FUSION FOR ENERGY

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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			
	Name	*Action*	*Affiliation*
Author	**Rodrigues D.**	**13 June 2016:signed**	**ADM**
Co-Authors			
Reviewers	**Baker K.**	**20 June 2016:recommended**	**PM**
	Barabaschi P.	**14 June 2016:recommended**	**BA**
	Counsell G.	**14 June 2016:recommended**	**ITERD**
	Esposito V.	**14 June 2016:recommended**	**ADM**
	Jahreiss H.	**13 June 2016:recommended**	**ADM**
Approver	**F4E-Director S. J.**	**20 June 2016:approved**	**DIR**
RO: Popescu Marcel-Stefan (F4E)			
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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'.

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QA SPECIFICATION

CONTROL PAGE

idm@F4E ref:	F4E_D_22F8BJ	Date:	10 June 2016

Document title:	**Supplier Quality Requirements (F4E-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.

Purpose

This document contains the general requirements on the Quality Management System of the suppliers. The Management Specification will specify the applicability of the quality and management requirements:

(i) the Bidder shall comply when preparing its offer/proposal;

(ii) the Supplier shall comply within the course of the Contract.

The description of the Supplier quality management system must be established in a dedicated *Quality Plan* for managing F4E work activities.

Scope

This document is applicable to all operational procurements and grants issued by F4E.

Reference documents

(external links)

[1] F4E-QA-010 –'Quality Classification' Procedure 22MD99
[2] F4E-QA-112 -- 'Naming Conventions' Instruction 22GGJ4
[3] F4E-QAP-ITER – F4E QA Programme the ITER Project 22MCBA
[4] IAEA GS-R-3 – Safety Requirements (2006) – 'The Management System for Facilities and Activities'.
[5] F4E CAD Manual F4E_D_22BE49.
[6] EN ISO 14731:2006 – 'Welding coordination - Tasks and responsibilities'.
[7] EN ISO 9712:2012 – 'Non-destructive testing. Qualification and certification of NDT personnel.
[8] F4E Dimensional Metrology Handbook (DMH) F4E_D_2693FC
[9] French Order 7 February 2012 - *République Française - Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base*. INB Order,
[10] The Pressure Equipment Directive – PED (97/23/EC).
[11] French Order on Nuclear Pressure Equipment - *Arrêté du 12 décembre 2005 relatif aux équipements sous pression nucléaires (ESPN)*.
[12] PIA Guideline 27WDLC
[13] F4E-QA-113 – 'Propagation of Generic Safety Requirements in the F4E Supply-Chain' 22JRQY
[14] F4E-QA-114 - Instructions for Suppliers Performing Design Analysis 22FR5T
[15] ITER Policy on Safety, Security and Environment Protection Management (ITER_D_43UJN7 v2.0)

Table of Contents

List of Captions

Abbreviations and Definitions

Term	Definition	Acronym
Acceptance Data Package	Package of documents linked to a deliverable of a procurement. An ADP is linked to a set of activities of the procurement (design, manufacture, tests, assembly, production of documents etc…) and is produced to provide evidence that the activities are correctly completed. (in case of document deliverables, it includes the deliverable).	ADP
Contract	The Contract can be the supply or service Contract as result of a procurement, or the Grant Agreement.	---
Defined Requirement (Safety)	(as defined in the French INB Order – 07 February 2012) *Requirement assigned to a protection-important component so that it may perform the function, with the characteristics expected, provided for in the Nuclear Safety demonstration, or assigned to a protection-important activity so that it may fulfil its objectives as regards this demonstration.* A defined requirement can be attached to a PIC or to a PIA.	SDR (PIC SDR) (PIA SDR)
Economic Operator	Any natural or legal person, public entity or group thereof that offers products, services or works on the market.	---
Final Report	The report to be submitted by the Supplier to F4E following the completion and delivery to F4E of the Works, as provided for by §2.1.3 (Final Report).	---
Fusion for Energy	The European Joint Undertaking for ITER and the Development of Fusion Energy.	F4E
IP/IPR	Intellectual Property or Intellectual Property Rights	IP or IPR
ITER Organization	The ITER International Organization. The term ITER used alone does not indicate the organisation but the project itself.	IO
Protection Important Component	(as defined in the French INB Order – 07 February 2012) *Component important for the protection of the interests mentioned in article L. 593-1 of the environment code (public safety, health and welfare, protection of nature and of the environment), i.e. structure, equipment, system (programmed or not), hardware, component or software present in a basic nuclear installation or placed under the responsibility of the operator, fulfilling a function necessary for the demonstration mentioned in the second paragraph of article L. 593-7 of the environment code, or checking that this function is ensured.*	PIC
Protection Important Activities	(as defined in the French Order – 07 February 2012) *Activity important for protection of the interests mentioned in L. 593-1 of the environment code (public safety, health and welfare, protection of nature and of the environment), i.e. activities participating in the technical or organisational provisions mentioned in the second paragraph of article L. 593-7 of the environment code, or that could affect them.*	PIA
Operator	The Nuclear Operator of the ITER Project: IO	
QA	Quality Assurance	QA

Term	Definition	Acronym
Quality Classification	F4E's Quality Classification procedure, as set out in Reference Document F4E-QA-010: 'Quality Classification'.	QCn
Quality Plan	The plan describing the quality management system	QP
R&D	Research & Development	R&D
Release Note	Certificate of Conformity of the deliverables that is the cover-page of the ADP. - Lists what is contained in the ADP - Declares that the activities included in the ADP have all been performed and that the documents included in the ADP, where applicable, have all been cleared (declared ready for the acceptance review: i.e. submitted and confirmed by F4E as adequate for the deliverable acceptance review).) in IDM - Declares conformity with the obligations of the contract, including processing of related deviations and/or non-conformity - If applicable, anticipates the amount of the payment due in relation with the acceptance of the ADP	RN
Safety Related Activity	Safety (Quality) Related Activity. S/QRA are a subclass of AIP	S/QRA
SIC	Safety Important Class SIC components are a subclass (important for nuclear safety) of PIC	SIC
Subcontractor	Any third party that performs a part of the Contract or provides the Supplier with resources for the performance of the Contract. In this document it includes those defined in the Contract as "Subcontractors" and "Qualified Operators".	---
Supplier	An economic operator that provides a product (supply or service) in accordance with the provisions of the Contract. The Supplier is an economic operator that is the Contractor as defined in the supply or service Contract, or the Beneficiary as defined in the Grant Agreement.	---
Supply-Chain	The supply-chain follows the scheme below: Subcontractor -> Supplier -> Organisation (F4E) -> Customer	---
Critical Activities	<u>Critical Items/activities:</u> Are items/activities that, if not performed correctly, may affect Safety, Functionality or Reliability. Critical items/activities definition is also aligned with: • Quality classification: a QC1 and QC2 item is a critical item (but a sub-item on the breakdown of the QC1 or QC2 might not be), • Protection Important Activities: PIAs are critical activities.	
WBS	Work breakdown structure	WBS
Work	The specified necessary production, manufacture, construction, research and development activities for the execution of the contract	---

1 INTRODUCTION

This document defines particular requirements of the Supplier management system to be implemented by the Supplier. These requirements are set out in the following sections:

1 – Introduction – this section defines the document overall structure and the Quality Plan.

2 – Quality and General Requirements – this section defines processes that the Supplier shall comply with throughout the execution of the Works.

3 – Quality Plan Requirements:

- Quality System Compliance - this subsection defines the requirements of the Supplier's Quality System Compliance part.
- Quality Implementation Plan – this subsection defines the minimum requirements of the Supplier's Quality Implementation Plan part.

4 – Control Plan Requirements – this section defines the requirements of the Supplier's Control Plan.

5 – Mandatory Forms – this section defines the mandatory forms referenced in the document.

Each requirement in this document is formally identified.

- *A requirement unambiguously starts with a paragraph containing the string "<# " followed by the requirement identifier "REQ-NNNN".*
- *Parent requirements are mentioned in the next paragraph(s) with the string "[Parent (specification identifier): paragraph number [requirement identifier]"*
- *requirement unambiguously ends with a paragraph containing the string "#>".*

Clarifications to the requirements and other information are provided outside of the requirements.

<# QA115-REQ-0001

The Supplier shall produce and maintain a Quality Plan structured as an assembly of 2 separate parts:

- A *System Compliance* part that must comply with the quality and general requirements defined in §3.1.
- An *Implementation Plan* part that must address the topics required by §3.2.

#>

<# QA115-REQ-0002

The Supplier shall produce and maintain a Control Plan listing the sequences of activities affecting quality as defined in §4 (Control Plan Requirements).

#>

The French Government has authorised the creation of the ITER facility (*Décret n° 2012-1248 du 9 novembre 2012*), classified as an *Installation nucleaire de base* (INB number 174).

By fulfilling the requirements in this document – and by knowing, understanding and applying the ITER Policy on Safety, Security and Environment Protection Management [15] - the Supplier ensures consistency of its activities with the 'Order of 7 February 2012' [9] (applicable from July 2013) via the F4E QA Programme for ITER and the Operator's quality programme.

<# QA115-REQ-0003

Where the responsibility for the PIC design lies with the Supplier, the Supplier shall produce and maintain a *Nuclear Safety File* containing the Defined Requirements (Safety) relating to PIC, their Verification Activities and their Evidence Records (as detailed by §2.1.3).

#>

<# QA115-REQ-0004

Suppliers and subcontractors must comply with all applicable laws and regulations (including the place where the product will be put into service). In situations where there is a conflict between applicable laws and regulations and the terms set out in this document, suppliers will be required to meet the higher standard.

#>

2 QUALITY AND GENERAL REQUIREMENTS

2.1 Project Meetings and Reports

2.1.1 Project Meetings

<# QA115-REQ-0005

The Contract must commence with an official Kick-off Meeting where the following items (as a minimum) must be discussed and agreed:

- Confirmation of the specifications, specific requirements and contractual input;
- The Supplier's Quality Plan, including all subsidiary plans;
- Revision of the Control Plan, the Control Points and, if applicable, the PIAs.
- The detailed schedule of the contractual activities, including milestones (that will be established as the baseline once agreed by F4E);
- Frequency of status verification of the Documentation Schedule and Control Plan (if not agreed otherwise, at least once a month);
- Contents of the Monthly Progress Reports to be prepared and submitted by the Supplier to F4E;
- Frequency of the update and submission to F4E of the Risk Plan (if not agreed otherwise, quarterly);
- Contents of the ADP and Contract Final Report (if not agreed otherwise, drafts submission period is one month);
- Documentation review lead time;
- The compliance matrix contents (if defined in the technical specification);
- Management of Intellectual Property;
- Dual-Use items/technologies list.

#>

The Documentation Schedule, Control Plan, and Risk Plan are defined in §3.2.5 (Documentation Schedule), §3.2.3 (Control Plan) and §3.2.9 (Risk Plan). The Dual-Use items/technologies list are defined in §3.2.15.

<# QA115-REQ-0006

The Supplier shall attend progress meetings throughout the duration of the Contract at a minimum frequency of one (1) per calendar month. The Supplier shall identify who will attend such meetings, on its behalf along with representatives of F4E.

#>

<# QA115-REQ-0007

Unless specifically agreed otherwise, Kick-off, Progress and Final Meetings are obligatory and conducted face to face.

#>

<# QA115-REQ-0008

Unless agreed otherwise, the Supplier shall be responsible for preparing the meeting minutes; and circulated within three (3) working days of the meeting to all attendees for review and comment, prior to formal issue.

#>

2.1.2 Progress Reports

<# QA115-REQ-0009

The monthly progress reports must contain all information the Supplier considers relevant to properly reflecting the progress of the Works following the template shown in §5 (Mandatory Forms). The reports must include, but not be limited to:

- Main scheduled tasks and milestones for the period;
- Main results, achievements and issues encountered during the period;
- Main scheduled tasks and milestones for the next period;
- Action list and status;
- Schedule variance (SV), Cost variance (CV), Schedule performance index (SPI), Cost performance index (CPI) as defined per the Earned Value Management;
- Pending deviations and open nonconformities;
- If applicable or in the case of a specific occurrence:
  - Update on Intellectual Property Rights and dual use technologies where applicable;
  - Subcontracting status;
  - Materials Availability;
  - Environmentally related incidents (for ITER Project site works);
  - Safety review of all safety related incidents that have occurred over the past month (for ITER Project site works).
- Re-programmed activities required to recover time on any activities behind programme.

#>

The definitions per the Earner Value Management (see also 3.2.10 Project Controls)
SV = EV – PV ; SV%= (SV/PV) x 100
CV = EV – AC ; CV% = (CV/EV) x 100
SPI = EV/PV
CPI = EV/AC
Where: PV: planned value, AC: actual cost, EV: earned value

The report should be limited to the activities of the WBS entries from the planning and control plan (report on the WBS).

<# QA115-REQ-0010
All documents referenced in the Progress Reports (e.g. latest control plan, documentation schedule, or time schedule) must be submitted together with the Progress Reports in electronic format a minimum of five (5) working days prior to the next progress meeting.
#>

2.1.3 Final Report

<# QA115-REQ-0011
On or before the end of the Contract, after the Works are completed, the Supplier must prepare and deliver to F4E a comprehensive Final Report.
#>

<# QA115-REQ-0012
The Final Report (or Manufacturing Dossier) must contain, but not necessarily be limited to:

- A detailed description of the works required by the Contract (status of the implementation);
- The final (as built) Contract Programme;
- The final Control Plan (with activities signed-off as required);
- The final Documentation Schedule;
- The final Contract Quality Plan;
- Final results summary; incorporating the results of all tests and surveys carried out;
- Material Certificates traceable to components;
- Results of qualification tests e.g. Welding Procedure Qualification Records, welder approvals, NDE operators approvals, Pressure/Leak Test Procedures, Weld Logs (Weld Plans);

- Copies of all as-built drawings (and CAD models where applicable), Supplier surveys, reports including photographic records of the progress and detail of the Works (where applicable);
- Commissioning test procedures and results, maintenance/installation/operation manuals and parts lists for any Plant/item installed within the Permanent Works (where applicable);
- A compilation of all Contract meeting minutes and reports, NCRs and DRs;
- Final IP Report summarising the information on IP provided foreground IPR declaration (Foreground declaration form, as supplied in the contract documentation);
- Dual-Use items/technologies final list with evidence of authorisation of export (where applicable).
- *Nuclear Safety File* (where the supplier is responsible for the PIC design) according to §2.14:
    1. The PIC breakdown for the contract
    2. The final revision of the Defined Requirements (Safety) for the Contract PIC
    3. The final version of the Nuclear Safety Compliance Record (as per F4E-QA-113 [13])
    4. The final version of the Compliance Matrix for the Contract
    5. List of PIA for the contract (or a cross reference to the Control Plans and QA Records)
    6. Final list of NCR and DR affecting PIC and PIAs
    7. Final Subcontracting Schedule showing all levels of the Supply-chain
    8. Surveillance plan of the Subcontractors performing critical activities at the final version.

#>

2.1.4 Reporting on Intellectual Property

<# QA115-REQ-0013

The supplier will be required to inform Fusion for Energy in the Progress and Final Reports on the progress of the work attributed to him including the creation of any Intellectual Property (IP). It shall therefore identify all the results that may take the form of an invention, information, trade secrets, designs, drawings, processes, software, database etc.

#>

<# QA115-REQ-0014

A form is provided in the list of Applicable Documents to help suppliers identifying IP foreground as appropriate. The declaration of IP foreground will be provided as soon as foreground is created. In addition to foreground the supplier shall give account on 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.

#>

<# QA115-REQ-0015

To facilitate the management of IP within the contract and to ensure that relevant information is protected where necessary the Supplier shall provide a foreground declaration, containing any IP related information. The foreground declaration shall be provided in an independent document to be provided with the relevant progress reports. The Final Report shall always be accompanied by a final foreground declaration.

#>

<# QA115-REQ-0016

To ensure the confidentiality and the proper management of strategic IP information such as trade secrets or information on patentable subject matters, the Supplier shall identify in the IP reports any confidential information.

