F4E QUALITY MANAGEMENT SYSTEM EVOLUTION AND REQUIREMENTS PROPAGATION

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Background

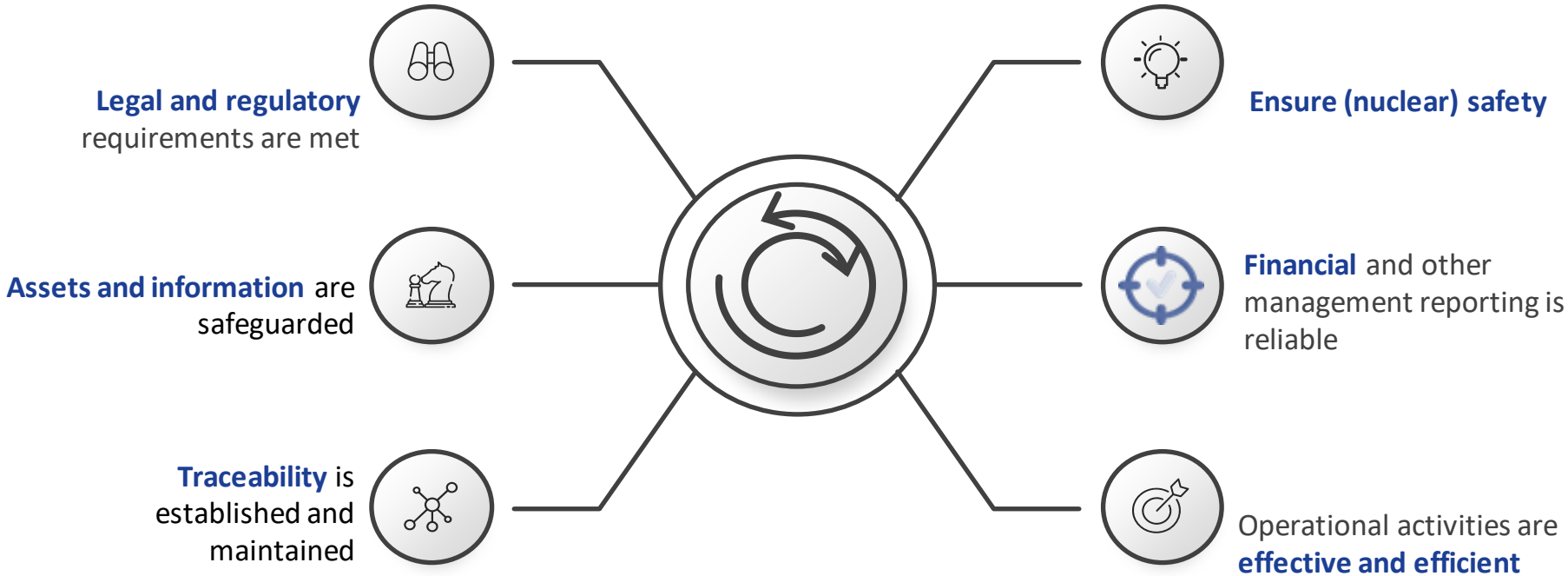
On 2007 F4E was established with the mission to bring fusion, the energy of the Sun and the stars, to Earth:

- **Fusion for Energy (F4E) is the European Union organisation managing Europe's contribution to ITER;**

- **In 2008 F4E developed a Management and Quality Programme (MQP) that allowed F4E to act as an external provider to IO with respect to the French Nuclear Regulation;**

