FUSION FOR ENERGY

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EXTERNAL REFERENCE

F4E Document

F4E-QAP-ITER - EUDA QA Programme for ITER Project

QA Programme for Items and Services Provided by the EU-DA to the ITER Project

Approval Process			
	Name	*Action*	*Affiliation*
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Change Log			
F4E-QAP-ITER - EUDA QA Programme for ITER Project (22MCBA)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	Signed	11 May 2010	
v1.1	Signed	24 May 2011	Corrected idm@F4E reference
v1.2	Signed	05 July 2011	Full update taking into account the new processes and new structure Added: - references to QA-115 'Supplier Quality Requirements' - Section V.5.8.5. Safety Arrangements Follow-Up - Section V.6.4 Risk Management - Annexes all updated to new and approved processes
v1.3	Approved	15 July 2011	Small corrections taking into account F. Casci comments (mainly): - Modified Fig. 1 - Corrected title of III.2.3 - Corrected typo in IV(c) - Divided V.5.1 into V.5.1 and V.5.2
v2.0	Signed	15 December 2015	Integrate the INB Order of 7 February 2012, the PIC and PIA terms and definitions and IO Policy on Safety | Quality Framework, introducing the IMSS | Update of the Quality Policy | operational structure | QA Coordination in ITER Department | Quality Approach to Safety | processes interaction scheme | include the possibility of Integrated Project Teams | Inclusion of the F4E RMV process (DOORS) | Safety Arrangements follow-up | Supplier Control Plan overall flow | Supplier Deliverable Acceptance overall flow | Update of all of the Annexes processes and flows
v2.1	Signed	04 August 2017	Changes introduced by v2.0 plus: included the INB Order and the IO policy on Safety | Management Standards update | updated Corporate Quality Policy | Updated Organisation Chart | new QAG and its responsabilities | updated process maps.
v2.2	Approved	11 August 2017	Small corrections in the text, in particular i section III.2 as requested by QA GL.

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QA PROGRAMME

DRS

Control Page

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Document title:	**QA Programme for the ITER project (F4E-QAP-ITER)** (EUDA QAP for items and services provided by the EU-DA)

Areas and functions

Document ownership:	Quality Manager
Area(s) concerned:	Quality Management System, Quality Assurance, Delivery to ITER
Function(s) concerned:	F4E Quality Manager for development, monitor and maintenance of the QMS Quality Assurance Group and QA Officers for implementation and monitoring All Operational Roles for implementation

Purpose

This document describes and establishes the overall framework to achieve the quality criteria for all F4E technical activities and in particular for safety relevant components and activities for the ITER project. The programme described in this document is an integral part of the F4E Quality Management System.

Scope

The programme described in this document applies to all technical activities performed by F4E providing Europe's contribution to the ITER project; including activities performed by contracted or subcontracting qualified economic operators. This document does not cover the activities directly contracted by IO with EU labs and industry.

Reference documents

[1] Quality Management Policy, F4E_D_25929B

[2] F4E-QA-010 –'Quality Classification' Procedure, F4E_D_22MD99

[3] F4E-QA-112 -- 'Naming Conventions' Instruction, F4E_D_22GGJ4

[4] F4E-QA-115 – 'Supplier Quality Requirements', F4E_D_22F8BJ

[5] IAEA GS-R-3 – Safety Requirements (2006) – 'The Management System for Facilities and Activities'
IAEA General Safety Requirements - GSR Part 2 - Leadership and Management for Safety (2015) (superseding IAEA GS-R-3)

[6] F4E CAD Manual, F4E_D_22BE49.

[7] French Order 7 February 2012 - *République Française - Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base*. INB Order,

[8] ISO 9001:2015 – 'Quality management systems -- Requirements'.

[9] ITER Policy on Safety, Security and Environment Protection Management (ITER_D_43UJN7)

External access to the F4E - Procurement and Grants – Key Reference Documents:
(http://fusionforenergy.europa.eu/procurementsgrants/keyreference.aspx)

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List of Captions

Abbreviations and Definitions

Term	Definition	Acronym
Audit (quality)	A systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. • Internal Quality Audit – audit performed to an internal (F4E) process or organisational entity • External Quality Audit - audit performed to an external (Supplier) process or entity	
Configuration baseline	A configuration of a product, formally established at a specific point in time, which serves as reference for further activities.	
Contract	The Contract can be the supply or service Contract as result of a procurement, or a Grant Agreement.	
Deviation	A planned alternative to a specified requirement • *Deviation Request* – request for a deviation to a stakeholder (normally upwards the supply chain) • *Deviation Notice* – Notify (normally downwards the supply chain) of a need for a Deviation (expect to receive an impact report as reply) • *Deviation Order* – Order (downwards the supply chain) to apply the Deviation as defined in the previously sent Deviation Notice (and the received impact report)	
Domestic Agency	Domestic Agency, an organisation appropriately formed and appointed within and by each 'Party' to be the supplier of in-kind goods and services to the ITER Organization on the basis of defined specifications.	DA
Economic Operator	Any natural or legal person, public entity or group thereof that offers products, services or works on the market.	
Fusion for Energy	The European Joint Undertaking for ITER and the Development of Fusion Energy	F4E
Grant or Procurement	An activity (or project) can be carried out by awarding: a contract pursuant to a procurement procedure or a a grant agreement pursuant to the procedure for awarding grants. Both of these procedures are laid down in the F4E Implementing Rules of the Financial Regulation	
ITER	ITER International Fusion Energy research project	
ITER Agreement	Agreement on the Establishment of the *International Fusion Energy Organization* for the Joint Implementation of the ITER Project'	
ITER Organization	*ITER International Organization*: *ITER International Fusion Energy Organization* for the Joint Implementation of the ITER Project, the Customer who receives the items and services provided by the EU-DA to the ITER project	*IO*
Nonconformity	Any condition that does not comply with the requirements specified (ISO9000: Non-Fulfilment of a Requirement). The following definitions apply to the nonconformity actions: • *Remedial Action*: An action taken to address the nonconformity condition (reject, 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.	NC RA CA
Parties	the ITER 'Parties' are the signatories of the Agreement on the Establishment of the *ITER International Fusion Energy Organization* for the Joint Implementation of the ITER Project	

Term	Definition	Acronym
Product	Supplies, services, works or results of R&D and demonstration activities provided by the F4E to the ITER project. 'result of a set of interrelated or interacting activities which transforms inputs into outputs'	
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
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
QA Officer	Quality Assurance Officer (Department Level)	QAO
QA Group	Quality Assurance Group (PM Department)	QAG
QMS	Quality Management System	
Quality Manager	F4E Quality Manager	QM
Safety Related Activity	Safety (Quality) Related Activity. S/QRA are a subclass of PIA	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.	---
Supplier	An economic operator that provides a product (supply or service) in accordance with the provisions of the Contract. The Supplier is defined as the Contractor in the supply or service Contract, or as the Beneficiary in the Grant Agreement.	---
Supply-Chain	The supply-chain follows the scheme below: Subcontractor -> Supplier -> Organisation (F4E) -> Customer (IO)	---
Work	The specified necessary production, manufacture, construction, research and development activities for the execution of the contract	---

I. INTRODUCTION

I.1. Quality Assurance Programme Promulgation

(a) The Quality Assurance Programme described in this document has the approval and total support from the F4E Director.

(b) The cooperation and support from all staff in performing all its activities according to the requirements defined in this program are preponderant factors to the maintenance and improvement of the Quality Assurance Programme, as well as to the Organisation performance.

I.2. Scope

(a) The programme described in this document applies to all technical activities performed by F4E providing Europe's contribution to the ITER project; including activities performed by contracted or subcontracting qualified economic operators.

(b) This document does not cover the activities directly contracted by IO with EU labs and industry.

I.3. Quality Framework

(a) The Integrated Management System being applied in F4E merges the requirements of the two control environments in which F4E operates since the beginning: - the (ISO-based) ITER-wide Quality System, which is intended to ensure the performance of ITER and the compliance with the nuclear safety requirements, and the (COSO-based) Internal Control Standards as implemented by the European Commission.

(b) This system is implemented through Quality Management which provides an effective and efficient method to perform the tasks, a perspective on the organisation and its risks. It allows F4E to continually improve the way of working and to reinforce the F4E corporate culture towards the stakeholder's expectations.

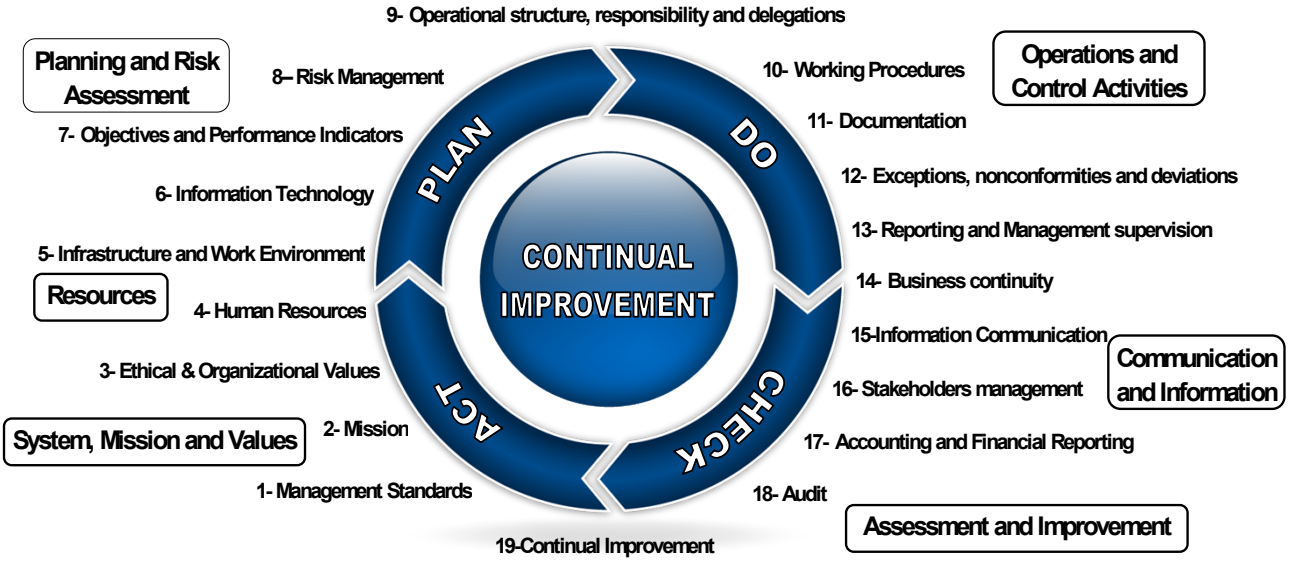


Figure 1 (I.3): F4E Integrated Management System (Management Standards v.2016)

The last up-to-date version of the Management Standards can be found here: Management Standards (24LQJM).

II. QUALITY POLICY

According to the F4E Quality Management System, the Corporate Quality Policy is:

FUSION FOR ENERGY

CORPORATE QUALITY POLICY

'Fusion for Energy' (F4E) implements a simple and effective Quality Management System tailored to its specific activities and customers. The management system is based on the implementation of project management best practices in order to comply with the customer requirements.

F4E operates an Integrated Management System (merging the quality management system and internal control standards) to ensure that:

- Operational activities are effective and efficient;
- Legal and regulatory requirements are met;
- Financial and other management reporting is reliable;
- Assets and information are safeguarded;
- Traceability is established and maintained;
- Safety has higher priority, and the quality system is used to ensure safety.

F4E is committed to providing the highest quality contributions and services to our stakeholders by:

- Consistently meeting or exceeding our stakeholders' expectations for quality and performance;
- Timely delivery of products and services to meet our customer's requirements;
- Continuous improvement of our processes, and systems;
- Ensuring that the requirements are prescribed and enforced when contracting with economic operators;
- Ensuring our staff is properly trained so they are able to deliver the highest quality service.

The F4E management system ensures consistency of the protection important activities with the Order of 07 February 2012 (General Rules relative to basic nuclear installations) via the F4E QA Programme for ITER and by applying the ITER Policy on Safety, Security and Environment Protection Management.

The implementation of the Integrated Management System is the responsibility of all officials. F4E expects the commitment of its entire staff to guarantee that its activities are prepared and carried out according to the established policies, manuals and processes.
This Policy is reviewed and renewed on a regular basis.

[idm review and approval)
Johannes Schwemmer
F4E Director

F4E_D_238EBF Corporate Quality Policy Page 1/1

Internal

III. FUSION FOR ENERGY

III.1. Presentation

III.1.1. About F4E

(a) The European Joint Undertaking for ITER and the Development of Fusion Energy or F4E is a type of European organisation known as a Joint Undertaking created under the Euratom Treaty by a decision of the Council of the European Union

(b) The Council Decision (Euratom) No 198/2007 of 27 March 2007 established the European Joint Undertaking for ITER and the Development of Fusion Energy (hereinafter F4E) for a period of 35 years from 19th April 2007 and is situated in Barcelona, Spain. The organisation has the following Members:

(i) Euratom, represented by the European Commission;

(ii) the Member States of Euratom;

(iii) third countries which have concluded cooperation agreements with Euratom in fusion that associate their respective research programmes with the Euratom programmes and which have expressed their wish to become Members.

(c) The current Members are therefore the 27 Member States of the European Union, Euratom and Switzerland as a third country.

(d) The objectives of F4E are:

(i) Providing Europe's contribution to the ITER International Fusion Energy Project as the designated Domestic Agency for Euratom;

(ii) Implement the Broader Approach agreement between Euratom and Japan as the designated Implementing Agency for Euratom;

(iii) Prepare in the longer term for the construction of demonstration fusion reactors (DEMO).

(e) In addition, F4E is technically managing the technology tasks previously launched by EFDA and that are on-going.

Reference and Applicable Documents

Council Decision No. 2007/198/Euratom of 27 March 2007 establishing the European Joint Undertaking for ITER and the Development of Fusion Energy and conferring advantages upon.
The full text of the Commission's proposal for the Broader Approach agreement
The full text of the Commission's proposal for the ITER Agreement

III.1.2. Products Supplied to the ITER Project

(a) As the European Domestic Agency for ITER, the F4E shall discharge the obligations of Euratom to IO as defined in, and for the duration of the ITER Agreement. In particular, it shall:

(i) Oversee preparation of the ITER site;

(ii) Provide components, equipment, materials and other resources to ITER Project;

(iii) Manage procurement arrangements vis-à-vis IO and in particular associated quality assurance procedures;

(iv) Prepare for and coordinate Euratom's participation in the scientific and technical exploitation of the ITER Project;

(v) Provide for the implementation of scientific and technological research and development activities in support of Euratom's contribution to ITER Project;

(vi) Provide Euratom's financial contribution to the ITER Project;

(vii) Provide arrangements to make human resources available for ITER Project;

(viii) Interface with ITER Project and carry out any other activities in furtherance of the ITER Agreement.

(b) Activities covered by the QA Programme under these activities include:

(i) R&D (Research and Development) and demonstration activities;

(ii) preliminary and / or detailed design of components and systems;

(iii) development of manufacturing and testing methods;

(iv) manufacturing, construction or integration of components and systems;

(v) development of assembly, inspection, maintenance tools and procedures;

(vi) development of new technologies of direct application to ITER machines;

(vii) development and validation of software for specific ITER applications;

(viii) development of safety analyses and software;

(ix) preparation / adaptation of technical specifications for tenders, standards and codes;

(x) development and qualification of materials and technologies for possible applications in ITER;

(xi) design, building, commissioning and operation of new test facilities for ITER materials / components / systems;

(c) In general, items and services are provided by assigning the relevant activities to qualified economic operators through contracts (or grant agreements), according to the legal framework laid down inter alia by the financial regulation of F4E and its implementing rules.

Reference and Applicable Documents

F4E CD	Council Decision No. 2007/198/Euratom of 27 March 2007 establishing the European Joint Undertaking for ITER and the Development of Fusion Energy and conferring advantages upon
F4E(15)-GB34	'New Financial Regulation of the Joint Undertaking and its Implementing Rules' (F4E_D_24F9UH)

III.2. Functions Description

(a) This subsection describes the functions with direct responsibility in the management and maintenance of the Quality Assurance Programme for items and services provided by the F4E to ITER.

(b) Responsibility for quality starts from the top with the F4E Director and the Heads of Departments and permeates through the entire organisation. Each Project Manager and Work Package Manager involved in the activities is responsible for the quality of his own work and that of their subordinates.

(c) Implementation of Quality Assurance is the daily responsibility of all persons. It is part of their professional duties to ensure that the activities each person is responsible for, are compliant with all applicable requirements of the Quality Management System and that the processes and procedures given herein are followed.

(d) Particular attention is drawn to a correct documentation of the construction process, from the design phase to the in-situ commissioning. This must be done with the tools described in the Quality Management System standards, in order to ensure availability of the relevant information and traceability of the end product over the whole project lifetime.

(e) Suppliers are bound to follow the Quality Management System for their work. They provide a dedicated Quality Plan that describes the quality provisions to be implemented in order to comply with the F4E quality requirements. Once approved by F4E, it can be used and is physically transferred to F4E at the end of the collaboration in order to ensure traceability of the delivered products over the whole project life.

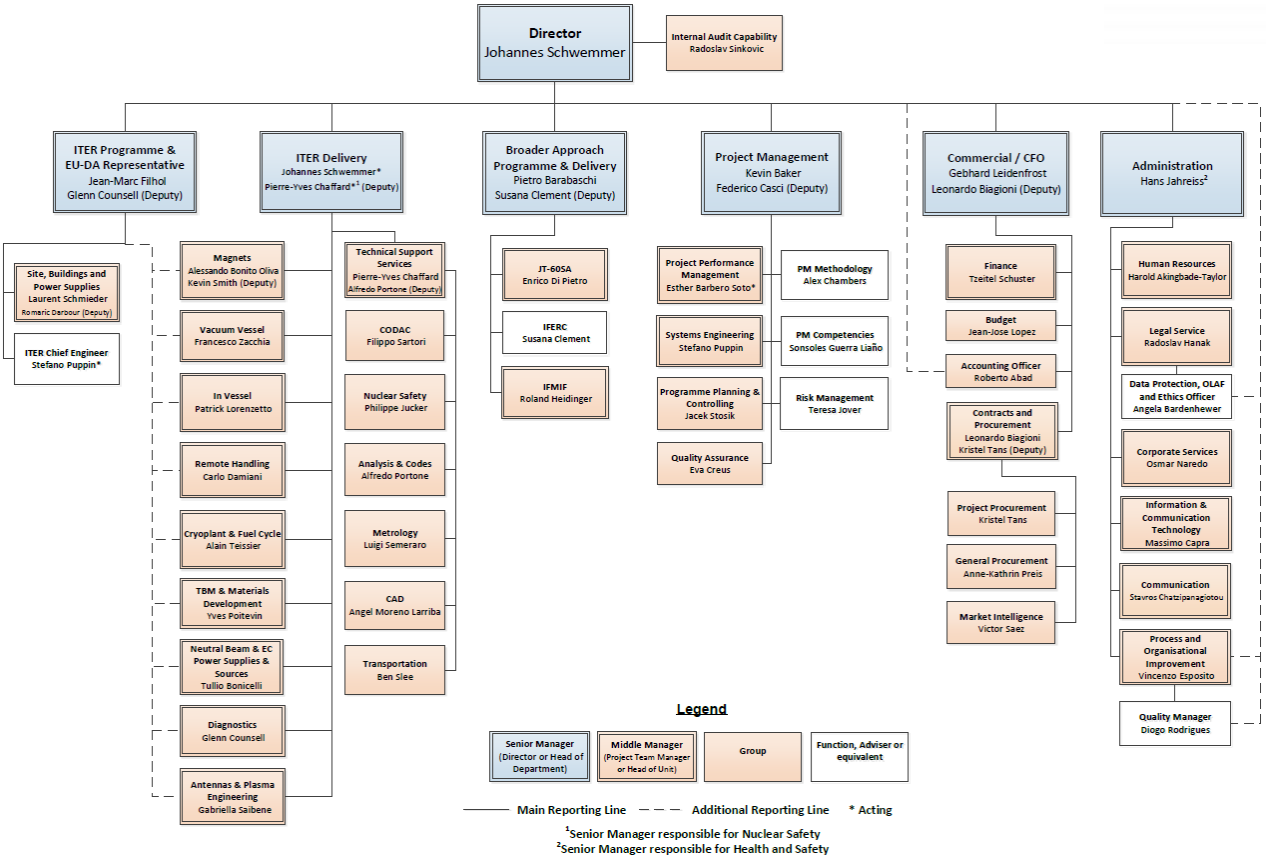


Figure 2 (III.2): Operational Structure (July.2017)

The up-to-date structure can be found on the F4E webpage.

