



CLASSIFICATION Unclassified Non-Sensitive	EDRM UID 809e67f7 - 1.0	ICP Number ITER_D_G2S6W9
EXTERNAL REFERENCE	VERSION CREATED ON / STATUS 15 Jun 2026 / Published	
PA DESIGN DOCUMENT TYPE N/A	DRAWING NUMBER	DRAWING REV
PA/TA NUMBER(s) 5.5.P1.US.01 - Diagnostic RGA		iDOCS UID

Statement of Work (SOW) for the Design and Fabrication of the Diagnostic Residual Gas Analyzer (DRGA)

Abstract or description:

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Author	Witek, Konrad	20 May 2026	Signed
Reviewer	Campbell, Amelia	01 Jun 2026	Recommended
Reviewer	Oram, Jeff	28 May 2026	Recommended
Reviewer	Quinlan, Brendan	21 May 2026	Recommended
Reviewer	Rowland, Clark	04 Jun 2026	Recommended
Reviewer	White, Andrew	22 May 2026	Recommended
Approver	Hart, Ainsley	15 Jun 2026	Approved

Change Log

Version	State	Date	Version Change Description
v1.0	Published	15 Jun 2026	Change magnetic shielding section to 25mT outer shield. Updated references, and implemented comments from initial review.

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1. INTRODUCTION

ITER is a joint international research and development project with the programmatic goal to demonstrate the scientific and technical feasibility of fusion power. The ITER machine is being constructed in Cadarache, France and is a collaboration with 7 partners consisting of the United States, European Union, China, Russia, South Korea, Japan, and India. The US ITER Project Office (USIPO) is hosted by Oak Ridge National Laboratory (ORNL), which is located in Oak Ridge, Tennessee and hereinafter referred to as the “Company”. ORNL works in partnership with Princeton Plasma Physics Laboratory (PPPL) and Savannah River National Laboratory (SRNL) on USIPO scope. The ITER Organization (IO) and Domestic Agencies consider nuclear safety, occupational health and safety, quality and environment as their first priorities, as defined in IO policy [3.1.29].

1.1 Project Overview

The Diagnostic Residual Gas Analyzer (DRGA) is a diagnostic device used to detect light gases in the sub-diverter region of the ITER tokamak. The DRGA will be used for various scientific measurements as well as basic control. The DRGA utilizes both mass and optical spectroscopy to measure the composition of exhaust gases in the edge and divertor regions, specifically to analyze the amounts of helium and hydrogen isotopes present in real time. There are two (2) DRGAs in the ITER tokamak facility, one located in Equatorial Port 11 (EP11), and one located in Lower Port 12 (LP12). Both EP11 and LP12 DRGA Analysis Stations will be delivered to the IO.

2. SCOPE

This statement of work (SOW) defines the activities to be performed by the Seller, consisting of the design, validation, fabrication, inspection, packaging, and preparation for shipment of both EP11 and LP12 DRGA Analysis Stations. The shipment of the items to the IO is not within the scope of this SOW and will be handled by the Company’s designated Logistics Services Provider (LSP). The technical requirements for the DRGA Analysis Chambers are defined in the corresponding DRGA Technical Specifications [3.1.2] and its corresponding references. All work performed per this SOW will conform to these requirements and standards.

This procurement begins with preparation of a Design Package of both EP11 and LP12 Analysis Stations. The Seller is expected to demonstrate that the proposed design will meet the technical requirements through a design review. This procurement may be executed in two phases: (1) Design Phase and (2) Fabrication Phase. Authorization to proceed to Fabrication Phase will be provided by the Company following approval of the Design Package, IO approval, and the close of the final design review. The Seller shall assume no fabrication work without written authorization to proceed from The Company. Qualification and factory acceptance testing of the unit will be performed.

- Design of EP11 Analysis Station includes:
 - Analysis Station Frame
 - Analysis Chamber (including pipes, gate valves, flanges, pressure gauges, QMS, magnetic shielding, etc.)

- Inter-Pump Volume & Forline (including pipes, flanges, orifice, pumps, pressure gauges, plasma cells, magnetic shielding, etc.)
- Calibration Gas System (including pipes, bottles, isolation valves, etc.)
- Enclosure
- Design of LP12 Analysis Station includes:
 - Analysis Station Frame
 - Analysis Chamber (including pipes, gate valves, flanges, pressure gauges, QMS, magnetic shielding, etc.)
 - Inter-Pump Volume & Forline (including pipes, flanges, orifice, pumps, pressure gauges, plasma cells, magnetic shielding, etc.)
 - Calibration Gas System (including pipes, bottles, isolation valves, etc.)

The technical specifications [3.1.2][3.1.3] and [3.1.4] provide a detailed classification by component. All deliverables must follow the DRGA Quality Plan [3.1.5] and applicable requirements in the ITER Vacuum Handbook [3.1.6]. Cable Block Diagrams (CBD) will be provided for EP11 [3.1.7] and LP12 [3.1.8]. Piping and Instrumentation Diagram (P&ID) will also be provided for EP11 [3.1.9] and LP12 [3.1.10]. General Arrangement (GA) Drawings will be provided [3.1.11] and [3.1.12].

In addition to the design package described above, the scope of this SOW includes the following for fabrication, in accordance with the requirements and references noted herein:

- Project management (including reporting)
- Creation of manufacturing drawings for fabrication of components
- Writing procedures and plans for fabrication of components
- Material Procurement
- Completion of the Manufacturing Readiness Review
- Fabrication
- Inspection and Testing
- Preparation for Transportation and Packaging

The hardware within the scope is classified as shown below:

Table 1: DRGA Classifications

Classification Type	Component Classification(s)
Safety Classification	SIC-2
Quality Classification	QC1
Vacuum Classification	VQC-1A
Pressure Equipment Classification	0 / SEP
Seismic Classification	SC1(S)
Tritium Classification	TC-1A

3. APPLICABLE DOCUMENTS

Unless otherwise specified, the correct revisions of national and international standards, US ITER technical documents, drawings, specifications and other job-related documents will be identified on the Current Reference List (CRL) for the Design and Validation of the Diagnostic Residual Gas Analyzer (DRGA) (EDRM 8089518a) provided at the time of award and as reference documents are updated.

