FUSION FOR ENERGY

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EXTERNAL REFERENCE

F4E Document

P-01.18 Management and Quality Programme for ITER Project (EUDA QAP)

Management and Quality Programme for Items and Services Provided by F4E to the ITER Project
(this is the IO requested EU-DA QAP to the ITER Project)

Approval Process			
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Approver	**F4E-Director S. J.**	**11 December 2019:approved**	**DIR**
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Change Log			
P-01.18 Management and Quality Programme for ITER Project (EUDA QAP) (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.
v3.0	Approved	26 November 2019	Change of title to MQP, update BPM and QAU, new organisation and PgM/PjM. Track changes in attachement

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STANDARD

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Document title:	**Management and Quality Programme for ITER Project (P-01.18)** **(EUDA QAP for ITER Project)**

Areas and functions	
Document Owner:	Business Process Manager (D. Rodrigues)
Document Responsible:	Business Process Manager (BPM) (D. Rodrigues)
Area(s) concerned:	Quality Management System, Quality Assurance, Delivery to ITER
Function(s) concerned:	BPM for development, monitoring and maintenance of the QMS as part of the Integrated Management System. All Operational Roles for implementation. QA Unit and QA Officers for implementation and monitoring at the level of the supply chain.

Purpose

The F4E Integrated Management System (IMS) covers the whole Management System and addresses the two control environments in which F4E operates - the ITER-wide Quality System which is intended to ensure the performance of ITER against the various technical requirements, including the nuclear safety requirements, and the EC Internal Control Framework.

The IMS is composed of the Quality Management System, the F4E Internal Control Strategy, the Business Process Management framework and the Documentation Management framework.

This document describes and establishes the dedicated F4E Quality Management System 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 Integrated 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] ISO 9001:2015 – 'Quality management systems -- Requirements'.
[2] IAEA General Safety Requirements - GSR Part 2 - Leadership and Management for Safety (2015)
[3] ITER Policy on Safety, Security and Environment Protection Management (ITER_D_43UJN7)
[4] French Order 7 February 2012 - *République Française - Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base*. INB Order,
[5] 'F4E Management and Internal Control Standards', P-02.20, F4E_D_24LQJM
[6] 'F4E Internal Control Strategy', P-02.09, F4E_D_2JW5PU
[7] 'Business Process Management', P-02.17, F4E_D_23XKQW
[8] 'F4E Documentation Management', P-02.23, F4E_D_24L87F
[9] F4E-QA-115 – 'Supplier (PM and) Quality Requirements', P-01.14, F4E_D_22F8BJ

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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	
Business Process Manager	F4E Business Process Manager	BPM
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 Activity	Protection Important Activity (definition in INB Order [4] article 1.3) *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	(definition in INB Order [4] article 1.3)(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	QAO
QA Unit	Quality Assurance Unit (PM Department)	QAU
QMS	Quality Management System	
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. In the scope of this document the Supplier is equivalent to External Provider (ISO9000:2015)	---
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. Management and Quality Programme Promulgation

(a) The 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 programme are preponderant factors to the maintenance and improvement of the Management and Quality Programme, as well as to the Organisation's 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 subcontracted qualified economic operators.

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

I.3. Integrated Management System

(a) The Quality Framework in F4E is captured in the F4E Integrated Management System.

(b) The F4E Integrated Management System covers the whole Management System and addresses 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 various requirements, including nuclear safety requirements, and the (COSO-based) Internal Control Framework as implemented by the European Commission.

(c) The backbone of the system is the Management and Internal Control Standards [5]. A set of standards specifically developed by F4E, integrating the ISO9001 quality requirements, the European Commission Internal Control Framework (ICF) and the ITER Project quality and safety requirements.

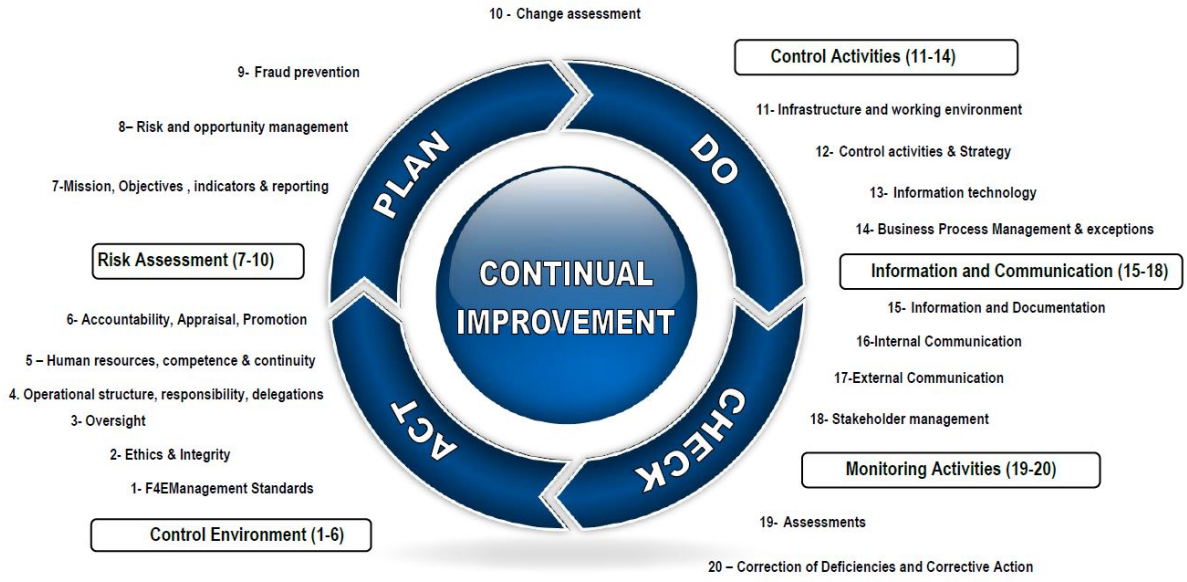

Figure 1 (I.3): F4E Management and Internal Control Standards

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

(d) Operationally, this system is implemented through the Quality Management System (as described in the F4E Management and Quality Programme) that 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.

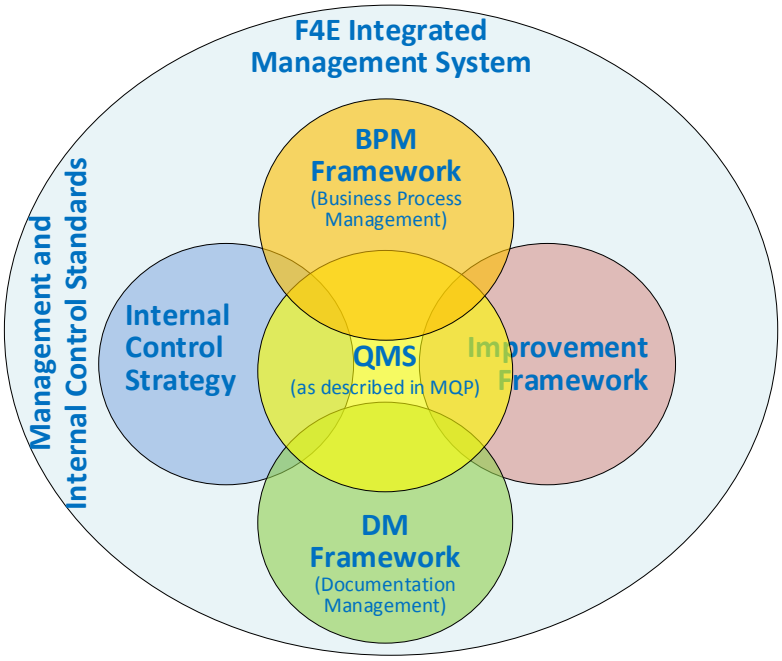

Figure 2 (I.3): F4E Integrated Management System and its building blocks

II. MANAGEMENT AND QUALITY POLICY

According to the F4E Integrated Management System, the Management and Quality Policy is:

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MANAGEMENT AND 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 requirements of the ITER-wide Quality System and the European Commission Internal Control Framework) 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 Management and Quality 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 staff. F4E expects the commitment of its entire staff to guarantee that its activities are prepared and carried out according to the established policies, processes and procedures.
This Policy is reviewed and renewed on a regular basis.

[idm review and approval)
Johannes Schwemmer
F4E Director

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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 28 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).

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) The coverage of this F4E Management and Quality Programme encompasses activities performed by or for F4E in the ITER project, ranging from research and development (R&D) to system acceptance. Furthermore, it is expected that F4E Suppliers will have implemented QA programs aligned with this MQP.

(c) In general, items and services are provided by assigning the relevant activities to qualified economic operators through contracts (or grant agreements), in accordance with the legal framework laid down inter alia by the Financial Regulation of F4E.

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-FR	'Financial Regulation of the Joint Undertaking' (F4E_D_24F9UH)

III.2. Functions Description

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

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

(g) Implementation of quality 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.

(h) Particular attention is given to 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 standards, in order to ensure availability of the relevant information and traceability of the end product over the whole project lifetime.

(i) 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 project management and 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.

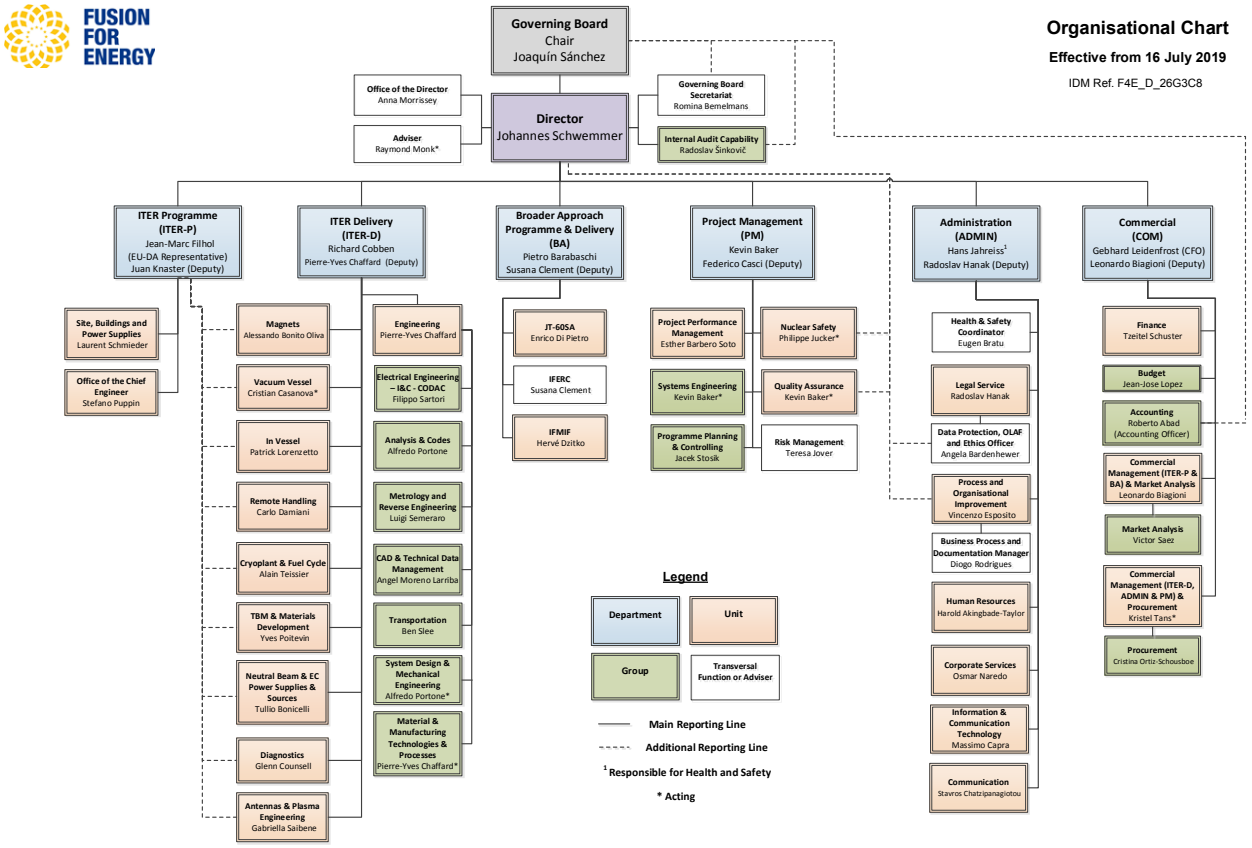


Figure 3 (III.2): Operational Structure (July.2019)

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 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) 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 in 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 in relation to dedicated work.

III.2.3. Head of Unit (or Programme Manager)

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

(b) The Head of Unit is responsible for:

(i) managing the programme(s) technically and financially 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. Decision-Making Meetings (Senior Management)

III.2.4.1. SMM (Senior Management Meeting)

(a) The Senior Management Meeting (SMM) is the main decision-making body for collectively directing, coordinating and controlling Fusion for Energy (F4E).

(b) The SMM members are collectively responsible for the management of F4E; they shall cooperate closely and keep each other informed on any developments that impact F4E.

(c) Without prejudice to the rights and obligations of the Director as Authorising Officer, the SMM shall address the subjects of Performance, Organisation, Compliance and Stakeholders.

(d) The Members of the SMM are the Director and Heads of Department supported by a Secretary. Members unable to attend may ask a deputy to represent them. Guests may be invited by SMM Members to attend meetings for specific agenda points.

(e) The SMM will typically take place every two weeks and is convened by the Secretary.

III.2.4.2. PSM (Project Steering Meeting)

(a) The Project Steering Meeting is a forum for monitoring and controlling the implementation of operational projects by F4E and for having decisions approved by Senior Management. The PSM monitors the overall progress of all of the ITER projects under F4E's responsibility.

(b) Major QA issues on the implementation of the operational projects are reported and discussed in the PSM.

(c) The PSM will typically take place every month and is convened by the Secretary.

III.2.4.3. ISC (Improvement Steering Committee)

(a) The Improvement Steering Committee provides a dedicated forum to decide on the improvement actions required for the organisation, arbitrating on priorities of resource allocation, aligning visions on efficiency requirements and monitor their progress.

(b) The main objectives of the ISC, quality wise, are:

(i) Adopt the strategy and ruling principles of the Integrated Management System including the development strategy of the F4E Manual to disseminate the information in an aligned way across the organisation;

(ii) Monitor the efficiency of the Management System and push it to reach higher process maturity levels;

(iii) Approve (corporate) improvement actions and their output.

(c) The Members of the ISC are the Director, the Heads of Department, the POI HoU, the BPM and is supported by a Secretary. Guests may be invited by SMM Members to attend meetings for specific agenda points.