III.2.1. F4E Director

(a) The Director is the Chief Executive Officer responsible for the European in-kind deliveries to ITER and for the day-to-day management of the F4E and is its legal representative.

(b) The Director implements the work programmes and directs the execution of the activities. He supplies the Governing Board (GB), the Bureau, the Procurement and Contracts Committee (PCC), the Technical Advisory Panel (TAP), Administration and Management Committee (AMC), the Audit Committee (AC), the Administration and Finance Committee (AFC) and any subsidiary bodies with all information necessary for the performance of their functions.

(c) The F4E Director assumes the overall responsibility for quality implemented into F4E.

III.2.2. Head of Department

(a) Each Department is headed by a 'Head of Department' nominated by the F4E Director.

(b) The Head of Department is responsible for:

(i) the management of the staff including the resource control for his Department;

(ii) the proper achievement of the activities (approved work proposals) from the endorsed Work Programme, which are in the scope of his Department;

(iii) the definition of the basic organisational structure of the department and its submission to the F4E Director for approval;

(iv) the nomination of the responsible officers on dedicated work.

III.2.3. Head of Unit (Project Team Manager)

(a) Each Unit (or Project Team) is headed by a 'Head of Unit' (or Project Team Manager) nominated by the F4E Director.

(b) The Head of Unit is responsible for:

(i) managing technically and financially the project under its unit (it has the adequate delegations from the Director to take operational decisions);

(ii) coordinating the staff in the unit;

(iii) coordinating any teams in the unit.

III.2.4. Management Meetings (Senior Management)

(a) The F4E senior management has regular meetings in order to deal with all the main concerns of F4E (scientific, financial, legal, programmatic, strategic…), the co-ordination between the different departments, their internal implementation of activities and their interfaces with the outside.

(b) Co-ordination between the different departments is ensured by the Senior Management Board.

(c) The main objectives of the Management Meetings are (quality wise):

(i) Regular review of the Quality Management System (normally once a year);

(ii) Assess the 3 or 5 top level Quality issues of the month has raised by the Quality Manager, and discuss its actions;

(iii) Assess the 3 or 5 top level operational QA topics raised by Quality Assurance Group, and discuss its actions.

(d) The Management Meetings are composed by the heads of departments and chaired by the F4E Director. When discussing quality, the Quality Manager (for QMS) and the Quality Assurance Group Leader (for operational QA) are invited to participate.

(e) The Director defines meetings frequency.

III.2.5. F4E Quality Manager

(a) The F4E Director appoints a senior member of its staff to act on his behalf to develop and maintain the Quality System: the Quality Manager.

(b) The missions of the Quality Manager (QM) are:

(i) To define, maintain, improve and monitor the effectiveness F4E's Corporate Quality Management System (QMS), the Quality Policy, Quality Objectives and improvements.

(ii) To define and develop the specific Quality Programmes and the General requirements on the Quality Management System of the suppliers (QA-115) as part of the management system definition.

(iii) To plans and manage the F4E Corporate Quality Management System Audit Plan implementation.

(iv) Coordinates the relations with the stakeholder's quality representatives on Quality Management System issues and the propagation of ITER Quality Requirements.

(v) To define and coordinate the implementation of F4E Quality Documentation and the so called working procedures including policies, process maps and management rules; ensuring consistency and its effectiveness across the organisation;

(vi) Monitor the operational and administrative delegations ensuring that any update is implemented effectively.

(c) The Quality Manager reports directly to the F4E Director.

III.2.6. Quality Assurance Group (Leader)

(a) Support the PTs on QA and QC topics ensuring that the F4E Quality Management System (QMS) is implemented through the supply chain.

(b) Advise the PTMs and the Responsible Officers (ROs) on quality matters;

(c) Develop and maintain the annual supplier monitoring and supplier audit programmes defining the planned supplier assessment activities.

(d) Perform quality activities such as monitoring, audits, documentation review, conformance processes, etc. Perform monitoring, audits and assessments of the QMS implementation within the F4E suppliers;

(e) Ensure correct functioning of the nonconformity control process. Generate suitable KPIs to show NCR performance and trends.

(f) Monitor the QA/QC activities and identify QMS opportunities for improvement and liaise with the QM to propose changes to the QMS;

(g) Organize regularly trainings of operational QA.

III.2.7. Quality Assurance Officers (QAO)

(a) Each Department, collaborating supplier etc., shall designate sufficient number of Quality Assurance Officers (the Quality Assurance Group designates operational QAOs), according to their activities. These Quality Assurance Officers should be knowledgeable and experienced persons in Quality Management and in the work to be performed by their own department, in particular in QA and QC for QA Officers of the Quality Assurance Group (from PM).

(b) The QA Officers have the authority to access work areas of the department and have the freedom to identify problems that could result in a degradation of quality and to propose corrective actions.

(c) The main missions of the Department' Quality Assurance Officers are:

(i) To support the implementation of the F4E quality system:

(1) To implement the Quality Management System in their department and reporting to the QA Group Leader of activities problems and status related to Quality Management System implementation;

(2) To provide needed quality procedures and templates.

(ii) To support the QA Group Leader and the Quality Manager in the relationship with QA representatives of IO;

(iii) To support the project managers and work package managers:

(1) To monitor the QA activities follow-up;

(2) To manage the relationship with the suppliers QA Officers;

(3) To integrate quality requirements in the technical specification and in the management specification issued to suppliers;

(4) To assess QA plans provided by the task suppliers;

(5) To coordinate the 'nonconformities' process implementation in the contracts and support the implementation of the 'deviations' process in the contracts.

(d) The ITERP Department (BIPS) QA officers report directly:

(i) On Quality Management System matters report to the Quality Manager;

(ii) On other subjects report to the inline Management (Head of Unit/Project Team)

(e) The PM Department QA officers report directly:

(i) On QA matters report to the QA Group Leader;

(ii) On other subjects report to the inline Management (QA Group Leader)

III.2.8. Quality Coordination Board (QCB)

(a) Co-ordination between the different QA officers, in terms of quality management system, is ensured by the Quality Coordination Board.

(b) The mandate of the Quality Coordination Board is to prepare, review and monitor the Quality Management System.

(c) The Quality Coordination Board is headed by the Quality Manager and is composed by the QA Group Leader and Quality Assurance officers of all the departments.

(d) The Quality Coordination Board reports to the F4E Director, and informs other boards whenever needed.

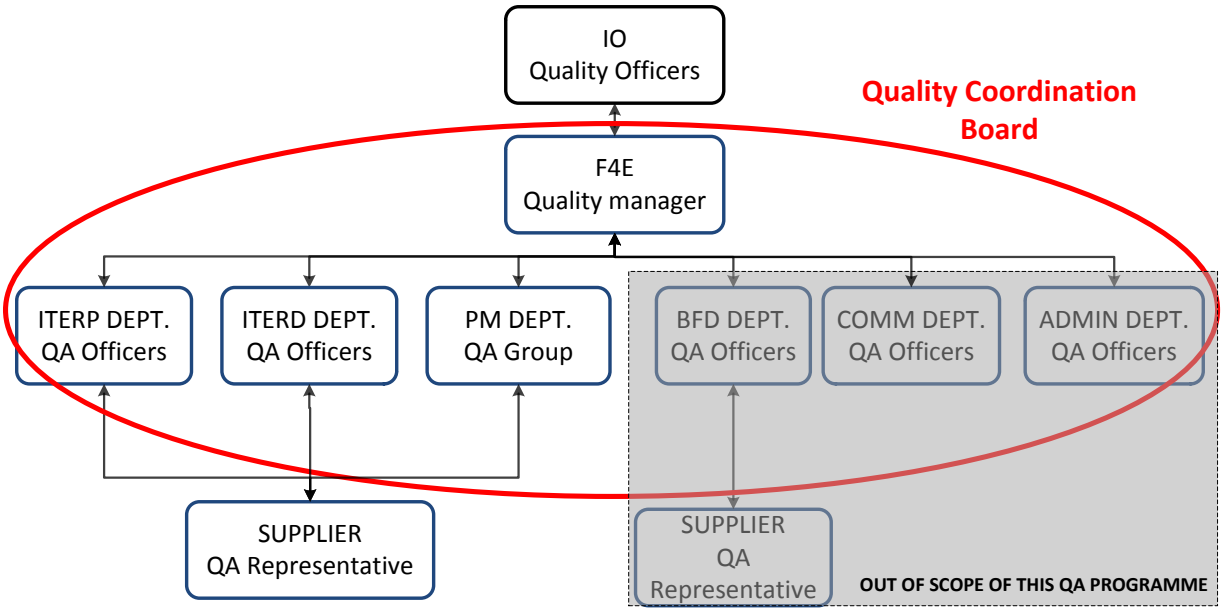


Figure 3 (III.2): Quality Coordination

III.3. Quality Assurance (QA) Programme

III.3.1. Propose

(a) The QA Programme provides the overall framework to establish, to execute, to evaluate and to continuously improve the quality management system following the same approach as outlined in ISO 9001 and in IAEA Safety Requirements GS-R-3 (2006) 'The Management System for Facilities and Activities' in order to ensure the quality of the in-kind items and services which relates to the business executed in F4E according to the ITER Agreement.

(b) This document allows F4E to act as an IO supplier with respect to French Nuclear Regulation.

(c) The present document defines the organisational structure of the organisation, the documental structure of the QA Programme and is supported, as necessary, by a set of documents that specify the activities or tasks to perform ('what', 'who', 'where', 'when', and 'how' are performed the activities/tasks).

III.3.2. Structure

(a) The present document is part of the F4E Quality Management System, and describes the specific quality management system established for managing the activities that relate to items and services provided to the ITER project.

(b) This document is organised by sections that identify the main themes. These are sub-divided by subsections and their points:

- Section I describes the scope of the Quality Assurance Programme
- Section II presents the Quality Policy
- Section III gives a summary of F4E, presents the QA Programme organisation and management. The functions/entities that have direct influence in the quality assurance are identified in this section
- Section IV presents the processes interaction within the process approach
- Section V describes F4E provisions to comply with the quality requirements

III.3.3. Review and Promulgation

(a) The Quality Assurance Programme is reviewed by the Quality Manager and senior management; its approval and promulgation is the competence of the Director.

(b) The Quality Manager has the responsibility to keep the master version on the F4E document server updated and inform the senior management.

(c) The master version being an electronic document, the Quality Manager must assure its protection against any undue change or any change that does not comply with the process 'Document Control' (PM-07, F4E_D_22KS43), the F4E Documentation Policy (F4E_D_24L87F) and the 'F4E Documentation Management System Policy (F4E_D_239SK2).

III.3.4. Versions and Issues

(a) The evolution of the Quality Management System and the QA Programme implies revisions to the sections of the QA programme. Effected changes from the last revision are registered on the 'Change Log' (present after the cover page and in the documentation system).

(b) The version state is identified and will be changed whenever the programme is partly or totally reviewed by the senior management. This decision is made by the Director whenever needed.

III.3.5. Distributions and Control

(a) The officer in charge of the preparation of the QA Programme is the Quality Manager.

(b) Printed copies of the QA Programme are not controlled (are considered for reference only). It is the responsibility of users to ensure that they are using the correct revision of this document by checking the document version level with that held on the F4E electronic document management system (master version).

Reference and Applicable Documents

PM-07	'Document Control' Process (F4E_D_22KS43)
PM-46	'QMS Maintenance' Process (F4E_D_22HK8L)
---	F4E Documentation Policy (F4E_D_24L87F)
---	F4E Documentation Management System Policy (F4E_D_239SK2)

III.4. Quality Approach to Safety

(a) F4E is not the Nuclear Operator, so not directly responsible for the assembly and operation of the nuclear facility. Nonetheless as a major contributor and the principal *external intervenient* (ASN's expression) to the ITER Project, F4E has the responsibility to demonstrate a good Safety Culture.

(b) Safety Culture can have a direct impact on safe performance. If someone believes that safety is not really important, even temporarily, then workarounds, cutting corners, or making unsafe decisions or judgements will be the result, especially when there is a small perceived risk rather than an obvious danger.

(c) F4E is committed into applying and propagating in its supply chain the ITER Policy on Safety, Security and Environment Protection Management [9]

III.4.1. Safety Culture

(a) Taking into account its scope, F4E broadly follows the definition below:

> *Nuclear safety culture is defined as the core values and behaviours resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment.*

(b) The Safety Culture in F4E is based on the following concepts:

(i) Safety has higher priority

(ii) The quality system is used to ensure safety

(iii) Commitment from management and staff

(iv) Training on Safety and Quality is a continual exercise

(v) Decision-making reflects safety first

(vi) Continual Improvement permeates from quality to safety, and from safety to quality

III.4.2. Objectives of Quality towards Safety

(a) Quality Management can be thought of as a way of managing a nuclear project to ensure that all project activities are accomplished in a planned, systematic, and controlled way. If such a system is operating well, there is a high degree of confidence that all project activities will be performed correctly and that failures, mistakes, and deficiencies in the design, construction and operation of the nuclear power will be avoided, or at least detected and rectified in time.

(b) F4E for the ITER Project implements the Quality Objectives towards Safety summarised as follows:

(i) Ensure that supplied or installed items meet the specified requirements as defined in the Preliminary Safety Report (DAC files), PAs/ITAs and the supporting design and technical specifications, drawings, etc.

(ii) Ensure that nonconformities and process deficiencies are reported and resolved through approved dispositions / resolutions and follow-up actions to confirm acceptable results.

(iii) Provide documentation that confirms compliance with applicable regulations and project requirements, and is sufficient to support production operations.

(iv) Provide early identification of process failures and hardware nonconformities to minimise rework cost and schedule impacts.

III.4.3. Propagation of the Nuclear Safety Requirements along the F4E Supply Chain

The following table identifies the requirements of the INB Order and the operator, and in which F4E document they are propagated.

Requirement to Propagate	INB Order art.	Propagation by F4E
Supply Chain and Surveillance of Suppliers Carrying Out PIA	2.2.1 to 2.2.4, 2.5.4	F4E requirements on Suppliers for the propagation of safety requirements throughout the Supply Chain are divided between F4E-QA-113 for requirements relating to the management of the Defined Requirements for PIC and F4E-QA-115 [4] for the management of PIA and QA functions. The F4E Surveillance of the F4E Supply Chain is in the F4E Supervision Plan, the requirements for Suppliers to perform supervision activities of subcontractors are within F4E-QA-115 [4].
Propagation, Recording and Reporting of Defined Requirement for PIC	2.5.1	The requirements for Suppliers to receive, manage and update the Defined Requirements for PIC and the references to their Verification Activities and evidence records is contained at F4E-QA-113. It specifies the Nuclear Safety Compliance Record (also called Nuclear Safety Control Plan in some contracts) and the Nuclear Safety File to be rendered by the Supplier.
Identification and Reporting of PIA	2.5.2, 2.5.3, 2.5.6	The F4E requirements for the propagation of PIA are stated within F4E-QA-115 [4]. It includes the safety requirements to: - Produce a Record list of PIA - Identify the codes and standards to which the PIA are being performed, which are known as Defined Requirements (Safety) when they apply to PIA. - Keep the updated evidence records of all PIA, index them and hand them up the Supply chain - keeping a full set of copies in a secure store for a further period defined by the Operator. The 'F4E PIA Guideline' to the selection criteria for PIA has been provided to assist Suppliers and their subcontractors to identify the activities which can be PIA, together with an explanation of the rationale for the selection of PIA.
Management of the Qualifications and Experience of Personnel	2.5.5	Each Supplier is required to have in place a system to manage the qualification and experience of personnel. The requirements are stated within F4E-QA-115 [4].
Management of Validation and Verification and Use of Different Staff	2.5.5 and 2.5.3	The management of Validation and Verification are stated within F4E-QA-115 [4]. The requirements to use different SQEP staff for the verification and validation to those performing the work are within F4E-QA-115 [4]
Identification and Management of Deviations and Nonconformities	2.6.1 to 2.6.5	The management of Deviations and Non Conformities are stated within F4E-QA-115 section 2.2 [4]
Reporting back to the INB Operator the Information Required for the Operating Licence Application PIA	2.5.5, 2.5.7	The requirement for a dossier called Nuclear Safety File and its contents are specified in F4E-QA-113. This is not the same dossier as the one required to be prepared by the operator. However the information within it will contribute directly to the preparation of the operator dossier.
Design methods, tools and their validation	3.8	The requirements for design of PIC carried out by F4E or its supply chain are contained in F4E-QA-114. In complement F4E-QA-115 Sec 2.5.6 addresses the Supplier requirements for Verification and Validation of Calculation and Modelling Tools.

Table III-1 Propagation of the Nuclear Safety Requirements

Reference and Applicable Documents

F4E-QA-013	Management of the Propagation of Generic Safety Requirements in the Supply Chain F4E_D_23CA9U
F4E-QA-016	F4E Supervision of the PIC Supply Chain F4E_D_23JXHS

F4E-QA-113	Propagation of Safety Requirements in the Supply Chain F4E_D_27MKTL
F4E-QA-114	Instructions for Suppliers Performing Design Analysis F4E_D_22FR5T
---	PIA Guideline F4E_D_27WDLC

IV. PROCESSES INTERACTION

(a) The F4E Quality Management System (QMS) is customer oriented, taking into account equally:

(i) the requirement definitions;

(ii) the customer feedback;

(iii) F4E compliance with the requirements

(b) The QMS becomes more efficient as its capacity to meet these requirements grows. This way the efficiency of the QMS is continually assessed and measured through the monitoring indicators of processes and the fulfilment of the specified Objectives.

(c) The processes interaction in F4E is represented in the figures below.

