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Provisions for Implementation of the Generic Safety Requirements by the External Actors/Interveners

In application of the article 2.2.1 of the INB Order, this document defines generic safety requirements to be implemented by all external actors in order to satisfy the requirements of the INB Order.
It is applicable to all external actors of the ITER project.

Approval Process			
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Change Log			
Provisions for Implementation of the Generic Safety Requirements by the External Actors/Interveners (SBSTBM)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	Approved	20 Nov 2015	
v1.1	Approved	10 Feb 2016	Slight reformulations on requirements , , and .
v2.0	Signed	15 May 2019	as per approved MQP doc Request - XKQ2A2, this document is updated to introduce elements related to Counterfeit, Fraudulent and Suspect Items (CFSI)
v2.1	Signed	03 Jul 2019	Updated according to reviewers comments.
v2.2	Approved	15 Jul 2019	Following reviewer's comment : modifications in order to keep " external actors/interveners"
v2.3	Approved	06 Nov 2024	- add safety requirement for CFSI management

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1 Purpose

As required by the INB Order [1], and notably its article 2.2.1, the nuclear operator (the ITER Organization, IO) must notify the of the necessary provisions for application of the INB Order.

The purpose of this document is to define the generic safety requirements to be implemented by the in order to satisfy the requirements of the INB Order.

2 Scope

This document applies to all of the ITER project. This includes every level in the chain of contractors: supplier, contractors, sub-contractor, sub-sub-contractor and so on.

This document is an applicable document to be included in the contracts to the (i.e. in the contracts involving Protection Important Components (PIC) and/or Protection Important Activities (PIA)), including Procurement Arrangements (PA).

3 References

[1] Order of 7 February 2012 *setting the general rules relative to basic nuclear installations*, called "INB Order" (7M2YKF)

[2] Propagation of the defined requirements for protection important components through the chain of external contractors (BG2GYB)

[3] List of ITER-INB Protections Important Activities (PSTTZL)

[4] Generic requirements for the competences and qualification of external interveners (SBT3UA)

[5] RPrS – Preliminary Safety report (French version) (35T7KK)

[6] Decree No. 2012-1248 dated 9 November *2012 authorizing IO to create a basic nuclear facility called "ITER"* (CZK7M5)

[7] ITER Policy on Safety Security and Environment Protection Management (43UJN7)

[8] Requirements for Producing an Inspection Plan (ITER_D_22MDZD)

[9] Procedure for management of Nonconformities (22F53X)

[10] Procedure for the management of Deviation Request (2LZJHB)

[11] Definition and classification of a significant event (JHBY7G)

[12] Management of Counterfeit, Fraudulent or Suspect Items (CFSI) (A52J3Z)

4 Definitions and acronyms

The definitions and acronyms used in this document are those of Nuclear safety common definitions (RLZXMV).

5 Safety requirements

In **every contract involving PIA and PIC**, disregarding the level in the supply chain of the , the following safety requirements must be clearly stated.

They also may be introduced in the contracts simply by introducing the following sentence:

<R1> **The supplier must comply with the all requirements expressed in "Provisions for implementation of the generic safety requirements by the external actors/interveners"** (SBSTBM)

Alternative, more detailed or more specific formulations may be acceptable provided they comply with the minimum requirements. They shall be subject to IO Technical Responsible Officer (TRO) acceptance in advance of their intended use.

<R2> **For each requirement, the external actors/intervenersmust explain in its quality system the dispositions taken to implement the requirements stipulated in this document**

5.1 Propagation of global safety information in the supply chain

<R3> **All must be informed that ITER is a nuclear facility (an "INB", for *Installation nucléaire de base*, "Basic nuclear installation" in French regulation) identified in France by the number "INB no. 174".**

In application of the ITER agreement, article 14, ITER follows the French Regulation for Nuclear safety. Because of its inventory in nuclear materials, ITER has been classified in France as a nuclear facility "*Installation Nucléaire de Base*" and in particular numbered as INB no.174 per the French Decree No. 2012-1248 dated 9 November 2012 authorizing IO to create a basic nuclear facility called "ITER" (ITER_D_CZK7M5) and the associated ASN Decision 2013-DC-0379 dated 12 November 2013 establishing the prescriptions applicable to ITER Organization for the design and construction of the licensed nuclear facility INB No. 174 called ITER (ITER_D_MU6PP3).

