

Implementation at ITER of the French Order of 7 February 2012, concerning Basic Nuclear Installations within the European Domestic Agency

P.Wouters¹, G. Serra¹, J. Furlan¹, Ph. Jucker¹

¹Fusion For Energy, C/Josep Pla, 2, Torres Diagonal Litoral B3, 08019 Barcelona, Spain

E-mail contact of main author: paul.wouters@f4e.europa.eu

Abstract. The ITER project is being undertaken at Cadarache, France, to construct and operate an experimental nuclear fusion facility. The paper describes the implementation of the French Order of February 7, 2012 requirements at European Domestic Agency “EU-DA”, which is a level one supplier of ITER Organization.

1. Introduction

The French Order of 7 February 2012 applies namely to the nuclear operator, ITER Organisation “IO”, but it involves the whole supply chain through the ‘top-down’ notification and monitoring of the necessary provisions of the Order. According to the “Nuclear Safety Demonstration”, in which the risks or inconveniences to people and the environment arising from the processes of the Basic Nuclear Installations, so called “INB”, are identified and are shown to be either prevented or limited by appropriate technical or organizational provisions, the Operator (IO) has identified Structures, Systems and Components (SSC) which have safety functions to either remove or mitigate the foreseen hazards. Under the French Order of 7 February 2012 or INB Order these SSC are identified as Protection Important Components, PIC. The processes to design, manufacture, transport, install, test, maintain and operate a PIC must be very strictly identified, controlled and reported. These processes are identified as Protection Important Activities, PIA. The provisions associated to those Protection Important Components and Protection Important Activities are to be propagated through the whole supply chain and in particular, the EU-DA shall notify them and monitor their implementation by its sub-contractors.

2. Implementation in EU-DA

The EU-DA, as first level in the IO chain of suppliers, plays a prime role in providing to the nuclear operator reliable information and sound demonstration in organization and responsibilities, nuclear safety analysis, traceability, validation of methods, qualifications, calculations and modelling, appropriate technical capacities, either internally or through subsidiaries or companies and supervision of the entire supply chain. In line with top level ITER Policy, the communication performed within the EU-DA organization and the supply chain stresses a continuous improvement on the nuclear safety culture, which is a first priority in the ITER project. The ITER Policy is propagated via EU-DA top level quality instructions towards its suppliers.

Concerning the technical aspects for PICs design and manufacturing, the EU-DA has duties regarding the levels of defence-in-depth, in terms of:

- Appropriate, clearly explained and validated methods,
- Qualified calculation and modelling tools,
- Substantiated design margins,
- Adequate redundancy, diversification and physical separation where necessary,
- Identification of possible failures and consequences at components level, including the ‘single failure’ principle of PIC components,

- Contribution to the nuclear safety demonstration at components, systems and structures level.

This is managed via the technical specifications.

Regarding the reliability and correctness of the information provided, demonstrated supervision and quality control of the activities and components delivered to the IO, the EU-DA has the duty to implement provisions to comply with the INB Order requirements. It is done according to a set of procedures of the EU-DA Quality System and to the use of a Requirements Management & Verification process (RMV).

The EU-DA procedures request the following provisions to be implemented:

- Quality Assurance requirements to EU-DA design suppliers. A unique specific dedicated QA procedure determines the whole set of QA requirements the Suppliers must comply with which covers the whole procurement process,
- The Protection Important Activities (PIAs) are identified by EU-DA suppliers in the quality control plans. The same quality control plans ensure a correct supervision of each identified PIA by a notification point, or review point, or hold point by one or more of the involved parties,
- Propagation of Defined Requirements in EU-DA contracts via a specific procedure,
- Instruction of Suppliers on the INB Order provisions. Sessions and lectures are given to suppliers,
- Ensure that Deviation Requests (DRs) and Non Conformities Requests (NCRs) are managed according to IO/EU-DA procedures,
- Perform surveillance of the chain of suppliers, according to supervision plans.

The supervision of the supply chain is done for each procurement arrangement package via a specific dedicated supervision plan, which may include the percentage of PIA monitored by EU-DA, and by dedicated nuclear safety inspections that are communicated a few weeks in advance to the suppliers. On a monthly basis, the responsible technical officers communicate their complete supply chain of subcontractors to ITER Organization. Every six months an independent check is done by a Nuclear Safety Officer of the full communication of subcontractors working on Protection Important Components to the IO. Specific actions are made according to procurement phases: Design or Manufacturing.