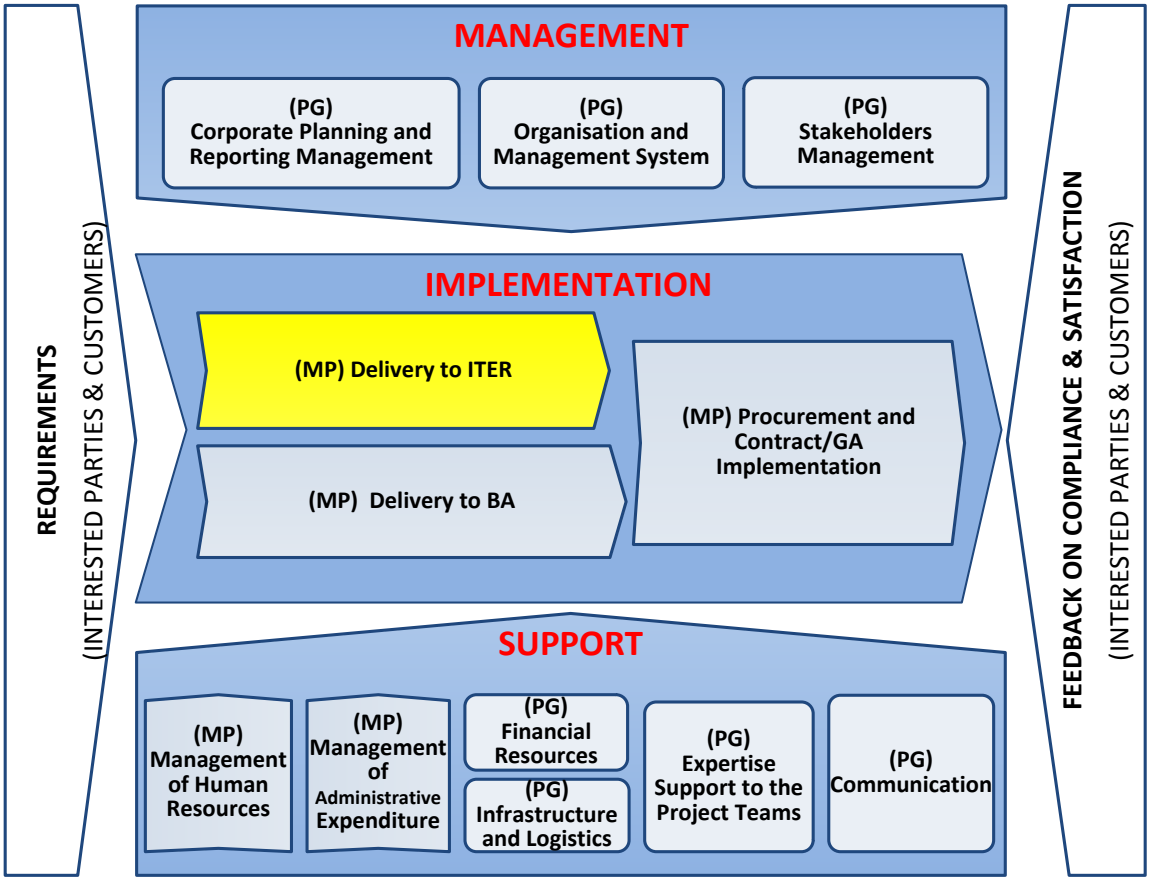


Figure 4 (IV): F4E Process Map

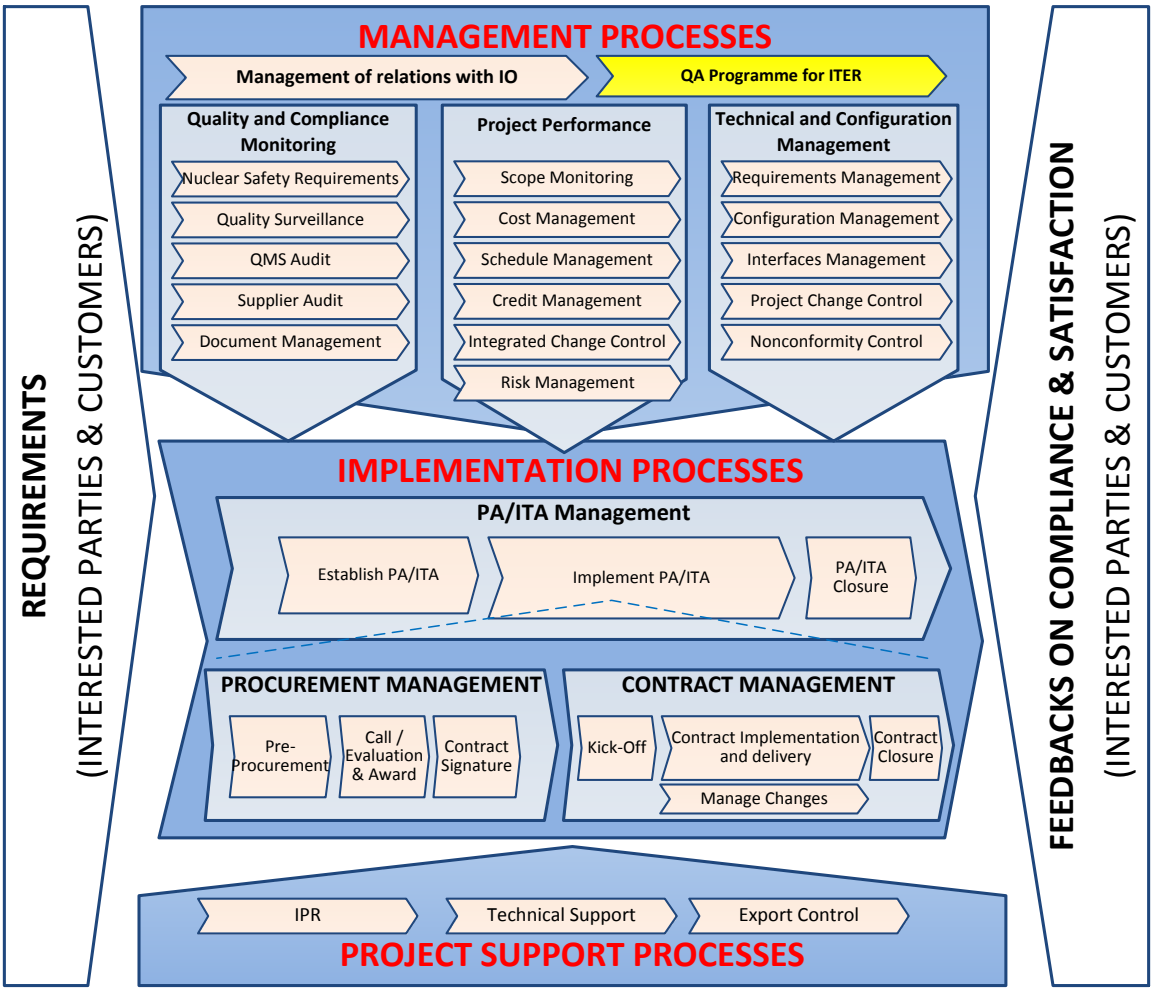


Figure 5 (IV): ITER Delivery Process Map

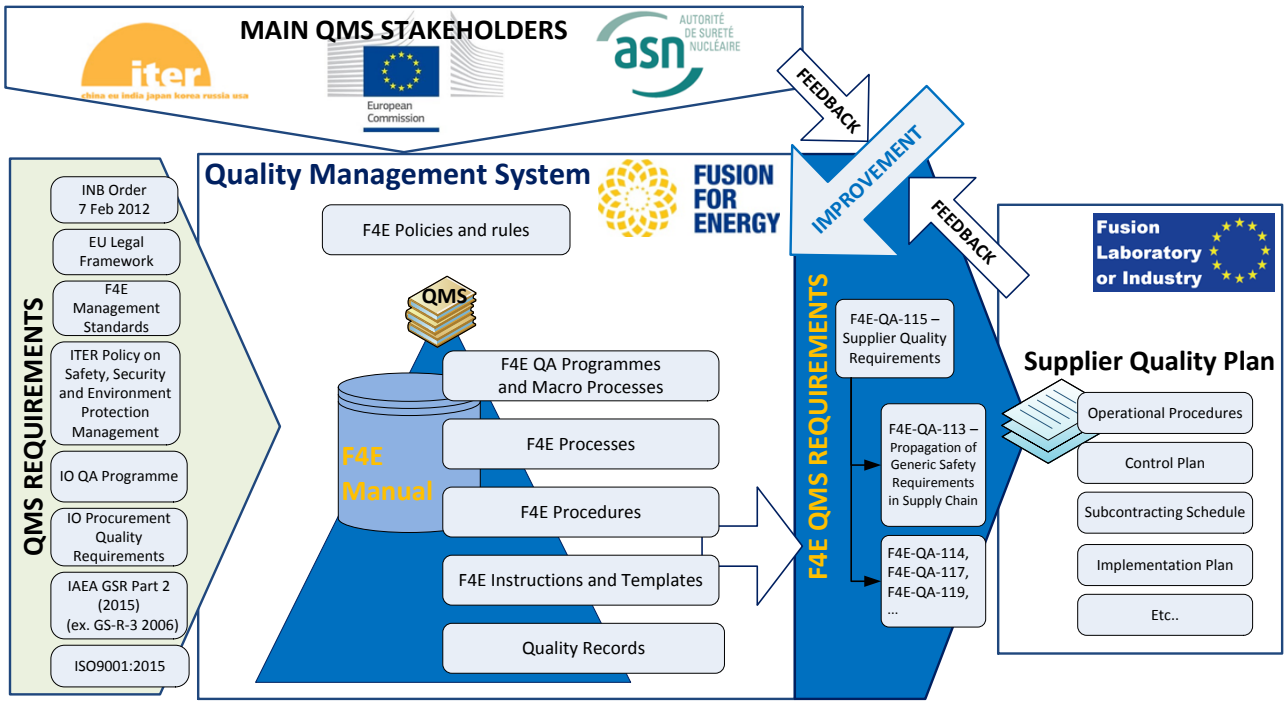


Figure 6 (IV): QMS Process Map

V. QUALITY MANAGEMENT SYSTEM

V.1. General Requirements

(a) This QA Programme is structured and adapted to the specific type of activity of F4E providing items and services to the ITER project, having as objective to establish a relationship between organisational structures, procedures, processes and other associated resources.

(b) The implementation and evolution of the QMS, and in particular the QA Programme, lays on a continual improvement methodology, in which, the actions 'plan', 'do', 'check' and 'act' are inherent to a global vision of all activity performances, according to the following steps:

(i) Quality Policy and Objectives: establish the Quality orientations and intentions;

(ii) Planning – identify the processes and their application within the organisation, the sequence an interaction of them, identify the risks associated, evaluate the risks, establish the criteria and method to ensure that the operation, control and monitoring of the processes are effective;

(iii) Execute and Implement – realization of the established activities;

(iv) Monitor, analysis and corrective actions – measure the performance of the QMS and prevent the occurrence of nonconformities, providing the necessary resources and information;

(v) Continual Improvement – implement the necessary actions to achieve planned results and the continual improvement of these processes.

(c) To ensure the control over any subcontracted process, the subcontract shall be awarded according to the adequate procedure (as defined in V.5.9).

V.1.1. Quality Classification

(a) Quality Assurance levels to be applied to items shall be tailored to their safety and impact importance. In particular, grading of quality requirements (including nuclear safety) shall be applied in accordance with the quality classification defined in the procedure 'Quality Classification' compatible with the ITER Quality Classification.

(b) The quality classification of a given procurement package or sub-package should be defined in the associated procurement arrangement.

Reference and Applicable Documents

F4E-QA-010	'Quality Classification' Procedure (F4E_D_22MD99)

V.2. Documentation

(a) The prepared QMS documentation constitutes and added value to F4E, as it provides the statement of intent and consequently assures the consistency of actions to develop.

(b) Thus, it provides the information necessary for the maintenance of the QMS and training schemes developed, even assuming an essential role for the proper planning and implementation of the necessary corrective actions.

(c) The Quality Management System documentation is organised according to the hierarchic levels defined in the figure below.

(d) The term document refers to information and the medium that is used to bring it into existence. A document can be digital or physical (e.g. specifications, quality manuals, quality plans, records, and procedure documents).

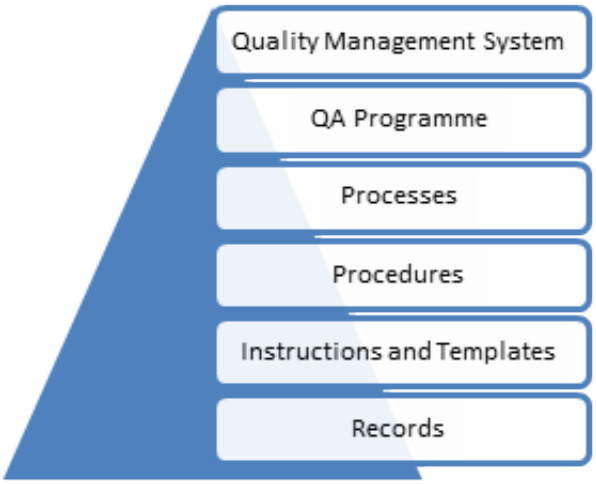


Figure 7 (V.2): Documentation Hierarchy

Quality Management System / Policy - document that provides consistent information, both internally and externally, about the F4E Quality Management System.

QA Programme / Plan – a description of the technical QMS and systems integration / interface harmonization management for Broader Approach and ITER procurement items

Processes - documents that provide information about how to perform the Organisation activities and processes consistently.

Procedures - describe a set of tasks, typically performed by role or a team, often part of a process activity but not exclusively.

Instructions and Templates - detailed descriptions of a task, explaining step by step how to perform it.

Records - documents that provide objective evidence of activities performed or results achieved.

(e) This Quality Assurance Programme, and all the quality documents, cover all F4E activities for the ITER project.

(d) The preparation, maintenance, review, approval and distribution of quality documentation is:

(i) ruled by the F4E Documentation Policy (F4E_D_24L87F);

(ii) described in the process 'Document Control' (PM-07, F4E_D_22KS43);

(iii) reviewed and approved as per the current Quality Documentation Sign-Off Authority.

(f) These documents ensure:

(i) that every actor 'needing to know' (F4E, IO or Supplier), has ready access to all the up to date information he needs to perform his task;

(ii) that all documents and records are properly identified, approved, distributed and stored;

(iii) that all quality documents are:

(1) archived for appropriate time;

(2) protected;

(3) well-preserved;

(4) easily accessible.

(iv) that associated to the 'Configuration Management Plan', 'Deviation Control' and 'Nonconformity Control' processes, all the needed documents and records are available in order to allow:

(1) evidence that nuclear safety requirements are fulfilled;

(2) traceability of activities and results performed in the course of the tasks;

(3) traceability of the deviations between deliverables and requirements.

Reference and Applicable Documents

PM-06	'Deviation Control' Process (F4E_D_22CCM4)
PM-07	'Document Control' Process (F4E_D_22KS43)
PM-35	'Nonconformity Control' Process (F4E_D_22MDXC)
PM-42	'Corrective Action Request' Process (F4E_D_29KV8Z)

---	F4E Documentation Policy (F4E_D_24L87F)
F4E-IO CMP	F4E-ITER Project Configuration Management Plan (F4E_D_22P3BC)
F4E-QA-112	'Naming Convention' Instruction (F4E_D_22GGJ4)

Applicable process flowchart

Annex 1	(PM-07) Documentation Flowchart

V.3. Management Responsibilities

V.3.1. Management Commitment

The F4E Director shall provide evidence of his commitment to the development and improvement of the QMS by:

(i) Complying with the IO requirements, as well as regulatory and legal requirements;

(ii) Establishing the Quality Policy and the Quality Objectives;

(iii) Conducting management improvement reviews;

(iv) Ensuring the necessary resources availability.

V.3.2. Stop Work Authority

(a) All F4E personnel with operational responsibilities has the right and responsibility to notify delegated management of unsatisfactory work or unapproved practices and, if necessary, stop unsatisfactory or unsafe work or control further processing, delivery, or installation of nonconforming materials.

(b) Restarting stopped work shall be by an established process that is commensurate with the complexity and significance of the stopped work and the reason it was stopped. As part of their training/F4E policy, personnel performing F4E activities shall receive instructions on the authority and the process to stop work.

(c) For stopped work associated with defined safety systems, notification shall be given to the IO explaining reason for stop work and proper justification for restarting that work activity.

V.3.3. Procurement Arrangement and ITER Task Agreements Requirements Focus

The legal and regulatory requirements related to the products developed by F4E are determined by meeting the ITER Procurement Arrangements and Task Agreements requirements. These requirements are fulfilled through methods and practices. All the Procurement Arrangements and Task Agreements shall properly define the specific requirements for each product. In the same way, the quality objectives are considered as well as all the processes interactions and all the necessary documentation to achieve the product.

V.3.4. Planning

V.3.4.1. Quality Objectives

F4E has its Quality Objectives defined internally for all functions and levels relevant to the QA Programme. The objectives are measurable and consistent with the Quality Policy and include a commitment to continual improvement. The objectives are accompanied by adequate indicators.

V.3.4.2. QA Programme Planning

(a) The Director shall:

(i) Ensure that all the resources necessary to reach the Quality Objectives are identified and planned. In F4E they are established:

(1) The responsibilities and authorities to reach the Objectives in each function and relevant organisation level;

(2) The means and deadlines to meet the Objectives and the respective schedule.

(ii) Periodically review the implementation processes, the Supplier Quality Requirements and evaluate the QA Programme; this activity is performed with the participation of the Quality Manager and Senior Management.

(b) The integrity of the implemented QA Programme is held through all the existing documentation, as well as through the process approach and the F4E Manual of procedures (F4E intranet repository), which relates all the requirements, and its documentation (main IO QA and management requirements in Annex 9).

V.3.5. Management Review

(a) Management shall yearly assess the status of the quality system in F4E. This shall be done in the Improvement Steering Committee and will include the key documents: an assessment of the adequacy of the QA Programme and F4E-QA-115 and the correct propagation of the quality and safety requirements from IO.

(b) Inputs to the assessment include performance measures, the results of audits and other assessments, IO and regulator feedback, nonconformities, corrective and preventive actions and identified opportunities for improvement.

(c) The assessment identifies weaknesses and barriers to achievement, decides on action for their amelioration, and identifies any need to change policies, plans, and objectives.

Reference and Applicable Documents

PM-42	'Corrective Action Request' Process (F4E_D_29KV8Z)
PM-46	'QMS Maintenance Process' (F4E_D_22HK8L)

V.4. Resources Management

(a) The necessary resources to implement, maintain and improve the QA Programme activities are defined in the functions description and in the system documentation. The resources are managed, so that they can always be readily available, to achieve customer satisfaction.

(b) Similarly, in F4E the resources are identified, made available and maintained, particularly where it concerns the necessary work space, related means, equipment and services to achieve the product conformity.

(c) The provisions implemented by F4E ensure its customers that:

(i) The F4E Staff involved in a project is competent and in sufficient number in regards with the work to perform.

(ii) The supplier Staff working for F4E is competent and in sufficient number in regards with the task to perform.

(iii) The need for qualified equipment is properly defined, specified to the supplier and controlled during the work implementation.

(d) These provisions are described per project/procurement in the 'Project Implementation Plan'.

Reference and Applicable Documents

F4E-QA-205	'Project Management Plan' for PA Template (F4E_D_22FUSH)
F4E-QA-205a	'Project Management Plan' for ITA Template (F4E_D_22CECH)

V.4.1. Training

V.4.1.1. Training Requirements

The F4E personnel will be trained, as appropriate, on F4E's specific policies & regulations, plans, and procedures for performing assigned tasks, including an annual training plan for each individual. Documentation of personnel training will be established and include such items as attendance lists, training outlines, and read-and-acknowledgment sheets, as appropriate, for the training given.

Reference and Applicable Documents

Staff Regulations	'Staff Regulations of Officials and the Conditions of Employment of other Servants of the European Communities'
F4E(07)-GB03-17	'Decision on the secondment of experts (Seconded National Experts - 'SNEs') to the Joint Undertaking'

V.4.1.2. Task-Specific Training

Training of project personnel will focus on the necessary knowledge and skills to perform the foreseen project functions. Training ensures that project personnel:

(i) performing work affecting safety and/or product quality have the necessary competence;

(ii) are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;

(iii) are aware of the QA requirements, project terminology and the organisational arrangements;

(iv) their knowledge is up-to-date on the changing requirements and conditions;

(v) understand assessments and the importance of continual improvement.

V.4.1.3. Qualification in Special Processes

(a) The qualifications of personnel who perform special processes such as welding, heat-treating, and non-destructive examination are the responsibility of the organisation assigned for the work activity. The standard of qualification of the personnel will be in accordance with specifications supplied by F4E (which are compatible with the specifications of the Procurement Arrangement with IO).

(b) These organisations will establish and maintain special process procedures and the documentation of personnel qualifications.

V.5. Project Management

(a) All the necessary processes to the F4E product achievement (items and services) are identified, taking into account its stages, activities, flows, training needs, materials and equipment, monitoring steps and other identified resources.

(b) All personnel have the responsibility over the execution of the product achievement activities assigned to them, according to the Quality Policy, the established objectives and the system documentation. Personnel have given the authority to perform their tasks, to comply with the specified requirements.

(c) The F4E Director nominates a Project Manager as the technical and management interface with the customer for *Procurement Arrangement* with IO or/and *ITER Task Agreement* (the project) and also between the relevant F4E Suppliers.

(d) The management of the ITER projects can be performed with IO in a non-integrated project team, or on an Integrated Project Team.

(e) Non-integrated Project Team

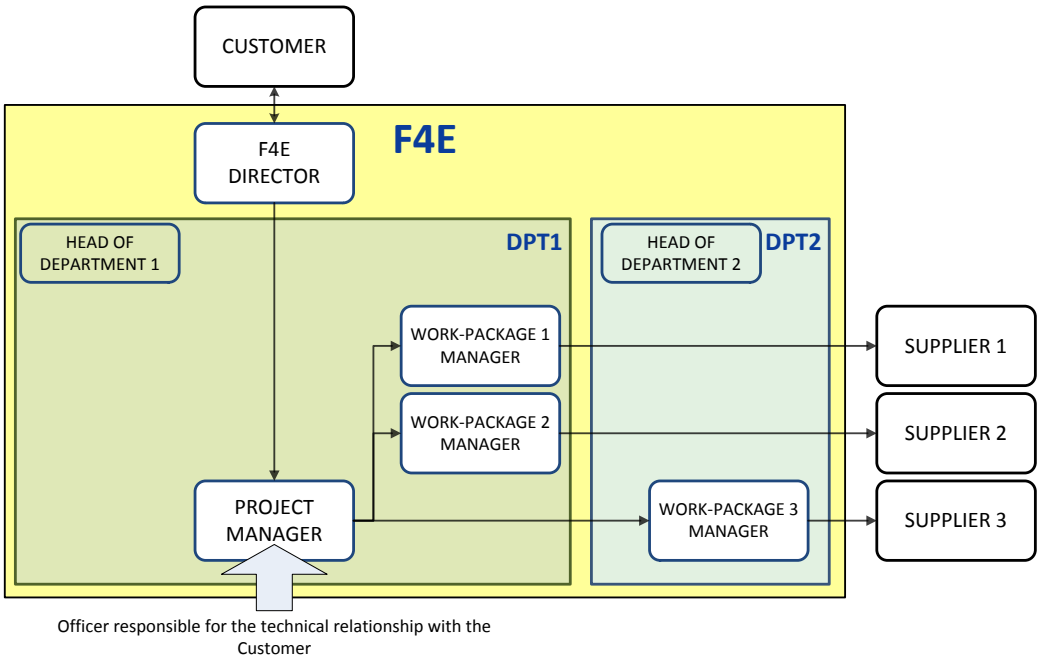


Figure 8 (V.5): Project Responsibilities on non-integrated Project Team

(i) The Project Manager is then responsible:

(1) to negotiate the final arrangements/agreements with the customer (PA/ITA as per §5.1 and §5.2);

(2) to issue and implement the Project Management Plan;

(3) to manage the interfaces between the work packages and all others provisions needed to properly monitor the project;

(4) to integrate the work packages of the project;

(5) to be the interface point for the customer for that Project.