3.1 References

- 3.1.1 *Current Reference List for the Design and Validation of the Diagnostic Residual Gas Analyzer (DRGA)*, 8089518a
- 3.1.2 *Technical Specification for the Design and Validation of the Diagnostic Residual Gas Analyzer (DRGA)*, 80989517
- 3.1.3 *Technical Specification for the ITER-Style Vacuum Flanges*, 8094a339
ITER_D_FDKZWK
- 3.1.4 *Technical Specification for DRGA Internal Bellows*, 8096cae1
ITER_D_FMY9VU
- 3.1.5 *ITER Quality Plan for Procurement Arrangement on Diagnostics Residual Gas Analyzers (DRGA)*, 803f2a04
- 3.1.6 *ITER Vacuum Handbook*, ITER_D_2EZ9UM
- 3.1.7 *Cable Block Diagram (CBD) for Diagnostics Residual Gas Analyzer (DRGA) in Equatorial Port 11*, 807a950d ITER_D_SLWES3
- 3.1.8 *Cable Block Diagram (CBD) for Diagnostics Residual Gas Analyzer (DRGA) in Lower Port 12*, 806c0a64 ITER_D_SLUQTZ
- 3.1.9 *Piping and Instrumentation Diagram (P&ID) for Diagnostic Residual Gas Analyzer (DRGA) in Equatorial Port 11*, 8042fced ITER_D_SK5UQC
- 3.1.10 *Piping and Instrumentation Diagram (P&ID) for Diagnostics Residual Gas Analyzer (DRGA) in Lower Port 12*, 803f0ef9 ITER_D_QX3GK4
- 3.1.11 *General Arrangement (GA) Drawing for Diagnostic RGA Equatorial Port 11 (EP11) Analysis Station, DWG 069164*, 808383f4 ITER_D_EAXH79
- 3.1.12 *General Arrangement (GA) Drawing for Diagnostic RGA Lower Port 12 (LP12) Analysis Station, DWG 069712*, 808383ef ITER_D_EAXE4G
- 3.1.13 *Validation Plan for 55.G4 Diagnostic RGA Quadrupole Mass Spectrometer (QMS)*, 80941fd0

Company Documentation

- 3.1.14 *Quality Plan Template for Suppliers and Subcontractors*, 8043657d
- 3.1.15 *US ITER Design Analyses and Calculations Procedure*, 803f35ae
- 3.1.16 *Test Method for ITER Equipment for Static Magnetic Fields* ITER_D_98JL4W
- 3.1.17 *Manufacturing Readiness Review Procedure*, 804a455c
- 3.1.18 *Deviation Request Procedure*, 803fee84
- 3.1.19 *Deviation Request Form*, 803f59df
- 3.1.20 *Non-Conformance Report Procedure*, 803f913f
- 3.1.21 *Non-Conformance Report Form*, 8043b412
- 3.1.22 *Contractor Release Note Procedure*, 8041191f
- 3.1.23 *Contractor Release Note Form*, 803f4967
- 3.1.24 *Inspection Plan (IP) Template*, 80411682
- 3.1.25 *Quality Clauses for Procurement*, 803fae52
- 3.1.26 *Procurement Arrangement Document Exchange Procedure*, 803f78cc
- 3.1.27 *Design and Analysis Calculation Qualification Record*, 80412251
- 3.1.28 *Design Analysis and Calculations Procedure*, 803f35ae

National/International Standards

- 3.1.29 *ITER Policy on Safety, Security, Quality and Environment Protection*, ITER_D_43UJN7
- 3.1.30 *General requirements for the competence of testing and calibration laboratories*, ISO/IEC 17025
- 3.1.31 *Conformity assessment — Supplier's declaration of conformity — Part 1: General requirements*, ISO/IEC 17050-1
- 3.1.32 *Conformity assessment — Supplier's declaration of conformity — Part 2: Supporting documentation*, ISO/IEC 17050-2
- 3.1.33 *Regulation of Wood Packaging Material in International Trade, International Standard for Phytosanitary Measures*, ISPM 15

3.2 Codes and Standards

European Norm (EN), International Organization for Standardization (ISO), American Institute of Steel Construction (AISC), American Society of Mechanical Engineers (ASME), American Society for Testing and Materials (ASTM), American Welding Society (AWS), International Electrotechnical Commission (IEC), and other International standards mentioned in this SOW may be considered in their last revision at the time of contract signature, provided that equivalency is demonstrated. For a comprehensive list of codes and standards used, refer to the Technical Specification [3.1.2]. Exceptions must be clearly communicated with the Company technical project officer (TPO) and submitted as deviation requests for review and approval before any related work begins.

In case of change of edition year or issuing standard, which supersedes the above-mentioned standards, the use of new Standards is allowed only if equivalency is demonstrated and with prior written Company approval.

The use of EN but non-Norme Française (NF; French National) standards is also allowed if equivalence with the corresponding NF version of the Standard is demonstrated.

Other equivalent national or international standards and codes proposed by the Seller may be acceptable with prior written Company approval, provided conformity assessment to all criteria is satisfied.

3.3 Acronyms

ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BPVC	(ASME) Boiler and Pressure Vessel Code
COTS	Commercial Off The Shelf
CRL	Current Reference List
DN	Diameter Nominal
DRGA	Diagnostic Residual Gas Analyzer
DWG	Drawing (number)
EP	Equatorial Port
GPS	Geometrical Product Specifications
EJMA	Expansion Joint Manufacturers Association
FRS	Floor Response Spectra
IO	ITER Organization
ISO	International Standards Organization

JP	Junction Box
LP	Lower Port
NDE	Non-Destructive Evaluation / Examination
NDT	Non-Destructive Testing
ORNL	Oak Ridge National Laboratory
PNI	Part Number of ITER
QC	Quality Classification
RGA	Residual Gas Analyzer
SC	Seismic Classification
SIC	Safety Importance Classification
TMP	Turbomolecular Pump
USIPO	US ITER Project Office
VCR	Vacuum Coupling Radiation
VQC	Vacuum Quality Classification
XRF	X-Ray Fluorescence

4. PERFORMANCE REQUIREMENTS

4.1 Task 1. Quality Plan

4.1.1 Task Description

- a. The Seller is responsible for producing a Quality Plan in accordance with the Quality Plan Template for Suppliers and Subcontractors [3.1.14] and Section 5.2 of this SOW. The Seller's Quality Plan will be reviewed by the Company and the ITER Organization (IO) for acceptance.
- b. Company and/or IO personnel may choose to return comments to the Seller's plan. The Seller will resolve all comments to the satisfaction of the Company and/or IO personnel. The final contents of the plan will be agreed upon by the Seller and the Company (inclusive of the IO). Further work under this contract shall not begin until notice is received from the Technical Project Officer (TPO) that the Quality Plan (QP) is approved.

4.1.2 Seller Subcontractors

- a. The Seller will identify all Seller Subcontractors within Seller's approved Quality Plan. Alternatively, the Seller may produce the list separately, per Section 4.2.2, however separate lists must be referenced within the Seller's Quality Plan.
- b. The Seller will indicate if each Subcontractor provides an individual Quality Plan and Inspection Plan. Indication will be annotated within the Seller's Quality Plan, or within a separate list per Section 4.2.2 and above.

4.2 Task 2. Project Management

4.2.1 Task Description

The Seller will prepare a Project Management Plan that integrates each element of this task into a concisely written document. The Seller will submit the Project Management Plan to the Technical Project Officer (TPO), with copy to Company Procurement Officer, for Company comment within one week after the award of contract (AOC) and before the Kickoff Meeting (see Section 4.3).

All work under this SOW is to be performed at the Seller's Company-approved facility. If work under this SOW is to be performed at a lower-tier subcontractor's facility, Company approval is required prior to the beginning of such work. The Seller shall provide all shop facilities, fabrication machines, qualified shop personnel, management personnel, materials, inspection services, testing services, cleaning services, packaging services, required suppliers/subcontractors, software, hardware, and office space for completing this scope of work. The vendor shall procure any software or applicable hardware that is required for any validation.