#>

<# QA115-REQ-0017

The purpose of the Final foreground declaration is to identify the information and IP, whether protectable or not, generated under a contract which, in combination with the background declaration, allow for a clear establishment of the ownership and rights of the results of the contract. Thus, the declaration shall consist of a compilation of IP relevant information independent from the Final Report, as a standalone self-explaining document. Each item shall include a short description of the item to allow for easy understanding of the nature of the item. Cross references to other parts of the Final Report must be avoided.

#>

2.1.5 Acceptance Data Package

<# QA115-REQ-0018

Every deliverable set out in the Technical Specification (Deliverables) has an associated Acceptance Data Package (ADP) that must to be submitted to F4E.

#>

For document deliverables, the deliverable is part of the ADP.

<# QA115-REQ-0019

The ADP must contain, but must not necessarily be limited to, the following documents:

- The Release Note form(s) (Certificate of Conformity);
- Related technical documentation, computational models or software;
- The deliverable Quality Plan implementation documentation;
- The Verification Control Documents;
- In Grant Agreements, the Activity Report (as part of the grant Periodic Activity Report package) is the equivalent of a Contract Deliverable and the ADP – the Periodic Activity Report package should include (as defined in the Grant Agreement): the Activity Report; the Report on the use of the resources; the Financial Statements/Cost claim; the report on the implementation of the plan for the use and dissemination of foreground; and any other report or deliverable required.

#>

2.2 Deviation and Nonconformity Management

<# QA115-REQ-0020

The Supplier shall maintain a divergence management system to monitor and record the quality of the work performed by the Supplier in comparison to the original specification for the Works.

Any divergence from the original specification for the Works must be documented by the Supplier and approved by F4E in accordance with the provisions set out in this Section and in any Sub-Clauses of the Contract.

#>

<# QA115-REQ-0021

These divergences must be identified by the following categories:

- Deviation – planned *alternative to a specified requirement*;
- Nonconformity – any condition that *does not comply with a specified requirement* (ISO 9000: non-fulfilment of a requirement).

Specified requirements shall be:

- The requirements of the Contract and in particular of the technical and management specification (of the Contract);
- Any safety requirement defined in the technical and management specification, applicable regulations and dedicated procedures;
- The requirements in a document submitted to a Regulatory Body.

#>

<# QA115-REQ-0022

The Supplier shall represent in a flowchart the process for managing each divergence (Deviation and Nonconformity).

#>

<# QA115-REQ-0023

The following definitions apply to the nonconformity actions:

- *Remedial Action*: An action taken to address the nonconformity condition (eliminate, rework, repair or use as is).
- *Corrective Action*: An action to eliminate the cause of a detected Nonconformity or other undesirable situation.
- *Preventive Action:* An action to eliminate the cause of a potential Nonconformity or other undesirable potential situation.

#>

<# QA115-REQ-0024

The supplier shall not grade nonconformities, furthermore the terms 'Major Nonconformity' and 'Minor Nonconformity' cannot be used by the Supplier in any of the contract documentation as these denominations are reserved for higher level requirements as defined by the Nuclear Operator.

#>

2.2.1 Deviation Management

<# QA115-REQ-0025

The Supplier shall detail the deviation management system that must include all deviations initiated by the Supplier, its Subcontractors, or Suppliers, and those issued by F4E. This system must ensure the provisions indicated below.

- Deviation Requests must be approved by F4E before implementation.
- An F4E Deviation Notice is followed by an F4E Deviation Order before implementation.
- A Deviation Request or a Deviation Order approved by the Parties is an agreement which constitutes an Amendment to the contract, unless F4E indicates otherwise in the Deviation Request or Deviation Order approval.
- Unless otherwise indicated by F4E, the Amendment enters into force upon the day of signature by the last Party.
- Implementation of the Deviation may not start before the entry into force of the Amendment.
- 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).
- The status of the current specifications, identifying all associated deviations is made available to F4E when requested.

#>

Deviation Request *Originating from Supplier* or Subcontractor:

<# QA115-REQ-0026
When a deviation is foreseen, the Supplier shall discuss it with F4E. If the proposal is considered beneficial, the Supplier shall request F4E's approval by issuing a Deviation Request in the F4E online register for deviations (or, if not available, in the format provided in §5.2 - Deviation Request).
#>

<# QA115-REQ-0027
The Deviation Request must contain or refer to all relevant material available to enable an informed decision to be taken. In particular, it must include an assessment of the deviation's consequences in terms of cost, delay and risk.
#>

<# QA115-REQ-0028
The Supplier shall implement the deviation only after reception of the approval of the Deviation Request from F4E.
#>

<# QA115-REQ-0029
The flow must be compliant with the Deviation from Supplier Flow (Figure 2.2-1)
#>

Deviation *Originating from F4E*:

<# QA115-REQ-0030
If F4E considers that a deviation may be required, it will notify the Supplier to this effect in the form of a *Deviation Notice*.
#>

<# QA115-REQ-0031
The Supplier shall issue an impact assessment report for each Deviation Notice received from F4E. The report must contain or include copies of all relevant material available to enable an informed decision on the course of action to be taken by F4E. In particular, it must include an assessment of the consequences of the deviation in terms of cost, time and risk.
#>

<# QA115-REQ-0032
The Supplier shall implement the deviation only after reception of a *Deviation Order* approved by F4E (confirming the impact assessment on the Deviation Notice).
#>

<# QA115-REQ-0033
The flow must be compliant with the Deviation from F4E Flow (Figure 2.2-2).
#>

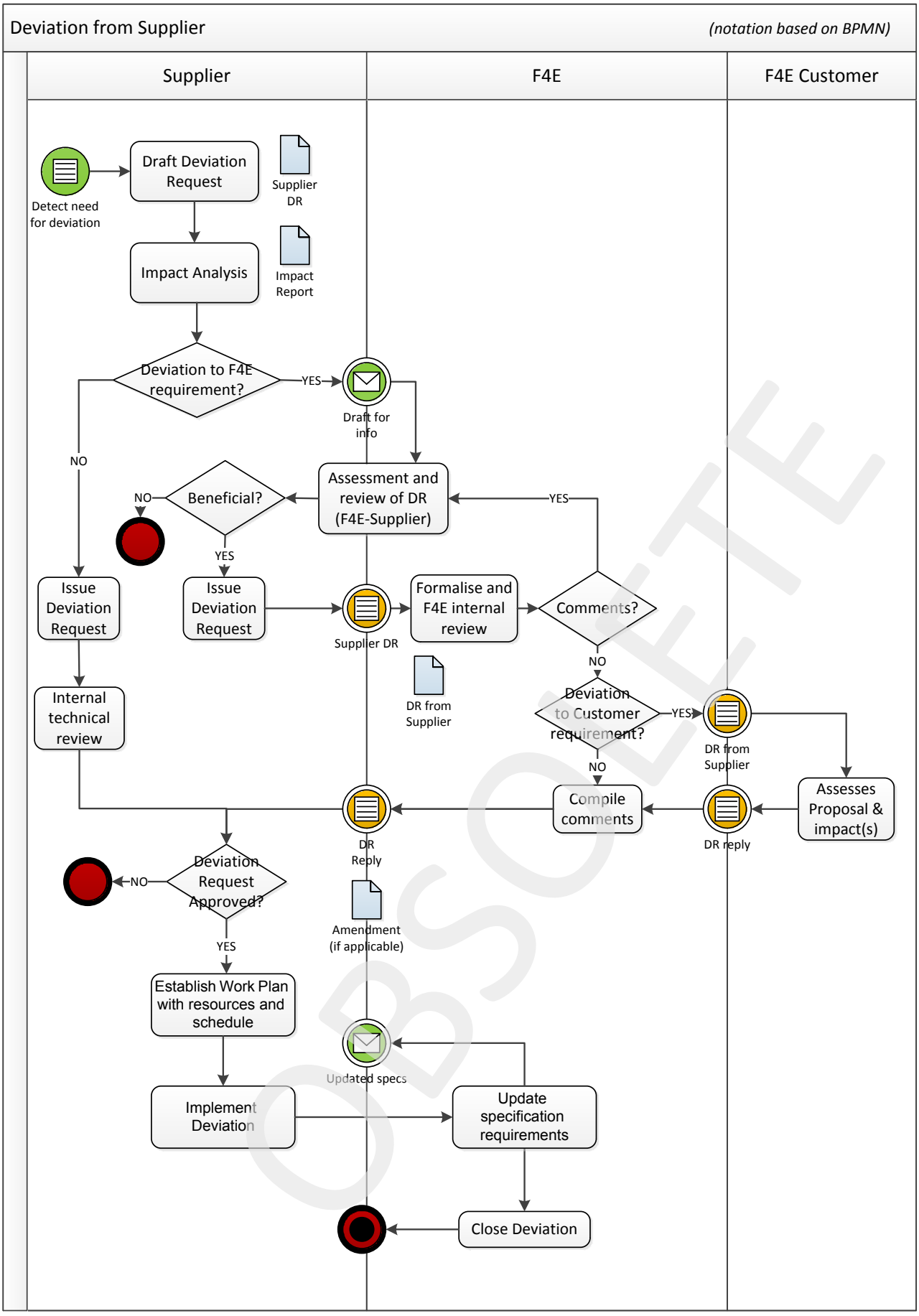

Figure 2.2-1 – Deviation from Supplier Flow

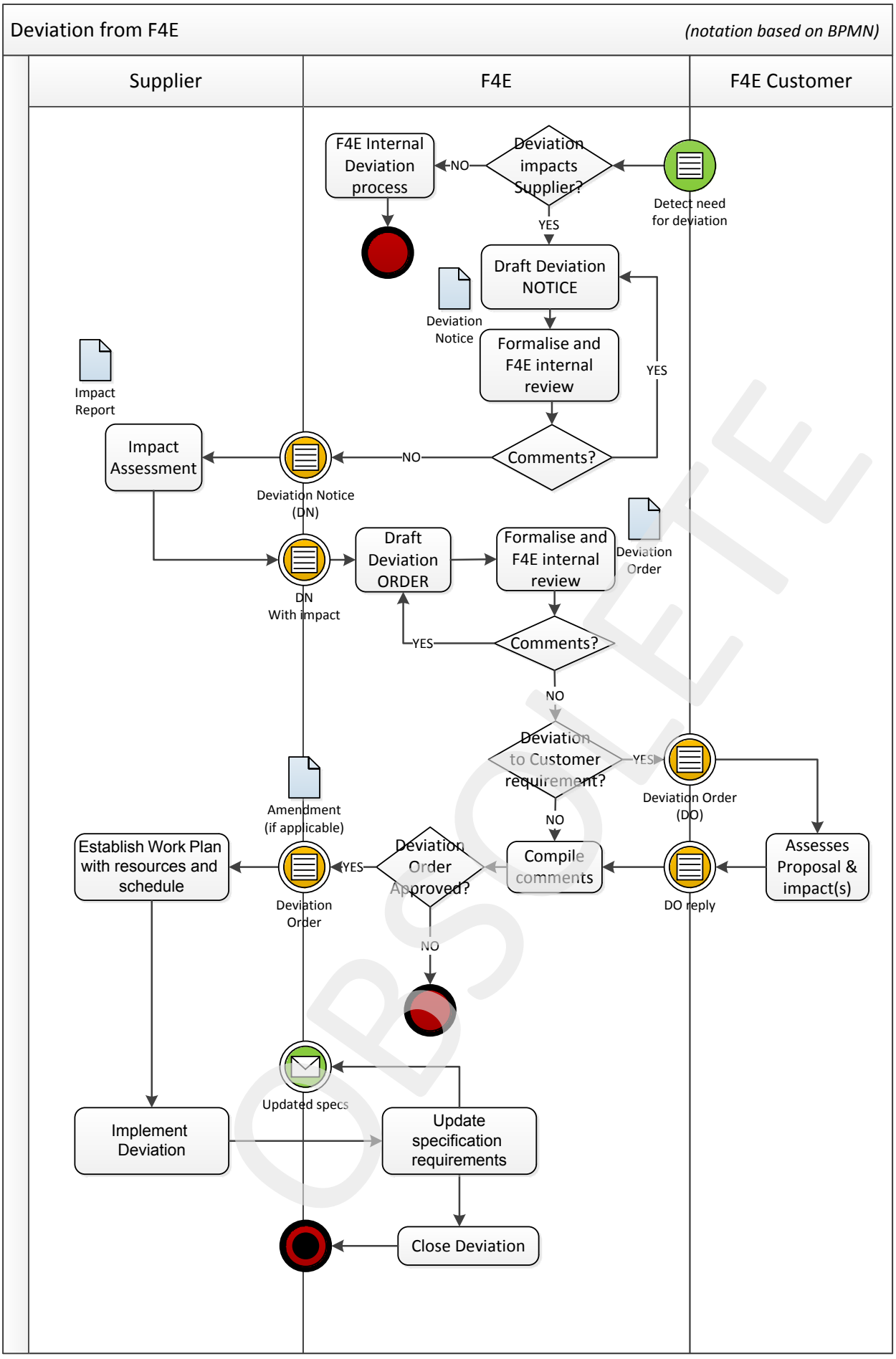

Figure 2.2-2 – Deviation from F4E Flow

2.2.2 Nonconformity Management

<# QA115-REQ-0034

The nonconformity management system must ensure that procedures are implemented in order to:

- Detect any nonconformity and segregate the nonconforming element of the Works or material (and stop the associated work);
- Maintain an up-to-date register of all nonconformities and their associated remedial actions and submit to F4E with each progress report. (or otherwise on request);
- Ensure that root causes are identified and if needed the appropriate Corrective Actions are implemented to prevent repetition of nonconformity;
- Ensure that appropriate improvements, in the form of Preventive Actions, brought about by the corrective actions, are implemented to prevent future nonconformities;
- Ensure that a nonconformity is raised by means of a nonconformity report, in case F4E or its appointed representatives issue a nonconformity note after detection of a pertinent discrepancy (normally in the form of a *Field Observation Report* or in an *Audit Report*);
- Ensure that if a nonconformity is detected F4E must be informed ASAP, and in the case of PIA or a PIC that information must be within 24h.
  Ensuring a fast response as to agreeing the remedial action.
- Ensure that:

  - if the Supplier considers that a nonconformity has occurred; OR

  - if F4E notifies the Supplier (in the form of a Field Observation Report or in an *Audit Report*) that it considers that one has occurred,

  the Supplier within five (5) working days notifies F4E to this effect in the form of a Nonconformity Report (if available in the F4E online register for nonconformities), before any remedial actions are implemented.
- Ensure that it is compliant with the *Supplier Nonconformity flow* (Figure 2.2-3)

#>

<# QA115-REQ-0035

If a nonconformity is found, the Supplier shall issue a Nonconformity Report (if available register it in the F4E online register for nonconformities) and provide F4E with a proposal for remedial action to remedy the nonconformity. No remedial action suggested by the Supplier is to be implemented until such remedial action has been approved by F4E.

#>

<# QA115-REQ-0036

Non-compliances to conditions that do not impact a specified requirement – normally to the supplier internal procedures and instructions – should be handled in a separate process and not to be graded in the same system as the nonconformities (as defined by F4E). The list of these internal non-compliances related to the Works must be periodically submitted to F4E.

#>

<# QA115-REQ-0037

To close a Nonconformity the Supplier shall:

- Make an analysis of the root causes of the nonconformity (such as determination of human or organizational causes, inadequate procedure, misuse of a code & standard, wrong set-up…) and summarize its result in the nonconformity report closure section;
- Provide to F4E the objective evidence of implementation of the remedial action(s).
- Provide to F4E the objective evidence of the initiation of implementation of the Corrective action(s) (if needed).
- Obtain the closure concurrence of F4E.

