

Technical Specifications (In-Cash Procurement)

Expert support in Implementation of Module H/H1 QAP

This technical specification is related to a one year call for expertise related to a support to NSD/PSE Group in the implementation of the French regulations for: Manufacture of Pressure Equipment (PE) and Nuclear pressure Equipment (NPE) Operation of PE / NPE Implementation and development of ITER specific Quality Assurance Program

**CALL FOR EXPERTISE
TECHNICAL SPECIFICATIONS**

Contract Title

**ENGINEERING SUPPORT FOR
IO PRESSURIZED EQUIPMENT GROUP**

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Technical Specifications

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1 Abstract

The purpose of this call for expertise is to provide engineering specific expertise to the Pressurized Equipment Group (PSE) of the Nuclear Safety Division in the area of the regulatory and safety demonstrations required for licensing files.

The aim of this document is to define the scope of the call for expertise, related to expertise to support NSD/PSE Group in pressurised equipment regulations for manufacture and operation of PE/NPE, regarding module H/H1 and in nuclear safety.

2 Background and Objectives

As part of the ITER licensing and following the Decree authorizing IO to create a basic nuclear facility called « ITER » (*Décret d'Autorisation de Création*), safety studies and safety demonstration have to be provided to the French Regulator (ASN: *Autorité de Sûreté Nucléaire*) in consistency with the 2012 INB order.

The safety demonstration covers:

- all the stages of life of ITER facility, from design phase to construction, assembly, commissioning, operation, decommissioning...
- all the potential impact on workers, on the environment and of members of the public, from any type of risks, radiological or not.

ITER Organization is the operator of INB 174 and during the last few years it has been decided in the interest of the project that in some cases ITER will also assumes the responsibility of Manufacturer of PE/NPE.

When assuming the role of Manufacturer ITER Organization applies a specific Module H/H1 Quality Assurance Program (QAP).

This specific Module H/H1 QAP was approved by Bureau Veritas (acting as Agreed Notified Body - ANB) as meeting the requirements of Module H/H1 defined in PED 2014/68/UE and French ESPN Order dated 30 December 2015 modified.

3 Scope of Work

The scope of this call for expertise is related to the technical, administrative and logistic expertise with regards to French regulations for Pressure Equipment and Nuclear Pressure Equipment, the related ASN guidelines requirements and basic fundamental safety rules.

Upon request, the expert shall provide an analysis in the preparation of communication on any topic related, to ASN and to the Agreed Notified Body in charge of the approval of ITER Module H/H1 Quality Assurance Program.

Reports need to be provided within the scope of this call for expertise.

The nature of expected expertise includes:

- Expertise to the PSE Group for the maintenance of Module H/H1 Quality Assurance Program

- Development of draft of procedures or working instruction constituting ITER Module H/H1 Quality Assurance Program,
- Expertise in the implementation of Module H/H1 Quality Assurance Program inside ITER Organization to the design, manufacturing, construction, assembly, operation,
- Support in the routine activities associated with the management of procedures and Module H/H1 Quality Assurance Program,
- Development of draft of procedure or working instruction related to operation of Pressure Equipment and Nuclear Pressure Equipment,
- Preparation, execution and evaluation of the results of surveys, related to Pressure Equipment and Nuclear Pressure Equipment training sessions,
- Expertise in the preparation, execution and management of the closure of findings identified during internal and external quality audits.

4 Duration of Call for expertise

The duration of the services is 12 months from the signature of the contract.

5 Work Description and Deliverables

5.1 Outline

The expert shall provide support to NSD/PSE Group in the areas of the topics identified in chapter 3.

The expert's activities will be defined by the IO contract responsible officer according to the needs of the NSD/PSE Group.

These activities will include advisory, analysis and support in relation with design, manufacturing, construction, assembly, operation of Pressure Equipment and Nuclear Pressure Equipment.