For design processes, the main steps are the following:

- Provision by IO of a clear PIC Defined Requirements specification,
- Incorporation in RMV Data Base,
- Ensure that PIC Safety Function, PIC Break-down, Defined Requirements, PIA and Verification Actions are well identified, refined and propagated in the chain of suppliers all along the design process. This is done thanks to identification and follow-up of PIAs in the suppliers' control plans,
- Ensure that PIA Design Analyses are performed by validated methods, according to provisions presented in Section 4,
- Ensure that the Requirements Identification Matrix (RIMx) and the Verification and Control Documents (VCD) are completed,
- Ensure that the elements/documents for the final Design "Nuclear Safety Dossier" are collected and recorded,
- Deliver to IO the Design "Nuclear Safety Dossier".

For manufacturing processes, the main steps are the following:

- Ensure that the PIC Safety Function, PIC Break-down and Defined Requirements are available from the Design phase and incorporated in RMV Data Base,
- Ensure that Manufacturing PIAs, related Defined Requirements and Verification Actions are identified, pointed out and propagated in the suppliers' control plans,
- Ensure that the elements, documents for the final Manufacturing "Nuclear Safety Dossier" are collected and recorded,
- Deliver to IO the Manufacturing "Nuclear Safety Dossier".

The final "Nuclear Safety Dossier", delivered jointly with the system to the nuclear operator (IO), must contain:

- The final PIC break-down, from the Design phase,
- The final version of the Defined Requirements (Safety), from the design phase,
- The final version of Nuclear Safety filter of Verification Control Document (VCD),
- The final version of the Compliance Matrix,
- The list of PIAs (or a cross reference to all the relevant Supplier Control Plans),
- The final list of NCR and DR affecting PIC and PIA,
- The final list of the subcontractor schedule,
- Supervision plans of the chain of suppliers and related records.

Each NCR affecting PIC and/or PIA, needs a correct root cause assessment and a dedicated supervision of the implementation of the remedial actions. On regular basis IO organizes a "Lessons Learnt Workshop" with the various involved domestic agencies, to exchange issues and remedial actions related to safety between the agencies.

3. Requirements Management and Verification (RMV) for Safety

The EU-DA applies a Requirements Management and Verification (RMV) process in order to track, control and verify all technical requirements applicable to ITER components under the EU-DA responsibility. This process is applied to the nuclear safety Defined Requirements in a way that allows all Defined Requirements on ITER components to be recorded and controlled at all the different levels of the supply chain in a systematic way (from n-1 to n-m). In order to support the RMV process, the EU-DA has developed a specific requirements database by tailoring the IBM Rational DOORS software for the ITER project. In this chapter, the term "Specification" means "a document stating requirements".

The RMV process follows three main phases (assessment of input requirements, propagation of requirements to the next level and requirements verification). All three phases and corresponding activities are performed with the support of IBM Rational DOORS, IBM Rational DOORS Requirements Management Framework Add-on, and EU-DA MIR (Manage ITER Requirements) Add-on (developed by EU-DA specifically for the ITER Project).

In the first phase, EU-DA ensures that all requirements applicable to the system at the given level (we will consider it Level n-1 for easier understanding) are identified, and assesses compliance to the requirements in a preliminary analysis. This means that all requirements have to be visibly marked as such in the input specifications and for the Safety ones, also marked as Defined Requirements to distinguish from the other technical requirements. Once the identification of all the input Defined Requirements is ensured, it means that EU-DA has a complete baseline of Defined Requirements to continue with the development of the System of interest. This baseline of requirements has to be agreed with ITER Organization (IO) so that the two organizations have a common understanding regarding the starting point of activities. This is also a typical client/supplier approach as per other big dimensional engineering projects (space, aeronautics, etc.). In addition to agreeing on the baseline of Defined Requirements, EU-DA performs a preliminary analysis in order to issue a Statement of Compliance towards those requirements and also to take the opportunity to flag and discuss possible difficulties encountered on some of them. Those difficulties could be related to an incomplete understanding of the Defined Requirement or its applicability to comply with it. Indeed, problems, non-compliances and other difficulties should be addressed as soon as possible in order to be able to deal with them as soon as possible. It is well known that the later the change, the more expensive its implementation becomes.