(d) The ISC will typically take place every month and is convened by the Secretary.

Reference and Applicable Documents:

SMM	Charter of the Senior Management Meeting of Fusion for Energy (F4E_D_25SFF4)
PSM	Charter of the Project Steering Meeting (F4E_D_28HR8T)
ISC	Charter of the Improvement Steering Committee, P-02.10 (F4E_D_26CDYY)

III.2.5. Business Process Manager

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

(b) The missions of the Business Process Manager (BPM) are:

(i) To define and permanently improve, in co-ordination with the process owners, the IMS encompassing F4E's Management and Quality Programme and related top-level Policies and Processes in compliance with the F4E Management and Internal Control Standards and the F4E Business Process Management framework;

(ii) To support the monitoring of the their effectiveness with the departments concerned as well as to ensure the organisation complies with F4E's regulatory framework;

(iii) To represent F4E in the IO-CT Management and Quality Programme Control Board (MQPCB) and liaise with managers and staff inside F4E that may be impacted by any decisions that are taken;

(iv) To coordinate the definition and implementation of the MQP ensuring overall consistency and its effectiveness across the organisation;

(v) To monitor the compliance with the MQP and the implementation of the operational and administrative delegations;

(vi) To programme and manage the annual QMS Audit Programme implementation.

(c) The Business Process Manager reports to the Head of Process and Organisation Improvement (POI).

III.2.6. Quality Assurance Unit (Leader)

(a) The mission of the Quality Assurance (QA) Unit is to ensure that the F4E quality requirements are correctly implemented and managed for the F4E contribution to ITER. In particular, the QA unit is responsible for providing support to the projects in the domains of Quality Assurance and Quality Control.

(b) The main responsibilities of the QA unit in this domain are:

(i) Support the Programmes on QA and QC topics ensuring that the Quality Management System as described in the F4E MQP is implemented through the supply chain. Advise the programme and project manager and officers on QA matters;

(ii) To define, coordinate, develop and implement the general Supplier Quality Requirements, including the annual Supplier Audit Programme;

(iii) To represent F4E in the IO-CT Management and Quality Programme Working Group (MPQWG) and liaise with managers and staff inside F4E that may be impacted by any decisions that are taken;

(iv) Develop and maintain the annual quality surveillance plan defining the planned quality assessment activities;

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

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

(vii) Manage the F4E Inspectors contract and any potential third party inspection Framework Contract for supporting the Programmes in QC activities;

(viii) Monitor the QA/QC activities and identify F4E MQP opportunities for improvement and liaise with the POI Unit to propose changes;

(ix) Organize regularly trainings of operational QA.

III.2.7. QA Officers

(a) The QA officers support the QA unit in achieving its mission. The QA Officers should be knowledgeable and experienced persons in QA/QC and in the work to be performed by the team(s) they are assigned to.

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

(c) They are assigned to the Programme teams to support the implementation of the MQP through the supply chain, including to:

(i) To monitor the QA and QC activities follow-up;

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

(iii) To integrate quality requirements in the management specification issued to suppliers;

(iv) To assess quality and control plans provided by the task suppliers;

(v) To coordinate the ‘nonconformities’ process implementation in the contracts.

III.2.8. BPM Network

(a) In order to support the implementation of Business Process Management Strategy, a BPM Network was set up to:

(i) provide a forum where the key and core process owners involved in the development of working procedures across Departments work together to implement the BPM approach coherently;

(ii) align views and methods in implementing the BPM approach and BPM principles in the respective areas of activity;

(iii) ensure the appropriate communication and dissemination of BPM outputs.

(b) The BPM is the coordinator of the network and QAU has a permanent representant to ensure the correct dissemination within the QA officers.

Reference and Applicable Documents:

BPM Network	BPM Network Charter (F4E_D_2FH8LB)

III.3. Management and Quality Programme (MQP)

III.3.1. Propose

(a) The Management and Quality Programme provides the overall framework to establish, to execute, to evaluate and to continually improve the Quality Management System following the same approach as outlined in ISO 9001 (2015) and in IAEA GSR Part 2 (Leadership and Management for Safety, 2015) [2] in order to ensure alignment to the IO MQP and 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 external provider to IO with respect to the French Nuclear Regulation.

(c) This document defines the organisational structure of the organisation, the documental structure of the MQP 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 MQP is part of the F4E Integrated 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 Corporate Quality Policy
- Section III gives a summary of F4E, presents the MQP organisation and management. The functions/entities that have direct influence in the Quality Management System 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 Management System and the MQP evolve with the organisation and the continual improvement approach (describe in § V.6.8).

(b) The MQP is reviewed by the Business Process Manager and the Improvement Steering Committee; its approval and promulgation is the competence of the Director.

(c) The Business Process Manager has the responsibility to keep the master version on the F4E document server updated and to inform the Senior Management.

(d) The master version being an electronic document, the Business Process 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) and the F4E Documentation Management Policy [8].

III.3.4. Versions and Issues

(a) The evolution of the Quality Management System and the MQP implies revisions to the relevant sections. Changes related to the latest revision are registered on the 'Change Log' (inserted after the cover page and in the documentation management 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 responsible for the preparation of the MQP is the Business Process Manager.

(b) Printed copies of the MQP 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)
[8]	F4E Documentation Management Policy (F4E_D_24L87F)

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 provider (*external intervenient* as per ASN) 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 to applying and propagating the ITER Policy on Safety, Security and Environment Protection Management [3] in its supply chain.

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 the highest priority

(ii) The quality management system as described in the MQP 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 generic MQP 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

(a) The key document in the propagation of the Nuclear Safety requirements is the F4E-QA-113 (Supplier Nuclear Safety Management Requirements), which is implemented using the quality assurance tools and complemented by the F4E-QA-115 (Supplier Quality Requirements) [9].

(b) The following table identifies the requirements in the scope of this MQP from the INB Order and the operator.

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 requires Suppliers to ensure the propagation of safety requirements throughout the Supply Chain, both relating to the management of the Defined Requirements for PIC and for the management of PIA and QA functions. The F4E monitoring and supervision of the Supply Chain is object of dedicated supervision plans issued at project/programme level. F4E requires Suppliers to perform supervision activities of subcontractors.
Propagation, Recording and Reporting of Defined Requirement for PIC	2.5.1	F4E requires Suppliers to receive, manage and update the Defined Requirements for PIC, as well as their Verification Activities and evidence records. 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 requires the propagation of PIA, including 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

Requirement to Propagate	INB Order art.	Propagation by F4E
		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.
Management of Validation and Verification and Use of Different Staff	2.5.5 and 2.5.3	Suppliers are required to perform the verification and validation of software to perform design analysis. Suppliers are also required to use different SQEP staff for the verification and validation to those performing the work.
Identification and Management of Deviations and Nonconformities	2.6.1 to 2.6.5	Suppliers are required to have management systems to define, identify, manage and record any deviation or non-compliance with the specified requirements (contract baseline). Including the need for F4E's authorisation to proceed, before the implementation new requirement or the remedy.
Reporting back to the INB Operator the Information Required for the Operating Licence Application PIA	2.5.5, 2.5.7	Suppliers are required to prepare a dossier called Nuclear Safety File with specific contents. 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	F4E provides specific requirements for design of PIC carried out by F4E or its supply chain, in a specific document: F4E-QA-114. In complement F4E also requires for the 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	'Supplier Nuclear Safety Management Requirements', Supplier Standard, (F4E_D_22JRQY)
F4E-QA-114	'Instructions for Suppliers Performing Design Analysis', Supplier Standard, F4E_D_22FR5T
---	PIA Guideline F4E_D_27WDLC

IV. F4E PROCESS MAP

(a) The F4E Integrated Management System (IMS) encompassing the Quality Management System is customer oriented, taking into account equally:

(i) the requirement definitions;

(ii) the customer feedback;

(iii) F4E compliance with the requirements.

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

(c) The F4E Process Map portrays the processes interaction in F4E and is represented in the figures below.

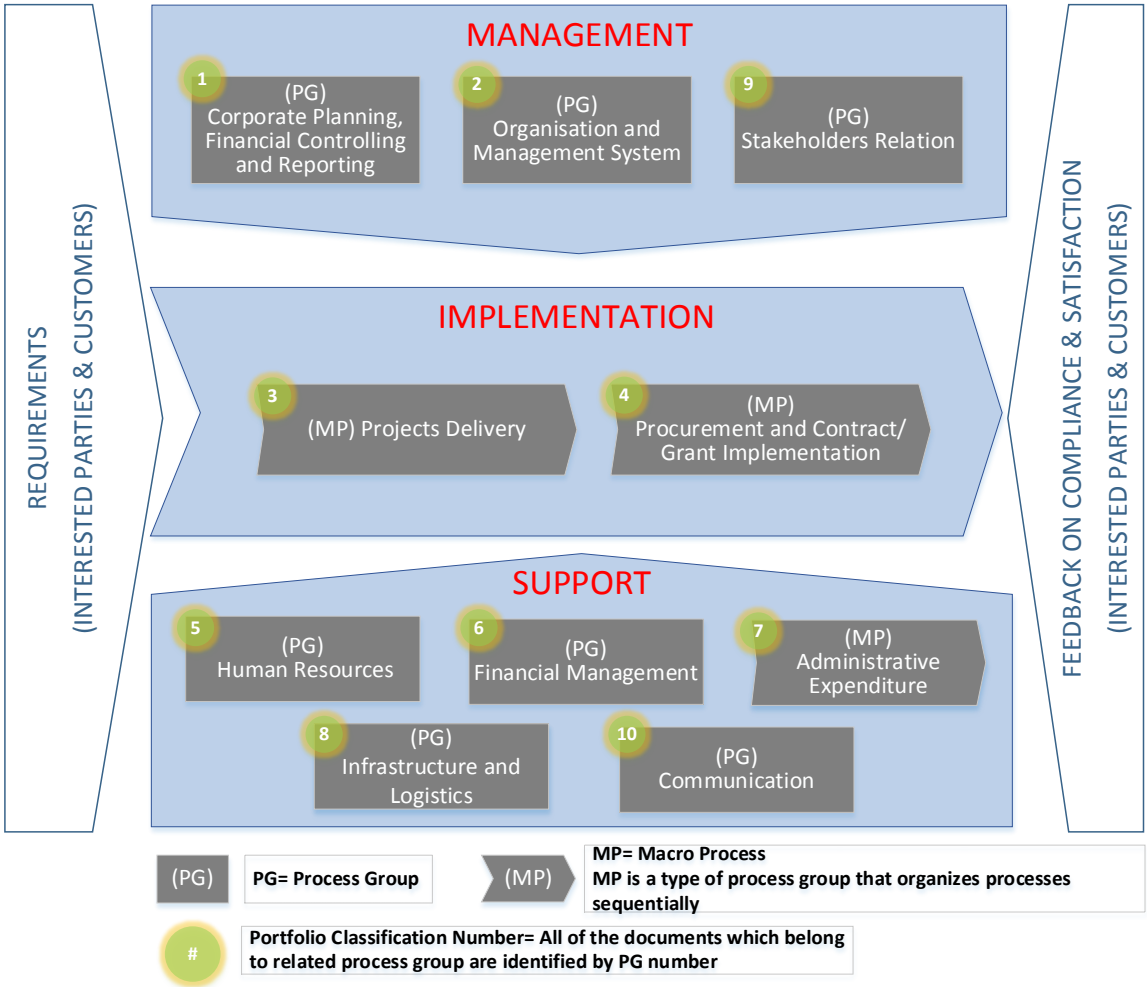


Figure 4 (IV): F4E Process Map

V. QUALITY MANAGEMENT SYSTEM

V.1. General Requirements

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

(b) The implementation and evolution of the Quality Management System (QMS), as described in this Management and Quality Programme, is built 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 the Corporate Objectives: establish the Quality orientations and intentions;

(ii) Planning – identify the processes and their application within the organisation, the sequence and their interaction, identify the associated risks, 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 – realisation 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 outsourced process, the contract to the external provider must be awarded in accordance with the adequate procedure (as defined in V.5.9).

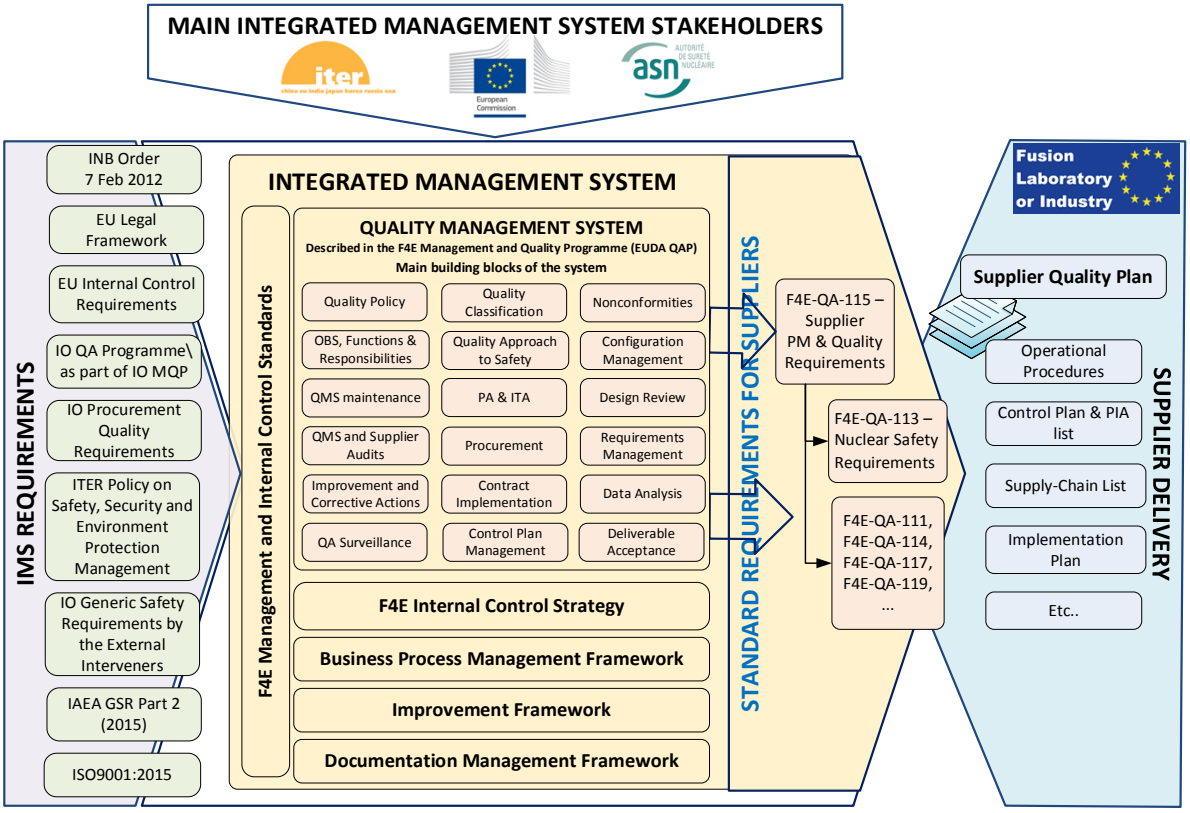


Figure 5 (V): IMS and Quality Management System map

V.1.1. Quality Classification

(a) Quality Assurance levels to be applied to items shall be tailored in line with 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)

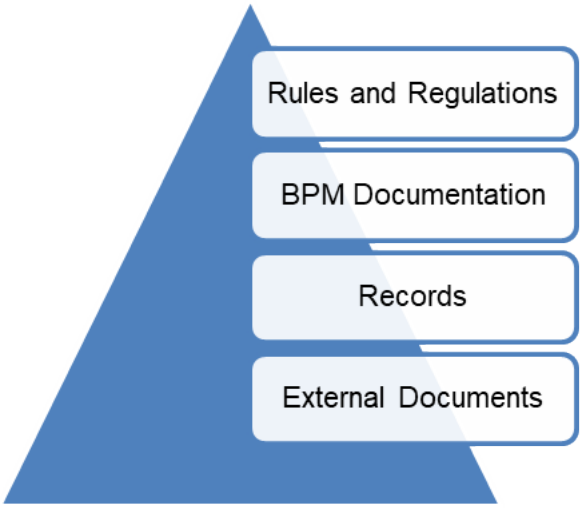
V.2. Documentation

(a) The prepared QMS documentation constitutes an 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 Business Process Management strategy, and is captured in the figures 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).



