA Officer)
Document Owner:	QA HoU (V. Meignan)
Process Group and Context:	Corporate Planning Financial Controlling & Reporting/ Quality Assurance
Function(s) concerned:	F4E: QAO, QA HoU, PjM, PA-IO-TRO, TPO, NSO (for Nuclear Safety Relevant activities) Supplier/ Subcontractor' organisation: Employees responsible for the definition of the Quality Class for SSC: Project Manager, Technical Representative, Quality Representative, Nuclear Safety Responsible, if applicable

Purpose

This purpose of this document is to define:

- the methodology to identify the Quality Class of the Strusture, System or Component (SSC);
- the applicability of quality assurance and project management minimum requirements based on the Quality Class of the SSC.

This document supersedes the following F4E documents:

1. SOP-01.30 Quality Graded Application (F4E-QA-100) (22EPT2), and
2. PM-09 Quality Classification (22DSEF).

Scope

The requirements of this document shall be followed:

- by F4E staff
- by Supplier/ Subcontractor personnel when applicable.
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Note for F4E staff: This document is fully applicable to all ITER project SSC under the direct responsibility of F4E for procurements procedures published not earlier than two (2) months before the signature of Multi-Party Amendment (MPA) F4E_2HTRUM (signed by F4E 26.07.2019). For any other F4E contracts implementing the Procurement Arrangements, F4E shall follow the respective provisions of the MPA.

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Reference Documents

[1] PM-06 Deviation Control (22CCM4)

[2] F4E Management and Quality Programme for ITER Project (22MCBA))

[3] P-01.14 Supplier Project Management and Quality Requirements (F4E-QA-115) (22F8BJ)

Applicable Documents

This document is developed based on the requirements of IO "Quality Classification Determination (ITER_D_24VQES v5.2) (PA Applicable Document).

Resources

1. Excel table to support the Quality Class calculation process (attached in IDM to this document);
2. List of F4E documents where the requirements are established (2PYCR5).

Definitions and Acronyms

Refer to F4E Acronyms, Glossary and F4E Roles in the Manual for more information

COTS	Commercial Off The Shelf items
SSC	Strusture, System or Component
IO	ITER ORganisation
PA/ ITA	Procurement Arrangement/ITER Task agreement

I. General Provisions

(a) Quality Class of the SSC is generally established by IO in PA/ITA.

(b) If required in PA/ ITA or F4E contract, **F4E or Supplier can be** responsible to grade the quality classification down to the component level (some of which may be lower than the related system classification), however they (F4E or Supplier) are responsible for ensuring the correct classification is applied as defined in the contract.

(c) Quality Class of **F4E contract/ SSC** is defined during the procurement call preparation process and is recorded in the Annex A of the contract (for a Framework Contract might be defined in the Task Description for the Specific Contract).

I.1. Main Responsibilities in the QUALITY CLASS Definition Process

Possible scenarios, where the QC has to be defined	Tool	F4E Project Manager (PjM)	F4E Technical Officer (TPO)	F4E Quality Assurance Officer (QAO)	QA HoU	IO Technical Responsible Officer (PA-IO-TRO)	Supplier
1. Quality Class is defined in PA/ITA, but when cascading requirements into contracts, **F4E** may define lower Quality Class of the SSC (based on the scope of the contract) during the pre-procurement phase.	*EUDA-QP *Contract Annex A	Accountable	Consulted	Responsible	Approver (F4E level)	Consulted (if related to PA/ITA)	Not involved
2. **F4E** requests IO to change (downgrade) the quality class of systems' components and spare parts	F4E Deviation	Responsible	Consulted	Consulted	Not involved	Approver (IO level)	Informed
3. **F4E Supplier** requests F4E to downgrade the Quality Class of SSC	Supplier Deviation Request (PM-06 Deviation Control (22CCM4))	Approver (F4E level)	Consulted	Consulted	Not involved	Approver (IO level - if related to PA/ITA)	Initiates (on approval to be reflected in PQMP, MIP, SCAR)
4. **F4E Supplier i**s responsible for the definition of Quality Class for SSC under development as a part of contractual scope of the Supplier.	This procedure to be followed. The proposed SSC Quality class shall be described in the supplier PQMP.	Approver (F4E level)	Consulted	Consulted	Not involved	Approver (IO level)	Initiatiates (on approval to be reflected in PQMP, MIP, SCAR)

F4E and Suppliers have full responsibility for cascading the QUALITY CLASS and application requirements to their suppliers/ subcontractors.

