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MQP Procedure

Propagation of the Defined Requirements for Protection Important Components Through the Chain of External Interveners

The purpose of this procedure is to establish the process of propagation of the nuclear defined requirements for Protection Important Components through the chain of external interveners and its final review and approval by ITER Organization in order to ensure that they have been cascaded down and refined in compliance with the Order of 7 February 2012.

Approval Process			
	Name	*Action*	*Affiliation*
Author	**Rodriguez Rodrigo L.**	**09 Mar 2017:signed**	**IO/DG/RCO/SD/EPNS/SCS**
Co-Authors			
Reviewers	**Chiocchio S.** **Elbez-Uzan J.** **Onozuka M.**	**16 Mar 2017:recommended** **09 Mar 2017:recommended** **16 Mar 2017:recommended**	**IO/DG/COO/CIO/CMD** **IO/DG/RCO/SD/EPNS** **IO/DG/COO/CIO**
Approver	**Bigot B.**	**25 Mar 2017:approved**	**IO/DG**
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Change Log			
Propagation of the Defined Requirements for Protection Important Components Through the Chain of External Interveners (BG2GYB)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v1.0	Approved	02 Oct 2012	
v1.1	In Work	08 Feb 2013	Changes in this version: 1. Page 3 definition added Applicable document A document issued by IO as nuclear operator containing requirements which compliance with must be demonstrated at each indicated INB lifecycle described into the document. 2. Page 3 reference added [1] Order of 10 August 1984 on Quality for Basic Nuclear Installations EN (ITER_D_ 27AGR5 v1.0) to be replaced from the 1st of July 2013 by title I and II of the Order 7th February 2012. 3. Page 4 section 6.1 text added: The preliminary list of safety requirements for a SIC component for IO and the DA is provided at step 2 and 3. This list is as exhaustive as possible at this stage. A more detailed list of sub-systems, components and sub-components which are SIC will be established when detailing more in depth the design. 4. Page 5 section 6.1 text added: The DA may ask support of IO for establishing the exhaustive list of safety requirements in step 4 of the process diagram in figure 1. 5. Page 12 to 15 tables 1, 2 and 3 of the excel file introduced in the document
v1.2	Signed	12 Feb 2013	Changes in Version 1.2 Page 11 definition added The operability is the ability to work in compliance with the specific requirements in the operating range intended to be use. Table 3 combination added SL-2 + internal flooding Changes in Version 1.1 1. Page 3 definition added Applicable document A document issued by IO as nuclear operator containing requirements which compliance with must be demonstrated at each indicated INB lifecycle described into the document. 2. Page 3 reference added [1] Order of 10 August 1984 on Quality for Basic Nuclear Installations EN (ITER_D_ 27AGR5 v1.0) to be replaced from the 1st of July 2013 by title I and II of the Order 7th February 2012. 3. Page 4 section 6.1 text added: The preliminary list of safety requirements for a SIC component for IO and the DA is provided at step 2 and 3. This list is as exhaustive as possible at