ITER Organization (IO) is the nuclear operator of this INB.

5.2 Propagation of specific safety requirement in the supply chain

<R4> In every contract involving PIA and PIC, disregarding the level in the supply chain of the contracting parties, it must be clearly stated that defined requirements on PIC and PIA have to be fulfilled.

For PIC and their defined requirement, the procedure [2] applies.

For PIA and their defined requirement, the document [3] applies.

Each is responsible for the transmission of the defined requirements for PIC and PIA's to its chain of contractors.

<R5> The must explain in its quality system:

- what are the dispositions taken to implement the requirement <R4>;
- what are the verifications made to check the appropriate propagation of the defined requirement;
- what are the records used to document this verification.

5.3 Policy on Protection of the interests mentioned under article L-593-1 of the Environmental Code. (articles 2.3.1 & 2.3.2)

<R6> The ITER Policy on Safety Security and Environment Protection Management (ITER_D_43UJN7) [7] must be circulated, known, understood and applied by all staff of the and cascaded down in the managerial lines of the and of contractors and sub-contractors.

5.4 Quality Management System (article 2.4.1)

<R7> The must be aware of the ITER dispositions for application of the INB Order [1], which are implemented:

- through the IO Integrated Management system "MQP" for the organizational and managerial matters;
- through the configuration management system for the technical matters.

The list of IO applicable documents for the contracts is provided in a specific annex of each contract and PA.

a. On this basis, the external actor must implement its own quality assurance program (QAP) and must demonstrate that it is compliant with the IO quality management requirements, in particular for the application of INB Order [1].
b. The external actor's QAP is submitted for approval/acceptance to IO before initiating any activity related to this contract.
c. For each step of this contract, external actor must provide the corresponding Quality Plans.

5.5 Supervision

5.5.1 IO supervision and right to access the premises of the external actors

In application of the article 2.2.2 and 2.5.4 of the INB Order [1], IO implements a surveillance of the external actors that perform Protection Important Activities and/or Protection Important Systems, Structures and Components.

IO will therefore establish a supervision plan for the external actor activities.

The following text must be indicated in the contracts and PAs:

<R8> The external actor must grant access rights to the IO and French nuclear regulatory authorities representatives to its facilities and records **and those of its suppliers and subcontractors** for the purposes of surveillance of defined requirements during the design, construction/manufacturing, commission, assembly, maintenance and surveillance of a PIC. This surveillance also includes the examination of all PIA and the follow-up and verification of all corrective actions which are to be implemented.

N.B.: This notification is not covered by the use of any specific code and standard or standard Quality Assurance Program. This text has to be specifically included for informing the external contractors that during the execution of their contract, they are subject to the Nuclear Operator (ITER Organization) surveillance.

5.5.2 External actor/intervener's supervision

<R9>	The external actor must establish a supervision plan for its own external actors.

<R10>	The external actors must establish and/or must request to its contractors to establish their inspection plans following IO procedure Requirements for Producing an Inspection Plan (ITER_D_22MDZD) [8]. – Activities classified as PIA's must be clearly identified in the corresponding inspection plan templates and in agreement with IO PIA definitions after IO review and approval/acceptance. – The type of the intervention points on the PIA's are marked up after approval/acceptance by IO and are properly tracked after the execution of the required technical controls.

5.6 Execution of the PIA

<R11>	For each PIA performed by the external actor or one of its sub-contractor (disregarding the level in the supply chain), the external actor must ensure that: – The PIA is performed in accordance with procedure and using means for meeting *a priori* the related defined requirement. – The PIA is traced to check *a posteriori* whether the defined requirement were met.

5.7 Technical control (article 2.5.3)

<R12>	For each PIA performed by the external actor, the external actor must performs also a technical control to ensure that: – The PIA is carried out in compliance with the appropriate defined requirements. – The appropriate corrective and preventive actions have been defined and implemented.

<R13>	The external actor must put in place an organization to guaranty that the persons carrying out the technical control for PIA's are distinct from the individuals who have accomplished the activities.

N.B.: It may be a different employee of the same company.