Management and Quality Programme

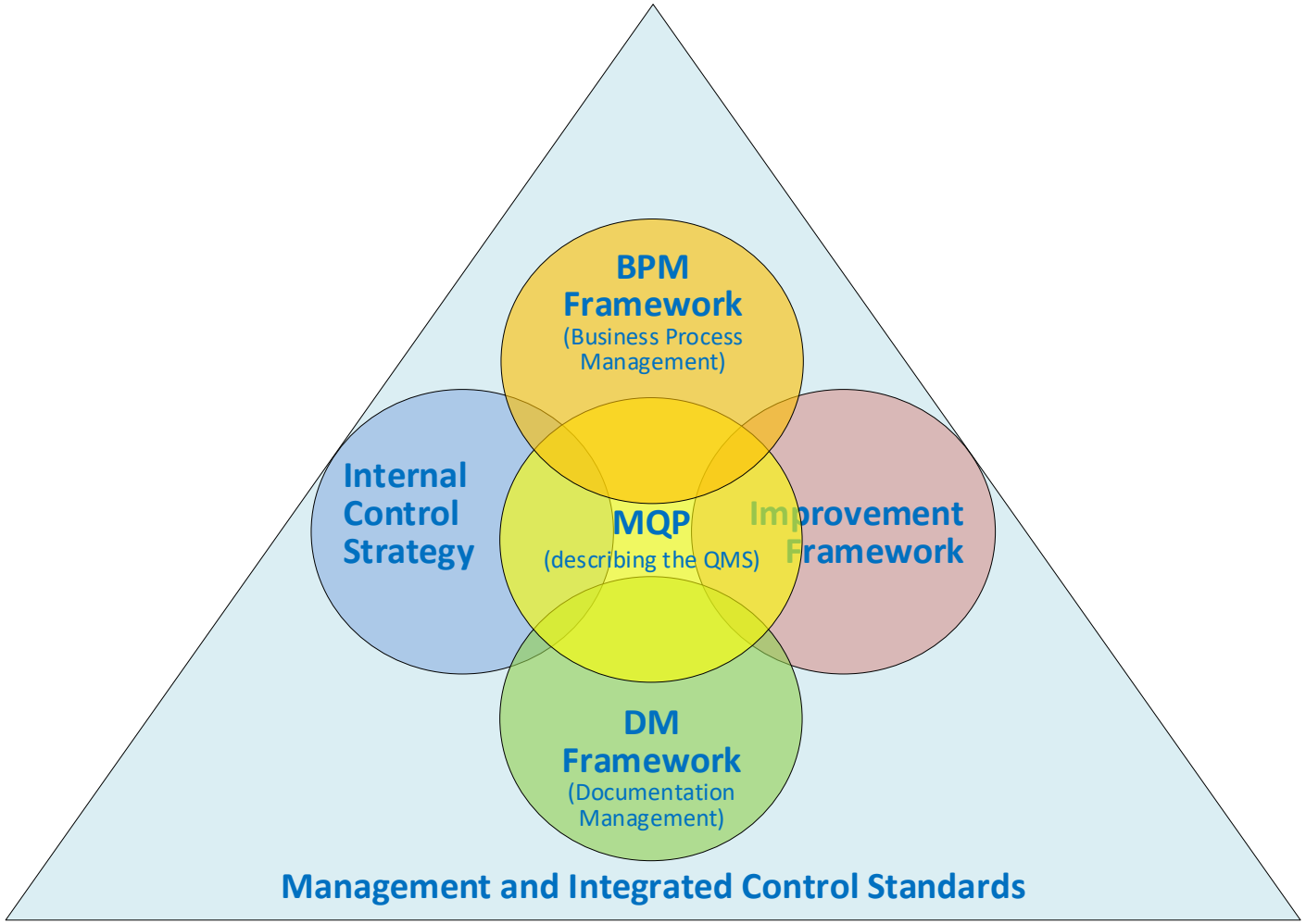
The Management and Quality Programme (MQP) is part of the F4E Integrated Management System, and describes the specific Quality Management System established for managing the activities that relate to items and services provided to the ITER project.



THE IMPLEMENTED MQP AIMS TO ENSURE:

The implementation and evolution of the Quality Management System (QMS), as described in the 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.

Integrated Management System



The Integrated Management System (IMS) is complementary to the **F4E Management and Internal Control Standards** and is composed of the following principles:

- F4E is implementing a process approach in line with the IAEA GSR Part 2 (Leadership and Management for Safety, 2015).
- F4E implements a **lean** and Quality Management System to its activities & customers.
- The Quality Management System is based on the implementation of **project management good practices** to comply with customer requirements (ITER Organization).
- The Management System is more efficient as its capacity to meet F4E's requirements grows. The efficiency of the system is continually assessed and measured through the **monitoring indicators of processes and the fulfilment of the specified objectives**.

