FUSION FOR ENERGY

idm@F4E UID / VERSION
22JRQY / 1.2

VERSION CREATED ON / STATUS
10 July 2015 / Obsolete

EXTERNAL REFERENCE

Quality Document

F4E-QA-113 - Supplier Nuclear Safety Management Requirements

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

Approval Process			
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	Locke D.	**22 May 2015:recommended v1.1**	**ITERD**
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Read Access	**LG: F4E_QAO, AD: IDM_Users, GG: IAS Audit on Document Management, project administrator, RO, LG: F4E Safety, LG: EC UL_NIER Technical Support , LG: EC UL_Extended Design Team, AD: IDM_F4E, AD: IDM IE-PE-00-00 Antennas and Plasma Engineering, GG: IAC, LG: EC UL_Legal & Procurement, LG: EC UL_Quality ...**		

Original Document MD5#: 18BE6B8A368A59F47615EBFEFCC022A9

Change Log			
F4E-QA-113 - Supplier Nuclear Safety Management Requirements (22JRQY)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v0.0	In Work	21 July 2014	
v1.0	Approved	21 July 2014	First Issue
v1.1	Signed	21 May 2015	Small update to align with the issue of QA-019 and QA-119.
v1.2	Approved	10 July 2015	Removed the use of NSCR, FMEA and IO-CT added it in the definition table Replaced ITER by IO-CT in 28.

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SPECIFICATION

Control Page

idm@F4E ref:	F4E_D_22JRQY	Date:	20 May 2015

Document title:	**Propagation of Generic Safety Requirements in the F4E Supply Chain (F4E-QA-113)**

Areas and functions	
Document Ownership:	F4E Director
Area(s) concerned:	F4E Manual (Operational)
Function(s) concerned:	Project Teams, Quality Officers, Nuclear Safety Officers
Level	[X] Corporate [ ] Department [ ] Unit

Purpose

This document describes the specific obligations of F4E suppliers who have design responsibility for PIC. It details the content of the Nuclear Safety File to be rendered at completion of the contract by F4E Suppliers. It should be read in conjunction with F4E-QA-115 [R3] and F4E-QA-119 [R7].

Scope

This document applies to Suppliers with F4E contracts which have the design of Protection Important Components within their scope of works.

Table of Contents

Reference documents

(external links)

[R1] French Order of 7 February 2012 - *République Française - Arrêté du 7 février 2012 fixant les règles générales relatives aux installations nucléaires de base*. ASN INB Order page

[R2] Decree No. 2012-1248 dated 9 November 2012 authorising ITER International Organization to create a basic nuclear facility called « ITER » "ITER DAC"

[R3] F4E-QA-115 – 'Supplier Quality Requirements' F4E_D_22F8BJ

[R4] PIA Guideline F4E_D_27WDLC

[R5] F4E-QA-119 - Requirements Management & Verification (RMV) Requirements for F4E Suppliers (242DG5)

[R6] Guidance for Protection Important Design by Analysis Activities (F4E-QA-114) (22FR5T)

Definitions

Term	Definition	Acronym
ASN	Autoritéé Sureté Nucléaire – French Nuclear Safety Authority	ASN
Basic Nuclear Facility *(Installation Nucléaire de Base)*	Nuclear facility which is licensed by the French nuclear safety authority.	INB
Chain of suppliers	Chain of *external interveners* to the ITER Project starting with F4E and including all the different levels	Supply Chain
Defined Requirement (Safety) (*exigence définie*)	(as defined in the French INB Order [R1]) *Requirement assigned to a protection-important component so that it may perform the function, with the characteristics expected, provided for in the Nuclear Safety demonstration, or assigned to a protection-important activity so that it may fulfil its objectives as regards this demonstration.*	SDR
External Intervener	(as defined in the French INB Order [R1]) *natural or legal person other than the licensee and its employees, performing operations or supplying goods or services:* *- which participate in an activity or an element important for protection;* *- or which participate in an action linked to such an activity and provided for in the present order,* *this particularly concerns the service providers and subcontractors, experimenters and users.* Note – This term covers the role of all the actors in the F4E Supply chain	--
FMEA	Failure Mode and Effect Analysis	FMEA
Generic Safety Requirements	Generic term for all the requirements of the INB Order	--
IO-CT	ITER Organisation – Common Team	IO-CT
ITER Project	The project to build (under the ITER DAC [R2]), operate and decommission the ITER INB.	ITER
Nuclear Operator	The organisation that holds the licences to construct and operate the nuclear facility.	
Nuclear Safety Demonstration (*démonstration de sûreté nucléaire*)	(as defined in the French INB Order [R1]) *All the content of the ITER safety files, in particular the preliminary safety report, in the impact study, and participating in the demonstration, which justify that the risks of radiological or non-radiological accident, the intensity of their consequences and the means to recover are, given the state of environmental knowledge, practices and vulnerability, as low as possible under economically acceptable conditions.* The Nuclear Safety Demonstration is confirmed by the ITER DAC [R2].	NSD
Preliminary Safety Analysis Report *(Rapport Préliminaire de Sûreté)*	Nuclear Safety Report for the ITER Facility which is submitted to the French Regulator for approval. This report provides part of the Nuclear Safety Demonstration for ITER.	RPrS

