FUSION FOR ENERGY

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02 October 2018 / Approved

EXTERNAL REFERENCE

Quality Document

F4E-QA-115 - Supplier Project Management and Quality Requirements

This document contains the general Project Management and Quality Requirements applicable to Fusion For Energy suppliers.

Approval Process			
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Change Log			
F4E-QA-115 - Supplier Project Management and Quality Requirements (22F8BJ)			
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 HDI ITER/PO
v1.2	Signed	28 June 2010	Corrected SIC to Safety Important Class
v1.3	Approved	04 November 2010	Added I.c) on the Control Plan Added I.d) on the quality order requirements for SIC Updated: - II.4. Subcontractors Management - III.2.1 Updated format (placement of the table) – old III.12.b) Added III.1 System Compliance Part Added template for Progress Report (V.7) Added IV Control Plan requirements Replaced QRA with SRA (new approach
v1.4	Signed	30 September 2011	- Format updated (new 'Control Page') - Overall correction of typos and usage of shall and must. - Added II.1.1(a)(viii) Compliance matrix at the KOM - Added II.4. (c) witness by F4E at the subcontracting process - Updated II.10.1(g) use of MS Project - Added text for the CE marking in II.11. - Rewritten paragraph III (subdivided in 2 paragraphs). - Added III.1.3 iv) acceptance requirements review. - Renamed III.2.1. to Contract Implementation and 'III.2.1.1. Objectives and Activities' and added the 'III.2.1.2 Management of the Contract" - Added III.2.6(a)(v) request for CV's. - Added III.2.7(a)(v) subcontractor assessment form. - Rewritten III.2.8(iv) to add dedicated time to the task. - Corrected title of III.2.11 to 'Incoming Items Requirements'. - Added IV.3 Control Plan process figure. - Added IV.4 'Markings in Use'.
v1.5	Signed	04 October 2011	- Changed title of II.3.1 - Added II.3.2 CAD Specific requirements
v1.6	Approved	05 October 2011	Format correction.
v1.7	Signed	25 November 2011	Updated sec II.2 and II.2.1 to include amendments to contracts
v1.8	Signed	30 November 2011	Changed 'subject matter' to 'scope' in II.2.1.(a)(iii).
v1.9	Approved	02 December 2011	Small reformulation of clause II.2.1.(a)(iii) as request from the legal team.
v2.0	Approved	15 June 2012	Full document update, changes are concentrated in: - I.Introduction – paragraph (e) as a reminder that the supplier must comply with the law - II.2. Deviation and Nonconformity Management – added paragraph (c)(ii) to specifically name the safety requirements - II.2.2 Nonconformity Management - as requested by Regulator (already have concurrence from IO) - II.5.3. Staff Qualification – removed NQA-1 qualification, added welding supervision staff and paragraph (c) for quality coordination. - II.5.5 Welding – new section with the clarification of the standard requirements - II.5.6 Validation of Analysis and Calculations Software – new section with the standard requirements - II.6. Acceptance of a Deliverable – (b)(iii) difference between contract and technical deliverables - II.11. Licensing Requirements – include the quality order (a) and (b). - II.12. Confidentiality – new section with the standard requirements, includes contact with media - III.2.8.1. Validation of Analysis & Calculations Software – updated to match II.5.6 - V.3. Nonconformity Report – updated to match II.2.2
v3.0	Signed	14 August 2013	- Overall - format update to match DOORS and requirement ID // Overall - replace Quality Order 10/Aug/1984 by the INB Order 07/Feb/2012 // Abbreviations - adapt the relevant acronyms and definitions // 2.1.5 - add section 2.1.5 Acceptance Data Package // 2.2 - clarification of specific requirements and nonconformity actions // 2.2.1 and 2.2.2 - include the mandatory flow for Deviations and Nonconformities // 2.2.2 - include the root cause requirement and the specific requirements for closure of an NCR // 2.3 - update section with requirement for revised documents // 2.5.4 - add section:

			Metrology // 2.6 - clarification of section acceptance of deliverable // 2.11 - update and clarification of section and include subsection CE Marking - 2.13 - add section: Comunication Methods and Signatures // 3.2.8.3 - add section: Measuring and Test Equipment // 3.2.14 - clarification of secction Codes (Regulatory Documents) and Standards // 3.2.16 - rename to Traceability // 5.3 - update nonconformity Report template Document generated from DOORS 9.5.1 to Word 2010 with IRDRMFAO 6.1.0.3. Statistics: this version of the specification contains 225 requirements
v3.1	Signed	16 August 2013	minor corrections of the format due to the DOORS conversion. Document generated from DOORS 9.5.1 to Word 2010 with IRDRMFAO 6.1.0.3. Statistics: this version of the specification contains 223 requirements
v3.2	Approved	18 September 2013	Reference Documents - corrected hyperlink to INB Order | corrected day in 2.2.2 (REQ0038) from 27 to 07 | added reference to frequency of update of the Risk Plan in the 2.1.1 | in 2.6 (REQ0098) added option for ADP to be submited after despatch | In 2.7 (REQ0101) specified that the Risk Plan is submitted with the Quality Plan. Document generated from DOORS 9.5.1 to Word 2010 with IRDRMFAO 6.1.0.3. Statistics: this version of the specification contains 223 requirements.
v4.0	Signed	14 August 2014	- Correction all over the document: the usage of PIC vs SIC and PIA vs SRA - Reference Documents (added PIA guideline and QA-113) - Updated definitions (PIC, PIA, Subcontractor) - Corrected many phrases from compliance with INB Order to propagation of the requirements - Included Nuclear Safety File in the Final Report (REQ0012) - Detailed that PIA must be independently verified (REQ0224) - Included Deliverable Acceptance Flow, for clarification - New Section 2.14 Nuclear Safety File - Clarification on Subcontracting Schedule and the lower tiers supply-chain - Updated the Control Plan Flow with more detail, for clarification - Update of templates: Control Plan (PIC/PIA usage), Documentation Schedule (deliverable and cat), Subcontracting Schedule (all tiers and references) Document generated from DOORS 9.5.1 - this version of the specification contains 225 requirements.
v4.1	Approved	02 October 2014	Correction of small typos and separation of definition of Critical and Major activity from Subcontractor
v4.2	Approved	11 December 2015	Integration of the "ITER Policy on Safety, Security and Environment Protection Management" | EVM terms and definitions | Full update of the Reporting on Intellectual Property section | Deviations and Nonconformities sections for the online registry and processing | Documentation review cycle with the documents submitted by F4E to Supplier | Update the PIAs requirements | Full update of the Verification and Validation of Calculation and Modelling tools sections | Update of the CE Marking section | Update of the Dual-Use Items/Technologies section | Update of the Mandatory forms section.
v4.3	Signed	07 June 2016	Definition of ADP and removal of pro-forma from requirement| Remove Major Activities (subcontracting)| Rewording of Deviation Management (2.2.1) | Inclusion of Subcontracting Acceptance Form to perform assessment (2.4, 3.2.7)| added Change in Subcontracting flow (2.4) | Update Deliverable Acceptance Flow and the use of release note (2.6) and flow | Updated Deviation Request and Release Note forms (5.2, 5.6). Document generated from DOORS - this version of the specification contains 225 requirements.
v4.4	Approved	13 June 2016	Short update of 4.3 top include some corrections from Legal: ADP definition, RN definition, 2.6 clarification of 'cleared' and of 'ready'.
v5.0	In Work	10 August 2018	- New structure to easily identify applicability; - Removed specific disciplines requirements and transferred to dedicated applicable documents (Nuclear Safety, Design Analysis, Metrology and RMV); - Processes and flowcharts removed to allow Supplier to work according its Quality Management System; - Concepts and terminology clarified in a dedicated Definition section; - 62 requirements removed or moved to Definition section (see Annex 1 for requirements cancelled from previous version); - Requirements rewritten according to ISO suggestions to increase clarify and simplicity with the aim to improve the understanding and the implementation (see Annex 1 for compliance matrix between previous and current version); - New requirements added based on: □ - IO new processes □ - F4E new processes □ - Quality Technical requirements

v5.1	Signed	13 August 2018	Final editorial revision
v5.2	Signed	27 August 2018	Final version after review. Total requirements removed from version 4.4: 49
v5.3	In Work	01 October 2018	Broader approach removed from the scope of applicability
v5.4	Approved	01 October 2018	Broader approach removed from the scope of applicability
v5.5	Approved	02 October 2018	Change on AD07 title

QA SPECIFICATION

Control Page

idm@F4E ref:	F4E_D_22F8BJ	Date:	2 October 2018

Document title:	Supplier Project Management and Quality Requirements (QA-115)

Areas and functions	
Document Ownership:	F4E Director
Area(s) concerned:	F4E Manual (Operational)
Function(s) concerned:	All Operational Roles, in particular during the contract implementation: • The Technical Project Officer for the follow-up of technical, management and quality requirements. • The Procurement Project Officer for the follow-up of the commercial requirements. • The QA Officer for follow-up of any quality issues. • F4E Suppliers and supply chain

Purpose

The purpose of the **F4E-QA-115 Supplier Project Management and Quality Requirements** is to define contract management and quality requirements to be considered by Tenderers and implemented by Suppliers providing services/supply goods to Fusion for Energy to ensure the compliance of the contract management and quality requirements of the deliverables.

This document has been developed based on the F4E QA Programme approved by IO (EUDA QA Programme for ITER Project - AD 25) and other input documents identified in section Applicable and Referenced Documents.

Scope and Applicability

This document is applicable to all the contracts for which the purpose is the delivery of services, works and components as a contribution to the ITER Organization.

For contracts including Protection Important Components and/or Activities in the meaning of the French Order of 7 February 2012 -–([FR]: “République Française - Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base”), AD 01 is also applicable in complement to this document.

The applicability of sections/requirements of this document depends on the scope and Quality Class of the Contract, and is defined during the preparation of Tender documents in the Management Specification (Annex A).

The F4E-QA-115 Supplier Project Management and Quality Requirements applies to the whole supply chain if not expressly waived by F4E.

F4E-QA-115 is a top level document which includes the main Project Management and Quality Requirements. Requirements in this document are complemented by dedicated documents for specific disciplines; these documents are referred in the text. The F4E supplier requirement documents structure and organization is shown in Figure 1.

The terms of the Contract take precedence over the terms set out in this document and any other applicable one.

All terms and acronyms used in this document are described in the section 'Abbreviations and Definitions' for clarification purposes.

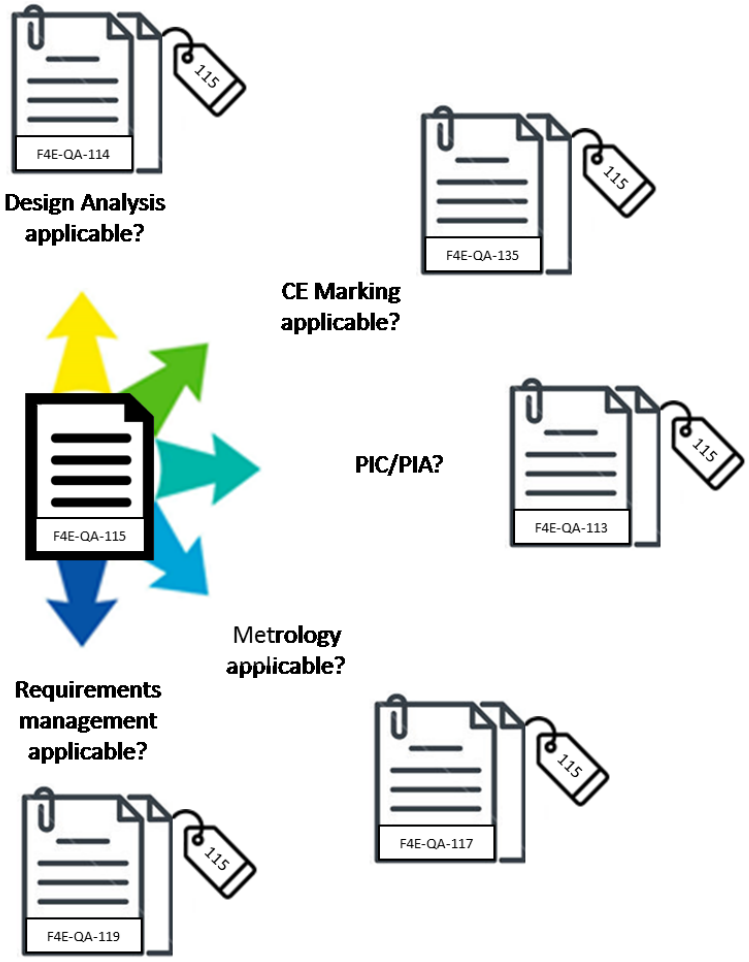


Figure 1: F4E Suppliers Requirements Organization

Table of Contents

Applicable and Reference documents

This section is divided in 3 subsections and the scope of each one is described below:

Applicable Documents:

This subsection includes documents which are referred as applicable during the text and which contain detailed requirements that complement for specific areas or disciplines, the current document requirements. The applicability level is defined in the text.

It also includes applicable regulations that contain applicable requirements not transferred to any F4E supplier requirements document.

This subsection also includes mandatory templates to be used during contract implementation.

The applicable version of documents in this section will be the one in force at the date of the signature of the contract and will be identified in the Tender documents or Contract Management Specifications (Annex A).

Reference Documents:
This subsection includes documents referred during the text which complements or expands the information of this document.

International Standards:
This subsection includes all International Standards used to develop the requirements on this document.

Applicable Documents

The following F4E Applicable documents and templates can be downloaded the following link: External Link

AD 01. F4E-QA-113 - Supplier Nuclear Safety Requirements
AD 02. F4E-QA-114 - Instructions for Contractors Performing Design Analysis
AD 03. F4E-QA-117 - F4E Dimensional Metrology Handbook
AD 04. F4E-QA-119 - Requirements Management and Verification (RMV)
AD 05. F4E-QA-135 - Supplier CE Marking Requirements
AD 06. F4E CAD Manual
AD 07. F4E-QA-111 - Supplier Risk and Opportunity Management Instruction
AD 08. Deviations and Contract Modifications Portal (DACC) – Rules of Use
AD 09. F4E-Supplier Documentation Exchange
AD 10. Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006
AD 11. Restriction of Hazardous Substances Directive 2002/95/EC, (RoHS 1)
AD 12. Configuration and Documentation List Template
AD 13. Management and Manufacturing and Inspection Plan Template
AD 14. Declared Components List – DCL Template
AD 15. Declared Materials List - DML Template
AD 16. Declared Mechanical Parts List - DMPL Template
AD 17. Declared Processes List - DPL Template
AD 18. FMEA / FMECA Template
AD 19. P-FMEA / P-FMECA Template
AD 20. Control Point Notification Template
AD 21. Release Note / Certificate of Conformance Template
AD 22. Requirements Propagation Matrix Template
AD 23. Risk Register Template
AD 24. Supply Chain Acceptance Register Template
AD 25. F4E-QAP-ITER - EUDA QA Programme for ITER Project

Reference Documents

RD 01. Machinery Directive 42/2006/CE
RD 02. Electronic signatures Directive 1999/93/EC

RD 03. Dual-use trade controls Regulation (EC) No 428/2009
RD 04. Management Specification – Contract Annex A
RD 05. Technical Specification – Contract Annex B
RD 06. Inspection Plan (IP) Template
RD 07. Requirements for Producing a Quality Plan
RD 08. Critical-item control ECSS-Q-ST-10-04C
RD 09. Verification ECSS-E-ST-10-02C
RD 10. ITER Procurement Quality Requirements
RD 11. IP provisions for model contract
RD 12. Requirements for Producing and Inspection Plan
RD 13. F4E Design Review procedure
RD 14. F4E Manufacturing Readiness Review procedure
RD 15. F4E General Tender Conditions
RD 16. IAEA Competency Assessments for Nuclear Industry Personnel
(https://www-pub.iaea.org/MTCD/publications/PDF/Pub1236_web.pdf)

International Standards

RS 01. ISO 9001 Quality Management Systems Requirements
RS 02. ISO 10007 Quality Management Systems – Guidelines for Configuration Management
RS 03. EN9223 Programme Management. Configuration Management. Configuration identification
RS 04. EN ISO 14731 Welding coordination - Tasks and responsibilities
RS 05. EN ISO 9712 Non-destructive testing. Qualification and certification of NDT personnel
RS 06. EN 10204 Metallic products/types of inspection documents
RS 07. ISO 5807 1985 Information processing Documentation symbols and conventions for data, program and system flowcharts, program network charts and system resources charts
RS 08. Council Regulation (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
RS 09. ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
RS 10. MIL-HDBK-338B Electronic Reliability Design Handbook
RS 11. MIL-STD-1629A Procedures for performing a failure mode, effects, and criticality analysis

Abbreviations and definitions

Term	Definition	Abbreviation
Acceptance	Acknowledgement that a product, deliverable or document is in compliance with the contractual requirements. No obligation and/or responsibility of the Supplier under a Contract are released until Final Acceptance. Note: Approval of any delivery or document by F4E by means of other conditions of those ones defined in the contract, does not constitute an acceptance.	ACC
Acceptance Data Package	Collection of documents delivered by the Supplier at any payment milestone that declares and demonstrates the conformance of the deliverable in all respect with the applicable specification(s), drawing(s) and all requirements. Contents of the ADP is defined in the DRD in section 8.5. Note: Acceptance Data Package replaces Final report, Manufacturing Dossier. Documents included in the previous Final report and Manufacturing Dossiers shall be included directly in the Acceptance Data Package.	ADP
As Low As Reasonably Achievable	Term used in risk management to declare that a residual risk of failure shall be reduced as far as reasonably practicable. For a risk to be considered ALARA, it must be possible to demonstrate that the cost involved in reducing it further would be grossly disproportionate to the benefit gained.	ALARA
Audit	Systematic, independent and documented process for obtaining evidence and objectively evaluating it to determine the extent to which the audit criteria are fulfilled. Source: adapted from ISO 9000:2015	
Baseline	Set of information which describes exhaustively a situation at a given instant of time or over a given time interval. Note: A baseline is generally used as a reference for comparison with and analysis of subsequent evolutions of the information. Source of the definition: adapted from ISO 10007:2003	
Certification Body	Organization that has been accredited by an EU Member State to assess whether a product meets certain preordained standards.	
Cleanliness	Degree to which the Supplier organisation keeps working premises clean and organised accordingly to the recognised industry standards or contract requirements.	
Cleanliness level	Level or quantity of any unwanted molecular or particulate matter (including microbiological matter) on the surface or in the environment of interest, that can affect or degrade the relevant performance or life time of the item.	
Commercial off-the-shelf items	Products/services available on the market that satisfies the requirements without the need to procure custom-made or bespoken solution.	COTS
Concession	Permission to use or release a product that does not conform to specified requirements. Note: Generally limited to the delivery of the product that has nonconforming characteristics within specified limits for an agreed time or quantity of that product. Source: ISO 10007:2003	
Configuration	Interrelated functional and/or physical characteristics of a product defined in configuration documents subject to configuration management. Adapted from ISO 10007:2003 and EN9223.	
Configuration and Documentation list	List of documentation deliverables as per template AD 12, which allows to control the configuration baseline and retrieve the history of revisions of the document. Note: Previously referred as the Documentation Schedule.	
Configuration Baseline	Approved status of requirements and design of a product at a project key milestone that serves as a reference for activities throughout the life cycle of the	

Term	Definition	Abbreviation
	product Adapted from ISO 10007:2003 and EN9223.	
Configuration control	Coordinated activities for controlling modifications to a configuration baseline. Adapted from ISO 10007:2003 and EN9223.	
Configuration identification	Coordinated activities to establish rules for configuration item selection, configuration baseline content definition, and product and document identifiers definition. Adapted from ISO 10007:2003 and EN9223.	
Configuration item	Any hardware software, processed materials, services or its discrete portions representing a separable entity that implements at least on end use function, designated for and treated as a single entity in the configuration management process. Adapted from ISO 10007:2003 and EN9223.	
Configuration management	Activity for establishing and maintaining consistent records of the performance parameters of a product and its functional and physical attributes compared to product design and operational requirements. Adapted from ISO 10007:2003 and EN9223.	
Configuration status accounting	Formalized recording and reporting of product characteristics and configuration information, the status of applicable changes and the status of their implementation. Adapted from ISO 10007:2003 and EN9223.	
Contract	An agreement concluded between F4E and a Supplier selected following a procurement procedure to obtain the supply of goods, the execution of works or the provision of services. In the context of F4E QA-115 the term "Contract" also refers to grant agreements.	
Control Plan	The list of the activities that provide evidence that all contractual management and/or quality activities have been properly executed and checked. F4E defines 2 types of Control Plans:	CP
	Management Control Plan (MCP) is the list of main management/technical activities. It applies to all type of contracts and covers all the phases including Design and Analysis. Examples of inputs for the MCP: the delivery of documentation related to design, procurement, design reviews, qualification status, key milestone deliverables, end of contract deliverables, shipping, etc.	MCP
	Manufacturing and Inspection Control Plan (MIP) is the list of activities directly related to the follow-up and verification of the quality and/or safety of the final product(s) and/or service(s) in the frame of prototyping, qualification and manufacturing activities. Examples of inputs for the MIP: the output of FMECA, output of Critical Quality items/activities list, Qualification Activities, Test Plan, Inspections, manufacturing procedures. Note: In former document version Management Control Plan was named Top Level Control and Manufacturing and Inspection Control Plan was named Phase Control Plan	MIP
Control Points	The following types of Control Points are authorized to be used in the Control Plans: Hold Point (HP/ATPP): Identifies an operation/activity after which works cannot proceed without a formal clearance by F4E by means of an Authorization to Proceed Point (ATPP). The CP is signed before the continuation of the related activities.	HP/ATPP

<table>
<tr><th>Term</th><th>Definition</th><th>Abbreviation</th></tr>
<tr><td></td><td><u>Notification Point (NP/W):</u> Identifies an operation/activity that must be notified in advance to F4E for potential witnessing (W). This inspection point does not affect the normal activities flow.
Template on section 9.9 shall be used for the notification.</td><td>NP/W</td></tr>
<tr><td></td><td><u>Review:</u> Identifies a document or report that must be reviewed and accepted. Can be performed at any moment without interrupting the production flow.</td><td>R</td></tr>
<tr><td></td><td>The following 3 schemes/combinations are allowed to be included in the Control Plans:
Option 1: HP/ATPP
<table><tr><td colspan="2">Verification</td></tr><tr><td>Supplier</td><td>F4E</td></tr><tr><td>HP</td><td>ATPP</td></tr></table>
Option 2: NP/W
If F4E decides to witness the activity
<table><tr><td colspan="2">Verification</td></tr><tr><td>Supplier</td><td>F4E</td></tr><tr><td>NP</td><td>W</td></tr></table>
Option 3: NP/-
If F4E decides <u>NOT</u> to witness the activity
<table><tr><td colspan="2">Verification</td></tr><tr><td>Supplier</td><td>F4E</td></tr><tr><td>NP</td><td>-</td></tr></table>
Note 1: The definition of Witness points are reserved for F4E/IO
Note 2: Where R is used for Radiography, this means that actual radiographs must be checked as well as the reports
Note 3: Control points and Intervention Points are equivalent terms
Note 4: The ‘-‘ identification in the Control Plan is mandatory in case of Option 3
Source of the definition: adapted from “Inspection Plan (IP) Template” (RD 06)</td><td></td></tr>
<tr><td>Corrective action</td><td>An action to eliminate the cause of nonconformity and to prevent recurrence.
Source: ISO 9000:2015</td><td>CA</td></tr>
<tr><td>Critical path</td><td>The longest path through a network of activities, which in-turn, determines the shortest time possible to complete all tasks in the project.</td><td></td></tr>
<tr><td>Critical Quality item/activity</td><td>Any activity or operation that if not performed correctly may affect safety, functionality or reliability.
In the context of this document, definition is complemented as follows:
An item/activity is critical if major difficulties or uncertainties are expected in the procurement, manufacturing, assembly, inspection, test, handling, storage and transportation that have the potential to lead to a major degradation in the quality of the product.
Examples of critical activities (not exhaustive list):
PIC/PIA as per definition in AD 01
Components, material and processes new or not qualified or not validated for intended application
Special process
An item design performance of which is difficult to demonstrate
Item not meeting the applicable failure tolerance requirement
Item constituting a residual single-point failure (SPF)</td><td>CIA</td></tr>
</table>

