NS SPECIFICATION

Control Page

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Document title:	Supplier Nuclear Safety Management Requirements (QA-113)

Areas and functions	
Process ownership:	F4E Director
Area(s) concerned:	F4E Manual (Operational)
Function(s) concerned:	All Operational Roles, in particular during the Contract implementation: - the Technical Project Officer for the follow-up of technical, management and quality requirements; - the Procurement Project Officer for the follow-up of the commercial Requirements; - the Nuclear Safety Officer for follow-up of any nuclear safety issues; - F4E Suppliers and Supply Chain.

Purpose

The purpose of the **F4E-QA-113 Supplier Nuclear Safety Requirements** is to define the specific nuclear safety requirements to be considered by tenderers and implemented by F4E Suppliers and their Subcontractors involved in tasks concerning Protection-Important Components or Protection-Important Activities.

Scope

This document contains the requirements related to Nuclear Safety to be complied with and implemented by all F4E Suppliers within F4E chain of External Interveners, including their possible Subcontractors and service providers, involved in activities classified as PIA and/or in tasks concerning PIC with activities classified as PIA.

For Suppliers, Subcontractors or service providers involved in such activities and/or tasks, this document supplements the F4E requirements on the Project Management and Quality Requirements (F4E-QA-115).

This document is applicable to all External Interveners in F4E Supply Chain (Suppliers and their Subcontractors, disregarding their level in the chain of External Interveners), in charge of Contracts dealing with PICs or PIAs.

Activities classified as PIA cover design, prototype and/or qualification, fabrication, installation, testing and commissioning, maintenance, handling, transportation, storage, … during the different phases of the project.

F4E Suppliers and their Subcontractors shall comply with these requirements during the execution of their Contract.

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Applicable and Reference documents

Applicable Documents

[1] F4E Policy on Nuclear Safety Management (F4E_D_26C3GS)

[2] F4E-QA-115 - Supplier Quality Requirements (F4E_22F8BJ)

[3] F4E-QA-135 - Contractor CE Marking Requirements (F4E_D_2CK5ZZ)

[4] Pressure Equipment Directive 2014/68/EU of 15th of May 2014 (PED)

[5] Arrêté du 30 décembre 2015 relatif aux équipements sous pression nucléaires - French Order of the 30th of December 2015 modified (ESPN Order)

Reference Documents

[6] Code de l'Environnement - French Environmental Code

[7] Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base - French Order of 7 February 2012 modified (INB Order)

[8] Decree No. 2012-1248 dated 9 November 2012 authorizing IO to create a basic nuclear facility called "ITER" - French version - (ITER_D_C2JZNX)

[9] ITER Policy on Safety, Security and Environment Protection Management (ITER_D_43UJN7) *(included in F4E Policy [1])*

[10] Provisions for Implementation of the Generic Safety Requirements by the External Interveners (ITER_D_SBSTBM)

[11] List of Protection Important Components (PIC list) (EN) (ITER_D_JDS5K7)

[12] Safety Important Functions and Components Classification Criteria and Methodology (ITER_D_347SF3 v1.8)

[13] List of ITER-INB Protections Important Activities (PIA) (ITER_D_PSTTZL)

[14] Protection Important Activities and Defined Requirements for All ITER Mechanical PIC Equipment (ITER_D_338G4B)

[15] PIA Guideline (F4E_D_27WDLC)

[16] IO Safety - Guideline for Identification of the Protection Important Activities (PIA) (ITER_D_SBYJXD)

[17] IO Working Instruction for Propagation of the Defined Requirements by F4E (ITER_D_V7KUPV)

[18] Overall Surveillance Plan of External Interveners Chain for Protection Important Components, Structures and Systems and Protection Important Activities (ITER_D_4EUQFL)

[19] ITER Abbreviations (ITER_D_2MU6W5)

[20] Nuclear safety common definitions (ITER_D_RLZXMV)

The applicable version of documents in this section will be the one in force at the date of the signature of the contract and will be identified in the Tender documents or Contract Management Specifications (Annex A).

Terms and Definitions	
ADP	Acceptance Data Package, has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
Contract	Has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
Critical Activities	In the context of this F4E-QA-113, activities that, if not performed correctly, may affect nuclear safety, functionality, reliability or interchangeability. PIAs are critical activities.
Deviation	Deviation, has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
ESR	The Essential Safety Requirements, laid down in the Pressure Equipment Directive [4], are to be applied to eliminate or reduce hazard existing for the pressure equipment (or apply protection measures when not possible). They define compulsory obligations in design, calculation method, test validation programme, examination, materials used, manufacturing, final proof test, operating instructions,...
External Intervener	Any natural or legal person other than the operator and his employees who carry out operations or who supply goods or services: - - who participate in a protection-important activity or a protection-important component; - or who participate in an action in application of the Order of 7 February 2012 [7] and related to such an activity. Suppliers, Subcontractors, service providers, experimenters and users are in particular concerned.
F4E Nuclear Safety Policy	The F4E Policy on Nuclear Safety Management [1] defines the principles and the rules in F4E to guide the compliance with the requirements of the French regulations related to nuclear safety (in particular but not exclusively the INB Order). As per requirement of the INB Order [7], the provisions specific to nuclear safety from the IO Policy on safety, security and environment protection management are included in the F4E Nuclear Safety Policy.
F4E-NSO F4E-TPO	Fusion for Energy Nuclear Safety Officer (in a Project Team or Technical Support Team) responsible for the nuclear safety aspects of the Procurement and the subsequent Contract. Fusion for Energy Technical Project Officer, has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2]. Roles and functions are defined in the respective Sign-Off Authority Policy, to be applied by each Project. Note: Reserved to F4E personnel.
INB	In French, an "*Installation Nucléaire de base*" is one of the following: - nuclear reactors; - installations for preparation, enrichment, manufacture, treatment or storage of nuclear fuel or the treatment or storage of radioactive wastes, meeting characteristics defined by the French "Conseil d'Etat"; - installations containing radioactive or fissile substances and having characteristics defined by the French "Conseil d'Etat"; - particle accelerators meeting the characteristics defined by the French "Conseil d'Etat"; - deep geological repositories of radioactive wastes mentioned in Article L.542-10-1 of the French Environmental Code [6]. The ITER facility is an INB.

Independent Verification	Verification of an activity, carried out by persons other than those who accomplished the activity. IMPORTANT: "Independent Verification" and "Technical Control" are distinct terms (see Technical Control).
IO	Iter Organization, has the meaning given to it in the section on abbreviations and definitions of F4E-QA-115 (Supplier Quality Requirements) [2].
Management System	Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives (organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives). Management Systems can address a single discipline or several disciplines, e.g. nuclear safety, quality management, financial management or environmental management.
MIP	In the context of this F4E-QA-113, the Manufacturing and Inspection Control Plan defines the sequence of activities to be performed by a Supplier or its Subcontractor. MIP shall also be established for design, calculation and commissioning test activities.
Monitoring	Routine or continuous activities performed by the Supplier to control the work of its personnel and Subcontractors and services providers Control activities performed by the F4E Project team to monitor the work of its personnel and its Subcontractors (1st-level Supervision).
NC	Nonconformity, has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
NCFSI	Non-conforming, Counterfeit, Fraudulent, or Suspect Items. All items potentially concerned by forgery, falsification, unauthorized, missing or hidden activities, …committed intentionally or not, concerning a PIC or a PIA (including the related Technical Control) Subject to a special declaration as per special request of the ASN and article 2.7.2 of the INB Order [7].
NCR	Nonconformity Report, has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
Nuclear Safety Demonstration	In French, "*Démonstration de Sûreté*", as per definition of the INB Order [7]. All the elements contained or used in the ITER Safety Report (RPrS) and contributing to the demonstration, as per article L. 593-7 of the French Environmental Code [6], which prove that the risks of an accident - radiological or not - and the scale of their consequences, given the current state of knowledge, practices and the vulnerability of the installation environment, are as low as possible under acceptable economic conditions.
Nuclear Safety Function	Fundamental Nuclear Safety Functions at the ITER facility are as follows: - confinement of radioactive material aiming at protecting the personnel, the public and the environment from releases of radioactive material; this function is achieved with confinement barriers and associated confinement systems; - limitation of internal and external exposure to ionizing radiation. All functions assigned to a PIC and that is required for the ITER Nuclear Safety Demonstration.
NSDR	Nuclear Safety Defined Requirement In French, "*Exigence Définie*", as per definition in the INB Order [7]: "*Requirement assigned to a PIC, so that it fulfils - with the required characteristics - the function provided for in the demonstration mentioned in the second paragraph of article L. 593-7 of the Environmental Code, or to a PIA so that it meets its objectives with respect to that demonstration.*" Nuclear Safety Defined Requirements for PIC: any requirement that has been assigned to a PIC allowing it to perform the Nuclear Safety Function necessary for the ITER Nuclear Safety Demonstration, with the required characteristics.

