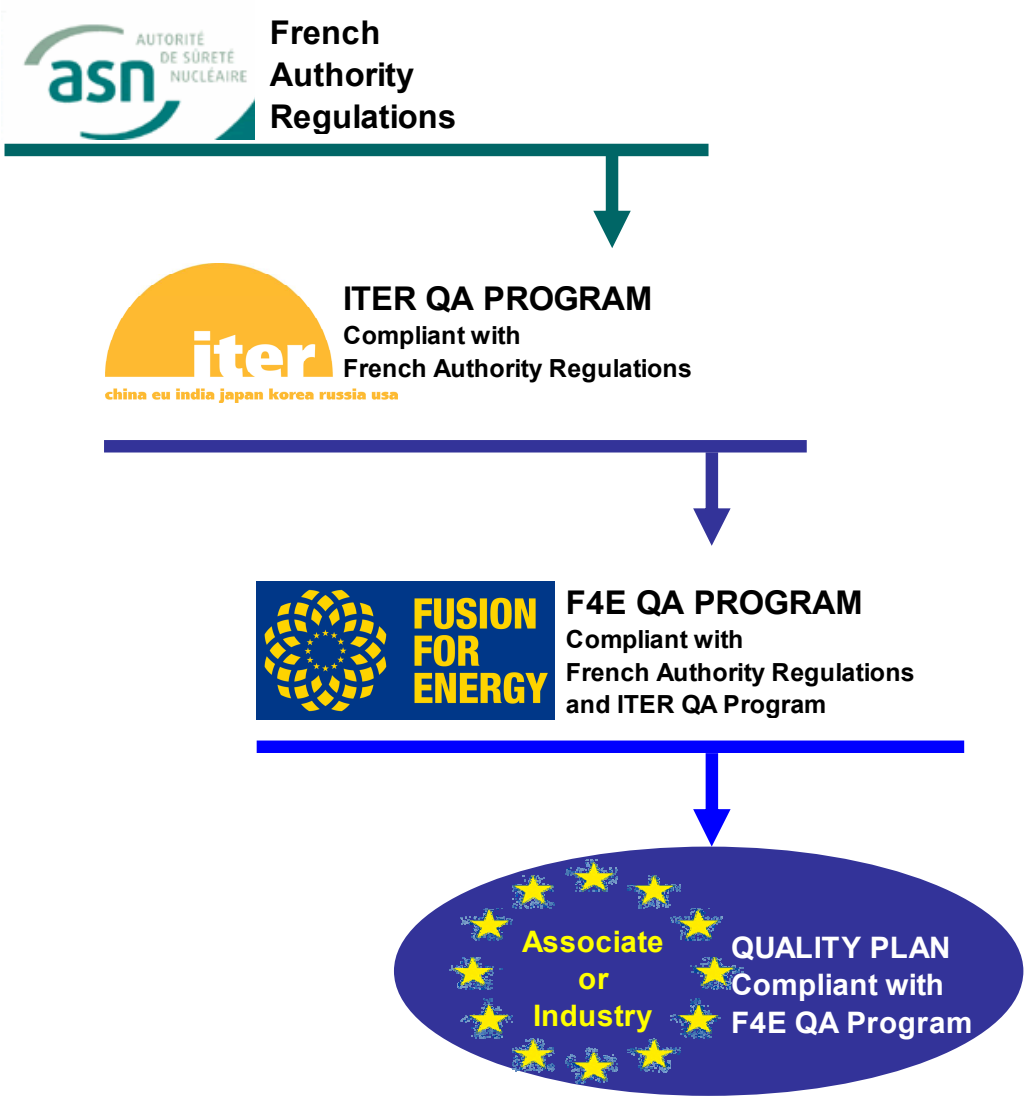
QA REQUIREMENTS CONTRACT IMPLEMENTATION

‘Fusion for Energy’

Origin - Quality Requirements



ITER has been classified as an "Installation Nucléaire de Base" (INB), and within this larger class recognising the objective limit of the risks, in the subclass of Labs and Fuel Plants

ITER must comply, Quality wise, with:

- ARRETE QUALITE DU 10 AOUT 1984
- IAEA Safety Requirements GS-R-3 (2006) – "The Management System for Facilities and Activities".