Rules and Regulations – documents that F4E must comply with to execute its duties, including the legal framework and international agreements.

BPM Documentation – Generic term that includes policies, processes, procedures and supporting tools. Define how staff must perform activities.

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

External Documents - documented information relevant to the quality management system and issued by an external entity

Figure 6 (V.2): Documentation Hierarchy

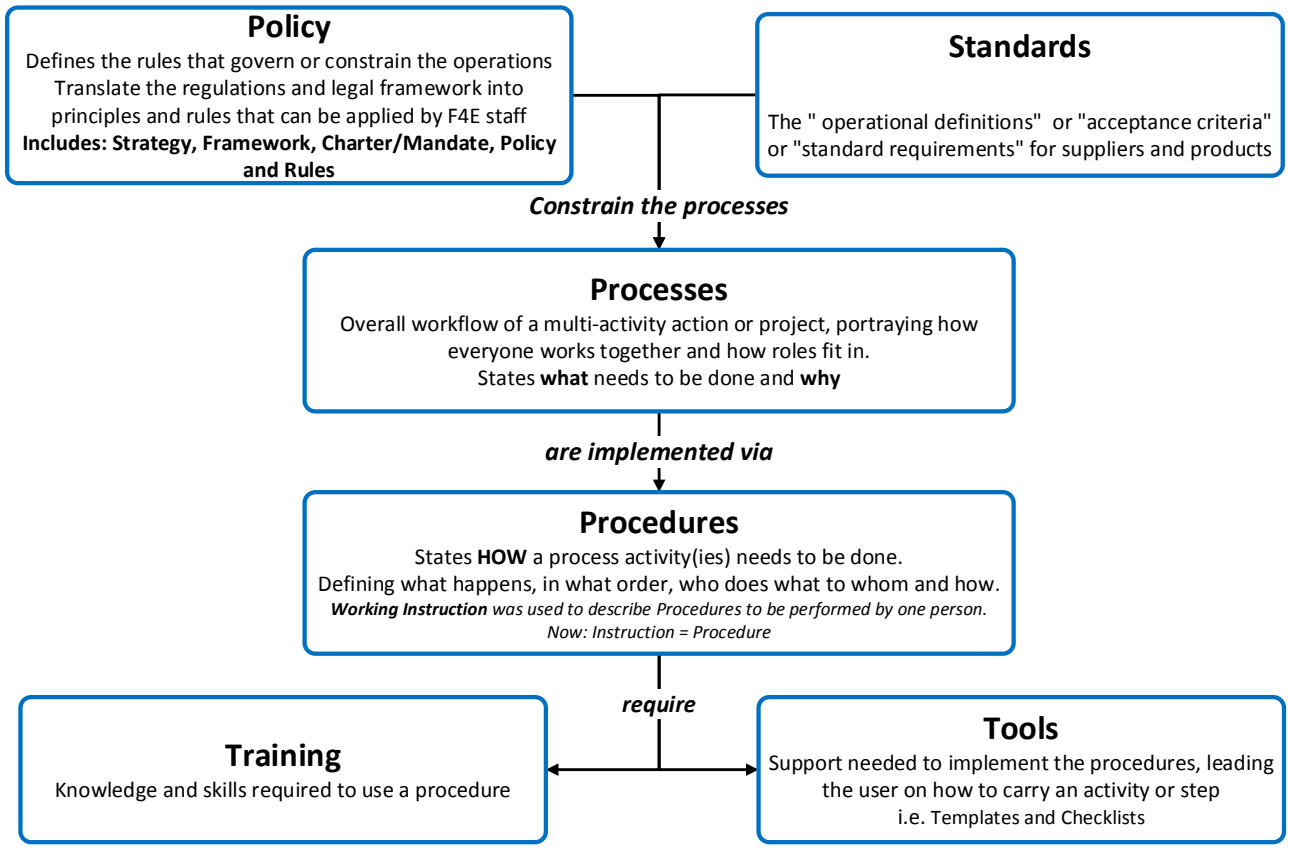


Figure 7 (V.2): Business Process Management Documentation Hierarchy

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

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

(i) ruled by the F4E Documentation Management Policy [8];

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

(iii) reviewed and approved as per the current Business Process Management policy [7].

(g) These documents ensure:

(iv) 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;

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

(vi) that all quality documents are:

(1) archived for appropriate time;

(2) protected;

(3) well-preserved;

(4) easily accessible.

(vii) that associated to the 'Configuration Management Plan', 'Deviation Control' and 'Nonconformity Control' processes, all the documents and records required 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)
[7]	'Business Process Management', P-02.17, F4E_D_23XKQW
[8]	'F4E Documentation Management' 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 appropriate Corporate 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 method that is commensurate with the complexity and significance of the stopped work and the reason it was stopped. As part of their training, 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

(a) 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 (as per this programme).

(b) All the Procurement Arrangements and Task Agreements shall properly define the specific requirements for each product. In the same way, the quality related 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. Corporate Objectives related to MQP

F4E has its Corporate Objectives defined internally for all functions and levels, and some are relevant to the Management and Quality Programme. These 'MQP' related objectives are measurable and consistent with the Management and Quality Policy and include a commitment to continual improvement. The objectives are accompanied by adequate indicators.

V.3.4.2. Management and Quality Programme Planning

(a) The Director must:

(i) Ensure that all the resources necessary to reach the Corporate Objectives (including the MQP related) 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 Management and Quality Programme; this activity is performed with the participation of the Business Process Manager and Senior Management.

(b) The integrity of the implemented Management and Quality 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 8).

V.3.5. Management Review

(a) Management shall yearly assess the status of the quality management system in F4E. This must be done in the Improvement Steering Committee, with the annual assessment of maturity of each activity and the definition of the annual BPM rolling plan, the assessment also ensures the correct propagation of the management and quality as well as safety requirements from IO.

(b) Inputs to the assessment include performance measures, the results of audits and other assessments, IO-CT MQPCB and MQPWG feedback, 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, identifying the adequate actions in the BPM rolling plan.

Reference and Applicable Documents:

[7]	'Business Process Management', P-02.17, F4E_D_23XKQW
PM-42	'Corrective Action Request' Process (F4E_D_29KV8Z)

V.4. Resources Management

(a) The necessary resources to implement, maintain and improve the Management and Quality 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 are complemented by competent external support in sufficient number with regards to 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 programme and project:

(i) Programme Management Plan (that includes the PA/ITA EU Quality Plan)

(ii) Project Execution Plan (that includes the PA/ITA EU Quality Plan).

Reference and Applicable Documents:

F4E-QA-205	'PA EUDA Quality Plan' for PA Template (F4E_D_22FUSH)
F4E-QA-205a	'ITA EUDA Quality Plan' Template (F4E_D_22CECH)

V.4.1. Training

V.4.1.1. Training Requirements

(a) F4E personnel is trained, as appropriate, on F4E's specific policies & regulations, plans, and procedures for performing assigned tasks, including an annual training plan for each individual.

(b) 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'
Training Policy	'Learning and development policy framework' (F4E_D_2D9UQ3)

V.4.1.2. Task-Specific Training

(a) Training of project personnel will focus on the necessary knowledge and skills to perform the foreseen project functions. Technical training is provided to project personnel to ensure a consistent approach on how to manage projects using a common language.

(b) These trainings are provided through a "F4E PM Academy" framework composed of regular half-day workshops of a maximum of 3 hours offered to all staff. The workshops are divided into five areas: Project Management, Systems Engineering, Quality, Nuclear Safety and Commercial Management and follow an interactive format, including real F4E case studies, short presentations and group work.

(c) 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 for 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 Management and 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 Arrangements* 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 project team only by F4E or integrated with IO (IO Project Team). In the latter case the majority of F4E activities are conducted by an F4E project team reporting to F4E management, and to IO for non-commercial aspects.

(e) In a project team composed only by F4E, he Project Manager is then responsible:

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

(ii) to issue and implement the Project Execution Plan (PEP) and the associated EUDA Quality Plan;

(iii) to manage the interfaces between the contracts and all others provisions needed to properly monitor the project;

(iv) to integrate the contracts of the project;

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

(f) The F4E Project Team, led by the Project Manager (under the coordination of the Programme Manager), is responsible to technically, commercially and financially manage the F4E contracts. Including:

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

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

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

(iv) Review and approval of supplier technical and quality documentation;

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

(vi) Archival and maintenance of the contractual documentation;

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

(g) In the case of the Project Teams that are integrated with IO, 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;

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

(ii) The 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 supervision, main Hold Points and Authorisation to Proceed points;

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

(iii) 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.

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

(1) Technical Project Officer (TPO), Product Specialists and Engineers, CAD Officer (CADO), Project Manager (PjM) when not the Authorising Officer

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

V.5.1. Establishment of Procurement Arrangement with IO

(a) The Procurement Arrangement is negotiated between the project manager and IO, reviewed by the Programme Manager (with the support of the QA Officer, Commercial Manager 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, revision of the technical specification, 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 Programme Manager (with the support of the QA Officer, Commercial Manager and Legal Officer) and then approved by the F4E Director (or its Delegate). The Programme 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 were adequately addressed and that the design stages and their responsibilities are identified according to each project to develop.

(b) The **Programme Management Plan (PMP)**, issued by the 'Programme Manager' from the product unit, covers one or more product trees, and outlines how the programme is to be managed, executed, and controlled. It evolves with the programme and is updated to reflect any relevant changes throughout programme execution.

(c) The PMP serves as the main communication vehicle on the programme to ensure that everyone is aligned on the programme objectives and strategy to achieve them. The audience of the document is F4E internal although some parts can be shared via a separate document with identified external stakeholders when judged adequate. This document also lists all deviations to the rules or working procedures that were previously adopted by the relevant authority.

(d) The **Project Execution Plan (PEP)** is the governing document that establishes the means to execute, monitor, and control a project. The plan serves as the main communication vehicle to ensure that everyone is aware and knowledgeable of project objectives and how they will be accomplished.

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

(f) The Project Execution Plan defines the main activities and their associated milestones for each contract.

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

(h) PA/ITA EU Quality Plan required by IO is then issued per PA/ITA by the Project Manager, based on the existing PEP (F4E-QA-205 - PA: F4E_D_22FUSH, ITA: F4E_D_22CECH).

(i) The estimated value of the contracts is assessed with the support of the Commercial Management units and the Programme Planning & Controlling Group (PM/PPC) in order to define, together with other criteria, the procurement procedure applicable.

(j) The PA or ITA EUDA Quality Plans are issued based on the defined related Project Execution Plans.

(k) The Director ensures the customer needs and requirements are properly allocated to the contracts 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)
PMP	'Programme Management Plan' model (F4E_D_2KFSFJ)
PEP	'Project Execution Plan' model (F4E_D_2KEXXF)
F4E-QA-205	'PA EUDA Quality Plan' for PA Template (F4E_D_22FUSH)
F4E-QA-205a	'ITA EUDA Quality Plan' 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. It is also applied to Procurement Arrangements of Maturity Build-to-Print signed after March 2015, but also to Build-to-print Procurement Arrangements including PIC or PIA signed before March 2015. For BIPS a separate process is used for Nuclear Safety Requirements.

(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 8 (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 resulting data.

(c) This programme describes the controls that the F4E suppliers shall apply to R&D activities to ensure good scientific practices that provide traceability and validity of the data. Any data to be used as inputs that were not obtained under a formalised 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 technical responsible, 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:

P-01.20	'Phase Gates' Policy (F4E_D_28ZFFS)
PM-06	'Deviation Control' Process (F4E_D_22CCM4)
PM-27	'Design Control' Process (F4E_D_22CLT3)
SOP-01.08	'Design Review' Procedure (F4E_D_23NYBM)
SOP-01.09	'Manufacturing Readiness Review' procedure (F4E_D_25CLBH)
QA-114	Instructions for Suppliers Performing Design Analysis, Supplier Standard (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 technical documents to with the technical requirements of the work to be performed;

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

(iii) Decision on the geographical rules of participation (limited to the members of F4E or World-wide);

(iv) The selection of the type procedure:

(1) For Grants– single or multiple beneficiary - shall be discussed by the project team based on the project strategy;

(2) For procurement – the procedures are selected as described below.

(v) Configuration of the contractual and commercial conditions;

(vi) Issue of call for tender or request to participate.