4.2.2 Project Management Plan

The Project Management Plan will include, as a minimum:

- Seller's Point of Contact
- List of Seller's Contractors, per QA Plan requirements
- List of Seller's Project Team
- Project Schedule including key milestones and dates for contract deliverables
- Monthly Progress Reports
- Periodic Progress Meetings
- List of Action Items

4.2.3 Language

The working language of the project is English. All documentation submitted in fulfillment of this SOW shall be in English. In the subsequent execution of the contract, misunderstandings, and their consequences due to mistranslations into or from the Seller's or Manufacturer's preferred language other than English are the responsibility of the Seller.

4.2.4 Units

The International System of units (SI units) will be used throughout the project. All dimensions and parameters shall be reported in SI units (e.g., mm, kg, N, MPa, °C) as the primary units. In the subsequent execution of the contract, misunderstandings, and their consequences due to mis-conversion of units into or from the Seller's and/or Manufacturer's preferred unit system other than SI are the responsibility of the Seller.

4.3 Task 3. Kickoff Meeting & Progress

4.3.1 Project Kickoff Meeting

- a. The project kickoff meeting shall be scheduled at a mutually agreeable time as soon as practical after the award of the subcontract. The primary purpose of the project kickoff meeting is to meet the principal participants and to ensure the scope and expectations of the subcontract are understood.
- b. Discussion topics at the project kickoff meeting shall include the following:
 - Overview of the technical specification
 - Overview of quality requirements for the project including personnel certifications.
 - Overview of Seller's proposed design methodology, documentation package, and deliverables to the Company
 - Overview of prototyping, including materials requirements, fabrication, validation testing, and documentation requirements.
 - Overview of manufacturing readiness review (MRR)
 - Fabrication requirements
 - Final documentation package (manufacturing dossier)
 - Project schedule
 - Inspection plan (IP)
- c. If requested, the Seller shall arrange for a tour of the facility(s) where the equipment will be manufactured and validated. Seller and Company shall also discuss means of remote surveillance including remote witnessing of requested Control Points, in case it is deemed necessary.
- d. The Seller shall prepare the project kickoff meeting minutes within five working days of the meeting. If Seller has a presentation for the kickoff meeting as a response to the requirements of the kickoff meeting, then the Seller may submit the presentation with a list of any resultant action items as suitable meeting minutes. Company approval of the minutes represents a control point.

4.3.2 Project Schedule

- a. The Seller shall prepare a project schedule which outlines, at a minimum, all tasks, meetings, deliverables, milestones, and control points. The Company TPO / Technical Representative has the option to add additional items to the project schedule. During the project kickoff meeting, the Seller shall indicate projected start and end of all phases, including prototyping, manufacturing, final documentation, and packaging activities. Seller shall identify the location, responsible party, and scope of all testing activities, including subcontracted testing, and provide quality plans and related procedures for any outside Company the Seller subcontracts with to fulfill the requirements of this SOW and its related technical specification.

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- b. Because the Company reserves the right to witness any fabrication and inspection event, dates shall be scheduled to comply with Company travel requirements.

4.3.3 Point of Contact

- a. The Seller shall designate an official single Point of Contact (POC) to work with the Company's TPO and Procurement Officer (PO).
- b. Technical issues shall be discussed with the Company's TPO.
- c. Subcontract administration issues shall be discussed with the Company's PO.

4.3.4 Progress Meetings

- a. Progress meetings shall occur biweekly and at minimum both prior to commencement and after completion of each Authorization to Proceed Point (ATPP) control point. The meeting shall occur at a time, location, and method mutually agreed upon between the Seller and the Company.
- b. Either the TPO or Seller POC may also request progress meetings outside of ATPP control points to be scheduled at a mutually agreed upon date, time, and format.
- c. The discussions may include the Seller's progress, potential problems, resources, technical issues, contractual issues, manufacturing issues, inspection results, and value engineering.
- d. The Seller shall prepare and send minutes of the teleconferences and meetings to the TPO for review and approval within five business days.

4.3.5 Design Gate Meetings

- a. 50% Design Gate Meeting

The 50% design gate meeting shall occur at a mutually agreeable time with attendees from the Seller, US ITER and the ITER Organization. The Seller shall present their preliminary design which includes preliminary drawings and preliminary analysis. Any discrepancies and deviations from technical requirements shall be identified in this meeting. Meeting minutes will record design issues for resolution prior to the 90% design gate.

- b. 90% Design Gate Meeting

The 90% design gate meeting shall occur at a mutually agreeable time with attendees from the Seller, US ITER and the ITER Organization. The Seller shall present their finalized design which includes final drawings, final analysis, and final design-related deviation requests. Meeting minutes will record design issues for resolution prior to Manufacturing Readiness Review (MRR). All design deliverables shall be final and approved prior to MRR approval.

4.3.6 Monthly Progress Reports

- a. Monthly progress reports shall be submitted to the TPO and PO throughout the contract period. Monthly reports with schedule updates shall be submitted by the 20th day (or first business day after that date) of each month.

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- b. These reports shall address the following:
- Completed tasks and milestones during the reporting period
 - Outstanding issues and action items from the reporting period and previous periods
 - A forecast schedule shall be submitted monthly with the progress report, updating the completion dates for each phase and the % complete of each phase
 - Variance explanations and corrective actions with cause and impact description
 - Anticipated cost variances associated with issues encountered

4.3.7 List of Deliverables

- a. The Seller is responsible for producing and maintaining a design compliance matrix which identifies the design requirements from the technical specifications and defines the method for addressing the requirement including document deliverables, tests, and/or deviation requests.

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4.4 Task 4. Design and Analysis

All analyses shall clearly define pass/fail criteria and demonstrate compliance with applicable codes, standards, and technical specification requirements.

4.4.1 Statement of methodology

The Seller will assess the design and analysis task from the Company and produce a statement of methodology for each task. The statement of methodology shall include:

- a. Scope of analysis
- b. Reference documents
- c. Engineering standards
- d. Software used in the analysis task
- e. Methodology
- f. Definition of assumptions, load cases, boundary conditions, and acceptance criteria
- g. Names and qualifications of Seller personnel conducting analysis
- h. Estimated schedule to perform, check, and approve the analysis task

4.4.2 Meshing of Models in Preparation for Defeaturing

The Seller is responsible for performing meshing of models in collaboration with the Company's designer to assist in defeaturing as appropriate.

4.4.3 Electromagnetic (EM) analysis

- a. When assigned EM analysis tasks, the Seller is responsible for performing the analysis and producing a DAC in accordance with [3.1.15].
- b. The DAC produced must include signatures from a reviewer, technical checker, and independent reviewer.
- c. Native files produced during the analysis shall be submitted with the DAC.

4.4.4 Piping / Inertial Load Analysis

- a. When assigned inertial load analysis tasks, the Seller is responsible for performing the analysis and producing a DAC in accordance with [3.1.15].
- b. The DAC produced must include signatures from a reviewer, technical checker, and independent reviewer.
- c. Native files produced during the analysis shall be submitted with the DAC.

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4.4.5 Structural / Seismic Analysis

- a. When assigned structural analysis tasks, the Seller is responsible for performing the analysis and producing a DAC in accordance with [3.1.15].
- b. The DAC produced must include signatures from a reviewer, technical checker, and independent reviewer.
- c. Native files produced during the analysis shall be submitted with the DAC.