	Nuclear Safety Defined Requirements for PIA: any requirement that has been assigned to a PIA, so that it meets its objectives with respect to the ITER Nuclear Safety Demonstration. In the ITER Project, NSDRs are categorized as Qualitative Defined Requirements, Technical Defined Requirements, Primary Defined Requirements and Derived Defined Requirements. For their definition and specific use, please refer to [17].
PBS	Plant Breakdown Structure
PIA	As per article 1.3 of the INB Order [7]: "*Activity important for protecting the interests mentioned under Article L. 593-1 of the Environmental Code (nuclear security – i.e. nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil security actions in the event of an accident –, public health and sanitation or protection of nature and the environment), i.e. activity participating in the technical or organizational provisions mentioned in the second paragraph of article L. 593-7 of the Environmental Code, or that could affect them".* In practice, in the context of this F4E-QA-113, it means any activity which can impact the performance of a PIC or the Nuclear Safety Demonstration. As stated in article 2.5.2 of the INB Order [7], a list of ITER PIAs and related Nuclear Safety Defined Requirements must be set up and kept updated by IO. The identification of PICs, PIAs and associated Nuclear Safety Defined Requirements is also a PIA.
PIC	Specific category of SSCs as defined per article 1.3 of the INB Order [7]: "*A component which is important for protecting the interests mentioned under Article L.593-1 of the Environmental Code (nuclear security – i.e. nuclear safety, radiation protection, the prevention and fight against malicious acts, and also civil security actions in the event of an accident –, public health and sanitation or protection of nature and the environment), i.e. structure, equipment, system (programmed or not), material, component or software that is present in the basic nuclear installation or that is under the responsibility of the operator and that implements a function required for the demonstration mentioned under the second paragraph of Article L. 593-1 of the Environmental Code (safety demonstration) or that ensures that this function is implemented*". In practice, in the context of this F4E-QA-113, it means any SSC whose correct operation under normal and accident conditions is necessary for ensuring the effectiveness of the Nuclear Safety Functions of ITER, as presented in ITER Safety Report. As stated in article 2.5.1 of the INB Order [7], the list of ITER PICs and their related Nuclear Safety Defined Requirements shall be set up and kept updated by IO.
RPrS	In French "*Rapport Préliminaire de Sûreté"* Reference document, submitted to the French Nuclear Safety Authority in 2011 for the authorisation of construction of the ITER nuclear facility.
SIC-1	The PIC SSCs required to bring to and to maintain ITER in a safe state.
SIC-2	The PIC SSCs used to prevent, detect or mitigate incidents or accidents, but not SIC-1 (not required for ITER to reach a safe state).
Significant Event	In French, "*Evénement Significatif*" Deviation of particular importance, according to criteria specified by the ASN. As per articles 1.3 of the INB Order [7], a Significant Event is defined as a "*Non-conformity of specific importance, pursuant to the criteria specified by the Nuclear Safety Authority*." The Significant Events must be declared to the nuclear regulator (ASN) in application of article 2.6.4 of the INB Order [7].
SQEP	In the context of this F4E-QA-113, Suitably Qualified and Experienced Person/Personnel represents individuals who have the requisite qualifications, training and experience – effectively, the competence – to carry out tasks that may affect the nuclear safety of any operations or activities on the site.

SSC PIC/SIC SSC	Structure, System and Component of the ITER facility. A PIC/SIC SSC either performs a Nuclear Safety Function which contributes towards meeting the general safety objectives of ITER during normal, incident/accident situations, or has been identified as Hard Core Component.
Subcontractor	Has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2]. In this document, it concerns only Subcontractors involved in PICs and/or PIAs (disregarding the level in the Supply Chain).
Supervision	Control activities, performed via reporting or by sampling (additional to continuous Monitoring activities)
Supply Chain	The Supply Chain follows the scheme below: *Subcontractor -> Supplier -> Organization (F4E) -> End-User (IO)* In the context of this F4E-QA-113, the end-user is the Nuclear Operator (IO).
Supplier	Has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2]..
Surveillance	Control activities performed by the Nuclear Operator as per the INB Order [7]
Technical Control	In French, "*Contrôle Technique*", as per definition of the INB Order [7]. Particular control, associated to each PIA, that shall demonstrate that the NSDR identified for the concerned PIA is reached. "Technical Control" shall not be confused with the "Independent Verification" requested by ISO 9001 nor with "action of verification" carried out by IO at each level of the Supply Chain, as requested by article 2.5.4 of the INB Order [7].
Validation of the product	Has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].
Verification the product	Has the meaning given to it in the section on abbreviations and definitions of the F4E-QA-115 (Supplier Quality Requirements) [2].

1. MAIN CONCEPTS

1.1 MAIN ACTORS

1.1.1 Nuclear Operator

As defined in article 1.3 of the INB Order [7]:

"*Natural or legal person operating a basic nuclear installation, whether its situation is in order or not, or having made a creation authorisation application provided for by article L. 593-7 of the Environmental Code with a view to operating such an installation*".

According to article 1 of the Decree of 9 November 2012 [8], the ITER Organization is the Nuclear Operator of the ITER installation (INB 174).

1.1.2 External Intervener

As per article 1.3 of the INB Order [7]:

"*Any natural or legal person other than the operator and his employees who carry out operations or who supply goods or services:*

- *who participate in a protection-important activity or a protection-important component;*
- *or who participate in an action in application of the Order of 7 February 2012 and related to such an activity.*

Suppliers, Subcontractors, service providers, experimenters and users are in particular concerned."

This means that any person, other than the ITER personnel, who does not participate in a PIA or a PIC, or a Technical Control, is not an External Intervener.

This definition includes, but is not limited to, every level of the chain of contractors: Supplier, Subcontractor, sub-subcontractor and so on. The definition also includes the Domestic Agencies.

Chain of External Interveners

The Nuclear Operator is considered as level 0 in the chain of propagation of the Nuclear Safety Defined Requirements.

The chain of External Interveners starts with the Nuclear Operator's first contractor, level 1 in the chain, which can be a Domestic Agency, down to the lowest level of Subcontractors for which it shall be guaranteed that the INB Order [7] is respected.

The European "Domestic Agency" Fusion for Energy is classified as level 1 of the chain of External Interveners (i.e. of the ITER Supply Chain). F4E's direct contractors are classified as level 2 and so forth.

Domestic Agency

A legal organization set up under the ITER Agreement to provide in-kind goods or services to the ITER Organization through Procurement Arrangements and Task Agreements.

Fusion for Energy is the European Domestic Agency, providing the European contribution to the ITER Organization.

Supplier

Please refer to its definition in the section on Terms and Definitions above.
In the context of this F4E-QA-113, the term Supplier refers to an External Intervener that performs work for a Domestic Agency, including:

- any third-party organizations;
- External Interveners that perform parts of the Contract;
- External Interveners that provide services or resources for the performance of the Contract.

Subcontractor

Please refer to its definition in the section on Terms and Definitions above.
In the context of this F4E-QA-113, the term Subcontractor refers to an External Intervener that performs work for a Supplier or another Subcontractor, including:

- any third-party organizations;
- External Interveners that perform parts of the Contract;
- External Interveners that provide services or resources for the performance of the Contract.

1.1.3 ASN

As per the article L592-1 of the Environmental Code [6]:

"*The Nuclear Safety Authority is an independent administrative authority involved in the control of nuclear safety, radiation protection and nuclear activities mentioned in Article L. 1333-1 of the Public Health Code.*

It participates in public information and transparency in its areas of expertise".

1.1.4 Notified Body / Agreed Notify Body

A Notified Body is a technical organization approved in an EU Member state, either for approval and monitoring of the manufacturer's Management System or for direct product inspection for the manufacture of Pressure Equipment.

