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**Annex A**

**5.5.P4.US.01 Annex A**

5.5.P4.US.01 (TIP, ECE & EP#9) Annex A

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*Change Log*

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5.5.P4.US.01 Annex A (BKTN9V_v1_1)	v1.1	Signed	29 Oct 2012	latest document version numbers added as requested by QA  ITER Requirements Regarding Contractors Deviations and Non Conformities (22F53X)  Procurement Arrangement related Documentation Exchange, Access and Storage Conventions (2DKFR2)
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# **Management Specification**

## **ANNEX A**

**to**

## **Procurement Arrangement**

### **5.5.P4.US.01**

**between**

**The ITER International Fusion Energy Organization**

**and**

**The United States of America ITER Project Office**

#### **Abstract:**

This document defines the management requirements in order to comply with the legal regulatory requirements, accepted sound project management practices, safety and QA requirements for the procurement of the 55.F2 Low Field Side Reflectometry of the ITER Diagnostics Procurement Package. It is an Annex that forms an integral part of the Procurement Arrangement.

## Applicable Documents

[Global Transportation MOU US DA \(6KXFZ6 v1.0\)](#)

Order of 10 August 1984 on Quality for Basic Nuclear Installations EN (27AGR5 v1.0)

Procedure for the Usage of the Protocol of CAD Design Collaboration (2EGJ27 v1.2)

Procedure for the Usage of the ITER CAD Manual (2F6FTX v1.1)

CEAR (Construction and Erection All Risk Policy) (6KUSN2 v1.0)

Design Review Procedure (2832CF v1.12)

Deviations and Non-conformities (2LZJHB v3.1)

ITER Planning & Scheduling Manual (2DWMCW v3.0)

Procurement Description (2LFF4U v1.6)

Health Protection and Safety General Coordination Plan ITER Site Work - Volume 0 - General Safety Rules (2NUEYG v4.1)

Internal Regulations (27WDZW v1.3)

ITER Configuration Management Plan (CMP) (27LHHE v1.11)

ITER Document Breakdown Structure Overview (43327Q v1.1)

ITER Plant Breakdown Structure (28WB2P v2.0)

00 - Nuclear Regulatory Framework for INB ITER (2WBB8P v3.2)

PA monthly report (2E346G v1.4)

PA template Credit Request Form (28B3TX v1.0)

Procedure for Management of CAD Work & CAD Data (Models and Drawings) (2DWU2M v1.7)

Procedure for the Preparation, Review, Approval and Award of Procurement Arrangements (2W4F7A v2.0)

Procedure on procurement documentation exchange between IO, DAs and contractors (35BVQR v2.1)

Project Change Procedure (22F4E5 v4.2)

Procurement Arrangement related Documentation Exchange, Access and Storage Conventions (2DKFR2 v3.4)

[Risk Register Standard Template \(2PMZYP v1.5\)](#)

Risk Management Plan (RMP) (22F4LE v2.1)

Working conditions on the ITER Organization site (2EQ9JM v1.1)

ITER Procurement Quality Requirements (22MFG4 v4.0)

ITER Requirements Regarding Contractors Deviations and Non Conformities (22F53X v5.1)

ITER Requirements Regarding Contractors Release Note (22F52F v4.1)

Requirements for Preparing and Implementing a Manufacturing and Inspection Plan (22MDZD v2.1)

[Safety Important Functions and Components Classification Criteria and Methodology \(347SF3 v1.8\)](#)

**Further applicable item-specific technical documents are listed in the relevant Annex B**

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## 1. Planning and Scheduling

1.1 Schedule progress updates and integration will be performed in line with the ITER P&S Manual (IDM reference: ITER\_D\_2DWMCW, v 3.0)

## 2. Procurement Execution

The execution of this PA shall be phased per Annex B:

### **TIP**

Phase I: Execution of the Preliminary Design.

Phase II: Execution of the Final Design.

Phase III: Fabrication and Manufacture of the Items, inclusive of Factory Acceptance Testing.

Phase IV: Delivery of the Items to respective delivery destinations.

Phase V: Technical Support during Assembly and Installation of the Items as defined in ITER D 4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase VI: Commissioning of the System as defined in ITER D 4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase VII: Provision of all Technical and Quality Documentation.

### **ECE**

Phase I: Execution of the Preliminary Design.