Term	Definition	Abbreviation
	• Limited-life and limited-cycle item (item with useful life duration or operating cycle's limitation; item prone to wear out, drift or degradation below minimum required performance in less than the storage and mission time) • Long-lead items (adverse impact of item procurement on project schedule) • Item with a known history of failures • Item highly sensitive to manufacturing processes • Use of unknown or new technologies • Items or functionalities that cannot be checked and tested after integration • Item requiring special handling procedures Source: Definition from Requirements for Producing a Quality Plan (RD 07) and ECSS-Q-ST-10-04C.	
Customer Critical Requirements	Requirements defined by the Customer which affect to the following aspects: • Performance • Safety • Environment • Regulatory • Reliability • Operability • Traceability • Interchangeability Note: In this definition Customer should be understood as IO (F4E Customer) Source: IO definition	
Deliverable	Tangible or intangible good or service produced as a result of a contract signed with F4E. A deliverable could be hardware, documentation, a software product, etc.	
Dependability	Measure of the degree to which an item is operable and capable of performing its required function at any (random) time during a specified project life-cycle profile. Note: Includes Reliability, Availability, Maintainability and Safety. Often also shorted as RAMS or RAMI. Source of the definition: RS 10	
Deviation	Permission to depart from the originally specified requirements of a product prior to realization. Note 1: Deviation permit is generally given for a limited quantity of product or period of time, and for a specific use. Note 2: Modification of administrative provisions having no impact on technical, safety, financial or overall schedule may be performed through an exchange of letters in certain circumstances (no deviation needed in that case). Source of the definition: ISO 9001 and AD 08	
Deviations and Contract Modifications Portal	Electronic Platform developed by F4E for managing Deviations, Amendments and Contract Changes with Suppliers and to process commercial operations in accordance with the Contract (e.g. Release of options, Indexation). Approval of documents in DACC is legally binding. Source of the definition: AD 08	DACC
Document Requirement Description	Mandatory list of contents specifying the minimum information to be included into the document for completeness. Note: There is no template to be followed, but each item from the list shall be addressed.	DRD
Document revision/version	Change in the content of document: • Major change indicates significant or multiple content changes (e.g. new section, change of the contents) is denoted as: v1.0, v2.0 etc. • Minor change indicates small changes in the content (e. g. typos, clarifications, change of reviewer) is denoted as: v1.1, v1.2 etc.	
Document Status	Document Status when activities can NOT proceed, if proceed is under Supplier	

Term	Definition	Abbreviation
	own risk: • Under Review – Document under F4E review • Revision Required - Document not accepted. New version requested • Received – Document is received by F4E • Rejected or Rejected with comments – Document rejected • Disapproved – Document is not accepted Document Status when activities can proceed: • Accepted – Document accepted • Accepted with comments – Document accepted. Comments must be implementation as soon as possible • Requested for obsolete – F4E requests to set the document as Obsolete • Obsolete – Document obsolete Source: Documentation Exchange Portal (Contract Tracker/CTS)	
Documentation Exchange Portal (Contract Tracker)	F4E application used to manage the contract and to exchange and trace documents, correspondence and meetings between F4E and the Supplier. Source: Adapted from F4E-Contractor Supplier Documentation Exchange	CTS
Dual-Use Items/ Technologies	Items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices. Note: Dual-Use Items is defined and regulated Regulation (EC) No 428/2009	DU
Earned Value Management	Project management technique to control the time and cost performance of a project/contract (based on the comparison of worked performed and work planned) and to predict the final project duration and cost.	EVM
Economic Operator	Any natural or legal person, public entity or group thereof that offers products, services or works to F4E.	
Electrical, Electronic and Electromechanical	Electrical, Electronic and Electromechanical part intended for use in ITER project	EEE
End user certificate	Document used in international transfers to certify that the buyer is the final recipient of the materials, and is not planning on transferring the materials to another party. Note: Any additional/new transfer shall be stated in the end user certificate	EUC
Failure Mode and Effects Analysis	Step by step approach for identifying possible failures in design, manufacturing or assembly process or a product or service, including the corresponding effects and mitigation actions.	FMEA/ FMECA
Fusion for Energy	The European Joint Undertaking for ITER and the Development of Fusion Energy.	F4E
International Traffic in Arms Regulations	United States regulatory regime to restrict and control the export of defense and military related technologies to safeguard United States national security and further United States foreign policy objectives.	ITAR
IP/IPR	Intellectual Property or Intellectual Property Rights.	IP or IPR
ITER Organization	ITER Organization - The ITER International Organization. F4E Customer.	IO
ITER Task Agreement	Contract related to the design, analysis or research activities carried out on behalf of IO concerning components for which the maturity level to be reached before the related PA signature has not been achieved and whose development is allocated to a Domestic Agency. Source: F4E manual	ITA
Kick-off-Meeting	First meeting where F4E and Supplier project teams define the baseline and rules	KoM

Term	Definition	Abbreviation
	for the execution of the contract. Mandatory starting points before any other contractual activities are initiated.	
Manufacturer	Entity that makes a good through a process involving raw materials, components, or assemblies, usually with different operations divided among different workers. Source of the definition: http://www.businessdictionary.com/definition/manufacturer.html	
Manufacturing flowchart	Graphical representation of the definition, analysis, or method of solution of a problem in which symbols are used to represent operations, data, flow, equipment, etc. 2 different manufacturing flowcharts are requested for serial production: • Macro: Contract level including all involved premises in the contract and logistics between activities • Micro: Activities inside each one of the premises described in Macro at work-station level Source: RS 07	
Manufacturing plan	Planning of manufacturing/production resources, which include the allocation of activities, employees, materials and other production capacity necessary to meet contract requirements.	MPL
Nonconformity	Any condition that does not comply with a specified requirement. A Nonconformity can be classified as: • A Major Nonconformity is a non-compliance to the Customer Critical Requirements (see Customer Critical Requirements definition). Could be understood also as non-compliance with HIGH risk to compromise the output/product/deliverable, in terms of quality, safety, cost and/or schedule and directly affecting to ITER reactor parts. • A Minor Nonconformity is a non-compliance to the Non-critical requirements Could be understood also as non-compliance with LOW risk to compromise the output/product/deliverable in terms of quality, safety, cost and/or schedule and directly affecting to ITER reactor parts. • A Relevant Nonconformity is a non-compliance to F4E requirements which has no impact on Customer's requirements and does not affect directly to ITER reactor parts.	NC
	Internal Non Compliance is a non-compliance to Supplier's internal quality management system requirements or any self-imposed requirements which potentially could affect F4E product or deliverable. Source: IO Procedure for management of Nonconformities and PM-35 Nonconformity control	INC
Nonconformity Report	Document detailing a nonconformity.	NCR
Notified Body	Technical organization approved in an European Union state, either for approval and monitoring of the manufacturer's quality assurance system or direct product inspection for the manufacture of Pressure Equipment. Source of the definition: RD 12	NB
Nuclear Operator	The Nuclear Operator of the ITER Project is ITER Organization. Licensee (fr. "Exploitant") natural or legal person operating a basic nuclear installation, whether its situation is in order or not, or having made a creation authorization application provided for by article L.593-7 of the environment code with a view to operation such an installation (Order of 7 February 2012, Article 1.3.).	NO

Term	Definition	Abbreviation
	Source: INB Order	
Nuclear Safety	The set of technical provisions and organizational measures related to the design, construction, operation, maintenance, shutdown and decommissioning of basic nuclear installations, as well as the transport of radioactive substances which are adopted with a view to preventing accidents or limiting their effects Note: Supplier Nuclear Safety requirements are described in the complementary document AD 01 Source of the definition: Article L.591-1 of the Environmental Code	NS
Phase Gate Review	Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives. This activity is considered a Hold Point and shall be indicated in the Control Plan and Time Schedule. Types of reviews:	
	Conceptual Design Review (CDR): Examination of the functional and performance requirements defined for the system and the preliminary program or plan to ensure that the requirements and the selected concept will satisfy the project.	CDR
	Preliminary Design Review (PDR): Demonstration that the preliminary design meets all system requirements with acceptable risk and within the cost and schedule constraints and establishes the basis for proceeding with detailed design. It will show that the correct design options have been selected, interfaces have been identified, and verification methods have been described.	PDR
	Final Design Review (FDR): Demonstration that the maturity of the design is appropriate to support proceeding with full-scale fabrication, assembly, integration, and test. FDR determines that the technical effort is on track to complete the project development and operation, meeting project performance requirements within the identified cost and schedule constraints.	FDR
	Manufacturing Readiness Review (MRR): Confirmation that the production baseline (process, documentation, planning, resources, qualification status etc.) is mature enough to authorize the start the manufacturing activities.	MRR
	Test Readiness Review (TRR): Demonstration that the test article (hardware/software), test facility, support personnel, and test procedures are ready for testing and data acquisition, reduction, and control.	TRR
	Delivery Readiness Review (DRR): Acceptance of the delivery after the entire work is completed, tested and inspected in accordance with the contract requirements.	DRR
Piping and Instrumentation Diagram	It is a detailed diagram showing the piping and vessels in the process flow, together with the instrumentation and control devices.	P&ID
Plan Particulier de Sécurité et de Protection de la Santé	Plan carried out by companies working on a construction site which is submitted to the Health and Safety Coordinator (SPS Coordinator) with a view, in particular, to the implementation of the general safety and health protection coordination plan.	PPSPS
Procurement Arrangement	Agreement that provides the legal basis and formalizes the procurement packages between ITER IO and F4E in order to provide in-kind components to ITER IO for the ITER project. Source: F4E Manual	PA
Project Quality Management Plan	Document describing the management system developed, implemented and maintained by the Supplier throughout the life-cycle of the Contract to ensure that the Contract Requirements are met and that evidence of such compliance is maintained.	PQMP
Protection Important Activities	Activity important for protecting the interests mentioned under Article L. 593-1 of the Environmental Code (nuclear security – i.e. nuclear safety, radiation	PIA

Term	Definition	Abbreviation
	protection, the prevention and fight against malicious acts, and also civil security actions in the event of an accident –, public health and sanitation or protection of nature and the environment), i.e. activity participating in the technical or organizational provisions mentioned in the second paragraph of article L. 593-7 of the environment code, or that could affect them. Note: Requirements for PIA are described in the complementary document AD 01 Source: As per article 1.3 of the INB Order	
Protection Important Component	Component which is important for protecting the interests mentioned under Article L.593-1 of the Environmental Code (nuclear security – i.e. nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil security actions in the event of an accident –, public health and sanitation or protection of nature and the environment), i.e. structure, equipment, system (programmed or not), material, component or software that is present in the basic nuclear installation or that is under the responsibility of the operator and that implements a function required for the demonstration mentioned under the second paragraph of Article L. 593-1 of the Environmental Code (safety demonstration) or that ensures that this function is implemented. Note: Requirements for PIC are described in the complementary document AD 01 Source: As per article 1.3 of the INB Order	PIC
Qualification	Process of assurance that the specific item (process, material, system, equipment…) is able to achieve the predetermined acceptance criteria to confirm the attributes of "fit/ready for intended use". The demonstration that the design (product/process) meets specified requirements. Source of the definition: adapted from RD 09	
Qualification Status List	Summary of the status achieved with respect to the planned qualification per each configuration item.	QSL
Quality Assurance Officer	Project team member responsible for the implementation of Quality Assurance Requirements of the Procurement Arrangement and verification of the implementation by the Supplier of Quality Assurance Requirements of the Contract. Note: Reserved for F4E staff	QAO
Quality Representative	Supplier project team member responsible for the implementation of Quality Assurance Requirements of the Contract. Note: Reserved for Supplier staff	QR
Raw Material	Basic substance in its natural, modified, or semi-processed state, used as an input to a production process for subsequent modification or transformation into a finished good.	
Raw Material Certificate	Document certifying that all the specified requirements of the material specification are fulfilled.	RMC
Release Note / Certificate of Compliance	First page of the Acceptance Data Package (duly signed by the Contractor) certifying that the supplied goods or services meet the requirements of contractual specifications and deliverables listed in the Release Note has been previously cleared by F4E.	RN/CoC
Remedial Action	Action taken to address the nonconformity condition and to restore the conformance of the item, meanwhile the root cause is identified and the corrective actions defined. Examples: Rework, repair, use as is etc.	RA
Report Date	The one on which the schedule status is being determined. For initial schedules it is the project commencement date; For schedule updates it is the reporting period cut-off date. Updated schedules depict the actual status of works done up to the reporting period. Note: Known as Data Date for Primavera users.	

Term	Definition	Abbreviation
Requirements Management and Verification	Process consisting on: • Tracking the development of the requirements • Verifying that the final design complies with requirements • Verifying that each manufactured product complies with requirements	RMV
Risk/Opportunity	An action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Source of the definition: RS 01 Note: previously referred to as "Preventive Action"	
Series/serial production	Manufacturing of more than 10 identical final products (to be delivered to F4E) based on the same design and following the same manufacturing route	
Single-point failure	The failure of an item which can result in the failure of the system and is not compensated for by redundancy or an alternative operational procedure. Source of the definition: RS 11	SPF
Software	A part of a computer system that consists of data or computer instructions, in contrast to the physical hardware from which the system is built	SW
Special Process	A process where the conformity of the resulting product cannot be readily or economically verified. Source of the definition: RS 01 The following processes are considered Special Processes (not exhaustive list): • Brazing, Welding and Filling (including repairs) • Non Destructive Testing / Examination (NDT / NDE) • Thermal treatments • Paint coating • Passivation • Chemical cleaning, linings and other process that may sensitize the materials	
Specified requirement	Singular documented physical or functional need that a particular design, product or process aims to satisfy. Note: Contract requirements are specified in the technical and management specification (annex A and B).	
Subcontractor	Economic operator, who is not Party to this Contract and who enters into a legal commitment with the Supplier in order to perform a part of the Contract. Source of definition: F4E model contract (www.f4e.europa.eu)	
Suitably Qualified and Experienced Personnel	Term equivalent to the International Atomic Energy Agency concept of 'competence' defined as "the ability to put skills and knowledge into practice in order to perform a job in an effective and efficient manner to an established standard". Source: ref. to RD 16	SQEP
Supervision activities	Systematic activities that F4E performs to monitor the performance of the Supplier and its' supply chain during the implementation of the contract.	
Supplier	Economic operator which has concluded a Contract with F4E. Note: Term equivalent to "Contractor" in the context of this document	
Supply Chain Acceptance Register	A list of economic operators involved in the execution of the Contract at any given time during contract implementation. Note 1: the register includes all (until the last level) Subcontractors, vendors, service providers etc. involved into the execution of the contract, who's activities potentially affect the quality of the product. Note 2: Previously known as Subcontracting Schedule	SCAR
Surveillance	Control activities performed by the Nuclear Operator. Note: From the point of view of Nuclear Safety provisions this term is reserved for the activities performed by ITER Organisation.	

Term	Definition	Abbreviation
	Source: INB Order.	
Systems Engineering Officer	Project team member responsible for the System Engineering of the Contract Note: Reserved to F4E staff	SEO
Takt-Time	Rate at which a finished product needs to be completed in order to meet customer demand. Takt-Time is calculated as follows: Net time available to work / (Demand + scrap)	TKT
Task Order	Documents containing a technical description of the tasks to be implemented within a specific contract, their scope/quantities and the execution schedule. Task orders are sent to contractors in order to request their availability to perform those tasks according to the terms of an existing framework contract.	TO
Technical Project Officer	Technical Project Officer (in a Project Team or Technical Support Team) responsible for the technical aspects of the Procurement and the subsequent Contract. Note: Reserved to F4E staff	TPO
Tenderer	Economic operator who has submitted a tender in reply to a call for tender Source: RD 15	
Traceability	Ability to trace, identify and measure all the stages that lead to the particular point in the process (applicable to component, document, material etc...).	
Validation of the product	Process which demonstrates that the product is able to accomplish its intended use in the intended operational environment.	
Verification the product	Process which demonstrates through the provision of objective evidence, that the product is designed and produced according to its specifications and the agreed deviations, and is free of defects.	
Welding Procedure Specification	Formal written document describing welding procedures, which provides direction to the welder or welding operators for making sound and quality production welds as per the code requirements.	WPS
Work Breakdown Structure	Deliverable-oriented breakdown of a project into smaller components.	WBS
Works	Outcome of building or civil engineering works taken as a whole that is sufficient in itself to fulfil an economic or technical function. Note 1: Works contracts cover either the execution, or both the execution and design, of works or a work related to one of the activities referred to in Annex II to Directive 2014/24/EU of the European Parliament and of the Council (1) or the realization, by whatever means, of a work corresponding to the requirements specified by the contracting authority exercising a decisive influence on the type or design of the work Note 2: The use of the term is reserved for the contracts under the control of F4E Site, Buildings and Power Supplies team (FIDIC contracts).	

Table 1 – Abbreviations and definitions

Note: Here and below if the word or acronym is in the text, it refers back to the definition in the list above.

1 Disclaimer

F4E's acceptance of any deliverable produced by the Supplier shall not limit the Supplier's responsibility or liability for the performance of the Contract or any of its other duties, obligations and liabilities pursuant to the Contract.

2 General (GL)

2.1 General Requirements (GL)

F4E-QA-115-GL-GL-001	The Supplier shall demonstrate the fulfilment of Health and Safety regulations as required by the legislation within the country where the activities will be developed as well as any specific health and safety regulations laid down by IO for any particular task performed in ITER site.
F4E-QA-115-GL-GL-002	**For ITER Project site works:** The Supplier shall define a Health and Safety Plan (PPSPS) describing the measures to implement to ensure that the Works are managed safely. PPSPS shall be submitted for validation by F4E or IO Health and Safety Coordinator depending if the work is performed under F4E or IO coordination. Note: F4E will reply within fifteen (15) days
F4E-QA-115-GL-GL-003	PPSPS shall be accepted before starting Works.
F4E-QA-115-GL-GL-004	PPSPS shall be followed by a common inspection with the Health and Safety Coordinator.
F4E-QA-115-GL-GL-005	For all Contracts involving CE Marking and other EC/ EU Directives and/or Regulations, the Supplier shall apply the requirements as per AD 05.

2.2 Nuclear Safety Requirements (NS)

F4E-QA-115-GL-NS-001	For all Contracts involving PIC/PIA activities, the Supplier shall apply requirements of AD 01 in addition to all requirements defined in this document.

2.3 Intellectual Property (IP)

F4E-QA-115-GL-IP-001	The Supplier shall identify all results of activities undertaken in the frame of the contract that may take the form of an invention, information, trade secrets, designs, drawings, processes, software, database etc., including the creation of any IP.
F4E-QA-115-GL-IP-002	The Supplier shall inform F4E in the Progress Reports and Acceptance Data Package about any IP related information.
F4E-QA-115-GL-IP-003	The Declaration of IP foreground shall be submitted to F4E as a standalone self-explaining document as soon as foreground is created. Each item shall include a short description of the item to allow the easy understanding of its nature.
F4E-QA-115-GL-IP-004	The Supplier shall inform F4E about any IP relevant issue, such as requests for access to IP by third parties or any IP issue that may impede performance of the contract.
F4E-QA-115-GL-IP-005	The Supplier shall identify in the IP reports any confidential information to ensure the confidentiality and the proper management of strategic IP information such as trade secrets or information on patentable subject matters.

2.4 Dual Use (DU)

F4E-QA-115-GL-DU-001	The Supplier shall produce and submit to F4E at Kick-off-Meeting, a detailed list of dual-use items/technologies, specifying the following: Item reference - Description - Quantity of items - Origin - Destination - Subcontractor - Estimated export date Note 1: For the items with origin in United States, the following shall be provided: commodity classification, reference to the United States of America Authorization and eventual restrictions to the re-exports that might apply. Note 2: In case there are no Dual Use items as part of their delivery, the Supplier shall confirm it at the KoM.
F4E-QA-115-GL-DU-002	If dual-use items are provided by F4E to be handled by the Supplier, the Supplier shall provide to F4E a duly signed end user certificate (EUC) for licensing or traceability purposes.
F4E-QA-115-GL-DU-003	If the Supplier requests F4E to sign the EUC, the Supplier shall draft EUC certificate and submit it to F4E (TPO) Dual Use Officer. An English version of such EUC shall be attached if the original requested is provided in a different language.
F4E-QA-115-GL-DU-004	Intra-Community transfer or export authorization reference, when applicable, shall be provided to F4E for all the transfers of dual use components.
F4E-QA-115-GL-DU-005	Any change to the dual-use items list during the implementation of the contract shall be formalized to F4E in the next progress report (except for ITAR items, which shall be communicated as soon as possible).
F4E-QA-115-GL-DU-006	The Supplier shall physically identify the dual-use item package, indicating clearly on the first page with the "Export Control" and clearly indicating the authorization reference/ licensing authority, if applicable.
F4E-QA-115-GL-DU-007	The Supplier shall identify the dual use associated commercial documentation (like packing lists or invoices) indicating clearly "Export Control" and clearly indicating the authorization reference/ licensing authority, if applicable.
F4E-QA-115-GL-DU-008	Dual-use items related documentation shall be kept for at least 10 (ten) years from the end of the calendar year in which the export took place or the brokering services were provided.
F4E-QA-115-GL-DU-009	The documentation shall be provided, on request, to the competent authorities of the Member State in which the exporter is established or to F4E. If possible, documents containing dual use information shall be segregated from the non-controlled information and identified.

2.5 Right of Access (RA)

F4E-QA-115-GL-RA-001	The Supplier (and all the Subcontractors) shall allow to F4E authorized representatives, IO authorized representatives, Agreed Notified Bodies and other third parties as per request of F4E, unrestricted access to: - Premises, where the execution of contractual tasks takes place - All the contractual documentation, operational procedures and specifications required for the execution of the contract - All the contract performance test results, analysis and reports - Supplier's confidential intellectual property during the performance of the contract (related to the performance of the contract) - Any service or product that flow from the performance of the contract Note 1: F4E authorized representatives meaning for example auditors, inspectors and other external staff Note 2: F4E or its representatives shall be permitted to take photographs and / or video recordings of any activity related to the Contract.

F4E-QA-115-GL-RA-002	During the visit of F4E representative(s) the Supplier shall explain, in English, the contents of the internal documentation used/applied by the Supplier during the execution of the Contract.
F4E-QA-115-GL-RA-003	The Supplier shall grant F4E inspectors unlimited access to the Supplier's workshops and technical/quality documentation. F4E reserves the right to appoint inspectors to supervise the implementation of the contract in the venue of the Supplier on the base of the working calendar provided upon request. In case internal rules of the Supplier limit the access of the external staff to the premises, where contractual activities are executed, the Supplier shall appoint the permanent escort to ensure to F4E inspector access to the relevant area/documentation on request. The Supplier shall ensure that the escort will be available, whenever necessary.
F4E-QA-115-GL-RA-004	If requested, the Supplier shall provide offices inside its workshops for the inspectors, equipped with a telephone, access to printers, computer with internet access and the IT support.

