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## F4E Quality Document

# F4E-QA-115 - SUPPLIER QUALITY REQUIREMENTS

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:

- the Bidder shall comply when preparing its offer/proposal;
- the Supplier shall comply within the course of the Contract.

The description of the Supplier quality management system shall be established in a dedicated QUALITY PLAN for managing F4E work activities.

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<i>Change Log</i>			
<i>Version</i>	<i>Latest Status</i>	<i>Date</i>	<i>Description of Change</i>
v1.9	Approved	02 Dec 2011	Small reformulation of clause II.2.1.(a)(iii) as request from the legal team.
v1.8	Signed	30 Nov 2011	Changed 'subject matter' to 'scope' in II.2.1.(a)(iii).
v1.7	Signed	25 Nov 2011	Updated sec II.2 and II.2.1 to include amendments to contracts
v1.6	Approved	05 Oct 2011	Format correction.
v1.5	Signed	04 Oct 2011	- Changed title of II.3.1  - Added II.3.2 CAD Specific requirements
v1.4	Signed	30 Sep 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'.
v1.3	Approved	04 Nov 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)

v1.2	Signed	28 Jun 2010	Corrected SIC to Safety Important Class
v1.1	Signed	17 Jun 2010	Updated reference to idm@F4E system and the correct version This version has been approved by the HDI ITER/PO
v1.0	In Work	11 May 2010	



## QA SPECIFICATION

### Control Page

<b>idm@F4E ref:</b>	F4E_D_22F8BJ v.1.9
<b>Document title:</b>	Supplier Quality Requirements (F4E-QA-115)
<b>Areas and functions</b>	
Document ownership:	F4E Director
Area(s) concerned:	Operational Manual (OP)
Function(s) concerned:	All Operational Roles, in particular during the contract implementation: <ul style="list-style-type: none"> <li>- The Technical Project Officer for the follow-up of technical, management and quality requirements.</li> <li>- The Procurement Project Officer for the follow-up of the commercial requirements.</li> <li>- The QA Officer for follow-up of any quality issues.</li> </ul>

### Purpose

(a) 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.

(b) 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

- [1] F4E-QA-010 – ‘Quality Classification’ Procedure ([F4E\\_D\\_22MD99](#), [external access](#))
- [2] F4E-QA-112 -- ‘Naming Conventions’ Instruction ([F4E\\_D\\_22GGJ4](#), [external access](#))
- [3] F4E-QA-P-IO – QA Programme for items and services provided by the EU-DA to the ITER Project ([F4E\\_D\\_22MCBA](#), [external access](#))
- [4] IAEA GS-R-3 – IAEA Safety Requirements GS-R-3 (2006) – ‘The Management System for Facilities and Activities’.
- [5] ASME NQA 1 – ANSI/ASME Code, NQA1 and NQA2 Quality Assurance Requirements for Nuclear Facility Applications.
- [6] EN 473:2000 – ‘Non-destructive testing. Qualification and certification of NDT personnel. General principles’
- [7] F4E CAD Manual ([F4E\\_D\\_22BE49](#))

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## Abbreviations

Term	Definition	Acronym
Acceptance Data Package	The package of documents linked to each deliverable set out in the Technical Specification (Deliverables) to be submitted by the Supplier for review by F4E.	ADP
Authorisation-To-Proceed-Point	A milestone date at which the Supplier is required to notify F4E that it has completed a specific task, deliverable or portion of a deliverable. The Supplier must then wait for authorisation from F4E before proceeding to the next task or to the next portion of the deliverable.	ATP
Contract	The Contract can be: <ul style="list-style-type: none"> <li>the supply or service Contract as result of a procurement, or</li> <li>the Grant Agreement</li> </ul>	---
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 §II.1.3 (Final Report).	---
Fusion for Energy	The European Joint Undertaking for ITER and the Development of Fusion Energy.	F4E
Hold Point	A milestone date pursuant to which the Supplier must notify F4E that a specific task, deliverable or portion of a deliverable, has or will shortly be completed. The Supplier shall stop related activities until the subsequent issue by F4E of a Hold Point Clearance.	HP
IPR	Intellectual Property Rights	IPR
ITER IO	The ITER International Organization The term ITER used alone does not indicate the organisation but the project itself.	ITER IO
Notification Point	A milestone date pursuant to which the Supplier must notify F4E that a specific task, deliverable or portion of a deliverable, will shortly be completed, and that the Supplier is proceeding to the next task or action associated with that deliverable.	NP
QA	Quality Assurance	QA
Quality Classification	F4E's Quality Classification procedure, as set out in Reference Document F4E-QA-010: 'Quality Classification'.	QC
Quality Plan	The plan describing the quality management system	QP
R&D	Research & Development	R&D
Safety Related Activity	Previously the 'Quality Related Activity'. The importance for safety of an activity is appreciated on the basis of direct or potential consequences for safety in case on inappropriate exercise of the activity	SRA
SIC	Safety Important Class (as defined in the Quality Order – 10 August 1984)	SIC
Subcontractor	All economic operators who supply items to the Supplier under the Contract.	---
Supplier	The Supplier is either: <ul style="list-style-type: none"> <li>the Contractor as defined in the supply or service Contract, or</li> <li>the Beneficiary as defined in the Grant Agreement.</li> </ul> The supply-chain follows the scheme below Supplier -> Organisation (F4E) -> Customer (e.g. ITER IO )	---
WBS	Work breakdown structure	WBS
Work	The specified necessary production, manufacture, construction, research and development activities for the execution of the contract	---

## I. Introduction

(a) 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:

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

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

Section III – 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.

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

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

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

(i) A *System Compliance* part that must comply with the quality and general requirements defined in §III.1.

(ii) An *Implementation Plan* part that must address the topics required by §III.2.

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

(d) For SIC components and services the Quality and the Control Plan must comply with the requirements of the 'Order of August 10 – 1984' (French Republic 'Arrêté du 10 Août 1984').