			this stage. A more detailed list of sub-systems, components and sub-components which are SIC will be established when detailing more in depth the design. 4. Page 5 section 6.1 text added: The DA may ask support of IO for establishing the exhaustive list of safety requirements in step 4 of the process diagram in figure 1. 5. Page 12 to 15 tables 1, 2 and 3 of the excel file introduced in the document
v2.0	Approved	21 Feb 2013	Changes in Version 2.0 Added in the purpose These guidelines give at the end a template for listing the safety requirements of ITER to be fulfilled by IO. In the process given in section 6, the Domestic Agencies may ask support of IO for establishing the exhaustive list of safety requirements. Changes in Version 1.2 Page 11 definition added The operability is the ability to work in compliance with the specific requirements in the operating range intended to be use. Table 3 combination added SL-2 + internal flooding Changes in Version 1.1 1. Page 3 definition added Applicable document A document issued by IO as nuclear operator containing requirements which compliance with must be demonstrated at each indicated INB lifecycle described into the document. 2. Page 3 reference added [1] Order of 10 August 1984 on Quality for Basic Nuclear Installations EN (ITER_D_ 27AGR5 v1.0) to be replaced from the 1st of July 2013 by title I and II of the Order 7th February 2012. 3. Page 4 section 6.1 text added: The preliminary list of safety requirements for a SIC component for IO and the DA is provided at step 2 and 3. This list is as exhaustive as possible at this stage. A more detailed list of sub-systems, components and sub-components which are SIC will be established when detailing more in depth the design. 4. Page 5 section 6.1 text added: The DA may ask support of IO for establishing the exhaustive list of safety requirements in step 4 of the process diagram in figure 1. 5. Page 12 to 15 tables 1, 2 and 3 of the excel file introduced in the document
v3.0	Revision Required	16 Apr 2015	- Change of document type to procedure as per MQP doc Request R4DCRR - Change of the title: Propagation of the defined requirements for Protection Important Components through the chain of external contractors. - Change of the wording in order to comply with INB order 7th February 2012 - The part corresponding to the working instructions [1] Establishing a list of defined requirement for a Protection Important Component-PIC (Q722X4

			v1.0) has been deleted - The workflow has been updated - The list of references have been updated
v3.1	Approved	20 Jul 2015	The modifications are the following 1-Take into account the new IO organization 2-Change "external contractor " where appropiated also in the title 3-Take into account reviewer's comments
v3.2	Signed	16 Feb 2017	This procedure has been updated following the DG comments. Following changes have been done: •A-Supervision replaced by “surveillance” •B-Changes in the chapter 7.3 Implementation of the Defined Requirements •C-Flowchart modified introducing the modifications above Update approved as per MQP doc Request UHU2DU
v3.3	Approved	09 Mar 2017	Definitions added for propagation, translation, notification Clarification on roles and responsibilities added

Table of Contents

1 Purpose

The purpose of this procedure is to establish the process of propagation of the Defined Requirements for Protection Important Components through the chain of external interveners and its final review and approval by ITER Organization in order to ensure that they have been flowed- down and refined in compliance with the Order of 7 February 2012 [1].

2 Scope

This document applies to all Protection Important Components (structures, systems, and components) and their associated Defined Requirements from the design phase to the "as-built" stage, whether their design development is conducted internally by ITER Organization (IO), by a Domestic Agency (DA), by an external contractor of a domestic agency or an external contractor of IO.

Nevertheless the Defined Requirements cover all the phases of the lifecycle of the ITER nuclear facility (INB 174) (INB-Installation Nucléaire de Base) from design to the dismantling, as this is identified through instructions given in [3] and [7].

The processes of verification that the final defined requirements have been properly implemented in the final product are out of the scope of this procedure and are described in the Overall Surveillance Plan [5] and the specific surveillance plans.

The propagation of the Defined Requirements for the PIA's is out of the scope of this procedure and is described in the Procurements arrangements annexe A, in the Overall Surveillance Plan [5] and in the annexes of the specific surveillance plans.

3 Definitions and acronyms

3.1 ITER Safety functions

Principal safety functions at the ITER facility are as follows:

- Confinement of radioactive and toxic substances to prevent their release;
- Limitation of external exposure to ionizing radiation.

Supporting Safety functions are given in [3] and [7].

3.2 Safety Structure system and component (SSC)

Structure, system and component (SSC) of ITER facility that perform a safety function and contribute towards meeting the general safety objectives of ITER during normal, incident/accident situations.

3.3 Nuclear Operator

As defined in article 1.3 of Order of 7 February 2012 [1] and article 7 of the Decree 2nd November 2007. For the INB 174 (ITER), this is the ITER Organization [2]. the nuclear operator is the **ITER Organization.**

3.4 External intervener

As per article 1.3 of [1]

"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 [1] and related to such an activity, service providers and subcontractors, experimenters and users are in particular concerned;"*

It means "any person other than the ITER Staff which participates in a PIA or a PIC". This means also that a person that does *not* participate in a PIA or a PIC is *not* an external intervener.