At the end of the first phase, EU-DA has a baseline of Defined Requirements and a common understanding with IO on EU-DA's capacity to comply with them. The second phase starts. EU-DA performs the propagation of the requirements of level n-1 in EU-DA specifications (level n). In order to do that, a secondary analysis on the Defined Requirements of level n-1 is performed in more detail, assessing which ones have to be propagated to the next level (n) below, to which PBS (Plant Breakdown Structure) node and to which specification(s) of level n. Once this is clear, EU-DA starts drafting the specification(s) to be provided to industry and linking (the term used in DOORS language) the new derived Defined Requirements of level n to their "parent" Defined Requirements from the baseline agreed at the end of the first phase (level n-1). This link is conventionally an arrow bottom-up (from level n to n-1) and is designated as a "Satisfies" relationship. There can be several Defined Requirements of level n (in the same or in different specifications) satisfying one Defined Requirement of level n-1, or there can be one Defined Requirement of level n satisfying one Defined Requirement of level n-1. It is also possible to have one Defined Requirement of level n satisfying several requirements of level n-1. In the latter case, it is a sign that the baseline of Defined Requirements of level n-1 is not well defined as the tendency should be a multiplication of requirements as we go down through the PBS levels.

One of the advantages of using a database for managing the technical requirements is that all these engineering activities are recorded and it is easier to assess the impacts up and down whenever a change is introduced in one requirement at any level. At EU-DA, generally, any "child" requirement of a Defined Requirement is marked as a Defined Requirement itself and it is therefore tracked as such, allowing to have full traceability along the PBS and Supply chain. Before releasing any specification of level n to the Industry suppliers, EU-DA is able to check whether all Defined Requirements planned to be propagated in a given specification of level n were indeed propagated to the exact specification of level n. In addition, EU-DA can check at any given moment how many of the Defined Requirements supposed to be propagated to level n still have no "child" requirement at level n. This provides interesting Key Performance Indicators (KPIs) to measure advancement of work. It is also possible to check whether all Defined Requirements of level n-1 supposed to be propagated to level n were indeed propagated in any of the specifications of level n.

The third phase consists in the verification activities. If the propagation is a top-down exercise, the verification is a bottom-up (the classical V shape development model). This means that the third phase includes the follow-up of the activities performed by the industrial suppliers, which include similar activities in terms of RMV as the ones performed by EU-DA in the first and second phase on the level n-1 Defined Requirements, only this time performed on the level n corresponding to the scope of the supplier. When the supplier issues the first Statement of Compliance (output of the preliminary analysis) on the level n Defined Requirements, EU-DA can confirm coherence with the Statement of Compliance issued by EU-DA on level n-1 Defined Requirements. Any inconsistency needs of course to be addressed and solved if there are impacts at level n-1.

The next step and final goal of this phase is to get from the suppliers evidence of verification for the requirements of level n. There are four types of verification considered, Test, Analysis, Engineering Review and Inspection, and there can be one or more verification efforts of a same or different type linked to each Defined Requirement. Two stages of verification are considered: the Qualification stage in order to qualify the design with regard to the Defined Requirements, and the Acceptance stage in order to guarantee that the system manufactured is verified towards those same Defined Requirements. Once Level n of Defined Requirements has been fully verified by the suppliers, and thanks to the use of the infrastructure put in place by EU-DA, the verification efforts linked to level n contribute to the verification of level n-1. To conclude the full RMV process, EU-DA establishes the remaining necessary verification efforts at level n-1 to complete the verification inherited from the level below.

4. Validation of methods, calculations and modelling

As a part of its duties regarding the compliance with the requirements of the INB Order, the EU-DA has the responsibility of propagating through the supply chain the requirements set forth in the INB Order applicable to the analyses supporting the design of the Structures, Systems and Components (SSC) of Quality Class 1. As such, the INB Order does not contain any specific requirement related to the performance of design analyses.

The SSCs of Quality Class 1 are Protection Important Components (PIC) and the analyses supporting their design make part of the safety demonstration and are Protection Important Activities (PIA). Requirements pertinent to the design analyses of SSC of Quality Class 1 are found in Article 3.8 of Title III of the INB Order related to the safety demonstration and in Title II of the INB Order about the required organization for performing PIAs.

Basically Article 3.8 in the INB Order requires the safety demonstration to be based on up-to-date and referenced data, to adopt well-argued, adequately explained and validated methods, and to use qualified calculations and modelling tools. The requirements of Article 3.8 are quite general as they are applicable to all analyses making part of the safety demonstration of the INB, for instance the accident analyses whatever they are deterministic or probabilistic.