An Agreed Notified Body is a Notified Body accepted by the French Nuclear Authority (ASN) to perform conformity assessment of Nuclear Pressure Equipment.

1.1.5 Third Party Organization

A Third Party Organization is an organization that has been accredited by a EU Member State to assess whether a product meets certain preordained standards.

For instance, Third Parties are accredited for the purpose of the tasks referred to in the European Pressure Equipment Directive (PED) 2014/68/EU [4], in particular the assessment of the Welding Procedure Qualification, Permanent Assembly Procedure Qualification, and Qualification of the personnel in charge of welding and non-destructive testing.

1.2 NUCLEAR SAFETY CLASS

Structures, systems and components (SSC) are assigned a particular Safety Importance Class (SIC) that is based on the consequences of their failure.

SIC SSCs are components whose failure would have the consequences taken in account in the ITER safety demonstration, or mentioned as required to reduce the gravity of potential accidents.

As a consequence, the SIC SSCs shall receive adequate attention during design, fabrication, installation, commissioning and operational stages. The objective is to ensure and demonstrate that they will meet the expected performance and reliability requirements throughout their intended lifecycle so that the Nuclear Safety Function is provided when required.

Further, they are also assigned a Quality Classification, Seismic Classification, as well as mechanical, electrical, instrumentation and control, and structural Classification in relation to their function in the ITER Nuclear Safety Demonstration.

The SSCs classified as PIC (formerly named SIC) are divided into:

- SIC-1 SSCs are those required to bring to and to maintain ITER in a safe state, during or after an incident or an accident according to the ITER Nuclear Safety Demonstration;
- SIC-2 SSCs are those used to prevent, detect or mitigate incidents or accidents according to the ITER Nuclear Safety Demonstration (not required for ITER to reach a safe state).

All other components are "non-SIC" or non-safety related.

However, some components, while not being SIC, may have some importance to nuclear safety. These components are labelled "Safety Relevant" (SR). They are not specified in the nuclear safety analysis and their failure would not adversely impact any Nuclear Safety Function. Per se, usually no Nuclear Safety Defined Requirement, as per definition of the INB Order [7], are associated with the design of SR components (however, some requirements may be associated with, e.g. periodical maintenance).

2. DISCLAIMER

The Supplier's responsibility and/or liability for the performance of the F4E Contract or any of its other duties, obligations and liabilities pursuant to the F4E Contract, remains unchanged and shall not be limited by ITER IO's approval/acceptance of any document produced by the Supplier.

In a similar way, the IO approval/acceptance or technical agreement shall not limit the Supplier's responsibility or liability for the performance of the F4E Contract or any of its other duties, obligations and liabilities pursuant to the F4E Contract.

3. BACKGROUND REQUIREMENTS

3.1 PROPAGATION OF THE NUCLEAR SAFETY POLICY AND SPECIFICATION

QA-113-GE-NS-01	The Supplier shall ensure that the priorities and provisions of the Policy in Nuclear Safety Management [1] are properly known, understood, and applied, and propagated to its personnel and to all the Subcontractors, when involved in PIC and PIA Contracts, disregarding the level in the Supply Chain.
QA-113-GE-NS-02	The Supplier shall ensure that the requirements contained in the present F4E-QA-113 specification are known, understood, and propagated to its personnel and to all the Subcontractors, when involved in PIC and PIA contracts, disregarding the level in the Supply Chain.

3.2 RESPONSIBILITIES OF THE EXTERNAL INTERVENERS

QA-113-GE-EI-01	The Supplier, and the Subcontractors, when involved in PIC and PIA Contracts, disregarding the level in the Supply Chain, shall be aware of the applicability of the French INB Order [7] to the ITER facility, and the associated F4E provisions stated in this F4E-QA-113 specification. [NOTE] The INB Order [7] is part of the French Regulatory Framework applicable to the ITER INB. As such, it applies to the ITER Organization being the Nuclear Operator, and to the External Interveners by consequence.
QA-113-GE-EI-02	The Supplier shall comply with the requirements contained in F4E-QA-113. The Supplier shall ensure that all its Subcontractors, when involved in PIC and PIA Contracts, disregarding the level in the Supply Chain, comply with all F4E-QA-113 requirements.
QA-113-GE-EI-03	The Supplier shall provide evidence of compliance with F4E-QA-113 requirements. The Supplier shall provide evidence that all its Subcontractors, disregarding the level in the Supply Chain, comply with F4E-QA-113 requirements.
QA-113-GE-EI-04	The Supplier shall demonstrate and evidence that the Nuclear Safety Defined Requirements associated to the PICs and PIAs concerned by the Contract have been fulfilled. The Supplier shall require all its Subcontractors, when involved in PIC and PIA Contracts, disregarding the level in the Supply Chain, to demonstrate and evidence that the Nuclear Safety Defined Requirements associated to the PICs and PIAs concerned by their Contracts have been fulfilled.
QA-113-GE-EI-05	The Supplier shall inform all employees working on PICs and PIAs that ITER is a nuclear facility (an "*INB*", for "*Installation Nucléaire de Base*" or, "*Basic nuclear installation*", in French regulation) and that ITER Organization (IO) is the Nuclear Operator of this INB. The Supplier shall ensure that employees of its Subcontractors working on PICs and PIAs are informed that ITER is a nuclear facility (an "*INB*", for "*Installation Nucléaire de Base*" or "*Basic nuclear installation*", in French regulation) and that ITER Organization (IO) is the Nuclear Operator of this INB.

QA-113-GE-EI-06	The Supplier involved in activities classified as PIA and/or in tasks concerning PIC with activities classified as PIA, shall have a certified Quality Management System following an international standard, e.g. ISO 9001, or equivalent internal Quality Management System. The Supplier shall require all its Subcontractors, disregarding the level in the Supply Chain, involved in activities classified as PIA and/or in tasks concerning PIC with activities classified as PIA, to have a certified Quality Management System recognized by an international standard, e.g. ISO 9001, or equivalent internal Quality Management System.
QA-113-GE-EI-07	The Supplier shall explain in its Project and Quality Management Plan the provisions taken to implement and ensure compliance with F4E-QA-113 requirements. The Supplier shall require to all its Subcontractors, disregarding the level in the Supply Chain to explain in their Project and Quality Management Plan the provisions taken to implement and ensure compliance with F4E-QA-113 requirements.
QA-113-GE-EI-08	The Supplier shall ensure that its Project and Quality Management Plan and all documentation applied in PIC and/or PIA Contracts are approved by F4E (without comment specifically identified as 'major') before implementing any activity. The Supplier shall require all its Subcontractors, disregarding the level in the Supply Chain to work with documents, including the Project and Quality Management Plan, approved by F4E (without comment specifically identified as 'major') before implementing any activity.
QA-113-GE-EI-09	For each Contract concerning PIC and/or activities classified as PIA, the Supplier shall nominate, and communicate in writing to F4E, a Suitably Qualified and Experienced Person(s) to manage the requirements for PIC and PIA undertaken by the Supplier.

4. GENERAL REQUIREMENTS

4.1 NUCLEAR SAFETY MANAGEMENT

QA-113-GR-MG-01	The Supplier shall develop a Nuclear Safety Management System which includes management practices and a work environment promoting on a long-term basis a nuclear safety culture including attitudes, behaviours and practices enabling: - the successful completion of PIAs, Technical Controls, verification and assessment tasks; - the development of the individual and collective competence; - a learning approach and a permanent questioning attitude contributing to the continuous improvement of the protection of the interests; - the reporting of any abnormal situation which could jeopardize the ITER protection of the interests mentioned under the article L. 593-1 of the Environmental Code [6].
QA-113-GR-MG-02	The requirements of the Nuclear Safety Management System implemented by the Supplier shall be based on an approach proportional to the importance of the risks and potential impacts associated to the PIA or PIC, and the potential consequences of the wrong performance of a PIA or the failure of a PIC.
QA-113-GR-MG-03	The Supplier shall adopt an approach promoting the detection and the treatment of the Deviations, and by collecting and analysing all the feedback available.
QA-113-GR-MG-04	The Supplier shall promote any action of F4E and IO for assessing its capability (or its Subcontractors') of applying the Policy in Nuclear Safety Management [1], for performing PIAs or supplying PICs, and for contributing to the improvement of the protection of the interests mentioned under the article L. 593-1 of the Environmental Code [6].