This definition includes, but is not limited to, every level of the chain of contractors: supplier, contractor, sub-contractor, sub-sub-contractor and so on. The definition includes also the Domestic Agencies. Being integral part of the ITER project, they play a specific and very important role in the propagation of Defined Requirement.

3.5 Domestic Agency

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

3.6 Subcontractor

A subcontractor is an entity that performs work for an external contractor. The subcontractors are also external contractors/interveners.

3.7 Chain of external interveners

The chain of external interveners (see reference [5]) starts from the first contractor, level 1 in the chain, which can be a Domestic Agency, down to the lowest level of subcontractors for which IO has to guarantee that the INB-Order is respected.

The nuclear operator is considered as level 0 in the chain of propagation of the defined requirements.

For the ITER Organization, depending on the scope of the contract, the external interveners of level 1 are:

- For in kind procurements: Domestic Agencies
- For ITER task agreements and agreements on R&D: Domestic Agencies
- The Project Team, when not hierarchically controlled by the Nuclear Operator
- For IO- direct contracts: direct suppliers to whom the contract has been awarded
- For expert contracts: the direct person to whom the contract has been awarded
- For any other agreements: the signatory entity having an agreement with IO for providing goods or services

For simplification, the level 1 of external interveners is called "DA" in the following, but may be any of the IO external interveners as defined above.

The ITER Organization does not limit the number of subcontractors levels in the chain of contractors, but a limit may be defined by the Domestic Agencies..

3.8 Protection Important Component (PIC)

Specific category of Systems, structures or components as defined per articles 1.3 and 2.5.1 of the Order 7th February 2012:

"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;"

As stated in article 2.5.1 of INB order, the list of ITER Protection Important Components (PIC) shall be set up and kept updated by IO.

3.9 Protection Important Activity (PIA)

As per articles 1.3 and 2.5.2 of the Order of 7 February 2012:

"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 that falls under the technical or organizational provisions mentioned under the second paragraph of Article L. 593-1 of the Environmental Code or that is liable to affect them;"

In practice, for the scope of this procedure, it means "Any activity which is related to or can impact a Protection Important Component".

As stated in article 2.5.2 of the INB order, a list of ITER Protection Important Activities (PIA) and their related Defined Requirements must be set up and kept updated by IO.

The identification of Protection Important Components and of Protection Important Activities and associated Defined Requirements is also a PIA.

3.10 Defined requirement

Any requirement that has been assigned to **a Protection Important Component** or **a Protection Important Activity** so that it may perform the function, with the characteristics expected, as specified in article 1.3 of the Order of 7 February 2012.

In this procedure, we consider only the list of Defined Requirements associated to each PIC.

3.11 Propagation of defined requirements

Refers in this document to the flow-down of the defined requirements in the chain of the external interveners or/and to transmission to a lower level of the corresponding of th ePlant Breakdown system (PBS).

3.12 Safety Applicable document

Any document issued by IO as nuclear operator containing safety requirements, which any participant to the Project must comply with, at each indicated INB lifecycle stage described in the document.

3.13 Notification

For the initial list of defined requirements, the notification is the act of notifying and making known the document for its use following the process described in here.

3.14 Translation

To convert a defined requirement to express it into technical requirements in order to make it specific to the SSC and appropriate for its design development, qualification, manufacturing, etc. Intermediate steps in the translation into technical requirements correspond to different levels of refinement of the defined requirements.