#>

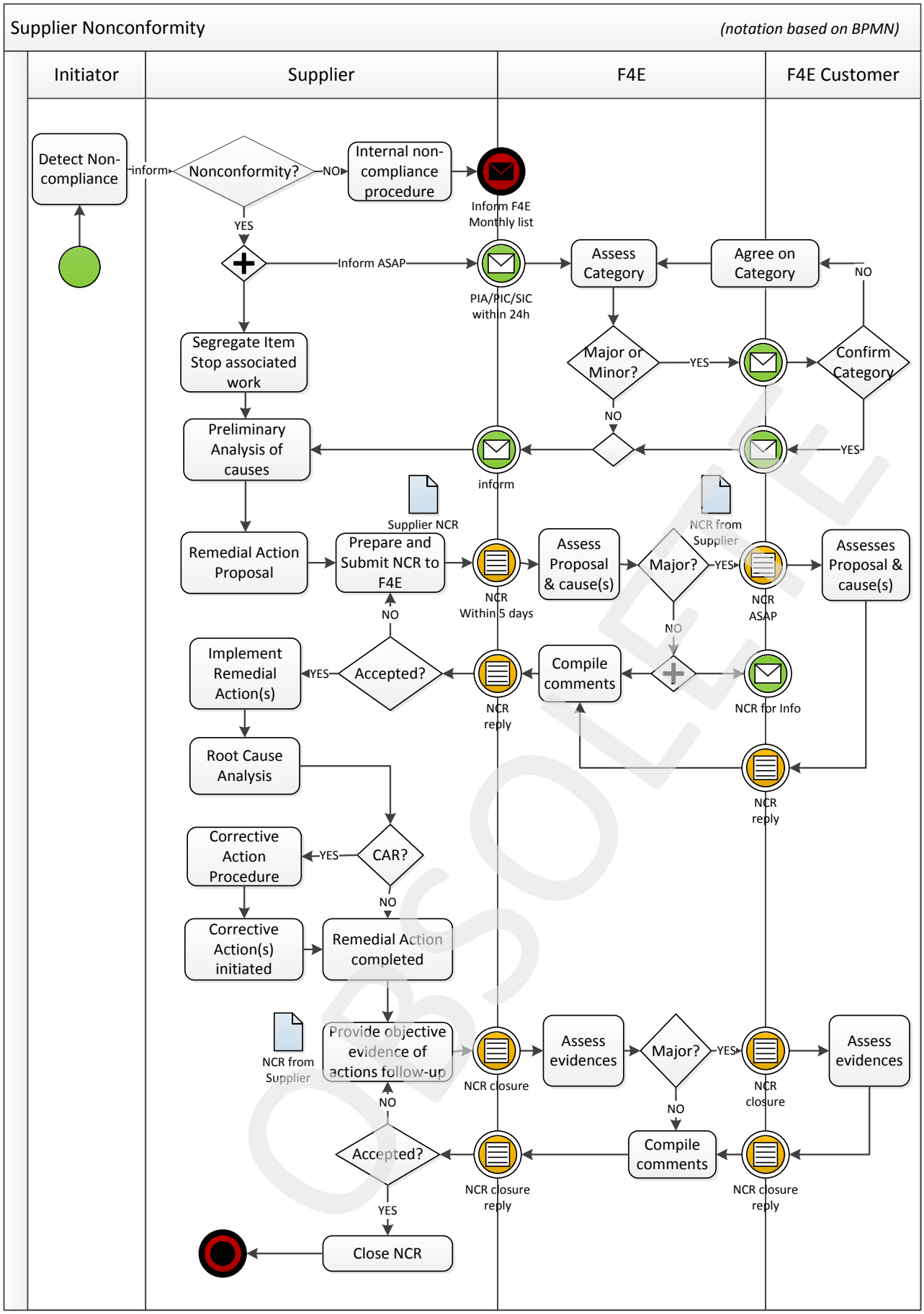

Figure 2.2-3: Supplier Nonconformity Flow

<# QA115-REQ-0038
The Supplier shall indicate how, when and by whom nonconformities will be processed including those originating from its Subcontractors.
#>

For PIA or PIC of the ITER Project:

The supplier is informed that a 'significant' NCR as defined in the 07 February 2012 [9] significant event: discrepancy of specific importance, pursuant to the criteria specified by the French Nuclear Safety Authority) might be reported by the Operator to the French Nuclear Safety Authority.

2.2.3 Deviation and Nonconformity Management Records

The Nonconformity Report and Deviation Request formats are shown in §5 (Mandatory Forms).

<# QA115-REQ-0039
The Supplier shall

- Number the Deviation Requests and Nonconformity Reports sequentially;
- Maintain an electronic register of all Deviation Notices, Deviation Orders, Deviation Requests and Nonconformity Reports issued in respect of this Contract that must contain an indication of their distribution and acceptance status.

#>

<# QA115-REQ-0040
Nonconformity Reports, Deviation Requests, Deviation Orders and deviation consequences assessment reports are an integral part of the Contract. On or before the end of the Contract, all Nonconformity Reports, Deviation Requests, Deviation Orders, associated reports, and any relevant documentary evidence, must be included in an appendix to the Final Report handed over to F4E.
#>

<# QA115-REQ-0041
The Supplier shall ensure that its Subcontractors implement the same procedures to control Deviations.
#>

F4E's acceptance of Nonconformity Reports and Deviation Requests:

- Shall be limited to the particular item referred to in the Request or Report;
- 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.

2.3 Information and Documentation Management

<# QA115-REQ-0042
The exchange of all quality and technical documentation and information between F4E and the Supplier must be conducted through and between F4E's Technical Officer responsible for the Contract and the Supplier's Project Manager.
#>

<# QA115-REQ-0043
The Supplier shall describe its documentation management system.
#>

<# QA115-REQ-0044
The Supplier shall be responsible for filing all documentation relevant to the Contract in F4E's document management system (unless agreed otherwise).
#>

The access methods to documentation exchange portal will be explained at the kick-off meeting (including any detailed presentation and manuals if needed).

<# QA115-REQ-0045

The Supplier shall represent the process for documentation flow in a detailed flowchart (including the internal review and approval and the interface with F4E).

#>

<# QA115-REQ-0046

Before being distributed, documents and data must be *verified by individuals not involved in their drafting*.

#>

<# QA115-REQ-0047

Unless specifically specified otherwise, the standard documentation review cycle must include:

- For documents submitted by the Supplier to F4E:
  - F4E will have fifteen (15) working days from the receipt of Supplier's Documents (except the Quality Plan) to review, comment on and/or, as the case may be, approve/accept them (in the case that a third-party is involved in the approval/acceptance, the time is increased by five (5) working days);
  - The Supplier shall have ten (10) working days from the receipt of commented documents to update and resubmit them to F4E via email; and
  - F4E will have ten (10) working days from the receipt of the Supplier's e-mail to review and return the documents (in the case that a third-party is involved in the approval/acceptance, the time to return the documents is increased by five (5) working days).
- For documents submitted by F4E to the Supplier:
  - The Supplier shall have fifteen (15) working days from the receipt of F4E's Documents to review, comment on and/or, as the case may be, approve/accept them;
  - F4E will have ten (10) working days from the receipt of commented documents to update and resubmit them to the Supplier via email; and
  - The Supplier shall have ten (10) working days from the receipt of the F4E's e-mail to review and return the documents.

Apart from the review cycle of the first submission, in each subsequent review cycle comments must be limited to:

- Text related to previous comments (either modified or deleted), or
- Newly inserted text.

#>

Revised dates or timescales may be adopted, subject to a written agreement between F4E and the Supplier.

The general process for document distribution and release is as follows:

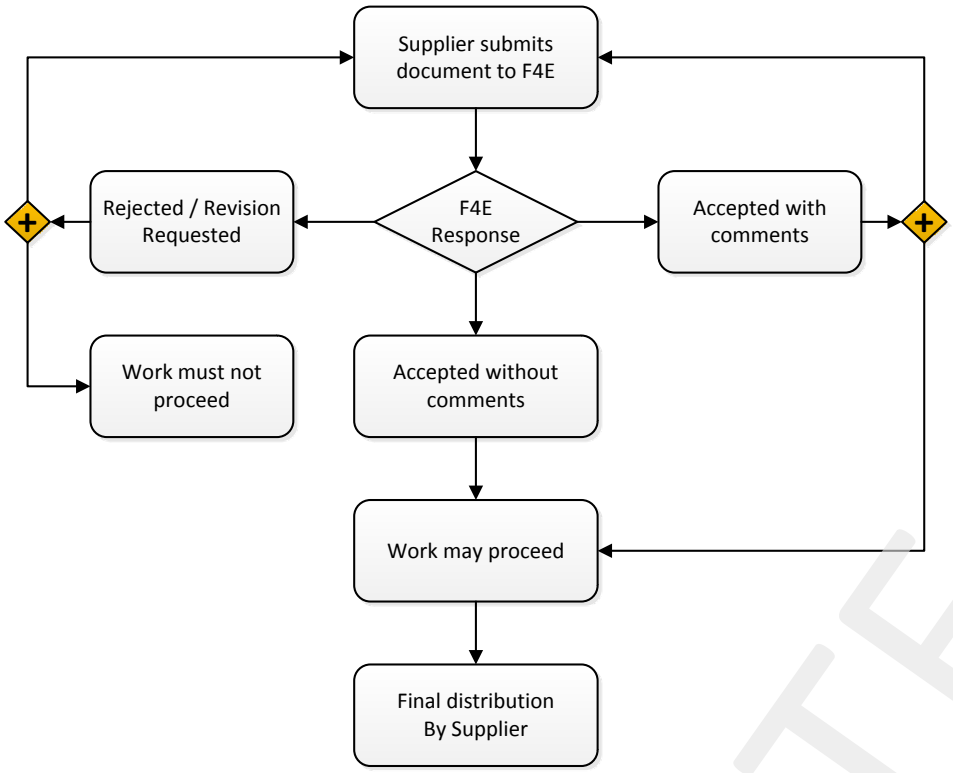

Figure 2.3-1: Document Distribution and Release General Process

<# QA115-REQ-0048

The Supplier shall provide a Documentation Schedule as defined in §3.2.5 (Documentation Schedule) and shall not commence its performance of the Contract until the Documentation Schedule has been accepted by F4E.

#>

<# QA115-REQ-0049

Technical and Quality Documents must include:

- *A revision history log* at the beginning of the document including at least the (Sub-)Sections that were changed.
- Identification of the changes in the text itself by one of the following methods: highlighting, writing in different colour or using change bars.

#>

<# QA115-REQ-0050

The documentation format must follow the requirements given in §2.10 (Mandatory Document Formats).

#>

<# QA115-REQ-0051

The Supplier shall keep all necessary documents and technical information related to the Contract and subcontracts for monitoring, quality assurance controls, checks and audits. If so required, the Supplier shall provide copies of such documents for the use of F4E.

#>

<# QA115-REQ-0052

Upon the completion of the Contract, the Supplier shall at its own cost store all documents relating to the Contract for an initial period of ten (10) years (or the period required by the Laws, whichever is longer) after the payment of the final balance of the Contract Price.

#>

<# QA115-REQ-0053
F4E's acceptance of the Documentation Schedule or technical documents such as drawings, sketches, or other specifications, shall not in any way limit the Supplier's duties and obligations pursuant to the Contract nor diminish any liability on its part in respect thereof.
#>

2.3.1 Design Documentation Control

<# QA115-REQ-0054
For deliverables or ADP that include CAD data, the Supplier shall implement a CAD data control system for any design activities.
#>

<# QA115-REQ-0055
The system must comply with the F4E CAD Manual, including the formats defined in §2.10.
#>

The preparation, review, and release of drawings are accomplished through controlled procedures that establish the release authorities and responsibilities.

<# QA115-REQ-0056
A design change, to modify an approved configuration baseline, is a 'deviation' and must be controlled according to §2.2.1. Alteration to drawings, without addressing configuration requirements, are defined as 'Drawing Modifications' - modifications inherent to the different stages of the drawing process (e.g. 'as defined', 'as detailed' and 'as built' stages).
#>

2.3.2 CAD Specific Requirements

<# QA115-REQ-0057
The Supplier shall use the latest release of Catia v.5 in compliance with the F4E CAD manual
#>

<# QA115-REQ-0058
The Supplier must receive training for each designer by F4E on CAD methodology including use of the F4E manual, skeletons etc. If working asynchronously it will include the CAD supplier package.
#>

If the design uses network elements: their representations (PFD and P&ID fluids diagrams), will be done through a remote connection to the *IGE+XAO SEE System Design* licenses and database of ITER IO which is the only reference solution on the ITER collaboration diagrams. For electrical circuits and electrical cubicle circuits separate licenses will be required:

- For PFDs and P&IDs SEE System Design will be used. (direct connection to the IO DB)
- For electrical cubicles *SEE Electrical Expert* will be used. (licenses to be purchased)

Before starting the manufacturing design, the contractor could be involved in the modification of the CAD data especially modifying *Multibody* models to *Multipart*.

For synchronous connections:

- *In case F4E asks the supplier to work synchronously with IO — the supplier shall be able to use an internet connection to have direct access to IO database Enovia VPM using the 'Teradici' PCoIP technology solution.*

  http://www.teradici.com/pcoip/pcoip-technology.php

- *Hardware requirements (to be provided per user / zero client): One USB keyboard and one USB mouse;* One screen; *Network cable with RJ45 connector; Zero Client.*

- *Software requirements*: A complete set of Catia licenses will reside at the IO in Cadarache per designer

- *Network Access requirements*:

  - The zero client requires network access to IO host card network either via Internet or VPN. IO IT requires network access to the zero client in order to manage it. That might be realised via screen sharing on a computer at remote site.

  - The bandwidth requirement per site depends on the number of workstations to connect to, where the required bandwidth per workstation is 4 Mbps (= 4000 kbps = 500 KB/s). This bandwidth is needed for each user, if they simultaneously rotate a Catia model or perform a similar action. For a large number of users the total bandwidth requirement may scale less than linear but any quantitative estimate can only be provided after more extensive use of this solution. Packet loss has to be below 0.1%.Maximum latency better than 100 ms. The PCoIP protocol can be used over higher latency networks, but the user experience will be impacted as latency increases and has to be validated on a per case basis. Packet reordering should be kept to a minimum.

  - If the Supplier is asked by F4E to use the Enovia direct connection each designer must receive training by F4E on the use of Enovia. Each designer must be certified before they can have access the IO Enovia VPM database.

2.4 Subcontractors Management

<# QA115-REQ-0059

The Supplier shall ensure that each of its Subcontractors has a quality system compliant with this document and if applicable, the requirements are cascaded to low-tier subcontractors. The Supplier shall issue an assessment (Subcontractor Acceptance Form) for each Subcontractor.

- The Subcontractors quality documents (including the relevant Quality Plan) must be approved by the Supplier and sent to F4E for acceptance.
- The Supplier shall ensure that subcontractors do not start work on any contract without a Quality Plan and a Control Plan in place that has been accepted by F4E.
- Subcontractors not performing critical quality activities (activity that if not performed correctly may affect Safety, Functionality or Reliability) may be exempted from the requirement to produce Quality Plans and Control Plans at the discretion of the F4E QA Officer and in discussion with the Supplier Quality Representative. This decision will be dependent on the level of detail about subcontracted work in the Suppliers Quality Plan. In such cases, the work can be included in the Supplier's Control Plan and managed in accordance with the Supplier's management system.

#>

<# QA115-REQ-0060

The Supplier shall provide a Subcontracting Schedule in compliance with the requirements set out in §3.2.7 (Subcontracting Schedule) (in compliance with the Change in Subcontracting flow – Figure 2.4-1).

#>

The subcontracting schedule identifies all the supply-chain, including the lower tier subcontractors.

<# QA115-REQ-0061

For PIA, the Supplier shall make provisions and give F4E (and if required the F4E observer — section 2.8.2) the opportunity to participate (as witness) in the process of selection and seek concurrence in the award of subcontracts.