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

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

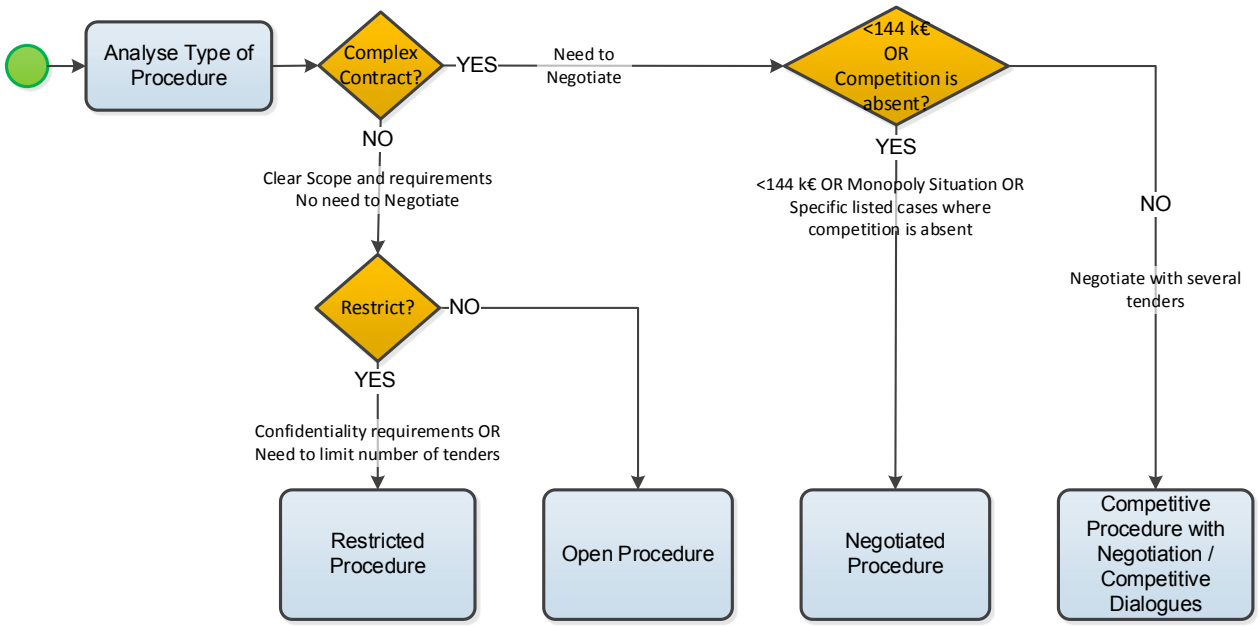


Figure 9 (V.5): Procurement Procedure Type Selection

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

(d) 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.

(e) 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.

(iii) 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 Procedure' Process (F4E_D_22JYUS)
PM-12	'Restricted Procedure' Process (F4E_D_22E3V6)
PM-13	'Competitive Dialogue Procedure' Process (F4E_D_22KBRR)
PM-14	'Negotiated Procedure' 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 Contract Manager together with the Procurement Officer (Commercial 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 (Project Management and) Quality Requirements'** supplier standard (F4E-QA-115 (F4E_D_22F8BJ)). The **Management Specification** that refers to that standard, as a basis 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 Contract 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 specific graded approach to the supplier management requirements is defined in the Management Specification.

(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 Quality Management System. 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 all the participants contribute to 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 compliance with the propagation of the requirements of the Order and in particular guarantee 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.

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) Deviations initiated by the supplier or by F4E must registered and processed in the F4E 'Deviations, Amendments and Contract Changes (DACC) tool.

(c) 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-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	'Supplier Nuclear Safety Management Requirements', Supplier Standard, (F4E_D_22JRQY)
F4E-QA-115	'Supplier (Project Management and) Quality Requirements', Supplier Standard, (F4E_D_22F8BJ)
F4E-QA-201	'Technical Specification for the Contract' Template (F4E_D_22EVAD)
F4E-QA-202	'Management Specification for the Contract' 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 / Programme Manager / Director: Programme Management Plan, Project Execution Plan and DA Quality Plan;

(iii) F4E Project Manager / Contract Manager: Project Execution Plan and DA Quality Plan ;

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

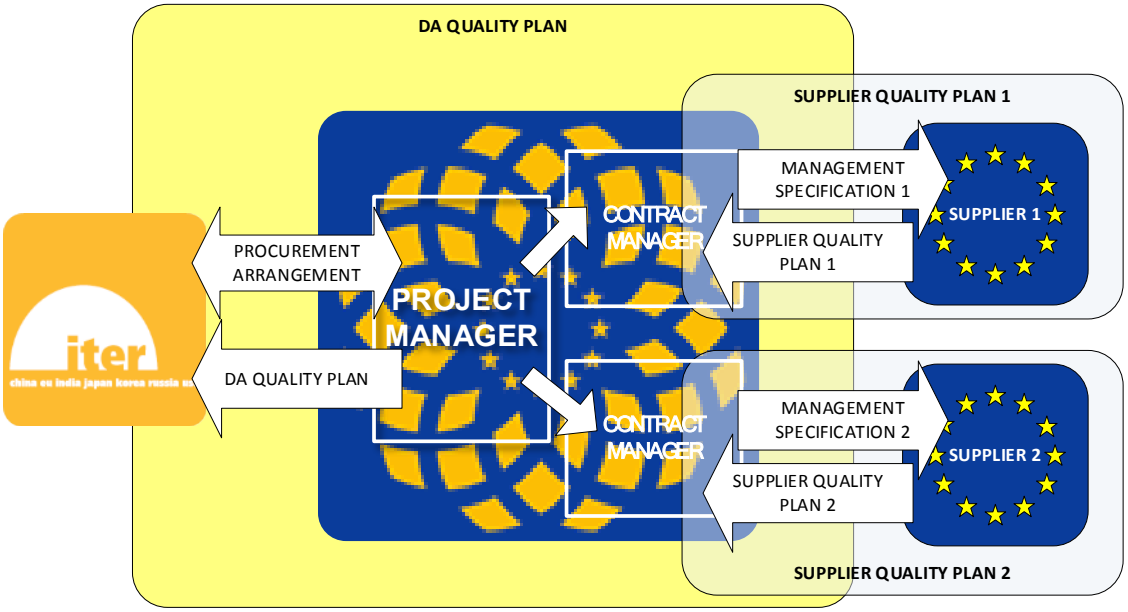


Figure 10 (V.5): Governance of the Management Relationships (F4E Project Team)

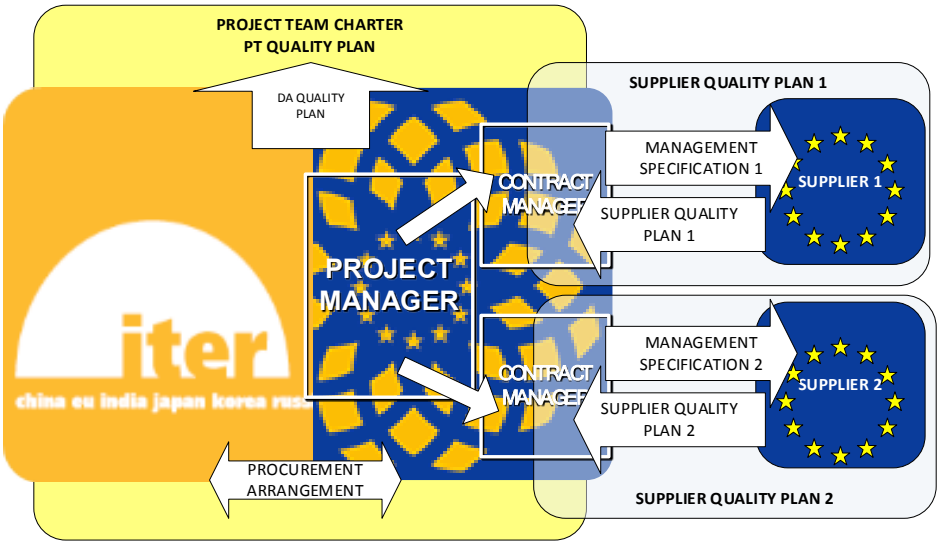


Figure 11 (V.5): Governance of the Management Relationships (Project Team integrated with IO)

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

(iv) 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) and the F4E Documentation Management Policy.

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)
P-02.23	F4E Documentation Management' policy, (F4E_D_24L87F)
F4E-IO CMP	F4E-ITER Project Configuration Management Plan (F4E_D_22P3BC)

Applicable process flowcharts

Annex 2	Deviation from Supplier and Deviation from F4E Overall Flowcharts (based on PM-06)
Annex 6	Supplier Deliverable Acceptance overall flow (PM-63)
Annex 7	Control Plan Overall Flow (based on QA-115)

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 ' Supplier Standard (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 BPM and the QAU (with the approval of the senior management, Improvement Steering Committee and support of the BPM Network) 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 improvement 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 programme performance. The sources of this feedback are:

(i) IO audit reports;

(ii) IO Management and Quality Programme reviews.

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

V.6.2. Quality Management System Audits

(a) Quality Management System audits are performed to verify the state of the Management and Quality Programme. The QMS audits results are recorded and analysed, and may trigger corrective actions or preventive actions, arising from audit findings (improvement areas or non-compliances). The reports of QMS audits are one of the inputs of the review by the Improvement Steering Committee of the QMS.

(b) Supplier Audits are also performed by F4E to verify the implementation of the Supplier Quality Plans in accordance with the quality criteria and the IO requirements. Supplier audit results are recorded and analysed, and may trigger supplier nonconformities corrective or preventive actions, arising from audit findings.

(c) The methodology regarding the planning, preparation, implementation and recording of internal and external quality audits is defined in a documented process (PM-28).

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

Reference and Applicable Documents:

PM-28	'QMS Audits and Supplier Audits' Process (F4E_D_22H84F)
F4E-QA-101	'QMS Audit Implementation', SOP-02.17 (F4E_D_24XXZF)
F4E-QA-102	'Supplier Audit Implementation', SOP-01.38 (F4E_D_296E7T)

Applicable process flowchart:

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

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 organisation.

(b) The continuous process of management of risks consists of the following activities:

Figure 12 (V.6): Risk Cycle

(c) All activities of an organisation 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 organisation'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 contract and project will identify its highest priority risks to the Project Manager or Programme Manager (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.

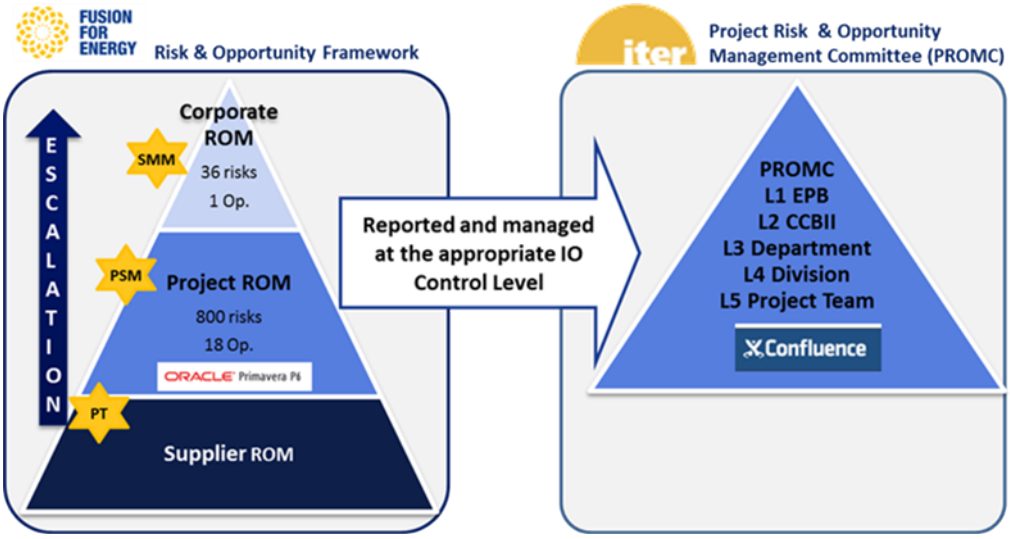


Figure 13 (V.6): Risk and Opportunity Management (ROM) levels and reporting

Reference and Applicable Documents:

P-02.05	'Risk & Opportunity Management' policy (F4E_D_29A34J)
PM-22	'Corporate/ Project Risk and Opportunity Management ' Process (F4E_D_22CZRF)
SOP-01.18	'Project Risk and Opportunity Management' Procedure (F4E_D_29SSKX)
F4E-QA-111	'Supplier Risk & Opportunity Management', Supplier Standard, P-01.11 (F4E_D_29XB3F)
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 Execution 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.6.6 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	Quality Surveillance Flowchart (PM-38)

V.6.6. Nonconformity Control

(f) 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.

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

(h) F4E has defined a process (PM-35) for handling all aspects of the detected nonconformities.

(i) 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).

(j) 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)

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 Management Quality Programme (QMS) in the project teams, 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) All the analysis and results are submitted to the BPM, and then taken to the BPM Network for review and if needed prepared for the senior management review (ISC).

V.6.8. Continual Improvement

The Director shall continually improve the QMS, by planning and managing the necessary processes. Continual improvement is achieved through the use of the Quality Policy, BPM policy, audit results, data analysis, corrective and preventive actions and the Improvement Steering Committee 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)

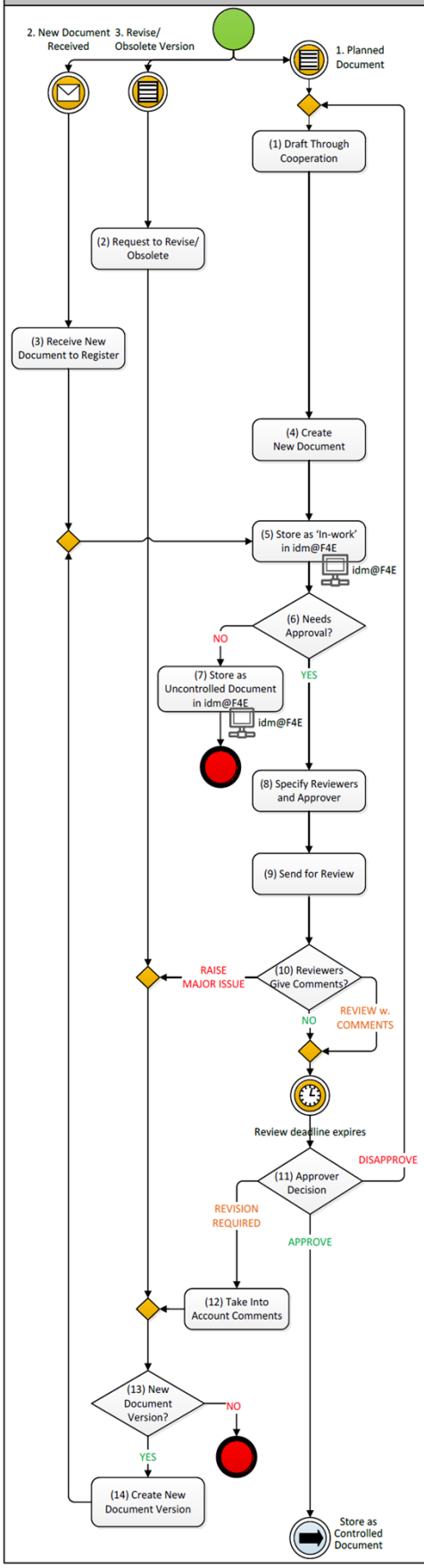
V.6.8.2. Preventive Actions

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.