4 References

[1] Order dated 7 February 2012 relating to the general technical regulations applicable to INB - EN (7M2YKF)

[2] Decree No. 2012-1248 dated 9 November 2012 authorizing IO to create a basic nuclear facility called “ITER” (French version) (C2JZNX)

[3] Safety Important Functions and Components Classification Criteria and Methodology (347SF3)

[4] List of Protection Important Components (PIC list) (EN) (JDS5K7)

[5] Overall Surveillance Plan of External Interveners Chain for Protection Important Components, Structures and Systems and Protection Important Activities (4EUQFL)

[6] Establishing a list of Defined Requirement for a Protection Important Component-PIC (Q722X4)

[7] Preliminary Safety Report (RPrS) (3ZR2NC)

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

[9] ITER Archive Management and Record-Keeping Policy (3SR7LG)

[10] ITER Plant Breakdown Structure (PBS) (28WB2P)

[11] Project Change Procedure (22F4E5)

[12] IO Deviations and Non-conformities (2LZJHB)

[13] Requirements for DA / Supplier / Subcontractors Deviations & Nonconformities (22F53X)

[14] Procedure for Processing Deviation Requests and Non-conformance Reports submitted by a DA, a Supplier or a Sub-contractor (3E65VE)

[15] ITER Corrective Action Request (9QELY2)

In addition specific surveillance plans are issued by PBS or sub-PBS or group of systems if they contain PIC and are available on MQP.

5 Responsibilities

5.1 Application of the Order of 7 February 2012

As nuclear operator, IO is responsible for the application of the Order of 7 February 2012.

In particular, IO shall, during the entire lifecycle of the INB and throughout every external intervener in the entire chain of external interveners:

- ensure the propagation of the Defined Requirements;
- survey that they are respected.

5.2 Responsibilities of IO and the external interveners

The list of PIC and associated Defined Requirements is under the nuclear operator responsibility as defined in article 2.5.1 of INB order.

The list of PIC by systems and subsystems at any level of the PBS must be reviewed and approved by a delegated person belonging to the Safety Department (SD).

The initial list of Defined Requirements at project level must be established by the safety responsible officer (SRO) for systems and subsystems.

The IO TRO shall:

- Know the content of the PIC list and associated Defined Requirements for their systems at all the phases of the design and manufacturing;
- Contribute to their correct transmission to all external interveners involved. The TRO shall:
    - perform or verify the allocation and propagation of the Defined Requirements at each level and in the next levels of the chain of external interveners or design levels;
    - request review and recommendation by the SRO for each Defined Requirement.
- contact the SRO regarding any doubt on the list of PIC and/or Defined Requirements.
- ensure that the identification of the PIC and their defined requirements is kept up to date and fully consistent with the current approved system design documents. The IOTRO shall review and recommend the initial list of Defined Requirements for his/her system and may gain the recommendation of the DATRO and DASRO for better understanding of this first stage in the propagation.

The DA's technical responsible officers DATRO and external contractors include the approved previous level list of Defined Requirements in their technical specifications for the next sub-levels (in the contractor chain and/or PBS sub-level).

The DATRO and/or the IO direct external contractor contact IO through the corresponding IO-TRO.

The IOTRO shall review and recommend the lower level lists of Defined Requirements for his/her system after receiving the SRO recommendation and must gain the recommendation of the DATRO and DASRO at each stage of the propagation.

Any list of Defined Requirements shall be approved by the head of the Environmental Protection & Nuclear Safety Division (SD/EPSN).