## II. Quality and General Requirements

### II.1. Project Meetings and Reports

#### II.1.1. Project Meetings

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

- (i) Confirmation of the specifications, specific requirements and contractual input;
- (ii) The Supplier's Quality Plan, including all subsidiary plans;
- (iii) The detailed schedule of the contractual activities, including milestones;
- (iv) Frequency of review of the Documentation Schedule and Control Plan, as defined in §III.2.5 (Documentation Schedule) and §III.2.3 (Control Plan) (if not agreed otherwise, at least once a month);
- (v) Contents of the Monthly Progress Reports to be prepared and submitted by the Supplier to F4E;
- (vi) Contents of the ADP and Contract Final Report (if not agreed otherwise, drafts submission period is one month);
- (vii) Documentation review lead time;
- (viii) The compliance matrix contents (if defined in the technical specification);
- (ix) Management of Intellectual Property;
- (x) Dual-Use items/technologies list (according §III.2.15).

(b) 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 his behalf along with representatives of F4E.

(c) Unless specifically agreed otherwise, Kick-Off, Progress and Final Meetings are obligatory and conducted face to face.

(d) 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.

#### II.1.2. Progress Reports

(a) 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 §V (Mandatory Forms). The reports must include, but not be limited to:

- (i) Main scheduled tasks and milestones for the period;
- (ii) Main results, achievements and issues encountered during the period;
- (iii) Main scheduled tasks and milestones for the next period;
- (iv) Action list and status;
- (v) Pending Deviations and Open Nonconformities;
- (vi) If applicable or in the case of a specific occurrence:

1. Update on Intellectual Property Rights and dual use technologies where applicable;
2. Subcontracting status;
3. Materials Availability;
4. Environmentally related incidents (for ITER Project site works);
5. Safety review of all safety related incidents that have occurred over the past month (for ITER Project site works).

(vii) Re-programmed activities required to recover time on any activities behind programme.

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

(c) All documents referenced in the Progress Reports must be submitted together with the Progress Reports in electronic format a minimum of five (5) working days prior to the next progress meeting.

### **II.1.3. Final Report**

(a) 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.

(b) The Final Report must contain, but not necessarily be limited to:

- (i) A detailed description of the works required by the Contract (status of the implementation);
- (ii) The final (as built) Contract Programme;
- (iii) The final Control Plan;
- (iv) The final Documentation Schedule;
- (v) The final Contract Quality Plan;
- (vi) Final results summary; incorporating the results of all tests and surveys carried out;
- (vii) 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);
- (viii) Commissioning test procedures and results, maintenance/installation/operation manuals and parts lists for any Plant/item installed within the Permanent Works (where applicable);
- (ix) A compilation of all Contract meeting minutes and reports;
- (x) Final IP Report summarising the information on IP provided foreground IPR declaration (Foreground declaration form, as supplied in the contract documentation);
- (xi) Dual-Use items/technologies final list with evidence of authorisation of export (where applicable).

### **II.1.4. Reporting on Intellectual Property**

(a) 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 tasks/operations leading to results as well as the results themselves that can take the form of an invention, information, business confidential information, trade secrets, software, database etc.

(b) A form (normally Annex D to the Contract) is provided 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.

(c) To facilitate the management of IP within the contract and to ensure that relevant information is protected where necessary the Supplier shall include any IP related information in an independent annex attached to the progress reports and to the Final Report (the 'IP Progress Report' and the 'IP Final Report').

(d) 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.

(e) The purpose of the Final IP Report is to have a compilation of IP relevant information that can be detached from the Final Report, as a standalone document, without losing its value. Cross references to other parts of the Final Report must be avoided. Where necessary, the Final IP report must include summary descriptions of the technical information included in the main body of the Final Report.

## II.2. Deviation and Nonconformity Management

(a) 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.

(b) These divergences must be identified by the following categories:

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

(c) Specified requirements include:

- (i) The requirements of the technical and management specification (of the Contract);
- (ii) The requirements of any document issued by the Supplier in connection with the contractual specifications and accepted or approved by F4E.

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

### II.2.1. Deviation Management

(a) 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.

- (i) Deviation Requests are approved by F4E before implementation.
- (ii) An F4E Deviation Notice is followed by an F4E Deviation Order before implementation.
- (iii) An *amendment* to the contract shall be required where a Deviation Request or F4E Deviation Order leads to a modification of the provisions of the contractual 'Specific

Conditions' and 'General Conditions' — in particular a variation on the overall contract value, payment modality, duration of contract (if mentioned in the specific conditions) or substantial change to the scope of the Contract.

Implementation of the Deviation may under no circumstances begin before the date of the entry into force of the associated amendment.

- (iv) Modification of administrative provisions — no impact on technical, safety, financial or overall schedule – may be performed simply through an exchange of letters in certain circumstances (no deviation needed).
- (v) In all the cases not referred in the two previous points — mainly operational provisions — the implementation can proceed after the approval of the Deviation Request or issue of the Deviation Order by F4E.
- (vi) The status of the current specification, identifying all associated deviations is made available to F4E when requested.

(b) Deviation Request *Originating from Supplier* or Subcontractor:

- (i) 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 format provided in §V.2 (Deviation Request).
- (ii) 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.
- (iii) The Supplier shall implement the deviation only after reception of the Deviation Request approved and signed by F4E and if applicable, the contract amendment.

(c) Deviation *Originating from F4E*:

- (i) If F4E considers that a deviation may be required, it will notify the Supplier to this effect in the form of a *Deviation Notice*.
- (ii) 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.
- (iii) The Supplier shall implement the deviation only after reception of a *Deviation Order* from F4E (confirming the impact assessment on the Deviation Notice) and if applicable, the contract amendment.

## II.2.2. Nonconformity Management

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

- (i) Detect any nonconformity and segregate the nonconforming element of the Works or material;
- (ii) Classify the nonconformity in two classes: major nonconformity and minor nonconformity
- (iii) 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);

- (iv) Ensure that the appropriate Corrective Actions are implemented to prevent repetition of nonconformity;
- (v) Ensure that appropriate improvements, in the form of preventive actions, brought about by the corrective actions, are implemented to prevent future nonconformities;
- (vi) 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 relevant discrepancy (normally in the form of a *Field Observation Report*);

(vii) Ensure that:

1. if the Supplier considers that a nonconformity has occurred;

or

2. if F4E notifies the Supplier (in the form of a Field Observation 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.