5.2 Tasks (Deliverables)

In accordance with 5.1 above, the expert shall perform, not limited to but for example, the following tasks (deliverables):

- Creation or Modification of technical documents following collaboration with Quality Management Division on the interfaces between ITER QAP and Module H/H1 QAP;
- Identification of potential risks and opportunities on Module H/H1;
- Preparation of the regular weekly and monthly PSE Group meetings (Planning, preparation of agenda, material and inputs for the meeting, preparation of the minutes of meetings and follow up of actions);
- Preparation and Participation to Quality internal and external audits (including Module H/H1 audits);
- Expertise related to the closure of the findings identified during the internal and external audits through JIRA;
- Preparation of the quarterly status to be sent to the ANB in relation with:
 - Update of the procedures constituting Modules H/H1 QAP,
 - Update of the PE/NPE manufactured by ITER;

- Planning and remote organization of modules H/H1 training sessions: Creation of online survey with IT, summary of test results, maintenance of the up to date list of certified staffs and of the PE/NPE Organization Chart, participation to periodic renewal sessions;
- Management support for the PSE Group action plan (in PSE Group sharepoint) and follow up of progress of related JIRA actions;
- Participation in different meeting preparation of Minutes of Meeting and related actions plan;
- Preparation of a list of Pressurized Equipment and Nuclear Pressure Equipment operated inside ITER;
- Supporting PSE Group members in the definition of the data to be integrated in SAP for the management of the follow up of the regulatory deadlines related to PE/NPE operated inside ITER.

Whenever required by the IO CRO, the above mentioned supports/deliverables shall be submitted in formal report form as below:

- Report on the analysis of update of Module H/H1 QAP and related procedures,
- Report on the analysis and synthesis of existing or new risks induced by the changes,
- Report on the analysis and synthesis of regulatory texts and their impact on the ITER existing QAP,
- Report on the analysis and synthesis of literature reviews (R&D results with impact on the ITER module H/H1 QAP),
- Summary report of the activities carried out by PE/NPE representative in the scope of Module H/H1 and in relation with PE/NPE operated inside ITER,
- Analysis report of Quality audits performed by the group on the contractor or by third parties on NSD/PSE Group.

6 Responsibilities (including customs and other logistics)

ITER Organization (IO):

ITER Organization will provide the needed information and access to the adequate ITER files for executing this work when needed following the implementation plan for design and manufacture of PE/NPE and Implementation for Installation and operation of PE/NPE.

In particular ITER Organization will make available any technical information, for example safety analyses already performed in support to the licensing. The documents containing this information must be returned to ITER Organization on completion of the call for expertise.

Expert:

The expert will provide results according to the scope of the work outlined above and will fulfil the implementation plan and conditions of present call for expertise.

The expert is responsible in non-divulging information obtained during the execution of this call for expertise.

7 Monthly Reports

The expert shall submit, a monthly report to be approved by IO. This monthly report shall report at least the following information:

- List of the activities assigned to the Expert during the month,
- Progress status of these activities,
- List of documents established or reviewed by the expert with IDM reference if applicable,
- Status of the update of the several data bases related to PE/NPE,
- Establishment of the status of the IO staff certification in relation with PE/NPE,
- Status of the closure of the finding identified during audits on NSD/PSE Group,
- Any major tasks foreseen for the next month either pending or new.

8 Acceptance Criteria (including rules and criteria)

8.1 Acceptance Criteria for Deliverables (Section 4)

The expert shall deliver the required deliverable and tasks required under Section 5 above without delay in schedule. They shall meet or exceed the adequate level of quality reasonably expected from the normal industry practice for this type of expertise. It is mandatory that the expert shall have proven skills and equivalent experiences of work in the fields defined in Section 5.2 above. All the deliverables must be always supported by good understanding and application of the relevant safety regulations and requirements.

8.2 Acceptance Criteria for Monthly Reports (Section 7)

The monthly report must demonstrate that the actual deliverables required under section 5 have been successfully completed by the expert during the relevant month.

8.3 Document Approval

The IO-Contract Responsible Officer (or person delegated by the IO-CRO for all technical matters,) shall review the deliverables and reply, within 10 days, with a commented version of the deliverable(s).