4.4.6 Assembly Tolerance Analysis

- a. When assigned assembly tolerance analysis tasks, the Seller is responsible for performing the analysis and producing a report identifying assembly tolerances and installation concerns. Discussions with technical team are expected to provide feedback during review.
- b. The report produced must include a list of reference drawings, documents and a 3D model.
- c. Native files produced during the analysis shall be submitted with the report.

4.4.7 Manufacturability Assessment

The Seller is responsible for performing a manufacturability assessment and producing a report. The report must include a list of manufacturing activities associated with the component design and comment on component manufacturing feasibility and assembly. Discussions with technical team are expected to provide feedback during review.

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4.5 Task 5. Magnetic Shielding Design, Testing, and Mitigation

4.5.1 Task Description

- a. Due to its location within the Tokamak, the DRGA and its constituent components must reliably operate within a magnetic field of 175 mT [3.1.2].
 - i. For the QMS referenced in the Technical Specifications [3.1.2], the vendor is responsible for reducing the magnetic field around the QMS (and any applicable attachments) to ≤ 25 mT (magnitude of maximum static magnetic field).
 - ii. The QMS shall be oriented to align with the tokamak radial direction. The magnetic field components are 141.17 mT (vertical) and 102.40 mT (radial). The matching unit shall be installed with the face of the electrical connections oriented toward the tokamak toroidal direction.
 - iii. If the vendor does not have a facility capable of magnetic shield testing up to 175 mT, the vendor shall provide a prototype shield for validation. Testing and validation of the prototype will be performed at The Company's facility. The Seller shall coordinate with the Company to schedule testing and shall deliver the prototype within a mutually agreed-upon testing window.
- b. The Seller shall develop a plan describing how compliance with magnetic shielding requirements will be demonstrated. Compliance shall be shown with the requirements in the validation plan [3.1.13]. Acceptance criteria shall include ≤ 25 mT at QMS location under 175 mT external field. The plan shall define test configurations, instrumentation, and acceptance criteria. The plan shall be reviewed and approved by US ITER prior to beginning of activities. Refer to the Technical Specification for the Design and Validation of the Diagnostic Residual Gas Analyzer (DRGA) [3.1.2], for magnetic shielding requirements.

4.5.2 Magnetic Shielding Test Plan

- a. For components and/or equipment that requires magnetic field testing, all testing will be conducted in accordance with Test Method for ITER Equipment for Static Magnetic Fields [3.1.16].
- b. The Seller will submit test plans developed for EMC testing to the Company for approval prior to conducting any and all EMC testing. Company and/or IO personnel may choose to return comments to the Seller's plan. The Seller is responsible for resolving all comments to the satisfaction of the Company and/or IO personnel. The final contents of the plan will be agreed upon by the Seller and the Company. Performance validation shall be performed in accordance with the US ITER Design Analyses and Calculations Procedure [3.1.15]. Validation testing will follow Test Method for ITER Equipment for Static Magnetic Fields (D.C.) [3.1.16].

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4.6 Task 6. Final Design and/or Testing

4.6.1 Prerequisite Task(s)

- US ITER approval of Task 1. Quality Plan
- US ITER approval of Task 2. Project Management
- US ITER approval of Task 3. Kickoff Meeting & Progress
- US ITER approval of Task 4. Design and Analysis
- US ITER approval of Task 5. Magnetic Shielding Design, Testing

4.6.2 Analysis Station and Frame Design

- 1) The Company will provide reference Analysis Station Frame drawings to the Seller in AutoCAD format. The reference drawings represent a frame design containing the components of the DRGA. If the Seller discovers information, characteristics, specifications, etc. are unachievable in the Company supplied or referenced information, the Seller will follow the instructions listed in Section 5.7.
- 2) Each of the individual Analysis Stations assembled by the Seller will have a different configuration (one for EP11, one for LP12). Specific configurations for each DRGA Analysis Station are outlined within the Technical Specification [3.1.2] and drawings.
- 3) The Seller will base each Analysis Station design on the reference drawings. The Seller is responsible for ensuring each Analysis Station configuration is a complete, fully functioning design.

NOTE: Reference 3.1.11 and 3.1.12 does not offer a detailed account of all internal components, cabling, and connectors required for each configuration. Final design of each Analysis Station is the responsibility of the Seller.

- 4) The Seller will produce a complete set of drawings in both Portable Document Format (*.pdf) and in CATIA format or, if not available, in AutoCAD format for each Control Cubicle configuration. The following drawings are required of each Analysis Station design package:
 - Analysis layout showing installation of all internal components
 - Wiring for the installed components
 - List of equipment based on actual installed components
- 5) EP11: The Seller will first produce a design package, inclusive of one set of drawings, for the EP11 DRGA Analysis Station. The package and drawings will be complete, checked, and in accordance with this Statement of Work and the requirements listed within the technical specifications [3.1.2]. The Seller shall submit the design package and drawings to the Company for review and approval

prior to manufacturing and/or assembly. The Seller may also be required to hold a formal design review (refer to Section 4.6.4). Company and/or IO personnel may choose to return comments to the Seller's design package and drawings. The Seller is responsible for resolving all comments to the satisfaction of the Company and/or IO personnel. The final contents of the design package and drawings will be agreed upon by the Seller and the Company. These packages are subject to the design review outlined in Section 4.6.4. Each design package and drawing set must be submitted to the Company for review and approval prior to manufacturing and/or assembly.

- 6) LP12: The Seller will first produce a design package, inclusive of one set of drawings, for the LP12 DRGA Analysis Station. The package and drawings will be complete, checked, and in accordance with this Statement of Work and the requirements listed within the technical specifications [3.1.2]. The Seller will submit the design package and drawings to the Company for review and approval prior to manufacturing and/or assembly, and may be required to hold a formal design review (refer to Section 4.6.4). Company and/or IO personnel may choose to return comments to the Seller's design package and drawings. The Seller is responsible for resolving all comments to the satisfaction of the Company and/or IO personnel. The final contents of the design package and drawings will be agreed upon by the Seller and the Company. These packages are subject to the design review outlined in Section 4.6.4. Each design package and drawing set must be submitted to the Company for review and approval prior to manufacturing and/or assembly.

4.6.3 Design Package Requirements

The Seller will submit the design packages to the Company for review. The initial contents of the design package will be by the Seller, but the final contents of the design will be agreed upon by the Seller and the Company. If the Seller discovers information, characteristics, specifications, etc. are unachievable in the Company supplied or referenced information, the Seller will follow the instructions listed in Section 5.7.1.