3 Documentation and Information Management (DM)

3.1 Language (LG)

F4E-QA-115-DM-LG-001	The official language of any (written or verbal) formal exchange related to the execution of the Contract shall be English. Note: This includes as well all administrative and technical documentation (e.g. Curricula Vitae (CVs), raw material certificates).
F4E-QA-115-DM-LG-002	Maintenance/installation/operation manuals shall be supplied in English and in the national language of the country of final use. Note: French language is waived for items whose usage destination is the ITER site in Cadarache, France.

3.2 Exchange of Contractual Information (EI)

F4E-QA-115-DM-EI-001	The Supplier shall use F4E's Contract Tracker System (CTS) for the official communication and submission of contractual deliverables. Deliverables shall be individually uploaded.
F4E-QA-115-DM-EI-002	The Supplier shall be responsible for uploading all documentation relevant to the Contract in CTS.
F4E-QA-115-DM-EI-003	For operational communications the following channels shall be used: - Technical matters: F4E Technical Project Officer - Commercial matters: F4E Contract and Procurement Officer - Quality matters: F4E Quality Assurance Officer
F4E-QA-115-DM-EI-004	The mandatory templates listed in section 'Applicable Documents' shall be used throughout the implementation of the Contract. Note: The applicable version can be downloaded by the Supplier from F4E web-site
F4E-QA-115-DM-EI-005	Supplier shall respect the deadlines established in Contract Management Specifications (Annex A) for: - Review, comment and accept documents submitted by F4E to the Supplier - Reply or/and issue a new version on documents submitted by the Supplier and reviewed by F4E

3.3 Documentation Management System (DS)

F4E-QA-115-DM-DS-001	The Supplier shall provide evidence of the suitability, robustness, reliability and compliance to F4E requirements of its Documentation Management System in the dedicated section of PQMP. The internal document management and approval circuit shall be described.

F4E-QA-115-DM-DS-002	The Supplier shall ensure that the suitable documents and data, needed for the execution of tasks, are available at the locations where related contractual activities are performed. Note: Suitable documents meaning approved version and revision
F4E-QA-115-DM-DS-003	The Supplier shall ensure that invalid or obsolete documents and data are removed from all points of issue or use, and/or prevent the unintended use of obsolete documents.
F4E-QA-115-DM-DS-004	The Supplier shall ensure that obsolete documents and data retained for legal or knowledge preservation purposes are identified as such.
F4E-QA-115-DM-DS-005	The Supplier shall predefine types of documents or documents requiring F4E acceptance during the implementation of the contract and agree this proposal with F4E.
F4E-QA-115-DM-DS-006	Before being submitted to F4E, all documents (including drawings) and data shall be internally reviewed by skilled individuals not involved in their drafting and approved by an authorized person. Evidence of the independent verification and approval shall be clearly identified in the document. Note: Author/co-author and reviewer cannot be the same person.
F4E-QA-115-DM-DS-007	The Supplier shall establish and maintain records to provide objective evidence of complete and successful performance of all contract tasks and to demonstrate compliance with requirements.
F4E-QA-115-DM-DS-008	Upon the completion of the Contract, the Supplier shall at its own cost, store all documents related to the Contract for an initial period of ten (10) years (or the period required by the applicable law, whichever is longer) after the payment of the final balance of the Contract price.
F4E-QA-115-DM-DS-009	The Supplier shall store contract documentation in a suitable environment to minimize deterioration or damage and prevent loss.

3.4 Document Requirements (DR)

F4E-QA-115-DM-DR-001	The Supplier shall describe in the PQMP the numbering convention used for the contract documentation. The structure for the document code shall be the following: *Organization - Contract# – Type – Sequential# – Version – FREE* Where: - Organization – acronym of the entity issuing the document (eg. BMO: Business Management Organization) - Contract# - contract code (eg. OPE-484) - Type – acronym for the type of document as per Annex 2 - Sequential# – three-digit sequential number starting with 001 - Version – version/revision starting by 1.0 - FREE – Space free to complement with any other text considered necessary or agreed with F4E *Example: BMO-OPE-484-VCD-001-v1.0* Note 1: Author acronym is not needed/requested for PQMP at tender phase. Entity acronym will be provided at the KoM. In that case tenderer can use its name instead. Note 2: If new types of documents are identified additionally to Annex 2, acronym to be used shall be described in the PQMP. New acronyms defined shall not coincide with anyone identified in Annex 2.
F4E-QA-115-DM-DR-002	Each document shall have a unique document code.
F4E-QA-115-DM-DR-003	The unique document code shall not be reused in case of the cancellation of the document.
F4E-QA-115-DM-DR-004	The Supplier shall ensure the consistency of the title and identification/coding of all activities in the different documents Example: consistency between the title/coding in the Schedule and in the Control Plan
F4E-QA-115-DM-DR-005	Supplier technical and quality documents shall include table of contents, bookmarks and change log at the beginning of the document with: - Identifications of the changed Sections/Paragraphs/Chapters - Short description of the changes (e.g. first issue, internal reviews, F4E reviews etc.)

<table>
<tr><td>F4E-QA-115-DM-DR-006</td><td>At least, the following information shall be included in the cover page of all technical and quality documents:
- Author name, position, signature and date
- Reviewers names, position, signature and date
- Approver name, position, signature and date
- Document code (as per requirement F4E-QA-115-DM-DR-001)
- CTS reference
- IO PA/ITA reference
- Contract title
- Quality class</td></tr>
<tr><td>F4E-QA-115-DM-DR-007</td><td>The code, title and the page number (indicating the total number of pages) shall appear on each page.</td></tr>
<tr><td>F4E-QA-115-DM-DR-008</td><td>Title of the document and of the file shall be self-explanatory of the content.
Note: Acronyms are allowed only in the case that title and file includes also the complete description</td></tr>
<tr><td>F4E-QA-115-DM-DR-009</td><td>Methods applied to mark changes made in documents shall be describe in the PQMP, options could be chosen between highlighted text, written in different colour or change bars or other (to be described).
Changes in drawings, diagrams, etc. shall be identified by the use of red clouds.</td></tr>
<tr><td>F4E-QA-115-DM-DR-010</td><td>The exchange and delivery of any communication or official documentation (through CTS) related to the contractual activities, in electronic format shall comply with the electronic document file formats shown in the table below.
<table>
<tr><th>Document Type</th><th>Format</th></tr>
<tr><td>Text document</td><td>pdf</td></tr>
<tr><td>Spread sheet</td><td>pdf</td></tr>
<tr><td>CAD models</td><td>dwg/dxf/stl/dgn</td></tr>
<tr><td>CAD drawings</td><td>pdf</td></tr>
<tr><td>Schedules, Programmes & Plans</td><td>xer/mpp</td></tr>
<tr><td>Scans and pictures</td><td>jpg/ png/ tiff</td></tr>
<tr><td>Video footage</td><td>avi/mp4</td></tr>
<tr><td>Presentations</td><td>pdf/ppt</td></tr>
</table>
Note: F4E reserves the right to request the editable version for working purposes.</td></tr>
<tr><td>F4E-QA-115-DM-DR-011</td><td>In the event of additional electronic document file formats being used, for example for specialized engineering calculations, the Supplier shall provide fully useable data input and output files.</td></tr>
<tr><td>F4E-QA-115-DM-DR-012</td><td>Final versions submitted for F4E review and acceptance shall be submitted in .pdf format except for schedule, CAD and software codes.</td></tr>
</table>

4 Configuration Management (CM)

F4E-QA-115-CM-CM-001	The Supplier shall identify configuration items. Note 1: RS 03 can be considered as a guideline for the configuration item definition process. Note 2: Product tree can be used as a starting point for the identification of the configuration item. Note 3: Software configuration items are not only programme code segments, but all types of documents according to the development (e.g. drivers for test, analysis documents, manuals, system configurations etc…).
F4E-QA-115-CM-CM-002	The Supplier shall maintain the Configuration and Documentation List per each configuration item as per template AD 12 during the course of the implementation of the Contract.
F4E-QA-115-CM-CM-003	The Supplier shall implement a configuration management system with the at least the following processes (for concept clarification please refer to RS 02 and RS 03): - Configuration identification - Configuration status accounting - Configuration verification and audit
F4E-QA-115-CM-CM-004	Supplier configuration management system shall be described in the PQMP.

4.1 Configuration Identification and Baseline Establishment (CI)

F4E-QA-115-CM-CI-001	The baseline documentation shall reflect the actual configuration of the product, at any given point of the product life cycle.
F4E-QA-115-CM-CI-002	The Supplier shall submit the documentation requested in section 7 at each life cycle milestone.
F4E-QA-115-CM-CI-003	The Supplier shall submit according to requirement F4E-QA-115-CM-CI-002, the Configuration and Documentation list to freeze the configuration baseline at each life cycle milestone.
F4E-QA-115-CM-CI-004	For physical deliverables, configuration baselines shall at least include the following documents with the corresponding applicable versions (when applicable): - Functional specification - Technical specification - General specifications (e.g. environment, radiation, design rules, interfaces) - Procurement specification for COTS - Engineering drawings (e.g. interface control drawings, parts and assembly drawings, and installation drawings) and associated lists - Interface control document - Configuration and documentation list - Verification Control Document as per AD 22 - Installation/user/operating/maintenance manual - Test specifications - Test procedures - Test reports - Applicable NCRs - Applicable Deviations
F4E-QA-115-CM-CI-005	For developed software products, configuration baselines shall at least include the following documents with the corresponding applicable versions (when applicable): - Software system technical specification - Software requirements document - Software design document - Interface control document - Software configuration file (including the source code listing) - Software release document - Installation/user/operating/maintenance manual - Configuration description of the development tools (e.g. compilers, and linkers) - Software validation testing specifications - Verification Control Document as per AD 22 - Software test procedures - Software test reports - Maintenance procedures - Applicable NCRs - Applicable Deviations
F4E-QA-115-CM-CI-006	For COTS software products, configuration baselines shall include the following documents: - User Manual - Software Release Note as provided by the Vendor

4.2 Configuration Status Accounting (SA)

F4E-QA-115-CM-SA-001	The Supplier shall establish a configuration status accounting system to record, store and retrieve status of the configuration baselines and approved changes.

4.3 Configuration Verification and Auditing (VA)

F4E-QA-115-CM-VA-001	Before freezing the configuration, the Supplier shall verify the information included into the Configuration and Documentation List against the associated contractual documents and documents of Supplier' documentation system to identify that all modifications, agreements, etc. are taken into consideration.
F4E-QA-115-CM-VA-002	The Supplier shall include Configuration Management into the scope of internal audits.

5 Project Management (PM)

5.1 Project Management (PM)

F4E-QA-115-PM-PM-001	The Supplier shall describe in the PQMP the Project Management approach replying to the requirements in section 5.
F4E-QA-115-PM-PM-002	For Framework Contracts the Supplier shall submit a PQMP covering the scope of the complete Framework and foreseen future activities under Specific Contracts.

5.1.1 Project Work Breakdown structure (WB)

F4E-QA-115-PM-WB-001	The Supplier shall establish the WBS for the activities, incorporating the WBS of the supply chain.
F4E-QA-115-PM-WB-002	The Supplier shall submit the Contract WBS and its updates for F4E acceptance.

5.1.2 Organizational structure and responsibilities (OR)

F4E-QA-115-PM-OR-001	The Supplier shall set up the project management organization in such a way that: - Adequate resources are allocated to the project to ensure timely completion of the Contract - The roles of team members, their tasks and responsibilities are clearly identified - In case of the consortium/third parties' involvement – responsibilities of consortium members/third parties and the coordination of management tasks and everyday activities related to the implementation of the contract are detailed
F4E-QA-115-PM-OR-002	The Supplier shall provide a project organization chart identifying the key personnel to be deployed on the work. Note: Including Project Manager, Technical Responsible, Quality Representative and other staff involved in key activities
F4E-QA-115-PM-OR-003	The Supplier shall establish, maintain and distribute a project directory with the key personnel (as per F4E-QA-115-PM-OR-002) including role and contact details (e.g. email, telephone numbers…). Back-up for key roles shall be also included. Note: For construction contracts, it is limited to the level of supervisors
F4E-QA-115-PM-OR-004	The Supplier shall ensure that the project manager has the authority and adequate resources to execute all tasks needed under the contract with direct access to his company management hierarchy to resolve conflicts at the appropriate level.
F4E-QA-115-PM-OR-005	The Supplier's project manager shall be the responsible for the planning, performance and control of all of the contractual activities including the ones assigned to Subcontractors.
F4E-QA-115-PM-OR-006	The Supplier shall appoint a Quality Representative for interfacing with F4E for QA matters.
F4E-QA-115-PM-OR-007	The Supplier's Quality Representative (or the department which belongs), shall have direct reporting line to the senior management.

F4E-QA-115-PM-OR-008	The Supplier quality representative shall act as focal point within the contract concerning quality matters and be responsible for the contract quality performance throughout the duration of the Contract at least being involved in following domains: - Development, implementation, monitoring and review of PQMP - Follow up of Audits results - Nonconformities management - Follow up of Corrective/preventive actions - Control of Configuration baselines - Subcontractors' supervision in quality matters (assessing, monitoring and controlling the quality tasks carried out by Subcontractors) - Participation in the internal phase gates review - Selection of procurement sources - Review of purchase orders for completeness with respect to requirements - Review of deviations impact assessments - Review and approval of the qualification strategy - Update of the Qualification status list - Control of the Critical-items - Control of stamps/signatures - Review of manufacturing, assembly and integration documents - Review and approval of test procedures - Review and approval of test reports - Review of ADP (Acceptance Data Package) - Control of the implementation of traceability requirements - Control of the implementation of part identification requirements - Control of the implementation of metrology and calibration requirements - Control of the implementation of handling, storage and preservation requirements - Control of the application of statistical quality techniques (if necessary) - Application of lesson learned - Follow up of improvement plans
F4E-QA-115-PM-OR-009	Any personnel involved into the contract implementation (in F4E, Supplier or supply chain) shall have the right and responsibility to notify unsatisfactory work or not authorized practices and, if necessary, stop unsatisfactory or unsafe work which could imply the risk of damaging the product or associated equipment and tooling (stop-work authority). F4E shall be informed in writing if the Supplier or subcontractors apply the stop-work right.
F4E-QA-115-PM-OR-010	The Supplier's Project Manager shall be the responsible for allowing the work to restart. F4E shall be promptly notified in writing of the details and circumstances for adopting such a decision.
F4E-QA-115-PM-OR-011	The change of the Project Manager, Technical Responsible or Quality Representative shall be considered as a deviation and shall be managed according to section 6.3.3.
F4E-QA-115-PM-OR-012	F4E reserves the right to stop the activities during the execution of the works if considers that the product quality might be compromised or a requirement is not fulfilled.

5.1.3 Personnel competencies, training and certification (PC)

F4E-QA-115-PM-PC-001	The Supplier shall demonstrate that all the personnel have the necessary qualification, skills and experience to perform the activities for which they have been proposed. Evidence of this suitability shall be provided.
F4E-QA-115-PM-PC-002	The Supplier shall established a training programme for all the personnel involved in the implementation of the contract, in particular whose performance determines or affects the contract activities. Records of evidence shall be provided upon F4E request (or F4E authorised representative/third party).

<table>
<tr><td>F4E-QA-115-PM-PC-003</td><td>The Supplier shall provide detailed information about the personnel involved into the contract activities specifying at least the following:
- The number and type of personnel involved in each activity with an estimate percentage of each one's total work time to be dedicated to it
- Measures in place to ensure adequate recruitment of sufficiently experience personnel (or detailed recruitment plans for vacant positions)
- Specific training provided to its personnel
- Specific qualifications held by those performing operations requiring special control measures and / or supervision</td></tr>
<tr><td>F4E-QA-115-PM-PC-004</td><td>The Supplier shall provide prior to start of any activity the Suitably Qualified and Experienced Personnel (SQEP) matrix to the project for all the positions within the Contract together with CVs/qualifications of all the proposed team members.</td></tr>
<tr><td>F4E-QA-115-PM-PC-005</td><td>Key project personnel shall have sufficient verbal and written communication abilities in the English language.
Note: English level can be declared in the CVs</td></tr>
<tr><td>F4E-QA-115-PM-PC-006</td><td>The Supplier and/or Subcontractor personnel performing or evaluating special processes shall be trained and certified according to the following standards accepted by F4E:
- EN ISO 14731:2006 – Welding coordination – Tasks and responsibilities (RS 04)
- EN ISO 9712 :2012 – Non-destructive testing. Qualification and certification of NDT personnel RS 05)
<table><tr><th>Supplier Staff</th><th>Minimum Qualification Required</th></tr><tr><td>Carrying out NDTs</td><td>EN ISO 9712 [7] – level one</td></tr><tr><td>Supervising, assessing and/or certifying NDTs and their results</td><td>EN ISO 9712 [7] – level two</td></tr><tr><td>Welding supervision staff</td><td>EN ISO 14731 [6] – level IWS</td></tr></table></td></tr>
<tr><td>F4E-QA-115-PM-PC-007</td><td>In case of no certification available on the market, the Supplier shall provide to F4E documented evidences of the required proficiency (e.g. internal training records, regular activity logs…).</td></tr>
</table>

5.1.4 Submission of contractual documents (DS)

<table>
<tr><td>F4E-QA-115-PM-DS-001</td><td>The Tenderer shall submit at tender phase the following documents for Quality Assurance evaluation:
<table><tr><th></th><th>Tenderer</th><th>Main Subcontractors</th></tr><tr><td>ISO 9001 certificate (or equivalent) or documentation (e.g. flow charts and/or process descriptions) demonstrating the compliance to this document</td><td>X</td><td>X</td></tr><tr><td>Declaration on Honour on exclusion and selection criteria</td><td>X</td><td>X</td></tr><tr><td>PQMP as per section 5 and 6</td><td>X</td><td>X</td></tr><tr><td>Control Plans (MCP and MIP) as per template 9.2</td><td>X</td><td>X</td></tr><tr><td>Supply Chain Acceptance Register as per template 9.13</td><td>X</td><td>-</td></tr><tr><td>Time schedule as per section 5.1.5</td><td>X</td><td>-</td></tr><tr><td>Risk register as per template 9.12</td><td>X</td><td>-</td></tr><tr><td>Compliance Matrix as per F4E-QA-115-QA-QM-004</td><td>X</td><td>X</td></tr></table></td></tr>
<tr><td>F4E-QA-115-PM-DS-002</td><td>The Supplier shall maintain updated the contractual documents during the course of the implementation of the contract.</td></tr>
</table>

F4E-QA-115-PM-DS-003	Any modification of documents shall be notified in the Progress Report including: - Document title - Document code with the new version - Document CTS number - Reason and brief description of the modification
F4E-QA-115-PM-DS-004	The Supplier shall deliver the following documents as a single submission (package of documents, each document with independent CTS number) proportionally to the duration of the contract with a ratio of ¼: - Management and Manufacturing and Inspection Control Plan(s) - Configuration and Documentation List - Time Schedule Note 1: For example for a given contract of 12 months, the submission will be every 3 months. Note 2: F4E reserves the right to request other documents to the above list in Contract Management Specifications (Annex A).
F4E-QA-115-PM-DS-005	The Supplier shall submit the package defined in requirement F4E-QA-115-PM-DS-004 for F4E acceptance within 15 working days after the KoM. Final versions shall be submitted for acceptance as part of Acceptance Data Package.
F4E-QA-115-PM-DS-006	Intermediate packages defined in requirement F4E-QA-115-PM-DS-004 shall submitted for review only.
F4E-QA-115-PM-DS-007	The Supplier shall implement F4E comments in the subsequent documentation submission if it not requested otherwise.
F4E-QA-115-PM-DS-008	For payment purposes, the Supplier shall include in addition to the documentation defined in requirement F4E-QA-115-PM-DS-004, the following information including classification and the status: - All NCRs (INCs to be included) - All Deviation Requests and Deviation Notices.

5.1.5 Schedule Management (SC)

F4E-QA-115-PM-SC-001	The Supplier Schedule shall be developed and maintained in a planning tool accepted by F4E (e.g. Primavera, MS Project, etc).
F4E-QA-115-PM-SC-002	The Supplier Schedule shall contain all activities performed by the Supplier for the execution of the contract including at least: - Contractual milestones - Technical milestones - Payment milestones - Stage milestones - Contract phase gate reviews (CDR, PDR, FDR, MRR, TRR and DRR) - Control points described in the Control Plans (Management and Manufacturing and Inspection Control Plans).
F4E-QA-115-PM-SC-003	WBS shall be the same (identical titles of activities, coding, etc) as the one presented and accepted in the PQMP.
F4E-QA-115-PM-SC-004	The calendar (or calendars) applied to the Supplier Schedule shall be appropriate to the country, where the contractual activities are executed including all national holidays and specific closure days of the organisation.
F4E-QA-115-PM-SC-005	All activities in the Supplier' Schedule shall have predecessors and successors, except for start and finish milestones.
F4E-QA-115-PM-SC-006	Any exception to requirement F4E-QA-115-PM-SC-005 shall be promptly justified by the Supplier and accepted by F4E.
F4E-QA-115-PM-SC-007	The Critical Path in the Schedule shall be reliable, robust and identifiable.
F4E-QA-115-PM-SC-008	The Critical Path shall run unbroken from the Report Date through to the end of the project, and must not include any support type Level of Effort activities.
F4E-QA-115-PM-SC-009	Supplier' Schedule baseline and forecasted in progress report shall be provided in its native, editable form.

F4E-QA-115-PM-SC-010	Supplier' Schedule baseline shall be agreed by F4E and the Supplier before the start of the activities. The forecasted Supplier' Schedule shall be reported in the progress report and agreed in the progress meeting.
F4E-QA-115-PM-SC-011	The Supplier's shall submit the Schedule and the corresponding progress updates according to the requirements defined in Management and Technical specifications (Annex A and B).
F4E-QA-115-PM-SC-012	Any variance on Supplier's Schedule Baseline shall be managed according to the Deviation requirements in section 6.3.3.

5.1.6 Risk and Opportunity Management (RK)

F4E-QA-115-PM-RK-001	Supplier shall describe in the PQMP the risk and opportunity management process according to AD 07.
F4E-QA-115-PM-RK-002	The Supplier shall describe the risk and opportunity management system, tools and techniques in the PQMP
F4E-QA-115-PM-RK-003	Supplier shall use the Risk Register to record the Risks and Opportunities as per template defined in AD 07.
F4E-QA-115-PM-RK-004	Supplier shall develop detailed risk response plans for each risk / opportunity and shall follow up their implementation

5.1.7 Project Meetings and Progress Reports (PG)

F4E-QA-115-PM-PG-001	The official Kick-off-Meeting shall precede the start of the implementation of the Contract and address at least the following topics: - Contractual specifications, specific requirements and inputs, the compliance matrix contents - The detailed schedule of the contractual activities, including milestones - Contents of Supplier' s Progress Reports and Progress Meetings - F4E Quality Assurance approach - Risk Management approach - Management of Intellectual Property - Dual-Use items/technologies list - Supplier's PQMP comments - Management and Manufacturing and Inspection Control Plan(s) and Control Points - Frequency of all documentation submission
F4E-QA-115-PM-PG-002	The Supplier shall organize progress meetings and provide an agenda throughout the duration of the Contract at a minimum frequency of one (1) per calendar month (if not agreed otherwise during the KoM).
F4E-QA-115-PM-PG-003	The Supplier shall draft minutes of Kick of Meeting and Progress meeting within three (3) working days after the meeting, and circulate them to all attendees for review and comment prior to upload to CTS.
F4E-QA-115-PM-PG-004	The Supplier shall submit to F4E for information, a Progress Reports as per DRD in section 8.2 with a minimum of five (5) working days prior to the next progress meeting.
F4E-QA-115-PM-PG-005	The Supplier shall maintain the structure of the progress report without any departure from the DRD 8.2 structure. Note 1: If for any reason a particular section of the report is not applicable or does not need to be updated it shall be explained in the text of the report. E.g.: "The Risk Register has been not updated because…." Or "This section is not applicable because…" Note 2: For Grants progress report requirements see F4E-QA-115-PM-PG-007
F4E-QA-115-PM-PG-006	Supplier shall summarize Subcontractors progress report main issues impacting F4E activities without attaching the full Subcontractor progress report.
F4E-QA-115-PM-PG-007	Periodic Activity Report package for Grants shall include: - Activity Report - Report on the use of the resources - Financial Statements/Cost claim - Report on the implementation of the plan for the use and dissemination of foreground - Any other report or deliverable required

6 Quality Management Requirements (QA)

F4E-QA-115-QA-QA-001	The Supplier shall describe in the PQMP the quality management approach replying to the requirements in section 6.