(b) A **major nonconformity** affects a critical requirement of the Contract (performance, safety, reliability, operability, traceability, regulatory requirements). If one is identified, the Supplier shall issue a Nonconformity Report 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 in writing.

(c) A **minor nonconformity** has no impact on F4E's critical contractual requirements. If one is found, the Supplier shall send a Nonconformity Report to F4E, and shall take remedial action to resolve the nonconformity in accordance with the Quality Plan.

(d) The Supplier shall indicate **how**, **when** and by **whom** nonconformities will be processed including those originating from its Subcontractors.

### II.2.3. Deviation and Nonconformity Management Records

(a) The formats for the Nonconformity Report and Deviation Request are shown in §V (Mandatory Forms).

(b) The Supplier shall:

- (i) Number the Deviation Requests and Nonconformity Reports sequentially;
- (ii) 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.

(c) 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.

(d) The Supplier shall ensure that its Subcontractors implement the same procedures to control Deviations.

(e) F4E's acceptance of Nonconformity Reports and Deviation Requests:

- (i) Shall be limited to the particular item referred to in the Request or Report;

- (ii) 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.

### II.3. Information and Documentation Management

- (a) The exchange of all quality and technical documentation and information between F4E and the Supplier must be conducted through and between F4E's Technical Project Officer (TPO) in charge of the Contract and the Supplier's Technical Responsible.
- (b) The Supplier shall describe his documentation management system.
- (c) The Supplier shall be responsible for filing all documentation relevant to the Contract in F4E's document management system (unless agreed otherwise).
- (d) The Supplier shall represent the process for documentation flow in a detailed flowchart (including the internal review and approval and the interface with F4E).
- (e) Before being distributed, documents and data must be *verified by individuals not involved in their drafting*.
- (f) Unless specifically specified otherwise, the standard documentation review cycle must include:
- (i) F4E will have fifteen (15) working days from the receipt of Supplier's Documents (with the exception of the Quality Plan) to review, comment on and/or, as the case may be, approve them;
  - (ii) The Supplier shall have ten (10) working days from the receipt of commented documents to update and resubmit them to F4E via email; and
  - (iii) F4E will have ten (10) working days from the receipt of the Supplier's e-mail to review and return the documents.
- (g) Revised dates or timescales may be adopted, subject to prior written agreement between F4E and the Supplier.
- (h) The general process for document distribution and release is as follows:

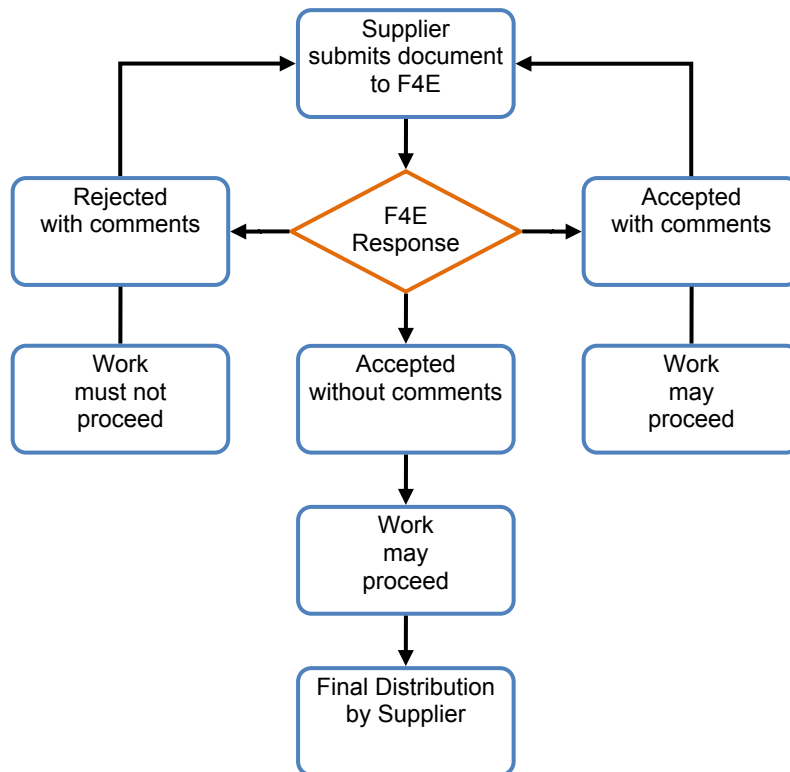


Figure II.3-1: Document Distribution and Release General Process

- (i) The Supplier shall provide a Documentation Schedule as defined in §III.2.5 (Documentation Schedule) and shall not commence his performance of the Contract until the Documentation Schedule has been accepted by F4E in writing.
- (j) The documentation format must follow the requirements given in §II.10 (Mandatory Document Formats).
- (k) 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.
- (l) 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 or, if F4E so requires, the Supplier shall at its own cost transfer the documents to F4E.
- (m) 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.

### II.3.1. Design Documentation Control

- (a) For deliverables or ADP that include CAD data, the Supplier shall implement a CAD data control system for any design activities.
- (b) The system must comply with the F4E CAD Manual, including the formats defined in §II.10.
- (c) The preparation, review, and release of drawings are accomplished through controlled procedures that establish the release authorities and responsibilities.
- (d) A design change, to modify an approved configuration baseline, is a 'deviation' and must be controlled according to §II.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).

### II.3.2. CAD Specific Requirements

(a) The Supplier shall use the latest release of Catia v.5 in compliance with the F4E CAD manual (and as specified in the IO CAD manual).

(b) 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.

(c) 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:

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

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

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#### For synchronous connections:

(a) In case F4E asks the contractor to work synchronously with ITER IO — the contractor shall be able to use an internet connection to have direct access to ITER IO database Enovia VPM using the 'Teradici' PCoIP technology solution.