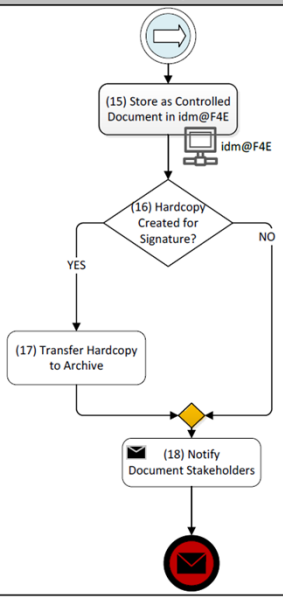
Reference and Applicable Documents:

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

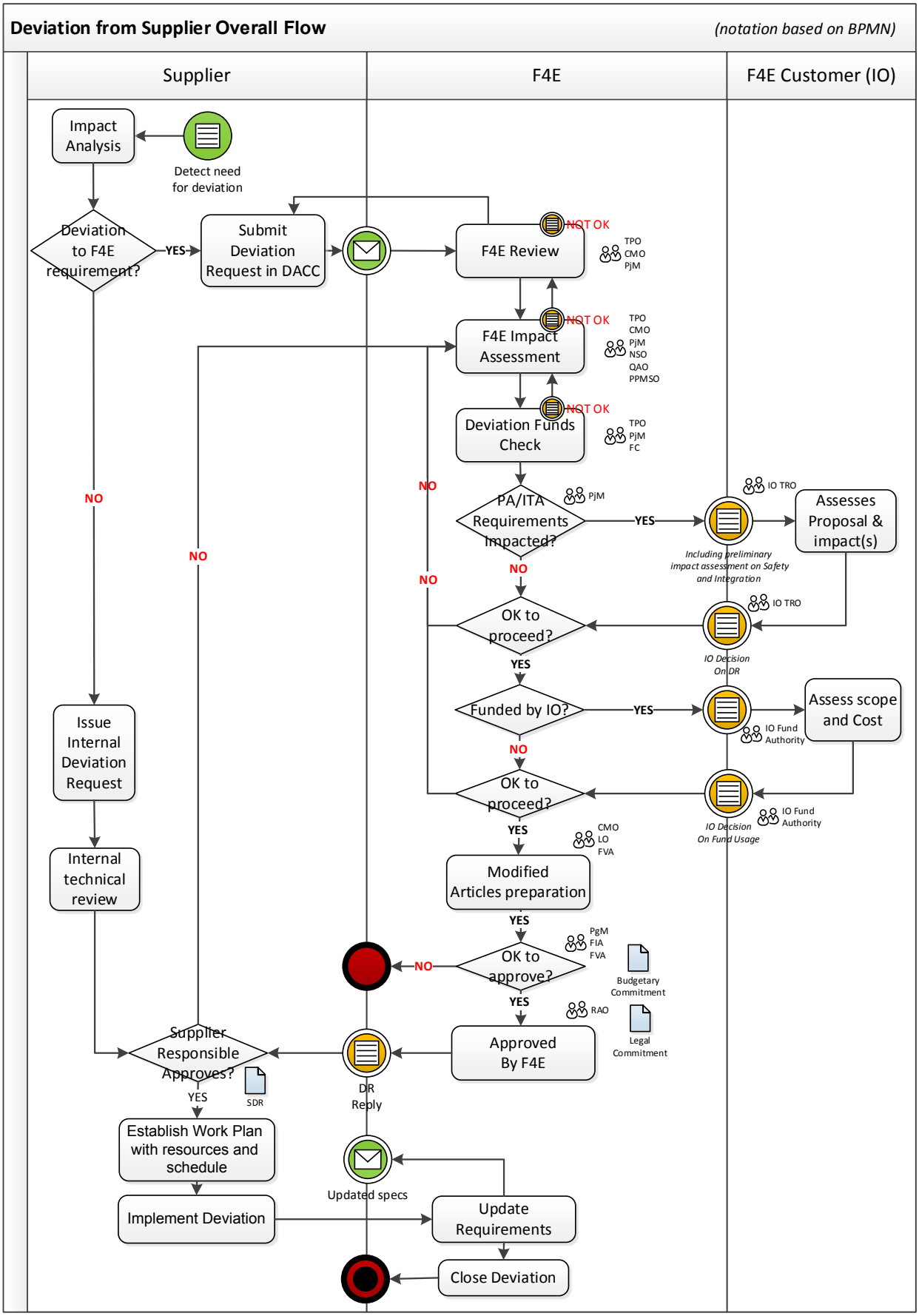
ANNEX 1 – DOCUMENTATION FLOW PROCESS

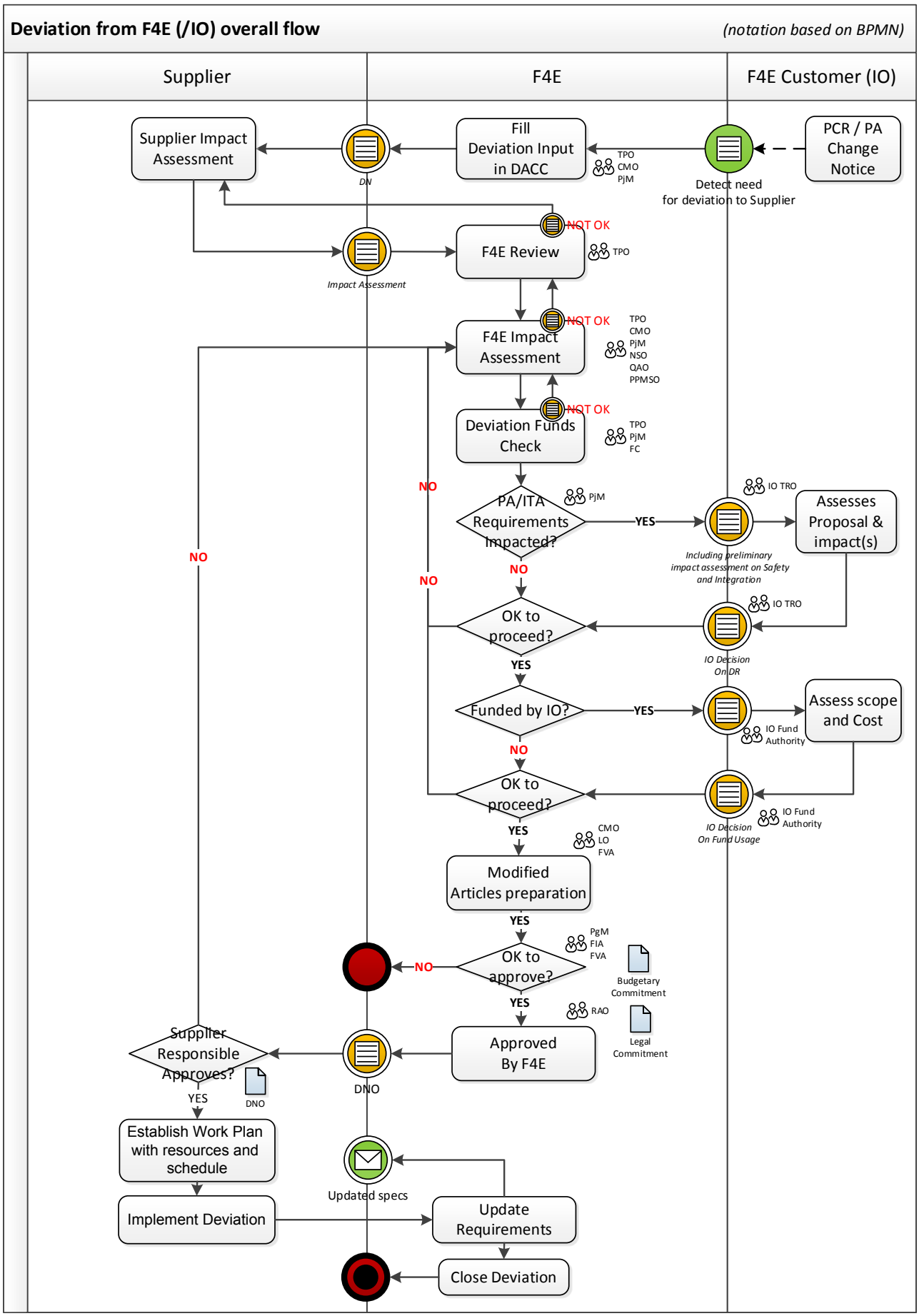


#	Resp.	Guidance
0		Process starts depending on the trigger type: 1. Criteria Planned Document/ version. Go-to 1. Draft Through Cooperation. 2. New Document Received. Go-to 3. Receive New Document to Register. 3. Criteria Revise/ Obsolete. Go-to 2. Request to Revise or Obsolete Version.
1	Author	**Draft Through Cooperation** Start a new document or decide to create a new version. For a new version the author must specify the version description. Go-to 5. Store as 'In-work' in idm@F4E.
2	Author (Signatory)	**Request to Revise or Obsolete Version** Request Reviewer(s) to revise the document within the assigned scope and given time frame or schedule, or, if the version has to become obsolete, request Approver (or DMO if needed) to declare it OBSOLETE. Go-to 13. Gate: 'New Document Version?'
3	Author (Signatory)	**Receive New Document to Register** Receive a message with a document to be registered (includes external documents). Go-to 5. Store as 'In-work' in idm@F4E.
4	Author	**Create New Document** Create a new document in idm@F4E selecting the correct document type, inserting a descriptive title and the abstract. Go-to 5. Store as 'In-work' in idm@F4E.
5	Author	**Store as 'In-work' in idm@F4E** Upload the document into idm@F4E and is responsible to correctly fill the metadata. Go-to 6. Gate: 'Needs Approval?'
6	--	**Gate: 'Needs Approval?'** Yes: Go-to 8. Specify Reviewers and Approver. No: Go-to 7. Store as Uncontrolled Document in idm@F4E.
7	Author	**Store as Uncontrolled Document in idm@F4E** This is an uncontrolled document. Then sign the document and the process ends.
8	Author	**Specify Reviewers and Approver** The document is controlled. Specify the reviewers and approver according to the prevailing SOAP or Process. Go-to 9. Send for Review.
9	Author	**Send for Review** Send for review (by signing the document and sending the idm email). Go-to 10. Gate: Reviewers Give Comments?
10	Reviewers	**Gate: 'Reviewers Give Comments?'** A reviewer may Introduce comments or Delegate review. Review with Comments: Go-to 11. Gate: 'Approver Decision.' No: Recommend. Go-to 11. Gate: 'Approver Decision.' Raise Major Issue: Go-to 13. Gate: 'New Document Version?'
--	Review deadline expires	
11	Approver	**Gate: 'Approver Decision'** The approver can take a decision at any given time (normally after all reviews but he/she can also do it before). Approve: The current version is OK for approval. Go-to 15. Store as Controlled Document in idm@F4E (Electronic). Disapprove: The current version is NOT OK for approval and justify. Go-to 1. Draft through Cooperation. Revision Required: Go-to 12. Take Into Account the Comments.
12	Author	**Take Into Account the Comments** Introduce replies to all comments. Go-to 13. Gate: 'New Document Version?'
13	Author	**Gate: 'New Document Version?'** Take a decision based on the comments: Yes: Create a new version. Go-to 14. Create New Document Version. No: Make the document obsolete. Process ends.
14	Author	**Create New Document Version** Create a new document version. Go-to 5. Store as 'In-work' in idm@F4E.
--	Continue process on next page.	

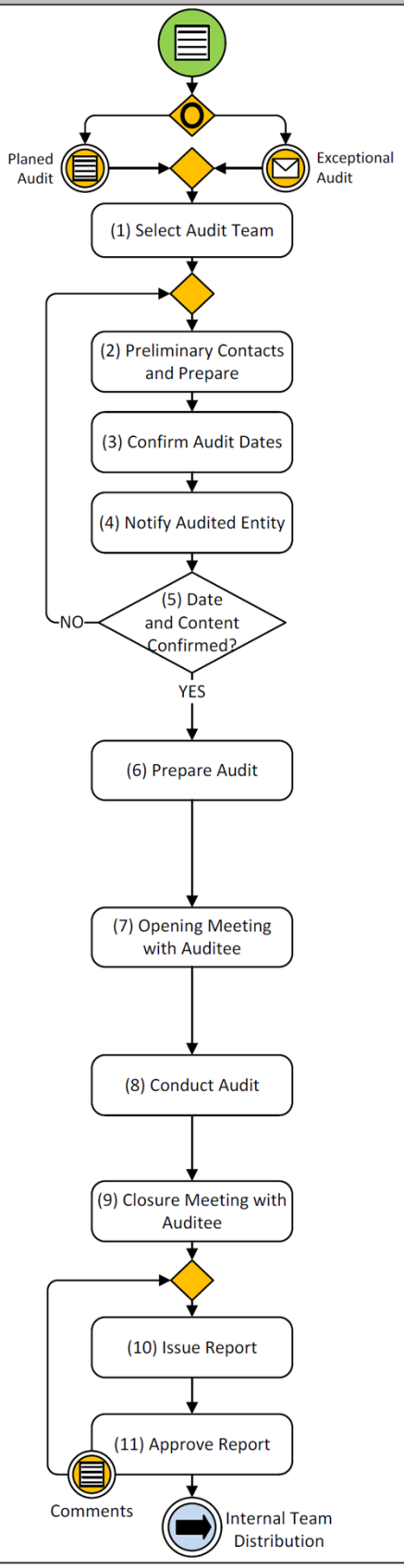
Activity	#	Resp.	Guidance
	--	Continue process.	
	15	--	**Store as Controlled Document in idm@F4E** The document is stored automatically as "Controlled document" in idm@F4E. Go-to 16. Gate: 'Hardcopy Created for Signature?'
	16	--	**Gate: 'Hardcopy Created for Signature?'** Yes: Upload scan as attachment (or new version if changed from approved). Go-to 17. Transfer Hardcopy to Archive. No: Decide to 'Disapprove' or to 'Revision Required'. Go-to 18. Notify Document Stakeholder.
	17	Author	**Transfer Hardcopy to Archive** Transfer the hardcopy to archive following the Archive Instruction. Go-to 18. Notify Document Stakeholder.
	18	Author (Signatory)	**Notify Document Stakeholders** Notify the document stakeholders. Process ends.
	--	Process ends.	