Quality Management System

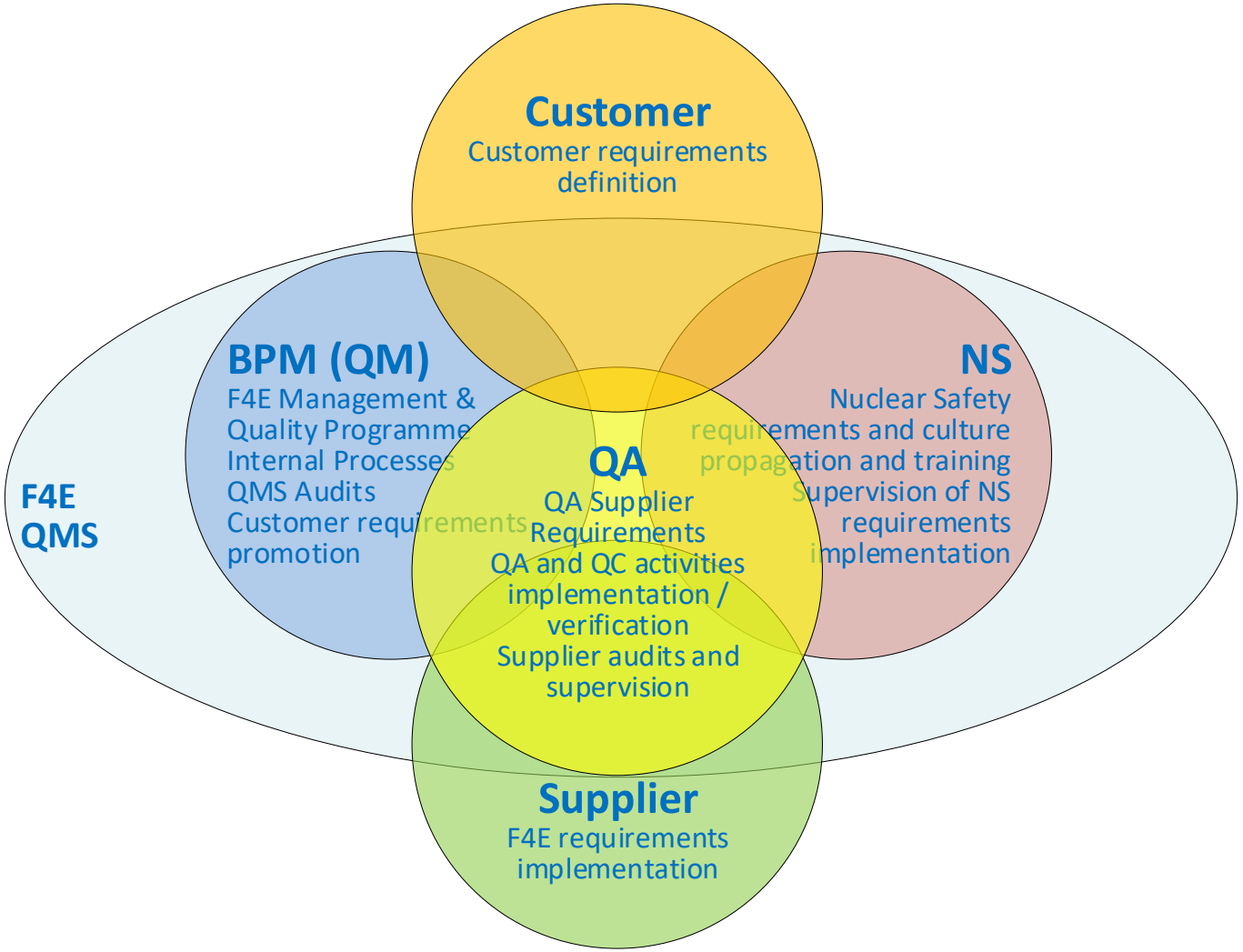
A set of working procedures that define the way F4E implements the IO required Quality System in F4E and they way F4E propagates the quality and management requirements to the supply-chain.

It also defines how the system is internally implemented and its maintenance and improvement.