Management Specification - Requests

Quality and Management requirements are addressed in Annex A

Annex A is the Management Specification and requests a Quality Plan

AT TENDER LEVEL

The Bidder shall provide, in its offer a meaningful outline of a dedicated Quality Plan where the plans, schedules and explanation of the provisions to comply with the following requirements will be assembled.

The Bidder will be evaluated, inter alia, on the basis of its Quality Plan according to the Tender Specifications.

During offer, due to the nature of the process, the Bidder might not have all the information that he will have as a successful Bidder. As result of this limitation, at this stage the Quality Plan cannot be a "complete" version and is referenced as an "outline' version where:

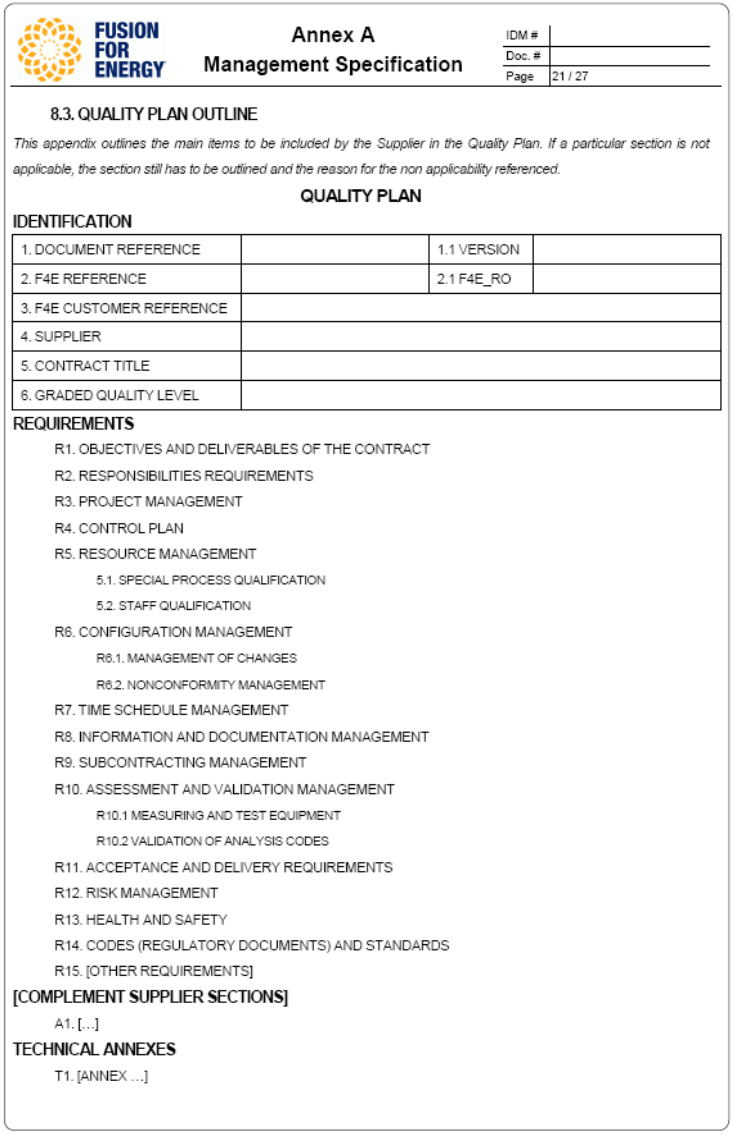
- Some sections will be addressed as a description of the previewed system (proposed system).
- The remaining sections shall have the description of the Bidder current system.

AT CONTRACT LEVEL

After the Contract signature, the Quality Plan shall encompass the following sequential stages (in accordance with § 5):

1. at the kick-off meeting the Supplier shall provide the proposed Quality Plan;
2. the Supplier shall not begin any work without the Quality Plan being released in writing by F4E;
3. during Contract implementation, the Supplier shall update the Quality Plan (or parts of it) as/if required and shall submit it to F4E for release.

QUALITY PLAN



FUSION FOR ENERGY

Annex A
Management Specification

IDM #	
Doc. #	
Page	21 / 27

8.3. QUALITY PLAN OUTLINE

This appendix outlines the main items to be included by the Supplier in the Quality Plan. If a particular section is not applicable, the section still has to be outlined and the reason for the non applicability referenced.