ANNEX 2 – DEVIATION PROCESS FLOWCHART

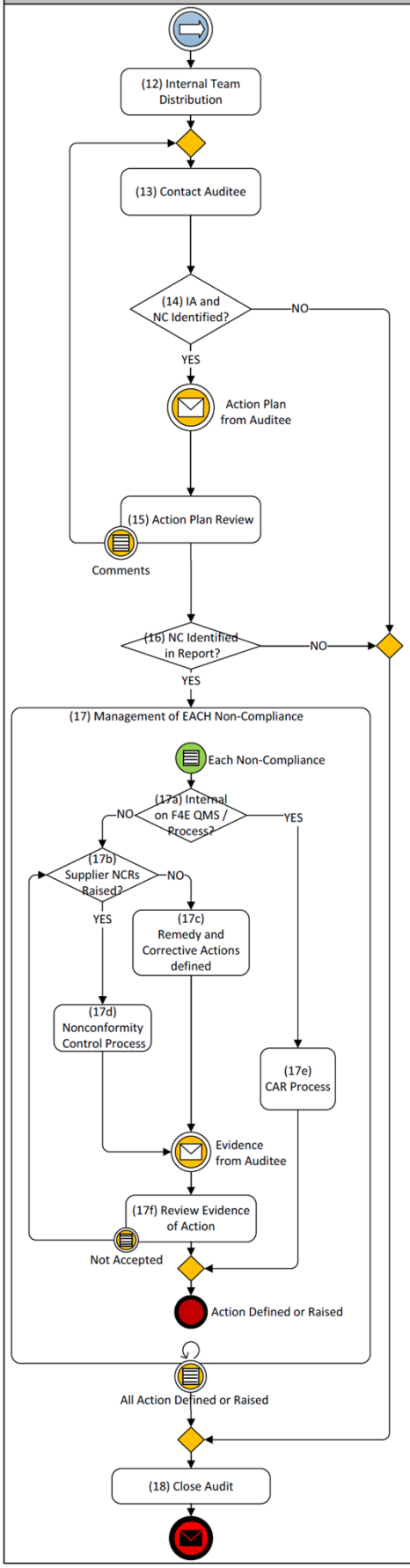




ANNEX 3 – QMS AND SUPPLIER AUDITS PROCESS FLOWCHART

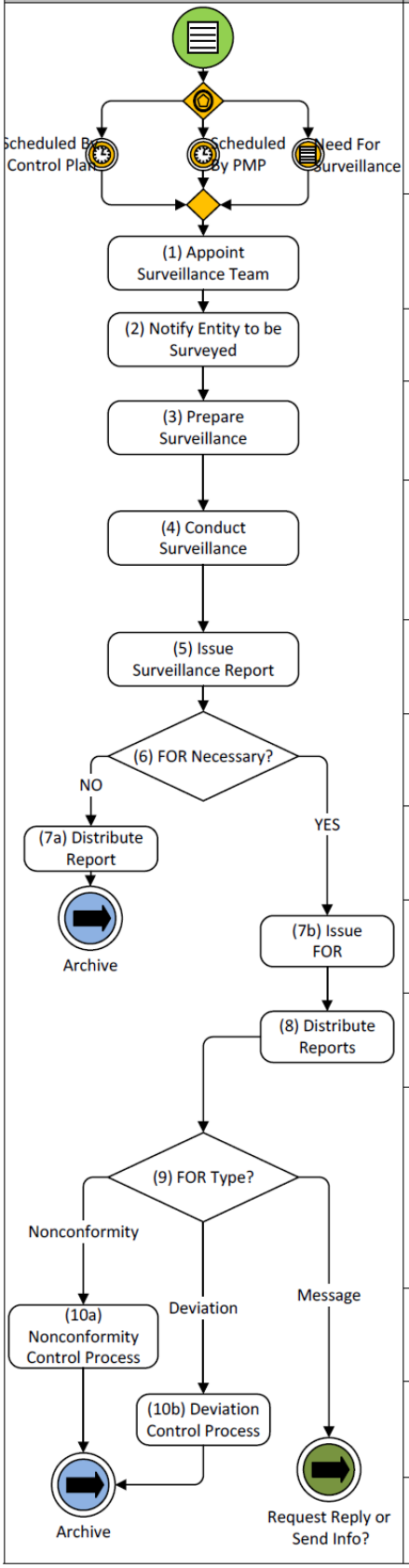


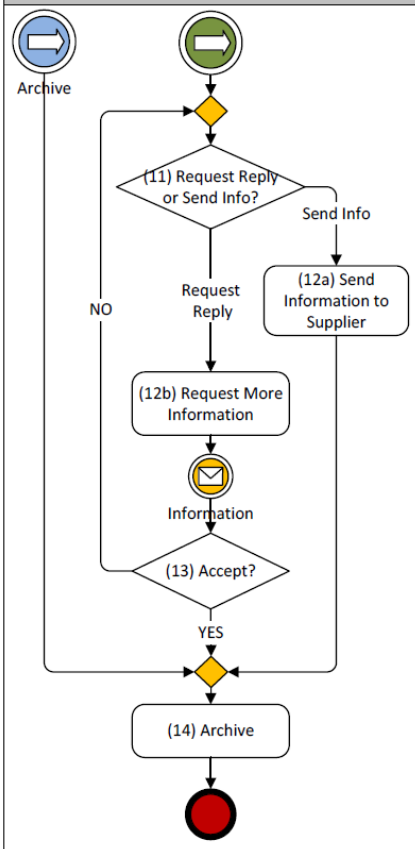
#	Resp.	Guidance
0		The process starts depending on the trigger type: **Plan** – **Planned Audit:** Based on the Yearly Audit Programme (QMS & Supplier) the Audit Manager starts the internal process 1.5 months before the planned audit date. **Message** – The process is triggered when the Audit Manager 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. Gate: 'Date and Content Confirmed?'
5	Audit Team	**Gate: '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.



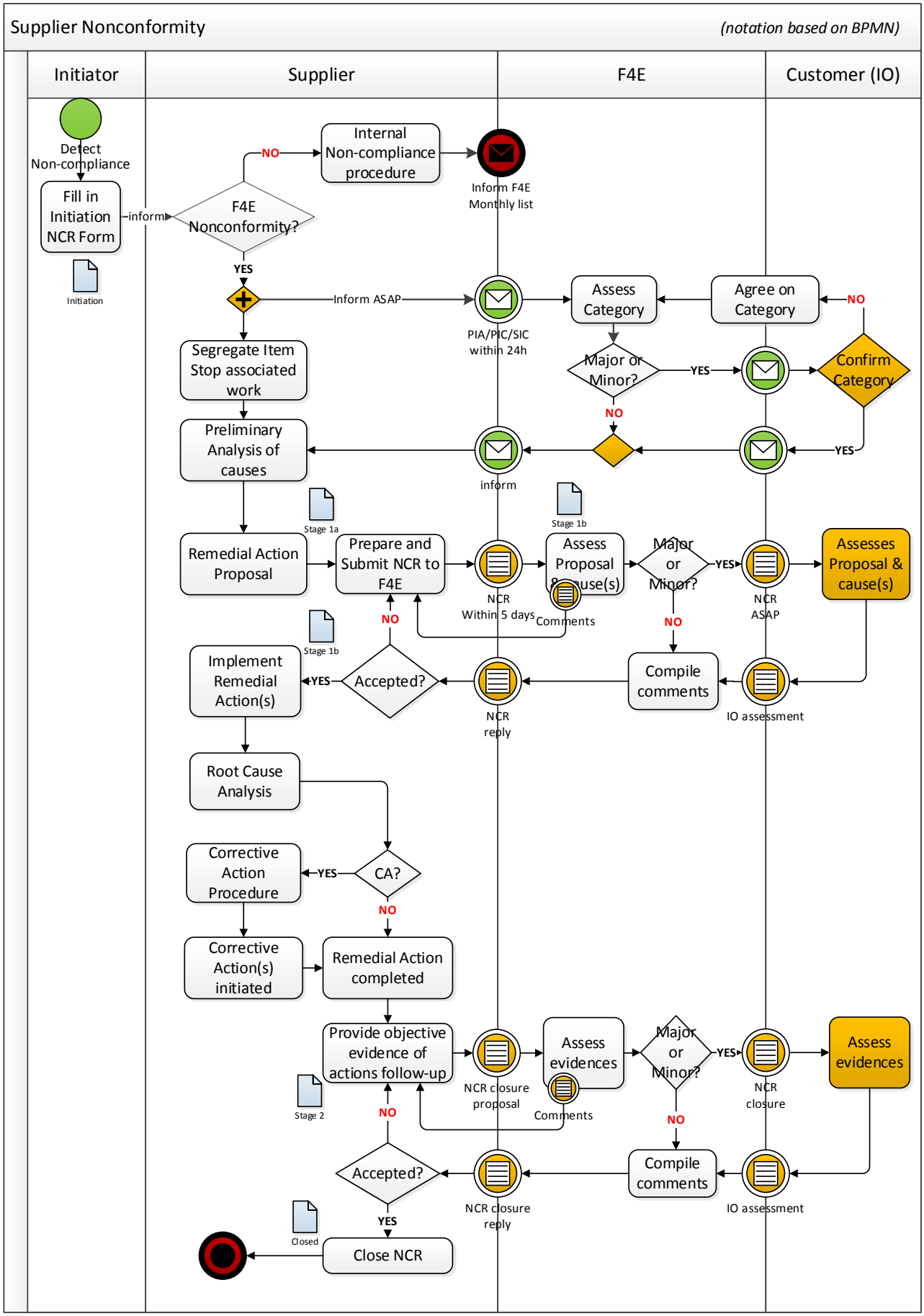
#	Resp.	Guidance
--		Continue process.
12	Lead Auditor	**Internal Team Distribution** The approved report is distributed to the subject Operational Responsible and QAO. Go-to 13. Contact Auditee.
13	Lead Auditor	**Contact Auditee** Distribute the documentation to the Auditee (Report or revised Action 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

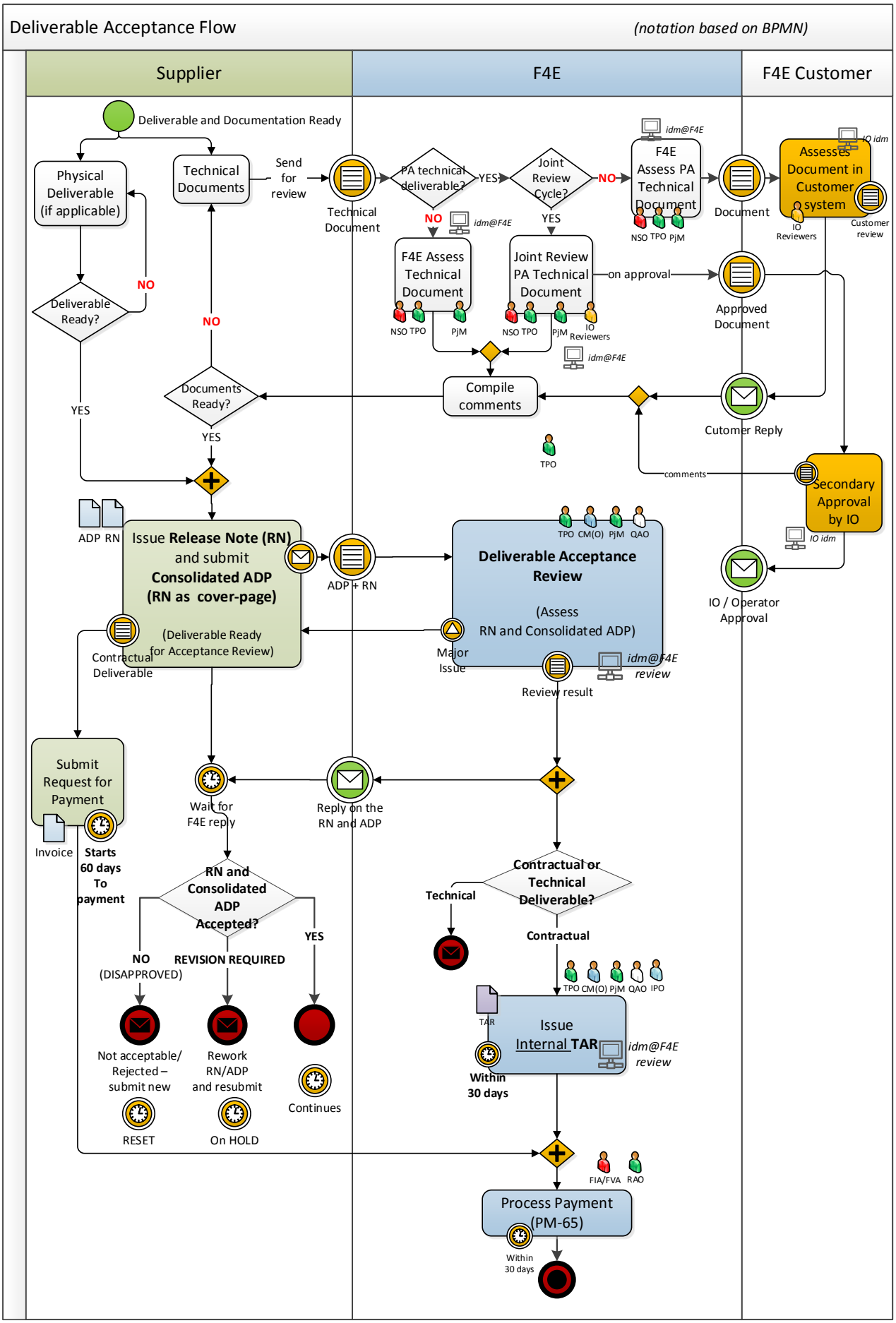
Activity	#	Resp.	Guidance
	**0**	--	The process is triggered when the need of a Quality Surveillance is identified by TPO, due to issues in the execution of the contract. The process starts depending on the trigger type: Schedule by CP: The process is triggered when the Control OR Surveillance Plan schedules 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.