Term	Definition	Acronym
Protection Important Activity *(activité importante pour la protection)*	(as defined in the French INB Order [R1]) *Activity important for protection of the interests mentioned in L. 593-1 of the environment code (public safety, health and welfare, protection of nature and of the environment), i.e. activities participating in the technical or organisational provisions mentioned in the second paragraph of article L. 593-7 of the environment code, or that could affect them.* The PIAs include the Quality Related Activities defined in the previous Quality Order (10 August 1984).	PIA
Protection Important Component *(élément important pour la protection)*	(as defined in the French INB Order [R1]) *Component important for the protection of the interests mentioned in article L. 593-1 of the environment code (public safety, health and welfare, protection of nature and of the environment), i.e. structure, equipment, system (programmed or not), hardware, component or software present in a basic nuclear installation or placed under the responsibility of the operator, fulfilling a function necessary for the demonstration mentioned in the second paragraph of article L. 593-7 of the environment code, or checking that this function is ensured.* The PIC components are the previous SIC Nuclear Components of the Quality Order of 1984 with addition Components important for Environment and Crisis Management PIC = SIC + EIC + CMC SIC = Safety Important Component (PIC-S) EIC = Environmental Important Components CMC = Crisis Management Components	PIC
Quality Control Plan	A control plan is a quality document to list all the processes within part of a project and indicate the level of control or acceptance required to sign off each item of the list. For F4E projects the control plan also indicates which of the detailed activities are PIA.	CP
Safety Important Class	The Safety Important Class component is a subset of the PIC and is a component important for protecting people and environment from radioactive hazards. The SIC are defined by the nuclear operator in two sub Classes: SIC1 - a structure, systems or component required to bring and to maintain ITER in a safe state. SIC2 – a structure, system or components used to prevent, detect or mitigate incidents or accidents.	SIC SIC-1 SIC-2
Structure System or Component	A structure, a system or a component of ITER that performs a safety function and contributes to meeting the Safety Objectives at ITER during incident / accident situations.	SSC
Suitably Qualified and Experienced Person	A person who has the relevant education standard, the professional qualifications and the experience of using these in the industry for a suitable period to demonstrate competence in the job role.	SQEP
Verification Compliance Document	The report which details all project requirements but in particular each Defined Requirement (Safety) relating to a PIC component or sub-system and the related verification activities and their evidence references which demonstrate that the safety functions required of the PIC have been met at that stage of the supply process. The term *Quality Compliance Record* is also used for the VCD document in contracts managed by F4E at Cadarache	VCD
Verification Activity *(Activité de Vérification)*	Activities which demonstrate the Defined Requirements (Safety) for PIC or PIA. For Protection Important Components these may be comprised of technical controls such as an inspection (INB Order art. 2.5.4), a test (INB Order art. 2.4.3) or a design document (including calculation documents) which demonstrate all or a portion of a Defined Requirement (Safety).	VA