Phase II: Execution of the Final Design.

Phase III: Fabrication and Manufacture of the Items, inclusive of Factory Acceptance Testing.

Phase IV: Delivery of the Items to respective delivery destinations.

Phase V: Technical Support during Assembly and Installation of the Items as defined in ITER D 4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase VI: Commissioning of the System as defined in ITER D 4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase VII: Provision of all Technical and Quality Documentation.

### **EP#9**

Phase I: Execution of the Preliminary Design.

Phase II: Execution of the Final Design.

Phase III: Fabrication and Manufacture of the Items, inclusive of first phase of Factory Acceptance Testing.

Phase IV Integrated Assembly and Integrated Functional Test (In Air)

Phase V: Integrated Environmental test in the PPTF inclusive of final Factory Acceptance Test.

Phase VI: Delivery to IO Site.

Phase VII: Technical Support during Assembly and Installation of the Items as defined in ITER\_D\_4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase VIII: Commissioning of the System as defined in ITER\_D\_4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase IX: Technical Support during the period of Technical Obligation as defined in ITER\_D\_4HCXYP - On site work by the U.S. Domestic Agency V1.0.

Phase X: Provision of all Technical and Quality Documentation.

### **3. Tendering Process**

- 3.1. The DA shall ensure that applied procurement procedures and contracts with suppliers in order to fulfil its obligation(s) under this PA comply with laws, rules and regulations applicable to the DA.
- 3.2. At least 20 (twenty) working days prior to the commencement of any tender action to potential suppliers for the Items subjected to this PA, the DA shall provide the IO with a written description of the procurement process for the award of contracts in support of this PA (hereinafter referred to as the "Procurement Description"). The IO shall, within 15 (fifteen) calendar days of receipt of the Procurement Description (PD), inform the DA in writing of its approval or disapproval of the PD. Failure to respond within 15 calendar days shall be deemed an approval and the procurement can proceed. The Procurement Description shall be prepared using the standard template to be retrieved from IDM (IDM reference: ITER\_D\_2LFF4U, v1.6). The Procurement Description shall describe the following:
  - a. the type of procedure to be followed,
  - b. tendering schedule, including the forecast tender issue dates, tender durations, estimated evaluation meeting dates and estimated award dates,
  - c. controls and processes to ensure an acceptable end item is provided if the DA determines that more than one supplier is to be awarded contracts,
  - d. Intellectual Property provisions unless already confirmed by the IO,
  - e. the selection criteria ensuring that suppliers have (1) the necessary technical and professional capacity and competencies to do the work, (2) demonstrated experience in providing similar supplies. The extent of necessary experience in terms of years will be determined by the



Parties, depending on the subject of tender, prior to the start of each tendering procedure.

- 3.3 Regarding items (d) and (e) of section 3.2, a Hold Point is established. Hold Point clearance shall be given within 10 (ten) working days after receipt of the Procurement Description. If Hold Point clearance or confirmation of disapproval is not provided within this time frame, the Procurement Description is deemed to be approved by the IO and the DA may continue its procurement activities. In case of IO disapproval, the Procurement Description shall be revised according to IO instructions. -
- 3.4 In case of a procedure other than open tender procedures, the DA shall provide the IO with the list of pre-selected candidates within 10 (ten) calendar days of the selection of the candidates. In case of open tender procedures, the DA shall provide the IO with the final list of tender firms within 10 (ten) calendar days of the receipt of the tenders.
- 3.5 In addition the DA shall provide to the IO with an advance notification of 10 (ten) calendar days prior to evaluation meetings in order to give the IO the opportunity to participate thereto. As part of the Items are safety important components, concurrence from IO regarding the award of contracts to Supplier and Subcontractors is required. Prior to the award of contracts by the DA, the IO shall have the opportunity to participate in the DA's supplier evaluation, which will occur after DA's review and preliminary assessment of proposals. An IO representative shall therefore be allowed to take part in the technical assessment of the tenders by serving as an advisor to the DA's evaluation team; however there is no need for the IO to assess the financial aspects, provided the financial health of a successful Supplier is not being questioned. After the award of the contract, subcontracting is subject to IO concurrence if the proposed sub-contractor(s) were not identified in the original proposal. If the DA does not receive written notification of the IO's objection to the proposed contract/subcontract within 7 (seven) working days, the DA and its Supplier may proceed with the award. All IO representatives will be required to execute a confidentiality certificate prior to reviewing any proposal information.
- 3.6. In case of any change to the original Procurement Description submitted by the DA to the IO, the IO shall be advised immediately by means of an update of the description. If such change is made with reference to items specified in points d., e. and f. of section 3.2 of this Annex, section 3.3 of this Annex shall apply *mutatis mutandis*.
- 3.7 The IO reserves the right to observe and advise in the DA procurement tendering process used under this PA within the limits set out in the ITER Agreement and subsidiary ITER Council approved documents, however, IO and DA shall mutually agree on the Selection Criteria of procurement tendering process before the call for tender.