4.2 PIC AND PIA

QA-113-GR-PI-01	The Supplier shall acknowledge receipt in writing of the list of Protection Important Components (PICs) in the scope of the Contract.
QA-113-GR-PI-02	The Supplier shall acknowledge receipt in writing of the list of Protection Important Activities (PIAs) in the scope of the Contract.
QA-113-GR-PI-03	From the overall list of PIAs for ITER [14, 15, 16, 17], the list of PIAs for the scope of the Contract shall be reviewed and agreed during the official Kick-off Meeting.
QA-113-GR-PI-04	The Supplier shall know and understand the concerned PIC functions and PIAs, as well as their associated Nuclear Safety Defined Requirements, for the systems, subsystems and components, concerned by the Contract, and in the different phase(s) involved in the Contract, e.g. design, manufacturing, verification, assembly, testing, etc… The Supplier shall ensure that all its Subcontractors, when involved in PIC and PIA Contracts, disregarding the level in the Supply Chain, know and understand the concerned PIC functions and PIAs, as well as their associated Nuclear Safety Defined Requirements, for the systems, subsystems and components, in the scope of the Contract, and in the different phase(s) involved in their contracts, e.g. design, manufacturing, verification, assembly, testing, etc…
QA-113-GR-PI-05	The Supplier shall ensure the correct propagation of PIAs and the associated Nuclear Safety Defined Requirements along its own chain of Subcontractors with the appropriate level of detail and adapted to the scope of work of each Subcontractor.
QA-113-GR-PI-06	The Supplier shall submit for F4E-NSO and F4E-TPO approval (before the final concurrence of the IO Nuclear Operator representative), any proposal for breakdown of PICs, by systems and subsystems, at any level of the PBS. [NOTE] The list of PICs and their associated Nuclear Safety Defined Requirements, are under Nuclear Operator responsibility (as defined in article 2.5.1 of the INB Order [7]).
QA-113-GR-PI-07	The Supplier shall contact the F4E-NSO and request validation, regarding any doubt about the list of PICs, PIAs and/or Nuclear Safety Defined Requirements.
QA-113-GR-PI-08	Taking into account the overall list of PIAs for ITER [14, 15, 16, 17], the Supplier shall refine, and propose for F4E-NSO and F4E-TPO approval (before the final concurrence of the IO Nuclear Operator representative), the specific PIAs which are the most appropriate according to Supplier's processes (during design, manufacturing, testing, …). [NOTE] This list of PIAs and their associated Nuclear Safety Defined Requirements, are under Nuclear Operator responsibility (as defined in article 2.5.2 of the INB Order [7]).
QA-113-GR-PI-09	Each PIA shall be refined into sub-PIAs, if necessary for the implementation of the Contract.
QA-113-GR-PI-10	Any evolution/change of refined PIAs shall be submitted for F4E and IO approvals.
QA-113-GR-PI-11	The Supplier shall ensure that PIAs are limited to activities intended to demonstrate and verify compliance with Nuclear Safety Defined Requirements associated to a PIC and/or a PIA. During the design phase of a PIC, the Supplier shall limit the activities classified as PIA to the sub-part(s) of the PIC that directly contribute(s) to the Nuclear Safety Function.
QA-113-GR-PI-12	The Supplier shall keep up-to-date during the Contract implementation, the lists of: - PICs and associated Nuclear Safety Defined Requirements; - PIAs and associated Nuclear Safety Defined Requirements.

QA-113-GR-PI-13	For each PIA performed by the Supplier or its Subcontractor, disregarding the level in the Supply Chain, the Supplier shall ensure, provide evidence and trace that: - the PIA is performed in accordance with approved procedures and use all the required means to meet a priori the related Nuclear Safety Defined Requirements; - the PIA is checked a posteriori to confirm that its Nuclear Safety Defined Requirements are met.

4.3 TECHNICAL CONTROL

QA-113-GR-TC-01	Each PIA shall be subject to systematic Technical Control (possibly divided in task subgroups) to ensure that: - the PIA is actually carried out in compliance with the Nuclear Safety Defined Requirements; - the outcome of the PIA meets the performance expected; - appropriate corrective and preventive actions, if needed, have been defined and implemented.
QA-113-GR-TC-02	Before starting a PIA, the Supplier or Subcontractor shall: - define the Technical Control and its organization; - justify that the Technical Control is appropriate to the Nuclear Safety Defined Requirements to be controlled; - obtain F4E acceptance of the Technical Control organization and justification. [NOTE] The Technical Control is independent of the verification requested by ISO 9001 and of the Surveillance carried out by IO.
QA-113-GR-TC-03	Technical Control shall be carried out by qualified persons, other than those who have performed the related PIA.
QA-113-GR-TC-04	For each PIA performed by the Supplier or its Subcontractor, disregarding the level in the Supply Chain, the Supplier shall ensure that each Technical Control activity is documented to demonstrate a priori and verify a posteriori that the PIA complies with its Nuclear Safety Defined Requirements.
QA-113-GR-TC-05	The Supplier shall record the evidence of each Technical Control activity.
QA-113-GR-TC-06	The Supplier shall keep and provide to F4E, up-to-date records of the implemented PIAs, their Technical Control, related verification and assessment, and more generally any evidence to demonstrate compliance with the Nuclear Safety Defined Requirements.

4.4 MANUFACTURING AND INSPECTION CONTROL PLAN

QA-113-GR-CP-01	The Manufacturing and Inspection Control Plan, encompassing the main activities of the whole scope of the Contract shall detail all the PIAs and their Technical Control activities and explicitly state the related Nuclear Safety Defined Requirements.
QA-113-GR-CP-02	The Supplier and its Subcontractors, disregarding the level in the Supply Chain, shall establish their own MIP. Upon agreement of the F4E-NSO when concerning PIA or its Technical Control, an exception can be envisaged for ISO 17025 certified laboratories performing test activities and for Subcontractors performing NDT activities with a certification recognized by an international standard in the framework of the test activities to be carried out. When they do not have their own MIPs, each Subcontractor performing PIAs shall complete the Supplier's MIP.

QA-113-GR-CP-03	The MIP shall clearly identify: - the requirements originated from the development and validation strategy as defined in the technical specification (qualification and validation requirements, needs for mock-up or prototypes…); - all activities and tests to be performed in order to comply with the applicable legislation, standards or codes and requirements as specified in Annex B (Technical Specifications); - the different entities carrying out the actions of verifications; - the PIAs in agreement with the list of PIAs defined after review and acceptance; - the Nuclear Safety Defined Requirements (or their precise reference) associated to PIAs; - the Technical Control associated to each PIA; - the control points for the PIAs; - the Nuclear Safety Class of the concerned PIC.
QA-113-GR-CP-04	To identify an activity as PIA, the abbreviation 'PIA' shall be written in the MIP's 'PIA/TC' column.
QA-113-GR-CP-05	To identify an activity as Technical Control defined for a PIA, the abbreviation 'TC' shall be written in the MIP 'PIA/TC' column, otherwise the Technical Control shall be defined and written in the MIP's 'Observation' column.
QA-113-GR-CP-06	If the MIP contains different PIAs, the first PIA will be identified 'PIA-1 and its associated TC identified 'TC-1', the second PIA will be PIA-2 and its TC will be 'TC-2' and so forth.
QA-113-GR-CP-07	The Nuclear Safety Defined Requirements shall be identified in the 'NSDR' column of the MIP.
QA-113-GR-CP-08	The performer of PIAs shall date, name and sign in the MIP 'Performer' column. The performer of a Technical Control shall date, name and sign in the MIP 'Technical Control' column.
QA-113-GR-CP-09	When Subcontractors do not have their own MIP, Subcontractors' performers of PIAs and TCs shall sign, date and name (including affiliation) in the Supplier's MIP.
QA-113-GR-CP-10	The Supplier shall clearly indicate in the MIP all records and evidences of PIAs and their Technical Control, including Technical Control reports, inspection reports, verification check lists, etc...
QA-113-GR-CP-11	When concerning PIC or PIA, the Supplier shall notify the F4E-NSO about each forthcoming activity related to the control points related to PIC or PIA, 10 (ten) working days in advance, with updated information concerning: - the status of all the related NCs, - the availability of evidences of remedial actions performance.
QA-113-GR-CP-12	In case of any evolution/change of the list of PIAs is approved by F4E and IO, the Supplier shall revise the MIP(s) accordingly.