6 Flow chart

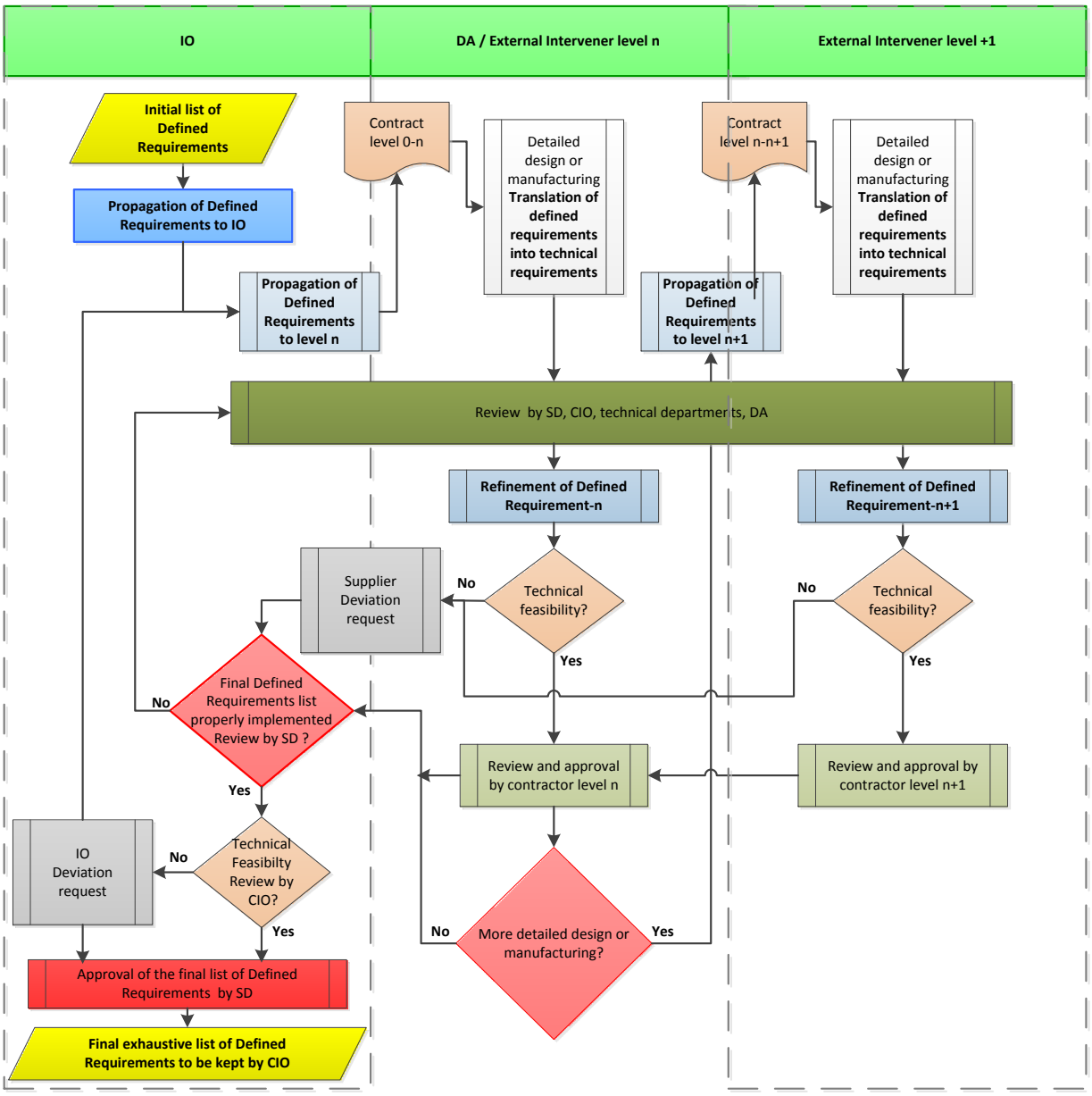

Figure 1: The flowchart for the propagation of the Defined Requirements for each PIC component or PIC system through the chain of external interveners.

7 Process of propagation of the Defined Requirements

7.1 Initial list of Defined Requirements for each PIC

7.1.1 Creation of the list

The initial list of Defined Requirement for each PIC is in principle allocated at the highest levels of the plant breakdown system (i.e level 0 (ITER Plant) or level 1 (System) as defined in [10]) and are already contained in the technical baseline (Project Requirements (PR) and System requirement documents (SRD) mainly).
This initial list of Defined Requirements for each PIC by level 1 PBS is provided by the SRO following the instructions for *"establishing a list of Defined Requirement for a Protection Important Component-PIC (Q722X4)" [6]*, in compliance with the RPRS, SRD, PR and

requirements given by the regulator. Some requirements can be found in the system load specifications.
The SRO establishes this list based on:

- the list of PIC established from the safety analysis provided in [3] and [4] for the corresponding PBS;
- the modifications endorsed by the project through Deviations Requests and Project Change Requests (References [11] to [14]), for each PIC component.