Minimum contents for the Seller's design package are as follows:

- Design Calculations
- Design 3D models and 2D drawings
- Manufacturing and Construction Drawings
- Bills of Materials and/or Parts Lists
- Component and/or COTS Item Catalog Cut Sheets
- Assembly Diagrams and/or Procedures

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- 1) Components will be engineered and/or designed to accommodate the effects of magnetic fields per Section 4.5.
- 2) The Seller's design will list the maximum allowable loads (force/moment magnitude and direction) and resulting deflections at all vacuum process interface connections (i.e., flanges and related connections).
- 3) The Seller's design shall ensure that the atmospheric air temperature within the Analysis Station enclosure remains within the limits specified in [3.1.2] during steady-state operating conditions.
- 4) All three-dimensional (3D) CAD models will be provided in two of the following formats.
 - Native format
 - A commonly used file exchange format, such as the Standard for the Exchange of Product Model Data (*.stp), Standard ACIS Text (*.sat), or Initial Graphics Exchange Specification (*.igs)
- 5) All two-dimensional (2D) drawings will also be provided in both Native format and in Portable Document Format (*.pdf).
- 6) The Seller shall maintain a revision-controlled CAD structure. All deliverables shall include revision identifiers consistent with submitted documentation.
- 7) The Seller's design package will include provision for the successful integration of each DRGA Analysis Station. The Seller's overarching design will accommodate fully functioning and complete mechanical, electrical, and communication points of interface.

4.6.4 Design Review

- 1) A formal design review meeting will be conducted and hosted by the Seller and/or Manufacturer with the Company and/or the IO. The purpose of the review meeting will be to assure that the detailed design solution is complete, verified, and properly documented.
- 2) The review will be held at the end of the design phase to support the acceptance and approval of the design by the Company. The basis of the review will include, but not be limited to, all relevant design documentation and to judge if the design is consistent, complete, and mature enough to be authorized for proceeding to manufacture, inspection, and testing.
- 3) The general objectives of the design review are as follows and are to be interpreted as minimums.
 - The Company will review and assess whether the proposed design addresses the design requirements, and that the design process was adequate for the complexity, quality, and safety importance of the equipment and/or system.

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- The Company and Seller will discuss critical points, and the Company may provide recommendations, only as required, for achieving the design requirements.
 - The Company will review and appraise the status of the design in terms of completeness and quality of the design output (drawings, models, documents, specifications, etc.).
 - The Company and Seller will discuss risk and schedule impacts of the design, only when required.
- 4) The Seller will provide the Company with their design documentation inclusive of an outline or listing of the information that will be sent at least ten (10) working days in advance of the meeting. Company and/or IO personnel may choose to return comments to the Seller's design documentation. The Seller is responsible for addressing or resolving all comments to the satisfaction of the Company and/or IO personnel prior to the review meeting.
 - 5) The final contents and characteristics of the design package will be agreed upon by the Seller and the Company at the review meeting.
 - 6) The Seller will not procure materials or begin manufacture, fabrication, and/or assembly of components or equipment until the design review is complete, all comments have been resolved, corrections have been made to the Seller's Design Package, and the Design Package has been approved by the Company and the IO.
 - 7) DRGA Analysis Stations for EP11 and LP12 will be the subject of the design review. All other Control Cubicles will not be subject to a design review unless individually mandated by the Company.
 - 8) In addition to the above, the responsibility of defining the criteria for design validation is BY SELLER; however, the validation activity must include a structured format linking the functional and performance requirements as defined in the technical specifications [3.1.2] with the Seller's design.
 - 9) Only one design review encompassing the Analysis Stations is required, even though several cycles of reviews may be needed to obtain Company approval and acceptance of the Seller's final design.

4.7 Task 7. Inspection Plan

- a. For items fabricated by the Seller, all steps in the manufacturing process from receipt of material to final packaging shall be documented in an IP. This plan shall also outline all document submittals the Seller is to provide the Company and include all material verification, fabrication drawings and processes, and quality documents. The Company shall review and approve the IP prior to commencement of any fabrication operations including procurement of materials and commencement of fabrication. The IP will be used to monitor quality control and inspection reports. **Control Points shall be assigned to the IP activities to notify the Seller when submittals and authorizations are required to proceed.**
- b. The requirement for an IP shall be flowed down contractually from the Seller to the Seller's suppliers and subcontractors (if deemed applicable) unless the requirement is waived in writing on a case-by-case basis by the Company.
- c. The Seller shall include Control Points in the IP. The Company will add any Control Points needed to the IP and will then send the IP to the ITER IO for addition of their Control Points, review, comment, or acceptance. A standard form is provided by the Company for documenting the IP [3.1.24].
- d. Any point designated as an Authorization to Proceed Point (ATPP) on the IP requires a written authorization to proceed with notification from the Company TPO.
- e. The Seller shall not proceed with any fabrication processes until the IP has been reviewed and approved by the Company and the ITER IO. Doing so will result in an NCR and may result in fabricated parts being rejected at Seller's expense.
- f. Early procurement or fabrication of long-lead items may be granted, subject to partial IP and/or conditional approval from the Company.
- g. Inspection plan shall follow all quality assurance requirements defined in 5.3 Inspection Plan.

4.8 Task 8. Validation Plan

- 1) The Seller and/or Manufacturer shall develop and submit a Design Validation Plan and a Factory Acceptance Testing (FAT) Plan for Company review. The Seller's scope shall be limited to validation of the system design, including structural integrity and piping, to demonstrate compliance with the requirements listed in this SOW. Final validation and performance qualification, including measurement accuracy and functional performance, will be performed solely by the Company. All validation and FAT plans must be completed to the satisfaction of the Company prior to release for fabrication.
- 2) In addition to the requirements listed above, the Seller's validation plan will include the following activities, as a minimum:
 - Evaluation/ Testing required for CE compliance
 - All inspections and tests associated with compliance to nationally recognized Code(s) and/or standards of fabrication, manufacture, and/or production.
 - Seismic Testing per [3.1.2]
 - Measurement data collection (for Company validation use)
- 3) Actual measured values will be recorded as opposed to general statements of conformance or other notations simply indicating acceptance, unless quantitative results cannot be achieved. The Seller may request that qualitative evaluations be used in lieu of quantitative methods where achieving such would result in unreasonable cost or a significant delay of schedule. It is the Seller's burden to prove need in such situations. Boolean responses, by design, are allowed.
- 4) The Seller's and/or Manufacturer's validation plan will be submitted to the Company for review and approval at least two (2) weeks prior to the start of Fabrication/Assembly activities. Company and/or IO personnel may choose to return comments to the Seller's and/or Manufacturer's plan. The Seller is responsible for resolving all comments to the satisfaction of the Company and/or IO personnel. The final contents of the plan will be agreed upon by the Seller and the Company.
- 5) Additionally, Company and/or IO personnel may wish to witness the inspection and validation activities. The Seller will issue official notification of the inspection and validation activities to the Company at least two (2) weeks prior to the commencement of the inspection and validation activities.
- 6) Successful completion and approval of validation plans and approval to proceed by the Company as well as acceptance by the IO, is required before the Seller is released for fabrication.

4.9 Task 9. Manufacturing Drawings for Fabrication

Sellers shall produce fabrication drawings as required to successfully fabricate and deliver the hardware. **Review of the Seller generated drawings shall constitute a Review control point on the IP.** Note that the final dimensional and acceptance inspection shall be performed to the Company provided drawing and not to the Seller generated fabrication drawing.