(ii) The F4E Project Team, led by the Project Team Manager, is responsible to technically, commercially and financially manage the F4E contracts. Including:

(1) Call launch, Evaluation and Award of F4E Contracts;

(2) Budgetary and Legal commitment of F4E towards the F4E Suppliers;

(3) Decisions on modification of the F4E contracts (claims, indexation, options, amendments, deviations, etc.);

(4) Review and Approval of Supplier Technical and Quality Documentation;

(5) Supplier surveillance, monitoring and follow-up and monitoring;

(6) Archival and maintenance of the contractual documentation;

(7) To manage the guarantees, invoices and payments of the F4E contracts.

(f) Integrated Project Team

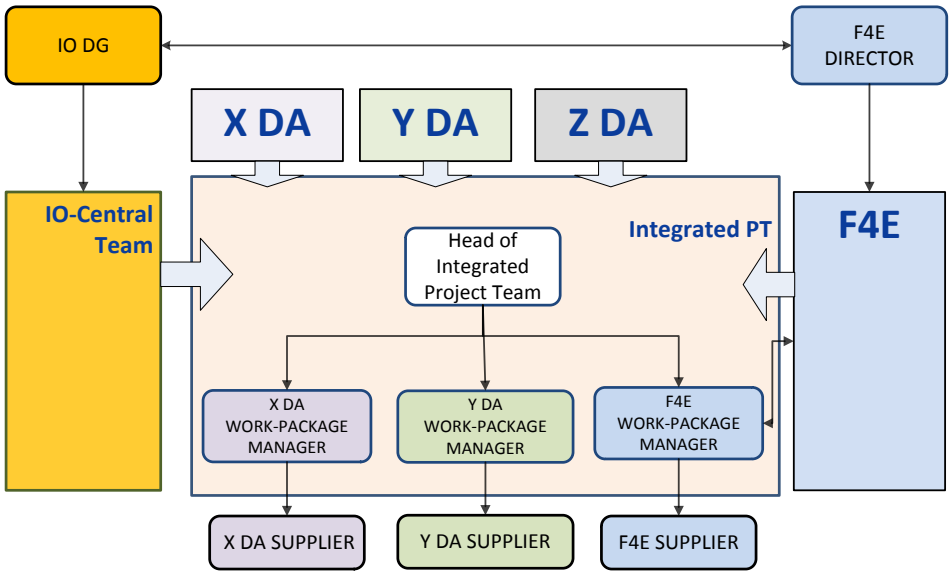


Figure 9 (V.5): Project Responsibilities on Integrated Project Team (with IO)

(i) The financial and contractual responsibilities remain with the IO-DAs Authorising Officers with respect to the IO-DAs' contracts and with the IO-CT Authorising Officer with respect to the IO-CT contracts;

(ii) Staff hierarchical line management remains on DAs and IO-CT respectively;

(iii) The integrated Project Team is then responsible for the technical implementation on the related PA/ITA and the technical follow-up of the dependent contracts:

(1) Review and Approval of Supplier Quality Documentation (Quality Plan, Control Plan, Quality Procedures, Subcontractor's quality documentation);

(2) Supplier Surveillance, main Hold Points and Authorisation to Proceed points)

(3) Supplier follow-up and monitoring, witness of activities, review of technical documentation and technical assessments.

(iv) F4E (IO-DA) maintains the following responsibilities on the F4E's contracts (non-exhaustive listing):

(1) Call launch, Evaluation and Award of F4E Contracts;

(2) Budgetary and Legal commitment of F4E towards the F4E Suppliers;

(3) Decisions on modification of the F4E contracts (claims, indexation, options, amendments, deviations, etc.);

(4) Archival and maintenance of the contractual documentation;

(5) Technical Assessment and Acceptance of Contractual Deliverables;

(6) Assessment and management of invoices, payments and guarantees related to the F4E Contracts.

(v) The technical roles in the F4E processes can be interchanged in the Integrated Project Team (performed by IO-CT or IO-DA personnel):

(1) Technical Project Officer (TPO), Coordinator (COO), CAD Officer (CADO), Project Team Manager (PTM) when not the Authorising Officer

(2) Horizontal operational activities: Project Performance Support Officer (PPMSO), QA Officer (QAO), Safety Officer (SAO), and Project Risk Officer.

V.5.1. Establishment of Procurement Arrangement with IO

(a) The **Procurement Arrangement** is negotiated between the project manager and the customer, reviewed by the Project Team Manager (with the support of the Quality RO, Procurement Officer and Legal Officer) and then approved by the F4E Director supported by the F4E Senior Management. The Director ensures the customer needs and requirements are properly understood and allocated to the work.

(b) The procurement arrangement defines:

(i) the scope of the supply, services or work to be provided by F4E, its technical and quality requirements;

(ii) the management specifications, to be implemented by F4E, in accordance with the quality classification of the procurement package and its sub-systems;

(iii) the legal provisions applicable.

(c) In this step, the customer may express specific wishes and requirements relative to its involvement in the procurement process (advices on the quality requirements and other selection criteria, advisory role in the selection process, etc.)

Reference and Applicable Documents

PM-79	'PA Preparation' Process (F4E_D_26GDU8)

V.5.2. Establishment of ITER Task Agreement with IO

(a) The **ITER Task Agreement** is negotiated between the project manager and the customer, reviewed by the Project Team Manager (with the support of the Quality RO and Procurement Officer) and then approved by the F4E Director (or its Delegate). The Project Team Manager ensures the customer needs and requirements are properly understood and allocated to the work.

(b) The task agreement defines:

(i) the scope of the supply, services or work to be provided by F4E, its technical and quality requirements;

(ii) the task monitoring, the general planning, the responsibility sharing and administrative provisions;

(iii) the project management structure applicable.

Reference and Applicable Documents

PM-02	'ITA Signature' Process (F4E_D_22GUU4)

V.5.3. Implementation Planning

(a) In F4E the Planning activities are performed and implemented to ensure that all the specified requirements where adequately addressed and that the design stages and their responsibilities are identified according to each project to develop.

(b) The **Project Management Plan**, issued by the 'Project Manager', describes the provisions implemented to comply with the customer requirements and the project reporting rules towards the F4E Heads of Department. The Project Management Plan governs all interfaces within the project and in particular, those between the project manager and the work package managers (see guidance/template F4E-QA-205 - PA: F4E_D_22FUSH, ITA: F4E_D_22CECH).

(c) It defines the division of the project in the various work packages that have to be contracted with economic operators. These work packages are issued from the development and validation strategy according to a risk identification and analysis.

(d) The Project Management Plan defines the main activities and their associated milestones for each work package.

(e) These milestones are defined in order to ensure a proper management of interfaces between the work packages and to allow the project manager to control the overall project.

(f) According to the requirements of the customer, the Project Management Plan refers to F4E detailed procedures for the following points:

(i) resource management;

(ii) internal control and quality audit;

(iii) information, documents, and records management;

(iv) configuration management and deviations management;

(v) nonconformity management, corrective and preventive actions;

(vi) procurement and grant management.

(g) The estimated value of the contracts is assessed with the support of the Contracts and Procurement Unit (COM/CPU) and the Programme Planning & Controlling Group (PM/PPC) in order to define, together with other criteria, the procurement procedure applicable.

(h) The Director ensures the customer needs and requirements are properly allocated to the work packages and that the development and validation strategy is defined and agreed with the customer for each of them.

Reference and Applicable Documents

PM-01	'ITA Implementation' Process (F4E_D_248JX8)
PM-39	'PA Implementation' Process (F4E_D_24DDKD)
F4E-QA-205	'Project Management Plan' for PA Template (F4E_D_22FUSH)
F4E-QA-205a	'Project Management Plan' for ITA Template (F4E_D_22CECH)

V.5.4. Management of Product Requirements

(a) F4E has implemented a Requirements Management & Verification Process (RMV) for the lifecycle of the systems/structures/components within its ITER scope projects and adopted DOORS as the requirements management and verification database support tool (RMVDB).

(b) The process applies to Procurement Arrangements of maturity Functional Specification and Detailed Design.

(c) F4E uses the RMV process along with the RMVDB to:

(i) Manage the requirements identified, baselined, and specified in the definition of the deliverables during system design;

(ii) Control bidirectional traceability from IO requirements to F4E requirements to Supplier requirements of the different systems/structures/components' under F4E procurement packages;

(iii) Provide the infrastructure to effectively perform the requirements verification

(iv) Manage the changes to established Requirements baselines over the life cycle of the products.

Figure 10 (V.5): Project Requirements Lifecycle

Reference and Applicable Documents

---	F4E 'Systems Engineering Management Plan' (F4E_D_2487GL)
QA-019	F4E 'Requirements Management & Verification' Procedure (F4E_D_2296FP)
QA-119	Requirements Management & Verification (RMV) Requirements for F4E Suppliers (F4E_D_242DG5)

V.5.5. Communication with IO and other DA's

F4E maintains the communication active with IO and the other DA's through the pre-defined communication channels. This communication is related to project information, procurement arrangement processing and IO queries, and its treatment is made according to the system documentation.

V.5.6. Research and Development (R&D)

(a) R&D work is necessary to generate appropriate data for the ITER project and also for the F4E contribution to the ITER project. The data needed shall be as clearly defined as possible within F4E and interface with IO, in order to develop the most efficient method of obtaining the data. These R&D tasks shall be performed using established technical specifications, requirements and criteria.

(b) R&D activities must be fully documented in order to support a critical peer review and provide traceability of the derived data throughout the development process. Any assumptions used in developing the needed data must be identified and the use justified. The principal concerns for these R&D activities are the validity and traceability of the resultant data.

(c) The quality programme controls that the F4E suppliers shall apply to R&D activities are those good scientific practices that provide traceability and validity of the data. Any data to be used as inputs that were not obtained under a formalized quality programme will be reviewed and evaluated for acceptability by the Project Manager and IO. The supplier's procedures will address such activities as peer review and technical review for the qualification of the data.

(d) The designs of experimental systems used in the development of data need to be formally reviewed (design review) to verify their adequacy for developing the desired data. Critical aspects of the experiment system that affect experimental results will be fully documented with appropriate records retained.

V.5.7. Design Management

(a) The Project Manager shall implement the design controls for applicable design activities assigned by the IO. The preparation, review, and approval of design documents for the assigned tasks are accomplished through controlled procedures that establish the approval authorities and responsibilities.

(b) F4E will use technical review meetings, regular weekly discussion and status reports, management review meetings, quarterly review meetings, and periodic design reviews as some of the design control techniques used in the review and approval of design work.

V.5.7.1. Design Input

(a) Each Project Manager shall ensure that all design tasks will be performed using technical specifications, requirements and criteria that are established in:

(i) functional and performance requirements;

(ii) applicable statutory and regulatory requirements;

(iii) where applicable, information derived from previous similar designs;

(iv) other requirements essential for design and development.

(b) The Project Manager shall review that the design input shall be suitable including complete, unambiguous and not in conflict with each other.

(c) Input requirements are incorporated into design documents, descriptions, specifications, or drawings by specific statement or by reference. The level of authority for review and approval of design input will be established by the project manager based on the importance of the structure, system, or component to overall facility safety and reliable operation.

(d) Following initial preparation, a design document or a change thereto is reviewed by the appropriate Responsible Officer, as needed, to verify that the document contains the applicable requirements. Review criteria include regulatory requirements; applicable codes and standards; quality requirements; suitability of materials and parts, nuclear physics, seismic stress, radiation, and safety analyses; access for inspection, maintenance, and repair; and testability. Also included is the establishment of acceptance criteria.

V.5.7.2. Design Interfaces

The designated design authority that has design responsibility will implement appropriate design controls and approve procedures that provide for both internal and external design interfaces. Each system will include the identification of all physical and functional interface requirements imposed by that system upon other systems.

V.5.7.3. Design Records

The final Design Report, which will consist of design documents, such as 'as-installed drawings', design review records, and associated changes, will be collected, stored, and maintained in a systematic and controlled manner. The record system procedures will specify the specific controls and identify the design records to be maintained. Typically, design records include design input basis documents, calculations, design development computer models, approved drawings, specifications, and computer programs used in design calculations.

V.5.7.4. Design Verification

(a) During the design process, design verification activities will be performed by a suitably qualified design expert to ensure the adequacy of their designs. Design adequacy may be verified through one, or a combination, of the following approaches:

(i) Conducting design reviews;

(ii) Performing independent confirmatory calculations;

(iii) Use of qualification tests or prototyping;

(iv) Benchmarking against a similar successful design;

(v) Project management meetings that produce written documentation.

(b) Design verification shall be conducted by individuals or groups other than those who originally performed the work in case that importance of the items and services requires independency of verification (for QC1 and PIC they shall be conducted by independent persons not in the same management chain).

(c) Computer programs used to provide data that serve as the design basis of a structure, system, or component will be formally verified and validated. The verification process will demonstrate that the computer program produces correct solutions for the encoded mathematical model within defined limits for each parameter employed. The validation process is to show that the encoded mathematical model produces a valid solution to the physical problem associated with the particular application.

V.5.7.5. Qualification Testing

Qualification testing to verify the acceptability of a specific design will be conducted in accordance with approved procedures that address, at a minimum:

(i) Use of adequate instrumentation;

(ii) Provisions for test monitoring;

(iii) Specification of suitable environmental conditions;

(iv) Delineation of test prerequisites, such as calibrated instrumentation, appropriate equipment, trained personnel, and data acquisition equipment;

(v) Demonstration of acceptable performance under conditions that simulate the appropriate adverse design conditions;

(vi) Delineation of performance specifications, including acceptable deviations from baseline (or mean) benchmarks.

V.5.7.6. Design Change/Deviation

(a) A design deviation is a 'deviation' and shall be controlled according to the process 'Deviation Control' (proposals from F4E to IO are made through the available Deviation Request).

(b) 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).

Reference and Applicable Documents

PM-06	'Deviation Control' Process (F4E_D_22CCM4)
PM-27	'Design Control' Process (F4E_D_22CLT3)
SOP-002	'Design Review' Procedure (F4E_D_23NYBM)
QA-114	Instructions for Suppliers Performing Design Analysis (F4E_D_22FR5T)

Applicable process flowchart

Annex 2	(PM-06) Deviation from Supplier and Deviation from F4E Overall Flowcharts

V.5.8. Computer Code & Model Development

(a) The computer model design must be formally reviewed and validated, as would its hardware counterpart. Complete model validation may not be possible until the final hardware product is created and operated. When this is the situation, operational testing plans must provide the necessary data points to fully validate the model or performance code for later uses. Interim benchmarks can and must be established that provide reasonable interim confidence in the model's validity as part of the formal process planned to fully verify the model.

(b) Where the above requirement cannot be met due to the experimental nature of the ITER project, such lack of control shall be clearly stated in the technical basis documents of the affected systems. The experimental program should then take into account of this issue with the aim of software verification along the program itself.

(c) Computer software management shall be established to maintain control of software used in the R&D and design activities to the ITER project. The procedures and work processes used to establish and maintain control of software formulate a software management methodology for software acquisition, development, change, maintenance, and disposition. The software management methodology consists of the following:

(i) Software planning and software requirements analysis (including qualification);

(ii) Analysis of benefits and costs;

(iii) Resource estimating;

(iv) Life-cycle management;

(v) Acquisition and development;

(vi) Configuration management;

(vii) Operational system reviews.

V.5.9. Procurement and Grants Management

(a) The items and services procurement and grants shall be implemented according to following phases:

(i) Issue of F4E operative documents to contract the work to be performed:

(1) Issue of call for expressions of interest or tender or negotiate when applicable;

(2) Decision on the scope of the tender (limited to the members of F4E or World-wide);

(3) The selection of the grant type – single or multiple beneficiary - shall be discussed by the project team based on the project strategy;

(4) The selection of the tender procedure shall be discussed by the project team based on the following scheme:

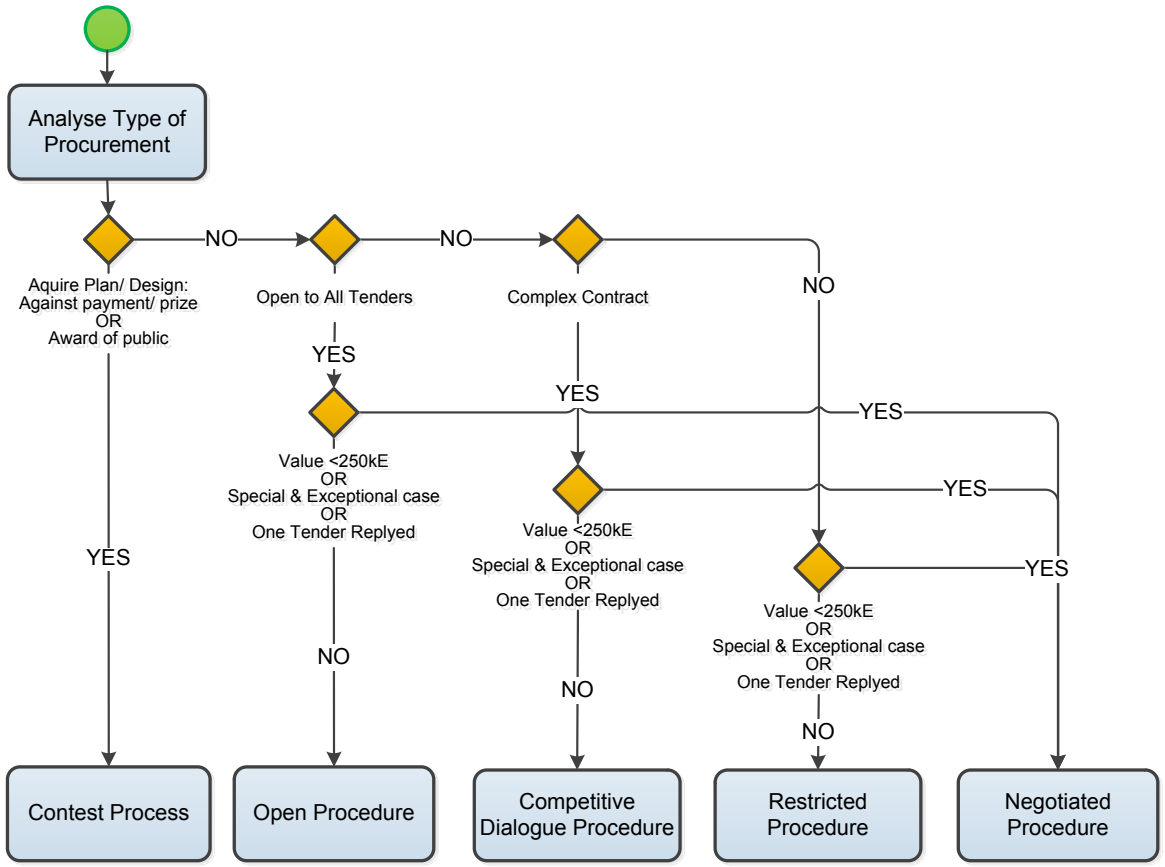


Figure 11 (V.5): Procurement Type Selection

(5) If applicable, negotiation, and/or validation of the specifications by the customer.

(6) Contracting of the work to be performed with the best bidder — Conclusion of the contract for the work to be performed.

(b) The principal role of F4E in relation to the ITER project is the procurement of items and services from European Fusion Associates and Industry.

(c) According to its mission and activities, F4E developed 'industry like manner' tendering procedures tailored to its specific needs. The five different procurement procedures are: open procedure, restricted procedure, competitive dialogue, negotiated procedure and contests.

(d) The objectives of these procedures are to:

(i) ensure a fair and transparent competition among European companies and Laboratories;

(ii) obtain the best possible quality of the supplies and services to be provided against payment of a fair price.