4.5 MONITORING, SUPERVISION, SURVEILLANCE

4.5.1 Monitoring and Supervision by the Contractor

QA-113-GR-SU-01	The Supplier shall perform Monitoring and Supervision of its own activities and of those of all its Subcontractors involved in PIAs (disregarding the level in the Supply Chain).
QA-113-GR-SU-02	The Supplier shall establish a supervision plan for its own Subcontractors. The supervision plan shall detail how, when and by whom the controls of Subcontractors is carried out. The frequency of the controls shall be higher for the Subcontractors performing PIAs.

QA-113-GR-SU-03	The supervision plan shall clearly state: - the PIAs and the related Subcontractors surveyed; - the nature of the controls; - the frequency of the controls; - the performer of the controls; - how controls are formalized; - any specific rules for management of the control records; - where records are maintained.
QA-113-GR-SU-04	The definition and the implementation of the controls shall be based on a proportionate approach taking into account: - the importance and complexity of the PIA and the products of this activity; - the risks and the potential impact assessment associated with the PIA and the products resulting from this activity; - the potential consequences of incorrect execution of the PIA or failure of a product resulting from this activity.
QA-113-GR-SU-05	The Subcontractors shall not start any PIA before the Contractor's supervision plan is approved by F4E.
QA-113-GR-SU-06	The ISO EN 17025 certified laboratories are exempt from Monitoring or Supervision.
QA-113-GR-SU-07	The Supplier shall inform the F4E NSO about any scheduled Supervision activity addressing nuclear safety.
QA-113-GR-SU-08	The Supplier shall ensure that monitoring and supervision activities are performed by Suitably Qualified and Experienced Personnel.
QA-113-GR-SU-09	The monitoring or supervision records shall contain, at least, the following information: - the nature of action(s) done, - the PIC(s) and PIA(s) concerned, - the date of the action(s), - the assessment of the action(s) done, - the name and the signature of the person(s) carrying out the monitoring or supervision actions.
QA-113-GR-SU-10	The Supplier shall submit an updated version of the supervision plan, including the reference to the monitoring records, together with the subsequent ADP or upon F4E request.
QA-113-GR-SU-11	The Supplier shall require to its Subcontractors, disregarding the level in the Supply Chain, to comply with the above requirements.

4.5.2 Supervision by F4E

In addition to the first level of Supervision performed by the F4E Project team on the activities of the Supplier (or its Subcontractor), a second level of Supervision is organized through the activities of the F4E Nuclear Safety team and the dedicated nuclear safety inspections, or other control activities performed by sampling.

QA-113-GR-SU-12	The Supplier shall be aware that F4E Nuclear Safety team can perform nuclear safety inspections on Contracts involving PICs and PIAs. The Supplier shall ensure that its Subcontractors, disregarding the level in the Supply Chain, are aware that F4E Nuclear Safety team can perform nuclear safety inspections on Contracts involving PICs and PIAs.
QA-113-GR-SU-13	The Supplier shall be aware that F4E, whenever considered as appropriate, will appoint a nuclear safety inspection team (inspectors) to certify that activities related to nuclear safety are carried out in accordance with the Contract, and with the regulations and all applicable codes and standards. Nuclear safety inspections also include the examination of all PIAs, Nuclear Safety Defined Requirements, NCRs and the follow-up and verification of all corrective actions which are to be implemented.

QA-113-GR-SU-14	The Supplier shall provide to F4E Nuclear Safety team representatives and inspectors copies of all relevant documentation and other information, they may consider necessary to verify that Nuclear Safety Defined requirements are being met.

4.5.3 Surveillance by IO

Two levels of Surveillance are defined:

1. by IO Project Team, through control activities on activities performed by the Contractor (and its Supply Chain, if any);
2. in addition, by IO Nuclear Safety Department through Surveillance of the External Interveners or dedicated nuclear safety inspections or other control activities.

QA-113-GR-SU-15	The Supplier shall grant IO representatives access to facilities, documentation and records, including those of Subcontractors, for the purpose of Surveillance during all execution phases of a Contract related to a PIC. This Surveillance includes the examination of all PIAs, NCRs and the follow-up and verification of all corrective actions to be implemented.
QA-113-GR-SU-16	The Supplier shall be aware that IO Nuclear Safety Department can implement, when required by IO, appropriate spot-checks of PIAs and Technical Controls. The Supplier shall ensure that its Subcontractors, disregarding the level in the Supply Chain, are aware that IO Nuclear Safety Department implement, when required by IO, appropriate spot-checks of PIAs and Technical Controls, and inform F4E about IO's requests.
QA-113-GR-SU-17	The Supplier shall grant access to premises, documentation and records, including those of its Subcontractors, during all execution phases of a Contract related to a PIC and a PIA, to IO Nuclear Safety Department representatives, for the purpose of Surveillance.
QA-113-GR-SU-18	The Supplier shall provide IO Nuclear Safety Department representatives with copies of all relevant documentation and other information or facilities as required to verify that Nuclear Safety Defined Requirements are met, and inform F4E accordingly.

4.6 ASN, ANB, THIRD-PARTY INSPECTIONS

QA-113-GR-TP-01	The Supplier shall grant to the French nuclear regulatory authority's representatives access to its facilities, documentation and records, including those of its Subcontractors, for the purpose of performing inspections in the framework of the regulatory Surveillance of the INBs during all execution phases of Contract related to a PIC and a PIA, and inform F4E accordingly. This Surveillance includes the examination of PIAs, NCRs and the follow-up and verification of corrective actions to be implemented.
QA-113-GR-TP-02	The Supplier shall provide French nuclear regulatory authority's representatives with copies of all relevant documentation and other information as required to verify that Nuclear Safety Defined requirements are met, and inform F4E accordingly.

4.7 STOP OF WORK

QA-113-GR-SW-01	The Supplier's 'Stop Work Authority' policy shall include that for stopped work associated with a PIA, notification to F4E shall be given within maximum 24h explaining reasons for work stop and proper criteria (and associated justification) for restarting the PIA.

QA-113-GR-SW-02	The Supplier shall immediately stop work related to a PIA in case F4E issues a Stop Work Order, requiring the Supplier or its Subcontractors to immediately suspend all operations related to the concerned PIC and/or PIA.

4.8 SUBCONTRACTOR MANAGEMENT

QA-113-GR-SM-01	For each Subcontractor to be involved in activities classified as PIA, the Supplier shall include a dedicated assessment of its capacity and experience in nuclear safety, in a Subcontractor acceptance report submitted to prior approval of F4E-NSO and F4E-TPO.
QA-113-GR-SM-02	The assessment of nuclear safety capacity and experience shall, at least, provide evidence of: - the recent experience in nuclear safety relevant to the subcontracted activities; - the skills and competences related to Nuclear Safety to be deployed for the Contract implementation.
QA-113-GR-SM-03	The Supplier shall submit for F4E acceptance a Supply Chain Acceptance Register, identifying all its Subcontractors involved in PIAs.
QA-113-GR-SM-04	When concerning a PIC or a PIA, the Supplier shall identify in the Supply Chain Acceptance Register the following information about the Supply Chain for the Contract: - all the Subcontractors performing PIAs; - all the Subcontractors performing Technical Control; with, at least, the information on: - the level of subcontracting of each Subcontractor; - the activities subcontracted; - the identity of the relevant Subcontractor, including the name of a contact person for nuclear safety matters (with contact information, e.g. phone number, email address, etc…); - the reference of applicable contractual documents between the Supplier and its Subcontractors containing Nuclear Safety Defined Requirements; - the reference of the Subcontractors' dedicated assessments of capacity and experience in nuclear safety, including the record of F4E approval. The Supplier shall request to F4E-NSO the formal authorization to waive the submission of the documentation concerning PIC or PIA .