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

(b) *Hardware requirements* (to be provided per user / zero client):

- (i) One USB keyboard;
- (ii) One USB mouse;
- (iii) One screen;
- (iv) Network cable with RJ45 connector;
- (v) Zero Client.

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

(d) *Network Access requirements*:

- (i) The zero client requires network access to ITER IO host card network either via Internet or VPN. ITER 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.
- (ii) 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.

(iii) If the Supplier is asked by F4E to use the Enovia direct connection each designer must

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receive training by F4E on the use of Enovia. Each designer must be certified before they can have access the ITER IO Enovia VPM database.

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## II.4. Subcontractors Management

(a) The Supplier shall ensure that each of its Subcontractors has a quality system compliant with this document. The Supplier shall issue an assessment report for each Subcontractor.

- (i) The Subcontractors quality documents (including the relevant Quality Plan) must be approved by the Supplier and sent to F4E for acceptance.
- (ii) 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 the F4E.
- (iii) 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.

(b) The Supplier shall provide a Subcontracting Schedule in compliance with the requirements set out in §III.2.7 (Subcontracting Schedule).

(c) For SIC items/services, the Supplier shall make provisions and give F4E (and if required the F4E observer — section II.8.2) the opportunity to participate (as witness) in the process of selection and award of subcontracts.

(d) The Supplier shall ensure that purchased or subcontracted goods and materials are supplied together with their certificate of conformity to the specified requirements (normally EN 10204 Type 2.1 for Quality Class 3 NSR and Type 3.1 for all the remaining cases of classes 1 to 3).

## II.5. Assessment and Validation

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:

- (i) Signed and dated Progress Reports in respect of each completed activity;
- (ii) 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.

### II.5.1. Manufacturing, Inspection and Testing

(a) Manufacture, inspection and testing must be carried out:

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

(b) 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.

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

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

**II.5.2. Qualification of Special Processes**

(a) The Supplier and his 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. 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:

- (i) Brazing, Welding and Filling (including repairs)
- (ii) Non Destructive Testing/Examination (NDT / NDE)
- (iii) Thermal treatments
- (iv) Chemical cleaning, linings and other process that may sensitise the materials.

(b) 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.

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

**II.5.3. Staff Qualification**

(a) In addition to the above (section II.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.

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

Supplier Staff	Qualification Required
Quality Assurance staff	ANSI - ASME NQA-1 [5] or equivalent
Carrying out NDTs	EN 473:2000 [6] level one (minimum)
Supervising, assessing and/or certifying NDTs and their results	EN 473:2000 [6] level two (minimum)

Table II.5-1 – Supplier staff qualification requirements

(c) Subcontracting of activities shall not exempt the Supplier from his responsibility to supervise and inspect those activities with qualified staff in accordance with the present document.

**II.5.4. Measuring and Test Equipment**

(a) The Supplier shall supervise and monitor all measurement and test equipment used in the execution of the Works.

(b) The Supplier shall maintain full and detailed records, and provide evidence to F4E, of the following:

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

(c) The Supplier shall maintain all appropriate test records that clearly identify any test equipment that has been used and its calibration status.

## II.6. Acceptance of a Deliverable

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

(b) Acceptance of a deliverable must encompass the following sequential stages:

(i) For deliverables that *consist uniquely of documentation* — the deliverable is part of the ADP:

- (1) Request deliverable despatch acceptance from F4E:  
At least ten (10) working days prior to the deliverable despatch, the Supplier shall submit to F4E a formal request (*unless agreed otherwise with the Technical Project Officer*, by a Supplier 'Release Note', see §V.6);
- (2) Once accepted by F4E — within fifteen (15) working days from reception of the request — the despatch will be accompanied by the written acceptance;
- (3) If required, upon delivery F4E or its representative will sign a 'consignment note' as recognition of reception only.

(ii) For *other deliverables*:

- (1) Request deliverable despatch acceptance from F4E:  
At least ten (10) working days prior to the deliverable despatch, the Supplier shall submit to F4E the signed Supplier 'Release Note' for acceptance (in the format set out in §V.6);
- (2) Once accepted by F4E — within fifteen (15) working days from reception of the request — the despatch will be accompanied by the accepted 'Release Note' (or when applicable a certificate of conformity);
- (3) 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.
- (4) The Supplier shall send the deliverable ADP for acceptance:
  - prior to the despatch of the deliverable (together with the Release Note), or
  - after successful delivery.

(iii) F4E will declare the *deliverable conformity* by issuing an 'Acceptance Note' after receiving the ADP, if:

1. The deliverable complies with the technical specification and contractual requirements;
2. The ADP is accepted.

(c) No despatch can be carried out without prior written acceptance from F4E.

(d) F4E's acceptance of the Supplier Release Note 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.

## II.7. Risk Management

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:

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

## II.8. Inspection and Quality Audits

(a) 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.

(b) 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.

(c) 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 his workshops for the inspectors, equipped with a telephone and facsimile with international access, and computers with internet access.

(d) F4E or his 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.

### II.8.1. Audits and Surveillance

(a) F4E or his 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.

(b) 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.

(c) 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.

(d) The NP, ATP, HP, and other markings in use (Control Plan) and the flow with F4E are defined in Section IV.4.

(e) The Supplier shall conduct periodic audits, reviews, surveillance and inspection of the Works, including in respect of the works performed by Subcontractors, 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.

(f) F4E will have the right to despatch its own inspectors or personnel to attend any of these activities.

(g) 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.

### **II.8.2. F4E Observer Access**

(a) 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.

(b) 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:

- (i) F4E Customer,
- (ii) next user of the deliverable.

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

### **II.8.3. Third-Party Inspection Authority (including the ANB)**

(a) 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.

(b) 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.

(c) 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 to assess whether the Contract deliverables meet the requirements of the Contract.

### **II.8.4. French Safety Authorities**

*[For SIC components and services only]*

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 §II.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.