<table>
<tr><th>Activity</th><th>#</th><th>Resp.</th><th>Guidance</th></tr>
<tr><td rowspan="9"> 
</td><td>--</td><td>--</td><td>Continue Process.</td></tr>
<tr><td>11</td><td>TPO</td><td>Request Reply or Send Info?<table><tr><td>Send Info</td><td>FOR addresses an issue that should be transmitted to the Supplier.
Go-to 12a. Send Information to Supplier.</td></tr><tr><td>Request Reply</td><td>FOR addresses an issue that requires further info/reply from the supplier.
Go-to 12b. Request More Information.</td></tr></table></td></tr>
<tr><td>12a</td><td>TPO</td><td>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.</td></tr>
<tr><td>12b</td><td>TPO</td><td>Request More Information
Send a message to the supplier with the request for further information concerning the surveillance action.
Go-to Gate 13: ‘Accept?’</td></tr>
<tr><td>--</td><td>--</td><td>Process flow cannot continue without receiving the reply from the supplier.</td></tr>
<tr><td>13</td><td>TPO</td><td>Gate 13: ‘Accept?’<table><tr><td>YES</td><td>The additional information raises no further concerns.
Go-to 14. Archive.</td></tr><tr><td>NO</td><td>The additional information raises further concerns.
Go-to Gate 11: ‘Request Reply or Send Info?’</td></tr></table></td></tr>
<tr><td>14</td><td>TPO</td><td>Archive
Close the Quality Surveillance Process and archive the related documentation.
Send the information to the PTM and Surveillance Team.</td></tr>
<tr><td>--</td><td></td><td>The process terminates.</td></tr>
</table>

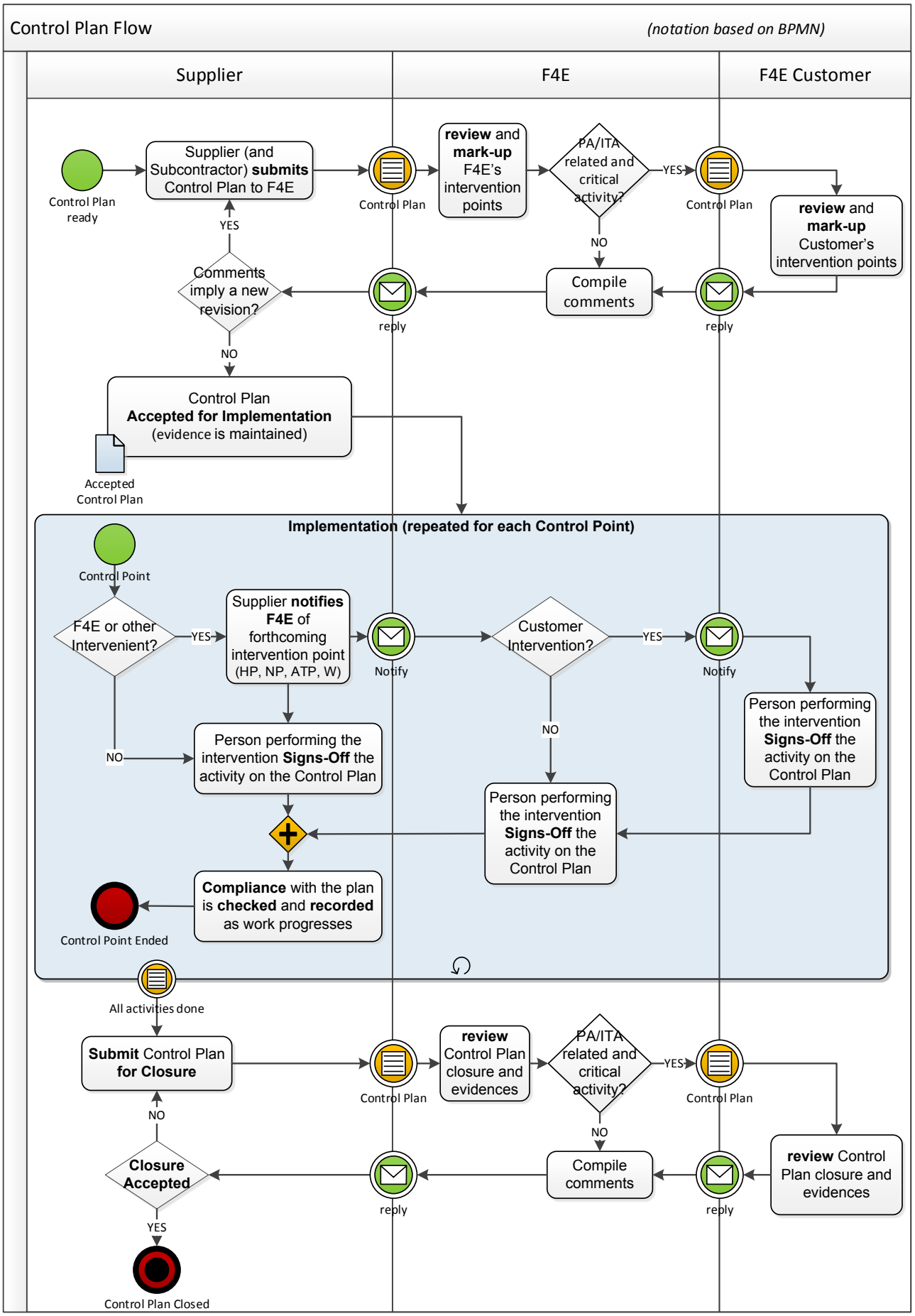
ANNEX 5 – NONCONFORMITIES OVERALL PROCESS FLOWCHART



ANNEX 6 – SUPPLIER DELIVERABLE ACCEPTANCE OVERALL FLOW



ANNEX 7 – CONTROL PLAN OVERALL FLOW



ANNEX 8 – MAIN IO QA & MANAGEMENT REQUIREMENTS

Up-to-date matrices: Matrix F4E Implementation and Propagation of ITER General Requirements (27RGZ4)

SECTIONS OF THIS ANNEX:

Main Referenced Documents

IO Document	F4E MQP and Propagation
• ITER QAP (ITER_D_22K4QX v8.5) • ITER PQR (ITER_D_22MFG4 v5.1) • ITER Policy on Safety, Security and Environment (ITER_D_43UJN7 v2.0) • PA Annex A (ITER_D_C7TMP3 v2.1)	F4E Management and Quality Programme (MQP) for ITER Project (F4E_D_22MCBA) F4E-QA-115 – Supplier (PM and) Quality Requirements (F4E_D_22F8BJ) F4E-QA-113 –Supplier Nuclear Safety Management Requirements (F4E_D_22JRQY) F4E-QA-114 – Instructions for Suppliers Performing Design Analysis (F4E_D_22FR5T) F4E-QA-119 – Requirements Management & Verification (RMV) Requirements for F4E Suppliers (F4E_D_242DG5) PIA_Guideline (F4E_D_27WDLC)

Compliance Matrix (Quality and General Requirements)

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
Procurement Arrangements Annex A (ITER_D_C7TMP3)			
Annex A - *4. Tendering Process* *4.2 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) v2.0	NA
Annex A – 6. Quality Assurance and Quality Control			
DA's Domestic Agency's dedicated "**Quality Plan**" (ITER_D_22MFMW)	Da Quality Plan §V.5.3	See matrix of PA-AD below [AD-015]	
Supplier's/Subcontractor's dedicated "**Quality Plan**" (ITER_D_22MFMW)	Supplier Quality Plan §V.5.9	See matrix of PA-AD below [AD-015]	
Supplier's/Subcontractor's "**Manufacturing and Inspection Plans (MIPs)**" (ITER_D_22MDZD)	Supplier Control Plan §V.5.2, §V.5.9	See matrix of PA-AD below [AD-016]	
During contract implementation Issue "**Deviation Request" and "Non-Conformance Reports**" as necessary (ITER_D_2LZJHB / ITER_D_22F53X)	Deviation Request §V.5.12 and DR from Supplier §V.5.9 Supplier NCR §V.6.6, §V.5.9	See matrix of PA-AD below [AD-018] and [AD-017]	
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	See matrix of PA-AD below [AD-019]	
Annex A – 7. Licensing requirements			
7.2 The Suppliers, Subcontractors, and any other actor ("External Interveners") involved in PIC/PIA must be informed that: • **ITER is a nuclear facility** identified in France by the number-**INB-174**; • In application of the "INB Order" the "Provisions for Implementation of the Generic Safety Requirements by the External Interveners (SBSTBM)" are provided in [**PA-AD 41**]; • The compliance with the "Provisions for Implementation of the Generic Safety Requirements by the External Interveners (SBSTBM)" [**PA-AD 41**] must be demonstrated in the **chain of Suppliers and Subcontractors**; • In application of Article II.2.5.4 of the "INB Order", contracted activities for **supervision purposes** are also subject to safety nuclear inspections done by the Nuclear Operator.	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 v4.4 *§1* F4E-QA-115 v4.4 *§2.14* F4E-QA-113 v2.1, F4E-QA-119 v1.7, F4E-QA-114 v1.0

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
*7.3 Certain Items that are the subject of this PA are classified as **Protection Important Component and/or Protection Important Activities** to which "INB Order" applies, as detailed in the relevant Annex B (if applicable).* *In **application of the "INB Order", the "**Procedure Working Instruction for Propagation of the Defined Requirements by F4E** (V7KUPV)" [**PA-AD 42**], which is in line with "Propagation of the Defined Requirements for Protection Important Components Through the Chain of External Interveners (BG2GYB)", shall be implemented to ensure the propagation of Defined Requirements related to PIC through the supplier chain.*	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 v4.4 *§2.14* F4E-QA-113 v2.1, F4E-QA-119 v1.7, F4E-QA-114 v1.0
Implementation of the Applicable Documents per subject	**See matrix of PA-AD below**		
ITER Quality Assurance Programme (QAP) (ITER_D_22K4QX)			
QAP 2 Management Responsibilities and Quality Requirements	*Section header*		
QAP 2.1 ITER Management	Functions Description §III.2. Management Responsibilities §V.3.	F4E Mission Statements (F4E_D_26JCNW)	F4E-QA-115 v4.4 §3.1.1 F4E-QA-115 v5.5 §5.1
QAP 2.2 Quality Assurance & Assessment Division	Functions Description §III.2	F4E Mission Statements (F4E_D_26JCNW)	F4E-QA-115 v4.4 §3.1.1 F4E-QA-115 v5.5 §5.1
QAP 2.3 Quality Classification Quality Classification Determination ITER_D_24VQES	Quality Classification §V.1.1.	See matrix of PA-AD below [AD-020]	
QAP 2.4 Management and Quality Program Objectives	Management and Quality Policy §II Corporate Objectives related to MQP §V.3.4.1.	Corporate Objectives QA Supervision Plan	F4E-QA-115 v4.4 §3.2.1 F4E-QA-115 v5.5 §5.1
QAP 2.5 Roles and Responsibilities	All document	F4E MQP for ITER Project (F4E_D_22MCBA)	F4E-QA-115 v4.4 §3.2.2 F4E-QA-115 v5.5 §8.1
QAP 2.6 Stop Work Authority	Stop Work Authority §V.3.2	---	F4E-QA-115 v4.4 *§3.2.2* F4E-QA-115 v5.5 §5.1.2
QAP 2.7 Continuous Quality Improvement	Assessment and Improvement §V.6. Continual Improvement §V.6.8.	Management and Internal Control 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 v4.4 *§2.2* F4E-QA-115 v5.5 §6.3.3
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 v4.4 *§2.2* F4E-QA-115 v5.5 §6.3.2
QAP 2.10 Personnel Training and Qualification	Training §V.4.1.	Training Management (F4E Manual)	F4E-QA-115 v4.4 *§2.5.3, §3.2.2* F4E-QA-115 v5.5 §5.1.3
QAP 2.11 Control of Activities affecting quality (through 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 v4.4 *§2.5, §4.0* F4E-QA-115 v5.5 §6.2, §6.3.1
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 v4.4 *§2.2* F4E-QA-115 v5.5 §4
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 v4.4 §2.3 F4E-QA-115 v5.5 §3
QAP 3.3 Design Control	Design Management § V.5.7	PM-27 (F4E_D_22CLT3) F4E Design Review Procedure (SOP-01.08) (F4E_D_23NYBM) F4E CAD Manual (F4E_D_22BE49)	F4E-QA-115 v4.4 *§3.1.10* F4E-QA-115 v5.5 §6.4
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 v4.4 *§2.4, §3.1.6, §3.2.7 Subcontracting Schedule* F4E-QA-115 v5.5 §6.5
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 v4.4 *§2.6*, §3.2.8 F4E-QA-115 v5.5 §6.8

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
QAP 3.6 Identification and Control of Items	Identification and Control of Items §V.5.13.	PM-38 - Quality Surveillance	F4E-QA-112 F4E-QA-115 v4.4 §3.2.16 F4E-QA-115 v5.5 §6.3.5
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 v4.4 *§3.2.6*https://idm.f4e.europa.eu/?uid=22F8BJ&action=get_document F4E-QA-115 v5.5 *§6.3.6*
QAP 3.8 Inspection and Testing Activities	Inspection and Testing §V.6.5	PM-38 Quality Surveillance (F4E_D_22DDMG)	F4E-QA-115 v4.4 *§3.2.12* F4E-QA-115 v5.5 *§6.3*
QAP 3.9 Handling, Storage and Transportation	Product Preservation and Transportation §V.5.14.	N/A	F4E-QA-115 v4.4 §3.2.17 F4E-QA-115 v5.5 *§6.3.7*
QAP 3.10 Software Control and Model Development	Computer Code & Model Development §V.5.8.	F4E-QA-114 v1.0	F4E-QA-115 v4.4 *§2.5.6*, §3.2.8 F4E-QA-115 v5.5 *§6.4.5,* §6.11 F4E-QA-114 v1.0
QAP 3.11 Research and Development	Research and Development (R&D) §V.5.6	---	F4E-QA-115 v4.4 *§1*
QAP 3.12 Operations and Maintenance	Design Management § V.5.7 Documentation §V.2.	--	F4E-QA-115 v4.4 *§3.1.10, §2.1.3* F4E-QA-115 v5.5 *§6.4*
QAP 3.13 Research Program	Project Management §V.5 Product Execution §V.5.10.	PM-29-WorkPackage Implementation	F4E-QA-115 v4.4 *§3.2.1, §3.2.8, §4.0* F4E-QA-115 v5.5 *§6*
QAP 4 Audits and Assessments	Section header		
QAP 4.1 Audits and assessments Quality Management System Audits (ITER_D_2DQTA8)	Quality Management System Audits §V.6.2	PM-28 QMS & Supplier Audits (F4E_D_22H84F)	F4E-QA-115 v4.4 *§2.8.1* F4E-QA-115 v5.5 *§6.3, §6.5*
	Inspection and Testing §V.6.5.	PM-38 Quality Surveillance (F4E_D_22DDMG)	
	Management Review §V.3.5.	Improvement Steering Committee	
QAP 4.2 Audits and assessment responses	Assessment and Improvement §V.6.	Improvement Steering Committee Improvement Network	F4E-QA-115 v4.4 *§2.8* F4E-QA-115 v5.5 *§6.3*
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 v4.4 §2.2, §2.8.1 F4E-QA-115 v5.5 §6.5.1
ITER Procurement Requirements (PQR) (ITER_D_22MFG4)			
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*	Quality Framework §I.3 Quality Assurance (QA) Programme §III	F4E MQP for ITER Project Management and Internal Control Standards (F4E_D_24LQJM)	F4E-QA-115 v4.4 §1 F4E-QA-115 v5.5 §6.1
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 v4.4 *§2.5.2, §2.5.5* F4E-QA-115 v5.5 §5.1.3, §6.8.7
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-63 Deliverable Acceptance (F4E_D_262PUA) PM-38 Quality Surveillance (F4E_D_22DDMG)	F4E-QA-115 v4.4 *§2.6* F4E-QA-115 v5.5 §6.10
PQR 5.10 Personnel Training And Qualification	See QAP 2.10	--	--
PQR 5.11 Access	---	Model Contracts	F4E-QA-115 v4.4 §2.8, §3.1.7 F4E-QA-115 v5.5 §2.5
PQR 6 Applicable ITER Quality Documents	---	See matrix of PA-AD below	---
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 v4.4 §1, §3.2.1.1 F4E-QA-113 v2.1 F4E–QA-119