The F4E Quality Management System for ITER is composed of:

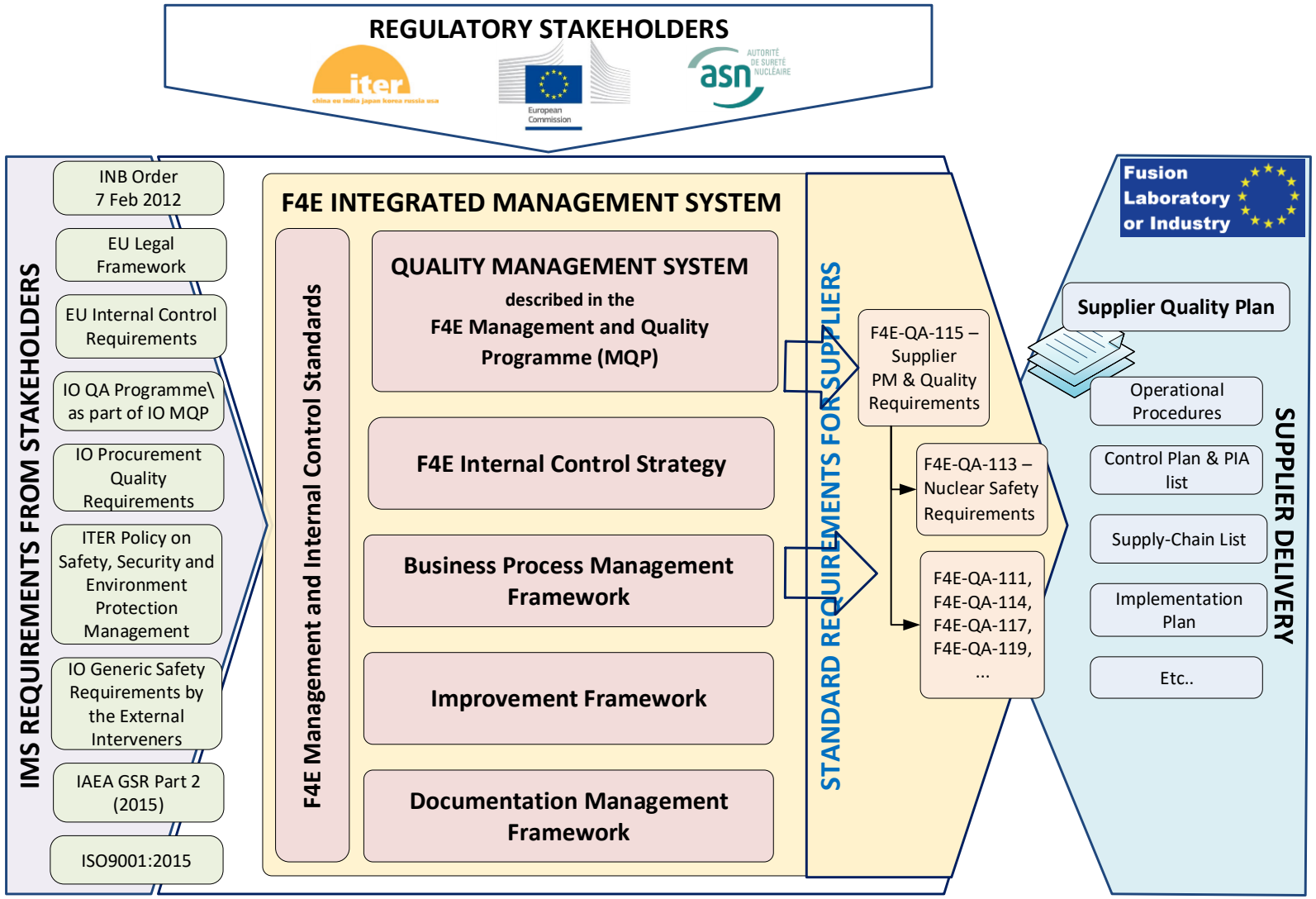
- F4E Management and Quality Programme Policy
- F4E Management and Quality Programme for ITER Project [EUDA QAP]
- Business Process Management Policy
- QA-115 Supplier PM and Quality Requirements
- Process Approach and the Process Map
- System Assessment for Improvement (QMS and Supplier Audits)