#### **4. Monitoring, Evaluation and Verification**

- 4.1. Procurement follow-up procedures are defined in section 3.2 of Annex B and include, among others, Notification Points, Authorization-to-Proceed Points, Hold Points, Witness and Surveillance Points.

- 4.2. Any contact with the suppliers of the DA under this PA by the IO shall be managed and coordinated by the DA.

### ***Periodic Reports and Meetings***

#### **Reporting**

- 4.3. The DA shall ensure that its suppliers submit periodic reports to the DA and agree on periodic review meetings with the DA in order to monitor contract execution. The DA shall also ensure that its suppliers maintain data and documents and make them available upon DA's request to verify that the PA requirements have been satisfied. Such reports, data and documents shall be transmitted to the IO, if required, for the approval/acceptance of milestones by the IO.
- 4.4 The DA shall provide to the IO a monthly progress report (per Annex B) on all works under this PA by the 5th working day of each month. The report shall be prepared using the standard template to be retrieved from IDM ([PA monthly report \(IDM reference: 2E346G\)](#), v1.4).
- 4.5. All documentation to be delivered to the IO must be in English unless the IO approves exceptions in the interest of rapid transmission. Final documentation for IO's records shall be in English. Quality control documents at the supplier level (such as procedure specifications) need not to be translated into English unless specifically requested by the IO.
- 4.6. The DA will report as soon as possible to the IO of any occurrence which could delay or jeopardize the proper execution of activities related to this PA.

#### **Progress meetings**

- 4.7. Progress meetings shall be conducted as required by the IO or the DA upon mutual agreement. The frequency of such meetings shall vary throughout the progress of the PA. The meetings shall be held by video conference, teleconference or physically on the IO or the DA premises or, upon approval by the DA, on the supplier's premises.
- 4.8. Meeting minutes shall be prepared by the DA and submitted to the IO not later than 5 (five) working days after the meeting.
- 4.9. The IO shall forward to the DA any comments within 5 (five) working days of the receipt of the minutes. If no comments are made within this time frame, the minutes are deemed to be accepted.

### ***Reviews and Inspections***

#### **Reviews**

- 4.10. The IO shall organize design reviews with the DA in line with the ITER Design Review Procedure (2832CF v1.12).
- 4.11. Reviews shall be carried out according to section 3.2.4 of Annex B1, Annex B2 and Annex B3.

- 4.12. In case of concerns regarding the quality of production, the IO reserves the right to perform unscheduled inspections and may request the DA to carry out on-the-spot checks in addition to the checks foreseen in the technical specifications. In such a case, the IO has to provide a description of its concerns and the rationale behind such request. Upon receipt of such request, the DA shall evaluate the potential impact of such unscheduled inspections on the production costs and schedule. Based on all these considerations, the Parties shall agree on a course of action to tackle such issues. The actual date(s) of the unscheduled inspections shall be determined by agreement between the Parties.

### **Right of Access**

- 4.13. The DA shall ensure that its suppliers inform the DA of all locations where contracts are implemented. The DA shall provide the IO with such information when requested. It shall further ensure that contracts include the rights of on-the-spot access to specified locations subject to the following provisions in this section. All the following rights of access shall be given for the sole purpose explicitly provided herein.

#### ***Right of access of the DA***

- 4.14. The DA shall ensure that its representatives are granted access to the premises of the suppliers and sub-suppliers in order to witness on-site tests and critical fabrication operations, and to participate in periodic review meetings.
- 4.15. The DA shall also ensure that its representatives are granted access to the premises of the suppliers and sub-suppliers at all reasonable times in order to carry out on-the-spot checks in addition to the tests foreseen in the technical specifications.
- 4.16. The IO shall ensure that the DA and its suppliers shall be granted appropriate access rights to the ITER Site for acceptance testing of the Items to be supplied to the IO.