#>

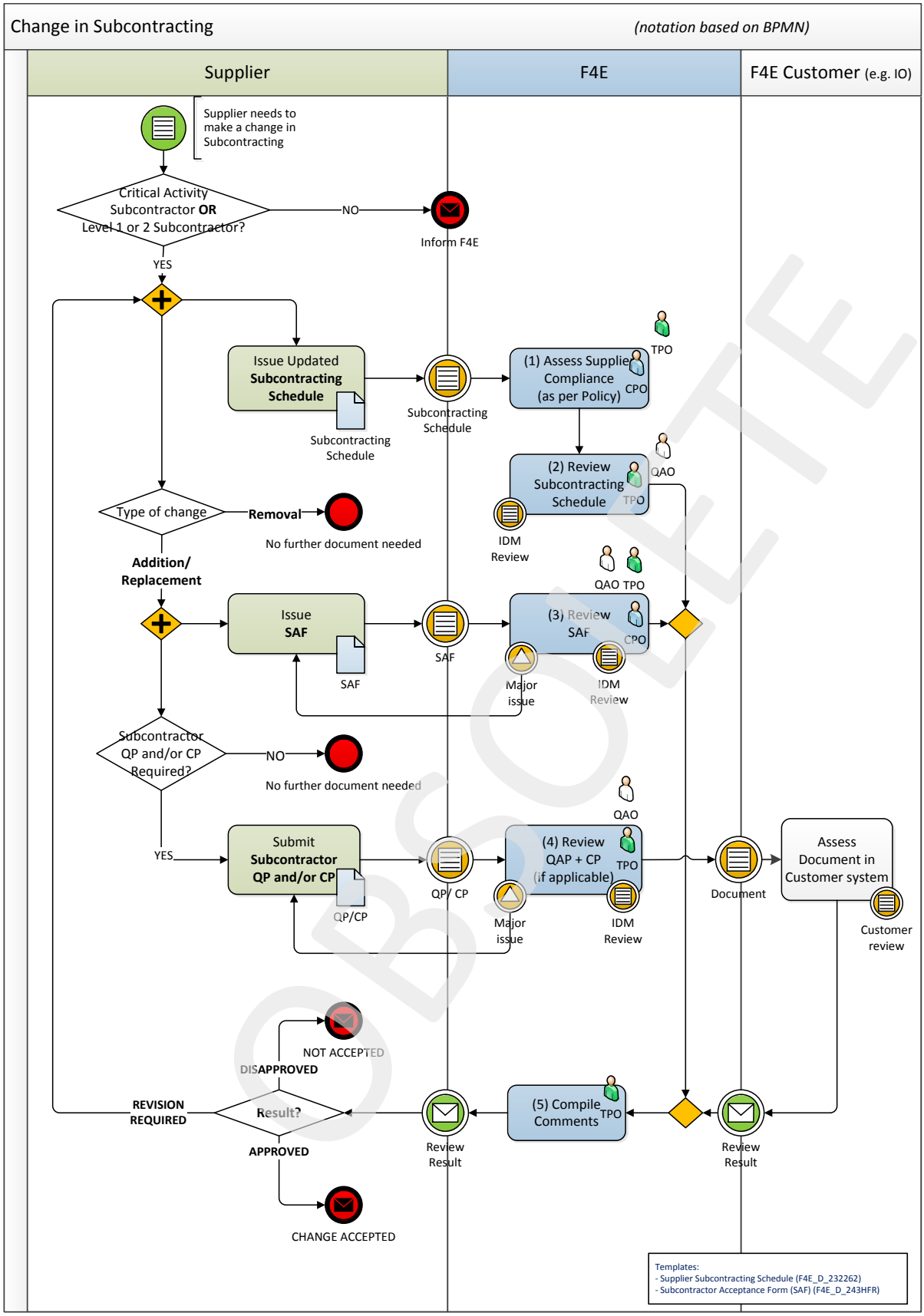

Figure 2.4-1: Change in Subcontracting Flow

<# QA115-REQ-0062

The Supplier shall ensure that purchased or subcontracted goods and materials (filler materials, base materials, etc.) are supplied together with their certificate of conformity to the specified requirements (normally EN 10204 Type 2.2 for Quality Class 3 NSR and Type 3.1 for all the remaining cases of classes 1 to 3).

#>

2.5 Assessment and Validation

<# QA115-REQ-0063

The Supplier shall demonstrate how it will monitor and record compliance with the Control Plan throughout the duration of the Contract. The record of compliance must contain as a minimum:

- Signed and dated performed activities or intervention points in respect of each completed activity;
- Identification and record of each report generated during the performance of any particular activity, such as test reports and Nonconformity Reports, and, where possible, the identification of any opportunity for improved performance under the Contract.

#>

<# QA115-REQ-0224

PIA (QC1 and QC2) and Quality Class 1 non-PIA activities of design and/or analysis (as per F4E-QA-010) must be verified (Verification Activity) by individuals not involved in performing the activity and this verification must be recorded and signed (and the record must be available).

#>

2.5.1 Manufacturing, Inspection and Testing

<# QA115-REQ-0064

Manufacture, inspection and testing must be carried out:

- following pre-established lists of operations in accordance with the Control Plan (§4).
- using approved and up-to-date drawings, procedures, instructions, standards or other documents directly accessible to those carrying out the work.

#>

<# QA115-REQ-0065

Processes that cannot be adequately inspected after completion (Special Processes) must be performed according to qualified procedures implemented by qualified personnel. Evidence of qualification must be available for F4E review prior to use.

#>

<# QA115-REQ-0066

Inspection and testing status of items and services must be readily identified.

#>

<# QA115-REQ-0067

Evidence of validation of computers and automated machining and inspection programs and software must be maintained.

#>

2.5.2 Qualification of Special Processes (or of processes requiring validation)

> A *process where the conformity of the resulting product cannot be readily or economically verified is frequently referred to as a 'special process' (ISO 9000).*

<# QA115-REQ-0068

The Supplier and its Subcontractors shall be responsible for the manufacture processes qualification tests when the qualification is required in the applicable codes and standards or is specified in other clauses of the Contract. In any case, qualification tests must be carried out before undertaking the corresponding processes.

#>

<# QA115-REQ-0069

The Supplier shall submit the qualification records to F4E for acceptance, along with the corresponding process execution procedures (e.g. welding WPS). The following processes, among others, must be qualified:

- Brazing, Welding and Filling (including repairs) (see also section 2.5.5)
- Non Destructive Testing / Examination (NDT / NDE)
- Thermal treatments
- Paint coating
- Chemical cleaning, linings and other process that may sensitise the materials.

#>

<# QA115-REQ-0070

Processes qualification must be included in the Control Plan (or detailed plan or Inspection Test Plan). F4E or its representatives will subject them to the same supervision requirements as to the rest of manufacture operations.

#>

The provisions of this section are also applicable to the operator's qualification (welders, etc) of these processes when so required by the corresponding standards.

2.5.3 Staff Qualification

<# QA115-REQ-0071

In addition to the above (section 2.5.2), staff both from the Supplier and its Subcontractors who participate in quality or safety related activities must be appropriately qualified. Staff qualification must be done according to applicable standards for each case.

#>

In addition to the special processes, other activities such as tests, miscellaneous inspections, audits, dimensional metrology and NDTs need staff qualification.

Supplier Staff	Minimum Qualification Required
Carrying out NDTs	EN ISO 9712 [7] – level one
Supervising, assessing and/or certifying NDTs and their results	EN ISO 9712 [7] – level two
Welding supervision staff	EN ISO 14731 [6] - level IWS

Table 2.5-1 – Specific Supplier staff qualification requirements

<# QA115-REQ-0072

Quality technicians and quality coordination staff shall have a minimum of completed secondary education, quality training (e.g. ISO-9001 training and quality management system training) and four years of work experience in quality management or quality assurance coordination (in a similar field as the scope of Work).

#>

<# QA115-REQ-0073
Subcontracting of activities shall not exempt the Supplier from its responsibility to supervise and inspect those activities with qualified staff in accordance with the present document.
#>

2.5.4 Metrology

<# QA115-REQ-0074
Component and assembly dimensional checks, shall be performed in agreement to the F4E Dimensional Metrology Handbook.
#>

<# QA115-REQ-0075
The Dimensional Metrology Handbook (DMH) outlines the mandatory requirements for dimensional control of the components, assemblies and systems. In addition the handbook provides significant guidance and helpful information on best practise for large volume metrology applications. The handbook also provides information on the ITER metrology infrastructure and the provision of alignment and metrology services during assembly of the machine and its ancillary components and systems.
#>

2.5.4.1 Measuring and Test Equipment

<# QA115-REQ-0076
The Supplier shall supervise and monitor all measurement and test equipment used in the execution of the Works.
#>

<# QA115-REQ-0077
The Supplier shall maintain full and detailed records, and provide evidence to F4E, of the following:

- test equipment identification and calibration status;
- proper use (range, precision, etc.);
- proper calibration.

#>

<# QA115-REQ-0078
The Supplier shall maintain all appropriate test records that clearly identify any test equipment that has been used and its calibration status.
#>

2.5.5 Welding (fusion and solid state welding and brazing)

This subsection defines the standard requirements of the use of the welding processes (the broader term welding used in this subsection refers to fusion and solid state welding and brazing). Further requirements might be imposed or defined by the applicable code or specification.

<# QA115-REQ-0079
The requirements of this subsection shall be applicable to prototypes, mock-ups, production, manufacturing and spare parts.
#>

Welding is defined as a *Special Process*.

<# QA115-REQ-0080
Any weld to be produced must be based on a Welding Procedure Specification (WPS). WPSs must be specific to the project.
#>

<# QA115-REQ-0081
All WPSs must be based on a qualified procedure before being used (according to the relevant standard).
#>

<# QA115-REQ-0082
Only certified welders (and operators) can produce welds or tack welds (according to the relevant standard and within the scope of the applicable WPS). The welder certificates must be presented and accepted by F4E (or its representative) before starting of the welding works.
#>

<# QA115-REQ-0083
All welders certification must be performed against a WPS with the presence of a recognized third party. For QC1 or QC2-PIA/PIC the welders certification must be performed against a project WPS.
#>

<# QA115-REQ-0084
Welding procedures and welders must be qualified by a recognized third party or *notified body (organisation that has been accredited by a EU Member State to assess whether a product meets certain preordained standards*).
#>

A WPS based on an existing qualified welding procedure (WPQR, WPAR or PQR) is acceptable if the following conditions are met:

- The qualification must have 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 must have been witnessed by a recognized third party (or *notified body).*

<# QA115-REQ-0085
F4E as a standard, must be invited to witness the welding qualifications (Notification Point)
#>

<# QA115-REQ-0086
The review and acceptance of the WPS and qualifications by F4E must be at least a Review Point.
#>

<# QA115-REQ-0087
F4E as a standard must be invited to witness the Production Test Welds (production proof samples) tests.
#>

<# QA115-REQ-0088
Any part/item that contains welds must have a corresponding *Weld Log* (sometimes also called weld record, map or plan), or be included in a more general assembly weld log.
#>

<# QA115-REQ-0089
The weld log ensures the traceability of the welds and must, at a minimum, include: weld references and joint detail; material data (Base Material and Filler Metal); process; welder; heat treatment; NDT performed and welding standard.
#>

<# QA115-REQ-0090
Any repairs must be clearly stated and identified as a new weld (repair, e.g. R) in the log.

#>

<# QA115-REQ-0091

The weld log must contain the Supplier approval visible and be included in the acceptance data package, normally inside the manufacturing book or dossier.

#>

<# QA115-REQ-0092

The weld log must be referenced in the adequate section of the relevant Control Plan.

#>

<# QA115-REQ-0093

The supplier must also be able to demonstrate that the welding equipment is properly maintained and calibrated in accordance with the relevant operation and maintenance schedules.

#>

2.5.6 Verification and Validation of Calculation and Modelling Tools

This subsection defines the standard requirements of the verification and validation of software to perform design analysis. Further requirements might be imposed or defined by the applicable code or specification.

<# QA115-REQ-0094

Use (including verification and validation) of specific calculation and modelling tools must be proposed to F4E before the beginning of the analysis. The analysis must start only after acceptance (release) from F4E.

#>

<# QA115-REQ-0095

The verification and validation process of calculation and modelling tools shall be limited only to the scope and purpose of the analysis calculations.

#>

<# QA115-REQ-0096

Calculation and modelling tools must be verified and validated according to QA-114 in the following cases:

- analyses of Structures, Systems and Components classified as Quality Class 1.
- analyses of Quality Class 2 Structures Systems and Components classified as PIC and/or with Defined Requirements (Safety).

#>

In case of commercially available software is used, the software distributor provides documents that ensure the software is performing properly for the physical problem associated with specific applications and within the defined limits.

In case of non-commercial software, verification and/or validation can be obtained by one of the methods defined below.

- Hand calculations (this generally applies only for software which use very simple algorithms)
- Independent calculations by independently checking the equations and algorithms for correctness and applicability and assess the input and output values.
- Establish and document the use of alternate software and why one should have confidence in the software.
- Results of experiments or tests. Use the same inputs as were applied to the experiments and/or tests and compare the outputs to the results of the experiments/tests.
- Comparison to the results of standard, confirmed, published problems with known solutions. Use the same inputs as were applied to the standard, confirmed, published problems and compare the solutions of the published problems with the output of the software.

Note that establishing confidence in calculation and modelling tools may include factors such as software developed under a qualified quality program (e.g. ISO-9001), number of users, expectations and familiarity with the software.

<# QA115-REQ-0097

Verification and validation processes are specific for the type of calculation (structural, electromagnetic, nuclear, etc.), model and code used. Before requesting the acceptance from F4E the supplier shall inquire F4E for:

- the applicable verification and/or validation procedure (from F4E or F4E customer) for the type of calculation, model and code;
- if the specific version of the model and code have been already been verified and/or validated at a previous task.

#>

2.6 Acceptance of a Deliverable

Prior to a complex release of deliverables, the Supplier *should* organise a documented deliverables-status acceptance review in accordance with the Contract requirements.

<# QA115-REQ-0098

Acceptance of a deliverable must encompass the following sequential stages (in compliance with the Deliverable Acceptance flow – Figure 2.6-1):

1. Issue the Release Note (Certificate of Conformity) as per Supplier 'Release Note' §5.6.

   By submitting the Release Note, the supplier confirms that all the contained documentation has been previously cleared by F4E (each document was ready for the acceptance review: i.e. submitted and confirmed by F4E as adequate for the deliverable acceptance review).
2. Send the consolidated ADP (including the Release Note) for Acceptance after clearance.
3. F4E will declare the *deliverable acceptance*, by

   - processing the related payment for Contract Deliverables (connected to payment), OR

   - sending an acceptance communication for Technical Deliverables (not connected to payment)

#>

<# QA115-REQ-0099

For deliverables which its acceptance will trigger a dispatch:

1) The dispatch can be carried out IF the Release Note is accepted AND the ADP is accepted.

2) Upon delivery F4E or its representative will sign a 'consignment note' (recognition of reception only) if:

- The deliverable is in the specified conditions;
- The transport was performed as required;
- the specified reception test results are accepted.

No dispatch can be carried out without prior acceptance of the Release Note and the ADP from F4E.

#>

The type of deliverable is defined in the contractual documentation (normally in the Technical Specification). If not defined otherwise, all identified deliverables are Contract Deliverables.

For Technical Deliverables (not connected to payment) that *consist uniquely of documentation* the Release Note is waived and the Supplier can dispatch the deliverable and ADP for acceptance.

<# QA115-REQ-0100

F4E's acceptance of the Release Note (Certificate of Conformity) must not in any way limit the Supplier's duties, responsibilities, and obligations pursuant to the Contract nor diminish any liability on its part in respect thereof.