F4E QMS and Relationships

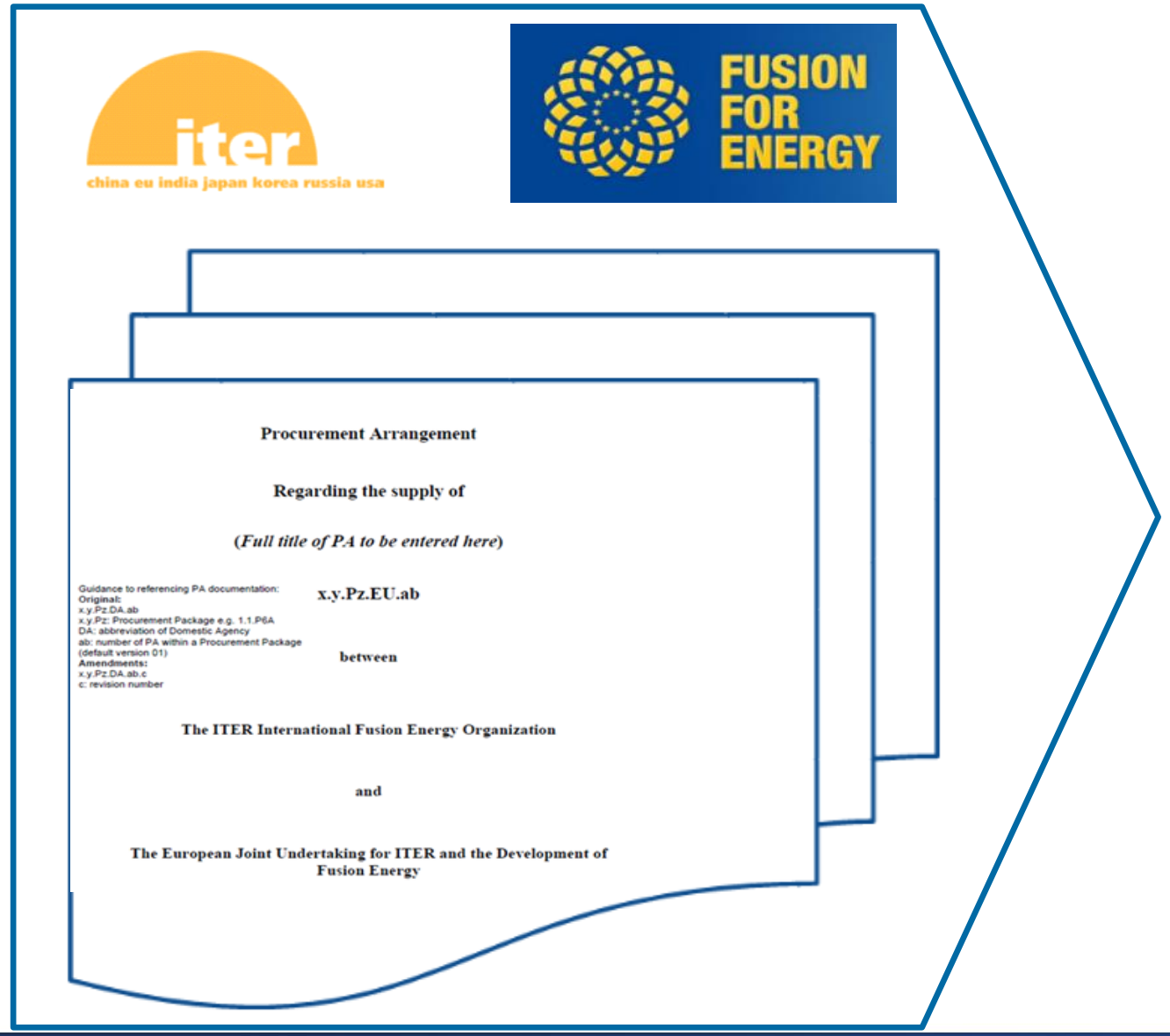


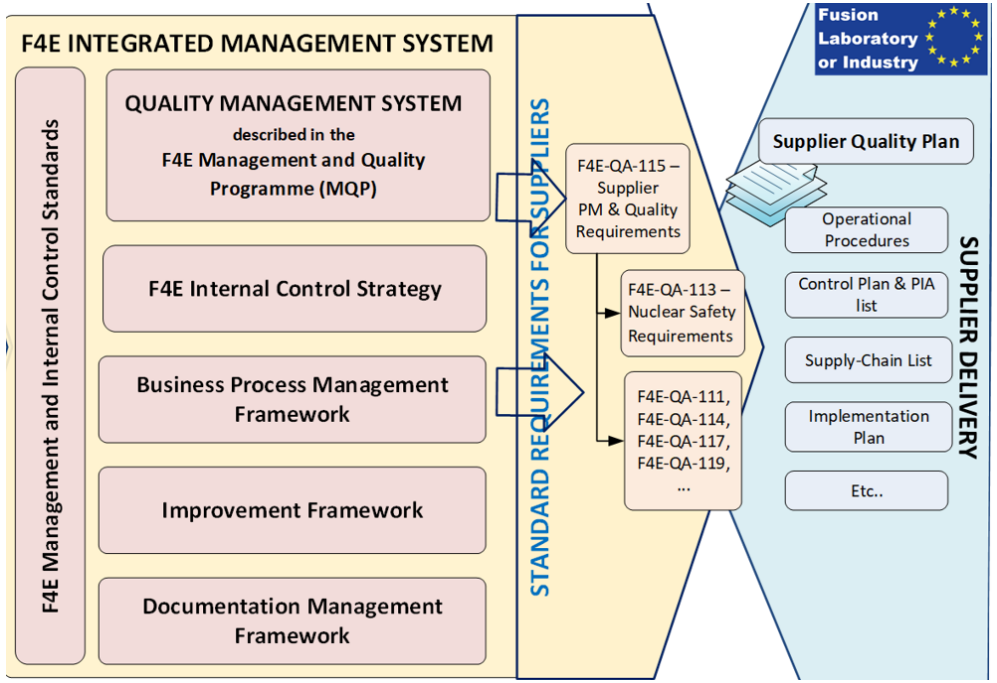
Propagation of Mandatory Requirements

Integrated Management System is the vehicle to receive, assess and convey the requirements into the supply chain.



Propagation of Requirements





Quality Class Determination

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The Quality Class is identified in the PA.

The rules for the Quality class determination is defined:

- [SOP-01.29 Quality Class Determination and Implementation (QA-010) (F4E_D_22MD99 V3.0)
- Quality Classification Determination (ITER_D_24VQES v5.2)

Factors to be Considered when Identifying the Quality Class of the System or Component and the Assessment of their Impact

		Class 1 Large Impact	Class 2 Adverse Impact	Class 3 Moderate Impact
Failure Consequence Factors				
Factor 1	**Functional & operational;**	*Failure has potential for a loss of plasma operations for long period or has impact on machine operation activities/ performances.*	*Failure has potential for loss of plasma operations for short period or leads to difficulties in machine operation activities.*	Failure has no potential for loss of plasma operation or loss of data essential for machine operation.
Factor 2	**Environment, industrial safety and health;**	Failure has potential for: (1) a death or total disability or severe adverse impact on the health or safety of a worker or the public, or (2) Environmental damage that could exceed regulatory limits or involve significant cleanup costs	Failure has potential for: (1) injury or illness requiring hospitalization, temporary or partial disability, or (2) moderately adverse impact on the environment or health or safety of a worker or the public.	Failure has potential for: (1) minimal impact on the health and safety of the public or a worker, such as injury or illness requiring minor supportive treatment but not requiring hospitalization, or (2) a negligible impact on the environment.
