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**F4E Document**

**P-01.25 Nuclear Safety Management**

This document defines the principles and the rules in F4E to guide the compliance with the requirements of the French regulation related to Nuclear Safety, in particular but not exclusively the INB Order.

It clarifies the concept of Nuclear Safety and the cascaded chain of role and responsibilities from IO to F4E and F4E suppliers.

It insists on the priority to be given to Nuclear Safety compliance, and the continuous implementation of the appropriate Nuclear Safety culture.

N.B. The F4E POLICY ON NUCLEAR SAFETY MANAGEMENT must be issued with its annex, below in IDM attachment).

<i>Approval Process</i>			
	<i>Name</i>	<i>Action</i>	<i>Affiliation</i>
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*Change Log*

**P-01.25 Nuclear Safety Management (26C3GS)**

<i>Version</i>	<i>Latest Status</i>	<i>Issue Date</i>	<i>Description of Change</i>
v1.0	In Work	05 December 2016	
v1.1	Approved	05 December 2016	(minor typo corrected in § Scope, F4E IDM réf. for IO Policy)
v1.2	Signed	09 September 2020	Document updated as per new F4E organizational changes (NSU changes) and comments implemented after internal review.
v1.3	Signed	06 October 2020	Correction of typos, Slight change on the definition of PIA (mention of the interests to be protected instead of referring to the French Environment Code and mention o examples of PIA).
v1.4	Approved	06 October 2020	Incorporates all comments from reviewers



## POLICY

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Document title: Nuclear Safety Management (P-01.25)

### Areas and functions

Version Responsible:	A. Fontaine (NSO)
Document Owner:	Nuclear Safety Unit (Acting HoU)
Process Group and Context:	Corporate Planning Financial Controlling & Reporting/ Nuclear Safety Management
Function(s) concerned:	All operational roles

### Purpose

This document 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 [3] and following IO's Provisions for Implementation of the Generic Safety Requirements by the External Actors/ Interveners [4].

It clarifies the concept of Nuclear Safety and the cascaded chain of roles and responsibilities from IO to F4E and from F4E to F4E suppliers.

It insists on the priority to be given to Nuclear Safety compliance, to Nuclear Safety Culture and to defined requirements, and the continuous implementation of the appropriate Nuclear Safety culture.

### Scope

This policy applies to all design and manufacturing actions, which include Protection Important Components and Protection Important Activities, as defined in the INB Order [3].

This policy applies solely to the activities undertaken for the INB 174 – ITER.

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### Reference documents

- [1] [ITER Policy on Safety, Security and Environment Protection Management \(ITER\\_D\\_43UJN7\)](#)
- [2] [Décret n° 2012-1248 du 9 novembre 2012 autorisant l'Organisation internationale ITER à créer une installation nucléaire de base dénommée « ITER » sur la commune de Saint-Paul-lez-Durance \(Bouches-du-Rhône\)](#)
- [3] [French INB Order of 7 February 2012](#)
- [4] [Provisions for Implementation of the Generic Safety Requirements by the External Actors/ Interveners \(ITER\\_D\\_SBSTBM\)](#)

Terms and Definitions		Refer to F4E <a href="#">Acronyms, Glossary</a> and <a href="#">F4E Roles</a> in the Manual for more information
<b>CFSI</b>	Counterfeit, Fraudulent and Suspect Items, CFSI	<p>(Introduced as S/CI by the International Atomic Energy Agency in the publication IAEA-TECDOC-1169 of August 2000, and referred into the present document as CFSI)</p> <p>Related to either items that may not conform to established industry-accepted specifications upon visual inspection or testing, or a copy or substitute without legal right or authority to do so, or items that are intentionally misrepresented with intent to deceive.</p>
<b>INB</b>	Nuclear Basic Installation	<p>(Installation Nucleaire de base, as defined by the article L593-2 of the French Environment Code)</p> <p>Fixed nuclear installation (not limited to reactors), exceeding isotopes activities thresholds provided by the French Environment Code and, as such, that can be only authorised via Decree and after approval by the French Nuclear Authority and public enquiry ; and for which, phases from conception to dismantling are regulated.</p>
<b>NSDR</b>	Nuclear Safety Defined Requirement	<p>(Exigence définie, as defined in the French INB Order [3])</p> <p>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</p>
<b>PIA</b>	Protection Important Activity	<p>(activité importante pour la protection, as defined in the French INB Order [3])</p> <p>Activity important for protection of public safety, health and welfare, nature and the environment, e.g. activities found at each phase of the lifecycle of a PIC (from design to dismantling), activities related to a safety function or activities that may impact the results of safety analysis.</p>
<b>PIC</b>	Protection Important Component	<p>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.</p>
<b>SQEP</b>	Suitably Qualified & Experienced Personnel	<p>Professionally qualified person, with several years of demonstrated experience in their area of expertise, and whose career path is documented enough to satisfy external regulatory authorities that appropriate personnel are in place along the supply chain to undertake critical responsibilities.</p>