The person carrying out the technical control of a PIA must have the appropriate skills and qualifications (see <R15>).

This technical control must also (see <R16>):

– Be documented to demonstrate a priori it complies with the above conditions.
– Be formalized to demonstrate it has been properly implemented.

<R14>	For each PIA performed by a sub-contractor of the external actor (disregarding the level in the supply chain), the external actor must ensure that the sub-contractor make analog provisions.

5.8 Skills and qualification of the actors/interveners (article 2.5.5)

<R15>	The external actor must ensure that the PIA and their technical controls are carried out by persons with the appropriate competences and qualifications. For that purpose, the external actor must notably apply the procedure [4]. The external actor must ensure that its sub-contractors (disregarding the level in the supply chain) make analog provisions. The external actor must explain in its quality system the dispositions taken to implement this requirement.

5.9 Records (article 2.5.6)

<R16>	The external actor must ensure that each PIA and the related technical controls: – Are documented to demonstrate *a priori* that they comply with the defined requirements, – Are traced to check *a posteriori* that they comply with the defined requirements, This applies to every PIA and technical controls performed by the first external contractor in the contractual chain or any one of its sub-contractor (disregarding the level in the supply chain).

<R17>	The external actor must keep updated records of the results of implemented PIA and their technical control, the related action of verification and the assessment when requested by IO and must provide them to IO per the specific IO procedures for documentation management. The external actor records must be easily accessible and legible by IO, protected, kept under appropriate conditions and archived for an appropriate and justified period of time.

5.10 Non-conformities (article 2.6.1)

The actions of raising, remediation, correction, and management of the non-conformities (NC), since its initiation until its close-out, are Protection Important Activities. They are therefore subject to every requirement on PIA in the present chapter.

The criteria for raising a non-conformity involving a Protection Important Activity and/or a Protection Important Component are defined in the IO procedure Procedure for management of Nonconformities (22F53X) [9].

<R18>	The external actor must implement the same criteria in its Quality Assurance System for categorization and remedial actions. In particular the detection of NC must be immediately communicated to IO and registered in the record system of the external actor and of IO (per section 5.9 “Records”).

<R19> The external actor must implement a management system in accordance with the requirement <R18> above, allowing in a short delay (less than one month):

- the opening and categorization of a NC;
- the performance of root cause analysis of the NC;
- the establishment of the remedial, preventive (PA) and corrective actions (CA);
- the follow-up of the evolution of the NC, PA and CA;
- the proper close-out of the NC.

<R20> The external actor must be in charge of the management of its NCR, including the tentative deadlines for the closure of the NC.

If the deadline for NC management cannot be respected, the external actor must communicate to IO the cause for this delay (managerial, technical, human reasons) and searches for solutions, in agreement with the importance of the discrepancy.

<R21> Before releasing any control milestones such as Hold Points or Notification Points in the inspection plan's, or any milestones indicated in the contract and Procurement Arrangement as Contractors Release Notes, each external actor must check that:

- all NC's have been resolved;
- objective evidences of remedial actions performance are available;
- all NC's are properly close-out.

<R22> Each external actor must:

- raise preventive and correctives actions when required, and scheduled them within an implementation program, following IO procedures.
- tracked their evolution until they are closed-out.

<R23> Each external actor must require its contractors to apply the above management of NC's, PA's and CA's.

5.11 Significant non-conformity (articles 2.6.4 and 2.6.5)

Any non-conformities having severe safety implications can be identified and classified as "significant" by IO, following the IO procedure Definition and classification of a significant event (JHBY7G) [11].

<R24> The external actor, aware of this classification, must provide skilled personnel able to immediately alert IO in case of possible significant event, as soon as detected.

The significant non-conformity is to be managed in a first step as an NC (see section 5.10) and then in IO system for its communication by IO to ASN and to other authorities if required by the regulation.

5.12 Lessons learned and continuous improvement

<R25> In addition to individually managing each one of its discrepancy, the external actor must periodically review the discrepancies in order to assess the cumulated effect of as-yet-uncorrected discrepancies and to identify and analyze the recurrence propensity for similar types of discrepancies.

If need be, any preventives and correctives actions must be identified and scheduled within an implementation program.

<R26> The external actor must systematically collect, analyze and communicate to IO the information that is likely to help IO improving the PIA activities.