Factor 3	**Cost /Schedule Impacts**	*Failure has potential for a financial loss of 1000K Euro or more.*	Failure has potential for: (1) a financial loss of 500K Euro or more or but less than 1000K (2) Impact on ITER construction schedule	Failure has potential for a financial loss less than 500K Euro *and no impact on construction schedule.*
Factor 4	Compliance with applicable laws and regulation.	Failure has potential for non-compliance with state, federal or international laws, regulations or requirements	Failure has potential for non-compliance with established IO management practices and procedures.	Failure has potential for minor non-compliance with established management practices.
Failure Probability Factors				
Factor 5	Other Classifications (safety class, vacuum class, tritium class etc.)	The SSC has other classifications: PIC/ SIC 1 or PIC/ SIC 2 or SR/ seismic class 1/ vacuum class 1/tritium class 1.	The SSC has other classifications: PIC /SIC 2 or SR / seismic class 2 / vacuum class 2 / tritium class 2.	The SSC has other classifications: SR / seismic class 3 / vacuum class 3 / tritium class 3.
Factor 6	Design complexity;	*The design requires multiple discipline, interfaces, complex verifications, independent validation of the design and special software and models.*	*The design efforts is normal, it involves different disciplines and independent validation of the design.*	*The design efforts are minimal.*
Factor 7	Complexity of the manufacturing process.	*The product has multiple critical characteristics and fabrication requires multiple number of manufacturing processes, special process, complex technologies and high qualified personnel that is involved in manufacturing process*	*The product has critical characteristics and the fabrication requires normal processes, normal fabrication technologies and qualified personnel that are involved in manufacturing process.*	*The product has characteristics easy to be realised and the product fabrication does not requires a multiple number of manufacturing processes*