#### ***Right of access of the IO***

- 4.17. The DA shall grant access rights to the IO and regulatory body representatives to its facilities and records and those of its supplier(s) for the purposes defined in the ITER Procurement Quality Requirements (IDM reference ITER\_D\_22MFG4, v4.0).
- 4.18. When visits for purposes other than indicated in article 4.17 are envisaged, the request of IO must be submitted at least 15 (fifteen) calendar-days in advance, unless otherwise agreed by the Parties. The DA shall make its best efforts to ensure that appropriate facilities are available for use by such representatives.
- 4.19. In case of marked up interventions in the Manufacturing and Inspection Plan, it is the DA's responsibility to ensure that adequate notice is given to the IO to facilitate such interventions and make travel arrangements.
- 4.20. The IO shall agree with the DA in advance of the appointed IO representatives who will participate in activities described in the preceding

sections. The appointed IO representatives must always be accompanied by DA representatives on their visits to the DA's and/or its suppliers' premises unless otherwise agreed by the Parties. The IO representatives shall be bound by appropriate confidentiality obligations to be agreed in advance.

- 4.21. The DA will assist in the expedition of the necessary access documentation (such as visas) for the appointed IO representatives, if required.
- 4.22. If the right to access by the IO involve individuals from Entities, Terrorist Sponsoring States, Denied Parties as defined under 5 CFR 744 then an applicable export control license may be required as required under U.S. Export Control Laws and Regulations. If the technology is controlled at a higher level, e.g. National Security, any foreign national who has such access to such technology may require an export license. Access by personnel falling under this section as well as those from sensitive countries requires at least 60 to 90 days prior notice, although it may take longer for a visa to be granted.
- 4.23. The IO may propose a one time clearance for a limited amount of people for certain duration upon which those people can enter the site without restriction during such period. This may include a few people from the IO.

***Right of access of interfacing DAs***

- 4.24. In the event where another DA interfacing with the DA, the DA shall ensure the supplying DA, and if applicable their suppliers, shall have appropriate access rights.
- 4.25. the other DAs shall nominate their representatives who will participate in activities described in the preceding section. The appointed DA representatives must always be accompanied by DA representatives on their visits to the DA's and/or its suppliers' premises unless otherwise agree. The other DA representatives shall be bound by appropriate confidentiality obligations to be agreed in advance.
- 4.26. The DA will assist in the expedition of the necessary access documentation (such as visas) for the appointed DA representatives, if required.
- 4.27. If the right to access by other DAs involve individuals from Entities, Terrorist Sponsoring States, Denied Parties as defined under 5 CFR 744 then an applicable export control license may be required as required under U.S. Export Control Laws and Regulations. If the technology is controlled at a higher level, e.g. National Security, any foreign national who has such access to such technology may require an export license. Access by personnel falling under this section as well as those from sensitive countries requires at least 60 to 90 days prior notice, although it may take longer for a visa to be granted .
- 4.28. The DA may propose a one time clearance for a limited amount of people for certain duration upon which those people can enter the site without restriction during such period. This may include a few people from the IO.

**Right of access of the French Safety Authorities and/or Third Party**

- 4.29. For the supply of Items to be procured under the PA, which are classified as “Safety Important Component (SIC)”, the DA shall ensure that the French Safety Authorities and/or Third Parties which are contracted for inspection purpose by the IO are granted appropriate access, in accordance with the provisions of section 4.16 herein, to the DA and the Suppliers and Subcontractors facilities and records for surveillance, inspection (including unscheduled inspections) or audit, as requested by them in accordance with the applicable national laws and regulations that the IO shall observe as stated in Article 14 of the ITER Agreement. Such access shall be coordinated in advance with the DA by the IO.
- 4.30. If the right to access by the French Safety Authorities and/or Third Party involve individuals from Entities, Terrorist Sponsoring States, Denied Parties as defined under 5 CFR 744 then an applicable export control license may be required as required under U.S. Export Control Laws and Regulations. If the technology is controlled at a higher level, e.g. National Security, any foreign national who has such access to such technology may require an export license. Access by personnel falling under this section as well as those from sensitive countries requires at least 60 to 90 days prior notice, although it may take longer for a visa to be granted