(e) The whole process is lean and flexible in order to match the schedule as foreseen and to promptly face any changes or nonconformities.

Reference and Applicable Processes

PM-05	'Open Procurement' Process (F4E_D_22JYUS)
PM-12	'Restricted Procurement' Process (F4E_D_22E3V6)
PM-13	'Competitive Dialogue Procurement' Process (F4E_D_22KBRR)
PM-14	'Negotiation Procurement' Process (F4E_D_22GCEF)
PM-131	'Competitive Procedure with Negotiation' Process (F4E_D_25644K)
PM-25	'Grant (Unique)' Process (F4E_D_22GTH2)
PM-26	'Grant (multiple)' Process(F4E_D_22MBJE)

V.5.9.1. Identification of Needed Items or Services

(a) The need for an item is usually identified from a parts list, bill of materials, or assembly drawing for a larger component or system. If the item is commercially available, then it should be fully specifiable by the vendor's identification number or by the published performance data. If the item must be fabricated specifically for an intended application, the item should be described in an equipment specification or on drawings of the item.

(b) If the services of a supplier are being obtained, then a technical specification or a statement of work should be prepared that specifies the services to be performed and the expected deliverables.

V.5.9.2. Establishment of Technical and Quality Requirements

Procurement and Grants documents are issued by each Work Package Manager and provided to the 'Administration Department' for issuing the calls (call for tender or call for proposals).

(i) The **Technical Specification** defines the object of each contract or grant agreement. It forms the 'as specified' form of the work to perform and defines the acceptance criteria of the contract or grant agreement. Depending on the type of work to perform, the Technical Specification should address at least the customer requirements (template F4E-QA-201 (F4E_D_22EVAD).

(ii) The quality and management requirements are defined in the '**Supplier Quality Requirements'** instruction (F4E-QA-115 (F4E_D_22F8BJ)). The **Management Specification** that refers to that instruction, as a base for requirements, defines the project organisation and the dispositions implemented to ensure a proper monitoring of the contract or grant agreement. It governs the relationship between the Work Package Manager and the supplier. Depending on the type of work to perform, the Management Specification should address at least the customer requirements (template F4E-QA-202 (F4E_D_22DWZP)).

It requires a 'Quality Plan' from the supplier/tenderer describing the provisions it will implement in order to ensure that the contractual requirements will be met.

V.5.9.3. Evaluation and Selection of Suppliers

(a) In selecting suppliers, their capability to provide the needed items or services will be evaluated.

(b) The assessment of the Quality Plan is part of the F4E evaluation of the tenderer's offer. The graded approach to the supplier management requirements are defined in the instruction 'Quality Graded Application'.

(c) When it is found that there is not a qualified supplier for the intended procurement, F4E shall evaluate available suppliers on an as needed basis and select one to provide that service with the needed additional management controls being supplied by F4E. This is especially important with vendors and suppliers that do not have a formal and suitable QA programme. In this case, the supplier's quality system requirements must be established prior to contract award.

V.5.9.4. Monitoring of Supplier Performance

The extent of supplier and subcontractor monitoring will be a function of the criticality of the item being supplied and the performance history of the supplier for similar items or services. Supplier and subcontractor monitoring shall be performed as in-process surveillance, inspections, or reviews at the supplier's (and subcontractor's) facility when a specific attribute of an item or process cannot be verified upon delivery of the completed item or service.

V.5.9.5. Safety Arrangements Follow-Up

(a) According to the French INB Order 07/Feb/2012, F4E implements a management process to make sure that, all along the F4E procurement process, the actions carried out by the whole participants will allow reaching the safety objectives.

(b) For the whole or concerned part of a Protection Important Component procurement, all activities performed by F4E itself or by Service companies which influence the Quality of the Protection related elements are named Protection Important Activities (PIA) and submitted to the procedure for 'Management of the Propagation of Generic Safety Requirements in the Supply Chain' (F4E-QA-013).

(c) Supervision of the activities is performed by F4E in order to ensure that the arrangements made by the supplier are relevant, efficient and allow complying with the propagation of the requirements of the Order and in particular guaranty that the Protection Important Activities (PIA) are performed in accordance with the requirements and that all the deviations are detected, brought under control and traced.

Reference and Applicable Documents

F4E-QA-013	Management of the Propagation of Generic Safety Requirements F4E_D_23CA9U
F4E-QA-016	F4E Supervision of the PIC Supply Chain F4E_D_23JXHS

F4E-QA-113	Propagation of Safety Requirements in the Supply Chain F4E_D_27MKTL

V.5.9.6. Item Deviation from Requirements

(a) Any deviation (or modification) to a specified requirement identified by the supplier shall be handled by the suppliers dedicated deviation procedure and the F4E configuration management process.

(b) The supplier's deviation procedure shall be described in the contract Quality Plan as required by the Management Specification.

V.5.9.7. Substandard Items and Services

Items and services that are found to be substandard and that suppliers have knowingly provided will be reported to F4E through the supplier nonconformity process, and handled within F4E through the Nonconformity Control Process.

Reference and Applicable Documents

PM-06	'Deviation Control' Process (F4E_D_22CCM4)
PM-35	'Nonconformity Control' Process (F4E_D_22MDXC)
F4E-IO CMP	F4E-ITER Project Configuration Management Plan (F4E_D_22P3BC)
F4E-QA-100	'Quality Graded Application' Instruction (F4E_D_22EPT2)
F4E-QA-115	'Supplier Quality Requirements' Instruction (F4E_D_22F8BJ)
F4E-QA-201	'Technical Specification for the Work Package' Template (F4E_D_22EVAD)
F4E-QA-202	'Management Specification for the Work Package' Template (F4E_D_22DWZP)

V.5.10. Product Execution

(a) F4E identifies and controls all the conception stages and the responsibilities, as well as the verification and validation according to each project planning. All the necessary inputs to the conception are taken into account in order to comply with the legal requirements and IO.

(b) During this phase the relationships between all the stakeholders are governed by the following documents:

(i) IO / F4E Project Manager: Procurement Arrangement, ITER Task Agreement;

(ii) F4E Project Manager / Director: Project Management Plan;

(iii) F4E Project Manager / Work Package Managers: Project Management Plan;

(iv) F4E Work Package Manager / Suppliers' Technical Responsible: Management Specification, Quality Plan.

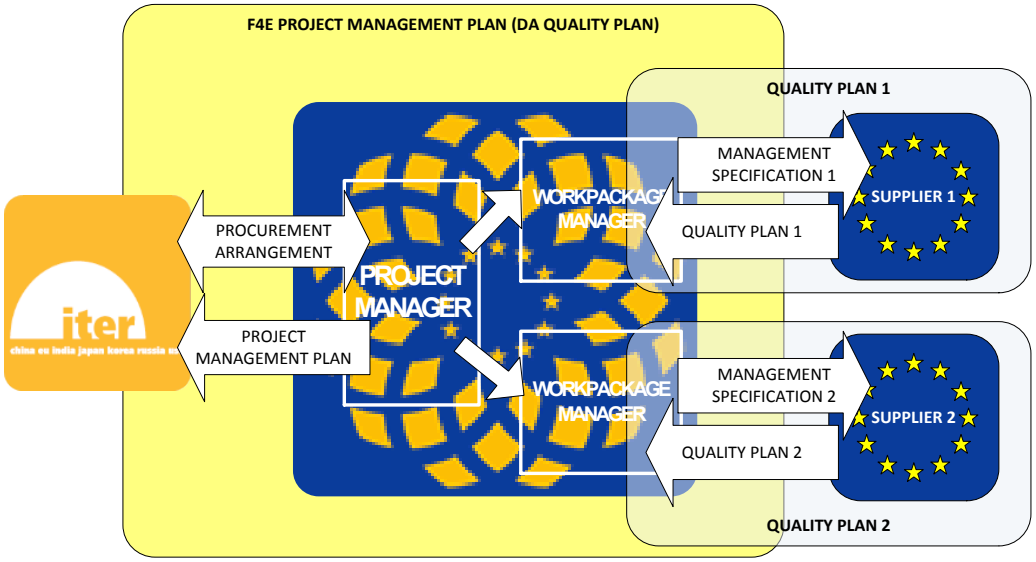


Figure 12 (V.5): Governance of the Management Relationships (non-Integrated Project Team)

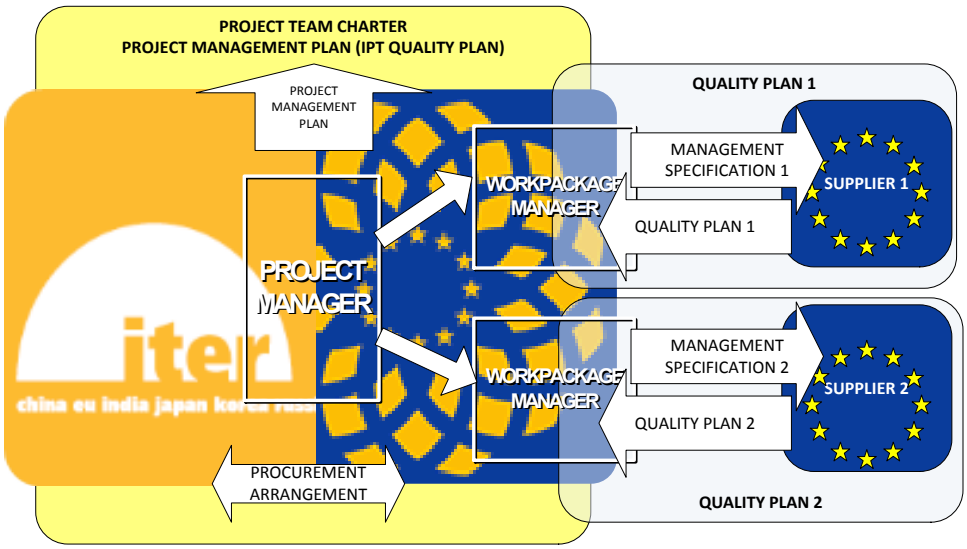


Figure 13 (V.5): Governance of the Management Relationships (Integrated Project Team)

(c) Manufacturing shall be controlled to the extent necessary to ensure items conform to the requirements. Those controls shall be in accordance with the agreed Quality Plan.

(d) Assembly and installation shall be controlled to the extent necessary to ensure that the installation of a particular item will not compromise the integrity/safety:

(i) of the item to be installed;

(ii) of the ITER facility.

(e) Work shall be carried out under controlled conditions:

(i) using approved drawings, procedures, standards and other documents,

(ii) according to approved pre-established control plans.

(f) Control Plans shall 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 and shall identify:

(i) the sequence of critical operations;

(ii) the instructions and requirements applicable to these operations;

(iii) the operations F4E and IO intends to witness;

(iv) the operations F4E and IO defines as Hold, Authorisation to Proceed and Notification Points;

(v) the completion status of the operations listed.

(g) The Supplier Control Plan overall flow is described in the Annex 7

(h) Prior to implementation, work documents shall be:

(i) reviewed for compliance with ITER requirements;

(ii) approved 'for manufacture' and controlled.

(i) Documents and records shall be maintained to reflect the actual configuration of the item, and approved 'as built' on item completion.

V.5.11. Product Verification / Validation

(a) Verification is carried out taking into account the provisions originally planned, in order to ensure that the established requirements produced outputs that meet the IO requirements.

(b) F4E verifies all requirements related to their products, before taking any commitment and ensuring that the differences between the specified requirements and the proposals will be solved, in order to find the best solutions and alternatives.

(c) All projects developed are assessed for compliance by F4E before delivery to the final customer that will make the final validation (IO).

(d) Thus the outputs of the conception should be consistent with the inputs, and should include information on:

(i) Product acceptance criteria;

(ii) Product features necessary to its secure implementation;

(iii) Relevant information to the purchases and the product implementation specifications.

(e) The Supplier Deliverable Acceptance overall flow is described in the Annex 6

V.5.12. Configuration Management

(a) Configuration management is the management process that ensures consistency is maintained among the parameters, the requirements, the physical and functional configuration of the IO product and its documentation, particularly as changes are made throughout the product life cycle.

(b) The methodology for the systematic and uniform review of all changes to a frozen specification or configuration (configuration baseline) (initiated by F4E or from the outside) is described in the procedure 'F4E-ITER Project Configuration Management Plan'. This method ensures that the impact of changes on performance, cost and schedule are identified and thoroughly evaluated before the decision to incorporate them is taken.

(c) The general process to be adopted is shown in a flowchart in Annex 2 (extract from the Deviation Control Process).

(d) Documents related to configuration management activities are held as specified in the process 'Document Control' (PM-07, F4E_D_22KS43) and the 'F4E Documentation Management System Policy (F4E_D_239SK2).

Reference and Applicable Documents

PM-06	'Deviation Control' Process (F4E_D_22CCM4)
PM-07	'Document Control' Process (F4E_D_22KS43)
PM-35	'Nonconformity Control' Process (F4E_D_22MDXC)
PM-63	'Deliverable Acceptance' Process (F4E_D_262PUA)
---	F4E Documentation Management System Policy (F4E_D_239SK2)
F4E-IO CMP	F4E-ITER Project Configuration Management Plan (F4E_D_22P3BC)
F4E-QA-216-3	'Deviation Request' form (F4E_D_22C4HG)

Applicable process flowcharts

Annex 2	(PM-06) Deviation from Supplier and Deviation from F4E Overall Flowcharts
Annex 6	(QA-115) Supplier Deliverable Acceptance overall flow
Annex 7	(QA-115) Control Plan Overall Flow

V.5.13. Identification and Control of Items

(a) The identification of materials essential to providing traceable activity results shall be according to the convention defined in 'F4E-QA-112 - Naming Convention'.

(b) Hardware and software items will be identified and controlled consistent with their intended use. The identification of each item should be established as early as practical in its creation or collection. The appropriate requirements for identification will be contained in the engineering documents, such as drawings and equipment specifications, or included in the procurement documents.

Reference and Applicable Documents

F4E-QA-112	' Naming Convention ' Instruction (F4E_D_22GGJ4)

V.5.14. Product Preservation and Transportation

(a) The preservation and transport requirements are part of product requirements. In each working phase, up to delivery to IO (or IO designated location), the product shall be preserved from damage and deterioration.

(b) The suppliers are informed and made aware of their responsibilities through technical specifications. Including the event of the evolvement of multiple organisations, the interface and any chain-of-custody requirements are specified.

(c) IO is informed about the optimal conditions for product preservation.

V.5.15. Measuring and Test Equipment

(a) F4E establishes and maintains a methodology to calibrate (according to ISO 10012), maintain the measuring and test equipment (MTE), and demonstrate compliance to specified product requirements. The MTE used are selected according to the intended function to ensure the knowledge of the error and compatibility with the required measurement.

(b) F4E suppliers will establish and maintain similar control of the MTE used in performing ITER project related activities.

V.5.15.1. Calibration Labeling and Documentation

(a) Measuring and test equipment (MTE) shall be labelled to identify its calibration status. The label shall include:

(i) instrument identification number;

(ii) identification of the person/entity that performed the calibration;

(iii) calibration date;

(iv) next calibration due date.

(b) If due to physical restrictions the MTE cannot be labelled, then it shall be identified and a document record, with the label equivalent information, maintained.

(c) Equipment that does not require calibration shall have a tag stating that calibration is not required, to identify its status (and avoid the use in a calibration required situation).

(d) Measuring and test equipment used for F4E activities shall have records of calibration retained in the project files. The record shall contain at least the equipment identification (type, model & maker, serial), calibration date, performer, procedure and standard used, and the as-found and as-left performance information.

V.6. Assessment and Improvement

(a) The QM with the support of the QAG (with the approval of the senior management and support of the QA Coordination Board) plans and implements actions that allow the monitoring and analysis of processes, to:

(i) demonstrate conformity to the product requirements;

(ii) ensure conformity with the QMS;

(iii) continual improve of the QMS effectiveness.

(b) The extent and application of these processes shall depend on their importance.

V.6.1. IO Feedback

(a) The IO feedback will be monitored as a measurement of the program performance. The sources of this feedback are:

(i) IO audit reports;

(ii) IO QA Programme reviews.

(b) This information is an important input for the revision of the QA Programme and the QMS.

V.6.2. Quality Management System Audits

(a) Quality Management System audits are performed to verify the state of the QA Programme and Quality Plans in accordance with the quality criteria and the IO requirements. The methodology regarding the planning, preparation, implementation and recording of internal and external quality audits is defined in a documented process (Quality Audits).

(b) The Quality Management System audits results are recorded and analysed, and may trigger corrective actions, deliverable/product nonconformities, or preventive actions, arising from audit findings (improvement areas or non-compliances). The reports of internal audits are one of the main inputs of the review by the senior management of the QMS.

(c) The general process to be adopted is shown in a flowchart in Annex 3 (extract from the process).

Reference and Applicable Documents

PM-28	'QMS Audits and Supply Audits' Process (F4E_D_22H84F)
F4E-QA-214-1	'Audit Programme' model (F4E_D_22X5XK)
F4E-QA-214-2	'Audit Check List' form - internal (F4E_D_22TWG9), external (F4E_D_22XK9A)
F4E-QA-214-3	'Audit Notification' form (F4E_D_22ZDKX)
F4E-QA-214-R	'Audit Report' form (F4E_D_22QYBT)

Applicable process flowchart

Annex 3	(PM-28) QMS Audits and Supplier Audit Flowchart

V.6.3. Monitoring and Measurement of Processes

F4E has established indicators that allow the monitoring and measurement of the execution processes (project management, procurement and grants management, resources management etc), indispensable to the fulfilment of the interested parties' requirements. The methods used and results obtained confirm the suitability of the procedures to meet the targets.

V.6.4. Risk & Opportunity Management

(a) Risk & Opportunities management is a set of coordinated activities to identify and manage the risk that may affect the objectives of an organization.
(b) The continuous process of management of risks consists of the following activities:

Figure 14 (V.6): Risk Cycle

(c) All activities of an organization involve risks that must be managed. The risk management process aids decision making by taking account of uncertainty and the possibility of future events or circumstances (intended or unintended) and their effects on agreed objectives.
(d) Risk management involves applying logical and systematic methods for:

(i) communicating and consulting throughout this process;
(ii) establishing the organization's context for identifying, analysing, evaluating, treating, and monitoring risk associated with any activity, product, function or process;
(iii) reporting the results appropriately.

(e) The risks are identified in order to avoid them, if possible, mitigate them or to accept and take provisions in case not possible the previous ones.
(f) The key to managing risk is not to wait until a risk materialises (and becomes a problem or a failure), but to decide what to do about it.
(g) F4E has defined the proceedings to identify, estimate, treat and monitor risks at project level:

(i) Each project will use its own techniques to identify risks internally.
(ii) Each work package and project will identify its highest priority risks to the Project Manager or Head of Unit (approximately top-5 risks) to report to the Project Steering Meeting.
(iii) Projects can suggest risks that involve other Projects.
(iv) The Project meeting will review the risks and for those that are retained as being important, will identify someone responsible for following the risk and reporting to the Project Manager.

(h) Significant resource or financial risks will be escalated to the Project Steering Meeting

(i) The risk tracking will be a standing item on the Project Steering Meeting agenda and Project Team meetings.

Reference and Applicable Documents

PM-22	'F4E Risk Management ' Process (F4E_D_22CZRF)
---	'Project Risk & Opportunity Management ' Procedure (F4E_D_22FXV9)
F4E-QA-221-R	'Risk Plan' Template (F4E_D_22HPB6)

V.6.5. Inspection and Testing

(a) The inspection and testing performed by F4E, to verify that the items and services comply with the established requirement, is done in accordance with the processes of 'Quality Surveillance' and Supplier Audit.

(b) The general process of Quality Surveillance to be adopted is shown in a flowchart in Annex 4 (extract from the process).

(c) The inspection and testing phases, during the development of the activities by the suppliers, are defined in the Project Management Plan and the suppliers Quality Plan (and its Control Plan).

V.6.5.1. Inspection

(a) Inspection planning should be developed based on specification requirements, drawing requirements, and degree of complexity. This planning should appropriately address:

(i) Inspection methods, including specific reference to inspection procedures;

(ii) Tests required to be monitored or witnessed;

(iii) Characteristics to be inspected;

(iv) Identification of mandatory hold points, as required, and acceptance criteria.

(b) The status of inspection of items and services shall be documented using labelling, tagging, reports, or signatures on control plans or receipt inspection documents. Status documentation ensures that inspections will not be bypassed and that equipment, material, or fabricated assemblies will not be released for further work activities until the inspections are complete and the results accepted.

(c) When inspection activities identify a nonconformity, the person performing the inspection will initiate the Nonconformity Control Process (see §V.6.5 and PM-35).