4.9 DEVIATION MANAGEMENT

QA-113-GR-DM-01	The management of a Deviation affecting nuclear safety (a PIC or a PIA) is a PIA.
QA-113-GR-DM-02	When concerning PIC or PIA, the Supplier or its concerned Subcontractor shall issue an assessment of the potential impact on the concerned Nuclear Safety Defined Requirements. This assessment, containing all relevant data available to enable an informed decision, shall be submitted for F4E-NSO and F4E-TPO approval.
QA-113-GR-DM-03	When concerning PIC or PIA, the Supplier shall check that the justification and impact assessment on nuclear safety, submitted for the Deviation approval by F4E, are based on: - up-to-date and referenced data and documentation; - appropriate, explicit and proven methods, which integrate assumptions and rules adapted to the uncertainties and to the sphere of knowledge of the phenomena involved; - qualified calculation and modelling tools adapted to the specific areas of use.
QA-113-GR-DM-04	In case of Deviation having a potential impact on nuclear safety or Nuclear Safety Defined Requirements, the related work can start only when all the relevant working documentation is updated and validated by F4E.

4.10 NONCONFORMITY MANAGEMENT

QA-113-GR-NC-01	The management of a Nonconformity affecting nuclear safety (a PIC or a PIA) is a PIA.
QA-113-GR-NC-02	The Supplier shall implement in its Management System the criteria for the categorization of Nonconformity on PICs or PIAs and the associated actions. Such Nonconformities affecting nuclear safety (a PIC or a PIA) are by definition classified as 'Major Nonconformity'.
QA-113-GR-NC-03	In case of Nonconformity affecting a PIC or a PIA, the detection shall be immediately communicated in writing (within the same business day of detection), to F4E-NSO and F4E-TPO, and registered in the agreed record system.
QA-113-GR-NC-04	In case of Nonconformity affecting a PIC or a PIA, before the NCR submission to F4E, the Supplier's Nuclear Safety representative shall agree on the information to be included (evaluation, disposition and actions definition).
QA-113-GR-NC-05	In case of Nonconformity affecting a PIC or a PIA, the Supplier, or its Subcontractor if concerned, shall implement in its Management System, the requirements covering the following actions to be performed by Suitably Qualified and Experienced Personnel: - the opening and categorization of a NC; - the performance of root cause analysis of the NC; - the definition of the remedial, corrective and preventive actions; - the implementation of the defined actions; - the assessment of the effectiveness of the actions implemented; - the proper close-out of the NC.
QA-113-GR-NC-06	In case of Nonconformity affecting a PIC or a PIA, the Supplier shall put the F4E-NSO in copy of all the communication related to the Nonconformity.
QA-113-GR-NC-07	In case of major Nonconformity affecting a PIC or a PIA, the delay to implement the corrective actions proposed by the Supplier and validated by F4E-NSO shall not exceed 2 months. The Supplier cannot resume the work before implementing the corrective actions, unless authorized by F4E-NSO and F4E-TPO.
QA-113-GR-NC-08	For any Nonconformity affecting a PIC or a PIA, the Supplier shall provide for F4E-NSO and F4E-TPO acceptance, the impact assessment on the concerned NSDR.
QA-113-GR-NC-09	In case of Nonconformity affecting a PIC or a PIA, the Supplier shall propose a NCR for closure only when all the related actions (remedial and corrective, if applicable) are implemented and evidences have been provided and accepted by F4E-NSO and F4E-TPO.
QA-113-GR-NC-10	On a monthly basis, the Supplier shall provide to F4E-NSO, the follow-up status of Nonconformities concerning nuclear safety, the correctives actions and preventive actions scheduling, the resolutions and efficiency of such activities.
QA-113-GR-NC-11	The Supplier shall be aware and shall inform its Subcontractors, that all NCRs are reported by the Nuclear Operator to the French Nuclear Safety Authority.
QA-113-GR-NC-12	Any Nonconformity having severe potential nuclear safety implications can be identified and classified as "Significant Event" by IO. The Supplier shall be aware of the Nonconformity classification and shall provide skilled personnel able to immediately alert F4E in case of possible Significant Event, as soon as detected.

4.11 NON-CONFORMING, COUNTERFEIT, FRAUDULENT OR SUSPECT ITEMS (NCFSI)

It concerns all items potentially concerned by forgery, falsification, unauthorized, missing or hidden activities, … committed intentionally or not, concerning a PIC or a PIA (including the related Technical Control). Suspicion of fraud, falsification and forgery are classified as Significant Event.

QA-113-GR-FR-01	Any event or detection leading to the suspicion of a Non-conforming, Counterfeit, Fraudulent, or Suspect Items shall be declared, in a written form, immediately after detection to F4E (F4E Project Team and F4E Nuclear Safety team). It could be subject to a special declaration, as per special request of the French Nuclear Safety Authority and the article 2.7.2 of the INB Order [7].
QA-113-GR-FR-02	The event shall be documented and all relevant material, that may be useful to establish the circumstances and validation (or invalidation) of the NCFSI shall be provided to F4E.
QA-113-GR-FR-03	The Supplier shall provide a substantiated analysis to allow the most appropriate decision related to the issue, and if required (including by F4E, IO or ASN) to issue a Stop-Work Order, until the event is totally explained and documented, the root-cause and responsibilities established, and the implementation of the required (organizational and technical) corrective actions started. In case of non-stopping the work, the Supplier shall submit to F4E approval the justification, which shall include at least a documented root-cause analysis and the evidence of corrective actions implemented. [NOTE] If not issued by the Supplier, a Stop-Work Order can be conservatively issued by F4E, until the event is totally explained and documented, the root-cause and responsibilities established, and the implementation of the required (organizational and technical) corrective actions started. As the case may be, the duration of the suspension, the premises or workshops concerned, and the associated deadlines for the documentation to be provided will be defined by F4E. If the fraudulent intention is established, notwithstanding the concerned contractual provisions, the Stop Work Order may be permanent, and the advice of the French Nuclear Regulator may be sought.

4.12 LESSONS LEARNED

QA-113-GR-LL-01	When concerning PIC or PIA, in addition to individually managing each Nonconformity, the Supplier shall periodically review the Nonconformities in order to assess the cumulated effect of as-yet-uncorrected Nonconformities and to identify and analyse the recurrence propensity for similar types of Nonconformities. Preventive and corrective actions shall be identified and scheduled for implementation program.
QA-113-GR-LL-02	The Supplier shall put in place a system to ensure systematic collection, analysis and communication to F4E of all information that may improve the execution of PIAs.
QA-113-GR-LL-03	For analysis activities (including calculation and modelling) that are PIAs, any relevant operational feedback from other installations (nuclear or not) shall be taken into account, as well as any relevant information coming from the worldwide research and development programs.

4.13 PERSONNEL AND PROCESS QUALIFICATION

QA-113-GR-PQ-01	The Supplier shall ensure that all PIAs and their Technical Control, actions of verification and assessments related to nuclear safety, are carried out by Suitably Qualified and Experienced Persons, i.e. with mandatory skills and qualifications, as well as a sound and demonstrated experience in the field of activity to be performed.
QA-113-GR-PQ-02	The Supplier shall list (and provide upon request) all personnel for the intended field of work, when related to PIC, PIA, Technical Control or nuclear safety impact assessment, in a SQEP matrix.
QA-113-GR-PQ-03	When concerning a PIC, the nuclear safety representatives, from both supplying and receiving parties, shall participate Nonconformities Review Board (NRB) and Phase Gate Reviews (CDR, PDR, FDR, MRR, TRR and DRR, as per F4E-QA-115).
QA-113-GR-PQ-04	The Supplier or its concerned Subcontractor shall implement a training programme (or periodic training activities) related to nuclear safety, for its personnel dealing with PIA, in order to maintain the appropriate level of skills and qualification, and to develop them as necessary.

QA-113-GR-PQ-05	The laboratories providing measurements or data related to PIC or PIA, and intended for the Nuclear Safety Demonstration, shall be EN ISO 17025 certified (or equivalent, providing a reconciliation report).
QA-113-GR-PQ-06	When concerning a PIC, a PIA or a Technical Control, special process qualification records shall be submitted for F4E-NSO and F4E-TPO approval.