Propagation of Requirements to F4E supply chain

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Mark your Scope **Sele**

Select	Scope of the Contract	Contract Value	Quality Class	
No	R&D Activities	between 2 and 10	QC1	
Yes	**Design**	**< 2 ME**	**QC1**	
Yes	**Analysis and Calculations**	**< 2 ME**	**QC1**	
No	Prototyping	between 2 and 10	QC2	
No	Qualification of Special Processes	> 10 ME	QC1	
No	Manufacturing Assembly Integration and Inspection	> 10 ME	QC1	
No	Testing	> 10 ME	QC1	
No	SW QA	< 2 ME	QC1	

NOTE: The following matrix is an extract of the QA-115. Concerning the abbreviations, call of applicab reference documents or sections, please refer to QA-115 v5.5.

Requirement	Requirement text
General Requirements	
F4E-QA-115-GL-GL-001	The Supplier shall demonstrate the fulfilment of Health and Safety regulations as required b the legislation within the country where the activities will be developed as well as any specific health and safety regulations laid down by IO for any particular task performed in ITER site.
F4E-QA-115-GL-GL-005	For all Contracts involving CE Marking and other EC/ EU Directives and/or Regulations, the Supplier shall apply the requirements as per AD 05.
General - Nuclear Safety Requirements	
F4E-QA-115-GL-NS-001	For all Contracts involving PIC/PIA activities, the Supplier shall apply requirements of AD 01 i addition to all requirements defined in this document.
General - Intellectual Property	
F4E-QA-115-GL-IP-001	The Supplier shall identify all results of activities undertaken in the frame of the contract that may take the form of an invention, information, trade secrets, designs, drawings, processes, software, database etc., including the creation of any IP.
F4E-QA-115-GL-IP-002	The Supplier shall inform F4E in the Progress Reports and Acceptance Data Package about IP related information.
F4E-QA-115-GL-IP-003	The Declaration of IP foreground shall be submitted to F4E as a standalone self-explaining document as soon as foreground is created. Each item shall include a short description of th item to allow the easy understanding of its nature.
F4E-QA-115-GL-IP-004	The Supplier shall inform F4E about any IP relevant issue, such as requests for access to IP third parties or any IP issue that may impede performance of the contract.
F4E-QA-115-GL-IP-005	The Supplier shall identify in the IP reports any confidential information to ensure the confidentiality and the proper management of strategic IP information such as trade secrets information on patentable subject matters.
General - Dual Use	
	The Supplier shall produce and submit to F4E at Kick-off-Meeting, a detailed list of dual-use

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ANNEX A – Management Specification

MANAGEMENT SPECIFICATION

FOR THE NAME OF YOUR SYSTEM

idm@F4E Reference:	F4E_D_XXXXXXX	Call No	F4E-TYP-NNN

Template F4E_D_22DWZP v4.7

Abstract

This document specifies project management and quality assurance requirements the Supplier shall comply with during the execution of the Contract or Grant Agreement.

Verification

While Quality Assurance relates to how a process is performed or how a product is made, Quality Control is more the inspection aspect of quality management. Quality Assurance processes are put in place to provide some comfort that the end product is what you want. Quality control is making sure the end product really is what you want.

Quality Audits:
Implemented by IAC/QM/QA on F4E and supplier activities

Nuclear Safety Assessments
Implemented by NSU
Supervision and inspection of PIC/PIA performers and suppliers.

Supervision Plan:
Developed & implemented by PTs on supplier activities

Supervision Activities:
Developed and implemented by QAG on supplier activities

Conclusion

F4E implemented a Quality Management System that complies with the requirements set by ASN and ITER.

F4E implemented Quality Management System provides confidence that:

- Requirements are properly identified based on the Safety Class, Quality Class and Failure Consequence Factors.
- Nuclear Safety and Management Requirements are properly cascade to all supply chain.
- Compliance is ensured through the supply chain

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