## II.9. Summary of Quality Requirements and Actions

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

Requirements
<p><i>With the offer / proposal:</i></p> <ul style="list-style-type: none"> <li>• Submit to F4E the meaningful 'preliminary' version of the Quality Plan:           <ul style="list-style-type: none"> <li>* Relevant 'Documentation Schedule' filled with all contractual documents linked to deliverables</li> <li>* Relevant Planning Schedule</li> <li>* Relevant 'Top Level Control Plan' with phases/tasks, milestones, deliverables and top level activities</li> </ul> </li> </ul>
<p><i>After Contract signature:</i></p> <ul style="list-style-type: none"> <li>• Submit to F4E before the kick-off meeting the 'provisional' versions of the Quality Plan           <ul style="list-style-type: none"> <li>* 'Top Level Control Plan' included</li> <li>* Relevant 'Documentation Schedule' and 'Subcontracting Schedule' defined included</li> </ul> </li> <li>• Update and Submit to F4E the working versions of the Quality Plan</li> <li>• Obtain F4E's acceptance of the relevant Quality Plan</li> </ul>
<p><i>Prior to procurement or subcontracting:</i></p> <ul style="list-style-type: none"> <li>• Verify that the 'Subcontracting Schedule' is up-to-date. If changed from accepted, obtain F4E's acceptance of the updated Schedule.</li> <li>• Obtain F4E's acceptance of the relevant documents identified in the 'Documentation Schedule'.</li> </ul>
<p><i>Prior to design, manufacture, inspection and test:</i></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• Obtain F4E's acceptance of the relevant documents identified in the 'Documentation Schedule'.</li> </ul>
<p><i>During design, manufacture, inspection and test:</i></p> <ul style="list-style-type: none"> <li>• Notify F4E representatives of any pending Hold, Authorisation-To-Proceed or Notification Point.</li> <li>• Complete the relevant entries in the 'Control Plan' as work progresses.</li> </ul>
<p><i>Prior to acceptance or delivery of a deliverable:</i></p> <ul style="list-style-type: none"> <li>• Complete the relevant 'Supplier Release Note'</li> <li>• Obtain F4E written release for despatch.</li> </ul>
<p><i>After delivery of a deliverable:</i></p> <ul style="list-style-type: none"> <li>• Complete the 'Acceptance Data Package'</li> <li>• Obtain F4E 'Acceptance Note'.</li> </ul>
<p><i>During Contract implementation:</i></p> <ul style="list-style-type: none"> <li>• Issue 'Deviation Requests' and 'Nonconformity Reports' as necessary.</li> </ul>
<p><i>Prior to Contract closing:</i></p> <ul style="list-style-type: none"> <li>• Issue Contract 'Final Report'</li> </ul>

Table II.9-1 – Summary of Quality Requirements

## II.10. Mandatory Document Formats

All communications and official documentation relating to the Works must be in English.

(i) For monolingual documentation, the language must be English.

(ii) For dual-language documentation, such as regulatory or safety documentation requirements:

1. 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;

2. 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.

### II.10.1. Electronic Documents

(a) 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.

(b) 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.

Document Type	Editable		Reference	Informative
	Format	Version	Format	Format
Text document	doc/rtf	MS Word v.97	pdf	---
Spreadsheet	xls	MS Excel v.97	pdf	---
CAD models and drawings	cat	CATIA v.5	cat	pdf of typical 3-D views
CAD drawings	cat		pdf	---
Schedules, Programmes & Plans	xer/mpp	(See item II.10.1.g)	pdf	pdf of all pages
Scans and pictures	jpg	---	pdf	---
Video footage	avi	---	avi	---
Presentations	ppt	MS PowerPoint v.97	pdf	---
Document sets	zip	---	---	---
Issued documents	---	---	pdf	---
Documentation Schedule	xls/doc	MS Office v.97	pdf	---
Control Plan	xls/doc	MS Office v.97	pdf	---

Table II.10-.1 – Mandatory Document Formats

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

(d) Where possible, such as in respect of text documents, spreadsheets, drawings, etc, editable versions of the deliverables must be provided.

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

(f) 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.

(g) 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).

### II.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.

## II.11. Licensing Requirements

(a) CE marking must be implemented wherever it is applicable.

(b) 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.

(c) For item(s) subject to specific requirements for Pressure Equipment (European Pressure Equipment Directive, PED, or French Order 1999) or for Nuclear Pressure Equipment (French Order on Nuclear Pressure Equipment, December 2005, ESPN), the Supplier shall ensure that the items are compliant with these requirements.

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*By affixing the CE marking to a product, the manufacturer declares on his/her sole responsibility that the product is in conformity with the essential requirements of the applicable directives providing for its affixing and that the relevant conformity assessment procedures have been fulfilled. Products bearing the CE marking are presumed to be in compliance with the applicable directives and hence benefit from free circulation in the European Market.*

*The manufacturer has sole and ultimate responsibility for the conformity of the product to the applicable directives,*

- *whether he designed and manufactured the product himself*
- *or is considered as a manufacturer because the product is placed on the market under his name.*

*Not all products must bear the CE marking. Only those product categories subject to specific directives that provide for the CE marking are required to be CE marked.*

*Further info: [http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic\\_en.pdf](http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf)*

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### III. Quality Plan Requirements

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

(b) 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:

- (i) *System Compliance* Part: address sections as defined in §III.1.
- (ii) *Implementation Plan* Part: address sections as defined in §III.2.
- (iii) The level of detail of both parts is as defined in the contract management specification.

#### III.1. Quality System Compliance Part

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

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

- (i) copy of the valid Quality Management System certification;
- (ii) Quality Manual reference;
- (iii) a statement of compliance with the General Requirements (QA-115 II);

#### III.1.1. Management of Scope

##### III.1.1.1. Management of Responsibility Allocation

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

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

##### III.1.1.2. Management of Nonconformity and Deviations Procedures

The Supplier shall:

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

#### III.1.2. Management of Schedule

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

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

#### III.1.3. Management of Deliverables

The Supplier shall:

- (i) describe (or refer to an attached procedure) the procedure to handle Documentation and Records;

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

#### **III.1.4. Risk Management**

The Supplier shall describe the risk management system to comply with §II.7.(Risk Management).

#### **III.1.5. Resource management and training**

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

#### **III.1.6. Subcontracting management**

The Supplier shall describe the Subcontracting management system to comply with §II.4. (Subcontracting).