**5. Quality Assurance**

- 5.1. Quality Requirements shall be in accordance with the ITER Procurement Quality Requirements (IDM reference: ITER\_D\_22MFG4 V4.0). The DA shall also ensure the quality of all components and services meet the requirements of Annexes A and B of the PA.
- 5.2. Should any question whatsoever arise with respect to the requirements defined in the ITER Procurement Quality Requirements or in Annexes A and B, the DA shall ask the IO for clarification prior to proceeding with the work.
- 5.3. The DA Quality Assurance Program (hereinafter referred to as “QAP”) subject to approval by the IO in accordance with the ITER QA Program shall be applied to all the work under this PA. The ITER QA Program is developed to meet the requirements of the French Quality Order dated August 10, 1984. For this purpose, the DA shall ensure that the suppliers carrying out contracts placed under the PA are in compliance with the QA requirements under the relevant QA classifications.
- 5.4. A list of the documentation associated with the ITER Procurement Quality Requirements is given in Table 1 below. Moreover, on completion of the tender process, a description of the supplier’s quality system is submitted to the IO for information.

IO Quality Requirements	IO Quality Documents
<b>Prior to commencement of work on the PA:</b> <ul style="list-style-type: none"> <li>▪ Obtain IO approval of Domestic Agency’s dedicated “Quality Plan”</li> </ul>	“Quality Plan”, ITER_D_22MFMW v3.0
<b>Prior to commencement of contract work :</b> <ul style="list-style-type: none"> <li>▪ Obtain IO acceptance of Supplier’s/Subcontractor’s dedicated</li> </ul>	

"Quality Plans"	
<b>Prior to start of manufacturing:</b> <ul style="list-style-type: none"> <li>▪ Obtain IO acceptance and mark up of Supplier's/Subcontractor's "Manufacturing and Inspection Plans (MIPs)"</li> </ul>	"Manufacturing and Inspection Plan", ITER_D_22MDZD v2.1
<b>During manufacture:</b> <ul style="list-style-type: none"> <li>▪ Update Quality Plans as necessary and seek IO re-acceptance</li> <li>▪ Notify IO representatives of any intervention points as marked up on the "MIPs"</li> <li>▪ Sign the relevant operations and interventions in the "MIPs" as work progresses.</li> </ul>	
<b>During contract implementation:</b> <ul style="list-style-type: none"> <li>▪ Issue "Deviation Request" and "Non-Conformance Reports" as necessary</li> </ul>	"MQP Deviations and Non Conformances", ITER_D_22F53X v5.1
<b>Prior to delivery:</b> <ul style="list-style-type: none"> <li>▪ Complete the "Contractor Release Note"</li> </ul>	"MQP Contractors Release Note", ITER_D_22F52F v4.1

Table 1: IO Quality Requirements.

5.5. Quality Plans are produced by the DA, Suppliers and Subcontractors unless otherwise agreed between the parties and describe how they will implement the ITER Procurement Quality Requirements. Approved DA Quality Plans are accepted by the IO, approved Supplier Quality Plans are accepted by the DA and accepted by IO, and approved Subcontractor Quality Plans are accepted by the Supplier and accepted by the DA, then sent to IO for acceptance.

5.6. MIPs are used to monitor Quality Control and acceptance tests and must be produced by each Supplier and Subcontractor, unless otherwise agreed between the Parties.

The DA marks up its intended intervention points on the Supplier's MIP, accepts the plan and sends it to IO for acceptance and mark-up of any IO interventions.

The Supplier mark up its intended intervention points on the Subcontractor's MIP, accepts the plan and sends it to the DA.

The DA marks up its intended intervention points on the Subcontractor's MIP, accepts the plan and sends it to IO for acceptance and mark-up of any IO interventions.

It should be noted that interventions additional to those required in Annex B may be included on the MIP by IO if justified.

5.7. MIPs are not normally required for the qualification of special processes however they are required for the manufacture of prototypes.