6.1 Project and Quality Management Plan Requirement (QM)

F4E-QA-115-QA-QM-001	The Supplier shall develop, maintain and implement a Project and Quality Management Plan in accordance to DRD in section 8.1. If PQMP refers to internal processes, a short summary demonstrating the compliance shall be given in the text of the PQMP.
F4E-QA-115-QA-QM-002	The PQMP shall describe the methodology implemented by the Supplier to comply with the requirement in this document.
F4E-QA-115-QA-QM-003	If the Supplier is partially or not compliant to any of requirement(s), the Supplier shall justify it and agree its acceptability with F4E. Note: Justification for acceptability will be discussed during the KoM
F4E-QA-115-QA-QM-004	The Supplier shall provide the compliance matrix on all the applicable requirements of this document as per DRD in section 8.4. Compliance Matrix shall reflect partial or not compliances as per F4E-QA-115-QA-QM-003.
F4E-QA-115-QA-QM-005	The Supplier shall attach a valid copy of the Quality Management System Certificate (ISO 9001 or equivalent), if is certified by a Certification Body. Note: The scope of the certification has to be in line with the scope of contractual activities.
F4E-QA-115-QA-QM-006	The Supplier shall not start any contractual activity or any impacted activity by the update(s) before the formal F4E acceptance of the PQMP and its update(s). Note: See Document Status definition in Table 1 for detailed information
F4E-QA-115-QA-QM-007	The Supplier shall commit to the following PQMP submission deadlines. **Timing of Submission** / **Version of PQMP** With the Tender Proposal / Issue 1.0 Maximum 15 working days after KoM / Frozen version for implementation. During the contract implementation / Update when necessary or before starting of activities under Specific Contracts Note: Concept of Preliminary Quality Plan has been removed.

6.2 Control Plan Requirements (CP)

F4E-QA-115-QA-CP-001	Supplier shall identify in the Management Control Plan (MCP) the main management activities covering all the phases of the contract, including milestones and deliverables.
F4E-QA-115-QA-CP-002	Supplier shall identify in the Manufacturing and Inspection Control Plan (MIP) all the activities directly related to the follow-up and verification of the quality of the product(s) and/or service(s) supplied.
F4E-QA-115-QA-CP-003	The level of detail in the Control Plans shall be such as: - To enable adequate planning, monitoring and verification of key activities (MCP) - To prevent the inadvertent bypassing of critical test and inspection points (MIP)
F4E-QA-115-QA-CP-004	Control plan shall list all foreseen control activities sequentially. Sequence shall be respected during the development of the activities. Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-005	Supplier shall submit the Control Plan for acceptance to F4E as per template AD 13. Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-006	The Supplier shall not start any contractual activity before Control Plan formal F4E acceptance. Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-007	When a modification is performed on Control Plan, the Supplier shall not continue any manufacturing activity before formal F4E acceptance of the new version. Note: Applicable to MCP and MIP

F4E-QA-115-QA-CP-008	Control plan shall be written in English, although they shall be also available in a language easily understood by those carrying out the activities. Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-009	The Supplier shall fill in every single field of the Control Plan as per template AD 13. Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-010	To Supplier shall ensure that Control Plan are: - Available to the personnel carrying out the activities - Available at the location where activities are carried out - Removed and stored in proper conditions once completed Note: Applicable to MCP and MIP
F4E-QA-115-QA-CP-011	The Supplier's staff in charge of performing the activity or its direct supervisor shall sign off (date, name, and signature) the Control Plan at the moment of the completion of each activity. Note 1: Whenever there is a report associated to the control activity, the activity is considered completed once the report is accepted. Note 2: Applicable to MCP and MIP
F4E-QA-115-QA-CP-012	The Supplier shall provide for each activity a close-out document (evidence) and make reference in "Evidence" Column with the F4E CTS reference. Note: NCRs, Deviations and Concessions if any, have to be also included in the same column
F4E-QA-115-QA-CP-013	In case of new release of the Control Plan, all activities already finished and signed at the moment of the new release remain valid. The new version shall include the following sentence for each activity already signed off: 'See version XX, CTS reference YYY"
F4E-QA-115-QA-CP-014	Supplier shall notify F4E TPO and QAO about each forthcoming activity related to the control point involving F4E and/or IO 10 (ten) working days in advance by using the template AD 20 Note: Supplier will receive confirmation of F4E participation at least 5 (five) working days before the scheduled activity.
F4E-QA-115-QA-CP-015	The Supplier shall be responsible on the expenses of the F4E staff mission in case of cancellation without notification. Note: F4E reserve the right to request a repetition of the control point at Supplier cost in case of incorrect notification
F4E-QA-115-QA-CP-016	Control Point clearance and waivers shall be traceable and clearly identified in Control Plan.

6.3 QA General Requirements

6.3.1 Critical Quality Items and activities control (CI)

F4E-QA-115-QA-CI-001	Supplier shall uniquely identify the critical quality item according to the definition in Table 1 Note: Inputs for the critical quality item identification can be FMEA/FMECA and/or risk register
F4E-QA-115-QA-CI-002	Supplier shall establish and maintain the critical quality item list (CIL) for the contract to allow the tracking and monitoring of all the critical quality items and activities identified as per DRD in section 8.3.
F4E-QA-115-QA-CI-003	Supplier shall define specific control measures for the critical quality items and activities and include them in the Manufacturing and Inspection Control Plan.

6.3.2 Nonconformities management requirements (NC)

F4E-QA-115-QA-NC-001	The Supplier shall include in the PQMP the description of its internal NCR management process including at least the following: - Roles and Responsibilities - Review and approval cycle - Root Cause Analysis methodology - Remedial and Corrective Actions follow-up - Risk impact analysis

F4E-QA-115-QA-NC-002	If Nonconformity impacting F4E contract occurs, the Supplier shall stop all related activities, segregate and identify any affected item and inform as soon as possible in written to F4E (TPO and QAO). Information shall include at least: - Affected Item(s) identification - Requirement affected - Detail description of the NC - Proposed remedial action, justification and due date
F4E-QA-115-QA-NC-003	The Supplier shall report the NC through the NCR database within a maximum of 5 working days. Note: NC includes the 2 possible detection sources Supplier or F4E and/or IO
F4E-QA-115-QA-NC-004	All NCR-related communication shall be dealt between Supplier and F4E QAO.
F4E-QA-115-QA-NC-005	Before NCR submission to F4E, the following Supplier's roles shall agree on the information included (evaluation, disposition and actions definition): - Project Manager - Technical Representative - Quality Representative - Any additional experts considered necessary
F4E-QA-115-QA-NC-006	The Supplier shall fill all its corresponding sections of the NCR database including the proposal for categorization based on the definitions in Table 1.
F4E-QA-115-QA-NC-007	The Supplier shall issue one NCR per NC.
F4E-QA-115-QA-NC-008	The Supplier shall not implement any remedial or corrective action before F4E agreement and acceptance, communicated through the F4E QAO.
F4E-QA-115-QA-NC-009	The Supplier shall perform a root cause analysis even if the remedial action is 'Use as is' or no further work/product is foreseen to be manufactured in the frame of F4E contract.
F4E-QA-115-QA-NC-010	The Supplier shall organize with F4E Nonconformities Review Board (NRB) after NCR submission in order to agree on root cause and corrective actions. Note: Several NCRs can be discussed in the same NRB.
F4E-QA-115-QA-NC-011	At least the Supplier Quality Representative and Technical responsible shall attend the NRB, additional expert can be invited if needed.
F4E-QA-115-QA-NC-012	The Supplier shall define remedial and corrective actions including responsible and due dates.
F4E-QA-115-QA-NC-013	In case of a 'Use as is' disposition for a remedial action which does not imply a deviation, the Supplier shall request a concession to F4E for the specific affected product. The list of concessions shall be included in the ADP and listed in the Release Note. Note: Concession can be requested by email. Request has to include at least the item affected, related NCR number and a unique identifier of the concession
F4E-QA-115-QA-NC-014	The Supplier shall propose a NCR for closure only when all the related actions (remedial and corrective if applicable) are implemented and evidences have been provided and accepted by F4E QAO and TPO.
F4E-QA-115-QA-NC-015	The Supplier shall only proceed with next steps on the manufacturing process related to the NC in the affected part, when all remedial actions related to the finding have been properly implemented, documented and accepted by F4E.
F4E-QA-115-QA-NC-016	The Supplier shall maintain a list of NCRs indicating the status of all of them, including INCs. Note: F4E reserves the right to request clarification and/or to upgrade an INC to a NCR if considers it necessary.
F4E-QA-115-QA-NC-017	The Supplier shall upgrade from INC to NCR if finding is repetitive.
F4E-QA-115-QA-NC-018	The Supplier shall consider the NC management process as high priority activity.
F4E-QA-115-QA-NC-019	The closure time shall not exceed 9 months. Note: This requirement could be extended to a maximum of 12 months when duly justified.
F4E-QA-115-QA-NC-020	For open NCRs impacting to next phases and related to a payment milestone, to proceed with the payment, the Supplier shall at list have: - Implemented the remedial action and - Finalized the root cause analysis
F4E-QA-115-QA-NC-021	NCRs status related to requirement F4E-QA-115-QA-NC-020 shall be declared as 'Closed with actions'.
F4E-QA-115-QA-NC-022	Pending actions related to requirement F4E-QA-115-QA-NC-021 shall be included in an open work list in the final ADP.

F4E-QA-115-QA-NC-023	The Supplier shall close all the NCRs and any pending Open Action by the time of the final ADP submission or by the closure of the contract.
F4E-QA-115-QA-NC-024	INCs shall be managed according to the Supplier Quality Management System.

6.3.3 Deviations management requirements (DR)

F4E-QA-115-QA-DR-001	The Supplier shall discuss any foreseen Deviation with F4E, and if it is considered beneficial, shall submit a Deviation Request for F4E review through DACC according to AD 08.
F4E-QA-115-QA-DR-002	The Supplier shall describe in the PQMP its internal Deviation management process, including at least the following information: - Roles and responsibilities - Review and approval cycle - Impact analysis methodology - Implementation strategy
F4E-QA-115-QA-DR-003	Supplier' Deviation management process shall include the management of all Deviations initiated be the Supplier, its Subcontractors and those issued by F4E.
F4E-QA-115-QA-DR-004	The Supplier shall keep updated a database/register of all Contract related deviations and their status and shall make it available upon F4E request.
F4E-QA-115-QA-DR-005	Depending on the type of deviation, at least the following Supplier's roles shall agree in the deviation evaluation, disposition and impact analysis definition before submission to F4E: - Project Manager - Quality Representative - Engineering Representative - Any additional experts considered necessary
F4E-QA-115-QA-DR-006	The Supplier shall issue an impact assessment including all relevant information to enable the decision including an assessment of consequences in terms of risk, cost and schedule for each Deviation.
F4E-QA-115-QA-DR-007	Deviation shall not be implemented before F4E formal accepted through DACC.
F4E-QA-115-QA-DR-008	The Supplier shall modify all the affected documentation in its internal management system as consequence of the Deviation approved to make it compliant with the new agreed requirements.

6.3.4 Stamp and signature control (SS)

F4E-QA-115-QA-SS-001	The Supplier shall establish and maintain a documented stamp or signature control system to ensure the correct and legitimate use of all fabrication and inspection stamps/signatures.
F4E-QA-115-QA-SS-002	Stamps/signatures shall be used to: - Sign the completion of operations and processes, and - Indicate inspection performance at source, incoming inspection, in process inspection and tests, final inspections, end point testing, storage and shipment.
F4E-QA-115-QA-SS-003	The use of stamps/signatures shall be restricted to authorized personnel as identified in the stamp/signature control system.
F4E-QA-115-QA-SS-004	Stamps/signatures shall be traceable to individuals responsible for their use.
F4E-QA-115-QA-SS-005	Stamps shall be applied directly to parts and materials, when specified by engineering drawings and specifications, and associated documents, records, labels
F4E-QA-115-QA-SS-006	Stamping materials and methods shall be compatible with the articles and their use.

6.3.5 Traceability and Identification (TR)

F4E-QA-115-QA-TR-001	The Supplier shall ensure traceability at least for QC1 contracts and always when requested in the Contract Management or Technical Specifications (Annex A and B).

F4E-QA-115-QA-TR-002	The Supplier shall define in PQMP the methodology to ensure the traceability, explaining: - How items requiring traceability are identified - Which methods and equipment are selected to ensure traceability - How the traceability of items is recorded - Which type of traceability has been selected including proper justification: individual items, batch production, etc.
F4E-QA-115-QA-TR-003	The Supplier shall ensure that a bidirectional and unequivocal relationship between parts, materials or products, assemblies and associated documentation or records is established and maintained.
F4E-QA-115-QA-TR-004	The Supplier shall be capable to trace data, personnel and equipment related to procurement, manufacturing, inspection, test, assembly, integration and operations activities.
F4E-QA-115-QA-TR-005	The Supplier shall be capable to trace forward the locations of materials from raw stock.
F4E-QA-115-QA-TR-006	The Supplier shall establish controls to ensure that: - identification numbers are assigned in a systematic and consecutive manner, - identification numbers of scrapped or destroyed items are not used again, - identification numbers, once allocated, are not changed, unless the change is authorized by its customer
F4E-QA-115-QA-TR-007	The Supplier shall keep trace of any temporary marking which might be removed in further phases (e.g. welding).
F4E-QA-115-QA-TR-008	Raw materials, sub-assemblies/sub-components and parts shall be identified according to the Contract Management and Technical Specifications (Annex A and B).

6.3.6 Metrology, equipment calibration and verification (MT)

F4E-QA-115-QA-MT-001	The Supplier shall describe in PQMP a dimensional control system for components, assemblies and systems for the ITER machine in accordance to the AD 03.
F4E-QA-115-QA-MT-002	The Supplier shall identify, calibrate and adjust all manufacturing, inspection, measuring and test equipment and devices that can affect product quality at prescribed intervals, or prior to use, against certified equipment. Note: Uncalibrated or out of calibration equipment have to be also identified.
F4E-QA-115-QA-MT-003	The Supplier shall establish, document and maintain calibration procedures, including details of equipment type, identification number, location, frequency of checks, check method, acceptance criteria and the action to be taken when results drift from the specified accuracy.
F4E-QA-115-QA-MT-004	The Supplier shall ensure that the manufacturing, inspection, measuring and test equipment is handled, preserved and stored such that the accuracy and fitness for use is maintained.
F4E-QA-115-QA-MT-005	The Supplier shall supervise and monitor all measurement and test equipment used in the execution of the activities including on loan or provided by F4E to demonstrate the conformance of product to the specified requirements.
F4E-QA-115-QA-MT-006	The Supplier shall use equipment in a manner which ensures that measurement uncertainty is known and is consistent with the specified measurement capability.
F4E-QA-115-QA-MT-007	The Supplier shall select manufacturing, inspection, measuring and test equipment appropriate for the test and in conformance with the required measurement accuracy and precision.
F4E-QA-115-QA-MT-008	The Supplier shall ensure that the manufacturing, inspection, measuring and test equipment is capable of the specified accuracy and precision.
F4E-QA-115-QA-MT-009	The Supplier shall identify manufacturing, inspection, measuring and test equipment with a suitable indicator or approved identification record to show the calibration status. Note: Individual identification (on the instrument) is preferable where feasible.
F4E-QA-115-QA-MT-010	The Supplier shall assess and document the validity of previous inspection and test results when manufacturing, inspection, measuring or test equipment is found to be out of calibration.
F4E-QA-115-QA-MT-011	The Supplier shall ensure that the environmental conditions are appropriate for the storage, calibration, inspection, measurement and test activities.

F4E-QA-115-QA-MT-012	The Supplier shall ensure that manufacturing, inspection, measuring and test facilities, including both test hardware and test software are protected against adjustments, which can invalidate the calibration setting.
F4E-QA-115-QA-MT-013	The Supplier shall maintain records of all calibration and verification activities.

6.3.7 Handling, storage and preservation (HS)

F4E-QA-115-QA-HS-001	The Supplier shall prevent handling damage during all phases of manufacturing, assembly, integration, testing, storage, transportation and operation.
F4E-QA-115-QA-HS-002	The Supplier shall place the following items in a secure/protected from the unauthorized access storage areas: - Incoming materials - Intermediate items needing temporary storage - End-items before shipping - Materials or goods under RS 08 Annex I
F4E-QA-115-QA-HS-003	The Supplier shall place the following items in designated segregated areas: - Limited life materials - Suspended limited life materials - Nonconforming items awaiting NRB disposition - Scraped items - Items designated to be stored separately for health and safety reasons
F4E-QA-115-QA-HS-004	Each segregated area shall be identified and labelled for its intended use.
F4E-QA-115-QA-HS-005	The Supplier shall maintain control over the storage and segregated areas.
F4E-QA-115-QA-HS-006	The Supplier shall maintain records to ensure that all stored items are within the usable life limits, controlled and retested, and to provide traceability within the storage or segregated area.
F4E-QA-115-QA-HS-007	The Supplier shall ensure that items subject to deterioration, corrosion or contamination through exposure to any environmental elements are preserved by methods that ensure maximum protection consistent with life and usage.

6.3.8 Statistical quality control and analysis (ST)

F4E-QA-115-QA-ST-001	Statistical quality control and analysis methods shall be used to maintain or improve quality performance.
F4E-QA-115-QA-ST-002	When applying statistical quality control and analysis methods, the Supplier shall ensure that all the conditions for use are enforced.
F4E-QA-115-QA-ST-003	Statistical quality control applications, when used by the Supplier for acceptance of materials, parts, processes and products, shall be submitted to F4E for acceptance.

6.3.9 Cleanliness (CL)

F4E-QA-115-QA-CL-001	The Supplier shall define adequate cleanliness methods to achieve contract requirements.
F4E-QA-115-QA-CL-002	The Supplier shall establish controls for cleanliness of the hardware and facilities, and measures for limiting the sources of contamination.

6.3.10 Lessons Learned (LL)

F4E-QA-115-QA-LL-001	The Supplier shall maintain a list of the lessons learned per contract. Note: This list is considered internal Supplier's knowledge and is not requested as deliverable. Reference to be provided upon request.
F4E-QA-115-QA-LL-002	The Supplier shall assess in the risk register, the applicability of lesson learned from one to another F4E contract.

6.4 QA Requirements for Design (QD)

6.4.1 Design rules

6.4.1.1 Producibility (PR)

F4E-QA-115-QD-PR-001	The Supplier shall ensure that the product is designed such that it can be produced with the specified level of quality. Note: Producibility includes provisions for the following aspects: - Design simplification and standardization, reduction in part types and part number - Guidelines for selection of preferred parts, materials and processes - Unambiguous definitions of the requirements and limits to be used - Definition of tolerance build–up methods, in order to simplify manufacturing, assembly, inspection. - Standardization of interfaces - Part accessibility for assembly and inspection - Definition of design criteria consistent with the capability of manufacturing processes - Definition of design methods to ensure that the cleanliness requirements are compatible with the capability of related cleanliness procedures and facilities

6.4.1.2 Repeatability (RP)

F4E-QA-115-QD-RP-001	The Supplier shall ensure that the product is designed such that its performances and characteristics can be reproduced over different models and serial production. Note: Repeatability includes provisions for the following aspects: - Definition of standard tolerances generally applicable - Recommended design concepts and solutions to ensure repeatability - Recommended manufacturing processes having proven repeatability - Design criteria that optimize implementation of automated manufacturing methods, or computer–aided manufacturing

6.4.1.3 Inspectability and testability (IT)

F4E-QA-115-QD-IT-001	The Supplier shall ensure that the product is designed such that it can be inspected and tested under representative conditions, for production, assembly, integration verification and operational environment Note: Inspectability and testability includes provisions for the following aspects: - Definition of inspection and test requirements, including acceptance or rejection criteria, expressed in an unambiguous and quantified manner - Part and component accessibility for inspection and test - Definition of tolerance methods for dimensional inspection performance (e.g. functional tolerances) - Definition of recommended design techniques to facilitate fault detection, identification and location (e.g. test points, modularity, built–in test software, and feedback loops)

6.4.1.4 Operability (OP)

F4E-QA-115-QD-OP-001	The Supplier shall ensure that the product is designed such that it can be operated in accordance with ITER Project constraints and requirements, throughout its whole life cycle including handling, storage, transportation, integration and operations.

6.4.2 Design Development and Verification (DV)

F4E-QA-115-QD-DV-001	The Supplier shall define the methodology for design development including requirements propagation, model philosophy (mock-up, prototype, engineering model, etc.), standards used.
F4E-QA-115-QD-DV-002	The Supplier shall establish and maintain a declared materials list (DML) in conformance with template AD 15.
F4E-QA-115-QD-DV-003	The Supplier shall establish and maintain a declared components list (DCL) in conformance with template AD 14.
F4E-QA-115-QD-DV-004	The Supplier shall establish and maintain a declared mechanical parts list (DMPL) in conformance with template AD 16.

F4E-QA-115-QD-DV-005	The Supplier shall establish and maintain a declared process list (DPL) in conformance with template AD 17.
F4E-QA-115-QD-DV-006	COTS shall be clearly identified in the dedicated column in the DML.
F4E-QA-115-QD-DV-007	The Supplier shall ensure that requirement verification is performed progressively and timely, as each stage of the contract is completed, and provides the organized base of data upon which qualification and acceptance is incrementally declared in accordance to AD 04.
F4E-QA-115-QD-DV-008	The Supplier shall ensure that verification methods are adequate and consistent with the type and criticality of the requirements.
F4E-QA-115-QD-DV-009	The Supplier shall ensure that appropriate reference to the verification documentation is recorded and status updated at project reviews up to final acceptance.

6.4.3 Design Review (RV)

F4E-QA-115-QD-RV-001	The Supplier shall ensure that design reviews at its level, are conducted in accordance with contract requirements and written procedures. Note: Design reviews address the following items such as, but not limited to: - Cost - Methods and data required for procurement, manufacturing, inspection and test are available and validated. - Product Safety - Quality requirements and criteria for design, producibility, repeatability, testability and operability are adequately considered in design documentation. - Regulatory Requirements - Risks of not achieving requirements are highlighted and adequately controlled. - Schedule
F4E-QA-115-QD-RV-002	Supplier Internal Design review report shall be submitted to F4E SEO and QAO for information.
F4E-QA-115-QD-RV-003	Supplier shall participate in F4E Design Reviews according to RD 13. The supplier expected contribution is defined in RD 13 section 'Roles and Responsibilities'.