## Nuclear Safety Management (P-01.25)

- (a) It is the policy of the ITER Organization (IO), as nuclear Operator, to perform its mission observing the applicable national laws and regulations of the Host State (France) in the fields of public and occupational health & safety, nuclear safety, radiation protection, licensing, nuclear substances, environmental protection and protection from acts of malevolence.
- (b) For that purpose, IO has issued the '[ITER Policy on Safety, Security and Environment Protection Management \(ITER D 43UJN7\)](#) [1], displaying its commitment to endorse and propagate the dispositions related to Nuclear Safety.
- (c) Derived from IO's first priority as declared by ITER Organization in [1], F4E first priority, above the progress in research or procurement activities related to the ITER construction, is to contribute to the "protection of the interests <sup>1</sup>" in terms of Nuclear Safety, Security and Environment Protection, by providing to IO sound and reliable evidences of the compliance of the activities performed and the components delivered.

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<sup>1</sup> The interests to be protected mentioned in the French Environmental Code Article L-593-1 are security, public health, and the protection of nature and the environment.

## 1. Definition and Roles

- (a) Nuclear Safety is the discipline to predict and control hazards against the public and the environment, in and around a nuclear facility, in order to predict, prevent and control any harmful effect. It comprises the set of all technical and organisational dispositions taken to achieve the objectives, and the corresponding demonstration and evidences.
- (b) Nuclear Safety implies commitment to the following topics:
- (i) The definition of the nuclear safety requirements and the identification of the Regulation obligations. This includes the correct propagation (and the evidence of such propagation) down the supply chain. This relies on sound and appropriate Quality Assurance systems at the different levels of the supply chain, and also involves extensive Quality Supplier Audits to check that the correctness of the procedures applied by the suppliers.
  - (ii) The nuclear safety demonstration. This comprises all the analyses performed and all the dispositions taken, during design, construction or operation, in order to demonstrate that the technical requirements or the organisational dispositions, and their evolutions, are and remain fully compliant and coherent with the Nuclear Safety dossier that has been or will be presented by the Nuclear Operator (IO) to the French Regulator (ASN).
  - (iii) The demonstrated controls along the design and construction, at all the levels of the supply chain. This relies on sound and appropriate Quality Control activities, to verify that the intermediate products under construction are respecting the expected performance. This also involves Quality Control inspections in workshops, possibly including material analyses or dimensional surveys. And conducting a series of Nuclear Safety Inspections to verify that the supplier is correctly interpreting and applying the various requirements placed upon it via the contract and associated applicable documents, in a coordinated manner with the Quality Assurance Unit audits.
- (c) In the Host State (France), a large set of “Nuclear Laws, Decrees and Orders” (hereafter designated as *Nuclear Regulations*) defines the legal obligations and liabilities of the Nuclear Operator that are then propagated to its Supply chain. The French “INB Order” of 7 February 2012 [3] is one of them.
- (d) Additionally, the ITER facility having been declared as the INB 174 [2], the French legislation states that all elements, even not radioactive, that could impact the health & safety of workers or public are then also submitted to examination (in terms of compliance with the related regulations) and authority of the ASN.
- (e) The ASN (*Autorité de Sûreté Nucléaire*) performs, on behalf of the French State, all the controls related to nuclear safety and radioprotection in France to protect the workers, the public or the environment against the risks related to nuclear activities or within nuclear facilities. The ASN is an independent regulatory governmental agency, entitled in its extended field of competencies, to examine authorization applications, deliver authorizations, inspect correctness of activities and information provided, and pronounce binding decisions.
- (f) The ITER Organization is the entity called Nuclear Operator who will operate the INB 174 as declared in [2], and who has submitted the application for the authorization of creation.
- (g) Following the French INB Order definition, F4E is an *external intervener* (or a tier-1 supplier in the IO supply chain) to the Nuclear Operator and has the duty to evidence the correct implementation and the control through F4E own supply chain of all the requirements from the *Nuclear Regulations* and from the IO.