Title III of the INB Order provides requirements for the PIAs with the objective of allowing those activities to meet the defined requirements associated thereto. Practically, step by step requirements are specified related to the determination of the defined requirements, the preparation of the PIA, the performance of the PIA and the systematic (independent) technical control.

Since the INB Order belongs to the set of the nuclear safety requirements set forth under the French regulations and also because it is implicitly requested by Article 2.3.2 in the Order, it is of prime importance that the requirements of the Order are adequately known, understood and implemented.

In the specific case where the design analyses are performed by EU-DA suppliers, it may happen that understanding the requirements of the INB Order is a real burden for those suppliers who are not used to apply them. In order to ease that possible burden, EU-DA issued instructions and guidelines for the application of the Order by its suppliers. More specifically a work instruction was issued for the EU-DA suppliers which perform calculations or analyses in support of the design of structures, systems and components for the ITER facility.

The objective of the work instruction is twofold. Firstly, to ensure that by strictly complying with it, the EU-DA suppliers will meet the requirements of the INB Order. Secondly, to allow EU-DA to provide via an evidenced supervision the required demonstration of its suppliers' compliance to the INB Order. The latter objective is also of the first importance regarding the as EU-DA responsibilities towards its suppliers and subcontractors.

The work instruction contains both requirements ensuring that the two objectives mentioned above are adequately satisfied and comments which are to be considered as an explanation or clarification of the requirements. The requirements translate the quite general requirements of the INB Order into specific step by step requirements specific to the design calculations or analyses. The comments, sometimes illustrated by examples, are considered essential as they have the objective of ensuring that all suppliers share a common understanding of the requirements of the work instructions. In some cases, the comments are rather definitions of terms as it frequently happens that words or expressions have a different meaning depending on the person using them. Therefore, words or expressions such as verification/validation, conceptual/mathematical models, and analysis methods are defined.

The specific requirements are written in such a way that the supplier knows what he has to do on his own but also which is the interrelationship between EU-DA and himself.

Basically, the performance of a specific design analysis includes the following steps:

- Transmission of the applicable defined requirements by the EU-DA to the supplier; although this first step is a necessary and essential step in the performance of the analysis, no requirement about that step is set forth in the work instructions because it is the responsibility of the EU-DA.
- Preparation of the design analysis; through several requirements, the supplier is requested to prepare and transmit to EU-DA for approval a document detailing the methods and the organizational technical and documentary means as well as the human and material resources necessary for performing the analysis. The document shall also justify how the methods, means and resources allow the analysis to meet satisfactorily the requirements assigned to it and especially the defined requirements.
- Completion of the analysis; three main subtasks of an analysis are subjected to requirements in the work instruction: the management of the input data, the verification/validation of the models and calculation codes, and the use of codes and standards. A particular attention is paid to the management of the input data as it is an essential condition for ensuring their appropriateness but also the consistency between the various analyses. Specific requirements are defined depending on the nature of the input data, i.e., data provided by the EU-DA, data coming from upstream analyses performed by the supplier, and reference data. For all the requirements related to this third step, strict interrelationship with the EU-DA is required by requesting transmittal for review/approval.

- Technical control; during the completion of the analysis, a requirement of the work instruction states that a self-check by the supplier shall be performed to verify that the requirements assigned to the analysis are effectively satisfied. Any discrepancy is required to be handled as a non-conformity. In addition, a requirement for technical control is included in the work specification. Technical control of each analysis, i.e. an independent verification by suitably qualified and experienced persons other than those having performed the analysis, is required to be performed and documented for review by the EU-DA.

The implementation of the EU-DA work instruction is aimed at solving most of the problems related to the application of the INB Order by EU-DA suppliers.

5. Pressure Equipment

In addition to the pressure equipment requirements set forth under title V of the INB Order, the nuclear pressure equipment designed specifically for the INB are also required to meet the provisions set by the Decree of 13 December 1999 related to the pressure equipment (ESP Decree) which is the transposition of the European Union Directive for Pressure Equipment into the French regulations, supplemented by the Order of 12 December 2005 (ESPN Order). The process of revising in France the regulatory requirements applicable to the nuclear pressure equipment started in 2015 and is not yet finalized. However, the content of this section should only be affected slightly.