The expert shall perform all the necessary modifications or iterations to the deliverables and submit a revised version.

Contract will be considered completed after ITER has accepted the last deliverable covered by the contract.

9 Specific requirements and conditions

The official language of the ITER project is English.

Therefore all input and output documentation relevant for this Contract shall be in English. The expert have an adequate knowledge of English, to allow easy communication and adequate drafting of technical documentation. Nevertheless, the official language when dealing with the French Regulator is French so the expert shall also have an adequate knowledge of French, to allow easy communication and adequate drafting of technical documentation.

The work requires the presence of the expert at the site of the ITER Organization, Route de Vinon sur Verdon, 13067 St Paul-lez-Durance, France, for the purpose of meetings and data gathering. However, some deliverables may also be executed from expert's offices with the clear agreement from IO contract responsible officer before the execution of the task.

10 Meeting schedule

The following meetings should be organised:

Scope of meeting	Point of check/Deliverable	Place of meeting
Kick-off contract	Work program	ITER site or video conference
Progress meetings if required by ITER or expert	Checking progress Permission for work continuation	ITER site or video conference or other locations linked to the examination
On-request meetings	Expert support during technical meetings linked to the examination	ITER site or video conference or other locations linked to the examination

11 Quality Assurance (QA) requirement

The organisation conducting these activities should have an ITER approved QA Program or an ISO 9001 accredited quality system.

The general requirements are detailed in ITER document ITER Procurement Quality Requirements (ITER_D_22MFG4).

Deviations ([2LZJHB](#)) and Non-conformities (ITER_D_22F53X) will follow the procedure detailed in IO document.

Documentation developed as the result of this task shall be retained by the performer of the task for a minimum of 5 years and then may be discarded at the direction of the IO. The use of computer software to perform a safety basis task activity such as analysis and/or modelling, etc shall be reviewed and approved by the IO prior to its use, it should fulfil IO document on Quality Assurance for ITER Safety Codes (Quality Assurance for ITER Safety Codes (ITER_D_258LKL).

These documents will be provided at the kick-off meeting.

12 Safety requirements

ITER is a Nuclear Facility identified in France by the number-INB-174 (“Installation Nucléaire de Base”).

For Protection Important Activities, the French Nuclear Regulation must be observed, in application of the Article 14 of the ITER Agreement.

In such case the expert must be informed that:

- The Order 7th February 2012 applies to all the components important for the protection (PIC) and the activities important for the protection (PIA).
- The compliance with the INB order must be demonstrated.
- In application of article II.2.5.4 of the Order 7th February 2012, contracted activities for supervision purposes are also subject to a supervision done by the Nuclear Operator.

For the Protection Important Activities, compliance with Provisions for Implementation of the Generic Safety Requirements by the External Actors/Interveners (SBSTBM) shall be ensured.

13 Terminology and Acronyms

Terminology and Acronyms

In the following table denominations and definitions are given of all the actors, entities and documents referred to in this Specification, together with the acronyms used in this document.

Denomination		Definition
Agreed Notified Body	ANB	Notified Body, agreed by ASN to perform conformity assessment of Nuclear Pressure Equipment
Autorité de Sûreté Nucléaire	ASN	French Regulator
ITER Organization (IO)	IO	For this Contract the ITER Organization
ITER Organization Contract Responsible Officer	IO-CRO	Person appointed by the ITER Organization with responsibility to manage all the technical aspects of this contract
Nuclear Pressure Equipment	NPE	Equipment contain pressure and radioactivity and in the scope of French ESPN Order (dated 30/12/2015 modified)
Nuclear Safety Division	NSD	
Pressure Equipment	PE	Equipment containing Pressure and in the scope of Pressure Equipment Directive 2014/68/UE
Protection Important Activity	PIA	
Protection Important Component	PIC	
Quality Assurance Program	QAP	Program developed by ITER to meet the requirements of the PE/NPE regulations.