#### **III.1.7. Assessment and validation management**

This section must describe the system to comply with II.5. (Assessment and validation), including:

- (i) procedure for the management of Measuring and Test Equipment;
- (ii) access to the Supplier premises;
- (iii) Supplier personnel and Supplier completed work activities for third party audit or inspection (see §II.8).

#### **III.1.8. Licensing Requirements**

The Supplier shall detail the licensing requirements assessment.

#### **III.1.9. Incoming parts management**

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

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

#### **III.1.10. Design management**

The Supplier shall describe:

- (i) the design management system (including review, verification & validation);
- (ii) in detail the design review procedure;
- (iii) the independent verification methods and indicate who will make this verification.

**III.2. Quality Implementation Plan Part**

(a) 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.

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

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

**III.2.1. Contract Implementation**

**III.2.1.1. Objectives and Activities**

(a) 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.

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

(c) The section must include a table, identifying:

Milestone	Task / Activity (WBS)	Deliverable	Related Documentation	Input Documentation	Level of Subcontracting	Responsible
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(i) All milestones and deliverables;

(ii) A short description of the related activities (including the number and quantity);

(iii) Related technical documentation (as-built drawings, material test results, photographic records and reports, and the like) confirming the as-built condition of the Works carried out (ADP);

(iv) All documentation (input) to be submitted to F4E in advance of execution work involving that activity commencing;

(v) The level of subcontracting;

(vi) Supplier responsible for that activity.

(d) For *SIC (Safety Important Class) components and services* the Supplier shall perform a technical analysis detailing:

(i) the Safety Related Activities (SRA) for safety related elements. In practice, these activities include:

1. Design tasks required for the product in question;
2. Subcontracting activities when the Supplier considers that the work ordered to its subcontractor is an SRA;
3. The manufacturing, inspection or testing activities listed in the Quality Plan and Control Plan.

(ii) the defined requirements (requirements to be fulfilled to obtain and maintain quality).

### III.2.1.2. Management of the Contract

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

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

### III.2.2. Organisation and Responsibilities

(a) 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, if applicable.

(b) 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 III.2.6).

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

- (i) The Supplier's Technical Responsible Person in charge of the Contract;
- (ii) The Supplier's Quality Representative for the Contract.

(d) The Supplier's Technical Responsible Person 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 Technical Responsible Person shall keep and maintain the Contract programme and time schedules and issue the Progress Reports.

(e) 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 his Subcontractors, including any works carried out at Subcontractors' premises.

(f) The Supplier shall not change or replace his Technical Responsible Person or Quality Representative without the prior agreement of F4E.

#### III.2.2.1. Stop Work Authority

*[For SIC components and services only]*

- (a) The Supplier shall state its 'Stop Work Authority' internal guideline.
- (b) The guideline must include that for stopped work associated with defined safety systems, notification must be given to F4E explaining reason for stop work and proper justification for restarting that work activity.

### III.2.3. Control Plan

(a) The Supplier shall include in this section the *Top Level Control Plan* for the works according to §IV (Control Plan Requirements). The Top Level Control Plan is issued and accepted with the Quality Plan.

(b) When required, according to §IV (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.

### III.2.4. Time Schedule (Programme)

(a) 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).

(b) The Supplier shall detail his 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 §II.10.1 (Electronic Documents).

(c) The Supplier shall also set out the process of reporting progress against programme to F4E.

### III.2.5. Documentation Schedule (list of documentation deliverables)

(a) The Supplier shall provide a Documentation Schedule (list of documentation deliverables) in the format set out in §V.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.

(b) 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).

(c) During the execution of the Works, the Documentation Schedule must be maintained as the reference for documentation status within the Contract.

(d) At each documentation delivery, the Supplier shall include the relevant extract of the Documentation Schedule identifying the documents within the delivered package.

(e) The Documentation Schedule must include the documents linked with main interface milestones.

### III.2.6. Contract Resources

(a) The Supplier shall provide details of the resources, detailing where applicable:

- (i) the number and type of personnel involved in each of the Contract activities;
- (ii) measures in place to ensure adequate recruitment of sufficiently experience personnel;
- (iii) specific training provided to its personnel;
- (iv) specific qualifications held by those performing particular operations, especially operations requiring special control measures and / or supervision;
- (v) 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.

(b) The Supplier shall maintain a register of all employees, and those of his subcontractors, that must demonstrate that all workers are appropriately qualified for the activities they are required to carry out.

### III.2.7. Subcontracting Schedule

(a) The Supplier shall provide a Subcontracting Schedule in the format set out in §V.5 (Subcontracting Schedule Form), detailing:

- (i) All major or critical items and activities to be subcontracted by the Supplier;
- (ii) Specifications of the associated items or activities to be performed;
- (iii) The identity of the relevant Subcontractor, including details of his contact officer;
- (iv) Proof of the Subcontractor's qualification, including for example ISO 9001 certification;
- (v) The subcontractor's assessment form (must be accepted by F4E);
- (vi) A record of F4E's consent obtained in accordance with the Contract.

(b) 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.

(c) 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.

### III.2.8. Execution Plan

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

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

#### III.2.8.1. Validation of Analysis Codes

(a) The use of a specific analysis code must be proposed to F4E before the beginning of the analysis.

(b) The analysis must start only after agreement (release) from F4E.

#### III.2.8.2. Special Processes Qualification

This Section includes the Special Processes approval records and reports.

### III.2.9. Risk Plan

The Supplier shall provide and maintain a Risk Plan for the Contract, following its Risk Management System (§III.1.4). An electronic template will be made available to the supplier.

### III.2.10. Project Controls

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).

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*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.*

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### III.2.11. Incoming Items Requirements

(a) The Supplier shall indicate the responsible(s) for assuring the correct implementation of the Incoming Parts management (in accordance with §III.1.9).

(b) The Supplier shall ensure that its Subcontractors implement the same procedures for control of acceptance of deliveries.