I.2. Factors to be Considered when Identifying the Quality Class of the SSC and the Assessment of their Impact

(a) All PIC/ SIC-1 systems and component parts shall be always classified as Quality Class 1;

(b) PIC/ SIC-2 systems and component parts can be either Quality Class 1 or Quality Class 2;

(c) The Quality Classes for buildings are established by IO in procurement documentation (System Requirements Documents (e.g. System Requirements Document SRD 63-61 Site Services Building (ITER_D_2FHHSJ), Procurement Arangements).

		Class 1 Large Impact	Class 2 Adverse Impact	Class 3 Moderate Impact
Failure Consequence Factors				
Factor 1	**Functional & 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.
Factor 2	**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 significant cleanup costs	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 (2) a negligible impact on the environment.
Factor 3	**Cost /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 but less than 1000K (2) Impact on ITER construction schedule	Failure has potential for a financial loss less than 500K Euro *and no impact on construction schedule.*
Factor 4	Compliance with applicable laws and regulation.	Failure has potential for non-compliance with state, federal or international laws, regulations or requirements	Failure has potential for non-compliance with established IO management practices and procedures.	Failure has potential for minor non-compliance with established management practices.
Failure Probability Factors				
Factor 5	Other Classifications (safety class, vacuum class, tritium class etc.)	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.
Factor 6	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.*
Factor 7	Complexity of the 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*

Note:

1. In case the Supplier is requested to define Quality Class of activities or sub-SSC, the Factors 1, 2, 3 shall be determined by F4E/IO as the Supplier might lack the information to establish proper QC.
2. For all factors, where the description might correspond to more than one Quality Class level, the QC with the highest level of requirements shall be selected.

I.3. Methodology to be used to calculate the Quality Class

1. Based on the Table 1 establish the applicable Class for each factor*:
   e.g. if Factor 1 has a Class 2, then **$F1_{QC}$** =2 (Fn_{QC} is the result of the Matrix)
2. Calculate the Final Quality Class (FCQ) applying the formula:
   F_{QC} = [($F1_{QC}$x1.5) + ($F2_{QC}$x1.5) + ($F3_{QC}$x1.5) + ($F4_{QC}$x0.75) + ($F5_{QC}$x0.75) + ($F6_{QC}$x0.5) + ($F7_{QC}$x0.5)] / 7
   *** If the factor is not applicable "zero" to be assigned as a value of the factor and the denominator shall be decreased by 1 for each factor not applicable.**
3. Apply the following table to interprete F_{QC} results:

F_{QC} Results	Quality Class
1<= F_{QC} < 2	1
2 <= F_{QC} <= 2.5	2
2.5 < F_{QC} < 3	3

Quality Class 4:

not Safety/ seismic etc. related items (no other classifications), whose failure has no significant operational, cost or schedule impact.

I.4. Application of Quality Classes

(a) Commercial Off The Shelf items (COTS) purchased using a manufacturer's catalogue or other commercially available documentation that have been assessed as Quality Class 1, 2 or 3, shall be supplied with a manufacturer's "Certificate of Conformity" whereas applicable and any other documents established in the PA's / Contracts.

(b) Raw materials shall be supplied with material certificate as per standards indicated in the PA's/ contracts (unless specified otherwise in the contracts).

(c) The assembly and installation activities shall be conducted following the quality class of the assembled/ installed system, structure and components (SSC).

The following table defines the applicability of key requirements:

QA/ PM activity or process	Key requirements (for the methodology refer to the List of F4E documents where the requirements are established (2PYCR5))	Class 1 & 2	Class 3
Design control	Design controls (gates) shall be applied (including design reviews and independent verifications)	Mandatory	Can be defined in Annex A of PA/ contract
Software Control & Models Development	Software and models used for design and operations (including life cycle management) shall be accepted by F4E/IO.	Mandatory	Can be defined in Annex A of PA/ contract
Procurement / Documents and Records	All F4E DA QP and Supplier Project and Quality Management Plans shall be approved/accepted by F4E and IO before the start of activities	Mandatory	Mandatory
	Management Control Plan (MCP) and/or Manufacturing and Inspection Plan (MIP) shall be approved/accepted by F4E and IO before the start of contractual activities	Mandatory	Can be defined in Annex A of PA/ contract
	Special Processes Qualification, manufacturing, testing and inspection, FAT, assembly & construction and other relevant procedures defined in contractual specifications shall be reviewed and approved by F4E and reviewed by IO before the start of activities.	Mandatory	Can be defined in Annex A of PA/ contract
	Before the delivery final ADP (including Manufacturing Dossier for manufactured items) shall be submitted to F4E (and IO) with completed and approved Contractor Release Note (as indicated in the PA's/ contracts)	Mandatory	Can be defined in Annex A of PA/ contract
	Declaration of compliance to order, material certificates and inspection documents according to the applicable standards indicated in the PA's / contracts, traceable to the component part and equipment (when applicable).	Mandatory	Mandatory
	During the hand-over - Necessary procurement documents provided by the Performers for F4E/IO acceptance. Applicable for construction and assembly/ installation activities	Mandatory	Mandatory
Manufacturing	The manufacturing activities shall be performed in accordance with MIP and approved procedures. No manufacturing activities will start without F4E and IO acceptance of MIP and testing/inspections/qualification/special process procedures. Manufacturing Readiness Review (MRR) process shall be applied before starting the manufacturing activities	Mandatory	Can be defined in Annex A of PA/ contract
	Quality Control and supervision activities to be applied based on the requirements of applicable procedures.	Mandatory	Mandatory
Construction, Installation and Assembly	Construction, installation and assembly, inspection and testing activities can start only after F4E and IO acceptance of ITP (Inspection and Test Plan) and testing/inspections/qualification/special process procedures.	Mandatory	Mandatory

	Construction Readiness Review (CRR) shall be applied before starting the activities. Applicable for IO and direct contracts only (not in the scope of PA implementation)	Mandatory	Mandatory
	Quality Control and supervision shall be applied for construction and assembly & installation activities based on the procedure.	Mandatory	Mandatory
Quality Audits	Unless otherwise agreed between IO and F4E, quality audits shall be perfomed at the suppliers/ contractors site. Alternative methods for suppliers/ contractors evaluation shall be applied in case audits are not performed.	Mandatory	Can be defined in Annex A of PA/ contract
	F4E auditors shall have the necessary skills / qualifications and experience to perform audit activities.	Mandatory	Can be defined in Annex A of PA/ contract
	The quality audits are not mandatory unless otherwise agreed between the parties. The evaluation of quality management system of the suppliers / contractors shall be performed based on documents review (ISO 9001 (or equivalent) certificate or copy of quality manual.	--	Mandatory
Handling, storage & Transportation	For PA/ITA deliverables the products delivery shall start only after contractors release note and shipping notification are accepted by IO.	Mandatory	Mandatory
	A specific technical specification for transportation and storage activities (issued by IO or F4E) and shipping plan for transportation activities shall be developed and applied.	Mandatory	Can be defined in Annex A of PA/ contract
	Minimum inspections and verifications to the products (sampling methods) shall be applied at reception time as per IO procedures and PA's / contracts requirements.	Mandatory	Can be defined in Annex A of PA/ contract
	Storage and preservation activities (in IO site & DA's site) shall be performed in accordance with applicable procedures, TRO request and manufacturer instructions.	Mandatory	Can be defined in Annex A of PA/ contract
NCR & DR control	All major NCR's related to ITER project shall be submitted to IO for review and acceptance. For all major NCR's related to ITER project, a root cause analysis shall be issued by the F4E/suppliers/subcontractors and approved by IO.	Mandatory	Mandatory
	All minor NCR's related to ITER project shall be submitted to IO following the requirements of applicable procedure or specific agreements between IO and F4E	Mandatory	Can be defined in Annex A of PA/ contract
	All the deviations to PA/ITA shall be submitted to IO for review and approval before the implementation.	Mandatory	Mandatory
	After the approval of the deviation, F4E is responsible for the follow-up of implementation.	Mandatory	Can be defined in Annex A of PA/ contract
Risk and opportunity management	Risk and opportunity management process shall be applied in accordance with applicable F4E procedures and contractual requirements. Training activities related to risk and opportunity management process	Mandatory	Can be defined in Annex A of PA/ contract
	Use of Project Risk and Opportunity Register Template	Mandatory	Mandatory

Minimum quality requirements **for QC4 items/ contracts** are defined in the Annex A (management specification) by TPO and QAO of the contract. For QA evaluation of the supplier performing QC4 activity a copy of ISO 9001 certificate (or equivalent) can be considered sufficient.