1. Background and Terminology

1. The radiological and environmental safety impact of basic nuclear facilities in France is minimised and ensured under the INB Order [R1]. The ITER Project nuclear operator (ITER Organisation) has demonstrated that the design of the ITER facility will meet French nuclear safety requirements in performing a preliminary nuclear safety demonstration to the French Nuclear Safety Regulator (ASN). As a result the ITER facility has been created and licensed for construction under the *DAC decree* [R2].
2. The Operator has performed a nuclear safety demonstration to analyse the hazards foreseen to be present throughout the life of the facility. It includes the means to prevent or mitigate those hazards through the identification of requirements known as Defined Requirements (Safety).
3. Systems or equipment which have specific nuclear or environmental safety functions to meet the Defined Requirements (Safety) are called Protection Important Components (PIC).
4. The processes to design, construct, deliver, test, commission, operate, maintain, dismantle PIC are known as Protection Important Activities (PIA).
5. The standards and codes employed to control production of PIA to meet their design requirements are also called Defined Requirements (Safety).
6. F4E is one of the seven parties of the ITER Project, and is responsible for providing Europe's contribution to ITER.
7. The whole group of Suppliers and subcontractors under a contract to F4E is called the Supply Chain.
8. All F4E documents which have been issued since 01 July 2013 are using the terminology in the INB Order [R1]. However there are F4E contracts which were signed before the INB Order came into force and which use the previous terminology. It is proposed not to update the terminology in those documents (but the INB Order still applies).
9. The nuclear operator, in compliance with the INB Order, has issued:
    - A guideline for *Management of propagation of nuclear safety requirements in the supplier chain* defining the requirements to propagate the safety requirements
    - An *Overall supervision plan to supplier chain for Protection Important Components, Structures and Systems and Protection Important Activities*

    F4E ensures consistency with the propagation implied in these two documents through the requirements integrated in the current specification (QA-113), the F4E Supplier Quality Requirements [R3] (QA-115) and a F4E Supervision Plan for the contract.
10. All F4E documents relating to the nuclear operator arrangements/agreements which have been issued since 01 July 2013 are using the terminology in the INB Order. The relationship between the new and previously used terminology is shown in the next table (table 1.1).
11. F4E documents for the Requirements Management and Verification F4E-QA-119 [R5] uses a different terminology for some terms. The key equivalents are demonstrated in the second table on the next page (table 1.2).

Old Terminology(French) Quality Order 10.Aug.1984	New Terminology INB Order 07.Feb.2012	Comment
Qualité Définie (art 1)	*Exigence Définie* SDR (Articles 1.3 & 2.5.2)	Safety Requirement
Exigence Définie (art 6)	*Exigence Définie* SDR (Articles 1.3 & 2.5.2)	Specific values or attributes of the Safety Requirement
Quality Related Activity QRA (art 7) called SRA in earlier F4E documents	Protection Important Activity PIA (Article 2.5.2)	Activities which could change the performance of Protection Important Components
Actions de Vérification (art 10)	*Actions de vérifications et d'évaluation* (Articles 2.5.5, 2.5.6)	The means to provide evidence that the Defined Requirement has been achieved (for each of the relevant PIA)
Safety Important Component - SIC (Defined by the nuclear operator not the Order)	Protection Important Component PIC-S which are to be known as SIC within ITER project as defined by the nuclear operator, not as defined by the Order	PIC are made up of items which have implications for; - Safety (PIC-S) - Environmental (PIC-E) - Conventional Security (PIC-EPE) - Disadvantages (PIC-D) - Emergency Management (PIC-EM)

Table 1.1 - Relationship between the new and previously used terminology

Terminology INB Order 07.Feb.2012	Terminology in F4E-QA-119	Comment
Exigence Définie SDR (Articles 1.3 & 2.5.1)	Defined Requirement	Safety Requirement as included in the generic description within DOORS
Actions de vérifications - VA	Verification Effort - VE and the element representing this in the DOORS database is a Verification Item - VI	The means to provide evidence that the Defined Requirement has been achieved
Structure System or Component (SSC)	Product	
Design Phase	Qualification phase	
Manufacturing Phase	Acceptance Phase	
Installation Phase	Installation	Includes transport and temporary storage
Construction Phase	Construction	
Test & Commissioning Phase	Commissioning	
Operations & Maintenance Phase	-	
Disposal & Decommissioning	*Disposal & Decommissioning*	

Notes - terminology for Requirements Management used by IO does not always match to that of F4E