6.4.4 CAD Requirements (CA)

F4E-QA-115-QD-CA-001	The Supplier shall implement a CAD data control system for any design activities complying with AD 06.
F4E-QA-115-QD-CA-002	The Supplier shall use the latest ITER official Catia v.5 version according to AD 06.
F4E-QA-115-QD-CA-003	If the Supplier works according to the synchronous scheme of CAD design collaboration, it is mandatory to use Teradici PcoIP technology solution (https://www.teradici.com) and fulfil the following requirements: - Hardware requirements: USB Mouse & keyboard, Display, Network cable with RJ45 connector and Power Cord. - Network requirements on Supplier side shall be: 4MB/s internet line per machine, Maximum latency is 150ms, TCP/UDP ports required for PcoIP technology (TCP: 4172, UDP: 4172), Public IP address for the Teradici Zero Client connection has to be communicated to ITER IO: Connection through ITER IO Firewall will then be granted. - The Supplier shall provide to F4E a complete set of ENOVIA + CATIA licenses which will reside at the IO in Cadarache per designer. If the production of CAD data includes CATIA Equipment&System the Supplier shall provide the proper CATIA license.

F4E-QA-115-QD-CA-004	If the Supplier works according to the asynchronous scheme of CAD design collaboration it is mandatory to comply with the following specific CAD requirements: - The Supplier shall install the corresponding "ITER CAD Supplier Package" to customize the setting on the Supplier's CATIA installation. - If the production of CAD data includes CATIA E&S the Supplier shall install the "ITER CAD Supplier Package E&S Add-on".
F4E-QA-115-QD-CA-005	If the Supplier works according to the schedule scheme of CAD design collaboration it is mandatory to comply with the following specific CAD requirements: - All CAD Specific Requirement for Asynchronous mode shall be applied for the Scheduled mode. - The supplier shall submit the CAD data to F4E with the agreed frequency for ENOVIA reintegration.
F4E-QA-115-QD-CA-006	Each designer of the Supplier shall attend the training provided by F4E on CAD methodology for synchronous scheme. Note: The training attendance is optional for asynchronous scheme as per AD 05.
F4E-QA-115-QD-CA-007	The Supplier designers working according to the synchronous scheme shall be certified by F4E on specific IO ENOVIA methodologies.
F4E-QA-115-QD-CA-008	Before starting the manufacturing design the Supplier shall ensure that the CAD data is modified from Multibody models to Multipart.
F4E-QA-115-QD-CA-009	If the design requires the use of network elements, their representations (PFD and P&ID fluids diagrams), shall be executed through a remote connection to the IGE+XAO SEE System Design licenses and ITER IO database. If the Supplier has to create PFD and P&ID fluids and/or electrical circuits' diagrams, it is mandatory to use the remote connection to the IGE+XAO SEE System Design licenses and ITER IO database.
F4E-QA-115-QD-CA-010	The Supplier designers shall be trained and certified by F4E on the usage of SEE System Design.
F4E-QA-115-QD-CA-011	The Supplier shall purchase separate licenses for SEE Electrical Expert software for the creation of detail electrical cubicle diagrams, and install the SEE Electrical Expert Environment provided by the IO.
F4E-QA-115-QD-CA-012	The Supplier shall train their designers on SEE Electrical Expert.

6.4.5 Calculation and modelling tools Requirements (CM)

F4E-QA-115-QD-CM-001	Supplier shall agree with F4E TPO before the start of the activities, the list of calculation and modelling tools to be used for specific calculation and modelling (including verification and validation).
F4E-QA-115-QD-CM-002	The list of calculation and modelling tools shall be presented as the following table in the PQMP:
F4E-QA-115-QD-CM-003	The verification and validation process of calculation and modelling tools shall be limited only to the scope and purpose of the analysis calculations.
F4E-QA-115-QD-CM-004	Supplier shall provide the basis of verification and validation justification, code inputs and all supporting documentation at the Kick-of-Meeting.
F4E-QA-115-QD-CM-005	For analyses of Structures, Systems and Components classified as QC1, calculation and modelling tools shall be verified and validated according to AD 02.
F4E-QA-115-QD-CM-006	For software COTS, the Supplier shall request to the distributor the documentation certifying that it is adequate for the intended used and within the defined limit.

Software	Date	Version	Input	Availability	Basis of Verification / Validation

F4E-QA-115-QD-CM-007	For a new software development, the Supplier shall verify it by choosing one of the following methods: - By hand calculations: for very simple algorithms - By independent calculations: to check the correctness and applicability of the equations and algorithms and to assess the input and output values - By comparison: with an alternative recognized software - By test: using the same inputs and comparing the outputs - By a known problem: comparing the results of standard, confirmed, published problems with known solutions. Note: Establishing confidence in calculation and modelling tools may include factors such as software developed under a qualified quality program (e.g. ISO 9001 or equivalent), number of users, expectations and familiarity with the software
F4E-QA-115-QD-CM-008	Verification and validation processes shall be specific for the type of calculation (structural, electromagnetic, nuclear, etc.), model and code used.
F4E-QA-115-QD-CM-009	Supplier shall request to F4E TPO the applicable verification and/or validation procedure for the type of calculation, model and code.

6.4.6 Dependability Requirements (DP)

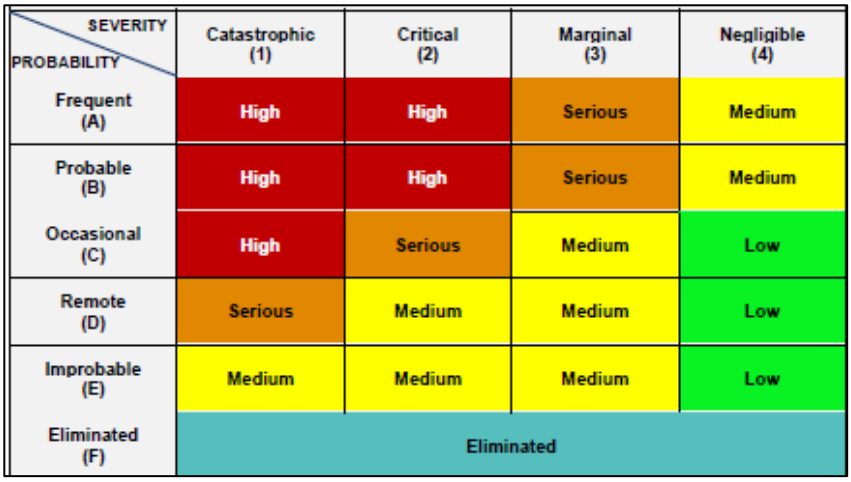
F4E-QA-115-QD-DP-001	The dependability assurance shall be implemented by means of a systematic process for specifying requirements for dependability and demonstrating that these requirements are achieved.
F4E-QA-115-QD-DP-002	Supplier shall describe the Dependability approach in PQMP.
F4E-QA-115-QD-DP-003	The dependability approach shall include at least a FMEA/FMECA in accordance with criteria defined in requirement F4E-QA-115-QD-DP-004 and RS 11 and as per template AD 18.
F4E-QA-115-QD-DP-004	The Supplier shall evaluate the potential failures based on the following criteria (as per RS 11): **Severity:** **Occurrence:**

Severity:

Description	Category	Result
Catastrophic	1	Could result in one or more of the following: Failure propagation to other systems or subsystems, death, permanent total disability, irreversible significant environmental impact, or monetary loss
Critical	2	Could result in one or more of the following: Loss of affected item, system or subsystem, permanent partial disability, injuries or occupational illness that may result in hospitalization of at least three personnel, reversible significant environmental impact, or monetary loss
Marginal	3	Could result in one or more of the following: Major affected item degradation, injury or occupational illness resulting in one or more lost work day(s), reversible moderate environmental impact, or monetary loss
Negligible	4	Could result in one or more of the following: Minor affected item degradation, injury or occupational illness not resulting in a lost work day, minimal environmental impact, or monetary loss

Occurrence:

Class	Probability level	Description
A	Frequent	Likely to occur often in the life of an item
B	Probable	Will occur several times in the life of an item
C	Occasional	Likely to occur sometime in the life of an item
D	Remote	Unlikely, but possible to occur in the life of an item
E	Improbable	So unlikely, it can be assumed occurrence may not be experienced in the life of an item
F	Eliminated	Incapable of occurrence. This level is used when potential hazards are identified and later eliminated.

F4E-QA-115-QD-DP-005	The Supplier shall classify the potential failures based on the following matrix (as per RS 11): **Assessment matrix** 
F4E-QA-115-QD-DP-006	Supplier shall define and implement mitigation actions for potential failures falling in the 'High' and 'Serious' category. Note 1: Risk of failure has to be reduced applying ALARA criteria. See Table 1 in section 'Abbreviations and definitions' Note 2: For categories 'Medium' and 'Low' mitigation actions are recommendable
F4E-QA-115-QD-DP-007	Mitigation actions shall be agreed and accepted by F4E TPO and QAO.
F4E-QA-115-QD-DP-008	Dependability analysis shall be considered as inputs for the: - Critical quality items/activities - Control points in MIPs - Spare parts list definition

6.5 QA Requirements for Procurement and Subcontractors Management (QP)

6.5.1 General requirements (GL)

F4E-QA-115-QP-GL-001	The Supplier shall describe in PQMP the methodology for the selection of procurement sources and Subcontractors.
F4E-QA-115-QP-GL-002	The Supplier shall submit to F4E for acceptance the Supply Chain Acceptance Register as per template 9.13, identifying all the Supply Chain including raw material contractors.
F4E-QA-115-QP-GL-003	The Supplier shall assess each Subcontractors technical, financial, project and quality management capability to comply with F4E requirements and shall submit to F4E, together with the Supply Chain Acceptance Register, as an evidence of such assessment the following documents including CTS references: - Subcontractor dedicated PQMP duly reviewed and approved by the Supplier as per DRD in section 8.1 (see Note 1 and Note 2) - Subcontractor Management Control Plan and/or Manufacturing and Inspection Control Plan (MCP/MIP) duly reviewed and approved by the Supplier AD 13 (see Note 1 and Note 2) - Valid ISO 9001 (or equivalent) certificate (if applicable) - Technical specifications reference used to propagate F4E Requirement to Subcontractors Note 1: Subcontractor can be exempted from the obligation to present PQMP and/or MCP/MIP if activities performed are not considered critical according to the definition in Table 1. In that case these activities can be described in the Supplier PQMP and/or MCP/MIP Note 2: Subcontractor providing COTS, raw material or processes and activities according to standard or recognized specification without any modification, are exempted

F4E-QA-115-QP-GL-004	The Supplier shall provide, upon request, evidence of the process followed for Subcontractors selection. Note: Example of selection criteria: - Quality Management System certification (for instance ISO 9001 or equivalent). - The Subcontractor is supplying, or has supplied in the past, items or services of the type and quality level being procured under other contracts. - The Subcontractor has demonstrated continuous capability to provide items or services of the type and quality level being procured
F4E-QA-115-QP-GL-005	The Supplier shall request to F4E QAO the formal authorization to waive the submission of the documentation requested in F4E-QA-115-QP-GL-003 Note 1 and 2. The authorization shall be uploaded in CTS.
F4E-QA-115-QP-GL-006	The Supplier shall ensure that Subcontractor does not start activities before F4E acceptance of the Supply Chain Acceptance Register. Note: Prerequisite is the acceptance of the respective PQMP, MCP and/or MIP.
F4E-QA-115-QP-GL-007	The Supplier shall update Supply Chain Acceptance Register: - To introduce the new Subcontractor - To change the Subcontractor - To change the information related to a Subcontractor - To remove an existing Subcontractor which finally will not be involved
F4E-QA-115-QP-GL-008	The Supply Chain Acceptance Register shall contain all Subcontractors involved into the contract even if activities have been completed (no deletion).
F4E-QA-115-QP-GL-009	The Supplier shall exercise audit and close supervision over all the activities carried out by its Subcontractors during the whole duration of the contract and shall ensure that the same supervision is carried over in the whole Supply Chain.
F4E-QA-115-QP-GL-010	The Supplier shall submit to F4E (if requested and for information), Subcontractor's audit/supervision visits schedule (type and extent to be included), and reports. Note: Including Supplier's resident staff at Subcontractor facilities reports
F4E-QA-115-QP-GL-011	The Supplier shall notify to F4E about the forthcoming audits/supervisions to provide the possibility to F4E representative to take part in the activities as an observer or to incorporate F4E information requests into the audit plan.
F4E-QA-115-QP-GL-012	The Supplier shall follow-up all the actions resulting from the activities as per F4E-QA-115-QP-GL-009.

6.5.2 Procurement Document Requirements (PO)

F4E-QA-115-QP-PO-001	The Supplier shall ensure that items and services are properly identified in the procurement documents.
F4E-QA-115-QP-PO-002	The Supplier shall ensure the traceability of the applicable requirements in the procurement documents at any level of the Supply Chain.
F4E-QA-115-QP-PO-003	The procurement documents shall contain, by statement or reference: - Comprehensive technical descriptions of the items and services to be procured - Details of the applicable requirements Note: For COTS need only to be supplied with Manufacturer CoC.

6.5.3 Incoming Inspection (II)

F4E-QA-115-QP-II-001	Incoming inspection activities shall include: - Verification of the packaging conditions - Visual inspection of the delivered items - Verification of correct identification and conformance to the ordering data - Verification of the evidence of inspection and tests performed by the Supplier and associated documentation - Performance of inspections and tests on selected characteristics of incoming supplies or test specimens submitted with the supplies - Identification of the shelf life of limited-life items - Identification of the inspection status and physical separation of the supplies in the incoming inspection area according to the following categories: o items for which the incoming inspection has not been completed o conforming items o nonconforming items - Prevention of unauthorized use of uninspected items - Identification of the items to be released for manufacturing or assembly with conformance status and traceability data to be recorded in manufacturing documents
F4E-QA-115-QP-II-002	The Supplier shall maintain incoming inspection records to ensure the traceability and availability of historical data to monitor supplier performance and quality trends.

6.5.4 Raw Materials requirements (RW)

F4E-QA-115-QP-RW-001	The Supplier shall ensure that purchased goods and materials are supplied together with their Certificate of Conformity (RMC) to the specified requirements according to RS 06 Type 2.2 for Quality Class 3 (no Nuclear Safety Related) and Type 3.1 for all the remaining cases of classes 1 to 3.
F4E-QA-115-QP-RW-002	The content of the RMC shall be as minimum the following (applicability according to Contract Annex B where this is identified): - Supplier's name - F4E Contract number (the parent contract in case of subcontracting) - Material standard designation - Material Batch/Lot number - Date of batch manufacturing - Manufacturing process - Records of specified Heat Treatments (if requested in Annex B) - Test results of the specified chemical composition measurements (if requested in Annex B) - Test results of the specified mechanical and physical tests (if requested in Annex B) - Records of specified micrographic examinations (if requested in Annex B) - Inspection results of the specified Non-Destructive Tests (if requested in Annex B) - Packaging data

6.6 QA Requirements for Prototyping (QR)

F4E-QA-115-QR-QR-001	Supplier shall propose in the PQMP a tailoring of section 6.8 for the activities related to prototyping.

6.7 QA Requirements for Qualification Activities (QQ)

F4E-QA-115-QQ-QQ-001	The Supplier shall ensure that all items and their constituent sub-items, either COTS or specifically designed, are properly qualified with margins commensurate with the application and use environment.
F4E-QA-115-QQ-QQ-002	Qualification strategy shall be documented in the PQMP and accepted by F4E.
F4E-QA-115-QQ-QQ-003	Qualification strategy shall be either by one of the following approaches: - Similarity: With an identical or similar product shall be justified by providing evidence that the new application is within the limits of the previously qualified design - Testing: The product used for qualification testing shall be produced in accordance with a full and clearly identified manufacturing and inspection file
F4E-QA-115-QQ-QQ-004	Requirements defined in section 6.9 shall apply for qualification by testing.
F4E-QA-115-QQ-QQ-005	Qualification results shall report the qualification status in conformance with the Qualification status list as per DRD in section 8.6.
F4E-QA-115-QQ-QQ-006	The Supplier Quality representative shall review and approve the qualification approach and the Qualification status list (QSL).

6.8 QA Requirements for Manufacturing, Assembly and Integration (QM)

6.8.1 Manufacturing Plan (MP)

F4E-QA-115-QM-MP-001	The Supplier shall document the planning of manufacturing, assembly and integration operations and inspections in the manufacturing plan or flowchart for the product, including: - The sequence of operations - Associated inspections and tests - Execution methods for all critical activities (procedures, work instructions, etc) - Site/premises where the activities will be performed - Supplier's equipment to be used - Resources planned to be employed - Site mobilization plan (if applicable)
F4E-QA-115-QM-MP-002	The Supplier shall submit the Manufacturing Plan to F4E TPO for acceptance.
F4E-QA-115-QM-MP-003	The Supplier shall issue and maintain manufacturing, assembly and integration documents in accordance with established plan.
F4E-QA-115-QM-MP-004	The Supplier shall develop clear working documents and instructions, such as drawings, procedure, pictures and instruction sheets, to enable operations to be correctly performed.
F4E-QA-115-QM-MP-005	Manufacturing plan shall include all control points defined in the Manufacturing and Inspection Control Plans in conformance with section 6.2, together with the reference to the procedures to be used.
F4E-QA-115-QM-MP-006	Supplier shall develop according to requirements in section 6.2, a dedicated MIP including all foreseen activities to be implemented directly related to the follow-up and verification of the quality of the final product(s) and/or service(s).
F4E-QA-115-QM-MP-007	Manufacturing documentation (e.g. instructions, drawings, registers) shall be referred in of MIP.
F4E-QA-115-QM-MP-008	Manufacturing documentation (e.g. instructions, drawings, registers) shall be written in the local language with a summary in English.
F4E-QA-115-QM-MP-009	For serial production requirements in section 6.8.6 apply.

6.8.2 Manufacturing Readiness Review (MR)

F4E-QA-115-QM-MR-001	The Supplier shall participate in F4E MRR process according to RD 14. The Supplier expected contribution is defined RD 14 'Roles and Responsibilities' section.
F4E-QA-115-QM-MR-002	The Supplier shall ensure that the Supply Chain is prepared for the MRR process covering the following topics: - Design is agreed and under configuration control - Qualification activities have been successfully performed - Manufacturing plan is adequate and feasible - Manufacturing documentation is adequate, enough and clear - Manufacturing facilities are adequate, ready and available - Tooling for handling, assembly or quality control activities is ready and adequate - Manufacturing staff is adequate, available and trained - Manufacturing Equipment is adequate and under correct calibration status - Risks are identified and mitigation actions defined or in place - Verification activities are foreseen
F4E-QA-115-QM-MR-003	Manufacturing activity shall only be authorized by the common agreement of the MRR panel members.

6.8.3 Control of processes (PC)

F4E-QA-115-QM-PC-001	Manufacturing, assembly and integration activities shall be performed following the pre-established manufacturing plan.
F4E-QA-115-QM-PC-002	Manufacturing, assembly and integration activities shall be performed using the last accepted versions of the manufacturing documentation.
F4E-QA-115-QM-PC-003	Manufacturing documentation shall be available to the personnel performing the activities.
F4E-QA-115-QM-PC-004	The Supplier shall monitor all processes used for manufacturing, assembly and integration through the accepted Manufacturing and Inspection Control Plans.
F4E-QA-115-QM-PC-005	The Supplier shall ensure that all manufacturing processes are covered by documented process specifications or standards.
F4E-QA-115-QM-PC-006	Process specifications shall include quality provisions, methods for inspection and test, number of samples, accept or reject criteria.

6.8.4 Materials and parts control (MC)

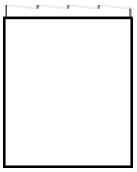
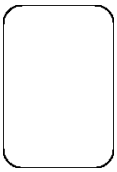
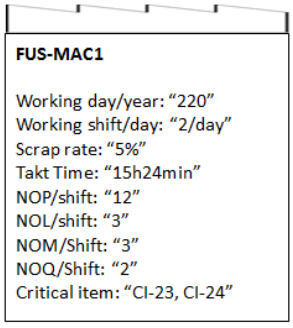
F4E-QA-115-QM-MC-001	The Supplier shall ensure that only conforming/inspected and accepted items are released and used, and that those not required for the operation involved are removed from work operation areas.
F4E-QA-115-QM-MC-002	Items having limited–life or definite characteristics of quality degradation or drift with age or use shall be marked to indicate the dates, test times or cycles at which life was initiated and at which the useful life expires.
F4E-QA-115-QM-MC-003	Items requiring special conditions (humidity, temperature, cleanliness, etc.) shall be processed or manufactured, inspected and tested in a controlled environment to prevent any degradation.

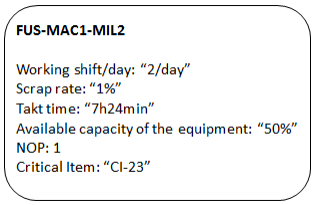
6.8.5 Maintenance and control of equipment (MN)

F4E-QA-115-QM-MN-001	The Supplier shall make provisions for accountability, identification and maintenance of manufacture, assembly and integration tooling and equipment.
F4E-QA-115-QM-MN-002	Manufacture, assembly and integration tooling and equipment shall be checked for its dimensional accuracy, regarding the product drawings, and correct function.
F4E-QA-115-QM-MN-003	Manufacture, assembly and integration tools shall be checked for accuracy during the production life at adequate intervals.
F4E-QA-115-QM-MN-004	Manufacture, assembly and integration tools shall be submitted to re–approval following modification.
F4E-QA-115-QM-MN-005	Manufacture, assembly and integration tools shall be properly stored to prevent misuse, damage and deterioration.

F4E-QA-115-QM-MN-006	Unnecessary manufacture, assembly and integration tools shall be removed from working areas.
F4E-QA-115-QM-MN-007	Records shall be kept of all manufacturing equipment and its maintenance.

