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F4E Quality Document

F4E-QA-010 - QUALITY CLASSIFICATION

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			
Version	*Latest Status*	*Date*	*Description of change*
v1.3	Approved	04 Feb 2011	Adopted comments of previous version (by F. Casci) Added SRA's and QA-013 as reference document.
v1.2	Signed	03 Feb 2011	Updated to new IO Quality Classification Determination (division of SIC into SIC1 and SIC2)
v1.1	Signed	17 Jun 2010	Updated reference to idm@F4E system and the correct version This version has been approved by the DIRECTOR
v1.0	In Work	11 May 2010	

Contents

Terms and Definitions

Term	Definition	Acronym
Contract	The Contract can be: • the supply or service Contract as result of a procurement, or • the Grant Agreement	---
IO or ITER	The ITER International Fusion Energy Organisation.	IO
NDE	Non Destructive Examination	NDE
NSR	Non-Safety Related	NSR
QA	Quality Assurance	QA
QAO	Quality Assurance Officer	QAO
SIC	Safety Important Class (as defined in the Quality Order – 10 August 1984)	SIC
Supplier	The Supplier is either: - the Contractor as defined in the supply or service Contract, or - the Beneficiary as defined in the Grant Agreement. The supply-chain follows the scheme below Supplier -> Organization (F4E) -> Customer (e.g. IO)	---
SSC	Structures, Systems and Components	SSC
SR	Safety Related	SR
Safety Related Activity	The importance for safety of an activity is appreciated on the basis of direct or potential consequences for safety in case on inappropriate exercise of the activity	SRA

Reference Documents

[1] F4E-QA-115 – Supplier Quality Requirements (F4E_D_22F8BJ)
[2] F4E-QA-100 - Quality Graded Application (F4E_D_22EPT2)
[3] F4E-QA-013 - Safety Arrangements Follow-Up (F4E_D_23CA9U)
[4] ITER Quality Classification Determination (ITER_D_24VQES)

1. Purpose

A Quality classification is introduced to provide a basis upon which a grade approach is used to implement the Quality Program requirements.
This document defines the quality classes and specifies the procedure for assigning quality classes.

2. Scope

Classification applies to Structures, Systems and Components (SSC) necessary for the Project operation or for supporting its operation, safety related or non-safety related.

3. Definition of Classes

3.1. Defining Quality Classes is a function of the Project Structures, Systems and Components end use as items classified by the project as Nuclear Safety Important (SIC), Safety Related (SR) or Non-Safety Related (NSR) but affecting the performance, cost or reliability of the Project facility.

3.2. 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.

3.3. Safety Important Class (SIC) is classified in two categories:

SIC-1	Those SIC components required to bring to and to maintain the Project in a safe state.
SIC-2	Those SIC components used to prevent, detect or mitigate incidents or accidents, but not required for the project to reach a safe state.

3.4. Items may belong to one of four (4) quality classes, defined as follows:

Class	Criteria
1	Any SIC-1 Item OR any item (SIC-2, SR, NSR) whose failure/malfunction could result in LARGE impact
2	Any safety important class 2 Item (SIC-2), safety related Item (SR) or non safety related item (NSR) whose failure could result in ADVERSE impact.
3	Any safety related Item (SR) or non safety related item (NSR) whose failure could result in MODERATE impact
4	Commercial Grade or Proprietary Items that are purchased using a manufacturer's catalogues or other commercially available documentation without the need to provide an engineering specification (even if initially assessed as QC 1, 2 or 3). Modified commercial or proprietary items shall conform to QA-115 – Supplier Quality Requirements. No specific Quality Plan required. A minimum of a Certificate of Conformity (CoC) is required on delivery.

3.5. 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.

3.6. 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.

4. Responsibilities

4.1. (Technical) Project Officers are required to indicate the classes relevant to the items placed under their technical responsibility.

4.2. The selection of quality classes and the grading of the QA requirements shall be in accordance with tables 1 and 2.

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

5. Determining Quality Class and Requirement

5.1. Preparation:

i. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

ii. Identify any specified regulatory requirements.

iii. Decide whether the activity will be used in or to support Project structures, systems, or components (SSC).

iv. Request assistance from a QAO if you have any questions on preparations.

5.2. Determine Quality Class:

If the activity will be used in or to support Project Structures, Systems, Components, determine Quality Class in accordance with tables 1 and 2.

i. Technical Project Officers responsible for the SSC are responsible for making the Class determination

ii. QAO assist in the determination as appropriate so that quality class is assigned to individual parts and the item/activity does not receive a “blanket assignment” of one quality class.

iii. For ITER tasks, in case of conflict between this classification and the ITER classification (ITER Quality Classification Determination ITER_D_24VQES), the ITER Quality Classification will prevail. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

5.3. Determine Quality Requirements:

i. The application of the Quality Requirements shall follow the indications of table 2 and the graded application described in FE-QA-100. Define plan/develop activity scope of work to a sufficient level of detail so that quality requirements can be identified.

Table 1. Determination of quality class

	QA Graded Quality Levels		
Risk Type	**Class 1** SIC-1 / SIC-2 / SR / NSR **Large Impact**	**Class 2** SIC-2 / SR / NSR **Adverse Impact**	**Class 3** SR / NSR **Moderate**
Functional	Failure has Potential for a loss of Plasma operations for more than 3 weeks.	Failure has Potential for loss of plasma operations for less than 3 weeks OR 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, 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.
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 (F4E or Customers).	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 OR (2) major Impact of Project construction schedule	Failure has potential for a financial loss less than 500K Euros.

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

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

Table 2. Actions appropriate to quality class

Quality Classification[(a)]	Class 1	Class 2		Class 3	
Safety Class	SIC-1 / SIC-2 / SR / NSR	SIC-2	SR / NSR	SR	NSR
Design	Design controls including design reviews and *independent* [b] 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, Control Plans (MIP), 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, Control Plans (MIP), 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.		Quality Plans, Control Plans, Certificate of Conformity according 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 measuring and test equipment (M&TE)				Controlled M&TE for validation processes
Minimum NDE (on welding) [(c-d)]	100% visual, surface and volumetric inspection and testing as *appropriate* [c]	100% visual, surface and 20% volumetric inspection and testing as *appropriate* [c]		100% visual, surface and 10% volumetric inspection and testing as *appropriate* [c]	
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
Safety Related Activities (SRA) [3]	For SIC (1 and 2): Assessment, Surveillance and Follow-up of the SRA		Limited Monitoring		No Monitoring, unless otherwise agreed between the parties

[a] To determine the grade and subsequent actions for an item or activity, first locate the appropriate risks on the matrix in Table 1. Example: Selection of any one of the four risk types in class 1 makes all the actions come from class 1.

[b] Independent means individual, groups, divisions, departments who were not involved in the original design. '*Independent*' can also mean a Third Party organization.
"The verification will take place in the course of examinations carried out by persons who did not participate directly in the performance of the study in question"
"The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the work. Verification, validation and approval shall be completed before implementation of the design"

[c] On welding where the required volumetric inspection is not practicable, reference shall be made to the specific inspection and testing requirements of the applicable Technical Specifications

[d] Permanent lifting attachments if welded must be 100% inspected using NDE before and after lifts