As such, the manufacturer of the nuclear pressure equipment ensures the responsibility of meeting the requirements of the ESP Decree and ESPN Order. The role of the EU-DA in the application of those requirements needs therefore to be clarified. According to a guide issued by the European Commission, the manufacturer is defined as the one "who is responsible for designing and manufacturing a product with a view of placing it on the Community market on his own behalf". The manufacturer shall therefore be in a position to actually ensure this responsibility and in particular shall know all information needed to make fundamental choices about design and manufacture of pressure equipment. In the case where the user or his authorized representative imposes to his supplier some of these fundamental choices, the user or his authorized representative could ensure the corresponding responsibilities. That is specifically the case of the EU-DA which imposes to the supplier the fundamental choices, e.g., by specifying the defined requirements. The EU-DA ensures therefore the responsibilities corresponding to its involvement in the design of the nuclear pressure equipment.

Basically, the nuclear pressure equipment with regard to both its design and its manufacturing, is required to comply with the essential safety requirements set forth in the ESP Decree supplemented by those of the ESPN Order and with the radiation protection requirements defined by the Order. Furthermore, conformity assessment is also required in order to verify the conformity of the equipment to the essential safety requirements and the radiation protection requirements. Nuclear pressure equipment is classified in five categories, from 0 to IV, depending on the risks associated with the temperature and pressure of the fluids they contain. Nuclear pressure equipment is also classified on three levels, N1 to N3, depending on the magnitude of the radioactive emissions that could result from failure of the equipment. The classification has consequences on the manufacturing (conformity assessment and essential safety requirements) and on the in-service inspection, the most stringent requirements being those applicable to Category IV, Level N1 nuclear pressure equipment.

The Vacuum Vessel, several sectors of which are delivered by EU-DA and first nuclear confinement barrier, is Category IV Level N2 nuclear pressure equipment. Other equipment of the ITER facility are also nuclear pressure equipment, however, it has been possible to exempt some of the equipment from the requirements of the ESP Decree and ESPN Order. The rationale for that exemption is detailed below.

The first condition mentioned in Article 2(I) of the ESPN Order for designating an equipment as a nuclear pressure equipment is that it is a pressure equipment as defined by Article 2(I) of the ESP Decree, i.e., the equipment is subject to a maximum allowable pressure PS exceeding 0,5 bar. However, equipment which should be pressure equipment according to the above mentioned definition are excluded from the scope of the ESP Decree since they meet one of the provisions mentioned in points (a) to (r) in Article 2(II) thereof. According to Article 2(I) of the ESPN Order, that equipment exempt from the scope of the ESP Decree do not satisfy the first condition for being nuclear pressure equipment.

In particular, the definition of exempt pressure equipment according to point (h) in Article 2(II) of the ESP Decree may be invoked for some equipment of the ITER facility. Point (h) excludes from the scope of the ESP Decree 'equipment comprising casings or machinery where the dimensioning, choice of material and manufacturing rules are based primarily on requirements for sufficient strength, rigidity and stability to meet the static and dynamic operational effects or other operational characteristics and for which pressure is not a significant design factor'. Some pressure equipment of the ITER facility such as the blanket modules, components of the Electron Cyclotron launchers fall within the definition of the equipment covered by point (h). Indeed, their design rules are governed by criteria of strength, rigidity and stability with regard to the electromagnetic and thermal loadings and the pressure is not a significant design factor.

Practically, a request for exemption from the scope of the ESP decree containing a well-argued justification is to be submitted by IO to the French Ministry in charge of the pressure equipment. A favourable answer of the Ministry is notified by the confirmation that the equipment complies with the definition of the equipment covered by point (h) in Article 2(II) of the ESP Decree.

The exemption of the equipment from the scope of the ESP Decree allows lightening the requirements of the ESP Decree and ESPN Order related to design and manufacturing without increasing the risk due to pressure loading. Indeed the exemption is based on the justification that the equipment does not pose a significant hazard due to pressure. Furthermore, for some components, the foreseen design could not allow the in-service inspection required by the ESPN Decree to be performed. The exemption eliminates therefore the necessity of looking for possible design changes that would allow the in-service inspection but also affect detrimentally the operability of the equipment.

6. Conclusion

This paper describes in detail how EU-DA implements the French INB Order of 7 February 2012, within the ITER project. The implementation is accomplished by the EU-DA through quality instructions, the Requirements Management & Verification process (RMV), the production of compliance matrices through IBM Rational DOORS, the suppliers' supervision plans, and the specificities of the ESP Decree and ESPN Order on ITER packages.

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