#>

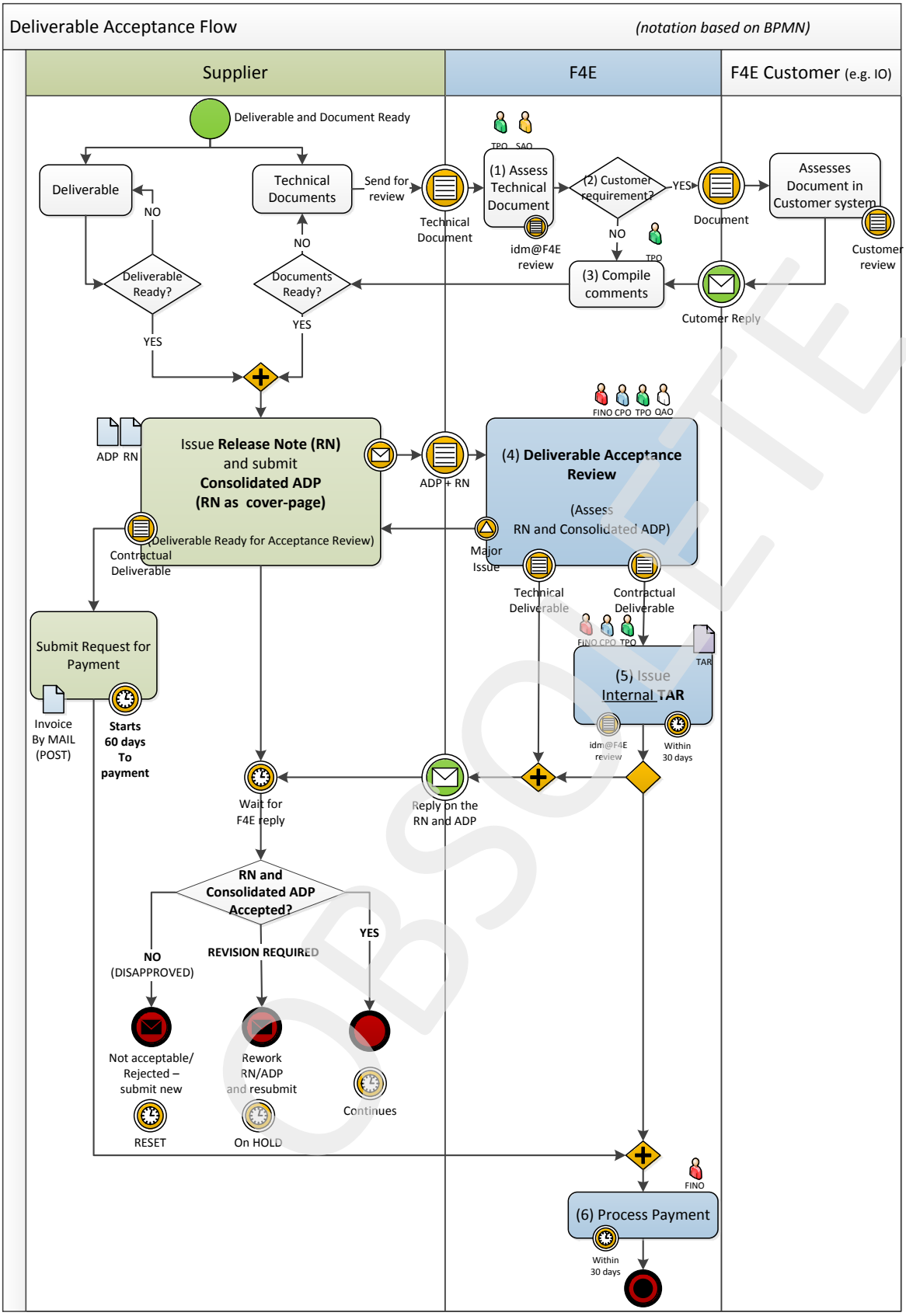

Figure 2.6-1: Deliverable Acceptance Flow

2.7 Risk Management

<# QA115-REQ-0101

The Supplier shall detail the measures to be implemented in order to eliminate or mitigate the risk of its failing to meet any contract or specification or programmed requirements. This includes, but is not limited to:

- preliminary risk analysis and assessment report of expected impact on cost, performances and schedule (*Risk Plan* submitted with the Quality Plan);
- review of performance against approved Contract programme and actions to identify potential development of delays;
- associated list of actions to implement in order to reduce the Contract's risk exposure;
- procedure to maintain the above documents up-to-date throughout the execution of the Works.

#>

2.8 Inspection and Quality Audits

<# QA115-REQ-0102

The Supplier shall take all necessary measures to allow F4E unrestricted access to all of the Supplier's documentation, premises and personnel (including that of its Subcontractors) during all stages of the Contract for the purpose of such audit, review, surveillance and inspection as F4E may consider necessary.

#>

<# QA115-REQ-0103

F4E reserves the right to make unscheduled visits to the Site or the Supplier or Subcontractors' work premises, and free access must be provided at all reasonable times.

#>

<# QA115-REQ-0104

F4E shall have the right to have permanent inspectors working inside the Supplier's workshops. Should this be required, the Supplier shall reserve an office inside its workshops for the inspectors, equipped with a telephone and facsimile with international access, and computers with internet access.

#>

<# QA115-REQ-0105

F4E or its representatives shall be permitted to take photographs and / or video recordings of any activity relating to the Contract. The material so obtained will remain confidential.

#>

2.8.1 Audits and Surveillance

F4E or its representatives may carry out periodic planned and documented audits, reviews, surveillance, and inspection of the quality system being operated by the Supplier to verify compliance with all quality and technical aspects of the Contract.

<# QA115-REQ-0106

These activities may be extended to the Supplier's Subcontractors, and the Supplier shall ensure that F4E's right to conduct periodic audits, reviews, surveillance, and inspection of the quality system being operated and to verify its compliance with all quality and technical aspects of the Contract, is incorporated into any subcontract. Should any deficiency in the quality system exist; the Supplier shall implement, or ensure that the Subcontractor implements, corrective actions, in accord with a timetable agreed by the Supplier.

#>

These activities include Notification Points (NP), Authorisation-To-Proceed points (ATP) and Hold Points (HP) at relevant steps as appropriate and must be integrated into the agreed schedule.

The NP, ATP, HP, and other markings in use (Control Plan) and the flow with F4E are defined in Section 4.4.

<# QA115-REQ-0107
The Supplier shall conduct periodic audits, reviews, surveillance and inspection of the Works, including in respect of the works performed by Subcontractors (following a surveillance plan), and in so doing shall notify F4E in advance, in writing, preferably via fax or email, and with sufficient notice to allow F4E to attend should it so wish.
#>

Subcontractors surveillance plans are specified in Section 3.2.12.

<# QA115-REQ-0108
F4E will have the right to dispatch its own inspectors or personnel to attend any of these activities.
#>

<# QA115-REQ-0109
Should the Supplier fail to conform with the notification requirement set out above, the Supplier shall reimburse F4E for any consequent expense incurred by it through the sending of its own inspectors or personnel as a result of incorrect notifications. F4E may in its absolute discretion request the Supplier to repeat, at its own expense, the activities considered as Notification or Hold Points that F4E was unable to witness due to incorrect notification by the Supplier.
#>

2.8.2 F4E Observer Access

<# QA115-REQ-0110
F4E shall have the right to be accompanied by observers in respect of any visit to the Supplier's premises for the purpose of any audit, review, surveillance, or inspection.
#>

Any observer who will attend the Supplier's premises with F4E will be identified and notified to the Supplier in advance and will belong to one of the following entities:

- F4E Customer,
- next user of the deliverable.

The observers will be bound by appropriate confidentiality obligations, to be agreed in advance.

2.8.3 Third-Party Inspection and Notified Bodies Authority

This section includes the ESPN [11] Agreed Notified Body (ANB) by the French safety authorities.

<# QA115-REQ-0111
F4E — whenever required by legislation or it considers it otherwise appropriate — shall be entitled to appoint an independent inspection authority to certify that activities are carried out in accordance with the Contract generally and with the Laws and all agreed codes and standards in particular.
#>

<# QA115-REQ-0112
The Supplier shall arrange free access for inspectors of the said inspection authority to the premises, its works or the works of its Subcontractors, so that the inspectors may carry out their duties as described.
#>

<# QA115-REQ-0113
The Supplier shall provide the independent inspection authority with copies of all relevant test reports and other information, documentation or facilities as it may require assessing whether the Contract deliverables meet the requirements of the Contract.
#>

2.8.4 French Safety Authorities

<# QA115-REQ-0114

[Only for PIA (PIC/SIC)] The Supplier shall take all necessary measures to allow appointed representatives of the French safety authorities the same unrestricted access as is accorded to F4E under §2.8 (Inspection and Quality Audit Visits). The Supplier shall provide, at the request of F4E, a representative able to explain, in French, the issues and progress to the French safety authorities.

#>

2.9 Summary of Quality Requirements and Actions

The following table gives an overview of F4E's quality requirements. It is not exhaustive.

Abbreviated Quality Requirement
With the offer / proposal: • Submit to F4E the meaningful 'preliminary' version of the Quality Plan: If applicable, the relevant 'Phases/tasks Control Plans.
After Contract signature: • Submit to F4E before the kick-off meeting the 'provisional' versions of the Quality Plan, including * 'Top Level Control Plan', and if applicable the relevant 'Phases/task Control Plans' * Relevant 'Documentation Schedule' and 'Subcontracting Schedule' defined included • Update and Submit to F4E the working versions of the Quality Plan • Obtain F4E's acceptance of the relevant Quality Plan
Prior to procurement or subcontracting: • Verify that the 'Subcontracting Schedule' is up-to-date. If changed from accepted, obtain F4E's acceptance of the updated Schedule. • Obtain F4E's acceptance of the relevant documents identified in the 'Documentation Schedule'.
Prior to design, manufacture, inspection and test: • Verify that the relevant phase 'Control Plan' is up-to-date and accepted by F4E. If changed from accepted, obtain F4E acceptance of the updated Plan. • Obtain F4E's acceptance of the relevant documents identified in the 'Documentation Schedule'.
During design, manufacture, inspection and test: • Notify F4E representatives of any pending Hold, Authorisation-To-Proceed or Notification Point. • Complete the relevant entries in the 'Control Plan' as work progresses.
Prior to acceptance or delivery of a deliverable: • Complete the relevant 'Supplier Release Note' • Send the consolidated 'Acceptance Data Package' (including the RN) • Obtain F4E acceptance of the Release Note • After the ADP and Deliverable acceptance, if applicable, dispatch the Deliverable.
During Contract implementation: • Issue 'Deviation Requests' and 'Nonconformity Reports' as necessary.
Prior to Contract closing: • Issue Contract 'Final Report' (Including the final 'Control Plan(s)' and 'Documentation Schedule')

Table 2.9-1 – Summary of Quality Requirements

2.10 Mandatory Document Formats

<# QA115-REQ-0115
All communications and official documentation relating to the Works must be in English.
#>

<# QA115-REQ-0116
- For monolingual documentation, the language must be English.

#>

<# QA115-REQ-0117
- For dual-language documentation, such as regulatory or safety documentation requirements:

  - The original and reference text must be in English and all interpretations of it will be based on the English text. In the event of a conflict between different translations, the English text will prevail;

  - The layout to be used is a dual-column page, where both versions of the document are in parallel, with English in the left column.

#>

2.10.1 Electronic Documents

<# QA115-REQ-0118
The exchange and delivery of any communication or official documentation relating to the Works in electronic format must comply with the electronic document file formats shown in the table below.

Document Type	Format (editable)	Format Version (editable)	Format (reference)	Format (informative)
Text document	doc/rtf	MS Word v.97-2003	pdf	---
Spread sheet	xls	MS Word v.97-2003	pdf	---
CAD models and drawings	cat	CATPart, CATProduct and CATDrawing	cat	pdf of typical 3D views
CAD drawings	cat		pdf	---
Schedules, Programmes & Plans	xer/mpp	(see REQ0122)	pdf	pdf of all pages
Scans and pictures	jpg	---	pdf	---
Video footage	avi	---	avi	---
Presentations	ppt	MS Office v.97-2003	pdf	---
Document sets	zip	---	pdf	---
Issued documents	---	---	pdf	---
Documentation Schedule	xls/doc	MS Office v.97-2003	pdf	---
Control Plan	xls/doc	MS Office v.97-2003	pdf	---

Table 2.10-1 – Mandatory Document Formats

#>

Any particular version provided in the Table represents the minimum acceptable version compatibility requirement.

<# QA115-REQ-0119
In the event of additional electronic document file formats being used, for example for specialised engineering calculations, the Supplier shall provide fully useable data input and output files. These files shall be provided in English, provided the creation of such files in English is a standard option of the particular program.

#>

<# QA115-REQ-0120
Where possible, such as in respect of text documents, spreadsheets, drawings, etc, editable versions of the deliverables must be provided.
#>

Alternative formats may be agreed at the Kick-Off Meeting. Any extra expense or care involved is the sole responsibility of the Supplier.

<# QA115-REQ-0121
The Supplier shall also maintain a register in spreadsheet format of all files issued identifying the current status of the each file throughout the duration of the Contract.
#>

<# QA115-REQ-0122
The Supplier shall use the same version of Primavera as F4E (contact F4E for information on the latest version in use) or the latest MS Project version compatible with v.97. During the contract implementation, it is expected that the Supplier update the software version in sync with F4E (at most once a year).
#>

2.10.2 File Names of Electronic Documents

The convention to be followed in the naming of electronic document files *should* be that set out in F4E-QA-112 – 'Naming Conventions' Instruction, provided as part of the Reference Documents.

2.11 Licensing Requirements

<# QA115-REQ-0123
The suppliers have to demonstrate compliance with the licensing requirements of ITER being a nuclear facility as required for PIC and PIAs through the propagation of the requirements of the 'Order of 7 February 2012' [9] (applicable from July 2013).
#>

<# QA115-REQ-0124
Defined Requirements (safety) for PIC and PIAs are defined in the technical and management specifications, regulations and dedicated procedures. These requirements must be cascaded to the subcontractors when dealing with PIC and PIAs.
#>

According to Article R4311-5 of French Labour Code, design and construction requirements for machines to be placed on EU market are not applicable for: "*(4) Machines specifically designed for nuclear related use and whose malfunctioning might result in nuclear emissions*" — CE marking is not requested for this type of equipment, that are submitted to other strong requirements by national regulation.

<# QA115-REQ-0125
If the Supplier considers that the scope of the works falls – partially or entirely - under the exclusion from the CE Marking requirement defined by the Article R4311-5 of French Labour Code and Machinery Directive 2006/42/EC Article 1, paragraph 2, item c, the Supplier shall:

- Submit to F4E a technical file defining the scope and substantiating the application of mentioned exclusion
- Request F4E's acceptance.

In case that no acceptance is granted, CE Marking applies.
#>

<# QA115-REQ-0126
For item(s) subject to specific requirements to the Nuclear Pressure Equipment (French Order on Nuclear Pressure Equipment, December 2005, ESPN [11]), the Supplier shall ensure that the items are compliant with these requirements.
#>

<# QA115-REQ-0127
Other specific licensing requirements might be given in the supplier technical specifications of the contracts and must be cascaded to subcontractors.
#>

2.11.1 CE Marking

<# QA115-REQ-0128
The supplier shall apply this section for all supplies, assemblies and components that have to comply with one or several EC/ EU Directives and require CE Marking:

- Machinery Directive 2006/42/EC
- Pressure Equipment Directive 97/23/EC, 2014/68/EU
- Simple Pressure Vessel Directive 2009/105/EC, 2014/29/EU
- Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres (ATEX) Directive 94/9/EC, 2014/34/EU
- Low Voltage Directive 2006/95/EC, 2014/35/EU
- Electromagnetic Compatibility Directive 2004/108/EC, 2014/30/EU
- Construction Products Regulation (EU) No 305/2011
- Other EC Directives as applicable.

#>

<# QA115-REQ-0129
National laws, regulations and administrative provisions adopted by EU Member States to comply with EC/EU Directives shall be observed as applicable. All the activities addressed to the fulfilment of these national laws and EC directives are included in the Supplier's scope of works.
#>

<# QA115-REQ-0130
Documents that the Supplier shall provide to F4E (where applicable):

- Manufacturer's Declaration of Conformity latest with the delivery of the component/assembly, Notified Body's Certificate of Conformity (if required) latest with delivery of the component/assembly,
- The operating instructions shall be supplied in English and in the national language of the country of destination (French language is waived for items whose usage destination is the ITER site),
- Safety Concept of the assembly and relevant data from the Risk Assessment (if requested).
- Safety Integrity Level (SIL) and/or Performance Level (PL) for Safety-relevant Instrumentation and Control devices and loops (if requested).