5.8. Subcontractors not performing critical quality activities may be exempted from the requirement to produce Quality Plans and MIPs at the discretion of the IO Quality Assurance Responsible Officer and in discussion with the DA Quality Assurance Responsible Officer. This decision will be dependent on the level of detail about sub-contracted work in the Suppliers Quality Plan. In such cases, the work can be included in the Supplier's MIP and managed in accordance with the Supplier's management system.

- 5.9. The DA shall ensure that suppliers and subcontractors do not start work on any contract without a Quality Plan in place that has been accepted by the IO.
- 5.10. The DA shall ensure that suppliers and subcontractors do not start manufacturing without an MIP in place that has been accepted by the IO.
- 5.11. The DA shall implement, in compliance with its QA Programme approved by the IO, the monitoring activities including quality audits and any inspections to verify the compliance with the requirements.
- 5.12. The IO shall designate appropriate certified auditors to conduct quality audits to verify compliance with the DA's Quality Assurance Program. The audit teams may be composed of IO personnel and/or specialist contracted personnel.
- 5.13. The IO shall designate appropriate inspectors to perform inspections of the DA's suppliers and sub-contractors to verify compliance with quality related activities. These inspections will be performed in accordance with the MIPs or in accordance with 4.12. The inspectors may be IO personnel or specialised inspectors contracted for that purpose.

## 6. Licensing requirements

- 6.1. Certain Items that are the subject of this PA are classified as Safety Important Component to which French Order dated August 10, 1984 applies, as detailed in Section 4.4.1 of Annex B.
- 6.2. For the Safety Important Components and systems of the nuclear facility, the DA shall ensure that:
- Quality Assurance requirements are fulfilled by a system that complies in particular with the requirements of Articles 3 and 4 of the Order of August 10, 1984 (Arrêté du 10 Août 1984) including all superseding orders;
  - The Suppliers and Subcontractors must be informed that a "significant" NCR, as defined in Article 13 of the Order of 10<sup>th</sup> August 1984 shall be reported by IO, as the operator, to the safety regulators as soon as possible;
  - A specific management system has to be implemented by any Supplier and Subcontractor working on nuclear safety related activities, on the basis of activities defined by the Supplier and Subcontractor. This system could be included in the Manufacturing and Inspection Plan or the Quality Plan, as set out in Pars. 5.5 and 5.6.

The DA shall ensure that the Suppliers and Subcontractors comply with the QA requirements under the relevant QA classifications.

- 6.3. The IO and the DA commit to apply all rules and implement all necessary actions imposed by the French Law applicable to the IO.
- 6.4. Pursuant to Article 14 of the ITER Agreement, the IO and DA shall apply all applicable rules and regulations resulting from French Laws and Regulations with respect to Licensing (ITER\_D\_2WBB8P) published at the date of

signature of the PA. Responsibility for cost (and schedule effects) of these regulatory changes after the date of signature of the PA shall be agreed through the project change management procedure and the PA shall be amended in accordance with Article 9.

## 7. CE Markings

7.1 CE Markings shall be implemented in accordance with European directives requirements.

7.2 The list of European directives concerning CE marking is available on the following web site <http://www.conformance.co.uk/directives/index.php>. Other useful information can be found in the "Guide of implementation of directives based on the New Approach and the Global Approach":  
[http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic\\_en.pdf](http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf)

## 8. Change Management

8.1 All requirements of this PA and subsequent changes proposed by either the IO or the DA during the course of execution of the PA are subject to the Deviation Request process described in "ITER Deviations and Non-Conformances" (IDM reference: ITER\_D\_22F53X, v4.4 or 2LZJHB v2.2) and referenced in Section 5.4 above.

## 9. Risk Management

9.1 The DA shall, within 90 (ninety) calendar days of the entry into force of the PA, draw up and submit to the IO, for information, a plan for managing risks associated with implementing the PA (hereinafter referred to as the "PA Risk Plan"). Additional details on the Risk Management Programme can be found in "MQP Risk Management Plan" (ITER IDM 22F4LE v2.1).

9.2 The PA Risk Plan shall set out a register of the risks which may impinge on the successful execution of the PA following the applicable DA Risk Management system and, for each identified risk shall provide:

- a summary assessment of likelihood of the risk materializing and of the potential consequences for the successful execution of the PA,
- possible measures for risk reduction or mitigation and conditions for triggering such measures,
- an attribution of responsibility in the structure of the DA for managing the risk,
- a plan, consistent with the baselined PA milestones (coded with IOMASTER-PABL), and arrangements for regular monitoring and review of the risk.