This list is as exhaustive as possible at this stage, reviewed by the IO-TRO, DA-TRO's and DA-SRO's and approved by the head of SD/EPSN division.

7.1.2 Use of the list

The initial list of defined requirements is issued for each PBS level 0 by the nuclear operator in compliance with the article 2.5.1 of the INB Order. It is not applicable for design at its initial issue and must be translated into technical requirements through its propagation. The list is notified to the external interveners or the IO PBS level 0 responsible officer for its propagation as described in chapters 7.2 to 7.5

7.2 Propagation of the list of Defined Requirements for each PIC

The propagation can happen simultaneously or in parallel depending of each specific situation for each PIC for flow-down to the external interveners or for transmission to lower PBS level.

7.2.1 Propagation to sub-systems

For the sub-systems, components and sub-components which will be established when detailing the design more in depth, the initial Defined Requirements will be refined in detailed Defined Requirements at each PBS level if needed. Each corresponding list of Defined Requirements must be allocated to the Plant Breakdown Structure (PBS) elements through the PBS tree decomposition provided in [10].

7.2.2 Propagation to an external intervener or in between external interveners

The initial list is provided by IO to the external intervener of level 1 (domestic agencies or IO direct contractors). If an external intervener of level 1 subcontracts part of the design, then the initial list of Defined Requirement is propagated to level 2 of the chain and so on. In this propagation, a more refined list of Defined Requirements can be produced when the sub-systems are developed as indicated in the point 7.2.1 above for the design and construction phase.

The list of Defined Requirements must be provided in the technical specifications of any contract with the level of refinement reached in the previous step of the chain of external interveners. **Any list of Defined Requirements must have been previously reviewed by IO SRO.**

7.3 Implementation of the Defined Requirements

The following steps are implemented:

1. The initial list of Defined Requirements is established as described in § 7.1. This list is provided to the external intervener to start the translation into technical requirements.

2. If the level 1 external intervener (DA or IO direct contractors) has subcontracted the design or manufacturing, they must review the list prepared by their sub-contractors and have it endorsed by IO, prior to proceed for a later development phases § 7.2.1 and/or 7.2.2.

At this stage the initial list of Defined Requirements will be translated into technical requirements.

3. The DA may ask at each stage for support from IO TRO and SRO for establishing this detailed list of Defined Requirements, involving engineers for design or manufacturing development, integration activities, configuration management and safety experts in a continuous process to find jointly the best solution (safety compliance, technical manufacturing and construction feasibility, maintenance, cost,..)

4. The DA will then provide a final proposal of detailed Defined Requirements (also call technical specific defined requirements).

5. The IO TRO has the responsibility of checking the establishment and implementation of the detailed Defined Requirements (article 2.2.2 of INB order) by technical review through the corresponding PBS and through the interfaces of the PBS at all the levels of the chain of interveners. In this formal process the Safety Department, represented by the IO SRO will verify that the proposed refined Defined Requirements comply with the previous less refined Defined Requirements and if needed, that safety demonstration has been properly done as per article 3.8 of the INB order.

6. In this process, if some issues are still pending, the Safety Department will support the IO-TRO and the DA's providing thorough explanations and suggestions for solutions. On this basis the DA will check the technical feasibility.

7. When no practical solution can be reached by the supplier, the DA shall raise a supplier deviation request (SDR) corresponding to the IO procedure [13]. Once the SDR is approved, the new requirement is ready for its integration in the Baseline.

8. The final DA proposal of detailed Defined Requirements agreed with the Safety Department will be submitted to a technical feasibility checking to be done by the Central Integration Office (CIO).

9. As in 7 above, if no practical solution can be found, CIO shall raise an IO Deviation Request [12]. Once the IO DR is approved by SD, the new requirement is ready for its integration in the Baseline.

10. When the requirements are modified they must be communicated back to the DA and the final list of detailed Defined Requirements modification cross-checked together with the SD support.

11. Once the compliance of final list of the Defined Requirements is reached, it is integrated into the Baseline and CIO issues the corresponding report.