#>

2.12 Confidentiality

The provisions of this section complement those on the same topic existing in the contractual 'Specific Conditions' and 'General Conditions'.

<# QA115-REQ-0131
For the purposes defined in the Contract and its annexes, F4E shall have access to:

- all the operational procedures and specifications required for the execution of the contract;
- all the contract performance test results, analysis and reports;

- if any, 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.

#>

If required F4E staff will sign a *non-disclosure agreement* or *confidentiality agreement* to be agreed in advance.

<# QA115-REQ-0132

Taking into account the provisions of this section, F4E cannot be prevented from accessing the contractual performance documentation and records on the base of confidentiality or confidential intellectual property.

#>

<# QA115-REQ-0133

Unless agreed otherwise, the standard dispositions on confidentiality shall be:

- Contractual and technical deliverables – as defined in the Intellectual Property clauses;
- Intermediate results and monitoring documentation – F4E is the end user and its distribution is limited.

#>

<# QA115-REQ-0134

For QC1 and QC2-PIA/PIC, the Supplier shall consult with F4E before issuing any press release with respect to the subject matter of this Contract and shall not issue any such press release or make any such public statements without the prior consent of F4E.

#>

2.13 Communication Methods and Signatures

<# QA115-REQ-0135

The standard methods for F4E and the suppliers to communicate will depend of the context:

- *Information* - the standard method will be electronically (email)
- *Contract and Guaranties* - formal communication with *blue ink* signature or qualified electronic signature
- *Acceptance/Rejection of a Deliverable, Deviations, Amendments, Nonconformities and other documents submitted by/to F4E* - email with the document electronically signed.

#>

2.14 Nuclear Safety File

(only applicable to suppliers that have the PIC design under their responsibility)

The 'Order of 7 February 2012' [9] known as the INB Order, requires many aspects of the nuclear safety reporting to be undertaken in each supply-chain which provides Protection Important Components (PIC) or that perform Protection Important Activities (PIA).

The level of reporting as required throughout this document is dependent on the stages of the PIC manufacture/production and its PIAs.

Simplified PIC Stages	Reviews	Reporting Evidence Required
Conceptual Design (feasibility)	CDR	Quality and Control Plan(s) QA/QC records
Preliminary Design (definition) (manage the PIC's SDRs)	PDR	Nuclear Safety File, and Quality and Control Plan(s) QA/QC records
Final Design (detail definition) (manage the PIC's SDRs)	FDR	
Manufacturing Design	MRR	Quality and Control Plan(s) QA/QC records
Fabrication/Production/Assembly	TRR	
Testing	ORR	
Operations		

For PIC the Supplier nominates a suitably qualified and experienced person to manage the requirements for PIC and PIA undertaken by the supplier (as defined in Section 3.2.2 REQ0160).

The table below indicates the activities which fall within the bounds of a quality system and which ensure the propagation of nuclear safety activities in the supply-chain for the design and/or provision of PIC or PIA in F4E contracts.

The level of reporting as required throughout this document is dependent on the stages of the PIC manufacture/production and its PIAs.

Area	Safety reporting requirement to comply with the INB Order
Defined Requirements (safety) and their Verification Activity(ies)	For each PIC, F4E will provide a list of (Safety) Defined Requirements (PIC-SDR), which is raised by the Operator (IO). The Supplier provides evidence demonstrating that the performance of the PIC to satisfy the SDR is not prejudiced during each phase of the supply process within the scope of the Contract (Sect. 1 REQ003).
Protection Important Components (PIC)	The Supplier will receive a list of Protection Important Components which is raised by the Operator.
Protection Important Activities (PIA)	The Supplier identifies which of the detailed design, production, manufacture, delivery, temporary storage, Installation, testing and commissioning activities are defined as PIA in every Control Plan issued under the scope of a PIC (as addressed in Section 4.1 REQ0208). Further information can be found on the non-mandatory PIA Guidance [12]. The standards to which each PIA is conducted (whether an inspection standard or a process standard) are also considered as Safety Defined Requirements (PIA-SDR).
Nonconformities and Deviations	The mandatory arrangements for Nonconformities and Deviation Requests are addressed in Section 2.2.

Area	Safety reporting requirement to comply with the INB Order
Supply-Chain Status	Updates of the status of the Supply-chain are included in the progress report from the Supplier to F4E (as addressed in Section 2.1.2 REQ0009). The Supply-chain includes every lower tier (as addressed in Section 2.4 REQ0059 and REQ0060)
Validation and Verification	Supplier validation and verification requirements are at section 2.5.6. The requirements for independent Third Party verification are at section 2.8.3.
Surveillance Plan	The requirements for a Surveillance Plan of Subcontractors performing PIA are at section 2.8.1 (REQ0107) and section 3.2.12 (REQ0190).
Management of Qualification and Experience of Personnel	The supplier needs a system to manage the qualifications, skills and experience of the personnel performing the PIA activities (in particular: technical reviews, validation, verification and design reviews) as defined in section 3.2.2 (REQ0160).

<# QA115-REQ-0225

The supplier (and the supply-chain) shall ensure that all personnel working on PIC (or on PIA for a PIC) are aware that they are PIC and that they are for supply to the ITER Project, and that they know, understand and apply the ITER Policy on Safety, Security and Environment Protection Management [14].

#>

3 QUALITY PLAN REQUIREMENTS

The Quality Plan describes the quality system to be implemented by the Supplier throughout the progress of the Works to ensure that the contract requirements are met and that evidence of such compliance is maintained.

Essential processes are documented through formal procedures and instructions or through informal procedures (in flowchart or diagram) – so that the organisation is able to provide objective evidence of the effectiveness of its processes.

<# QA115-REQ-0136

Each part of the Quality Plan shall comply and address the topics defined in the following subsections.

#>

The content of each part of the Quality Plan depends of the supplier's quality system certification, the Quality Class of the deliverables and the nature of the works:

- *System Compliance* Part: the supplier shall address sections as defined in §3.1.
- *Implementation Plan* Part: the supplier shall address sections as defined in §3.2.
- The level of detail of both parts is as defined in the contract management specification.

3.1 Quality System Compliance Part

<# QA115-REQ-0137

The Supplier Quality System for the contract must be compliant with this document and the F4E QA Programme for the ITER Project [3].

#>

<# QA115-REQ-0138

Suppliers with a certified Quality Management System based on a recognised quality standard(s) shall also include:

- copy of the valid Quality Management System certification;
- Quality Manual reference;
- a statement of compliance with the General Requirements (QA-115 §2);

#>

3.1.1 Management of Scope

3.1.1.1 Management of Responsibility Allocation

<# QA115-REQ-0139

The Supplier shall identify and define the key roles to ensure that:

- the activities performed in connection with the contract are planned, implemented and controlled and their progress monitored;
- the contract requirements are to be reviewed and the review recorded.

#>

3.1.1.2 Management of Nonconformity and Deviations Procedures

<# QA115-REQ-0140

The Supplier shall:

- describe (or refer to an attached procedure) the procedure to handle Nonconformities;
- describe (or refer to an attached procedure) the procedure to handle Deviations;
- add the individual Flowchart per process/procedure (deviation and nonconformity).

#>

3.1.2 Management of Schedule

<# QA115-REQ-0141

The Supplier shall describe its Time Schedule Management system, including:

- the usage of specific tools (PRIMAVERA or other control system);
- time Schedule Evolution Report definition.

#>

3.1.3 Management of Deliverables

<# QA115-REQ-0142

The Supplier shall:

- describe (or refer to an attached procedure) the procedure to handle Documentation and Records (Documentation Management System);
- add the Flowchart for the Documentation Flow process/procedure, including the interaction with F4E;
- define the Configuration Management records definition and maintenance;
- describe (or refer to an attached procedure) the procedure of acceptance requirements review/verification before dispatch;
- describe the Control Plan update process.

#>

3.1.4 Risk Management

<# QA115-REQ-0143

The Supplier shall describe the risk management system to comply with §2.7 (Risk Management).

#>

3.1.5 Resource Management and Training

<# QA115-REQ-0144

The Supplier shall describe the resource management and training system to comply with the contract requirements.

#>

3.1.6 Subcontracting Management

<# QA115-REQ-0145

The Supplier shall describe the Subcontracting management system to comply with §2.4. (Subcontracting).

#>

3.1.7 Assessment and Validation Management

<# QA115-REQ-0146

This section must describe the system to comply with §2.5. (Assessment and Validation), including:

- procedure for the management of Measuring and Test Equipment;
- access to the Supplier premises;
- Supplier personnel and Supplier completed work activities for third party audit or inspection (see §2.8).

#>

3.1.8 Licensing Requirements

<# QA115-REQ-0147

The Supplier shall detail the licensing requirements assessment.

#>

3.1.9 Incoming Parts Management

<# QA115-REQ-0148

The Supplier shall indicate how and when acceptance of goods and materials to Site/premises are controlled (including any storage requirements).

#>

<# QA115-REQ-0149

This must include for the provision for review and acceptance of manufacturer's compliance certificates, independent inspection certificates and any associated test certificates relating to the materials being delivered.

#>

3.1.10 Design (also embraces calculations and analysis) Management

<# QA115-REQ-0150

The Supplier shall describe:

- the design phases (calculations, analysis and design) management system (including review, verification & validation);
- in detail the design review procedure;
- if PIA or if applicable: the analysis or calculations review procedure;
- the independent verification methods and indicate who will make this verification (for Design, Analysis and Calculations – mandatory for QC1 and QC2-PIA/PIC).

#>

3.2 Quality Implementation Plan Part

<# QA115-REQ-0151

The Implementation Plan must be an assembly of separate and well-identified documents that cover the whole scope of the Contract, including work performed by Subcontractors. The main Implementation Plan and all subsidiary plans as detachable documents — Top Level Control Plan, Documentation Schedule, Risk Plan, Subcontracting Schedule, etc — compose this assembly.

#>

<# QA115-REQ-0152

The following sub-sections specify the implementation requirements for the Contract that must be addressed in various specified sections of the Implementation Plan.

#>

<# QA115-REQ-0153

These elements are not exhaustive and must be supplemented by the Supplier as considered appropriate.

#>

3.2.1 Contract Implementation

3.2.1.1 Objectives and Activities

<# QA115-REQ-0154

The Supplier shall describe its understanding of the nature of the works and requirements of the Contract. The section must also state the strategy for execution of the works and should include a description of the project's key drivers and details of the sequencing of key activities.

#>

<# QA115-REQ-0155

The supplier shall include the work breakdown structure (WBS) for the contract.

#>

<# QA115-REQ-0156

The section must include a milestone table, identifying:

Milestone	Task/Activity (WBS)	Deliverable	Related Documentation	Input Documentation	Level of Subcontracting	Responsible

- All milestones and deliverables;
- A short description of the related activities to achieve milestone (including the number and quantity);
- The level of subcontracting;
- Supplier's responsible for that activity.

#>

<# QA115-REQ-0157

For *PIC (Protection Important Components)* the Supplier shall perform a technical analysis detailing:

- the PIA (Protection Important Activities) for PIC (refer to the PIA Guideline [12] for selection). In practice, these activities include:
  - Design tasks required for the product in question;
  - Subcontracting activities when the Supplier considers that the work ordered to its subcontractor is an PIA;
  - The manufacturing, inspection or testing activities listed in the Quality Plan and Control Plan.
- the Defined Requirements (safety) of PIA (PIA SDR) (requirements to be fulfilled to obtain and maintain quality).

#>

3.2.1.2 Management of the Contract

<# QA115-REQ-0158

The supplier shall describe the contract management provisions for the task, including:

- task *activities coordination* methods, tools and meetings;
- coordination, attendance and frequency of the *progress meetings*;
- responsibility for preparation of the *agenda* and *minutes* of meetings;
- definition of the form and frequency of the required *progress reports.*

#>

3.2.2 Organisation and Responsibilities

<# QA115-REQ-0159

This section must set out the Supplier's plan for resourcing the project. It must include details of the Supplier's mobilisation plan and an organisation chart identifying the resources, organisation, and responsibilities allocated at senior and intermediate management level and the personnel appointed to these positions as well as defining the allocation of responsibilities between consortium members (the different organizations involved shall be shown in an organization chart), if applicable.

#>

<# QA115-REQ-0160

Particular reference must be made to the provision of Suitably Qualified and Experienced Personnel (SQEP) to the project and a SQEP register for all significant positions within the Supplier's proposed organisation (also in compliance with 3.2.6).

#>

<# QA115-REQ-0161

The Supplier shall identify the names, experience and contact details of:

- The Supplier's Project Manager in charge of the Contract;
- The Supplier's Quality Representative for the Contract.

#>

<# QA115-REQ-0162
The Supplier's Project Manager shall be responsible for the provision of the Works including the planning, performance and control of all of the Works, and all work assigned to Subcontractors. The Supplier's Project Manager shall keep and maintain the Contract programme and time schedules and issue the Progress Reports.
#>

<# QA115-REQ-0163
The Supplier's Quality Representative shall be responsible for ensuring that the quality requirements are met and that the Quality Plan, quality procedures and detailed work instructions are followed throughout the duration of the Contract. The Supplier's Quality Representative shall assess and control the management quality regime of its Subcontractors, including any works carried out at Subcontractors' premises.
#>

<# QA115-REQ-0164
The Supplier shall not change or replace its Project Manager or Quality Representative without the prior agreement of F4E.
#>

3.2.2.1 Stop Work Authority

<# QA115-REQ-0165
The Supplier shall state its 'Stop Work Authority' internal guideline.
#>

<# QA115-REQ-0166
[For PIC/PIA only] The guideline must include that for stopped work associated with defined protection/safety systems, notification must be given to F4E explaining reason for stop work and proper justification for restarting that work activity.
#>

3.2.3 Control Plan

<# QA115-REQ-0167
The Supplier shall include in this section the Top Level Control Plan for the works according to §4 (Control Plan Requirements). The Top Level Control Plan is issued and accepted with the Quality Plan.
#>

<# QA115-REQ-0168
When required, according to §4 (Control Plan Requirements), the Supplier shall issue and maintain separate Control Plans detailing the phase/task works. These control plans must be individually referenced documents, issued during implementation of the contract and must be accepted by F4E before the concerned works start.
#>

3.2.4 Time Schedule (Programme)

This section contains or refers to a separately provided project schedule. The schedule should be in the form of a fully resourced programme based on the Work Breakdown Structure identifying all significant *milestones*, *deliverables*, *activities,* and their interdependencies, durations and anticipated start and finish dates and the project critical path(s).

The detailed schedule proposed at the official Kick-off Meeting by the Supplier, once agreed, will be used as baseline.

<# QA115-REQ-0169
The Supplier shall detail its approach to monitoring, updating and controlling the contract programme, including the use of appropriate software. The software must be compatible with the formats defined in §2.10.1 (Electronic Documents).
#>

<# QA115-REQ-0170
The Supplier shall also set out the process of reporting progress against programme (actual versus the defined baseline) to F4E.
#>

3.2.5 Documentation Schedule (list of documentation deliverables)

<# QA115-REQ-0171
The Supplier shall provide a Documentation Schedule (list of documentation deliverables) in the format set out in §5.4 (Documentation Schedule), detailing all documents, records, drawings, plans, schedules, manuals and data relevant to the implementation of the Contract, including work performed by Subcontractors, and the performance of the Works and the Supplier's other duties, obligations and liabilities pursuant to the Contract.
#>

<# QA115-REQ-0172
The Supplier shall update the Documentation Schedule throughout the continuance of the Contract. The schedule starts as a small list of previewed contractual documents and is updated throughout the contract until the final version at the end of the contract (the full list of all relevant documents).
#>

<# QA115-REQ-0173
During the execution of the Works, the Documentation Schedule must be maintained as the reference for documentation status within the Contract.
#>

<# QA115-REQ-0174
At each documentation delivery, the Supplier shall include the relevant extract of the Documentation Schedule identifying the documents within the delivered package.
#>

<# QA115-REQ-0175
The Documentation Schedule must include the documents linked with main interface milestones.
#>

3.2.6 Contract Resources

<# QA115-REQ-0176
The Supplier shall provide details of the resources, detailing where applicable:

- the number and type of personnel involved in each of the Contract activities;
- measures in place to ensure adequate recruitment of sufficiently experience personnel;
- specific training provided to its personnel;
- specific qualifications held by those performing particular operations, especially operations requiring special control measures and / or supervision;
- the supplier shall provide CVs/qualifications of all the proposed team members (or detailed recruitment plans for vacant positions), with an estimate of the percentage of each one's total work time to be dedicated to the activities.