<R27> On a monthly basis, the external actor must provide follow-up status of non-conformities, correctives actions and preventive actions scheduling, resolutions and efficiency of such activities.

5.13 Safety demonstration (article 3.8)

The **Authorization Basis** defines the ITER reference baseline and safety basis authorized by the regulator which includes:

- The regulation to be applied in France for Nuclear Facilities, "*Installation Nucléaire de Base*" such as ITER.
- And the ITER Regulatory Files, including:
  - Licensing files specified in the Act 13th June 2006 and French Decree No. 2007-1557 in particular Articles 8 and 20 as well as the files required by the Code of Environment related to Basic Nuclear Installations. This includes the 14 files of the request for Authorization for Creation (DAC) and notably Preliminary Safety Report (RPrS) [5] and Impact Study.
  - Safety files required during the licensing process by the Safety Authorities as demonstrations and justifications of the required complements of information as safety analysis, code calculations, hazard controls, etc.

The Authorization Basis is given by Authorized Operating Domain in the RPrS [5] and confirmed by DAC decree [6], associated technical prescriptions, ASN decisions, recommendations and requirements provided in the ASN inspection letters.

All the requirements foreseen to guarantee the "Authorization Basis" are provided by the ITER reference baseline.

5.13.1 Studies and Calculations for safety demonstration

<R28> Any safety demonstration must be in compliance with the Authorization basis.

<R29> For detailed design or construction studies and calculation related to complementary safety demonstration, the external actor must provide results based on a solid safety demonstration as per article 3.8 of the INB Order [1] and the instructions provided by IO for its application.

5.13.2 Deviation of safety requirements

During the design, construction, commissioning, and operation phases, any deviation from those requirements will lead to a Deviation Request following the IO procedures.

<R30>	For any deviation, the external actor must raise a deviation request under the IO Procedure for the management of Deviation Request (2LZJHB).

<R31>	The external actor must require its contractors to raise a Deviation Request as soon as detected.

<R32>	The external actor and its contractors must provide together the deviation request evidences of compliance with the authorization basis. The external actor must check that the provided evidences are based on a solid safety demonstration as per article 3.8 of the INB Order [1] and the instructions provided by IO for its application.

5.14 Prevention, detection and treatment of Counterfeit, Fraudulent and Suspect Items (CFSI)

Counterfeit, Fraudulent and Suspect Items considerably jeopardize the Nuclear Safety.

The external actors/interveners shall take provisions to prevent, detect and treat Counterfeit, Fraudulent and Suspect Items (CFSI).

In particular, the external actors/interveners shall prevent the occurrence of CFSI by, among other provisions, sensitizing the persons involved in the execution of PIAs and the supply of PICs for the ITER project.

CFSI can be detected during the course of the work by any person. A specific attention to potential CFSI shall be taken by the persons in charge of the Technical Check, of the Surveillance and more globally of any supervision activity.

Unscheduled inspections, independent analysis of samples, verification of certificates etc. are adequate means to detect CFSI.

Any person who detects a CFSI shall immediately report to his / her line manager. ITER Organization has to be informed immediately as well, through usual channels (in particular through DAs when applicable). It is possible to report CFSI to ITER Organization anonymously in the case the person considers that disclosing this information could expose him / her to consequences. In that case, a letter can be sent to the Director General of ITER Organization at the following address with the mention “ITER CONFIDENTIAL”:

ITER Organization, Building 72
Route de Vinon-sur-Verdon - CS 90 046
13067 St Paul Lez Durance Cedex – France

This possibility of reporting CFSI to the ITER Organization should be communicated to the collaborators of the external actors, as necessary.

The French Regulator, ASN, has set up means so that any person detecting potential or recognized CFSI can inform the ASN. The external actors should inform their collaborators of the existence of this system.

The ASN website link is the following: https://www.asn.fr/Informer/Actualites/L-ASN-cree-un-nouveau-portail-de-signalement-pour-les-lanceurs-d-alerte]

<R33>	CFSI cases shall be managed according to the ITER procedure Management of Counterfeit, Fraudulent or Suspect Items (CFSI) (A52J3Z) [12].

The CFSI shall be addressed in the Lessons Learned, see Section 5.12.