- (h) The Nuclear Safety Defined Requirements, as defined by the INB Order, are placed by the Nuclear Operator, and assigned to each Protection Important Component (PIC) or Activity (PIA).
- (i) Nuclear Safety wise, the responsibility of F4E is to duly propagate (and propose refinement when needed) the Nuclear Safety Defined Requirements, to demonstrate that the procured systems will fulfil the expected performance, therefore the safety functions as defined in the Nuclear Safety Demonstration, and to guarantee the soundness and the reliability of all the information and evidences provided by F4E for Nuclear Safety Files.

## 2. Strategic Activities

Based on the requirements of the relevant articles of the INB Order and the appropriate nuclear regulations, and in order to achieve its duty, F4E shall carry out three strategic activities.

### 2.1 Ensure that the First Priority is given to Nuclear Safety by:

- (a) Dedication and commitment from management and every actor and staff;
- (b) Implementing and maintaining a corporate “Nuclear Safety Culture”, focussing on the specificities of nuclear facility construction project under French Nuclear Regulation, through periodic awareness trainings for all F4E staff members, recording of deviations and communication of lessons learned;
- (c) Identifying and qualifying F4E staff members performing Protection Important Activities;
- (d) Encouraging responsible, transparent, open and participative behaviours on nuclear safety, security and quality;
- (e) Implementing a robust supervision of Protection Important Activities, through a reliable control, independent and complementary to the one performed by the project teams and their suppliers.

### 2.2 Ensure that the Nuclear Safety Defined Requirements fulfil the Nuclear Safety Functions, with the Expected Performance by:

#### (a) Nuclear Safety Defined Requirements collection:

- (i) Ensuring that IO Nuclear Safety Defined Requirements are incorporated, when required in the PA or ITA, normally in the Contract Technical Specifications;
- (ii) Making sure that all defined requirements and guidelines for defining PIAs are available within F4E;
- (iii) Using Requirements Management and Verification methodology and/or appropriate tools to identify and monitor the Nuclear Safety Defined Requirements;

#### (b) Propagation:

- (i) When F4E is required to perform or to complete the design, control that the Nuclear Safety Defined Requirements and the corresponding regulations are dutifully applied in all F4E activities, adequately incorporated in the Supplier’s contracts, transmitted, understood and properly respected along the F4E supply chain, until the end of the procurement process;
- (ii) Checking that all PIAs are correctly identified, followed, reported for all F4E project units, and that correct evidence are gathered along all the products or projects phases;
- (iii) Issuing a set of appropriate processes and detailed procedures, completed by contractual dispositions when needed, to ensure the correct propagation and recording of Nuclear

Safety Defined Requirements and regulatory obligations by Suitably Qualified & Experienced Personnel (SQEP) staff;

(c) Demonstration and Records:

- (i) Conducting independent supervision activities to ensure that PIAs are being identified, performed and reported correctly by SQEP staff;
- (ii) Producing definitive and reliable records for the demonstration of requirement achievement during design, production, and delivery phases;
- (iii) Ensuring that nonconformities and process deficiencies are reported and resolved through approved dispositions and follow-up actions, to confirm acceptable results;
- (iv) Implementing and performing calculations and proven analysis methods supporting or justifying the design, based on qualified calculation and modelling tools adapted to the specific areas of use;
- (v) Contributing to Nuclear Safety Demonstration through specific analyses at component level (Defence in depth, FMEA, accidental initiating events identification, ...), when needed;

(d) Reporting to IO:

Defining and checking of the content, in terms of completion, correctness and reliability, of all the information provided by F4E or F4E suppliers for the Nuclear Safety Files or contained in the final data packages to be issued to IO.

**2.3 Implement the F4E Policy on Nuclear Safety Management and apply it to All F4E and F4E Suppliers by:**

- (a) Circulating this policy among the staff of F4E, the external contractors working for F4E, and all F4E suppliers delivering PIC or PIA;
- (b) Prioritizing nuclear safety through Supplier's adherence to written procedures that implement this policy through their respective Quality Assurance Plans;
- (c) Writing, revising and/or streamlining any time needed, the F4E QA and QC instructions concerning the propagation, the verification and the record of Nuclear Safety Defined Requirements, including the lessons learnt, in a traceable and compliant way;
- (d) Ensuring with all concerned F4E staff that fulfilling this policy by knowing and implementing the applicable plans and procedures, including awareness of changes, is their mandatory duty.
- (e) Sensitizing and enabling F4E staff and contractors to raise an alert when detecting any item, behaviour or activity that could be a threat to Nuclear Safety, such as CFSI, or wishful misconduct.