9.3 The DA shall implement possible measures for risk reduction and mitigation following a graded approach and shall provide to the IO progress reports on a quarterly basis in accordance with the standard template to be retrieved from IDM ("Risk Identification and Analysis Template", ITER\_D\_2PMZYP v1.4).



- 9.4 If and when conditions to trigger specific risk reduction and mitigation measures occur, the DA shall inform the IO promptly. The Parties shall consult on the appropriate actions to be taken and on their consequences for the execution of this PA.

## 10. Information and Documentation Requirements

### General Documentation Requirements

- 10.1 The DA shall prepare the following documents in the English language unless otherwise provided in this PA:
- Intellectual Property provisions,
  - each definitive technical specification for a contract under this PA,
  - day-to-day correspondence and administration between the Parties,
  - all documents that are necessary to determine the progress and status of work and validate the capabilities of involved suppliers,
  - all QA and safety related documentation,
  - Other documentation as agreed by the Parties.
- 10.2 The working language of the ITER Project is English. In subsequent execution of a contract, misunderstandings due to mistranslation into the Member's preferred language other than English are the responsibility of the DA.
- 10.3 The DA shall issue, manage and control its documents and records in accordance with its QA Programme.
- 10.4 The DA shall ensure that all documents and records are uniquely identified and traceable by PA references, including subsequent revisions, and are made accessible to IO authorized individuals.

### Design Documentation Requirements

- 10.5 The DA shall ensure that all designs and manufacturing drawings prepared by the DA or its Suppliers comply with Design Collaboration Implementation Form (DCIF) for the Design activities related to the Procurement of Low Field Side Reflectometry Items (IDM reference: ITER\_D\_6NV6WF, v3.0 ), Procedure for the Usage of the Protocol of CAD Design Collaboration (ITER\_D\_2EGJ27 v1.2) and the Procedure for the Usage of the ITER CAD Manual (ITER\_D\_2F6FTX v1.1)
- 10.6 The DA shall exchange CAD data relevant for the design and associated interfaces with the IO in the CATIA version indicated in the latest version of the ITER CAD Manual released by the Design Office of the IO. CAD data associated only with production may be exchanged in other formats if compatible with the IO software and if agreed by the IO. The DA shall ensure then that CAD data from its Suppliers is accurately converted to such version of CATIA.
- 10.7 All 3D models and 2D drawings are subject to the Procedure for the Management of CAD Work & CAD Data (Models and Drawings, IDM reference: ITER\_D\_2DWU2M, v1.7).
- 10.8 The DCIF reference for TIP is [5.5.P4.US.01 DCIF for the Toroidal Interferometer/Polarimeter \(A4YTM2\)](#)

The DCIF reference for ECE is [5.5.P4.US.01 DCIF for the ECE Front End and Receiver \(BP4XJF\)](#)

The DCIF reference for UP#09 is [5.5.P4.US.01 DCIF for Equatorial Port#9 Engineering \(BP7RS9\)](#)

## Quality Records

10.9 Quality Control and Acceptance Test records shall be maintained according to the procedures defined in Section 1.6.2 of Annex B. Availability to the IO of the required data is a pre-requisite for granting Authorizations to Proceed and Hold Point clearances.

## 11. Environment, Safety and Health<sup>1</sup>

11.1 The DA shall ensure that its Supplier observes all applicable environment, safety and health provisions for work on the ITER Site in Cadarache, as well as specific requirements set out in Annex B.

11.2 Any activity by DA personnel or its Suppliers at the ITER Site shall be subject to the “Internal Regulations” (IDM reference: ITER\_D\_27WDZW, v1.3) and “Working Conditions on the ITER Organization Site” (IDM reference: ITER\_D\_2EQ9JM, v1.1).

11.3 Any activity by DA personnel or its Suppliers and Subcontractors on the ITER Construction Site shall be subject to the “General Safety Rules – Volume 0” (Ref: ITER\_D\_2NUEYG v1.3) and resulting procedures. Any additional applicable provisions regarding environment, safety and health shall be communicated by the IO to the DA at least 30 calendar days in advance of the activities to be performed at the ITER Site.

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<sup>1</sup> In case the Contractor is to be engaged in the work performed on site.