

## List

# Provisions for implementation of the generic safety requirements by the external 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 interveners in order to satisfy the requirements of the INB Order. It is applicable to all external interveners of the ITER project.

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## 1 Purpose

As required by the INB Order [1], and notably its article 2.2.1, the nuclear operator (IO) must notify the external interveners 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 external interveners in order to satisfy the requirements of the INB Order.

## 2 Scope

This document applies to all external intervener 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 external interveners (i.e. in the contracts involving PIC and/or PIA).

## 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 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](#))

## 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 external interveners, 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 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 TRO acceptance in advance of their intended use.

<R2> **For each requirement, the external intervener must 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 external interveners 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 external intervener is responsible for the transmission of the defined requirements for PIC and PIA’s to its chain of contractors.

<R5> The external intervener 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 \(ITER\\_D\\_43UJN7\)](#) must be circulated, known, understood and applied by all staff of the external intervener and cascaded down in the managerial lines of the external intervener and of contractors and sub-contractors.

### 5.4 Quality Management System (article 2.4.1)

<R7> The external intervener must be aware of the ITER dispositions for application of the INB Order, 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.

- a. On this basis, the external intervener 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.
- b. The external intervener’s QAP is submitted for approval to IO before initiating any activity related to this contract.
- c. For each step of this contract, external intervener must provide the corresponding Quality Plans.

## 5.5 Supervision

### 5.5.1 *IO supervision and right to access the premises of the external interveners*

In application of the article 2.2.2 and 2.5.4 of the INB Order, IO implements a surveillance of the external interveners that perform Protection Important Activities (PIA) and/or Protection Important Systems, Structures and Components (PIC).

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

The following text must be indicated in the contracts:

<R8> The external intervener 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 intervener's supervision

<R9> The external intervener must establish a supervision plan for its own external interveners.

<R10> The external interveners must establish and/or must request to its contractors to establish their manufacturing inspection plans (MIP) following IO procedure [Requirements for Producing a Manufacturing and Inspection Plan \(ITER\\_D\\_22MDZD\)](#).

- Activities classified as PIA's must be clearly identified in the corresponding MIP templates and in agreement with IO PIA definitions after IO review and acceptance.
- The type of the intervention points on the PIA's are marked up after 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 intervener or one of its sub-contractor (disregarding the level in the supply chain), the external intervener 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 intervener, the external intervener 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 intervener 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 intervener (disregarding the level in the supply chain), the external intervener must ensure that the sub-contractor make analog provisions.

## 5.8 Skills and qualification of the interveners (article 2.5.5)

<R15> The external intervener 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 intervener must notably apply the procedure [3].  
The external intervener must ensure that its sub-contractors (disregarding the level in the supply chain) make analog provisions.  
The external intervener must explain in its quality system the dispositions taken to implement this requirement.

## 5.9 Records (article 2.5.6)

<R16> The external intervener 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 intervener 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 intervener 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 NC (article 2.6.1)

The actions of raising, remediation, correction, and management of the non-conformities, 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 (PIA) and/or a Protection Important Component (PIC) are defined in the IO procedure [Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities \(22F53X\)](#).



- <R18> The external intervener 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 intervener and of IO (per section 5.9 “Records”).
- <R19> The external intervener 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 intervener 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 intervener 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 MIP’s, or any milestones indicated in the contract as release notes, each external intervener 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 intervener 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 intervener must require its contractors to apply the above management of NC’s, PS’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 \(JHBY7G\)](#).

- <R24> The external intervener, 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 intervener must periodically reviews 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 intervener 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 intervener 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) 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 intervener must provide results based on a solid safety demonstration as per article 3.8 of the INB order 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 intervener must raise a deviation request under the IO procedure conditions.

<R31> The external intervener must require its contractors to raise a deviation request as soon as detected.

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