QUALITY PLAN

IDENTIFICATION

1. DOCUMENT REFERENCE		1.1 VERSION	
2. F4E REFERENCE		2.1 F4E_RO	
3. F4E CUSTOMER REFERENCE			
4. SUPPLIER			
5. CONTRACT TITLE			
6. GRADED QUALITY LEVEL			

REQUIREMENTS

- R1. OBJECTIVES AND DELIVERABLES OF THE CONTRACT
- R2. RESPONSIBILITIES REQUIREMENTS
- R3. PROJECT MANAGEMENT
- R4. CONTROL PLAN
- R5. RESOURCE MANAGEMENT
  - 5.1. SPECIAL PROCESS QUALIFICATION
  - 5.2. STAFF QUALIFICATION
- R6. CONFIGURATION MANAGEMENT
  - R6.1. MANAGEMENT OF CHANGES
  - R6.2. NONCONFORMITY MANAGEMENT
- R7. TIME SCHEDULE MANAGEMENT
- R8. INFORMATION AND DOCUMENTATION MANAGEMENT
- R9. SUBCONTRACTING MANAGEMENT
- R10. ASSESSMENT AND VALIDATION MANAGEMENT
  - R10.1 MEASURING AND TEST EQUIPMENT
  - R10.2 VALIDATION OF ANALYSIS CODES
- R11. ACCEPTANCE AND DELIVERY REQUIREMENTS
- R12. RISK MANAGEMENT
- R13. HEALTH AND SAFETY
- R14. CODES (REGULATORY DOCUMENTS) AND STANDARDS
- R15. [OTHER REQUIREMENTS]

[COMPLEMENT SUPPLIER SECTIONS]

- A1. […]

TECHNICAL ANNEXES

- T1. [ANNEX …]

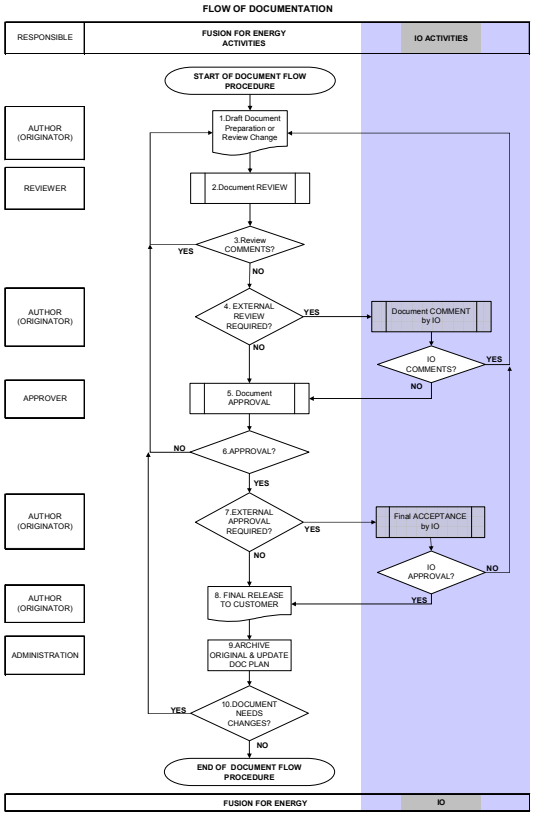
The dedicated Quality plan describes the operational quality system implemented by the bidder/supplier to ensure that:

- Contract requirements will be met,
- Evidence of such compliance will be maintained.

The compliance with the Quality Plan shall replace any need for QA certification.