ITER Requirement	F4E QA Programme	F4E Implementation	Supply Chain Propagation
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)		F4E-QA-019 F4E–QA-016	F4E-QA-115 v4.4 §2.8.1, §3.2.12, §2.1.2 and §2.4 F4E-QA-113 v2.1
Identification and Reporting of **PIA** (INB Order art.. 2.5.2, 2.5.3, 2.5.6 Ch.V)		F4E-QA-013 F4E-QA-016	F4E-QA-115 v4.4 § 4.1 REQ-0208. PIA Guideline F4E-QA-113 v2.1
Management of the **Qualifications and Experience of Personnel** (INB Order art. 2.5.5 (Ch.V)		F4E-QA-013	F4E-QA-115 v4.4 §3.2.2. F4E-QA-113 v2.1
Management of **Validation and Verification** and Use of Different Staff (INB Order art. 2.5.5 and 2.5.3 Ch.V)		F4E-QA-013	F4E-QA-115 v4.4 §2.8.1, §2.5 F4E-QA-113 v2.1
Identification and Management of **Deviations and Nonconformities** (INB Order art. 2.6.1 to 2.6.5 Ch. VI)		PM-06 Deviation Control PM-35 Nonconformity Control	F4E-QA-115 v4.4 §2.2 F4E-QA-115 v5.5 §6.3.3, §6.3.2 F4E-QA-113 v2.1
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)		F4E-QA-013 F4E-QA-113 v2.1	F4E-QA-115 v4.4 §2.14, §2.1.3 F4E-QA-113 v2.1
Requirements relating to the **verification of design** (INB Order art 3.8 Titre III)		F4E-QA-013 F4E-QA-016	F4E-QA-115 v4.4 §2.5.6. F4E-QA-113 v2.1 F4E-QA-114 v1.0

Matrix of Implementation and Propagation of PA-AD

PA Applicable Document	Ver.	F4E Implementation	Ver.	Supply Chain Propagation
Procurement				
[AD-001] CEAR (Construction and Erection All Risk Policy) (6KUSN2)	1.0	N/A	--	N/A
[AD-002] Global Transportation MOU EU DA (6KWXUQ)	1.0	N/A	--	N/A
Design				
[AD-003] Design Review Procedure (2832CF)	4.1	SOP-01.08 'Design Review' Procedure (F4E_D_23NYBM)	5.4	F4E-QA-115 v4.4 §3.1.10 F4E-QA-115 v5.5 §6.4.3
[AD-004] Procedure for the CAD Management Plan (2DWU2M)	2.0	F4E CAD Manual (F4E_D_22BE49)	8.0	F4E-QA-115 v4.4 §2.3.2 F4E-QA-115 v5.5 §6.4.4
[AD-005] Procedure for the Usage of the ITER CAD Manual (2F6FTX)	1.1	F4E CAD Manual (F4E_D_22BE49)	8.0	F4E-QA-115 v4.4 §2.3.2 F4E-QA-115 v5.5 §6.4.4
[AD-006] Procedure for Analyses and Calculations (22MAL7)	5.1	(F4E MQP §V5.7)	--	F4E-QA-114 v4.0 F4E-QA-115 v4.4 §2.5, 3.1.10 F4E-QA-115 v5.5 §6.4.5
[AD-007] Procedure for Identification and Controls of Items (U344WG)	2.2	(F4E MQP §V5.9.1)	--	F4E-QA-112 v2.0 F4E-QA-115 v4.4 §3.2.16 F4E-QA-115 v5.5 §6.3.5
Project Management:				
[AD-008] ITER Planning & Scheduling Manual (2DWMCW)	4.1	SOP-01.12 Activity Information in Detailed Working Schedules (F4E_D_2PX8HU)	1.1	F4E-QA-115 v4.4 *§3.2.4* F4E-QA-115 v5.5 *§5.1.5*
[AD-009] ITER Configuration Management Implementation Plan (CMP) (27LHHE)	3.3	F4E-ITER Project Configuration Management Plan (F4E_D_22P3BC)	1.1	F4E-QA-115 v4.4 *§3.1.3* F4E-QA-115 v5.5 *§4.0*
[AD-010] Project Change Procedure (22F4E5)	8.1	PM-04 Project Change Request (PCR) and Direct Implementation Control (F4E_D_22UJDU)	5.4	N/A
[AD-011] ITER Document Breakdown Structure Overview (43327Q)	1.1	P-02.26 PA and ITA Documentation (F4E_D_26P4J8)	1.2	N/A
[AD-012] ITER Plant Breakdown Structure (PBS) (28WB2P)	2.0	N/A	--	(same as AD-007)
Quality Assurance:				
[AD-013] ITER Quality Assurance Program (QAP) (22K4QX)	8.5	[See Compliance Matrix above]	--	--
[AD-014] ITER Procurement Quality Requirements (22MFG4)	5.1	[See Compliance Matrix above]	--	--
[AD-015] Requirements for Producing a Quality Plan (22MFMW)	4.0	(DA QP: F4E MQP §V.5.2, Supplier QP: F4E MQP §V.5.9)	--	F4E-QA-115 v4.4 §1 F4E-QA-115 v5.5 §6.1
		F4E-QA-202 DA Quality Plan template (F4E_D_22DWZP)	--	
		PM-29- WorkPackage Implementation (F4E_D_22DUJM)	2.7	
[AD-016] Requirements for Producing an Inspection Plan (22MDZD)	3.7	(F4E MQP §V.5.10)	--	F4E-QA-115 v4.4 §2.2.3, §4 F4E-QA-115 v5.5 §6.2 F4E-QA-113 v2.1
[AD-017] Procedure for the Management of Nonconformities (22F53X)	8.2	PM-35-Nonconformity Control (F4E_D_22MDXC)	5.0	F4E-QA-115 v4.4 §2.2.2 F4E-QA-115 v5.5 §6.3.2 F4E-QA-113 v2.1
[AD-018] Procedure for the Management of Deviation Request	7.3	PM-06 Deviation Control (F4E_D_22CCM4)	4.4	F4E-QA-115 v4.4 §2.2.1

PA Applicable Document	Ver.	F4E Implementation	Ver.	Supply Chain Propagation
(2LZJHB)				F4E-QA-115 v5.5 §6.3.3
[AD-019] Requirements for Producing a Contractors Release Note (22F52F)	5.0	F4E-QA-202 Annex A template (F4E_D_22DWZP) F4E-QA-238 F4E RN template (F4E_D_22K7W3)	--	F4E-QA-115 v4.4 *§2.6* F4E-QA-115 v5.5 §6.10.1
[AD-020] Quality Classification Determination (24VQES)	5.2	SOP-01.29 Quality Classification (F4E-QA-010) (22MD99)	3.0	F4E-QA-202 Annex A
[AD-021] Quality Management System Audits (2DQTA8)	5.0	PM-28 QMS Audits and Supplier Audits (F4E_D_22H84F)	3.1	F4E-QA-115 v4.4 *§2.8.1* F4E-QA-115 v5.5 §6.5
		F4E-QA-101 – QMS Audit Implementation (F4E_D 24XXZF)	1.5	
		SOP-01.38 Supplier Audit Implementation (F4E-QA-102) (F4E_D 296E7T)	2.6	
In-Kind Management:				
[AD-022] Procedure for the Preparation, Review, Approval Award and Amendment of Procurement Arrangements (2W4F7A)	4.1	PM-79 PA Preparation for Signature (F4E_D_26GDU8)	2.7	N/A
[PA-AD 23] MQP Document Change Control procedure (VDVFHY)	2.0	P-02.17 Business Process Management policy (F4E_D_23XKQW)	1.3	N/A
		SOP-02.06 Development of Working Procedures (F4E_D_2295HX)	3.0	
[PA-AD 24] Template F4E-QA-233 - Procurement Description (22DGSL)	2.0	F4E-QA-233 - Procurement Description (F4E_D_22DGSL)	--	N/A
[PA-AD 25] PA monthly report (2E346G)	1.4	F4E-QA-235 - Progress Report Template (F4E_D_22GQFU)	1.4	N/A
[PA-AD 26] PA template Credit Request Form (28B3TX)	1.0	PM-78 PA Credit Allocation (F4E_D_24Z4Y6)	3.2	N/A
[PA-AD 27] Working Instruction for the Credit Process of PA Database (PN5Q69)	1.2	PM-78 PA Credit Allocation (F4E_D_24Z4Y6)	3.2	N/A
[PA-AD 28] Working Instruction for RO Change of Signed PA (PAZWT3)	1.0	[F4E Manual]	--	N/A
[PA-AD 29] IO/DA Documentation Exchange and Storage (35BVQR)	4.1	P-02.23 F4E Documentation Management (F4E_D_24L87F)	3.0	F4E-QA-115 v4.4 §2.3 F4E-QA-115 v5.5 §3 F4E-Supplier Documentation Exchange (F4E_D_23CKVU v2.1)
Procurement Arrangement Related Documentation Access and Storage Conventions for Work Supervised by a Project Team (QV5TVY)	2.1			
Procedure on Procurement Documentation Exchange Between IO, DAs and Contractors for Work Supervised by a Project Team (QYTN6D)	3.0			
Risk Management:				
[PA-AD 30] Risk and Opportunity Management Procedure (22F4LE)	6.3	PM-22 Corporate / Project Risk & opportunity Management process (F4E_D_22CZRF)	2.1	F4E-QA-111 v1.3 F4E-QA-115 v4.4 §3.2.9 F4E-QA-115 v5.5 *§5.1.5*
		SOP-01.18 'Project Risk and Opportunity Management' Procedure (F4E_D_29SSKX)	1.1	
On-Site Activities:				
[PA-AD 31] Health Protection and Safety General Coordination Plan - ITER Construction Site - Volume 0 - General Safety Rules (2NUEYG)	5.7	[implement IO document]	--	IO document
[PA-AD 32] Internal Regulations (27WDZW)	2.2	[implement IO document]	--	IO document
[PA-AD 33] Environmental requirements (97WRFP)	1.3	[implement IO document]	--	N/A
[PA-AD 34] Contractor Safety Management Procedure (Q2GBJF)	1.4	[implement IO document]	--	N/A
[PA-AD 35] Procedure for Occupational Health and Safety Hazard Identification and Assessment (AJLQRF)	6.0	P-02.01 F4E Health and Safety (F4E_D_282GG4)	2.5	IO document (if needed)
		SOP-02.13 F4E H&S Risk Assessment and Preventive Measures (F4E_D_2DT8EJ)	2.1	
[PA-AD 36] Vehicule Access and Traffic Circulation and Parking on the ITER Site (N3MG3V)	1.2	[implement IO document]	--	IO document
[PA-AD 37] ITER Site access Procedure (S3893D)	3.1	[implement IO document]	--	IO document
Nuclear Safety:				
[PA-AD 38] Safety Important Functions and Components Classification Criteria and Methodology (347SF3)	1.8	[implement IO document]	--	N/A
[PA-AD 39] ITER Policy on Safety, Security and Environment Protection Management (43UJN7)	3.1	[F4E MQP §III.4]	--	F4E-QA-113 v2.1 F4E-QA-115 v4.4 *§1*
[PA-AD 40] Guideline for Identification of the Protection Important Activities (PIA) (SBYJXD v1.4)	1.4	P-01.17 PIA Guideline (F4E_D_27WDLC)	2.0	P-01.17 PIA Guideline
[PA-AD 41] Provisions for Implementation of the Generic Safety Requirements by the External Interveners (SBSTBM)	2.2	[F4E MQP §III.4, §V.5.9.5]	--	F4E-QA-113 v2.1 F4E-QA-115 v4.4 *§2.14*
		Management of the Propagation of Generic Safety Requirements in the Supply Chain (F4E-QA-013) (F4E_D_23CA9U)	3.0	
		Supplier Nuclear Safety Management Requirements (F4E-QA-113) (F4E_D_22JRQY)	2.1	

PA Applicable Document	Ver.	F4E Implementation	Ver.	Supply Chain Propagation
[PA-AD 42] Procedure Working Instruction for Propagation of the Defined Requirements by F4E (V7KUPV)	1.0	[F4E MQP §III.4.3]	---	F4E-QA-115 v4.4 §1, §2.14 F4E-QA-113 v2.1 F4E-QA-119 v1.7
		Management of the Propagation of Generic Safety Requirements in the Supply Chain (F4E-QA-013) (F4E_D_23CA9U)	3.0	
		F4E-QA-019 - F4E Requirements Management & Verification Procedure (F4E_D_2296FP)	2.3	
[PA-AD 43] Overall Surveillance Plan of External Interveners Chain for Protection Important Components, Structures and Systems and Protection Important Activities (4EUQFL)	7.4	[F4E MQP §III.4, §V.5.9.5]	--	F4E-QA-115 v4.4 §2.8.1, §3.2.12, §2.1.2 and §2.4 F4E-QA-113 v2.1
Applicable Laws and Regulations:				
[ALR 1] Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN (7M2YKF)	1.7	[See Compliance Matrix above]	--	--
[ALR 2] Nuclear Regulatory Framework for INB ITER (2WBB8P)	3.8	[implement IO document]	--	N/A

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