#>

<# QA115-REQ-0177
The Supplier shall maintain a register of all employees, and those of its subcontractors, that must demonstrate that all workers are appropriately qualified for the activities they are required to carry out.
#>

3.2.7 Subcontracting Schedule

<# QA115-REQ-0178
The Supplier shall provide a Subcontracting Schedule in the format set out in §5.5 (Subcontracting Schedule Form), detailing:

- Activities (to be) subcontracted:
  - All PIAs (any level);
  - All critical activities (any level);
  - All other activities that are part of the scope of the contract (including any deliverable or part of it, defined in the contract and its annexes) up to level 2 below the Supplier.
- Specifications of the associated items or activities to be performed;
- The identity of the relevant Subcontractor, including details of its contact officer;
- Proof of the Subcontractor's qualification, including for example ISO 9001 certification;
- The subcontractor's assessment by the supplier (using the Subcontractor Assessment Form - SAF): F4E concurrence is required (the SAF must be submitted to F4E);
- A record of F4E's consent obtained in accordance with the Contract.

#>

<# QA115-REQ-0179
The Supplier shall update the Subcontracting Schedule, or parts thereof, as and when required. No part or revision of the Subcontracting Schedule is to be implemented by the Supplier until it has been approved by F4E in writing.
#>

The 'Subcontracting Schedule' summarises the list of approved Subcontractors at any given time during the contract implementation (includes all contractors, vendors, subcontractors, etc. even those accepted at contract award), identifying the complete supply-chain, including the lower tier subcontractors.

Any modification of the approved Subcontractors (either those approved at award or those proposed after contract signature) will be reflected in the 'Subcontracting Schedule' and re-submitted for F4E for acceptance.

<# QA115-REQ-0180
F4E's acceptance of the Subcontracting Schedule shall not in any way limit the Supplier's responsibilities, duties and obligations pursuant to the Contract nor diminish any liability on its part in respect thereof.
#>

3.2.8 Execution Plan

<# QA115-REQ-0181
The Supplier shall provide, either here or in a separately provided Execution Plan (or Manufacturing Plan), details of its intentions for all activities. This must include, but shall not be limited to:

- Execution methods for all significant activities (including all specific procedures and work instructions to be applied);
- Site/Premises facilities to be provided by the Supplier;
- Supplier's equipment to be used during the execution of the Works;
- Resources to be employed on all significant activities, including the total effort each team member will contribute to each significant activity;

- Site mobilisation plan (if applicable).

#>

3.2.8.1 Verification and Validation of Calculation and Modeling tools

<# QA115-REQ-0182

In this section the supplier shall indicate the proposed calculation and modelling tools in compliance with §2.5.6. The proposal shall be in a table format:

Name	Date	Version	Input	Availability	Basis of Verification/Validation

#>

<# QA115-REQ-0183

The basis of verification and validation justification, code inputs and all supporting documentation must be provided at least by the Kick-of-Meeting.

#>

3.2.8.2 Processes Qualification

<# QA115-REQ-0184

In this section the supplier shall include the Processes that require validation (including special processes) approval records and reports.

#>

3.2.8.3 Measuring Test Equipment

<# QA115-REQ-0185

In this section the supplier shall include the Measuring and Test Equipment records and indicate the method of indicating and recording calibration status.

#>

3.2.9 Risk Plan

<# QA115-REQ-0186

The Supplier shall provide and maintain a Risk Plan for the Contract, following its Risk Management System (§3.1.4). An electronic template will be made available to the supplier.

#>

3.2.10 Project Controls

<# QA115-REQ-0187

This section must set out the Supplier's intended Work Breakdown Structure along with the Supplier's plan for maintaining control of project activity and costs. F4E recommends, unless the Supplier has an alternative system implemented, the use of Earned Value Management – EVM (with either a simple technical performance implementation or integrating technical and schedule performance, depending of the complexity of the project).

#>

Earn Value Management (EVM) is a project management technique for measuring project progress in an objective manner. EVM has the ability to combine measurements of scope, schedule, and cost in a single integrated system. When properly applied, EVM provides an early warning of performance problems.

3.2.11 Incoming Items Requirements

<# QA115-REQ-0188

The Supplier shall indicate the responsible(s) for assuring the correct implementation of the Incoming Parts management (in accordance with §3.1.9).

#>

<# QA115-REQ-0189
The Supplier shall ensure that its Subcontractors implement the same procedures for control of acceptance of deliveries.
#>

3.2.12 Inspection and Quality Audits

<# QA115-REQ-0190
This section must set out the Supplier's proposed audit schedule and the surveillance plan of the Subcontractors performing critical activities (includes PIAs). The surveillance plan defines and details the strategy, the type and frequency of the reviews and surveillance of the subcontractors.
#>

<# QA115-REQ-0191
The audit schedule must encompass the widest practicable range of project activities that must include all consortium members and significant subcontractors, and detail:

- Subjects/Activities/Work Locations to be audited
- Frequency of audit
- Type of audit e.g. internal/external/subcontractor

#>

3.2.13 Health and Safety

<# QA115-REQ-0192
The Supplier shall demonstrate that it fulfils the health and safety regulations as required by the Legislation within the country where the activities will be developed as well as any specific health safety regulations laid down by F4E's Customer (e.g. IO) for any particular task.
#>

For ITER Project site works:

<# QA115-REQ-0193
The Supplier shall provide to F4E a detailed report on the measures it shall adopt to meet these requirements; and F4E will accept, or comment on the report within fifteen (15) working days. If for technical reasons F4E is unable to approve the report in this time, F4E will inform the Supplier before the end of the fifteen (15) day period of the reasons behind such non-acceptance.

The Supplier shall define the measures, either here or in a separately provided Health and Safety Plan, referenced from here, that the Supplier intends to implement to ensure that the project is managed safely and that all personnel involved in the project and members of the public who interact with the project benefit from a safety conscious project team.
#>

3.2.14 Codes (Regulatory Documents) and Standards

<# QA115-REQ-0194
The supplier must reference all applicable technical codes, standards, and regulatory requirements applicable.
#>

3.2.15 Dual-Use Items/Technologies

<# QA115-REQ-0195
The supplier shall produce, if applicable, a detail list of dual-use items/technologies, specifying the item reference / description / number of items / origin / destination / subcontractor / estimated export date.

For the items with origin in United States, the following shall be provided: commodity classification, reference to the US Authorization and eventual restrictions to the re-exports that might apply.

For the items received from F4E and handled by the supplier, F4E may ask the signature of an end user certificate for licensing or traceability purposes.

#>

> *"Dual-use items: items, including software and technology, which can be used for both civil and military purposes. This term also includes 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 - as referred in Annex I of the internationally agreed dual-use Council Regulation No 428/2009 as updated through the Regulation (EU) No 388/2012)."*

<# QA115-REQ-0196

For each item in the list, a relevant milestone must be associated in the 'Control Plan' and in the Schedule, and an entry for the relevant documentation for licenses purposes must be created in the 'Documentation Schedule'. Intra-Community transfer or export authorization reference, when applicable, shall be provided to F4E for all the transfers of dual use components.

#>

<# QA115-REQ-0197

Any change to the list during the implementation of the contract must be communicated as soon as possible to F4E.

#>

<# QA115-REQ-0198

The supplier shall mark the dual use controlled deliverables (or associated commercial documentation, like packing lists or invoices) indicating clearly "Export Control" and that those items are subject to controls if exported from the Community and with the reference to the Authorization, when applicable; related documentation shall be kept for at least ten years from the end of the calendar year in which the export took place or the brokering services were provided and be produced, on request, to the competent authorities of the Member State in which the exporter is established or to F4E.

When handling dual use documents, dual use information shall be segregated and identified as far as possible from the non-controlled information.

Dual Use controlled documents shall be marked on the first page with the "Export Control" and clearly indicating the authorization reference, licensing authority (if applicable) and that those items are subject to controls if exported from the Community or any other restrictions applicable from EU or non-EU Jurisdictions

#>

3.2.16 Traceability

<# QA115-REQ-0199

Where traceability is a requirement or necessary for the adequate control of the work, the plan must define its scope and extent, including:

- how affected items are to be identified;
- how contractual and regulatory traceability requirements are identified and incorporated into working documents;
- what records relating to such traceability are to be generated and how and by whom they are to be controlled;

#>

3.2.17 Handling, Storage, Packing, Shipping and Delivery

<# QA115-REQ-0200

The plan must show how, when and by whom handling, storage, packing, shipping and delivery will be controlled.

- how contract requirements for handling, storage, packaging and shipping are to be met;
- how the item will be delivered to the specified site in a manner that will ensure that its required characteristics are not degraded.

#>

3.2.18 Statistical Techniques

<# QA115-REQ-0201

Where statistical techniques are relevant for establishing, controlling, and verifying process capability and its characteristics, they must be indicated in the plan.

#>

4 CONTROL PLAN REQUIREMENTS

The Control Plan is the central compliance document for a given phase, a (set of) deliverable(s) or task, were each performed activity signature is supported by objective evidence.

<# QA115-REQ-0202

For each particular activity, the Control Plan must identify:

- the applicable requirements and instructions;
- whether or not that activity is to be witnessed or whether notification is required;
- the provision for recording the verification and completion of the listed operations;
- if the activity is a PIA and explicitly mention the related defined requirements (PIA SDR).

No activity can be performed without that activity being covered by an F4E accepted Control Plan.

#>

For each PIA the specification and criteria, columns of the Control Plan, are the defined requirements of PIA (PIA SDR).

The type of Control Plan covering the activity depends of the type of phase/task where the activity is integrated:

Activity in Phase / Task Type	Control Plan Required	Remarks
Manufacturing/execution Manufacture of prototypes	Phase/Task Control Plan (§4.2)	Detailed Control Plan with all activities affecting quality, milestones, key points and reviews
Qualification of Special Processes	normally do not need a specific Qualification Control Plan	Top level activities are referenced in the phase Control Plan where the qualification occurs
R & D Supply of services Issue of report or study	normally covered by the Top Level Control Plan (§4.1)	Top level activities affecting quality are referenced in the Top Level Control Plan

Table 4-1 – Control Plan type

<# QA115-REQ-0203

To ensure that activities are carried out as directed in the Control Plan, the Supplier shall make the document directly accessible to those carrying out the Works.

#>

<# QA115-REQ-0204

The Control Plan must be in English but can also be available in a language easily understood by those carrying out the Works.

#>

<# QA115-REQ-0205

F4E's acceptance of the Control Plan(s) shall not in any way limit the Supplier's duties and obligations pursuant to the Contract nor diminish any liability on its part in respect thereof.

#>

<# QA115-REQ-0206

The Control Plan must be in the format shown in §5.1 (Control Plan Form). No change to this format will be accepted without the prior written approval of F4E.

#>

4.1 Top Level Control Plan

<# QA115-REQ-0207

The supplier shall provide the Top Level Control Plan in the Implementation Plan part of the Quality Plan (subject to F4E's acceptance before the works start).

#>

<# QA115-REQ-0208

The Top Level Control Plan must encompass the whole scope of the Contract, including any work to be performed by Subcontractors and must detail:

- the division of the contract in phases/tasks;
- the *outline sequence* of the *top level* activities that affect quality in each phase/task according to the schedule, if not covered by a subsidiary Phase/Task Control Plan;
- all contractual milestones (including HP, NP and ATP);
- all contractual deliverables;
- for PIC, all the PIAs (if not addressed in a subsidiary Phase/Task Control Plan) and explicitly mention the related defined requirements;
- Reference, when applicable, the subsidiary Phase/Task Control Plans.

A Top Level Control Plan (included in the Quality Plan) is an integral part of the Contract. Upon completion of the works, the completed Top Level Control Plan must be included in the Final Report provided to F4E.

#>

4.2 Phase/Task Control Plan

<# QA115-REQ-0209

When required, in §4.0, the Supplier shall provide a Phase/Task Control Plan describing the sequence of the work activities affecting quality, milestones, key points and reviews within the phase/task.

#>

<# QA115-REQ-0210

The Control Plan must encompass the whole scope of the phase/task, including any work to be performed by Subcontractors, and range from review of drawing, verification of materials, manufacturing/execution operations, inspection and test to delivery.

#>

<# QA115-REQ-0211

The Control Plan must identify as a minimum, the items below.

- Requirements originated from the development and validation strategy as defined in the Technical Specification (qualification and validation requirements, needs for mock-up or prototypes…).
- A list of the required hold points, witness points (required by F4E or a third-party inspection agency), notification points and all reports, reviews, and approvals, as required.
- Identification of all activities and tests to be performed in order to comply with the applicable legislation, standards or codes and requirements as specified in the Technical Specification.
- For PIC, all the PIAs.

#>

<# QA115-REQ-0212

The level of detail in the Control Plan must be such as:

- to prevent the inadvertent bypassing of critical test and inspection points;
- to enable adequate planning, monitoring and verification of key activities.

#>

<# QA115-REQ-0213

For some sequences of the Control Plan, a more detailed inspection and test plan (e.g. ITP - Inspection Text Plan) might be required. For these, the reference of the detail plan must be indicated in the sequence entry of the Control Plan. The detailed plan must have the same outline format as the Control Plan.

#>

<# QA115-REQ-0214

A Control Plan is an integral part of the Contract. Upon completion of the phase/task works, the completed Control Plan must be included in the relevant ADP provided to F4E.

#>

4.3 Control Plan Procedure

<# QA115-REQ-0215

The supplier and any subcontractors shall process the Control Plan following the flow in figure 4-1(including the submission for acceptance to F4E).

#>

F4E (normally the F4E Technical Project Officer and the QA Officer) reviews the document and returns the Control Plan with the mark-up of the F4E intervention points;

If F4E decides that essential activities are missing on the submitted Control Plan or that the comments imply a new version, the Control Plan will be returned to the supplier for correction;

<# QA115-REQ-0216

Evidence of F4E's acceptance of the Control Plan must be maintained;

#>

<# QA115-REQ-0217

A revised Control Plan must be subject to the same acceptance procedure as the original Control Plan.

#>

<# QA115-REQ-0218

It is the supplier's responsibility to notify F4E of any forthcoming intervention points (HP, NP, ATP, and Witness Points etc). Adequate notice must be given to permit F4E to send a representative to the supplier's facility if deemed necessary.

#>

<# QA115-REQ-0219

The intervention points must be signed-off and dated at the time of attendance by the relative party by the person performing the intervention.

#>

<# QA115-REQ-0220

Compliance with the plan must be checked and recorded as work progresses.

- each completed operation must be dated and signed off at the time of completion by the performer or its direct supervisor;
- the identification of records generated during the performance of the particular operation (e.g. test report, nonconformity report, etc.) must be recorded on the Control Plan.