### III.2.12. Inspection and Quality Audits

(a) This section must set out the Supplier's proposed audit schedule, not covered by the Control Plan, detailing:

- (i) Subjects/Activities/Work Locations to be audited
- (ii) Frequency of audit
- (iii) Type of audit e.g. internal/external/subcontractor

(b) The audit schedule must encompass the widest practicable range of project activities that must include all consortium members and significant subcontractors.

### III.2.13. Health and Safety

(a) 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.

(b) For ITER Project site works:

- (i) 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.
- (ii) 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.

### III.2.14. Codes (Regulatory Documents) and Standards

The Plan must reference all codes, standards, and regulatory requirements applicable to the quality and management of the Works.

### III.2.15. Dual-Use items/technologies

(a) 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.

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*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.*

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(b) 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'.

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

### III.2.16. Identification and control of items

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

- (i) how affected items are to be identified;
- (ii) how contractual and regulatory traceability requirements are identified and incorporated into working documents;
- (iii) what records relating to such traceability are to be generated and how and by whom they are to be controlled;
- (iv) method of indicating and recording calibration status.

### III.2.17. Handling, storage, packing, shipping and delivery

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

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

### III.2.18. Statistical techniques

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

## IV. Control Plan Requirements

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

(b) For each particular activity, the Control Plan must identify:

- (i) the applicable requirements and instructions;
- (ii) whether or not that activity is to be witnessed or whether notification is required;
- (iii) the provision for recording the verification and completion of the listed operations;
- (iv) if the activity is a Safety Related Activity (for SIC elements).

(c) No activity can be performed without that activity being covered by an F4E accepted Control Plan. 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	Phase/Task Control Plan (§IV.2)	Detailed Control Plan with all activities affecting quality, milestones, key points and reviews
Manufacture of prototypes		
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	normally covered by the Top Level Control Plan (§IV.1)	Top level activities affecting quality are referenced in the Top Level Control Plan
Supply of services		
Issue of report or study		

Table IV-1 – Control Plan type

(d) 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.

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

(f) 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.

(g) The Control Plan must be in the format shown in §V.1 (Control Plan Form). No change to this format will be accepted without the prior written approval of F4E.

### IV.1. Top Level Control Plan

(a) 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).

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

- (i) the division of the contract in phases/tasks;
- (ii) 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;
- (iii) all contractual milestones (including HP, NP and ATTP);

- (iv) all contractual deliverables;
- (v) for SIC components and services, all the SRA (if not addressed in a subsidiary Phase/Task Control Plan);
- (vi) Reference, when applicable, the subsidiary Phase/Task Control Plans.

(c) 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.

## **IV.2. Phase/Task Control Plan**

(a) When required, in §IV(c), 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.

(b) 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.

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

- (i) Requirements originated from the development and validation strategy as defined in the Technical Specification (qualification and validation requirements, needs for mock-up or prototypes...).
- (ii) 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.
- (iii) 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.
- (iv) For SIC components and services, all the SRA.

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

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

(e) 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.

(f) 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.

## **IV.3. Control Plan Procedure**

- (a) The supplier and any subcontractors shall submit a Control Plan to F4E for acceptance;
- (b) 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;
- (c) If F4E decides that essential activities are missing on the submitted Control Plan, the Control Plan will be returned to the supplier for correction;
- (d) Evidence of F4E's acceptance of the Control Plan must be maintained;

- (e) A revised Control Plan must be subject to the same acceptance procedure as the original Control Plan.
- (f) 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.
- (g) The intervention points must be signed-off and dated at the time of attendance by the relative party by the person performing the intervention.
- (h) Compliance with the plan must be checked and recorded as work progresses.
  - (i) each completed operation must be dated and signed off at the time of completion by the performer or his direct supervisor;
  - (ii) the identification of records generated during the performance of the particular operation (e.g. test report, non-conformance report, etc.) must be recorded on the Control Plan.

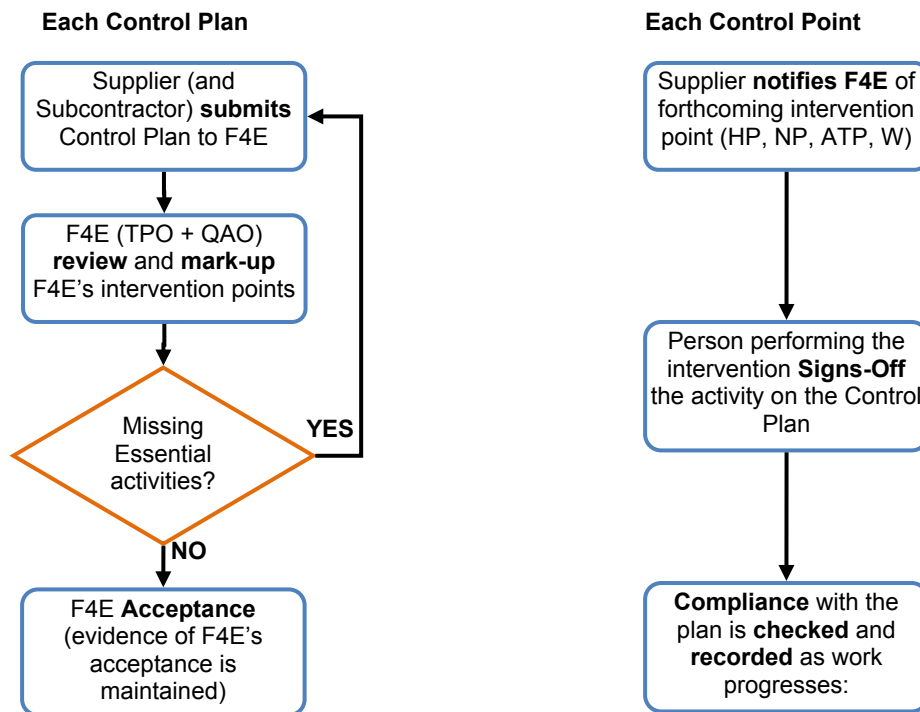


Figure IV-1 – Control Plan Process

#### IV.4. Markings in Use

Mark	Short Description
<b>NP</b>	<i>Notification Point</i> - 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
<b>W</b>	<i>Witness</i> - 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 in order to allow the mandatory inspection/monitor/surveillance
<b>HP</b>	<i>Hold Point</i> - 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, etc. Production flow for associated process is interrupted until clearance is given
<b>ATP</b>	<i>Authorisation to Proceed</i> - 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.
<b>R</b>	<i>Review</i> - 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). The use of 'D' is also acceptable. Can be performed at any moment without interrupting the production flow.
<b>S1 or S2</b>	<i>Surveillance</i> - identifies an operation that requires 100% (S1) inspection or random/spot (S2) inspection. Normally used by ANB, NB, third party inspectors.
<i>Performer</i> - The activity performer (e.g. produce a report) needs no additional marking – just sign and date its column to prove the activity is complete.	