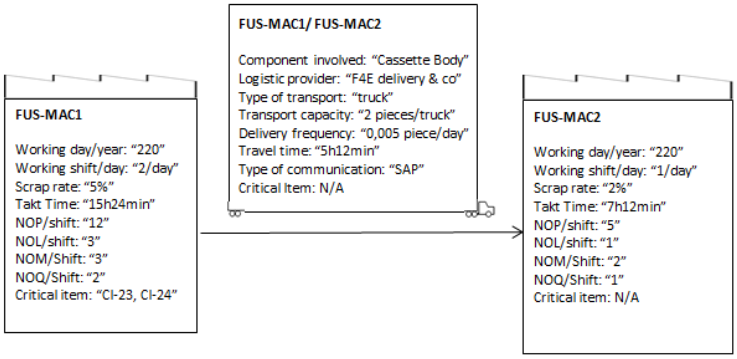
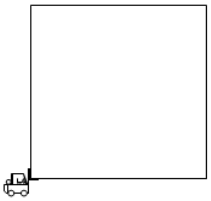
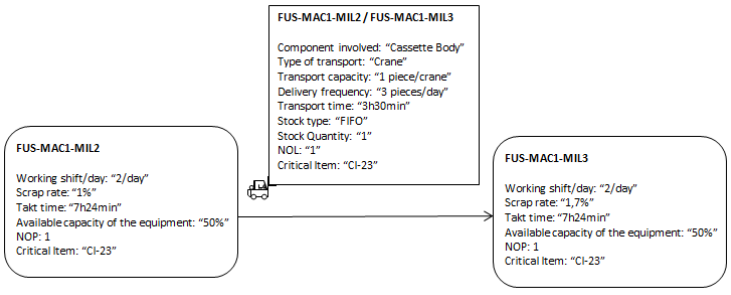
6.8.6 Series production (SE)

<table>
<tr><td>F4E-QA-115-QM-SE-001</td><td>Manufacturing flowchart requested in section 6.8.1, shall be defined at 2 (two) zoom levels for serial production:
- Macro
- Micro
Note: See F4E-QA-115-QM-SE-004</td></tr>
<tr><td>F4E-QA-115-QM-SE-002</td><td>The Supplier shall develop and maintain a Process FMEA/FMECA (P-FMEA/FMECA) as per template 9.8 which shall be input for the definition of the critical quality items.</td></tr>
<tr><td>F4E-QA-115-QM-SE-003</td><td>The Supplier shall identify critical quality items/activities related to serial production in a manufacturing flowchart (macro and micro).</td></tr>
<tr><td>F4E-QA-115-QM-SE-004</td><td>The Supplier shall use the following symbols flowcharts to identify premises (macro) and work-station (micro):
<table>
<tr><th>Macro</th><th>Micro</th></tr>
<tr><td>  </td><td>  </td></tr>
<tr><td>Example
MACRO Premise example:
Company name: FUSION FOR ENERGY
Activity: Machining on part 1
 

Legend:
FUS-MAC1: Machining process on part 1 at FUSION FOR ENERGY premises</td><td>Example
MICRO Work station example:
Company name: FUSION FOR ENERGY
Activity: Machining on part 1
Work station: Milling machine number 2
 

Legend:
MIL2: Milling machine 2</td></tr>
</table>
</td></tr>
<tr><td>F4E-QA-115-QM-SE-005</td><td>The Supplier shall define an acronym list (acronym + legend) for all premises using the symbol requested in requirement F4E-QA-115-QM-SE-004.
For the definition of the acronym in macro flowchart, the following rules shall be used:
- Premise acronym: Same than in F4E-QA-115-DM-DR-001.
- Activity acronym: Activity shall be identified with a 3 letters acronym and a sequential number. Sequential number shall be only used if there are several activities of the same type (e.g. 2 different welding activities could be identified as WEL1 and WEL2).
- Final acronym (macro) shall be: Premise acronym – activity acronym</td></tr>
</table>

F4E-QA-115-QM-SE-006	The Supplier shall define an acronym list (acronym + legend) for all work-stations using the symbol requested in requirement F4E-QA-115-QM-SE-004. For the definition of the acronym in micro flowchart, the following rules shall be used: - Final acronym (macro) (see F4E-QA-115-QM-SE-005) - Work-station acronym shall be identified with 3 letters identifying activity of the work-station (e.g. INC for Incoming inspection). Sequential number can be used if there are several work-stations performing same or similar activity. - Final acronym (micro) shall be: Final acronym (macro) – work-station acronym
F4E-QA-115-QM-SE-007	Final acronym (macro) and (micro) shall be included inside the symbol defined in F4E-QA-115-QM-SE-004.
F4E-QA-115-QM-SE-008	The Supplier shall include also inside the symbol in requirement F4E-QA-115-QM-SE-004, the following information for the Macro flowchart: - Working days/year - Working shift/day - Global expected Scrap rate (%) - Takt-Time - Number of operators involved in Production by shift (NOP) - Number of operators involved in Logistic by shift (NOL) - Total number of operators involved in Maintenance by shift (NOM) - Total number of operators involved in Quality by shift (NOQ)
F4E-QA-115-QM-SE-009	The Supplier shall include also inside the symbol in requirement F4E-QA-115-QM-SE-004, the following information for the Micro flowchart: - Working shift/day - Global expected Scrap rate (%) - Takt-Time - Available capacity of the equipment (% time) - Number of operators involved in Production by shift by work-station (NOP) - Critical quality item/activity identification (if applicable)

F4E-QA-115-QM-SE-010	The Supplier shall use the following symbols flowcharts to identify logistics between premises (macro) and work-station (micro): **Macro**  Example  **Micro**  Example 
F4E-QA-115-QM-SE-011	The Supplier shall connect the premises in the macro flowchart by using the identification in F4E-QA-115-QM-SE-010 and including inside the following information: Premise acronym – activity acronym $_{\text{premise 1}}$ / Premise acronym – activity acronym $_{\text{premise 2}}$

F4E-QA-115-QM-SE-012	The Supplier shall add the following information in addition to the requested in F4E-QA-115-QM-SE-011: - Component involved - Logistic provider - Type of transport (truck, plane, etc) - Transport capacity (pieces by truck/plan, etc) - Delivery frequency (pieces by day) - Transport expected time - Type of communication (SAP, MRP, etc) - Critical quality item/activity identification (if applicable)
F4E-QA-115-QM-SE-013	The Supplier shall connect the premises in the micro flowchart by using the identification in F4E-QA-115-QM-SE-010 and including inside the following information: Work-station acronym$_1$ / Work-station acronym$_2$
F4E-QA-115-QM-SE-014	The Supplier shall add the following information to the requested in F4E-QA-115-QM-SE-013: - Component involved - Type of transport (forklift, AGV, crane, etc) - Transport capacity (pieces by forklift, AGV, crane, etc) - Delivery frequency (pieces by day) - Transport expected time - Stock type (FIFO, LIFO, etc) - Stock quantity - Number of operators involved in Logistic by shift (NOL) - Critical quality item/activity identification (if applicable)

6.8.7 Special Processes (SP)

F4E-QA-115-QM-SP-001	Supplier shall establish and implement procedures and controls for special processes.
F4E-QA-115-QM-SP-002	Special Processes shall be qualified before starting its use. Qualification shall be performed according to requirements defined in section 6.7.
F4E-QA-115-QM-SP-003	Special Processes qualification records shall be submitted to F4E TPO and QAO for acceptance.
F4E-QA-115-QM-SP-004	Special Processes shall be considered a critical quality activity and included in the Critical Quality Items List as per requirement F4E-QA-115-QA-CI-002.
F4E-QA-115-QM-SP-005	Special processes qualification activities shall be included in the MIP as per requirement. F4E-QA-115-QA-CP-001.
F4E-QA-115-QM-SP-006	Materials, equipment, computer systems and software, and procedures involved in the performance of the special process shall be validated and monitored.
F4E-QA-115-QM-SP-007	Coordination shall be maintained between the Supplier engineering, quality and manufacturing functions to ensure the proper selection of the inspection techniques, acceptance criteria, tools, etc. for the evaluation of process performance.

6.8.7.1 Special Process: Welding (WD)

F4E-QA-115-QM-WD-001	The Supplier shall consider welding as Special process for prototypes, mock-ups, production, manufacturing and spare parts.
F4E-QA-115-QM-WD-002	The Supplier shall execute each weld based on a project-specific Welding Procedure Specification (WPS) accepted in advance by F4E.
F4E-QA-115-QM-WD-003	Only certified welders (and operators) shall perform welds or tack welds.
F4E-QA-115-QM-WD-004	The welder certificates shall be presented and accepted by F4E before starting of the welding activities.
F4E-QA-115-QM-WD-005	WPS and welders shall be qualified by a Certification or Notified Body.

F4E-QA-115-QM-WD-006	A WPS based on an existing qualified welding procedure (WPQR, WPAR or PQR) shall not be acceptable if the following conditions are not met: - The qualification has been performed in the same environment as proposed for production, using the same welding technique, process, joint configuration and welding equipment (for mechanised welds) - The allowable ranges are the same with regard to essential variables (ASME) or within the qualification range of qualification (EN) - The qualification was performed in accordance with applicable standard - The qualification has been witnessed by a Certification or notified Body
F4E-QA-115-QM-WD-007	The Supplier shall invite F4E to witness the welding qualifications. Note: Control Point has to be considered a Notification Point
F4E-QA-115-QM-WD-008	The Supplier shall submit the qualified welding procedure for acceptance of the WPS qualification.
F4E-QA-115-QM-WD-009	The Supplier shall invite F4E to witness the Production Test Welds (production proof samples) tests.
F4E-QA-115-QM-WD-010	The Supplier shall maintain a Weld Log for any part/item that contains welds or include it in a more general assembly weld log (also called weld record, map or plan).
F4E-QA-115-QM-WD-011	Weld log shall at least include for traceability purposes, the following information: - Weld references and joint detail - Material data (Base Material and Filler Metal) - Heat number - WPS - Process - Welder (identification and certificate number) - Heat treatment (procedure and report number) - NDT performed and welding standard: o NDT method such as VT/PT/RT/UT/LT o NDT operator ID and/or certificate o NDT report number o NDT applicable standard
F4E-QA-115-QM-WD-012	Any repairs shall be clearly identified as a new weld in the log, logging it as 'RWK'. Note: RWK stands for ReWorK
F4E-QA-115-QM-WD-013	The weld log shall contain the Supplier approval (date, position and signature) and shall be included in the ADP.
F4E-QA-115-QM-WD-014	The weld log shall be referenced in Records section of the Manufacturing and Inspection Control Plan (MIP).

6.9 QA requirements for Testing (QT)

6.9.1 Testing facilities (TF)

F4E-QA-115-QT-TF-001	The Supplier shall ensure that test facilities, either internal or external, conform to specified requirements and are adequate to the purpose of the test.

6.9.2 Test equipment (TE)

F4E-QA-115-QT-TE-001	The Supplier shall ensure that test equipment, either internal or external, conform to specified requirements and are adequate to the purpose of the test.
F4E-QA-115-QT-TE-002	Test equipment used to provide evidence of compliance to a requirement shall be calibrated.

6.9.3 Test plan and documentation (DC)

F4E-QA-115-QT-DC-001	Supplier shall develop according to requirements in section 6.2, a dedicated MIP including all foreseen test activities to be implemented.

F4E-QA-115-QT-DC-002	Test sequence defined in the MIP shall include intermediate functional verifications stages after critical tests to identify any potential post-test damage.
F4E-QA-115-QT-DC-003	The Supplier shall ensure that tests are performed in accordance with documented procedures, which shall include, as a minimum the requirements defined in DRD in section 8.8.
F4E-QA-115-QT-DC-004	The Supplier shall ensure that all tests are comprehensively documented in test reports which shall include, as a minimum the requirements defined in DRD in section 8.9, in case of no applicable standards apply.
F4E-QA-115-QT-DC-005	Reference to test procedures and reports shall be included in the relevant section of the MIP.

6.9.4 Test Readiness Review - TRR (TR)

F4E-QA-115-QT-TR-001	The Supplier shall call for the TRR prior to the start the first test of the test campaign. TRR has to cover the topics defined in DRD in section 8.7.
F4E-QA-115-QT-TR-002	The TRR shall be composed, at least, of the following members: F4E: - QAO, or authorized representative, as chairman - TPO, or authorized representative Supplier or Subcontractor representatives: - QA Representative, or authorized representative - Project Manager, or authorized representative - Higher level customers' representative(s), as observers
F4E-QA-115-QT-TR-003	The TRR panel shall be responsible for authorising the start of the test activities and certifying in writing that: - Items under test are ready and without any visual damage - The items under test are under correct configuration control - All test procedures have been properly accepted and according to test plan - All requirements to be covered by test are already foreseen to be verified in at least one procedure - Acceptance criteria are clear and well defined - Test facilities are available and adequate - Test personnel is available, adequate and properly trained - Test equipment is adequate and under correct calibration status
F4E-QA-115-QT-TR-004	Test activity shall only be authorized by the unanimous agreement of the TRR panel members.

6.9.5 Test performance monitoring (MN)

F4E-QA-115-QT-MN-001	Supplier shall not start the testing activities without all procedures accepted by F4E.
F4E-QA-115-QT-MN-002	Any departure from the accepted test procedure/protocol shall be managed as a NCR as per section 6.3.2.
F4E-QA-115-QT-MN-003	If items under test are damaged, the Supplier shall stop immediately the test, communicate it to F4E TPO and QAO and raise a NCR as per section 6.3.2.
F4E-QA-115-QT-MN-004	Test witnessing by Quality Representative shall be considered when manual intervention is performed, at the setting–up, start and end of continuous fully automated test sequences, or when no automatic recording of test parameters or results is available. Note: The objectives of the witnessing are the following: - To verify that the correct and accepted version of the test procedures is the one foreseen to be used - The equipment foreseen to be used is the accepted one and properly calibrated - The test set-up is properly performed - Test personnel is qualified - No deviations with respect to the foreseen procedures - All NCRs are raised and documented during the test - Test procedure is followed as accepted - Test results are correctly taken and documented

6.10 QA requirements for Acceptance and Delivery (QL)

6.10.1 Acceptance Data Package – ADP (AP)

F4E-QA-115-QL-AP-001	The Supplier shall deliver to F4E an Acceptance Data Package (ADP) before any payment milestone. This package shall include evidence of all activities performed for that milestone. Note: In Grant Agreements, the Activity Report is the equivalent of a Contract Deliverable and the ADP.
F4E-QA-115-QL-AP-002	The Supplier shall provide a complete Acceptance Data Package (ADP) as per DRD in section 8.5, at the end of the activities included in the contract. Note: If a particular section in the ADP is not applicable, then a statement shall be made e.g.: "There are no "Loose Items" present in this equipment" or "This section is not applicable".
F4E-QA-115-QL-AP-003	Acceptance Data Package requested in F4E-QA-115-QL-AP-002, shall include a Release Note/Certificate of Conformity (RN/CoC) after the cover-sheet.

6.10.2 Acceptance and delivery process (PR)

F4E-QA-115-QL-PR-001	The Supplier shall define a formal acceptance process for all deliverable items within the Supply Chain to ensure that conformance of the items to be delivered is fully assessed and documented. Note: Process must be compliant with F4E requirements
F4E-QA-115-QL-PR-002	The Supplier shall comply with the following steps for the acceptance of the deliverable: 1. Supplier to submit the RN/CoC to F4E as per Template 9.9 2. F4E TPO to sign the RN/CoC confirming that all activities have been properly performed 3. F4E TPO to send back RN/CoC to Supplier 4. Supplier to include the RN/CoC as first page of the ADP 5. Supplier to proceed with the final payment invoice Note: Control Point for delivery in the MCP has to be divided in 2 steps: 1. Submission of the RN/CoC 2. Submission of the ADP

6.10.3 Delivery Readiness Review – DRR (FA)

F4E-QA-115-QL-FA-001	Final acceptance of the deliverable at all levels of the Supply Chain shall be decided by in a Delivery Readiness Review (DRR). At least the following roles of supplying and receiving parties shall be present in the DRR: - Project Manager or authorized representative (the project manager of the receiving organization acting as chairman) - QA Representative or authorized representative - Engineering or design manager, or authorized representative - Higher level customers' representative(s), as observers (if needed)
F4E-QA-115-QL-FA-002	DRR shall verify the following topics to authorize the delivery/shipment of the items under acceptance. Authorization shall be certified in writing through the RN/CoC as per template in AD 21: - The items conform to the contractual requirements and to an approved design configuration - All nonconformance's are closed–out, or corresponding plans, compatible with the delivery, are accepted - All deviations are approved and implemented - The relevant ADP is complete and accurate - The items are free from material and workmanship deficiencies (for hardware delivery) - The items have been validated as complete product (for software delivery)
F4E-QA-115-QL-FA-003	Delivery shall only be authorized by the unanimous agreement of the DRR panel members.

6.10.4 Preparation for delivery (PD)

F4E-QA-115-QL-PD-001	The Supplier shall ensure packaging materials, methods, procedures and instructions to protect the items while are at the Supplier's premises, during transportation, and at delivery.
F4E-QA-115-QL-PD-002	The Supplier shall ensure that appropriate marking and labelling for packaging, storage, transportation and shipping of items are performed in accordance with requirements defined in Management and Technical Specifications (Annex A and B).
F4E-QA-115-QL-PD-003	Type and contents of labelling as well as precautions during storage and transportation shall be described in PQMP and shall be compliant with requirements defined in Management and Technical Specifications (Annex A and B).
F4E-QA-115-QL-PD-004	Hazardous goods shall be handled according to AD 10 and/or AD 11.

6.10.5 Delivery

6.10.5.1 Shipping control (SC)

F4E-QA-115-QL-SC-001	The Supplier shall ensure that the items to be shipped from his facilities are inspected before release and found to be complete, adequately preserved and packaged, correctly marked and accompanied by all the required documentation.
F4E-QA-115-QL-SC-002	If special care shall be taken in the handling of the delivered hardware, attached to the outside of the shipping container, the handling and packing or unpacking procedure and any relevant safety procedures shall be included.

6.10.5.2 Transportation (TS)

F4E-QA-115-QL-TS-001	The Supplier shall make provisions for the prevention of damage to items during transportation.

6.11 Software Quality Assurance Requirement (QS)

6.11.1 Verification an Validation of Calculation and Modelling Tools (VV)

F4E-QA-115-QS-VV-001	The Supplier shall define the software development life cycle in the PQMP including description of the following: - Phases - Input and output of each phase - Status of completion of phase output - Milestones - Dependencies - Responsibilities
F4E-QA-115-QS-VV-002	The Supplier shall identify and describe the following activities in the PQMP: - Development - Specification, design and customer documents to be produced - Configuration and documentation management - Verification, testing and validation activities - Maintenance
F4E-QA-115-QS-VV-003	The Supplier shall propose the Software criticality level based on international standards.
F4E-QA-115-QS-VV-004	The Supplier shall define and implement measures to avoid propagation of failures between software components of different criticality such as separate hardware platforms, isolation of software processes or prohibition of shared memory (segregation and partitioning).
F4E-QA-115-QS-VV-005	The Supplier shall classify Software components whose malfunction may cause failures of higher criticality components in accordance with the consequences of those failures according to the selected international standards criteria of the requirement F4E-QA-115-QS-VV-003.

F4E-QA-115-QS-VV-006	The Supplier shall perform regression testing on critical software after: - Any change of functionality of the underlying platform hardware - Any change of the tools that affect directly or indirectly the generation of the executable code
F4E-QA-115-QS-VV-007	The Supplier shall (re-)execute unit, validation and integration testing on non-instrumented code.
F4E-QA-115-QS-VV-008	The Supplier shall provide software configuration file and the software release document with each software delivery.
F4E-QA-115-QS-VV-009	The Supplier shall maintain the software configuration file available and up to date for each project milestone.
F4E-QA-115-QS-VV-010	The Supplier shall control the following documents: - Procedural documents describing the quality system to be applied during the software life cycle - Planning documents describing the planning and progress of the activities - Documents describing a particular software product, including: o Development phase inputs o Development phase outputs o Verification and validation plans and results o Test case specifications, test procedures and test reports o Traceability matrices o Documentation for the software and system operators and users o Maintenance documentation
F4E-QA-115-QS-VV-011	The Supplier shall identify a method and tool to protect the supplied software against corruption.
F4E-QA-115-QS-VV-012	The Supplier shall define a checksum-type key calculation for the delivered operational software and provide it in the software configuration file with each software delivery.
F4E-QA-115-QS-VV-013	The Supplier shall define a set of process and product metrics to be used to manage the development and to assess the quality of the development processes, including as a minimum the following: - Duration: how phases and tasks are being completed versus the planned schedule - Effort: how much effort is consumed by the various phases and tasks compared to the plan - Number of problems detected during verification - Number of problems detected during integration and validation testing and use - Size (code) - Complexity (design, code) - Fault density and failure intensity - Test coverage - Number of failures
F4E-QA-115-QS-VV-014	The Supplier shall report the metrics as part of the progress report as per DRD in section 8.2.
F4E-QA-115-QS-VV-015	The Supplier shall specify verification activities of the quality requirements such as review, inspection, testing, walk-through, cross-reading, desk-checking, model simulation, etc.
F4E-QA-115-QS-VV-016	In case of software containing deactivated code, the Supplier shall specifically verify that that the deactivated code cannot be activated or that its accidental activation cannot harm the operation of the system.
F4E-QA-115-QS-VV-017	In case of software containing configurable code, the Supplier shall specifically verify that any unintended configuration cannot be activated at run time or included during code generation.
F4E-QA-115-QS-VV-018	The Supplier shall specify and observe coding standards (including consistent naming conventions and adequate commentary rules).
F4E-QA-115-QS-VV-019	The Supplier shall propose, based on the criticality of the software, the test coverage goals for each testing level and their achievement monitored by metrics.

7 Deliverable Baseline

Document Title	Acronym	Template	DRD	Tender	After KoM	CDR	PDR	FDR	MRR	TRR	DRR	Comments
Project Management Documents												
Project and Quality Management Plan	PQMP	-	8.1	R	A	-	A	A	R	-	A	To be updated as needed
Intellectual property foreground declaration		-	-	-	-	-	-	-	-	-	A	And as needed
Progress Report			8.2	-	-	-	-	-	-	-	-	As per req. F4E-QA-115-PM-DS-004
Time Schedule		-	-	-	-	-	-	-	-	-	-	As per req. F4E-QA-115-PM-DS-004
Deviation	DR	-	-	-	-	-	-	-	-	-	-	As needed / DACC tool to be used
Management Control Plan	MCP	9.2	-	R	A	-	A	A	R	-	A	To updated as needed
Supply Chain Acceptance Register	SCAR	9.13	-	A	-	-	A	A	R	-	A	
Risk Register		9.12	-	-	-	-	-	-	-	-	-	As defined in AD 07
Release Note / Certificate of Conformance	RN	9.10	-	-	-	-	-	-	-	-	A	
Acceptance Data Package	ADP	-	8.5	-	-	-	-	-	-	-	A	
Dual-use List				R	A	A	A	A	-	-	A	
Configuration Documents												
Configuration Management Plan		-	-	R	A	-	A	A	R	-	A	Could be included in the PQMP. To updated as needed
Configuration and Document List		9.1		-	-	A	A	A	A	A	A	And as per req. F4E-QA-115-PM-DS-004
Deviation Status list		-	-	-	-	A	A	A	-	-	A	List including minimum: - Title - Code - Topic - Status

Document Title	Acronym	Template	DRD	Tender	After KoM	CDR	PDR	FDR	MRR	TRR	DRR	Comments
Engineering Documents												
Design and Development Plan		-	-	R	A	-	A	A	-	-	A	
Assembly Integration and Validation Plan		-	-	-	-	-	A	A	A	A	A	
Technical specification		-	-	-	-	A	A	A	-	-	-	
Interface documents/drawing		-	-	-	-	-	A	A	-	-	-	
Product Tree		-	-	R	A	A	A	A	-	-	A	
Failure Mode and Effect (Criticality) Analysis	FMEA / FMECA	9.7	-	-	-	R	A	A	-	-	-	
Process Failure Mode and Effect (Criticality) Analysis	P-FMEA / P-FMECA	9.8	-	-	-	-	R	A	A	-	-	
Design Report/Description		-	-	-	-	A	A	A	-	-	-	
Drawings		-	-	-	-	A	A	A	A	-	-	
Analysis		-	-	-	-	A	A	A	-	-	-	
Quality Documents												
Verification Control Document	VCD	-	-	-	-	A	A	A	A	A	A	As per AD 04
Manufacturing and Inspection Control Plan	MIP	9.2	-	-	-	-	-	R	A	A	A	
Previous reviews status List		-	-	-	-	-	R	R	R	R	A	List including minimum: - Action ID - Title - Status
Declared Materials List	DML	9.4	-	-	-	-	A	A	R	-	A	
Declared Components List	DCL	9.3	-	-	-	-	A	A	R	-	A	
Declared Processes List	DPL	9.6	-	-	-	-	A	A	R	-	A	
Declared Mechanical Part List	DMPL	9.5	-	-	-	-	A	A	R	-	A	
Critical quality items List	CIL	-	8.3	-	-	A	A	A	-	-	A	
Qualification Status List	QSL	-	8.6	-	-	-	R	A	A	-	A	
Manufacturing Plan		-	-	-	-	-	R	A	A	-	A	

Document Title	Acronym	Template	DRD	Tender	After KoM	CDR	PDR	FDR	MRR	TRR	DRR	Comments
List of Spares		-	-	-	-	-	-	A	A	-	A	List including minimum: - Description - Type - Product tree allocation - Manufacturer - Part number - Serial number - Storage place
Test Procedure		-	8.8	-	-	-	-	A	-	A	-	
Test Report		-	8.9	-	-	-	-	-	-	-	A	
Nonconformity Report	NCR	-	-		-	-	-	-	-	-	-	As needed through NCR database
NCR Status list		-	-	-	-	-	-	-	-	A	A	List including minimum: - Title - Code - Topic - Status
Operations Documents												
User Manual		-	8.10	-	-	-	-	R	-	-	A	
Handling, Utilization, Transportation and Storage Documents		-	-	-	-	-	-	R	-	-	A	

Note: For documents under configuration control the delivery extends to issue of updates.
R = Review, A = Acceptance

8 Document Requirement Definition

8.1 Project and Quality Management Plan (PQMP) DRD

8.1.1 Identification

This DRD is called in sections 2, 3, 4, 5 and 6.
The primary objective of this document is to:

- State the purpose and provide a brief introduction to the project management system
- Describe the activities to be performed by the supplier to assure the quality of the product/service with regard to the specified objectives
- Demonstrate compliance to the applicable managerial, technical and quality requirements

8.1.2 Expected response (mirroring this document sections/subsections):

A. General and Legal Requirements
Describe the requirement project approach in conformance with the requirements as defined in section 2

B. Documentation and Information management
Describe the documentation and security management approach and the used tools in conformance with the requirements as defined in section 3.