4.14 NUCLEAR SAFETY FILE

QA-113-GR-SF-02	The Supplier shall include the Nuclear Safety File in the Acceptance Data Packages of the Contract, or when required by F4E for a particular item delivery, submitted for F4E-NSO and F4E-TPO approval.
QA-113-GR-SF-01	The Supplier shall provide a Nuclear Safety File containing as a minimum: - the final PIC breakdown for the Contract; - the final revision of the Nuclear Safety Defined Requirements related to PIC for the Contract; - the final revision of the Verification Control Document (VCD) sorted by Nuclear Safety Defined Requirements for the Contract; - the final revision of the Requirements Propagation Matrix (RPM) sorted by on Nuclear Safety Defined Requirements for the Contract; - the list of PIAs and their defined Nuclear Safety Requirements for the Contract; - the final list of NCRs and Deviation Requests affecting PICs and PIAs and their Nuclear Safety Defined Requirements; - the final revision of the Supply Chain Acceptance Register showing all levels of the Contractor's Supply Chain, including evidence of qualification and F4E approval; - the final revision of the supervision plan for Subcontractors performing PIAs.
QA-113-GR-SF-03	The Supplier shall require from its Subcontractors, when performing PIA, disregarding the level in the Supply Chain, to issue their own Nuclear Safety File (or to provide the required identified information, clearly identified per Subcontractor, for completion of the Contractor's Nuclear Safety File).

5. PROPAGATION OF REQUIREMENTS

5.1 NUCLEAR SAFETY DEFINED REQUIREMENTS

QA-113-RQ-DR-01	The Supplier shall verify the correct propagation of the Nuclear Safety Defined Requirements associated to PICs and to PIAs at each level of its Supply Chain. If deemed necessary, the Supplier shall submit the list of all refined Nuclear Safety Defined Requirements, for F4E-NSO and F4E-TPO approval (before the final concurrence of the IO Nuclear Operator representative).
QA-113-RQ-DR-02	Where the responsibility for the PIC design lies with the Supplier, all documentation provided shall clearly identify the associated Nuclear Safety Defined Requirement and provide evidence that they are met.
QA-113-RQ-DR-03	Where the responsibility for the PIC manufacturing lies with the Supplier, all the technical specifications, technical procedures, instructions, … issued in the framework of the Contract shall identify the Nuclear Safety Defined Requirements: - whenever possible on drawings, e.g. in bold text and surrounded by a square; - by other means, clearly differentiating them from other requirements and identified in captions.

5.2 TOOLS FOR PROPAGATION OF NUCLEAR SAFETY DEFINED REQUIREMENTS

5.2.1 Verification Control Document (VCD)

QA-113-RQ-TO-01	The Supplier shall keep up-to-date the VCD with the latest version of Nuclear Safety Defined Requirements and associated Verification Activities and Technical Controls.
QA-113-RQ-TO-02	The Supplier shall record in the VCD the evidence that the verification activities required for the Nuclear Safety Defined Requirements are all completed (MIP, inspection reports, analysis and calculation reports, …). Unless agreed otherwise, the Supplier shall show the up-to-date VCD to F4E at the staged acceptance points (or agreed hold points).
QA-113-RQ-TO-03	The Supplier shall provide, whenever required by F4E, IO or ASN nuclear safety inspectors, any VCD under completion for inspection or review.
QA-113-RQ-TO-04	The Supplier shall include the completed VCD, approved by F4E, in the Nuclear Safety File.

5.2.2 Propagation of Nuclear Safety Defined Requirements

QA-113-RQ-TO-05	If the Contract includes design of PICs, the Supplier shall, at the different design phases, propose an updated version of the Nuclear Safety Defined Requirements, taking into account: - current version of the PBS, - technological choices made. [NOTE] If the Contract includes design (preliminary and/or final design) of PICs, the Supplier will receive the following documents: - the list of concerned PICs for the Contract; - the list of the associated Nuclear Safety Defined Requirements; [NOTE] If the Supplier subcontracts some contractual tasks to another qualified party, the abovementioned information shall be propagated to each Subcontractor, adapted to the scope of the subcontracted work.
QA-113-RQ-TO-06	If the Contract includes design of PICs, the Supplier shall, at the different design phases, submit to F4E approval the reporting documents of the verification activity associated to Nuclear Safety Defined Requirements. [NOTE] Every updated version of the Nuclear Safety Defined Requirements shall be validated by F4E (before the final concurrence of the IO Nuclear Operator representative).
QA-113-RQ-TO-07	The Requirements Propagation Matrix associated to a PIC shall provide evidence that related Nuclear Safety Defined Requirements are linked and satisfied by Nuclear Safety Defined Requirements of its sub-systems.
QA-113-RQ-TO-08	The Supplier shall alert F4E and IO when it identifies a missing Nuclear Safety Defined Requirement, at any level of the PBS. The Supplier shall identify the cause of a missing Nuclear Safety Defined Requirement, that can be identified as a result of: - propagation (a Nuclear Safety Defined Requirement identified at a level N has no parent at level N-1); - design studies for the operation of the PIC; - studies of interface with the process; - identification of new threat (for example, resulting from a Failure Mode and Effects and Criticality Analysis); - choice of a technology; … Upon F4E request, the Supplier shall raise a proposal to complete and/or detail the missing Nuclear Safety Defined Requirement, whilst ensuring the compliance with the existing requirements.

5.2.3 Transmission of Nuclear Safety Defined Requirements

QA-113-RQ-TO-09	For every PIA (and the corresponding Nuclear Safety Defined Requirement) to be transmitted to a Subcontractor, the Supplier shall record the evidence of F4E and IO approvals.
QA-113-RQ-TO-10	The Supplier shall transmit to all its concerned Subcontractors, the propagated PICs and PIAs, and their corresponding Nuclear Safety Defined Requirement(s), adapted ('refined') to their scope of work. The Supplier shall maintain the list of refined Nuclear Safety Defined Requirements updated and submit any revision to F4E for approval.

6. ANALYSIS AND CALCULATION REQUIREMENTS

The requirements mentioned in the following section only apply if the Supplier is involved in the performance of analysis and calculation activities related to PICs and PIAs.

QA-113-AC-GE-01	The Supplier shall ensure that analyses and calculations performed comply with the ITER Authorization basis, by ensuring compliance with the Nuclear Safety Defined Requirements and with the requirements stipulated in this document:
QA-113-AC-GE-02	The Supplier shall clearly identify in the analysis documentation: - the PICs and the associated Nuclear Safety Defined Requirement(s) concerned by the analysis and/or calculations; - the PIAs and the associated Nuclear Safety Defined Requirement(s) concerned by the analysis and/or calculations.
QA-113-AC-GE-03	The Supplier shall ensure compliance with the specification F4E-QA-114 when performing analysis and calculation classified as PIA.

6.1 VALIDATED INPUT DATA AND MODEL TRACEABILITY

QA-113-AC-VI-01	Prior to use, input data as well as their justification shall be formally transmitted in writing to F4E for approval. The use of these input data is only permitted after F4E approval. For traceability, these input data shall be clearly identified in the final analysis report.
QA-113-AC-VI-02	The Supplier shall clearly explain and justify the assumptions proposed for the analysis. These assumptions shall come from: - technical codes and standards selected for the SSC and their applicable domain; - best practice in the applicable domain; - research and development results in the applicable domain; - input data related to lessons learned in other facilities for the specific applicable domain, as specified in the article 2.7.2 of the INB Order [7].
QA-113-AC-VI-03	In some cases of use of calculation codes and standards, best practices or lessons learned may not be sufficient to define an assumption in the applicable domain. The Supplier shall carry out sensitivity studies, in order to assess the impact of the full range of assumptions on the results and whether a cliff-edge effect is possible. If these ranges remain unknown, then all non-arguable conservative assumptions shall be applied.

6.2 VALIDATED METHODS

QA-113-AC-VM-01	The Supplier shall use verified, validated and qualified calculation and modelling methods for the application fields in which they are used.