Table 1.2 - Key equivalents between INB Order and DOORS F4E terminology

2. Propagation of the Nuclear Safety Requirements along the F4E Supply Chain

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

Requirement to Propagate	INB Order art.	Propagation by F4E
Supply Chain and Surveillance of Suppliers Carrying Out PIA	2.2.1 to 2.2.4, 2.5.4	F4E requirements on Suppliers for the propagation of safety requirements throughout the Supply Chain are divided between this document F4E-QA-113 for requirements relating to the management of the SDR for PIC and QA-115 [R3] for the management of PIA and QA functions and F4E-QA-119 [R5] for the procedures to report Defined Requirements (Safety) in the F4E database [R5]. The F4E Surveillance of the F4E Supply Chain is in the F4E Supervision Plan, the requirements for Suppliers to perform supervision activities of subcontractors are within QA-115 [R3]
Propagation, Recording and Reporting of SDR and PIC	2.5.1	The requirements for Suppliers to receive, manage and update the Defined Requirements (Safety) relating to PIC and the references to their Verification Activities and evidence records is contained at sections 3 and 4 of this document and the project requirements verification controls are at [R5]. It specifies the reporting of Nuclear Safety Verification Activities in the Verification Compliance Document Record (also called Nuclear Safety Control Plan in contracts originating from F4E Barcelona before 2015 and called the Quality Compliance Record for all contracts originating from F4E Cadarache) and the Nuclear Safety File to be rendered by the Supplier.
Identification and Reporting of PIA	2.5.2, 2.5.3, 2.5.6	The F4E requirements for the propagation of PIA are stated within QA-115 [R3]. It includes the safety requirements to: - Produce a Record list of PIA - Identify the codes and standards to which the PIA are being performed, which are known as Defined Requirements (Safety) when they apply to PIA. - Keep the evidence records of all PIA, index them and hand them up the Supply chain - keeping a full set of copies in a secure store for a further period defined by the Operator. The F4E PIA Guideline [R4] assists in the identification of the activities which can be PIA and also together with an explanation of the rationale for the selection.
Management of the Qualifications and Experience of Personnel	2.5.5	Each Supplier is required to have in place a system to manage the qualification and experience of personnel. The requirements are stated within QA-115 [R3]
Management of Validation and Verification and Use of Different Staff	2.5.5 and 2.5.3	The management of requirements, including safety requirements, is contained in F4E-QA-119 - Requirements Management & Verification (RMV) Requirements for F4E Supplier [R5]. The management of Validation and Verification are stated within QA-115 [R3].The requirements to use different SQEP staff for the verification and validation to those performing the work are within QA-115 [R3]
Identification and Management of Deviations and Nonconformities	2.6.1 to 2.6.5	The management of Deviations and Non Conformities are stated within QA-115 [R3]
Reporting back to the INB Operator the Information Required for the Operating Licence Application PIA	2.5.5, 2.5.7	The requirement for a dossier called *Nuclear Safety File* and its contents are specified in this document at Section 4. This is not the same dossier as the one required to be prepared by the operator. However the information within it will contribute directly to the preparation of the operator dossier.
Design methods, tools and their validation	3.8	The requirements for design of PIC carried out by F4E or its supply chain are contained in F4E-QA-114 [R6]

3. Nuclear Safety Requirements to be Propagated for PIC and their SDR

3.1. GENERAL

13. This section specifies the propagation of the Defined Requirements (Safety) for the design of Protection Important Components.

<# QA113-REQ-0001

14. Each Supplier with a scope of work which includes design (preliminary and/or final design) of PIC will receive and shall ensure the availability of the following documents;

    i. the list of the propagated Defined Requirements for the contract scope (normally from Annex B) referencing the nuclear operator's document that contains the Defined Requirements (Safety).

    ii. a list of PIC for the contract, referring to the specific Defined Requirements (Safety) document issued by the nuclear operator.

    iii. a record to indicate how the Defined Requirements (Safety) are demonstrated in the relevant project phases. When initially completed by the Supplier it will show how and in which documents the designer intends to demonstrate that the Defined Requirements (Safety) will be verified throughout all relevant phases of Supply.

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15. Each Defined Requirement (Safety) in the VCD, introduces a requirement for the PIC to which it relates and the required Verification Activities to demonstrate that the SDR are completed.

<# QA113-REQ-0002

16. The Supplier shall produce the evidence of the Verification Activities that demonstrate the aspects of the PIC performance which are demonstrated at each main phase of the supply process.