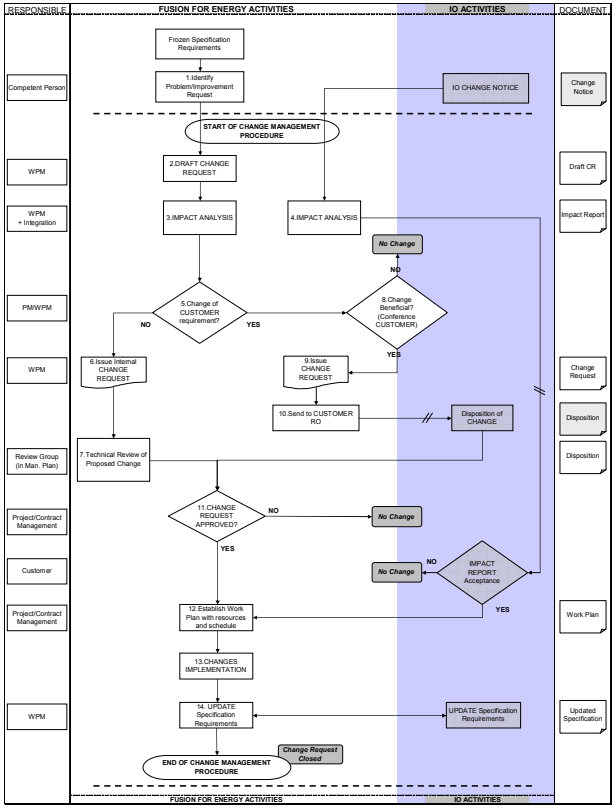
Certification is not mandatory, but recommended.

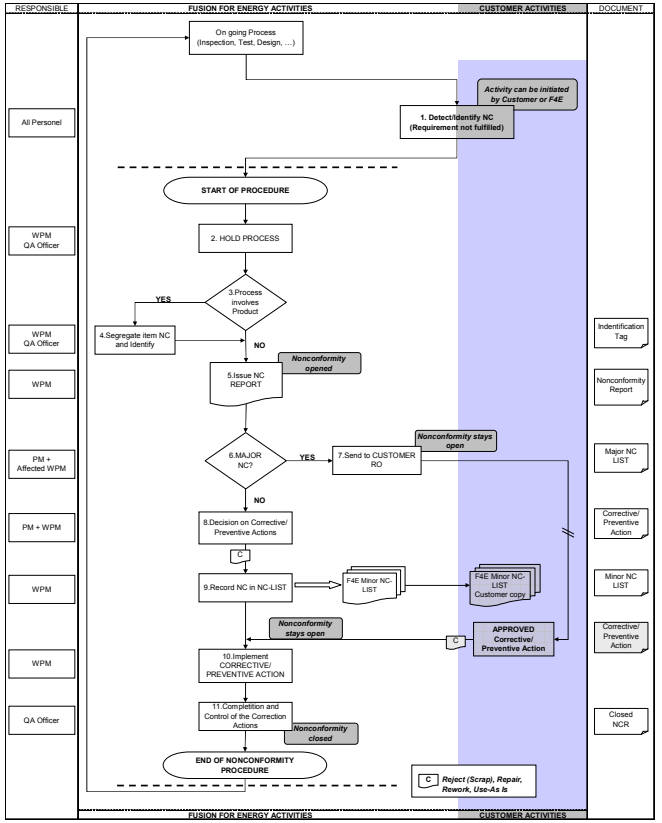
PROCESSES FLOWCHARTS



DOCUMENTATION FLOW

CHANGE & DEVIATION HANDLING





NONCONFORMITY HANDLING

French Regulation for Nuclear Safety Quality Order (resume)

QUALITY ORDER OF AUGUST 10, 1984 FRENCH REGULATION FOR NUCLEAR SAFETY

The required quality is obtained and maintained on one hand by activities performed and on the other hand by organized and appropriate verification.

Art 1. Graded quality management system according to safety importance of components and activities (SIC). Set up at the design stage and extended throughout all the subsequent stages of existence of the Installation.

Art 2. Definition of safety relevant activities.

Art 3. Definition of Operator and contractors.

Art 4. Operator is responsible for safety and responsible of application by contractors of adequate QA system.

Art 5. QA manual + QA compliance report + contractors assessment.

Art 6. Safety requirement are defined and monitored.

Art 7. Appropriate human and technical resources in agreement to safety objectives.

Art 8. Independent verification of safety relevant activities.

Art 9. QA management team + Evaluation and correction monitoring.

Art 10. Records and reporting + frequency.

Art 11. Correctly storage records and hardcopies.

Art 12. & 13. Deviations definition, deviation records, declare to NSA, feedback.

Art 14. Safety relevant studies are concerned by QA (apply QA during design).