QA-113-AC-VM-02	The Supplier shall describe and obtain F4E approval, for the methodology used to: - review and list the input data, check referenced data used for calculations and modelling; - select and, if required, qualify calculation and modelling tools for the application fields used; - review and assess the results.
QA-113-AC-VM-03	The Supplier shall clearly express and justify: - calculation and modelling methods to be employed, - analysis methods, - acceptance criteria, - codes and standards, - verification and validation.
QA-113-AC-VM-04	The Supplier shall justify the selection of a calculation method for a specific application. This justification shall be submitted to F4E for approval. In particular, the justification shall demonstrate the selected method is totally adapted to the specific application, also considering possible errors and uncertainties associated to the predictive values of the outputs.
QA-113-AC-VM-05	The calculation methods shall be applicable for use in a nuclear environment and shall be chosen in consistency with the ITER Nuclear Safety Demonstration. For this reason, the Supplier shall notify F4E, in writing, prior to launch a calculation, in order to allow F4E to check that the method is compatible with the ITER Nuclear Safety Demonstration. These methods shall be recognized in the applicable domain used for the technical assessment or the performance of the calculations. State of the art shall be considered for the selected methods. The methods shall be compatible with a deterministic approach.
QA-113-AC-VM-06	The Supplier shall clearly mention the validation domain of the analysis method used giving the limits of applicability.
QA-113-AC-VM-07	In case of development of a specific calculation method, the Supplier shall establish and submit for F4E approval the set of verification activities to be conducted to demonstrate the applicability and the qualification of the tool.
QA-113-AC-VM-08	The uncertainties associated with the calculation methods shall be quantified and mentioned in the Final Analysis Report. When these uncertainties are not known, additional margins shall be added and substantiated by means of sensitivity studies.
QA-113-AC-VM-09	The Supplier shall propose and justify its acceptance criteria to be used for: - validating the methods, - qualifying the calculation and modelling tools, - assessing the results of the studies carried out.

6.3 VALIDATED CALCULATION CODES

QA-113-AC-VC-01	The Supplier shall establish a list of calculation codes that are applicable in the domain of technical interest and in the scope of the Contract. These calculation codes shall be recognized in the applicable domain used for the technical assessment or the performance of the calculations.
QA-113-AC-VC-02	Verification and validation processes are specific for the type of calculation (structural, electromagnetic, nuclear, etc.), model and calculation code used. Before requesting F4E acceptance, the Supplier shall inquire F4E for: - the applicable verification and/or validation procedure for the type of calculation, model and calculation code; - if the specific version of the model and calculation code has previously been verified and/or validated.

QA-113-AC-VC-03	The Supplier shall justify, before using any calculation code outside the list agreed by IO, why no code inside the IO list can be used instead. If using a calculation code outside the list agreed by IO, the Supplier shall justify that the result of the computation is properly verified and validated.
QA-113-AC-VC-04	The Supplier shall establish a justification of the calculation codes used for analyses with regards to their validation domain and uncertainties. When different from the ones prescribed by F4E and IO, this justification shall include the validation level against international benchmarks and experimental data, research and development, and validated correlations.
QA-113-AC-VC-05	The uncertainties associated with the calculation codes shall be quantified and reported in the analysis report. If uncertainties are not known, additional margins shall be added and substantiated by means of sensitivity studies.
QA-113-AC-VC-06	If the calculation code, software or data library is intended to be used in the ITER safety demonstration or for ITER Safety calculations, the Supplier shall inquire F4E for its approval before used. If needed, F4E will send to the Supplier the templates for verification, validation and qualification requested by the Nuclear Operator. Those templates shall be filled/completed by the Supplier.

6.4 TECHNICAL CONTROL FOR ANALYSIS AND CALCULATION

QA-113-AC-TC-01	The Supplier shall ensure that a Technical Control according to section 4.2 of this document is performed on each analysis classified as PIA
QA-113-AC-TC-02	The Technical Control for analysis and calculations shall contain the following: - check that the Nuclear Safety Defined Requirements are met; - check that the input data appropriately reflect the geometrical data and interfaces of the object under analysis; - check the basic approach, assumptions, subject-specific data (such as loads), and any equations or formulas applied are appropriate; - check that input data (*) are consistent with requirements or validated by referenced sources (**); - check the calculations are mathematically correct; - check the requirements and acceptance criteria are appropriate and used correctly; - check the conclusions reached are reasonable and consistent with the analysis or calculation approach, assumptions, input, and acceptance criteria; - check that the software is validated for the scope and purpose of the analysis. (*) If a calculation has numerous input and output values, the Technical Control performer can select a representative sample of the total input and output values, for review as appropriate. In this case, the values selected in the review documentation shall be justified. (**) All references cited have to be retrievable and applied correctly.
QA-113-AC-TC-03	If alternative calculations are used as a Technical Control method, the Supplier shall properly document the performed alternative calculation, the results comparison and shall archive the document and developed software and models.
QA-113-AC-TC-04	The Technical Control performer shall check and record that his/her comments on the analysis and calculation have been addressed

6.5 FINAL ANALYSIS REPORT

QA-113-AC-AR-01	The analysis report issued by the Supplier shall include: - subcontracted activities; - input data (referenced, justified, approved); - uncertainties in input data; - assumptions (justified and approved); - analysis methods used (justified and approved); - calculation codes used in the assessment/calculations including validation domain, limits and uncertainties; - acceptance criteria; - final results; - intermediate results, in case needed for final results.

7. REGULATORY COMPLIANCE UNDER ASN AUTHORITY

The ASN is the competent regulatory body also for conventional and non-nuclear equipment, installed in the INB.

7.1 PRESSURE EQUIPMENT

QA-113-RC-PE-01	According to the operator roles defined in the Pressure Equipment Directive [4], the Supplier shall comply with the requirements applicable to the concerned SSCs in the scope of the Contract.
QA-113-RC-PE-02	According to the operator roles defined in the Pressure Equipment Directive [4], the Supplier shall demonstrate that the SSCs in the scope of the Contract comply with the concerned requirements on Pressure Equipment Directive, according to their classification. When needed, the Supplier shall require its Subcontractors, disregarding the level in the Supply Chain, to demonstrate that the SSCs in the scope of the Contract comply with the requirements on Pressure Equipment Directive, according to their classification.
QA-113-RC-PE-03	For the SSCs within the scope of Pressure Equipment Directive, and according to their classification, the conformity with the Essential Safety Requirements (ESR) shall be demonstrated by the manufacturer. When required, the Notified Body in charge of the conformity assessment shall be involved throughout the life of the Contract.
QA-113-RC-PE-04	For Pressure Equipment of categories II, III and IV, the welding process shall be qualified by a Notified Body.
QA-113-RC-PE-05	For Pressure Equipment of categories II, III and IV, the welder qualification shall be qualified by a Notified Body.
QA-113-RC-PE-06	For Pressure Equipment of categories III and IV, the personnel performing Non Destructive Tests shall be qualified by a Notified Body.
QA-113-RC-PE-07	The Supplier shall inform F4E as soon as possible in case of inappropriateness or evolution of the classification of the Pressure Equipment in its scope of work.

7.2 NUCLEAR PRESSURE EQUIPMENT

QA-113-RC-NP-01	According to the operator roles defined in the Order of the 30th of December 2015 modified related to Nuclear Pressure Equipment [5], the Supplier shall comply and demonstrate the compliance of the SSCs in the scope of the Contract with the concerned requirements of the Nuclear Pressure Equipment Order. When needed, the Supplier shall require to its Subcontractors, disregarding the level in the Supply Chain, to comply and demonstrate the compliance of the concerned SSCs in the scope of the Contract with the requirements of the Order of the 30th of December 2015 modified related to Nuclear Pressure Equipment [5].
QA-113-RC-NP-02	For the SSCs within the scope of Nuclear Pressure Equipment, conformity with the Essential Safety Requirements (ESR) included in regulations shall be demonstrated by the manufacturer. The Agreed Notified Body in charge of the conformity assessment shall be involved throughout the life of the Contract.
QA-113-RC-NP-03	For Nuclear Pressure Equipment, the welding process shall be qualified by an Agreed Notified Body.
QA-113-RC-NP-04	For Nuclear Pressure Equipment, the welder qualification shall be qualified by an Agreed Notified Body.
QA-113-RC-NP-05	For Nuclear Pressure Equipment, the personnel performing Non Destructive Tests shall be qualified by an Agreed Notified Body.
QA-113-RC-NP-06	The Supplier shall inform F4E as soon as possible in case it detects incoherence in the classification of the Nuclear Pressure Equipment in their scope of work.

7.3 CE MARKING

QA-113-RC-CE-01	The Supplier shall ensure compliance with the CE marking requirements stipulated in the F4E-QA-135 [3]. The Supplier shall require its Subcontractors, disregarding the level in the Supply Chain, to comply with the CE marking requirements stipulated in the F4E-QA-135 [3].