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<# QA113-REQ-0003

17. The Supplier shall record in the VCD the Verification Activities with the document references of the evidence and submit it to F4E, for approval.

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<# QA113-REQ-0004

18. When the initial VCD containing the proposed Verification Activities is approved it will be returned to the Supplier. The Supplier shall then add the reference of the verification evidence document(s) to demonstrate that each Verification Activity (VA) is completed. The Supplier shall record these in the VCD for presentation to F4E, unless specifically agreed otherwise, at the Final Design Review or previous suitable hold point.

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<# QA113-REQ-0005

19. During the contract, the Supplier shall provide the VCD (Defined Requirements (Safety)) for inspection and review whenever required (by F4E, the nuclear operator or the ASN) until all specified activities have been completed and recorded in it.

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<# QA113-REQ-0006

20. When the VCD is complete with the references of the evidence records, the VCD will be submitted to F4E for approval as part of the Safety File at the completion of the contract. On approval it will be stored within the Nuclear Safety File which will be stored within the Quality Files of the contract.

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<# QA113-REQ-0007

21. The Supplier shall ensure that suitably qualified and experienced personal are nominated, as required by QA-115, that will specifically manage the Defined Requirements (Safety) for PIC (and PIA) undertaken by the Supplier and its supply chain.

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<# QA113-REQ-0008

22. The Supplier shall ensure that all personnel working on these components, including all relevant personnel in the Supply Chain, will be made aware that the components are PIC, the processes which can influence their performance are PIA and that they are for supply to the *project ITER (INB-174), located at Cadarache, France.*

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<# QA113-REQ-0009

23. The Supplier shall ensure that the requirements in this document are cascaded to its subcontractors where their scope of work includes design activity of a PIC component or system (as defined in the contract's Annex B Compliance Matrix).

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3.2. SPECIFIC DESIGN ACTIVITIES REQUIRED FOR PIC

<# QA113-REQ-0010

24. During the design phase, the Supplier shall perform design studies using the guidance in F4E_QA_114 [R6], in particular FMEA (Failure Mode and Effects Analysis) or other similar recognised failure mode identification technique for the PIC. The aim of the FMEA is to demonstrate that there are no unforeseen failure modes within the design of the PIC.

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<# QA113-REQ-0011

25. Design studies, including FMEA must be performed by SQEP personnel.

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<# QA113-REQ-0012

26. If any new, possible, Defined Requirements (Safety) are identified from the design studies for the operation of the PIC or its interface with the process, then, the Supplier shall raise a proposal to design out the foreseen hazard, using the Deviation Request to F4E under the requirements QA-115 [R3].

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27. In this way, potential hidden failure modes will be identified and designed out.

28. If the Deviation Request is approved, the Defined Requirements (Safety) document will be updated by IO-CT and the Verification Control Document by F4E.

<# QA113-REQ-0013

29. F4E will update the VCD with specific Verification Activities for the new Defined Requirement (Safety) which the Supplier shall then update as already required above.

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4. Contract End - Nuclear Safety Requirements Propagation Evidence Records

30. This section defines the requirements for the evidence reports and records that all the Generic Safety Requirements propagated in the Supply Chain have been met.

<# QA113-REQ-0014

31. At the end of the Contract the Supplier shall raise a dossier which records the evidence documents of all the activities defined in the previous sections. This dossier containing the Nuclear Safety Reports for that contract shall be named as the “Nuclear Safety File for the Contract F4E-XXX-NNNN”.

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<# QA113-REQ-0015

32. The “Nuclear Safety File for the Contract F4E-XXX-NNNN” must contain as a minimum:

i. Final PIC breakdown for the contract.

ii. The final revision of the Defined Requirements (Safety) for the Contract PIC.

iii. The final version of the Nuclear Safety filter of the Verification Control Document.

iv. The final version of the Compliance Matrix for the Contract.

v. List of PIA for the contract (or a cross reference to all the relevant Supplier Quality Control Plans within the contract QA Records).

vi. Final list of NCR and DR affecting PIC and PIA.

vii. Final list of the Subcontractor Schedule showing all levels of the Supply Chain.

viii. Subcontractor’s supervision plan for the contract at the final version.

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- End of the Document -