V.6.5.2. Testing

(a) Testing is accomplished where critical performance characteristics of an item cannot be verified by static inspection methods.

(b) Test planning should determine the type of tests required and document the test parameters, methods, test article configuration, and acceptance limits.

(c) The test requirements and acceptance criteria should be based on item performance requirements, approved by the Responsible Officer (for defined safety systems IO should approve).

(d) Testing to verify or validate the acceptability of specified requirements will be conducted in accordance with approved procedures that address, as applicable:

(i) Instructions on test performance, including hold points, as required;

(ii) Provisions for test monitoring, calibrated instrumentation, and data acquisition;

(iii) Safety of the facility;

(iv) Suitable environmental conditions;

(v) Qualification of testing personnel;

(vi) Established acceptance criteria.

(e) Test records shall be maintained, identifying:

(i) Item or system tested, including test boundaries;

(ii) Date(s) of test;

(iii) Test personnel or data recording personnel;

(iv) Type of observation (e.g., pressure over time) and results observed;

(v) Notation of deviations and subsequent evaluations;

(vi) Signature of person accepting results.

Reference and Applicable Documents

PM-28	'QMS Audits and Supply Audits' Process (F4E_D_22H84F)
PM-35	Nonconformity Control (F4E_D_22MDXC)
PM-38	Quality Surveillance (F4E_D_22DDMG)
F4E-QA-220-R	Surveillance Report (F4E_D_22LCYR)

Applicable process flowchart

Annex 4	(PM-38) Quality Surveillance Flowchart

V.6.6. Nonconformity Control

(a) Nonconformity is a non-fulfilment of a requirement. This requirement might come from the procedures, the items and services specifications or from the IO feedback.

(b) All F4E personnel are responsible for the identification and reporting of any nonconformity detected.

(c) F4E has defined a process (Nonconformity Control) for handling all aspects of the detected nonconformities.

(d) The Nonconformities to the customer requirements shall be resolved with high priority and that this resolution shall not exceed 9 months in average and 12 months individually, except initial agreement from the customer (IO DG or the IO QAA Head).

(e) The Nonconformity Control process within F4E is described in the flowchart in Annex 5:

Reference and Applicable Documents

PM-35	Nonconformity Control (F4E_D_22MDXC)
F4E-QA-218-R	'Nonconformity Report' Form (F4E_D_22F7EU)

Applicable process flowchart

Annex 5	(PM-35) Supplier Nonconformities overall flow

V.6.7. Data Analysis

(a) The QA Officers collect and analyse the appropriate data to determine the adequacy and effectiveness of the QMS and QA Programme, and can therefore identify improvements that could be made. This process includes data generated by the activities of measurement and monitoring and / or other sources deemed relevant.

(b) The analysis results taken to the QA Board for review and an annual report are prepared for the senior management review.

V.6.8. Continual Improvement

The Director shall continually improve the QMS, by planning and managing the necessary processes. The continual improvement is achieved through the use of the Quality Policy, the Objectives, audit results, data analysis, corrective and preventive actions and management review.

V.6.8.1. Corrective Actions

The internal corrective actions are triggered by the occurrence of failures in the quality management system and internal services, in order to eliminate the cause and prevent repetition. Its management is defined in the process of the Corrective Action Request.

(i) The definition and elimination of causes of QMS and service non-compliances;

(ii) The appropriate actions to prevent the recurrence of problems;

(iii) Records of activities and results.

Reference and Applicable Documents

PM-42	'Corrective Action Request' Process (F4E_D_29KV8Z)

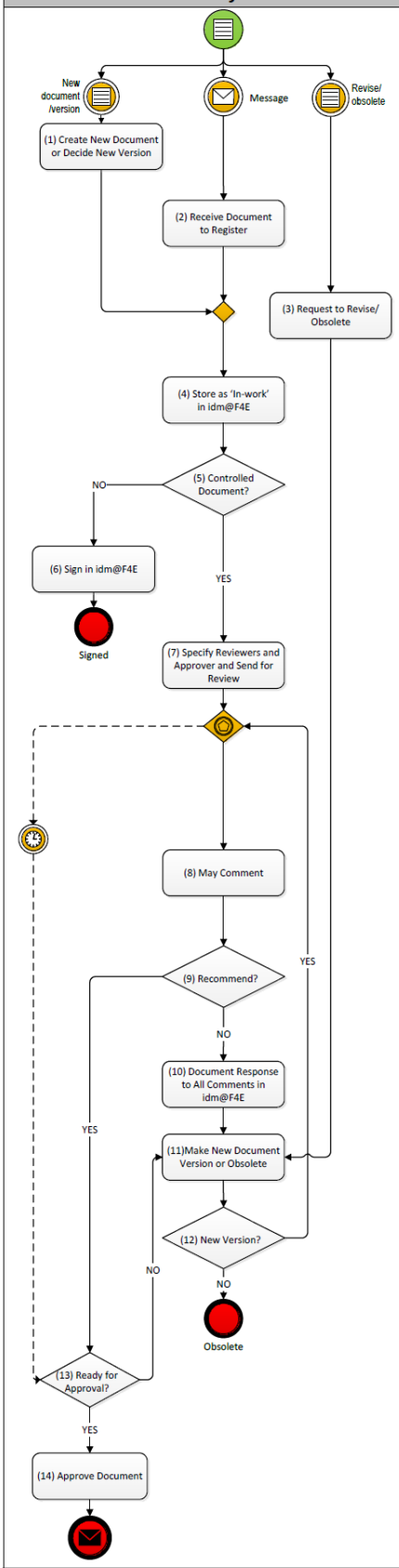
V.6.8.2. Preventive Actions

The internal preventive actions are identified and adequate to eliminate the cause of a potential QMS and service non-compliances or other undesirable potential situation, preventing its occurrence.

Reference and Applicable Documents

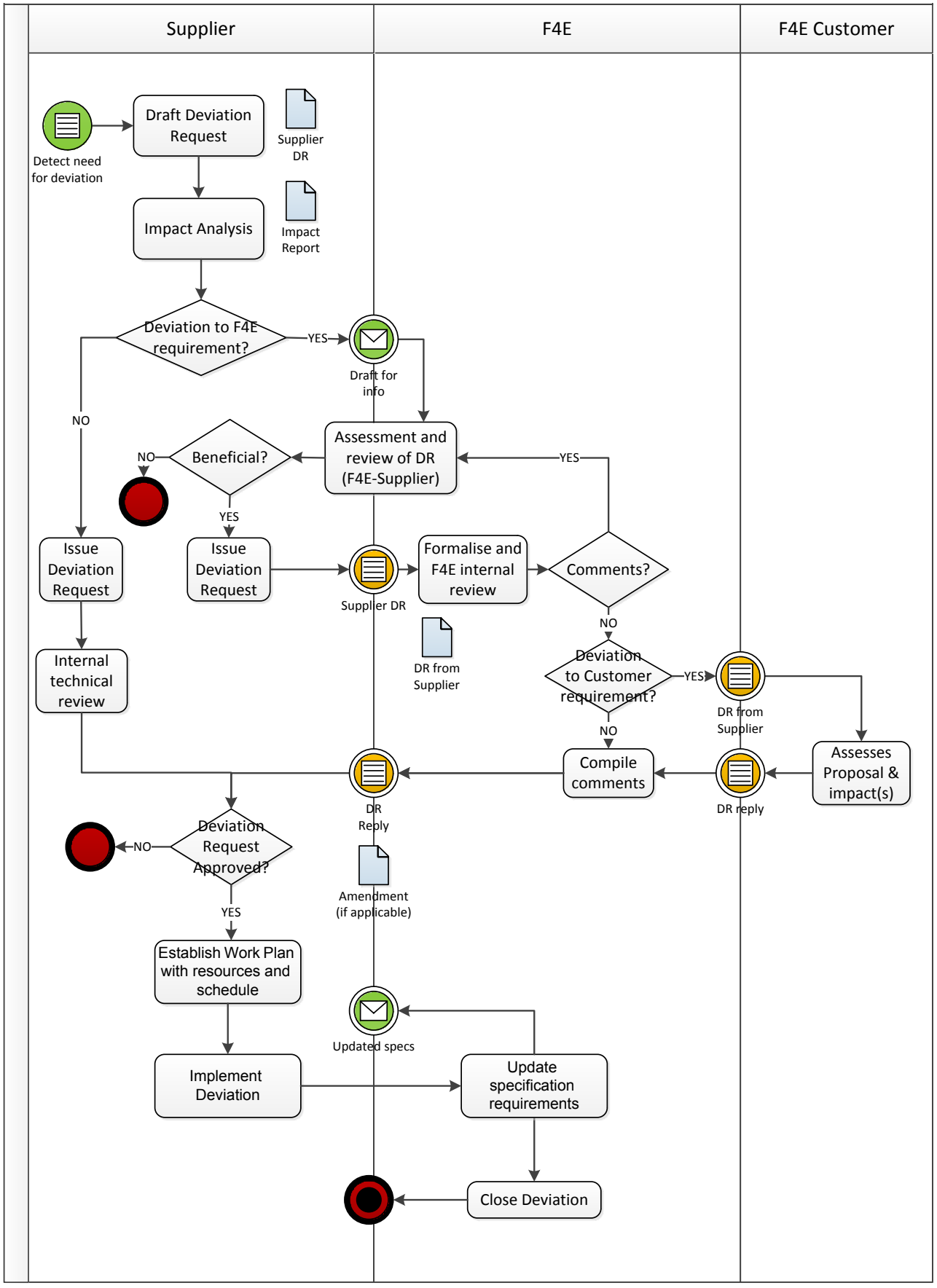
PM-42	'Corrective Action Request' Process (F4E_D_29KV8Z)

ANNEX 1 – DOCUMENTATION FLOW PROCESS

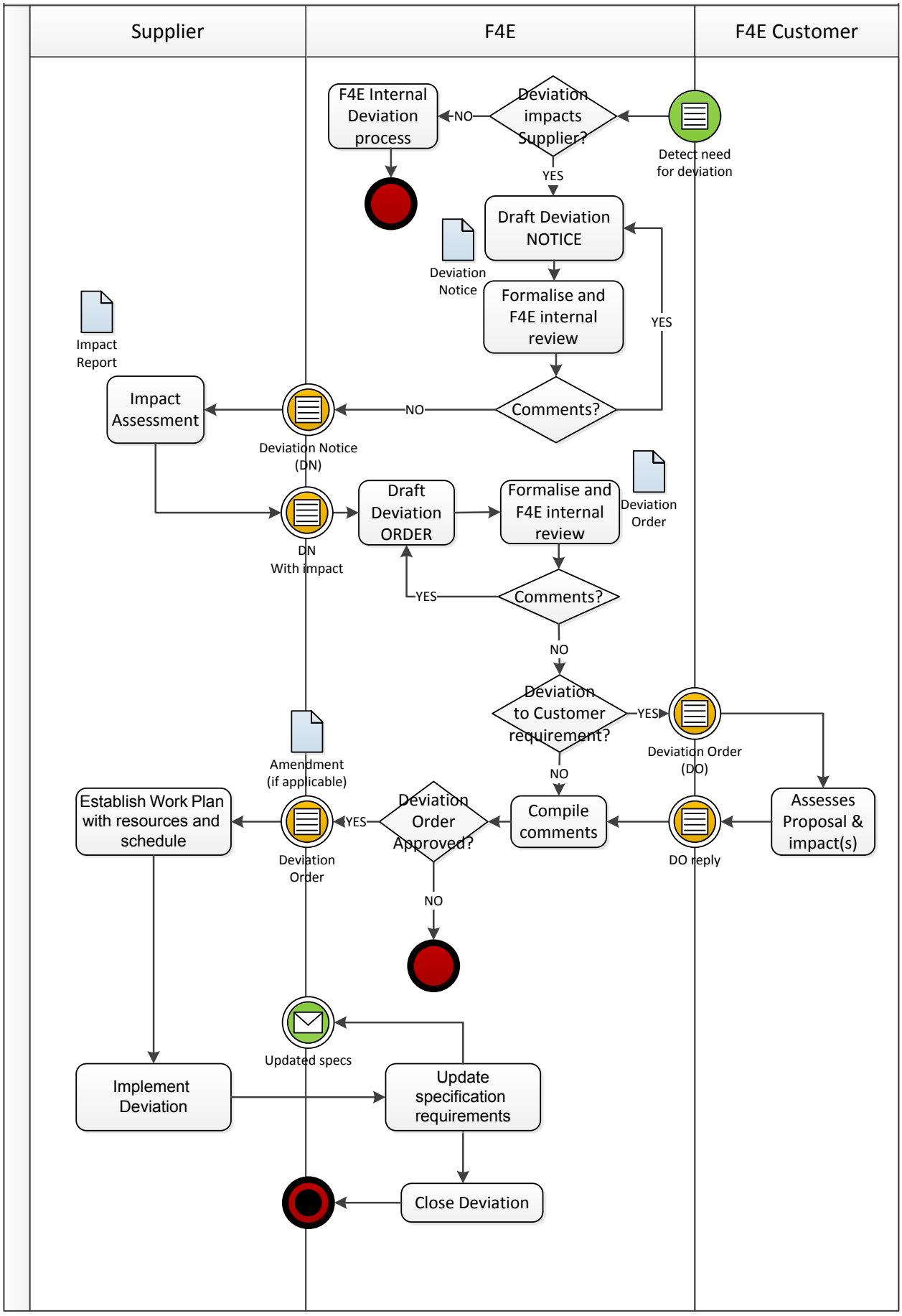
Activity	#	Resp.	Guidance
	**0**	--	Process starts depending on the trigger type: 1. Criteria New document/ version. Go-to 1. 2. Message receives document. Go-to 2. 3. Criteria revise/ obsolete. Go-to 3.
	1	Author	**Create New Document or Decide New Version** Start a new document or decide to create a new version. For a new version the author must specify the version description. Go-to 4. Store as 'In-work' in idm@F4E.
	2	Author (Signatory)	**Receive Document to Register** Receive a message with a document to be registered (includes external documents). Go-to 4. Store as 'In-work' in idm@F4E.
	3	competent person	**Request to Revise/ Obsolete** Detect or identify that a document requires a revision or has become obsolete. Go-to 11. Make New Document Version or Obsolete.
	4	Author	**Store as 'In-work' in idm@F4E** Upload the document into idm@F4E and is responsible to correctly fill the metadata. Go-to Gate 5: 'Controlled Document?'
	5	Author	**Gate 5: 'Controlled Document?'** Yes – Go-to 7. Specify Reviewers and Approver and Send for Review. No – Go-to 6. Sign in idm@F4E.
	6	Author	**Sign in idm@F4E** This is an uncontrolled document. Then sign the document and the process ends. Go-to 7. Specify Reviewers and Approver and Send for Review.
	7	Author	**Specify Reviewers and Approver and Send for Review** The document is controlled. Specify the reviewers and approver according to the prevailing SOAP or Process. Send for review (by signing the document and sending the idm email). Go-to 8. May Comment.
	--	--	The process continues based on: Reviewers may comment. Go-to 8. May Comment. At any given time the approver can take a decision (normally after all reviews but can also do it before). Go-to Gate 13: 'Ready for Approval?'
	8	Reviewers	**May Comment** A reviewer may Introduce comments or Delegate review. Go-to Gate 9: 'Recommend?'
	9	Reviewers	**Gate 9: 'Recommend'** Review result can be: Yes – The current version is OK for approval. Recommend the document for approval. Go-to Gate 13: 'Ready for Approval?' No – Comments. The current version is NOT OK for approval and justify. Go-to 10. Document Response to All Comments in idm@F4E.
	10	Author	**Document Response to All Comments in idm@F4E** Introduce replies to all comments. Go-to 11. Make New Document Version or Obsolete.
	11	Author	**Make New Document Version or Obsolete** Make a decision based on the inputs. Go-to Gate 12: 'New Version?'
	12	Author	**Gate 12: 'New Version?'** Take a decision based on the comments: Yes – Create a new version. Go-to 8. May Comment No – Make the document obsolete. Process ends.
	13	Approver	**Gate 13: 'Ready for Approval?'** The approver is fully responsible for the decision, so might decide to approve a document even if some of the reviewers did not recommend the document: Yes – Decides to approve. Go-to 14. Approve Document. No – Decides to 'Disapprove' or to 'Revision Required' Go-to 11. Make New Document Version or Obsolete.
	14	Approver	**Approve Document** Approve the document. If the document was not fully reviewed or recommended, enter a reason in order to explain the decision of approving and this justification is recorded in the system.
	--	--	Process ends.