C. Configuration Management
Describe the configuration management approach/system/tools to be in conformance with the requirements as defined in section 4.

D. Project Management
Describe the project management approach with regard to the topic in section 5 and to be in conformance with the requirements as defined in section 5

E. Quality Assurance Management
Describe the established, maintained and implemented approach to be in conformance with the requirements as defined in section 6.

Suggested sub-sections, mirroring the present document, are:

E 1. Project and Quality Management Plan Requirements
E 2. Control Plan Requirements
E 3. QA General Requirements
E 4. QA requirements for design
E 5. QA requirements for procurement and Subcontractors Management
E 6. QA Requirements for Prototyping
E 7. QA Requirements for Qualification Activities
E 8. QA requirements for Manufacturing, assembly and Integration
E 9. QA requirements for Testing
E 10. QA requirements for Acceptance and Delivery
E 11. SW QA requirements

8.2 Progress Report DRD

8.2.1 Identification

This DRD is called in sections 2 and 5 and 6.11.1.
The primary objective of this document is to provide all actors with actual information concerning the status of the project.

8.2.2 Expected response:

A. Executive Summary
   1. The project manager's assessment of the current situation in relation to the forecasts and risks
   2. IPR, CE Marking and dual use technologies
   3. Risk Register
   4. Action Item List & Status for Management, Technical, Quality and Safety Nuclear and Health, Safety and Environment domain
   5. Recovery Plan if needed Re-programmed activities required to recover time on any activities behind programme

B. Contract Status
   1. Tasks Achieved during the period
   2. Task Foreseen for the next period
   3. Task not achieved during the period
   4. Planned Activities transferred to further period:

Activity ID/Title	Initial Expected Date	Current Planned Date	Planned last month	Actual Execution date	Closure Reference document	Justification for Delay

Note: Tasks to be reported are:
- Control Points from MCP and MIP
- Planned Milestones/Meetings/Reviews
- Unforeseen Task (e.g. Actions from NCRs/Deviations/Audits)

C. Procurement Status for items with impact on schedule:
   1. Material Procurement
   2. Long Lead Items
   3. Dual-use Items

D. Schedule Management
   1. Schedule Variance
   2. Entire updated schedule (source file).
   3. List of changes affecting schedule
   4. Main milestones 45 degree chart
   5. EVM trend (schedule) from the beginning of the contract and the justification in case of discrepancies.

E. Financial Status
   1. Milestone Payment Plan
   2. Forecasted invoices planned to be submitted to F4E (planned amount and date) / 3 months forecast
   3. Cost Management:
      a) Cost at a contract signature (date).
      b) List of changes affecting cost (date and corresponding increase)
      c) Total cost of changes

d) Total as at the date of the report
e) Deviations with the cost impact in the approval circuit including proposed cost.
f) EVM trend (cost) from the beginning of the contract and the justification in case of discrepancies.

F. Technical Status
1. Status of the progress of work being performed by the Supplier
2. Status Documentation submission
3. A summary of Subcontractors progress reports identifying main issues impacting F4E activities, when applicable

G. Manufacturing Status

H. Quality Assurance Status

1. Audit & Monitoring plan and status and results at all levels (including internals)
2. Status list of all NCRs (including INC) and Deviations
3. Status of the Critical Quality Items/Activities
4. Qualification status
5. Status of activities (internal and at Subcontractor) requiring quality representative involvement

I. Nuclear Safety Status

J. Software development:

1. Process and product metrics
2. Status of verification activities

K. For IO site:
1. H&SE incidents
2. HS&E reviews and assessment

8.3 Critical Quality Items and Activities List (CIL) DRD

8.3.1 Identification

This DRD is called in section 6.3.1
The primary objective of this document is to summarise, in a table format (as per example below) all critical quality items and/or activities.

8.3.2 Expected response:

A. Number: it uniquely identifies the critical quality item.
B. Critical quality item: it uniquely identifies the critical quality item.
C. Risks associated: it is the technical risk(s) associated with the critical quality item.
D. Document reference: it is a reference to the document in which the item is identified as critical and/or to the design, manufacturing and test documentation related to the critical quality item.
E. Criticality level: it is the criticality level of the critical quality item in accordance with the classification in section 6.4.6.
F. Cause: it contains the description of the cause which makes this item critical.
G. Control activities: it contains planned activities to reduce or control the risk and the statement of verification of the control implementation
H. Due date: It shows the expected completion date of the control activities.
I. Status: the status of action as “Open” or “Closed” and in case of closed action, it provides the reference to the close-out document

No.	Critical quality item	Risks associated	Reference doc.	Criticality level	Cause	Control activities	Due date	Status

8.4 Compliance Matrix to F4E-QA-115 DRD

8.4.1 Identification

This DRD is called in Section 6.1
The primary objective of this document is to declare the conformance of the Supplier management system to the F4E project management and quality requirements.

8.4.2 Expected response:

A. Requirement number

B. Requirement description

C. Status: Compliant (C) / No compliant (NC) / Partial compliant (PC) / Not applicable (NA)

D. PQMP section where requirement is described

E. Observation / Justification to describe reasons for No compliant and Partial Compliant

8.5 Acceptance Data Package (ADP) DRD

8.5.1 Identification

This DRD is called in Sections 5.1.2, 6.3.2, 6.8.7, 6.8.7.1, 6.10.1, 6.10.2, 6.10.3 and 6.11
The primary objective of this document is to declare the conformance of the item(s) in all respect with the applicable specification(s), drawing(s) and requirement(s).

8.5.2 Expected response:

A. Applicable Certificates
   a) Release Note or Certificate of Compliance
   b) EC/EU Declaration of Conformity (if applicable)
   c) Declaration of guarantee (if applicable)
B. Final Foreground Declaration
C. Dual-Use items/technologies final list with evidence of authorization of export;
D. Final risk register
E. Technical report (e.g Design Report) of the work required and its implementation status
F. Final accepted Contract Quality Plan
G. Final accepted Configuration and documentation List
H. Final accepted Subcontractor List
I. Final accepted Management and Manufacturing and Inspection Control Plans
J. Final accepted Product Tree
K. Final accepted DML, DPL, DMPL and DCL
L. Final accepted Manufacturing Plan
M. As-Build Definition Document:
   1. Final Drawings
   2. Final CAD Models
   3. Contract Schedule with resources
   4. Final accepted Declared Material, Process and Components Lists
N. User Manual
O. Procedures to be used for the proper handling of the product after its final delivery
P. List of all NCRs and all INCs, and justification for open NCRs/INCs affecting next stages.
Q. List of spares
R. Open Work List (in the configuration baseline)
S. List of all Deviations
T. Verification Control Document;
U. Related 2D CAD Drawings and 3D CAD models;
V. Related Design Log Book filled to allow traceability of the CAD data;
W. Tests:
   1. Final accepted Procedures
   2. Accepted Test reports
X. Material Certificates traceable to components

Y. Qualification Campaign (e.g welding, special processes…):

1. Accepted Qualification Plan/Procedure
2. Accepted Qualification test report

8.6 Qualification Status List (QSL) – DRD

8.6.1 Identification

This DRD is called in Section 6.7
The primary objective of this document is to summarize, in a table format (as per example below), for each item the status achieved with respect to the planned qualification.

8.6.2 Expected response:

A. Scope
B. Content:
   1. Item Designation: Identification of hardware by name and Configuration Item number (or Product tree or WBS)
   2. Next higher assembly level: Identification of next higher assembly
   3. Manufacturer's name: Identification of Item Supplier
   4. Reference of requirements documents: Reference numbers of applicable requirement specifications
   5. Design heritage:
      (a) Specify if the design is "New", otherwise identification of the contract in which the design was used.
      (b) Summary of current qualification status:
         - Basis for qualification: qualification test results, heritage, and qualification on other contract
         - Contract on which the test was conducted
   6. Reference of Qualification plan document:
      (a) Current qualification status/screening and applicability of qualification test versus requirements
      (b) Reference numbers of Qualification Plan(s)
   7. Reports:
      (a) Reference to Verification Control Document and/or reference to Analyses, Test and Inspection Reports
      (b) Qualification Authority: Organization in charge of the item qualification (if any).
   8. The qualification status:
      - QUALIFIED,
      - TO BE QUALIFIED,
      - QUALIFICATION IN PROGRESS
   9. Open Actions / Due dates/Remarks:
      (a) For an open action: summary of missing qualification actions and planned dates for the closure of such actions
      (b) List of major NCRs

Item Designation	Next Higher Assembly	Manufacturer's name	Requirements Specifications	Design Heritage	Qualification			
				Summary data	Plans/ Procedures	Reports	Status	Open actions / Due dates/ Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)

8.7 Test Readiness Review Agenda (TRR) – DRD

8.7.1 Identification

This DRD is called from section 6.9.4
The primary objective of this document is to declare if the system under review is ready to proceed into formal testing.

8.7.2 Expected response:

A. Introduction
   a) General Information
   b) Scope
   c) Verification Cross Reference
B. Documents
   a) Applicable Documents
   b) Reference Documents
C. Configuration Status: definition of the item under test
D. NCRs and Deviation Status: justification on Open NCRs and Deviation to be given to assess the impact on the test campaign
E. Test Procedure Status / Issue / Red marked updates
F. VCD Status: verification status against the Verification Matrix
G. Test Item Status: eg. Latest checks, inspections recently performed etc, any activity that could impact on the test item
H. Test Equipment Status: availability, calibration status (refer to Test Procedure DRD – 8.8)
I. Health and Safety related items: e.g. appropriate personnel safety regulations and precautions for the specific test (e.g. high voltage, high pressure…)
J. Test Schedule
K. Test Personnel
L. Problem Areas, Open Work, Test Constraints: final fixations, limited-life items etc.
M. Conclusion and Test release statement:

   "F4E and XXX authorize YYY to proceed with testing subject to completion of above mentioned actions."

N. AOB

8.8 Test Procedure – DRD

8.8.1 Identification

This DRD is called in section 6.9.3
The primary objective of this document is to summarize, in a table format, for each item the status achieved with respect to the planned qualification.

8.8.2 Expected response:

A. Scope of the test, including the identification of the requirement being verified
B. Identification of the test object
C. Applicable documents, with their revision status
D. Requirements to be verified
E. Test flow
F. Test participants
G. Test conditions
H. Test set–up
I. Test equipment
J. General description of the test steps specifying those ones to be witnessed by Quality Representative
K. Recording of data
L. Pass or fail criteria and test data evaluation requirements
M. Criteria for deviation and NCR

8.9 Test Report – DRD

8.9.1 Identification

This DRD is called in section 6.9.3.
The primary objective of this document is to summarize, in a table format, for each item the status achieved with respect to the planned qualification.

Note:
The Test report DRD is waived in case the test standard used requires a different content, in such a case the Test Report shall comply with the standards.

8.9.2 Expected response:

A. Reference to the applicable test procedure
B. Test data records and evaluation
C. Pictures from the test set-up and test execution
D. Equipment calibration status and certificates
E. List of NCRs and deviations from accepted procedure
F. Summary of test results
G. Conclusions

8.10 User Manual

8.10.1 Identification

This DRD is requested in DRD 8.5
The primary objective of this document is to give assistance to people using a particular item.

8.10.2 Expected response:

The document should describe the following topics as per RD 01, for machinery under CE marking. Content can be tailored as needed for any other type of items:

- The business name and full address of the manufacturer and of his authorized representative
- The designation of the machinery as marked on the machinery itself, except for the serial number
- The EC/EU declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature
- A general description of the machinery
- A description of the intended use of the machinery
- The drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning
- A description of the workstation(s) likely to be occupied by operators
- Warnings concerning ways in which the machinery must not be used that experience has shown might occur
- Assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted
- Instructions relating to installation and assembly for reducing noise or vibration
- Instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators
- Information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted
- Instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided
- The essential characteristics of tools which may be fitted to the machinery
- The conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns
- Instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately
- The operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked
- The description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed

- Instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations
- The specifications of the spare parts to be used, when these affect the health and safety of operators
- For COTS, commercial user manual will be accepted

9 Mandatory Templates

9.1 Configuration and Documentation List (AD 12)

9.2 Management and Manufacturing and Inspection Control Plan (AD 13)

9.3 Declared Components List - DCL (AD 14)

9.4 Declared Materials List - DML (AD 15)

9.5 Declared Mechanical Parts List - DMPL (AD 16)

9.6 Declared Processes List - DPL (AD 17)

9.7 FMEA / FMECA (AD 18)

9.8 P-FMEA / P-FMECA (AD 19)

9.9 Control Point Notification (AD 20)

9.10 Release note/Certificate of Conformance (AD 21)

9.11 Requirements Propagation Matrix (AD 22)

9.12 Risk Register (AD 23)

9.13 Supply Chain Acceptance Register (AD 24)

Annex 1 F4E-QA-115 version 4.4 track changes

Requirements withdrawn and reason:

Requirement #	Change
QA115-REQ-0003	Concept addressed by F4E-QA-113
QA115-REQ-0004	Concept addressed in Model Contract
QA115-REQ-0015	Concept addressed in section 2.3
QA115-REQ-0021	Moved to Table 1 and addressed in Section 6.3.2 and 6.3.3
QA115-REQ-0023	Moved to Table 1
QA115-REQ-0024	Obsolete with the introduction of IO NCR DB
QA115-REQ-0040	Concept addressed in 8.5
QA115-REQ-0050	Superseded by Section 1
QA115-REQ-0051	Concept addressed in Section 4
QA115-REQ-0053	Superseded by Section 1
QA115-REQ-0056	Superseded by implementation of DACC
QA115-REQ-0072	Concept addressed in Section 5.1.3
QA115-REQ-0073	Concept addressed in Section 5.1.3
QA115-REQ-0100	Superseded by Section 1
QA115-REQ-0108	Concept addressed in Section 2.5
QA115-REQ-0111	Concept addressed in Section 2.5
QA115-REQ-0112	Concept addressed in Section 2.5
QA115-REQ-0113	Concept addressed in Section 2.5
QA115-REQ-0114	Concept addressed by F4E-QA-113
QA115-REQ-0121	Concept addressed in Section 4
QA115-REQ-0123	Concept addressed by F4E-QA-113
QA115-REQ-0124	Concept addressed by F4E-QA-113
QA115-REQ-0126	Concept addressed by F4E-QA-113
QA115-REQ-0129	Concept addressed by F4E-QA-135
QA115-REQ-0130	Concept addressed in Section 6.10
QA115-REQ-0133	Concept addressed in Section 2
QA115-REQ-0134	Concept addressed in Section 2
QA115-REQ-0135	Concept addressed in Model Contract
QA115-REQ-0140	Superseded by use of DACC and IO NCR Database
QA115-REQ-0145	Concept addressed in Section 6.5
QA115-REQ-0147	Concept addressed by F4E-QA-113
QA115-REQ-0152	Concept superseded in the new version of F4E-QA-115
QA115-REQ-0153	Concept superseded in the new version of F4E-QA-115
QA115-REQ-0154	Concept superseded in the new version of F4E-QA-115
QA115-REQ-0156	Concept addressed in Section 5.1
QA115-REQ-0157	Concept addressed by F4E-QA-113
QA115-REQ-0171	Concept addressed in Section 9
QA115-REQ-0172	Concept addressed in Section 10.1.5
QA115-REQ-0173	Concept addressed in Section 4
QA115-REQ-0174	Concept addressed in Section 10.1.5
QA115-REQ-0175	Concept addressed in Section 10.1.5
QA115-REQ-0180	Concept addressed in Section 6.5
QA115-REQ-0186	Concept addressed in Section 10.1.6
QA115-REQ-0194	Concept addressed in Model Contract
QA115-REQ-0205	Superseded by Section 1

Requirement #	Change
QA115-REQ-0208	Concept addressed in Section 6.2
QA115-REQ-0221	Moved to Table 1
QA115-REQ-0224	Concept addressed by F4E-QA-113
QA115-REQ-0225	Concept addressed by F4E-QA-113

Traceability Matrix between F4E-QA-115 v5.5 (current version) and v4.4 (previous version)

F4E-QA-115 version 5.5	F4E-QA-115 version 4.4
F4E-QA-115-GL-GL-001	QA115-REQ-0192
F4E-QA-115-GL-GL-002	QA115-REQ-0193
F4E-QA-115-GL-GL-003	QA115-REQ-0193
F4E-QA-115-GL-GL-004	QA115-REQ-0193
F4E-QA-115-GL-GL-005	QA115-REQ-0128 QA115-REQ-0125
F4E-QA-115-GL-NS-001	Addressed as applicable document
F4E-QA-115-GL-IP-001	QA115-REQ-0013
F4E-QA-115-GL-IP-002	QA115-REQ-0014
F4E-QA-115-GL-IP-003	QA115-REQ-0014
F4E-QA-115-GL-IP-004	QA115-REQ-0016
F4E-QA-115-GL-IP-005	QA115-REQ-0017
F4E-QA-115-GL-DU-001	QA115-REQ-0195
F4E-QA-115-GL-DU-002	QA115-REQ-0195
F4E-QA-115-GL-DU-003	QA115-REQ-0195
F4E-QA-115-GL-DU-004	QA115-REQ-0196
F4E-QA-115-GL-DU-005	QA115-REQ-0197
F4E-QA-115-GL-DU-006	QA115-REQ-0198
F4E-QA-115-GL-DU-007	QA115-REQ-0198
F4E-QA-115-GL-DU-008	QA115-REQ-0198
F4E-QA-115-GL-DU-009	QA115-REQ-0198
F4E-QA-115-GL-RA-001	QA115-REQ-0105 QA115-REQ-0131 QA115-REQ-0132 QA115-REQ-0114 QA115-REQ-0110 QA115-REQ-0106 QA115-REQ-0103
F4E-QA-115-GL-RA-002	QA115-REQ-0115 detailed
F4E-QA-115-GL-RA-003	QA115-REQ-0104
F4E-QA-115-GL-RA-004	QA115-REQ-0104
F4E-QA-115-DM-LG-001	QA115-REQ-0115 QA115-REQ-0116
F4E-QA-115-DM-LG-002	QA115-REQ-0117
F4E-QA-115-DM-EI-001	QA115-REQ-0120
F4E-QA-115-DM-EI-002	QA115-REQ-0044
F4E-QA-115-DM-EI-003	QA115-REQ-0042
F4E-QA-115-DM-EI-004	QA115-REQ-0223
F4E-QA-115-DM-EI-005	QA115-REQ-0047
F4E-QA-115-DM-DS-001	QA115-REQ-0043 QA115-REQ-0045 QA115-REQ-0142
F4E-QA-115-DM-DS-002	QA115-REQ-0203
F4E-QA-115-DM-DS-003	QA115-REQ-0064 extended
F4E-QA-115-DM-DS-004	QA115-REQ-0043 detailed
F4E-QA-115-DM-DS-005	QA115-REQ-0048 extended
F4E-QA-115-DM-DS-006	QA115-REQ-0046
F4E-QA-115-DM-DS-007	QA115-REQ-0142
F4E-QA-115-DM-DS-008	QA115-REQ-0052
F4E-QA-115-DM-DS-009	QA115-REQ-0043 detailed
F4E-QA-115-DM-DR-001	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-002	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-003	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-004	Detailed from Reference Document [2]

F4E-QA-115 version 5.5	F4E-QA-115 version 4.4
F4E-QA-115-DM-DR-005	QA115-REQ-0049
F4E-QA-115-DM-DR-006	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-007	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-008	Detailed from Reference Document [2]
F4E-QA-115-DM-DR-009	QA115-REQ-0049
F4E-QA-115-DM-DR-010	QA115-REQ-0118
F4E-QA-115-DM-DR-011	QA115-REQ-0119
F4E-QA-115-DM-DR-012	QA115-REQ-0118
F4E-QA-115-CM-CM-001	QA115-REQ-0142 extended
F4E-QA-115-CM-CM-002	QA115-REQ-0048 extended
F4E-QA-115-CM-CM-003	QA115-REQ-0142 extended
F4E-QA-115-CM-CM-004	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-001	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-002	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-003	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-004	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-005	QA115-REQ-0142 extended
F4E-QA-115-CM-CI-006	QA115-REQ-0142 extended
F4E-QA-115-CM-SA-001	QA115-REQ-0142 extended
F4E-QA-115-CM-VA-001	QA115-REQ-0142 extended
F4E-QA-115-CM-VA-002	QA115-REQ-0142 extended
F4E-QA-115-PM-PM-001	QA115-REQ-0158
F4E-QA-115-PM-PM-002	QA115-REQ-0158
F4E-QA-115-PM-WB-001	QA115-REQ-0155
F4E-QA-115-PM-WB-002	QA115-REQ-0155
F4E-QA-115-PM-OR-001	QA115-REQ-0159 QA115-REQ-0139
F4E-QA-115-PM-OR-002	QA115-REQ-0161
F4E-QA-115-PM-OR-003	QA115-REQ-0159
F4E-QA-115-PM-OR-004	QA115-REQ-0159
F4E-QA-115-PM-OR-005	QA115-REQ-0162
F4E-QA-115-PM-OR-006	QA115-REQ-0161
F4E-QA-115-PM-OR-007	QA115-REQ-0162 extended
F4E-QA-115-PM-OR-008	QA115-REQ-0162 extended
F4E-QA-115-PM-OR-009	QA115-REQ-0165 QA115-REQ-0166
F4E-QA-115-PM-OR-010	QA115-REQ-0162 extended
F4E-QA-115-PM-OR-011	QA115-REQ-0164
F4E-QA-115-PM-OR-012	Derived from model contract section II.1.1
F4E-QA-115-PM-PC-001	QA115-REQ-0177 QA115-REQ-0188
F4E-QA-115-PM-PC-002	QA115-REQ-0144
F4E-QA-115-PM-PC-003	QA115-REQ-0176
F4E-QA-115-PM-PC-004	QA115-REQ-0176 QA115-REQ-0160
F4E-QA-115-PM-PC-005	QA115-REQ-0115
F4E-QA-115-PM-PC-006	QA115-REQ-0071
F4E-QA-115-PM-PC-007	QA115-REQ-0084
F4E-QA-115-PM-DS-001	QA115-REQ-0207 QA115-REQ-0167
F4E-QA-115-PM-DS-002	Section 2.9 detailed
F4E-QA-115-PM-DS-003	Section 5.7 detailed
F4E-QA-115-PM-DS-004	QA115-REQ-0010 relaxed
F4E-QA-115-PM-DS-005	QA115-REQ-0010 relaxed
F4E-QA-115-PM-DS-006	QA115-REQ-0010 relaxed