4.10 Task 10. Manufacturing Procedures for Fabrication

Sellers shall produce fabrication procedures as required to successfully fabricate and deliver the hardware. **Review of the Seller generated procedures shall constitute a Review control point on the IP.**

4.11 Task 11. Material Procurement

[Some material and components (i.e. Gate Valves) may be provided to Seller by the Company]

NOTE: Procurement of material and receipt of material certs shall be an ATPP control point on the Inspection Plan. Material data and receipts provided by Seller shall certify the quantities of materials procured are sufficient. The Company will not signify satisfaction of this control point until satisfied with quantity of raw material.

- a. The Seller is responsible for providing all materials required for fabrication of the hardware. The Seller shall ensure that all raw materials and prefabricated components comply with the requirements of the technical specification.
- b. Additionally, Seller shall provide the Company with inspection reports that document the as received condition of all items listed below. Satisfaction of these requirements constitutes an ATPP control point.

1. Raw Materials

All raw material used for the fabrication of the hardware or their constituent components, shall be accompanied by a Type 3.1 Certificate of Conformity (CoC).

2. Commercial Off The Shelf (COTS) Items

Any COTS items used in construction of the component(s) shall be accompanied by a Type 2.1 CoC. Examples of these items include but are not limited to VCR fittings, fasteners, and gaskets.

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4.12 Task 12. Manufacturing Readiness Review

- 1) The Seller and/or the Manufacturer will coordinate and host a Manufacturing Readiness Review (MRR).
- 2) “Design Review” must be completed by the Seller and accepted by the Company prior to, or in conjunction with, the MRR. The approved version of the Seller’s design is an essential component in the Seller’s ability to satisfy the requirements of the MRR Task.
- 3) Failure by the Seller and/or Manufacturer to comply with the requirements associated with Manufacturing Readiness as described herein will not relieve the Seller and/or Manufacturer from scheduled milestones and/or deliverables.
- 4) The Seller shall participate and supply all relevant documents needed for the MRR process and coordinate with the TPO regarding scheduling an MRR date which includes all necessary review panelists. The Seller will not be released for manufacturing until formally clearing the ATPP in the IP.

4.13 Task 13. Fabrication

The Seller is responsible for fabricating the Analysis Stations in accordance with approved procedures and drawings.

4.14 Task 14. Inspection and Testing

The Seller shall perform testing from Task 8. Validation Plan and as required by the technical specification [3.1.2]. The methods and results of all testing and examinations shall be documented and provided to the Company. The Seller inspection report shall document that all required testing and examinations have been performed.

4.15 Task 15. Preparation for Transportation and Packaging

The Seller shall package and prepare each item for shipment to the ITER Organization. The packaging shall protect the items from the elements, anticipated transport loads (including those based on cargo securement design accelerations in US Department of Transportation and International Maritime Organization standards), and any conditions (e.g., shock, impact, weather) that could cause damage resulting in nonconformity with the applicable requirements. The item shall be packaged to protect all sealing surfaces from scratches or other leak-inducing damage. Specific to any items being shipped internationally, packaging shall comply with relevant sections of international standards affecting packaging. Further details are provided in Section 6.

4.16 Task 16. Documentation

1. Contractor Release Note (CRN):
 - a. The Seller is to prepare a CRN for each delivery utilizing the *Contractor Release Note Procedure* [3.1.22] and *Contractor Release Note Form* [3.1.23]. The CRN is a document that, for an equipment/service:
 - identifies the applicable requirements,
 - certifies that the equipment/service complies with these requirements,
 - records the status of the documentation, and
 - highlights any outstanding obligation.
 - Item identification details (frame number and part number identification (PNI) designator).
2. Certificate of Conformity (CoC)
 - a. The Seller shall prepare a CoC for the frames. The CoC shall state that the items meet all requirements defined in the technical specification [3.1.2] and this SOW. The designated POC shall submit the completed CoC to the TPO.
 - b. The Seller may use any suitable format for the CoC. At a minimum, the CoC shall include:
 - Manufacturer's details (name, address, etc.)
 - Declaration that the equipment meets the applicable requirements (specifically list requirements documents)

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- Any standards the item complies with
- Signature of Sellers authorized representative.

3. Manufacturing Dossier

- a. The Seller shall prepare a manufacturing dossier for the support structures and submit it to the Company for approval. The manufacturing dossier shall consist of the documents agreed upon during the first progress meeting and organized in a fashion which allows traceability from the supplied documentation to the individual support to which it is applicable. **Approval of the manufacturing dossier represents an ATPP Control Point.** At minimum, the Manufacturing Dossier shall contain the documents listed below, when applicable:

- CRN
- A fully executed copy of the approved IP, including all control points signed off or evidence of completion attached to the IP. In the case of evidence, each item shall be clearly related to the specific control point it addresses.
- Any supplemental drawings or detail drawings developed by or for the Seller for this scope of work
- Material certifications
- Documentation certifying the painting/coating applied
- Seller inspection reports – dimensional and welding
- Welding certification (per Code of Construction), including but not limited to, procedure qualification record (PQR), welding procedure specification (WPS), and certification records for personnel used to perform welding operations in fulfillment of this SOW.
- Approved deviation requests (if applicable)
- Non-destructive examination (NDE) inspector personnel qualifications, processes / methods used, and equipment used (if applicable).
- QA records for NDE inspection, visual testing (VT), magnetic testing (MT), ultrasonic testing (UT), and radiographic testing (RT)
- Approved Non-Conformance Reports (NCRs) (if applicable)
- CoC
- Compliance marks (e.g., ISPM-15, CE) (if applicable)
 - All items in the SOW shall comply with applicable European Directives and shall carry a CE mark where applicable. All items bearing a CE mark shall be supported by a Declaration of Conformity. Where applicable, a Declaration of Incorporation shall be provided.

- b. The manufacturing dossier shall also include:

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- Cover page that identifies the item(s) (part and /or serial number, and name) as well as a space for signature of the Seller's authorized representative and dates signed
- Table of Contents with the page number on which each section begins
- Summary page describing key points relevant to fabrication of the part(s)
- Inclusive page numbers (x of x) for the entire dossier
- Optical Character Recognition (OCR) of the dossier before delivery to the Company.

4. Manuals

- a. The Seller is responsible for providing a manual for the hardware and any software which provides instructions for transportation, storage, installation, commissioning, operation, and maintenance of the equipment.
- b. Manuals may be submitted for individual parts of assemblies, but the Seller is responsible for furnishing a manual which describes the overall integration of the assembly.

4.17 Task 17. Data management

1. Company Provided Information

Information provided by the Company to the Seller shall not be used for any activity except those specified by this SOW.

2. Original Copies

- a. The Seller shall keep and maintain the original copies of all signed documents. Copies shall be supplied to the Company as part of the manufacturing dossier.
- b. The Seller shall provide electronic copies of all documentation in searchable Portable Document Format (.pdf). Electronic documents shall be supplied to the Company using email, USB storage device, or file transfer tools such as the ORNL File Upload System, Drop Box, or other such electronic tool for securely transferring large files.

5. QUALITY ASSURANCE

5.1 Quality Assurance Program

The Seller shall comply with the requirements of their Company-approved quality assurance program as applicable. The Seller shall provide their documented quality assurance program including quality assurance manuals.

5.2 Quality Plan

NOTE: This plan is in addition to the pre-established quality program, management system description, quality manual, or equivalent of the Seller's organization as detailed in section 5.2.