ANNEX 2 – DEVIATION PROCESS FLOWCHART

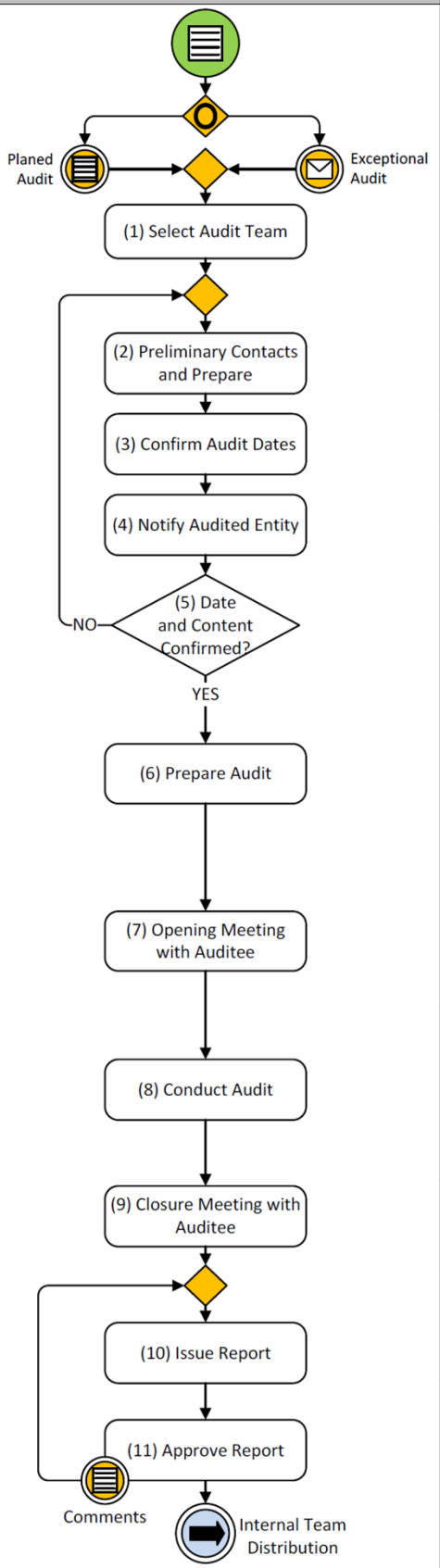
Deviation from Supplier Overall Flow

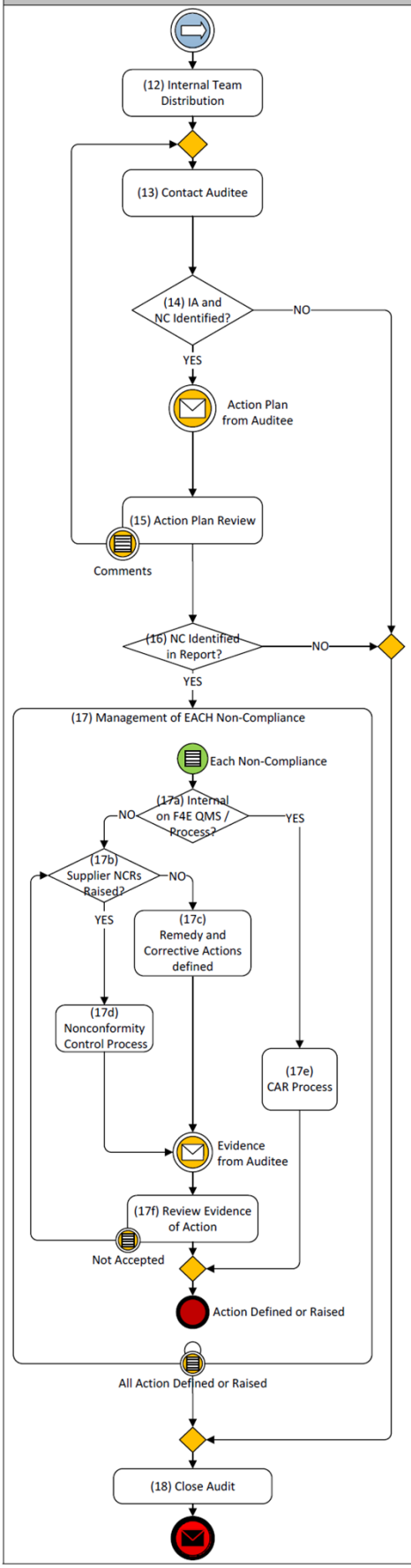


Deviation from F4E Overall Flow

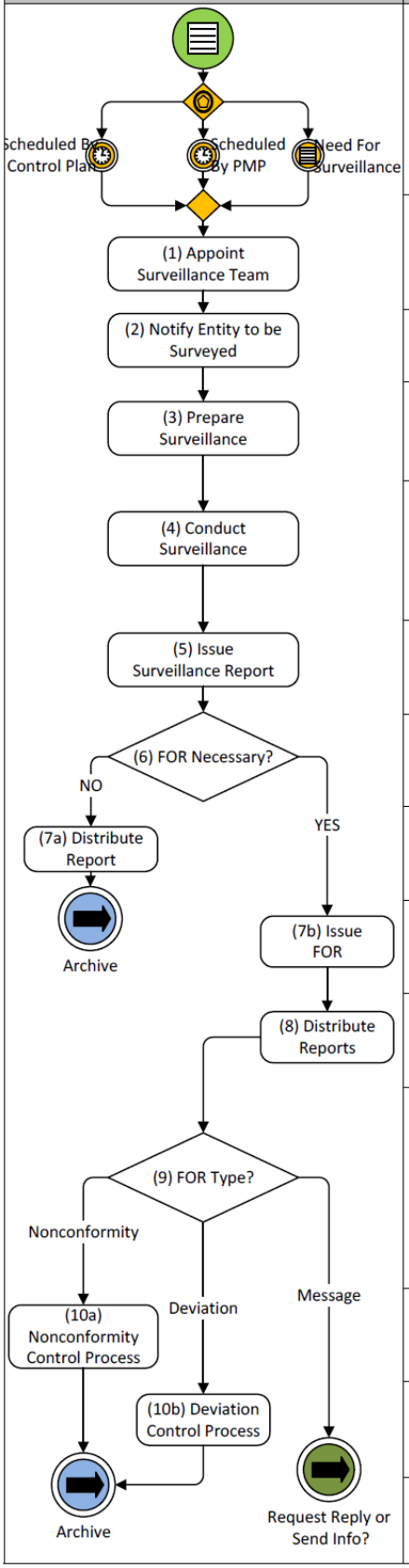


ANNEX 3 – QMS AUDITS AND SUPPLIER AUDITS PROCESS FLOWCHART

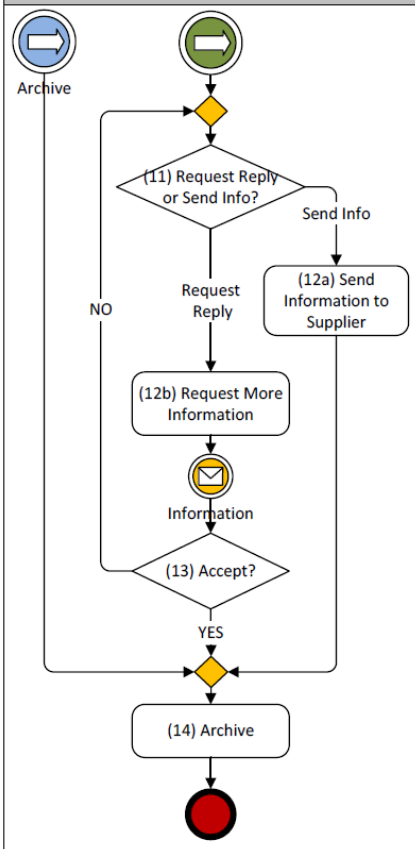
Activity	#	Resp.	Guidance
	**0**	--	The process starts depending on the trigger type: Plan: **Planned Audit:** Based on the Yearly Audit Programme (QMS & Supplier) the Audit Manager starts the internal process 1.5 months before the planned audit date. Message: The process is triggered when the Audit Manager receives a message requesting an **Exceptional Audit.** Go-to 1. Select Audit Team
	1	Audit Manager	**Select Audit Team** Confirm the Audit Team from the Audit Programme (or nominate new members), that shall consist of (at minimum) Lead Auditor and a technical/ QA Auditor. Go-to 2. Preliminary Contacts and Prepare.
	2	Audit Team	**Preliminary Contacts and Prepare** Make the preliminary contacts with the Auditee (schedule audit date) and do a preliminary preparation of the audit. The idm@F4E audit folder is created (request to Audit Manager). Go-to 3. Notify Audited Entity.
	3	Audit Team	**Confirm Audit Dates** Confirm the audit dates with the audited entity/ Operational Responsible. Go-to 4. Gate: 'Confirm Audit Dates.'
	4	Audit Team	**Notify Audited Entity** Prepare the Audit Notification (22ZDKX) defining the audit plan, and process its approval (as per §I.7) in the audit folder. Send to the audited Entity/ Operational Responsible, at least 15 days before the scheduled date. Go-to 5. Date and Content Confirmed?
	5	Audit Team	**Gate 5: 'Date and Content Confirmed?'** YES: The auditee confirms the dates and contents of the audit. Go-to 6. Prepare Audit. NO: The auditee does not confirm the date or the content and the audit team must readjust the preparation documentation. Go-to 2. Preliminary Contacts and Prepare.
	6	Audit Team	**Prepare Audit** Review the audit documentation and prepare the Audit Check list, taking into account the general quality audit objectives: • Assure the conformity of the implemented quality system, as per checklist defined in the Implementation Instruction; • Verify the effectiveness of the quality system implemented and its maintenance; • Supply the necessary suggestions to the adequate functioning of the quality system. Go-to 7. Opening Meeting with Auditee.
	7	Audit Team	**Opening Meeting with Auditee** Perform the opening meeting with the Auditee, presenting the team and the audit objectives, confirming the notification program. If necessary, the audit team conciliates dates and schedules. Go-to 8. Conduct Audit.
	8	Audit Team	**Conduct Audit** Conduct the audit, taking into account the Audit Check List, including:: • Perform interviews; • Review documents and records associated with the process or auditee entity/section; • Register all findings; • During the interviews, verbally inform the auditee of findings. Go-to 9. Closure Meeting with Auditee.
	9	Audit Team	**Closure Meeting with Auditee** Perform a brief resume (or draft report) of the findings to the entity/ section leader with the same presences as in the opening meeting. Go-to 10. Issue Report.
	10	Lead Auditor	**Issue Report** Issue the Audit Report (22QYBT) including the identification of of the findings: strong areas (SA); improvement areas (IA); Non-Compliances (NC). Process its review in idm@F4E Audit Report folder as per §I.7. Go-to 11. Approve Report.
	11	Audit Manager	**Approve Report** Perform the approval check of the Audit Report. On check: With Comments: The Audit Manager has comments to the report. The report and the comments are sent back to the Audit Team. Go-to 10. Issue Report Normal Exit: The Audit Manager accepts the report. Go-to 12. Internal Team Distribution
	--		Continue process on next page.

Activity	#	Resp.	Guidance
	--	--	Continue process.
	12	Lead Auditor	**Internal Team Distribution** The approved report is distributed to the subject Operational Responsible and QAO. Go-to 13. Contact Auditee.
	13	Lead Auditor	**Contact Auditee** Distribute the documentation to the Auditee (Report or revised Action Plan). Go-to 14. Gate: "IA and NC Identified?"
	14	QAO	**Gate 14: 'IA and NC Identified?'** Are Improvement Area and/ or Non-Compliance identified? YES: Issues to be addressed by the auditee in an Action Plan to be submitted to F4E within the specified time frame (15 days as defined in the Audit Report). Go-to 15. Action Plan Review. NO: Go-to 18. Close Audit.
	--	--	Process cannot continue without receiving the Action Plan from the Auditee.
	15	Audit Team	**Action Plan Review** Upload the Action Plan in idm@F4E (report folder) and performs the review (review by the team and audit manager). On review: With Comments: The team has comments to the plan. The plan and the comments are sent back to the Auditee. Go-to 13. Contact Auditee Normal Exit: The team accepts the report. Go-to 16. Gate: 'NC Identified in the Report?'
	16	QAO	**Gate: 'NC Identified in the Report?'** Are Non-Compliances identified in the Audit Report? YES: Go-to 17. Management of EACH Non-Compliance. NO: Go-to 18. Close Audit.
	17		**Management of EACH Non-Compliance**
	17a	--	**Gate : 'Internal on F4E QMS/Process?'** YES: Go-to 17e. CAR process NO: Go-to 17b. Supplier NCRs Raised?.
	17b	--	**Gate : 'Supplier NCRs Raised?'** YES: Go-to 17d. Nonconformity Control Process. NO: Go-to 17c. Remedy and Corrective Actions defined.
	17c	QAO	**Remedy and Corrective Actions defined** The proposed actions to adress the Non-Compliance as defined on the Action Plan must be initiated. Go-to 17f. Review Evidence of Actions.
	17d	QAO	**Nonconformity Control Process** The nonconformities to be raised by the Auditee will be followed by the QAO of the contract/area. PM-35 Nonconformity Control (22MDXC) Go-to 17f. Review Evidence of Actions.
	17e	Audit Team	**CAR Process** The Corrective Action Request(s) to be initiated by the Audit Team and will be followed by the QAO of the Subject. PM-42 CAR (29KV8Z) Go-to End of Management EACH Non-Compliance
	--	QAO	The process cannot continue without receiving evidences.
	17f	Audit Team	**Review Evidence of Started Actions** Perform the review/ check of the evidence of actions (if needed a further Audit can be scheduled). On review/check: Not Accepted: Does not accept the evidences. Comments are sent to the Auditee. Go-to 17b. Supplier NCRs Raised? Normal Exit: Accepts the evidences. Go-to End of Management EACh Non-Compliance.
			Once all NCRs raised, all CARs initiated and all remaining actions defined in the approved Action Plan Go-to 18. Close Audit
	18	Audit Team	**Close Audit** After the first Action Plan is approved and all the occurring Non-Compliance are addressed, the responsible for closure ensures the correct archival of the reports and associated documentation in idm@F4E and informs the Audit Manager. The Audit Manager closes the Audit.
	--		The process terminates.

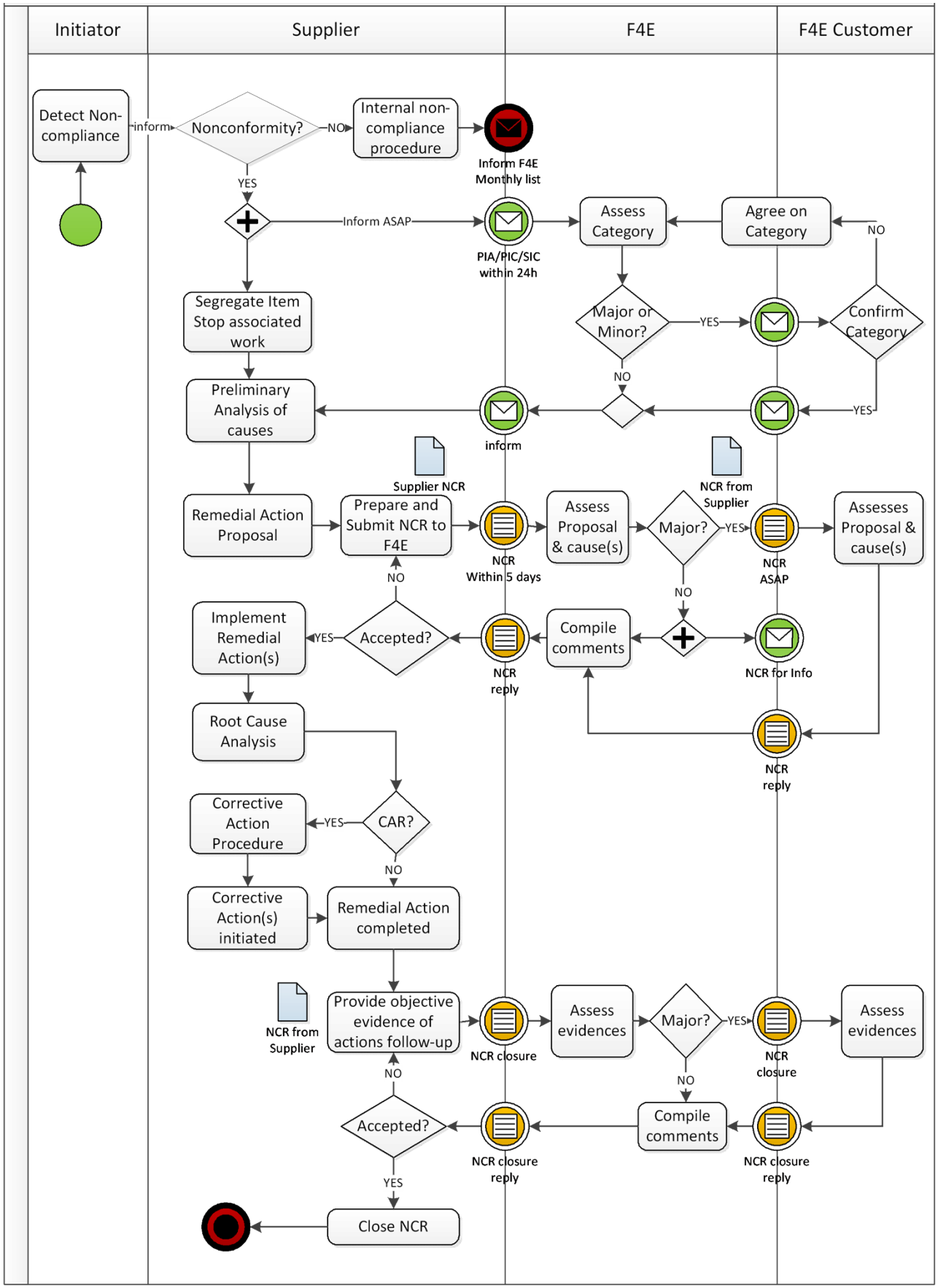
ANNEX 4 – QUALITY SURVEILLANCE PROCESS FLOWCHART



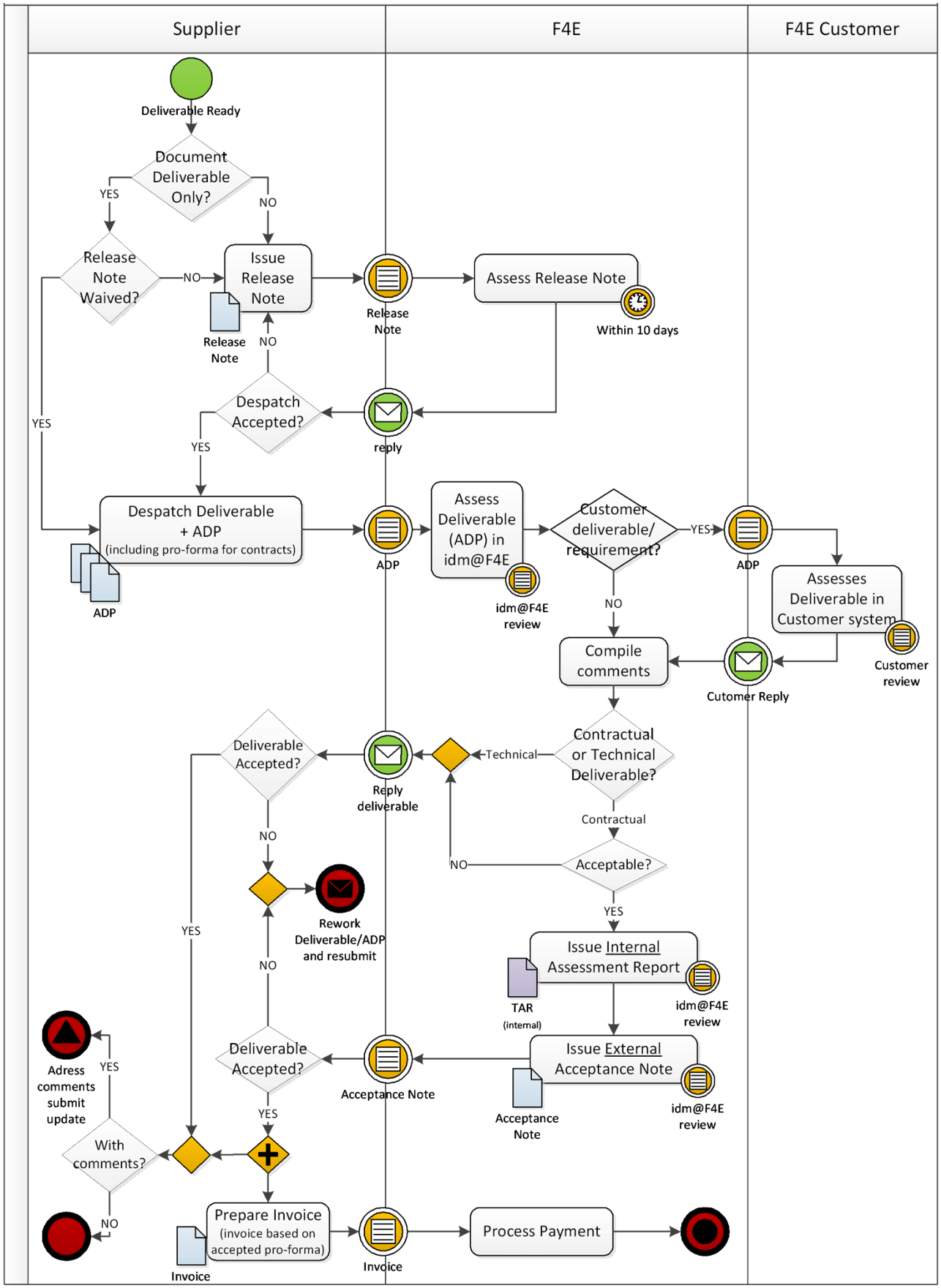
Activity	#	Resp.	Guidance
	0	--	The process is triggered when the need of a Quality Surveillance is identified by TPO, due to issues in the execution of the contract. The process starts depending on the trigger type: Schedule by CP: The process is triggered when the Control OR Surveillance Plan schedules a Quality Surveillance. Schedule by PMP: The process is triggered when the PMP schedules a Quality Surveillance. Criteria: Detect / Identify the need for surveillance.
	1	PTM	**Appoint Surveillance Team** Select an appropriate team (1 or more members) according to the competences required. (Indicated surveillance team is composed by TPO and QAO). Go-to 2. Notify Entity to be Surveyed.
	2	Surveillance Team	**Notify Entity to be Surveyed** Send a message with notification to the entity to be surveyed. Go-to 3. Prepare Surveillance.
	3	Surveillance Team	**Prepare Surveillance** Prepare the surveillance by creating a list of activities to perform according to the possible issues. Go-to 4. Conduct Surveillance.
	4	Surveillance Team	**Conduct Surveillance** The surveillance includes the activities foreseen in the preparation or other activities the Surveillance Team regards necessary to perform once it is on site. The surveillance will determine the necessity of raising a Field Observation Report (FOR). Go-to 5. Issue Surveillance Report.
	5	Surveillance Team	**Issue Surveillance Report** Prepare the Surveillance Report QA-220-R (22LCYR), register in idm and process its approval (as per §I.7). Go-to Gate 6: 'FOR Necessary?'
	6	Surveillance Team	**FOR Necessary?** NO: A FOR is not necessary. Go-to 7a. Distribute Report. YES: A FOR is necessary. Go-to 7b. Issue FOR.
	7a	Surveillance Team	**Distribute Report** Send the Surveillance Report to the entity surveyed (e.g. supplier) and distribute it internally (inline management). Go-to 14. Archive.
	7b	Surveillance Team	**Issue FOR** Prepare the Field Observation Report F4E-QA-211 (22EFNJ), register in idm and process its approval (as per §I.7). Go-to 8. Distribute Reports.
	8	Surveillance Team	**Distribute Reports** Send the Surveillance Report and FOR to the Supplier and distribute it internally (inline management & QAO). Go-to Gate 9: 'FOR Type'
	9	Surveillance Team	**FOR Type?** The process continues depending on the type: Deviation: FOR depicts a Deviation with one of the items under Surveillance. Go-to 10a. Nonconformity Control Process. NC: FOR depicts an NC with one of the items under Surveillance. Go-to 10b. Deviation Control Process. Message: FOR requests to send a message to the supplier. Go-to Gate 11: 'Request Reply or Send Info?'
	10a	Surveillance Team	**Nonconformity Control Process** The FOR triggers a Nonconformity to be processed according to Nonconformity Control process (F4E_D_22MDXC). On resume, Go-to 14. Archive.
	10b	Surveillance Team	**Deviation Control Process** The FOR triggers a Nonconformity to be processed according to Deviation Control process (F4E_D_22CCM4). On resume, Go-to 14. Archive.
	--	--	Process continues on next page.