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F4E-QA-115-PM-DS-007	QA115-REQ-0010 relaxed
F4E-QA-115-PM-DS-008	QA115-REQ-0018
F4E-QA-115-PM-SC-001	QA115-REQ-0141 QA115-REQ-0169 QA115-REQ-0170 QA115-REQ-0122 QA115-REQ-0187 QA115-REQ-0155
F4E-QA-115-PM-SC-002	QA115-REQ-0196
F4E-QA-115-PM-SC-003	QA115-REQ-0141
F4E-QA-115-PM-SC-004	QA115-REQ-0141
F4E-QA-115-PM-SC-005	QA115-REQ-0141
F4E-QA-115-PM-SC-006	QA115-REQ-0141
F4E-QA-115-PM-SC-007	QA115-REQ-0141
F4E-QA-115-PM-SC-008	QA115-REQ-0141
F4E-QA-115-PM-SC-009	QA115-REQ-0141
F4E-QA-115-PM-SC-010	QA115-REQ-0141
F4E-QA-115-PM-SC-011	QA115-REQ-0141
F4E-QA-115-PM-SC-012	QA115-REQ-0141
F4E-QA-115-PM-RK-001	QA115-REQ-0101
F4E-QA-115-PM-RK-002	QA115-REQ-0143
F4E-QA-115-PM-RK-003	QA115-REQ-0101
F4E-QA-115-PM-RK-004	QA115-REQ-0101
F4E-QA-115-PM-PG-001	QA115-REQ-0005
F4E-QA-115-PM-PG-002	QA115-REQ-0006 QA115-REQ-0007
F4E-QA-115-PM-PG-003	QA115-REQ-0008
F4E-QA-115-PM-PG-004	QA115-REQ-0009 QA115-REQ-0010 QA115-REQ-0193
F4E-QA-115-PM-PG-005	QA115-REQ-0009 detailed
F4E-QA-115-PM-PG-006	QA115-REQ-0009
F4E-QA-115-PM-PG-007	QA115-REQ-0019
F4E-QA-115-QA-QA-001	QA115-REQ-0136 detailed
F4E-QA-115-QA-QM-001	QA115-REQ-0001 QA115-REQ-0150
F4E-QA-115-QA-QM-002	QA115-REQ-0136 detailed
F4E-QA-115-QA-QM-003	QA115-REQ-0136 detailed
F4E-QA-115-QA-QM-004	QA115-REQ-0137
F4E-QA-115-QA-QM-005	QA115-REQ-0138
F4E-QA-115-QA-QM-006	QA115-REQ-0215
F4E-QA-115-QA-QM-007	Detailed from section 2.9
F4E-QA-115-QA-CP-001	QA115-REQ-0202
F4E-QA-115-QA-CP-002	QA115-REQ-0211
F4E-QA-115-QA-CP-003	QA115-REQ-0212
F4E-QA-115-QA-CP-004	Added concepts in QA115-REQ-0212
F4E-QA-115-QA-CP-005	QA115-REQ-0206 QA115-REQ-0207
F4E-QA-115-QA-CP-006	QA115-REQ-0216 QA115-REQ-0217
F4E-QA-115-QA-CP-007	QA115-REQ-0217
F4E-QA-115-QA-CP-008	QA115-REQ-0204
F4E-QA-115-QA-CP-009	QA115-REQ-0206 clarified

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F4E-QA-115-QA-CP-010	QA115-REQ-0202 QA115-REQ-0211 QA115-REQ-0002 QA115-REQ-0206 QA115-REQ-0209 QA115-REQ-0210 QA115-REQ-0215 QA115-REQ-0168
F4E-QA-115-QA-CP-011	QA115-REQ-0203
F4E-QA-115-QA-CP-012	QA115-REQ-0063 QA115-REQ-0219 QA115-REQ-0220
F4E-QA-115-QA-CP-013	QA115-REQ-0063 QA115-REQ-0219 QA115-REQ-0220 QA115-REQ-0218 QA115-REQ-0222
F4E-QA-115-QA-CP-014	QA115-REQ-0222
F4E-QA-115-QA-CP-015	QA115-REQ-0218 QA115-REQ-0222
F4E-QA-115-QA-CP-016	QA115-REQ-0109
F4E-QA-115-QA-CI-001	New
F4E-QA-115-QA-CI-002	New
F4E-QA-115-QA-CI-003	New
F4E-QA-115-QA-NC-001	QA115-REQ-0034 QA115-REQ-0035 QA115-REQ-0038 QA115-REQ-0039 QA115-REQ-0037
F4E-QA-115-QA-NC-002	QA115-REQ-0024
F4E-QA-115-QA-NC-003	New
F4E-QA-115-QA-NC-004	New
F4E-QA-115-QA-NC-005	QA115-REQ-0034
F4E-QA-115-QA-NC-006	New
F4E-QA-115-QA-NC-007	QA115-REQ-0035
F4E-QA-115-QA-NC-008	QA115-REQ-0035
F4E-QA-115-QA-NC-009	QA115-REQ-0034
F4E-QA-115-QA-NC-010	QA115-REQ-0034 clarified
F4E-QA-115-QA-NC-011	QA115-REQ-0034 clarified
F4E-QA-115-QA-NC-012	QA115-REQ-0034 QA115-REQ-0035
F4E-QA-115-QA-NC-013	QA115-REQ-0034 clarified impact of ‘use as is’
F4E-QA-115-QA-NC-014	QA115-REQ-0037
F4E-QA-115-QA-NC-015	QA115-REQ-0034
F4E-QA-115-QA-NC-016	QA115-REQ-0036
F4E-QA-115-QA-NC-017	QA115-REQ-0034 clarified
F4E-QA-115-QA-NC-018	QA115-REQ-0034 clarified increasing priority in problem solving
F4E-QA-115-QA-NC-019	New
F4E-QA-115-QA-NC-020	QA115-REQ-0037 clarified closing process for intermediate phases
F4E-QA-115-QA-NC-021	QA115-REQ-0037 clarified closing process for intermediate phases
F4E-QA-115-QA-NC-022	QA115-REQ-0037 clarified closing process for intermediate phases

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F4E-QA-115-QA-NC-023	QA115-REQ-0037 clarified closing process for intermediate phases
F4E-QA-115-QA-NC-024	QA115-REQ-0036
F4E-QA-115-QA-DR-001	QA115-REQ-0026
F4E-QA-115-QA-DR-002	QA115-REQ-0020 QA115-REQ-0022 QA115-REQ-0025 QA115-REQ-0039 QA115-REQ-0026 QA115-REQ-0030 QA115-REQ-0031 QA115-REQ-0032 QA115-REQ-0033 QA115-REQ-0027 QA115-REQ-0028 QA115-REQ-0029 QA115-REQ-0056
F4E-QA-115-QA-DR-003	QA115-REQ-0041
F4E-QA-115-QA-DR-004	QA115-REQ-0039
F4E-QA-115-QA-DR-005	QA115-REQ-0031 clarified roles and responsibilities
F4E-QA-115-QA-DR-006	QA115-REQ-0027 QA115-REQ-0031
F4E-QA-115-QA-DR-007	QA115-REQ-0025 QA115-REQ-0028 QA115-REQ-0032
F4E-QA-115-QA-DR-008	QA115-REQ-0025 clarified
F4E-QA-115-QA-SS-001	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-SS-002	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-SS-003	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-SS-004	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-SS-005	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-SS-006	QA115-REQ-0199 correlation between activities and performers improved
F4E-QA-115-QA-TR-001	QA115-REQ-0199 detailed
F4E-QA-115-QA-TR-002	QA115-REQ-0199
F4E-QA-115-QA-TR-003	QA115-REQ-0199
F4E-QA-115-QA-TR-004	QA115-REQ-0199 detailed
F4E-QA-115-QA-TR-005	QA115-REQ-0199 detailed
F4E-QA-115-QA-TR-006	QA115-REQ-0199 detailed
F4E-QA-115-QA-TR-007	QA115-REQ-0199 detailed
F4E-QA-115-QA-TR-008	QA115-REQ-0199 detailed
F4E-QA-115-QA-MT-001	QA115-REQ-0074 QA115-REQ-0075 QA115-REQ-0066 QA115-REQ-0076 QA115-REQ-0077 QA115-REQ-0078 QA115-REQ-0146 QA115-REQ-0185
F4E-QA-115-QA-MT-002	
F4E-QA-115-QA-MT-003	
F4E-QA-115-QA-MT-004	
F4E-QA-115-QA-MT-005	
F4E-QA-115-QA-MT-006	
F4E-QA-115-QA-MT-007	
F4E-QA-115-QA-MT-008	
F4E-QA-115-QA-MT-009	

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F4E-QA-115-QA-MT-010	
F4E-QA-115-QA-MT-011	
F4E-QA-115-QA-MT-012	
F4E-QA-115-QA-MT-013	
F4E-QA-115-QA-HS-001	QA115-REQ-0200
F4E-QA-115-QA-HS-002	QA115-REQ-0200 detailed
F4E-QA-115-QA-HS-003	QA115-REQ-0200 detailed
F4E-QA-115-QA-HS-004	QA115-REQ-0200 detailed
F4E-QA-115-QA-HS-005	QA115-REQ-0200 detailed
F4E-QA-115-QA-HS-006	QA115-REQ-0200 detailed
F4E-QA-115-QA-HS-007	QA115-REQ-0200 detailed
F4E-QA-115-QA-ST-001	QA115-REQ-0201
F4E-QA-115-QA-ST-002	QA115-REQ-0201
F4E-QA-115-QA-ST-003	QA115-REQ-0201
F4E-QA-115-QA-CL-001	QA115-REQ-0069 extended to all potential activities
F4E-QA-115-QA-CL-002	QA115-REQ-0069 extended to all potential activities
F4E-QA-115-QA-LL-001	QA115-REQ-0063 detailed
F4E-QA-115-QA-LL-002	QA115-REQ-0063 detailed
F4E-QA-115-QD-PR-001	QA115-REQ-0150 extended
F4E-QA-115-QD-RP-001	QA115-REQ-0150 extended
F4E-QA-115-QD-IT-001	QA115-REQ-0150 extended
F4E-QA-115-QD-OP-001	QA115-REQ-0150 extended
F4E-QA-115-QD-DV-001	Transferred from Annex B
F4E-QA-115-QD-DV-002	Transferred from F4E Design Review Process
F4E-QA-115-QD-DV-003	Transferred from F4E Design Review Process
F4E-QA-115-QD-DV-004	Transferred from F4E Design Review Process
F4E-QA-115-QD-DV-005	Transferred from F4E Design Review Process
F4E-QA-115-QD-DV-006	Transferred from F4E Design Review Process
F4E-QA-115-QD-DV-007	Transferred from Annex B
F4E-QA-115-QD-DV-008	QA115-REQ-0150 detailed
F4E-QA-115-QD-DV-009	QA115-REQ-0150 detailed
F4E-QA-115-QD-RV-001	QA115-REQ-0150 detailed
F4E-QA-115-QD-RV-002	QA115-REQ-0150 detailed
F4E-QA-115-QD-RV-003	QA115-REQ-0150 detailed
F4E-QA-115-QD-CA-001	QA115-REQ-0054 QA115-REQ-0055 QA115-REQ-0057
F4E-QA-115-QD-CA-002	QA115-REQ-0057
F4E-QA-115-QD-CA-003	QA115-REQ-0058
F4E-QA-115-QD-CA-004	QA115-REQ-0058
F4E-QA-115-QD-CA-005	QA115-REQ-0058
F4E-QA-115-QD-CA-006	QA115-REQ-0058
F4E-QA-115-QD-CA-007	QA115-REQ-0057
F4E-QA-115-QD-CA-008	QA115-REQ-0057
F4E-QA-115-QD-CA-009	QA115-REQ-0057
F4E-QA-115-QD-CA-010	QA115-REQ-0057
F4E-QA-115-QD-CA-011	QA115-REQ-0057
F4E-QA-115-QD-CA-012	QA115-REQ-0057
F4E-QA-115-QD-CM-001	QA115-REQ-0094 QA115-REQ-0182
F4E-QA-115-QD-CM-002	QA115-REQ-0094 QA115-REQ-0182

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F4E-QA-115-QD-CM-003	QA115-REQ-0095 QA115-REQ-0183
F4E-QA-115-QD-CM-004	QA115-REQ-0095 QA115-REQ-0183
F4E-QA-115-QD-CM-005	QA115-REQ-0096
F4E-QA-115-QD-CM-006	QA115-REQ-0096
F4E-QA-115-QD-CM-007	QA115-REQ-0096
F4E-QA-115-QD-CM-008	QA115-REQ-0097
F4E-QA-115-QD-CM-009	QA115-REQ-0097
F4E-QA-115-QD-DP-001	Transferred from Annex B
F4E-QA-115-QD-DP-002	Transferred from Annex B
F4E-QA-115-QD-DP-003	Transferred from Annex B
F4E-QA-115-QD-DP-004	Transferred from Annex B
F4E-QA-115-QD-DP-005	Transferred from Annex B
F4E-QA-115-QD-DP-006	Transferred from Annex B
F4E-QA-115-QD-DP-007	Transferred from Annex B
F4E-QA-115-QD-DP-008	Transferred from Annex B
F4E-QA-115-QP-GL-001	QA115-REQ-0059 detailed
F4E-QA-115-QP-GL-002	QA115-REQ-0178 QA115-REQ-0060
F4E-QA-115-QP-GL-003	QA115-REQ-0059
F4E-QA-115-QP-GL-004	QA115-REQ-0061 extended to all type of contracts
F4E-QA-115-QP-GL-005	QA115-REQ-0059
F4E-QA-115-QP-GL-006	QA115-REQ-0059
F4E-QA-115-QP-GL-007	QA115-REQ-0179
F4E-QA-115-QP-GL-008	QA115-REQ-0060
F4E-QA-115-QP-GL-009	QA115-REQ-0190
F4E-QA-115-QP-GL-010	QA115-REQ-0190
F4E-QA-115-QP-GL-011	QA115-REQ-0190 QA115-REQ-0107
F4E-QA-115-QP-GL-012	QA115-REQ-0106
F4E-QA-115-QP-PO-001	QA115-REQ-0127 extended to include all requirements propagation
F4E-QA-115-QP-PO-002	QA115-REQ-0199
F4E-QA-115-QP-PO-003	QA115-REQ-0127 extended to include all requirements propagation
F4E-QA-115-QP-II-001	QA115-REQ-0148 QA115-REQ-0149 QA115-REQ-0188 QA115-REQ-0189
F4E-QA-115-QP-II-002	QA115-REQ-0149
F4E-QA-115-QP-RW-001	QA115-REQ-0162 extended
F4E-QA-115-QP-RW-002	QA115-REQ-0162 extended
F4E-QA-115-QR-QR-001	QA115-REQ-0136 detailed
F4E-QA-115-QQ-QQ-001	QA115-REQ-0184
F4E-QA-115-QQ-QQ-002	QA115-REQ-0136 detailed
F4E-QA-115-QQ-QQ-003	QA115-REQ-0184 extended
F4E-QA-115-QQ-QQ-004	QA115-REQ-0184 extended
F4E-QA-115-QQ-QQ-005	QA115-REQ-0184 extended
F4E-QA-115-QQ-QQ-006	QA115-REQ-0184 extended
F4E-QA-115-QM-MP-001	QA115-REQ-0181
F4E-QA-115-QM-MP-002	QA115-REQ-0181 approval requirement specified
F4E-QA-115-QM-MP-003	QA115-REQ-0064
F4E-QA-115-QM-MP-004	QA115-REQ-0064

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F4E-QA-115-QM-MP-005	QA115-REQ-0181
F4E-QA-115-QM-MP-006	QA115-REQ-0202
F4E-QA-115-QM-MP-007	QA115-REQ-0206 MIP content clarified
F4E-QA-115-QM-MP-008	QA115-REQ-0204
F4E-QA-115-QM-MP-009	New
F4E-QA-115-QM-MR-001	QA115-REQ-0150 extended to manufacturing activities
F4E-QA-115-QM-MR-002	QA115-REQ-0150 extended to manufacturing activities
F4E-QA-115-QM-MR-003	QA115-REQ-0150 extended to manufacturing activities
F4E-QA-115-QM-PC-001	QA115-REQ-0064
F4E-QA-115-QM-PC-002	QA115-REQ-0064
F4E-QA-115-QM-PC-003	QA115-REQ-0203 QA115-REQ-0064
F4E-QA-115-QM-PC-004	QA115-REQ-0210
F4E-QA-115-QM-PC-005	QA115-REQ-0064
F4E-QA-115-QM-PC-006	QA115-REQ-0064
F4E-QA-115-QM-MC-001	QA115-REQ-0148 clarified for all tests
F4E-QA-115-QM-MC-002	QA115-REQ-0148 clarified for all tests
F4E-QA-115-QM-MC-003	QA115-REQ-0148 clarified for all tests
F4E-QA-115-QM-MN-001	QA115-REQ-0076
F4E-QA-115-QM-MN-002	QA115-REQ-0093
F4E-QA-115-QM-MN-003	QA115-REQ-0076 detailed
F4E-QA-115-QM-MN-004	QA115-REQ-0076 detailed
F4E-QA-115-QM-MN-005	QA115-REQ-0076 detailed
F4E-QA-115-QM-MN-006	QA115-REQ-0076 detailed
F4E-QA-115-QM-MN-007	QA115-REQ-0077
F4E-QA-115-QM-SE-001	New
F4E-QA-115-QM-SE-002	New
F4E-QA-115-QM-SE-003	New
F4E-QA-115-QM-SE-004	New
F4E-QA-115-QM-SE-005	New
F4E-QA-115-QM-SE-006	New
F4E-QA-115-QM-SE-007	New
F4E-QA-115-QM-SE-008	New
F4E-QA-115-QM-SE-009	New
F4E-QA-115-QM-SE-010	New
F4E-QA-115-QM-SE-011	New
F4E-QA-115-QM-SE-012	New
F4E-QA-115-QM-SE-013	New
F4E-QA-115-QM-SE-014	New
F4E-QA-115-QM-SP-001	QA115-REQ-0068
F4E-QA-115-QM-SP-002	QA115-REQ-0068 QA115-REQ-0069
F4E-QA-115-QM-SP-003	QA115-REQ-0068 QA115-REQ-0069
F4E-QA-115-QM-SP-004	New
F4E-QA-115-QM-SP-005	QA115-REQ-0070
F4E-QA-115-QM-SP-006	QA115-REQ-0067
F4E-QA-115-QM-SP-007	QA115-REQ-0158
F4E-QA-115-QM-WD-001	QA115-REQ-0079
F4E-QA-115-QM-WD-002	QA115-REQ-0080 QA115-REQ-0081
F4E-QA-115-QM-WD-003	QA115-REQ-0082
F4E-QA-115-QM-WD-004	QA115-REQ-0082

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F4E-QA-115-QM-WD-005	QA115-REQ-0084 QA115-REQ-0083
F4E-QA-115-QM-WD-006	QA115-REQ-0084
F4E-QA-115-QM-WD-007	QA115-REQ-0085
F4E-QA-115-QM-WD-008	QA115-REQ-0086
F4E-QA-115-QM-WD-009	QA115-REQ-0087
F4E-QA-115-QM-WD-010	QA115-REQ-0088
F4E-QA-115-QM-WD-011	QA115-REQ-0089
F4E-QA-115-QM-WD-012	QA115-REQ-0090
F4E-QA-115-QM-WD-013	QA115-REQ-0091
F4E-QA-115-QM-WD-014	QA115-REQ-0092
F4E-QA-115-QT-TF-001	QA115-REQ-0076 extended to the control of test facilities
F4E-QA-115-QT-TE-001	QA115-REQ-0076
F4E-QA-115-QT-TE-002	QA115-REQ-0078
F4E-QA-115-QT-DC-001	QA115-REQ-0209
F4E-QA-115-QT-DC-002	QA115-REQ-0212 QA115-REQ-0213 extended to hardware protection
F4E-QA-115-QT-DC-003	QA115-REQ-0064
F4E-QA-115-QT-DC-004	QA115-REQ-0064
F4E-QA-115-QT-DC-005	QA115-REQ-0063
F4E-QA-115-QT-TR-001	New
F4E-QA-115-QT-TR-002	New
F4E-QA-115-QT-TR-003	New
F4E-QA-115-QT-TR-004	New
F4E-QA-115-QT-MN-001	QA115-REQ-0064
F4E-QA-115-QT-MN-002	QA115-REQ-0064 added consequences for not following approved procedures
F4E-QA-115-QT-MN-003	QA115-REQ-0035 clarified
F4E-QA-115-QT-MN-004	QA115-REQ-0163
F4E-QA-115-QL-AP-001	QA115-REQ-0011 QA115-REQ-0019
F4E-QA-115-QL-AP-002	QA115-REQ-0012 QA115-REQ-0214 QA115-REQ-0208 QA115-REQ-0130
F4E-QA-115-QL-AP-003	QA115-REQ-0098
F4E-QA-115-QL-PR-001	QA115-REQ-0098
F4E-QA-115-QL-PR-002	QA115-REQ-0098
F4E-QA-115-QL-FA-001	QA115-REQ-0099 Phase Gate added
F4E-QA-115-QL-FA-002	QA115-REQ-0019 QA115-REQ-0099
F4E-QA-115-QL-FA-003	QA115-REQ-0099 Phase Gate added
F4E-QA-115-QL-PD-001	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-PD-002	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-PD-003	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-PD-004	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-SC-001	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-SC-002	QA115-REQ-0200 extended requirement
F4E-QA-115-QL-TS-001	QA115-REQ-0099 extented
F4E-QA-115-QS-VV-001	New
F4E-QA-115-QS-VV-002	New
F4E-QA-115-QS-VV-003	New
F4E-QA-115-QS-VV-004	New
F4E-QA-115-QS-VV-005	New

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F4E-QA-115-QS-VV-006	New
F4E-QA-115-QS-VV-007	New
F4E-QA-115-QS-VV-008	New
F4E-QA-115-QS-VV-009	New
F4E-QA-115-QS-VV-010	QA115-REQ-0043 specified for software
F4E-QA-115-QS-VV-011	New
F4E-QA-115-QS-VV-012	New
F4E-QA-115-QS-VV-013	New
F4E-QA-115-QS-VV-014	New
F4E-QA-115-QS-VV-015	New
F4E-QA-115-QS-VV-016	New
F4E-QA-115-QS-VV-017	New
F4E-QA-115-QS-VV-018	New
F4E-QA-115-QS-VV-019	New

Annex 2 List of acronyms per type of document

Type of document	Acronym
Acceptance Data Package	ADP
Bill Of Material	BOM
Calculation Report	CLR
Change Request	CRR
Compliance matrix or verification matrix	CXM
Configuration and documentation list	CDL
Management Control Plan	MCP
Manufacturing and Inspection Control Plan	MIP
Critical Items List	CIL
Deliverable List	DDL
Design Description	DDD
Design Plan	DPN
Detailed Model	DMD
Drawing	DRG
Engineering Analyses	EAN
Instruction or Procedure	ITP
Instructions Manual	MAN
Interface Control Document	ICD
Issue / Risk / Opportunity Report	IRO
List	LST
Load Specification	LSS
Logbook	LBK
Matrix	MTX
Minutes of Meeting	MOM
Nonconformity Report	NCR
Open work list	OWL
Piping & Instrumentation Diagram (P&ID)	P&ID
Plan	APL
Process Flow Diagram	PFD
Project Management and Quality Plan	PQMP
Release Note / Certificate of Compliance	CoC
Report/Register	ACR
Requirements propagation matrix	RPM
System Requirements Document	SRD
Technical Specification	PTS
User Manual	UMN

Type of document	Acronym
Verification & Validation (V&V) Plan	VVP
Verification Control Document	VCD
Verification Report	MIR
Work Breakdown Structure	WBS