- a. ITER requires that a Quality Plan be prepared by the Seller specifically for the subcontract, identifying how they will fulfill the specific subcontract requirements.
- b. Work on the subcontract may not begin until notice is received that the Quality Plan is approved by the Company.
- c. The requirement for a subcontract-specific Quality Plan shall be flowed down contractually from the Seller to the Seller's suppliers and subcontractors, unless the requirement is waived in writing on a case-by-case basis by the Company. (Example: COTS items (not modified for ITER)).
- d. A revised quality plan (at all levels) shall be subject to the same approval and acceptance procedure as the original quality plan. In case of revision, work shall continue in accordance with the current approved quality plan until the revised quality plan is accepted.
- e. A standard template [3.1.14] is available from the Company for documenting the contract-specific quality plan, but the Seller may propose to use their own equivalent format.

5.3 Inspection Plan

- a. Sellers who contract to manufacture items shall prepare an IP specific to the production of the item(s) described in the contract and submit it for approval.
- b. A standard template [3.1.24] is available from the Company for documenting the IP. A Seller may propose to use its own equivalent format; however, it must be accepted by the IO Quality Division.
- c. Manufacturing may not begin until notice is received that the IP has been approved by the Company.
- d. The requirement for an IP shall be flowed down contractually from the Seller to the Seller's suppliers and subcontractors unless the requirement is waived in writing on a case-by-case basis by the Company. The following examples do not require an IP:
 - COTS items (not modified for ITER)
 - Research and development activities
 - Supply of services

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- e. The IP will list the sequence of manufacturing operations encompassing the whole scope of the subcontract, including review of drawings, verification of materials, manufacture, inspection, test, and delivery. It will be used to monitor quality control and acceptance tests.
- f. The Company will add any Company intervention points and send the IP to the IO for acceptance and mark-up of any IO intervention points, before returning it “approved” to the Seller.
- g. All inspection operations performed by the Seller shall be detailed on the IP. These operations shall also be listed with sign off verification on the support traveler. The final dimensional inspection and final volumetric and welding inspections shall be listed as an ATPP on the IP.
- h. Volumetric NDE (RT or UT method) records shall be preserved for each inspection performed. Traceability between the record and inspection shall be clear. Digitized copies of the records are preferred. Records shall be transmitted periodically, such as at the conclusion of final inspection for each major component.
- i. QA record controls shall provide a method for identifying records received, receipt and inspection of incoming records, record retention, and transmittal of records.
- j. QA record transmittals may include NDE VT, Penetrant Testing (PT), MT, UT and RT inspection(s). QA records shall be maintained as appropriate for the currently qualified personnel, processes, and equipment of each special process.
- k. Designated QA records transmittal intervals shall be assigned for certain welds such as in-process welds that may become inaccessible or very difficult to inspect or recreate NDE results (e.g., where outer shielding may prevent accessibility to internal piping, welds in highly stressed areas, suspected problem areas, and at the conclusion of final inspection for each major component).
- l. QA records may include calibration and measurement or measuring & test equipment (M&TE) which includes all devices or systems used to calibrate, certify, measure, gauge, troubleshoot, test, or inspect in order to control data or to acquire data to verify conformance to specified requirements.
- m. All M&TE is uniquely identified, calibrated, and controlled and provides accuracy traceability. The critical parameters of all M&TE, including range, precision, and accuracy. are documented; the documents shall be retrievable and maintained as quality records.
- n. Prior to commencement of welding operations, Seller shall submit, for approval all WPSs and PQRs to be utilized to perform the required welds. Additionally, certifications for the welders and weld inspectors to the required codes as stated in the technical specification shall also be provided. Review and approval of the welding documentation shall constitute an ATPP on the IP.

NOTES: For Nuclear Pressure or conventional Pressure Equipment, the Company or Seller will provide the IP to the relevant Notified Body or Agreed Notified Body to allow them the opportunity to mark their interventions on the IP. Non-
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pressure equipment subject to other European Directives (e.g., Machinery Directive) may also have to engage a Notified Body with the IP.

5.4 Software Control and Validation Program

The Seller will provide evidence of their Software Control and Validation Program in accordance with [3.1.15].

5.5 Seller-Requested Deviations

The Seller may propose deviations from the specifications, drawings, or other technical or administrative requirements of this scope. If time is a consideration, then the Seller may communicate the proposed deviation directly to the TPO (via e-mail correspondence), with a copy to the Company's PO. The request shall identify the affected items, drawing/specification number and revision number, a description of the proposed deviation, and the engineering justification for it. A form is available for the Seller to submit deviation requests, *Deviation Request Form* [3.1.19]. The Company's TPO will evaluate the technical aspects and document a recommendation (cannot be verbal) to the PO, who will communicate acceptance or disapproval to the Seller.

NOTE: The acceptance of a deviation request in no way limits or affects the warranty provision of the subcontract. Such a request shall not establish a precedent or obligation to accept existing or future items not conforming to all provisions of the subcontract.

5.6 French Order of 7 February 2012 (INB regulation)

The ITER facility is an INB (Installation Nucléaire de Base – Basic Nuclear Installation) in France. However, the quality and technical requirements necessary for the Seller to satisfy INB regulations are embedded in this SOW.

5.7 Seller-identified Nonconformances

- a. The Company expects to receive equipment items, components, materials, software, and documentation that conform to all codes, standards, specifications, and procedures in the subcontract. When a nonconforming condition is identified, the Seller shall control the nonconforming item or process, document the condition and resolve the issue
- b. The Seller shall perform the following:
 - Identify and segregate when practical, the non-conforming item,
 - Stop any further work on the item until a decision is made,
 - Provide written notification of the discovered nonconformance and the discovery date (via email, copy of internal NCR form, the Company NCR form partially filled out) to the TPO, with a copy to the PO and QA responsible officer, as soon as possible but no longer than five business days from discovery.
 - After the discovery process is complete, provide any additional details, proposed dispositions, and justifications (as necessary) to the Company in an NCR using the Company's *Non-Conformance Report Form* [3.1.21].

NOTE: The issuance and acceptance of an NCR in no way limits or affects the warranty provision of the subcontract. Such a request shall not establish a precedent or obligation to accept existing or future items not conforming to all provisions of the subcontract.

- c. Two categories of nonconformances are considered: Major and Minor. The categorization will be made by the Company with concurrence from the IO Technical Responsible Officer. Generally, a major nonconformity could affect a critical requirement, such as performance, safety, reliability, operability, traceability, interchangeability, or regulatory. Minor nonconformances normally cause no such impact.

- **Major Nonconformance:**

Nonconformances identified as major will require completion of a root-cause analysis. Subsequently, the proposed remedial action for a major nonconformance shall be implemented only after written acceptance from the Company.

- **Minor Nonconformance:**

A noncompliance with a requirement not indicating a repeat condition or negative performance trend; something at least initially considered singular. Therefore, the repeat of a minor NCR symptom or cause would constitute a major NCR. If the Company decides the nonconforming condition is not a major nonconformance, the Seller shall take actions to resolve the nonconformance only after receiving written approval by the Company.