Activity	#	Resp.	Guidance
	--	--	Continue Process.
	11	TPO	**Request Reply or Send Info?** Send Info: FOR addresses an issue that should be transmitted to the Supplier. Go-to 12a. Send Information to Supplier. Request Reply: FOR addresses an issue that requires further info/reply from the supplier. Go-to 12b. Request More Information.
	12a	TPO	**Send Information to Supplier** Send the relevant information to the follow-up and correct execution of the contract to the supplier for his consideration. Go-to 14. Archive.
	12b	TPO	**Request More Information** Send a message to the supplier with the request for further information concerning the surveillance action. Go-to Gate 13: 'Accept?'
	--	--	Process flow cannot continue without receiving the reply from the supplier.
	13	TPO	**Gate 13: 'Accept?'** YES: The additional information raises no further concerns. Go-to 14. Archive. NO: The additional information raises further concerns. Go-to Gate 11: 'Request Reply or Send Info?'
	14	TPO	**Archive** Close the Quality Surveillance Process and archive the related documentation. Send the information to the PTM and Surveillance Team.
	--		The process terminates.

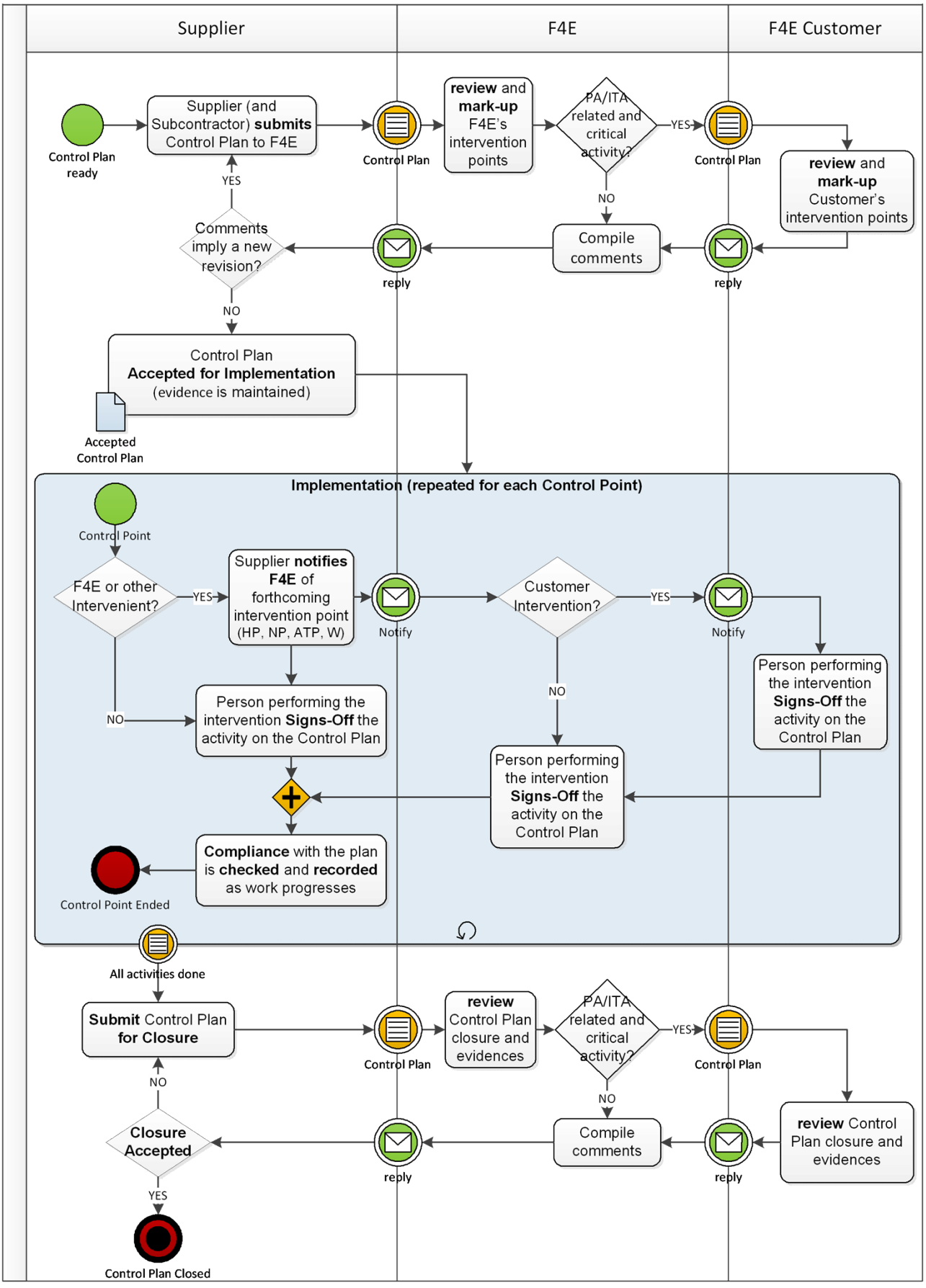
ANNEX 5 – NONCONFORMITIES OVERALL PROCESS FLOWCHART



ANNEX 6 – SUPPLIER DELIVERABLE ACCEPTANCE OVERALL FLOW



ANNEX 7 – CONTROL PLAN OVERALL FLOW



ANNEX 8 – MAIN IO QA & MANAGEMENT REQUIREMENTS

Please refer to Matrix F4E Implementation and Propagation of ITER General Requirements (27RGZ4) for the up-to-date matrix.

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
Procurement Arrangements and ITAs			
Annex A - *4. Tendering Process* *4.2.2 At least 20 (twenty) calendar days prior to the commencement of any tender action to potential Suppliers for the Items subject to this PA, the DA shall provide the IO with a written description of the procurement process for the award of contracts in support of this PA* ***"Procurement Description"*** ITER_D_2LFF4U v1.8	Procurement Description (PA) §V.5.2	F4E-QA-233 (F4E_D_22DGSL)	NA
Annex A – 6. Quality Assurance			
(old PAs)	Document Schedule §V.2	PM-07 (F4E_D_22KS43)	F4E-QA-115 §1
DA's Domestic Agency's dedicated "**Quality Plan**" (ITER_D_22MFMW / ITER_D_RTN9L8)	Project Management Plan §V.5.2	F4E-QA-205 (F4E_D_22FUSH)	NA
Supplier's/Subcontractor's dedicated "**Quality Plan**" (ITER_D_22MFMW / ITER_D_RTN9L8)	Supplier Quality Plan §V.5.9	F4E-QA-202 (F4E_D_22DWZP) PM-29-WorkPackage Implementation	F4E-QA-115 *§1*
Supplier's/Subcontractor's "**Manufacturing and Inspection Plans (MIPs)**" (ITER_D_22MDZD)	Supplier Control Plan §V.5.2, §V.5.9	F4E-QA-202 (F4E_D_22DWZP) PM-38 - Quality Surveillance	F4E-QA-115 *§2.2.3 & §4*
During contract implementation Issue "**Deviation Request" and "Non-Conformance Reports**" as necessary (ITER_D_22F53X / ITER_D_RGF2R7)	Deviation Request §V.5.12 and DR from Supplier §V.5.9 Nonconformity Report Supplier NCR §V.6.6	PM-06 Deviation Control (F4E_D_22CCM4) PM-35 Nonconformity Control (F4E_D_22MDXC) PM-42 Corrective Action Request (F4E_D_29KV8Z)	F4E-QA-115 *§2.2*
Prior to delivery, complete the "**Contractor Release Note**" "(ITER_D_22F52F / ITER_D_RTP6VG)	Release Note, from Supplier Quality Plan. F4E Release Note §V.5.9	F4E-QA-202 (F4E_D_22DWZP) F4E-QA-238 (F4E_D_22K7W3)	F4E-QA-115 *§2.6*
Annex A – 7. Licensing requirements			
7.1 The Suppliers and Subcontractors must be informed that: • **ITER is a nuclear facility** identified in France by the number-**INB-174**; • The **Order 7th February 2012** applies to all the components and the activities important for the protection; •The compliance with the INB-order must be demonstrated in the **chain of Suppliers** and Subcontractors; •In application of article II.2.5.4 of the Order 7th February 2012, contracted activities for **supervision purposes** are also subject to a supervision done by the Nuclear Operator.	Quality Approach to Safety §III.4. Propagation of the Nuclear Safety Requirements along the F4E Supply Chain. §III.4.3. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-016 F4E-QA-019	F4E-QA-115 *§1* F4E-QA-115 *§2.14* F4E-QA-113, F4E-QA-119, F4E-QA-114
*7.3 For the **Protection Important Components**, structures and systems of the nuclear facility, the DA shall ensure that (if applicable):* *Quality Assurance requirements are fulfilled by a **system that complies in particular with the requirements of title II Order 7th February 2012**…;* *The Suppliers and subcontractors must be informed that a **"significant" event or NCR**, as defined in chapters 2.6.4 and 2.6.5 of the Order 7th February 2012 shall be reported by IO, the nuclear operator, to the safety regulator as soon as possible;*	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-016 F4E-QA-019	F4E-QA-115 *§2.14* F4E-QA-113, F4E-QA-119, F4E-QA-114

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
Applicability of ITER Policy on Safety, Security and Environment Protection Management (ITER_D_43UJN7 v2.0)	Quality Approach to Safety §III.4.	---	F4E-QA-115 *§1*
Generic Safety Requirements by the External Interveners (ITER_D_SBSTBM)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-113	QA-115 §2.14
Overall Surveillance Plan of External Interveners Chain for PIC, Structures and Systems and PIA (ITER_D_4EUQFL)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-016	F4E-QA-115 §2.8.1 REQ-0107, §3.2.12 REQ-0190, §2.1.2 REQ-0009 and §2.4 REQ-0059 REQ-0060) F4E-QA-113
Annex A - 10. Risk Management 10.1 Risk management will be performed in accordance with the "Risk Management Plan" / "Risk Management Procedure" (ITER_D_22F4LE v5.1) and implemented through the DA Project Risk Management Process.	Risk Plan (inside PMP) Project Risk Management §V.5.2	F4E-QA-205 (F4E_D_22FUSH) F4E -QA-221-R (F4E_D_22HPB6) PM-23 Project Risk Management	F4E-QA-115 *§3.2.9*
ITER Quality Assurance Programme (QAP) (ITER_D_22K4QX v8.5)			
QAP 2 Management Responsibilities and Quality Requirements	*Section header*		
QAP 2.1 ITER Management	Functions Description §III.2. Management Responsibilities §V.3.	Quality Management Policy (F4E_D_25929B)	F4E-QA-115 §3.1.1
QAP 2.2 Quality Assurance & Assessment Division	Functions Description §III.2	Quality Management Policy (F4E_D_25929B)	F4E-QA-115 §3.1.1
QAP 2.3 Quality Classification Quality Classification Determination ITER_D_24VQES v4.1	Quality Classification §V.1.1.	'Quality Classification' Procedure (F4E_D_22MD99)	F4E-QA-202 Annex A
QAP 2.4 Management and Quality Program Objectives	Quality Policy §II Quality Objectives §V.3.4.1.	Corporate Objectives QA Surveillance/Supervision Plan	F4E-QA-115 §3.2.1
QAP 2.5 Roles and Responsibilities	All document	F4E QA Programme for ITER Project (F4E_D_22MCBA)	F4E-QA-115 §3.2.2
QAP 2.6 Stop Work Authority	Stop Work Authority §V.3.2	---	F4E-QA-115 *§3.2.2*
QAP 2.7 Continuous Quality Improvement	Assessment and Improvement §V.6. Continual Improvement §V.6.8.	Management Standards (F4E_D_24LQJM)	--
QAP 2.8 Deviation Request	Deviation Request §V.5.12 and DR from Supplier §V.5.9	PM-06 Deviation Control (F4E_D_22CCM4)	F4E-QA-115 *§2.2*
QAP 2.9 Non-conformance Reporting	Nonconformity Report Supplier NCR §V.6.6	PM-35 Nonconformity Control (F4E_D_22MDXC) PM-42 Corrective Action Request (F4E_D_29KV8Z)	F4E-QA-115 *§2.2*
QAP 2.10 Personnel Training and Qualification	Training §V.4.1.	Training Management (F4E Manual)	F4E-QA-115 *§3.2.2* F4E-QA-115 *§2.5.3*
QAP 2.11 Control of Activities affecting quality (thru MQP documents)	Project Management §V.5 Product Execution §V.5.10. Monitoring and Measurement of Processes §V.6.3	PM-29-WorkPackage Implementation F4E-QA-016 PM-38 - Quality Surveillance	F4E-QA-115 *§2.5* F4E-QA-115 *§3.2.1* F4E-QA-115 *§3.2.8* F4E-QA-115 *§4.0*
QAP 3 Project Realization Process	*Section header*		
QAP 3.1 Configuration Management	Configuration Management (PCR Control) Deviation Request §V.5.12 and DR from Supplier §V.5.9	F4E-IO CMP (F4E_D_22P3BC) PM-06 (F4E_D_22CCM4)	F4E-QA-115 *§2.2.1*
QAP 3.2 Documents and Records	Documentation §V.2.	PM-07 Document Control (F4E_D_22KS43) F4E Documentation Policy (F4E_D_24L87F)	F4E-QA-115 §2.3
QAP 3.3 Design Control	Design Management § V.5.7	PM-27 (F4E_D_22CLT3) F4E Design Review Procedure (SOP-002) (F4E_D_23NYBM) F4E CAD Manual (F4E_D_22BE49)	F4E-QA-115 *§3.1.10*
QAP 3.4 Procurement Process	Procurement and Grants Management §V.5.9.	Procurement and Grant Procedures (F4E Manual) PM-98 Changes in Subcontracting (F4E_D_24DB5W)	F4E-QA-115 *§2.4, §3.1.6,* F4E-QA-115 *§3.2.7* *Subcontracting Schedule*

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
QAP 3.5 Manufacturing, Assembly and Installation Process	Product Execution §V.5.10 Product Verification / Validation §V.5.11	PM-29-WorkPackage Implementation PM-63 Deliverable Acceptance (F4E_D_262PUA)	F4E-QA-115 *§2.6* F4E-QA-115 §3.2.8
QAP 3.6 Identification and Control of Items	Identification and Control of Items §V.5.13.	PM-38 - Quality Surveillance	F4E-QA-115 §3.2.11 F4E-QA-112 Naming Convention (F4E_D_22GGJ4)
QAP 3.7 Calibration of Monitoring and Data Collection Equipment	Measuring and Test Equipment (MTE), Supplier MTE § V.5.15	F4E-QA-219 (F4E_D_22TKRJ)	F4E-QA-115 *§3.2.6*
QAP 3.8 Inspection and Testing Activities	Inspection and Testing §V.6.5	PM-38 Quality Surveillance (F4E_D_22DDMG)	F4E-QA-115 *§3.2.12*
QAP 3.9 Handling, Storage and Transportation	Product Preservation and Transportation §V.5.14.	NA	F4E-QA-115 §3.2.17
QAP 3.10 Software Control and Model Development	Computer Code & Model Development §V.5.8.	F4E-QA-114	F4E-QA-115 *§2.5.6*, §3.2.8.1 F4E-QA-114
QAP 3.11 Research and Development	Research and Development (R&D) §V.5.6	---	F4E-QA-115 *§1*
QAP 3.12 Operations and Maintenance	Design Management § V.5.7 Documentation §V.2.	--	F4E-QA-115 *§3.1.10* F4E-QA-115 *§2.1.3* QA115-REQ-0012
QAP 3.13 Research Program	Project Management §V.5 Product Execution §V.5.10.	PM-29-WorkPackage Implementation	F4E-QA-115 *§3.2.1* F4E-QA-115 *§3.2.8* F4E-QA-115 *§4.0*
QAP 4 Audits and Assessments	Section header		
QAP 4.1 Audits and assessments Quality Management System Audits (ITER_D_2DQTA8 v5.0)	Quality Management System Audits §V.6.2	PM-28 QMS & Supplier Audits (F4E_D_22H84F)	F4E-QA-115 *§2.8.1*
	Inspection and Testing §V.6.5.	PM-38 Quality Surveillance (F4E_D_22DDMG)	
	Management Review §V.3.5.	PM-46 QMS Maintenance Process (F4E_D_22HK8L)	F4E-QA-202 Annex A
QAP 4.2 Audits and assessment responses	Assessment and Improvement §V.6.	Improvement Steering Committee Improvement Network	F4E-QA-115 *§2.8*
QAP 4.3 Documentation of results	Assessment and Improvement §V.6.	PM-28 QMS & Supplier Audits (F4E_D_22H84F) PM-38 Quality Surveillance (F4E_D_22DDMG)	F4E-QA-115 §2.2 F4E-QA-115 §2.8.1
ITER Procurement Requirements (PQR) (ITER_D_22MFG4 v5.0)			
PQR 5 ITER Procurement Quality Clauses	Section header		
PQR 5.1 Quality Management System *The performers of IO project activities shall establish and implement a quality system capable of ensuring that: contract requirements are met and evidence of such compliance is maintained* (PQR 5.1)	Quality Framework §I.3 Quality Assurance (QA) Programme §III	F4E QA Programme for ITER Project Management Standards (F4E_D_24LQJM)	F4E-QA-115 §1
PQR 5.2 R&D Activities	See QAP 3.11		
PQR 5.3 Design	See QAP 3.3		
PQR 5.4 Qualification Of Special Processes	Qualification in Special Processes §V.4.1.3.	---	F4E-QA-115 *§2.5.2, §2.5.5*
PQR 5.5 Manufacturing, Inspection And Testing	See QAP 3.8 & QAP 3.5		
PQR 5.6 Measuring And Test Equipment	See QAP 3.7		
PQR 5.7 Handling, Storage And Shipping	See QAP 3.9		
PQR 5.8 Deviations And Non-Conformances	See QAP 2.8 & QAP 2.9		
PQR 5.9 Acceptance And Delivery	Product Verification / Validation §V.5.11.	PM-38 Quality Surveillance (F4E_D_22DDMG) PM-63 Deliverable Acceptance (F4E_D_262PUA)	F4E-QA-115 *§2.6*
PQR 5.10 Personnel Training And Qualification	See QAP 2.10		
PQR 5.11 Access	---	Model Contracts	F4E-QA-115 §2.8 F4E-QA-115 §3.1.7

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
PQR 6 Applicable ITER Quality Documents	---	PA Annex A	---
Propagated Nuclear Safety Requirements			
Propagation, Recording and Reporting of Safety Defined Requirements and PIC (INB Order art. 2.5.1, Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E–QA-019	F4E-QA-115 §1 REQ-0003 §3.2.1.1 REQ-0157 F4E-QA-113 F4E–QA-119
Supply Chain and Surveillance of Suppliers Carrying Out PIA (INB Order art. 2.2.1 to 2.2.4 Ch.II, 2.5.4 Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-019 F4E–QA-016	F4E-QA-115 §2.8.1 REQ-0107, §3.2.12 REQ-0190, §2.1.2 REQ-0009 and §2.4 REQ-0059 REQ-0060) F4E-QA-113
Identification and Reporting of **PIA** (INB Order art.. 2.5.2, 2.5.3, 2.5.6 Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-016	F4E-QA-115 §4.1 REQ-0208. PIA Guideline(F4E_D_27WDLC) F4E-QA-113
Management of the **Qualifications and Experience of Personnel** (INB Order art. 2.5.5 (Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013	F4E-QA-115 §3.2.2 REQ-0160. F4E-QA-113
Management of **Validation and Verification** and Use of Different Staff (INB Order art. 2.5.5 and 2.5.3 Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013	F4E-QA-115 §2.8.1, §2.5 F4E-QA-113
Identification and Management of **Deviations and Nonconformities** (INB Order art. 2.6.1 to 2.6.5 Ch. VI)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	PM-06 Deviation Control PM-35 Nonconformity Control	F4E-QA-115 §2.2
Reporting back to the INB Operator the **Information Required for the Operating Licence Application** (INB Order art. 2.5.5, 2.5.7 Ch.V)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-113	QA-115 §2.14, §2.1.3 REQ-0012
Requirements relating to the **verification of design** (INB Order art 3.8 Titre III)	Quality Approach to Safety §III.4. Safety Arrangements Follow-Up §V.5.9.5	F4E-QA-013 F4E-QA-016	F4E-QA-115 §2.5.6. F4E-QA-114 Instructions for Suppliers Performing Design Analysis

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