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7.4 Approval of the final list of Defined Requirements

As the result of the detailed design and the manufacturing process, the initial list of Defined Requirements will evolve into a final exhaustive list of refined Defined Requirements at the "as built" stage of each Protection Important Component. This final version of the list must be approved by the Head of the Environmental Protection and Nuclear Safety division after checking the compliance of the product with the defined requirements and it is part of the "as built" package.

7.5 Tools for propagation of the Defined Requirements

- The evidence of propagation of the Defined Requirements for PIC is attached to the requirement documents developed at each level of the PBS structure. These requirements shall be either referred to or explicitly listed in the contractual documentation (PA, Purchase order, contract, Task Agreement etc.) through any level of the chain of external interveners, as for example:
  - Annex A of the contracts where the information of the application of the Order of 7 February 2012 for PIC and PIA is provided and procedures to comply with are given.
  - Annex B of the contracts where the PIC are identified and the list of Defined Requirements are provided at the corresponding level of PBS and/or contract (see sections 7.2.1 and 7.2.2).
- The rules for implementation of the Defined Requirements in the chain of external interveners below the first level in the chain of interveners must be established through clear contractor's procedures as indicated in the Overall Surveillance Plan [5].
- The information through the established lists of Defined Requirements for PIC must be propagated to:
  - All involved IO technical and safety responsible officers as per definition of roles and responsibilities in the departments and divisions;
  - The responsible technical and safety officers in charge of the contract or procurement arrangements in the Domestic Agency or any external intervener providing goods or services to IO.
  - The Central Integration Office
- In addition the following communications tools shall be used to ensure a correct interpretation understanding of the Defined Requirements by the entire supply chain:
  - Workshops to review the list of Defined Requirements with the IO technical responsible officers;
  - Kick-off meetings between customer and suppliers, where the list of defined requirements (from customer) and technical requirements (from supplier) are confronted , follow-up and review meetings for the contracts;
  - Design and Design Interfaces Reviews (very important): Presentation of the list of derived safety requirements on lower tier design, on the interfaces and design compliance matrices,
  - Presentation when feasible of the list of Defined Requirements by IO to the Domestic Agencies;

- Presentation when feasible of the list of Defined Requirements to the external interveners by IO or by the Domestic Agencies;
- Any other recorded communication means.

7.6 Surveillance of the propagation of the Defined Requirements

The surveillance of the correctness of the propagation of Defined Requirements and the proper refinement is done in application of articles 2.2.2, 2.5.3 and 2.5.4 of the 2012 INB Order following the specific surveillance plans for the corresponding PBS. The IO TRO and IO SRO review the Defined Requirements characteristics and compliance for PIC in particular through the manufacturing and inspection plans or control plans proposed by DAs and/or their external contractors, where the Protection Important Activity are identified. The list of the PIA's and Defined Requirements for the ITER-INB are provided in [8].

IO monitors the propagation, knowledge and respect of the Defined Requirements throughout the ITER Organization, the Domestic Agencies, the IO direct external contractors and any sub external contractors of the DAs or of direct contractors [5].

7.7 Management of the non-conformities

The management of the non-conformities on the propagation of the Defined Requirements follows the IO procedures for NCR's in IO [12] and for external interveners and their management by IO [13][14]. In addition, specific management of NCR's may be given in specific surveillance plans.

7.8 Remedial actions, preventative and corrective actions

For each non-conformity, remedial actions are reported in the non-conformity reports (NCR) and approved by IO following the defined procedures [12] to [14].

Preventative and correctives actions issued from lessons learned from the treatment of the NCR's and improvement of the involved processes may lead to new Defined Requirements that must also be propagated through the full chain of external interveners. The management of the corrective actions is provided in [15].

8 Forms and templates

Not applicable.

9 Records

All the activities related to this procedure are Protection Important Activities and must be properly documented and recorded following ITER record policy.

Each update of each specific list of Defined Requirements must be recorded following ITER record policy at each PBS level and/or each level of chain of external interveners.