#>

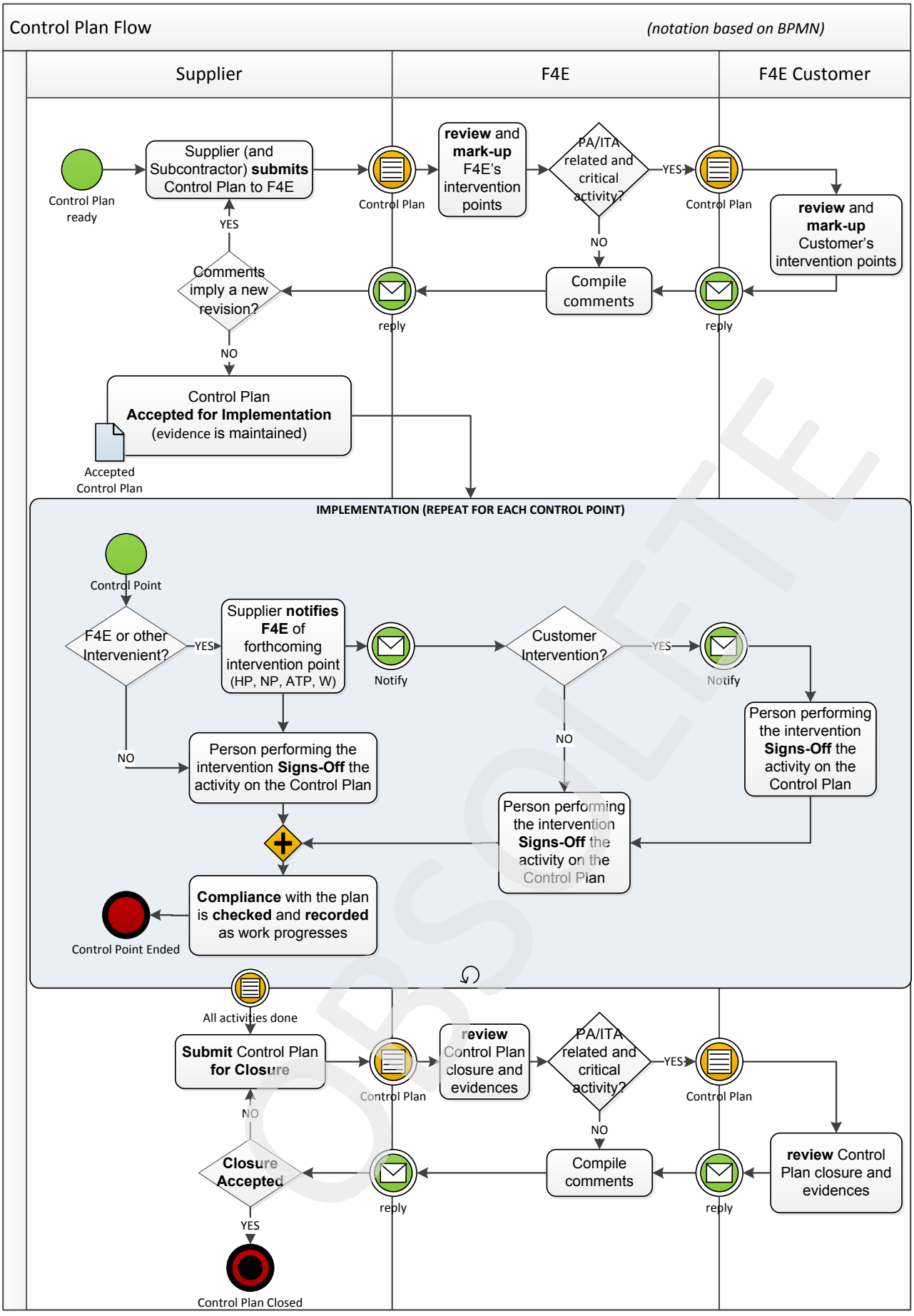

Figure 4-1 – Control Plan Process

4.4 Markings in Use

<# QA115-REQ-0221

The following definitions shall apply to the control points:

Mark	Short Description
NP	*Notification Point* - means that a notification must be sent to the entity (of the column) before a task is performed. The notified can decide to visit or not (written/email proofs are needed to justify dates and waivers). NP does not affect the production flow of the Supplier.
W	*Witness* - means a visit/presence at the action to witness/monitor. Action cannot occur without the presence or without a written waiver. The production flow is interrupted (before the action) in order to allow the mandatory inspection/surveillance.
HP	*Hold Point* - the process and all related activities cannot continue (work cannot proceed beyond this point) without the relevant HP being cleared. This can be a record of acceptance, an event, a written waiver, etc. Production flow for associated process is interrupted (after the action) until clearance is given.
ATP	*Authorisation to Proceed* - the current process cannot continue (next tasks) without the relevant ATP being cleared. This can be a record of acceptance, an event. Only the linked deliverable is affected (production flow is interrupted), not the rest of the production.
R	*Review* - identifies a document that must be reviewed by the entity (of the column). Differs from HP because it does not stop the process (the document still needs to be reviewed). Can be performed at any moment without interrupting the production flow.
S1 / **S2**	*Surveillance* - identifies an operation that requires 100% (S1) inspection or random/spot (S2) inspection. Normally used by ANB, NB, third party inspectors and F4E Customer.
The Supplier does not have a particular marking, as it is expected to verify all activities affecting quality	

<# QA115-REQ-0222

For each control point the following flow with F4E shall apply:

Mark	Flow with F4E (unless specifically specified otherwise)
NP	• Notification sent to F4E ten (10) working days before scheduled operation. • F4E notifies Supplier up to five (5) working days before scheduled operation of its intentions.
W	• Notification sent to F4E ten (10) working days before scheduled operation. • F4E notifies Supplier up to five (5) working days before scheduled operation of its intentions. • In case of No-Show of a duly pre-notified party: Supplier shall notify the no-show party and can proceed with production after 48h.

HP	• Notification sent to F4E
	• F4E notifies Supplier within ten (10) working days of the result.
	  ○ On rejection: Supplier has five (5) working days to propose a recovery plan.
	  ○ On objection (duly justified): Supplier has ten (10) working days to answer (and if applicable propose a recovery plan).
	• For HP requiring presence (eg test or inspection) in case of No-Show of a duly pre-notified party: Supplier shall formally notify the no-show party and can proceed with production after 48h.

ATP	• Notification sent to F4E
	• F4E notifies Supplier within seven (7) working days of the result.
	  ○ On rejection: Supplier has five (5) working days to propose a recovery plan.
	  ○ On objection (duly justified): Supplier has five (5) working days to answer (and if applicable propose a recovery plan).

5 MANDATORY FORMS

<# QA115-REQ-0223

The following forms must be used as necessary throughout the Contract, and in the latest version provided by F4E (that will provide electronic templates to the Supplier).

#>

5.1 Control Plan

Doc. Number:	[*Control Plan 00.001*]	Revision:		Sheet:		of	
F4E reference:	[*contract / grant reference*]	F4E Customer ref:	[*PA/ITA/DWO reference*]				
Supplier:		DMS #:					
Quality Class	[*QC1/QC2/QC3/QC4*]	Protection/Safety	[*PIC(SIC1/SIC2)/SR/NSR]*				
Item/Title:							

Supplier		F4E or Integrated PT	Operator/ Other	* Code		
Prepared:	Approved	Acceptance	Acceptance		R = Document Review W = Witness (or Monitor) NP = Notification Point ATP = Authorisation to Proceed point HP = Hold Point S = Surveillance (S1:100%, S2:Spot or Random)	F4E = F4E or representative TP/NB = Third Party Inspection Authority (TP) / Notified Body (NB) or French Safety Authority (ASN) Other = other entity (Interested Party)
Name, Sign & Date	*Name, Sign & Date*	*Name, Sign & Date*	*Name, Sign & Date*			

Item No.	Activity (manuf., inspection)	Expected Date	Specification (procedure, DRW, ...)	PIA (Y/N)	Acceptance Criteria	Verification by						Records (report, NCR, ...)	Observations
						Supplier		F4E / Inte. PT		TP / NB	Operator/ Other		
						Name, Sign & Date (independent for PIA)		*Name, Sign & Date*		*Name, Sign & Date*	*Name, Sign & Date*		
						XX XX	*		*		*		

5.2 Deviation Request

All sections to be completed by the Supplier

Supplier DR #:		Supplier DMS #:		Ver.	

1.	F4E Contract/Grant Ref:	[*contract / grant / call ref*]
2.	Supplier:	
3.	Subject of Deviation:	
4.	Quality Classification:	☐ **QC1** ☐ **QC2** ☐ **QC3** ☐ **QC4**
5.	Safety:	*(if PIC/SIC inform F4E within 24h)* ☐ **PIC** ☐ **PIA** ☐ **SR** ☐ **NON-SR**

6. ORIGINAL REQUIREMENT:

7. NEW/CHANGED REQUIREMENT:

8. JUSTIFICATION:

9. LIST OF ATTACHMENTS:

10. IMPACT ANALYSIS:

10.1 INTERFACES	☐ **NO**	☐ **YES**	Report:
10.2 SCHEDULE	☐ **NO**	☐ **YES**	Report:
10.3 TECHNICAL SCOPE	☐ **NO**	☐ **YES**	Report:
10.4 COST	☐ **NO**	☐ **YES**	Report:
VALIDITY OF PROPOSAL	**6** **Months** (minimum 6 months from supplier approval date)		
10.5 OTHER:	☐ **NO**	☐ **YES**	Report:

Project Manager			Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

5.3 Nonconformity Report

Section 1 – to be completed by the Supplier – Identification and Initiation

Supplier NCR #:		Supplier DMS #:		Ver.	

1. Title of Nonconformity					
2. Supplier:		3. Date of Detection:			
4. F4E Ref:	[*contract / grant / call ref*]	5. F4E Customer Ref.:	[*PA/ITA/DWO reference*]		
6. Quality Classification:	☐ **QC1**	☐ **QC2**	☐ **QC3**	☐ **QC4**	
7. Safety:	*(if PIC/SIC inform F4E within 24h)*	☐ **PIC**	☐ **PIA**	☐ **SR**	☐ **NON-SR**

8. REQUIREMENT:

9. DESCRIPTION OF NONCONFORMITY:

10. PROPOSED REMEDIAL ACTION: ☐ **use as is** ☐ **rework** ☐ **repair** ☐ **reject** ☐ **other***

(Remedial action implemented only after F4E written acceptance) *can include modification of documentation

11. JUSTIFICATION OF THE PROPOSAL *(for Protection Important Components, include safety justification)*

12. IMPACT ON 'AS BUILT' DRAWINGS:

☐ Update of "as built" drawings
☐ Drawings are not updated. The NCR is to be referenced in the "as built drawings"
☐ No impact on "as built drawings"

13. LIST OF ATTACHMENTS:

14. PRELIMINARY ANALYSIS OF CAUSES

	Supplier Technical Responsible	Supplier Quality Responsible
Name		
Date		
Signature		

Section 2 – to be completed by F4E

Section 3 – to be completed by the Supplier – follow-up of NCR

1. ROOT CAUSE ANALYSIS: (include process failed if applicable)

2. CORRECTIVE ACTION: ☐ **NO** ☐ **YES:** CAR Reference:

(summarise the corrective action)

3. FOLLOW-UP ON ACTIONS:

The remedial action indicated in Section 1 has been completed	☐ NO*	☐ YES
The corrective action(s) has been initiated (if applicable)	☐ NO*	☐ YES
I recommend the closure of this NCR.	☐ NO*	☐ YES

[comments]

	Supplier Technical Responsible
Name	
Date	
Signature	

5.4 Documentation Schedule

Doc. Number:	[*doc list #1*]	Revision:		Sheet:		of	
F4E reference:	[*contract / grant / call reference*]	F4E Customer ref:	[*PA/ITA/DWO reference*]				
Supplier:		DMS #:					
Item/Title:							

Supplier			F4E	Notes & acronyms
Prepared	Reviewed	Approved	Acceptance	Type: drawing, procedure, specification, NC, DR, .
Name, Sign & Date	*Name, Sign & Date*	*Name, Sign & Date*	*Name, Sign & Date*	Propose: of Submission to F4E (for Approval, for Acceptance or for Information) Status: of the document (Preliminary, Submitted For Approval, Approved by F4E, As-Built) Cat: category (Dual Use) DU ⚠ ,(Intellectual Property) IP ◆

Document							Supplier Internal Flow			Propose	Status	idm@F4E
Title	Type	Deliverable Nr.	Cat	ID (of Supplier)	Version	Expected / Milestone	Author	Reviewer	Approver	APP/ ACC / INF	PRE/SUB/ APP/AB	ref

[LIST OF DOCUMENTATION DELIVERABLES: Up-to-date list of documents/ records/ drawings/ models/ plans/ schedules/ manuals/ data expected during the contract and/or essential to perform the task and/or part of the ADP]

5.5 Subcontracting Schedule

Doc. Number:	[*doc list #1*]	Revision:		Sheet:		of	
F4E reference:	[*contract / grant / call reference*]	F4E Customer ref:	[*PA/ITA/DWO reference*]				
Supplier:		DMS #:					
Item/Title:							

Supplier		F4E	
Prepared by:	Approved by	Acceptance	Notes & acronyms QP = Quality Plan CP = Control Plan
Name, Sign & Date	*Name, Sign & Date*	*Name, Sign & Date*	

Subcontractors (1st Tier)				Sub-Subcontractors (2nd tier)				3rd tier
Identity	Item/Service	Quality	Control	Identity	Item/Service	Quality	Control	Identity
[name] [facility address]	[item] [contract ref] [PIC/PIA/ SR/NSR]	[Assessment Ref] [QP or waiver ref]	[Control Plan Ref.]	[name] [facility address]	[item] [contract ref] [PIC/PIA/ SR/NSR]	[Assessment Ref] [QP or waiver ref]	[Control Plan Ref.]	[name] [address]
				...				
				...				
...				...				
				...				
				...				

(the table must be expanded – rows and columns- to include all information for all existing tiers)

5.6 Supplier Release Note / Certificate of Conformity

Section 1 – to be completed by the Supplier

1. F4E reference:	[*contract / grant / call reference*]			
2. F4E CUSTOMER ref.:	[*PA/ITA/DWO reference*]			
3. Supplier:				
4. Subject:				
5 Invoicing Information: *(Contract Deliverable(s) ONLY)*	Deliverable/Milestone Ref. (one line for each)		Net Amount (€)	VAT Amount (€)

Section 2 – Conformity statement to be completed by the Supplier

1. With the exception of the deviations listed below (section 2.6), we certify that the following equipment/service:
(describe)
2. Has been manufactured/performed, inspected and tested in accordance with the requirements described in the following documents:
(documents list)
3. That the equipment/service is complete.
4. That all relevant verifications, inspections and tests are complete and satisfactory.
5. That the following documents are those required by the Contract and have been cleared by F4E:
(detailed list of all the ADP)
6. List of any deviation request and nonconformity report:
(attached)
7. Include Dual-Use items/technologies? ☐ Yes ☐ No
(if yes, indicate were – item/document chapter)
8. Foreground Declaration? ☐ Yes ☐ No
(if yes, indicate reference. If no, justify)

Supplier's Technical Responsible			Supplier's Quality Representative		
Name	*Signature*	*Date*	*Name*	*Signature*	*Date*

Section 3 – to be completed by F4E

F4E Technical Responsible Officer	F4E Project Manager (GL) / QA Representative
1. DECISION:	2. COMMENTS:
Name	*Name*
Review and approval is performed and recorded in idm@F4E	

5.7 Supplier Progress Report

Section 1 – Report References

Report Number:	[*Report#Month#Year#*]	Revision:		Sheet :		of	
1. F4E reference:	[*contract / grant / call reference*]	F4E Customer ref:	[*PA/ITA/DWO reference*]				
2. DMS#:							
3. Supplier:							

Section 2 – Reporting

4. Project Status Check		Contract period *(weeks)*	
Elapsed Time from KOM *(weeks)*		Time Remaining to task completion *(weeks)*	

5. Main scheduled tasks and milestones for the period:
WBS

6. Main results, achievements and issues encountered during the period:
WBS

7. Main scheduled tasks and milestones for the next period:
WBS

8. Action list	STATUS AND REFERENCES
WBS	

9. Pending Deviations and Open Nonconformities:

10. Other Pending Activities:
Subcontracting Foreground – Intellectual Property

Section 3 – Supplier internal verification and validation

Author	Review / Approval
[Name] / [Role]	[Name] / [Role]
Date:	Date:

- End of the Document -