Mark	Flow with F4E (unless specifically specified otherwise)
<b>NP</b>	Notification sent to F4E fourteen (14) calendar days before scheduled operation F4E notifies Supplier up to seven (7) calendar days before scheduled operation of its intentions
<b>W</b>	Notification sent to F4E fourteen (14) calendar days before scheduled operation F4E notifies Supplier up to seven (7) calendar 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
<b>HP</b>	Notification sent to F4E F4E notifies Supplier within fourteen (14) calendar days of the result. On rejection: Supplier has five (5) calendar days to propose a recovery plan. On objection (duly justified): Supplier has ten (10) calendar days to answer (and if applicable propose a recovery plan).
	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
<b>ATP</b>	Notification sent to F4E F4E notifies Supplier within seven (7) calendar days of the result. On rejection: Supplier has five (5) calendar days to propose a recovery plan. On objection (duly justified): Supplier has five (5) calendar days to answer (and if applicable propose a recovery plan).



## V.2. Deviation Request

<b>SUPPLIER DEVIATION REQUEST</b>					
<b>Section 1 – to be completed by the Supplier</b>					
Supplier DR #:		Supplier DMS #:		Ver.	
1. F4E Ref:	[contract / grant / call ref]				
2. F4E Customer Ref.:	[PA/ITA/DWO reference]				
3. Supplier:					
4. Subject of Deviation:					
5. ORIGINAL REQUIREMENT:					
6. DEVIATION PROPOSAL:					
7. JUSTIFICATION AND COMMENTS:					
8. LIST OF ATTACHMENTS:					
9. IMPACT ANALYSIS:					
9.1 INTERFACES	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:		
9.2 SCHEDULE	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:		
9.3 PERFORMANCE	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:		
9.4 COST	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:		
9.5 OTHER: <input style="width: 100px;" type="text"/>	<input type="checkbox"/> NO	<input type="checkbox"/> YES	Report:		
<b>Technical Responsible</b>			<b>Quality Representative</b>		
<i>Name</i>	<i>Signature</i>	<i>Date</i>	<i>Name</i>	<i>Signature</i>	<i>Date</i>

**[ELECTRONIC TEMPLATE WILL BE MADE AVAILABLE TO THE SUPPLIER]**

### V.3. Nonconformity Report

**NONCONFORMITY REPORT**

**Section 1 – to be completed by the Supplier**

<b>Supplier NCR #:</b>		<b>Supplier DMS #:</b>		<b>Ver.</b>	
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<b>1. F4E Ref:</b>	[contract / grant / call ref]
<b>2. F4E Customer Ref.:</b>	[PA/ITA/DWO reference]
<b>3. Supplier:</b>	
<b>4. Subject:</b>	

**5. REQUIREMENT:**

**6. DESCRIPTION OF NONCONFORMITY:**

**7. PROPOSED REMEDIAL ACTION:**     use as is     rework     repair     reject

**8. LIST OF ATTACHMENTS:**

**9. PROPOSED NONCONFORMITY CATEGORY:**

**MINOR** NONCONFORMITY (Report to be sent to F4E for information and remedial action implemented)

**MAJOR** NONCONFORMITY (Remedial action implemented only after F4E written acceptance)

**10. CORRECTIVE / PREVENTIVE ACTION:**

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

**[ELECTRONIC TEMPLATE WILL BE MADE AVAILABLE TO THE SUPPLIER]**





### V.6. Supplier Release Note

<b>SUPPLIER RELEASE NOTE</b>
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**Section 1 – to be completed by the Supplier**

Note Number:	[Note #Lot1.1]	Revision:		Sheet:		of	
1. F4E reference:	[contract / grant / call reference]	F4E Customer ref.:	[PA/ITA/DWO reference]				
2. DMS#:							
3. Supplier:							

**Section 2 – Conformity statement to be completed by the Supplier**

1. With the exception of the discrepancies listed below (§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: (detailed list)
6. List of any deviation request and nonconformity report: (attached)
7. Include Dual-Use items / technologies? <input type="checkbox"/> Yes <input type="checkbox"/> No (if yes, indicate where – item/document chapter)

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

**Section 3 – to be completed by F4E**

F4E Technical Project Officer			F4E Project Manager / QA Representative		
1. DECISION:			2. COMMENTS:		
Name	Signature	Date	Name	Signature	Date

**[ELECTRONIC TEMPLATE WILL BE MADE AVAILABLE TO THE SUPPLIER]**

## V.7. Supplier Progress Report

<b>SUPPLIER PROGRESS REPORT</b>			
<b>Section 1 – Report References</b>			
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:			
<b>Section 2 – Reporting</b>			
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 <u>period</u> :			
WBS			
6. Main results, achievements and issues encountered during the <u>period</u> :			
WBS			
7. Main scheduled tasks and milestones for the <u>next period</u> :			
WBS			
8. <u>Action list</u>		STATUS AND REFERENCES	
WBS			
9. <u>Pending Deviations and Open Nonconformities</u> :			
10. Other Pending Activities:			
Subcontracting			
Foreground – Intellectual Property			
<b>Section 3 – Supplier internal verification and validation</b>			
Author		Review / Approval	
[Name] / [Role]		[Name] / [Role]	
Date:		Date:	

**[ELECTRONIC TEMPLATE WILL BE MADE AVAILABLE TO THE SUPPLIER]**