NOTE: For all minor NCRs with a disposition of “rework” or “repair” and affecting a deliverable to the IO, evidence of completion/closure shall be included in the manufacturing dossier with a clear link to the NCR in the dossier.

- d. Examples of minor nonconformances could include (but are not limited to) the following:

- Slight variance from a tolerance specified on a design drawing that has no effect on equipment form, fit, or function.
- Noncompliant cleanliness of material at receipt inspection that is remedied during fabrication by an approved cleaning process.
- Failure of packaging that did not result in damage to the material or equipment.
- Failure to adequately complete an administrative process (e.g., document review and approval matrix) that does not affect the quality of final product.
- Flow controller accuracy range not consistent with Manufacturer’s data sheet, but data were correctable after device calibration.

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5.7.1 Nonconformance Report

The report shall contain or refer to all relevant material available to enable an informed decision on the definite course of action to be taken. A standard form [3.1.21] is available from the Company for documenting the nonconformance.

5.8 Definitions

- 5.8.1 **Verification:** Activities performed by the Seller to demonstrate that the design and fabrication meet specified requirements (e.g., structural, piping, and quality compliance).
- 5.8.2 **Validation:** Activities performed by the Company to confirm system performance, measurement accuracy, and functional operation.
- 5.8.3 **Factory Acceptance Testing (FAT):** Testing performed by the Seller to demonstrate readiness for delivery and compliance with fabrication and assembly requirements. FAT does not constitute system performance validation unless explicitly specified.

6. PACKAGING, LOADING, AND STORAGE

6.1 Packaging

- a. The Seller shall package and prepare each piece of equipment for shipment to the ITER site in Cadarache, France. The packaging shall protect the equipment from any conditions (e.g., shock, impact, weather, etc.) which could cause damage to the equipment resulting in nonconformity with applicable requirements. The Seller shall provide a package design document which includes the proposed packaging design as well as analysis showing it can withstand air, land, and sea transport. The package design document must be approved by the Company.
- b. The Seller is required to mark each package with the following:
 - Subcontract number
 - Delivery address
 - Consignor (Seller's name, address, and contact information)
 - Package number (as identified on the packing list)
 - ITER Equipment Identification Number(s) (if applicable)
 - Gross Weight (kg)
 - Net Weight (kg)
 - Handling instructions (in English and French)
 - Lifting/Lashing/Jacking points
 - Center of Gravity (in 3 dimensions)
 - Compliance marks (e.g., ISPM-15, CE) (if applicable)

6.2 Loading

The Seller is required to load items to be transported onto the Logistics Service Provided (LSP) conveyance (e.g., truck, van, trailer, vessel, ocean container, air freight container, rail car) at the factory. In doing so, Seller shall provide all necessary and customary equipment, personnel, and safety equipment for proper loading into the vehicle.

6.3 Storage of finished Products

The Company, at its discretion, may require Seller to postpone the date of shipment by up to 60 days from the agreed upon shipment. If the date of the shipment is postponed, the Seller shall, at no additional cost, store finished products in a safe and secure manner that protects their condition and preserves the integrity of all components and packaging. If the storage is required beyond 60 days, Seller agrees to good faith negotiation of extended storage terms.

6.4 Creation and Submittal of Pre-Shipment Documentation

The Seller shall provide information and documentation required for international shipment in accordance with the following schedule:

1. Pre-Shipment Deliverable Package No. 1
 - a. A pre-shipment deliverable package shall be provided by the Seller no later than 10 business days after the project kickoff meeting.
 - b. The pre-shipment deliverable package #1 shall contain the following items:

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- Written notice of the planned date on which the goods will be packaged and available for shipment.
- Contact information for Seller's shipping/logistics coordinator.
- Technical characteristics of the packaged components are as follows:
- Physical data and drawings showing dimensions, total and distributed weights, center of gravity (in 3 dimensions), shipping orientation;
- Address of the location where items are to be picked up by the LSP;
- Documentation (e.g., material safety data sheet) regarding relevant compliance regimes, such as export control, transportation of dangerous goods, and environmental protection;
- Identification of any items that have been identified as safety important components (SIC) or protection important components (PIC).
- Conditions or precautions to be respected when moving, loading/offloading, handling/sliding, and storing/marshaling to include, when required, specific provisions and controls to be performed and recorded while under the control of the LSP;
- Documentation confirming that packaging is designed to protect components from damage and contamination, considering anticipated environmental conditions and multimodal (e.g., highway, ocean) handling/transit accelerations;

NOTE: All packaging using wood products must comply with the requirements of ISPM-15

- Packaging specification including confirmation of compliance with international packing standards (e.g., International Standard for Phytosanitary Measures (ISPM)-15, Conformance Européenne/CE certification for relevant package lifting appurtenances such as eyes/rings), agree barcoding requirements and regulations relating to packaging materials used;
- Definition of packaging/frame, when the components are packed or tarped, including any particular procedures for handling, moving, clean-up, maintenance, storage;
- Specification for securing and hanging packages/frames including jacking/lifting/lashing conditions, procedures, and acceptable securing points;

NOTE: Any specialized packing/handling frame or tool should be detailed in drawings, meet relevant domestic and international requirements (e.g., Occupational Safety and Health Administration, CE), and is subject to approval by LSP

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- Identification of specialized equipment/hardware (e.g., custom lifting fixture) interface requirements between each point of use within the supply chain;
- Description of Interface between Seller and LSP (e.g., release conditions for loads, Seller's loading means, etc.);
- Technical data concerning monitors (e.g., shock, vibration, tilt, acceleration, temperature) utilized to detect events during transit which may cause damage to components.

2. Pre-Shipment Deliverable Package No. 2

- a. Pre-shipment deliverable package #2 is to be provided no later than 90 days prior to the planned date of shipment.
- b. The pre-shipment deliverable package #2 shall contain the following items:
 - Written confirmation of the date goods will be ready for shipment or submit revised shipment date for approval.
 - Contact information for Seller's shipping/logistics coordinator
 - Fabrication value of goods (for insurance purposes-should not include destination site support services)
 - Transport drawings with sufficient detail to facilitate lifting / lashing / stowage and approval of the operators (e.g., steamship line, air carrier).
 - The following business documents (in English language):
 - i. Pro-Forma/commercial invoice on Seller's letterhead listing at a minimum:
 - Subcontract number
 - Description and quantity of goods
 - Value of goods
 - Incoterm 2010 rule
 - Schedule B number (for U.S. exports) or Harmonized System code
 - Country of origin
 - Export control determinations (e.g., "ECCN: EAR99, No Export License required")
 - Consignee: Note – If shipped to the ITER site, use the address below:

ITER Organization
 Route de Vinon sur Verdon, CS90 046
 13067 St. Paul lez Durance CEDEX, France
 Contact: Yanchun Qiao (+33-4-42-17-62-57;

Cell: +33-6-26-31-29-96) Yanchun.Qiao@iter.org

- Duty Free Declaration

Shipments on behalf of the ITER International Fusion Energy Organization (“ITER Organization”) for its official use are eligible to duty-free customs clearance under the Agreement on the Privileges and Immunities of the ITER International Fusion Energy Organization for the Joint Implementation of the ITER Project, done in Paris on 21 November 2006 and ratified, accepted and approved by the People’s Republic of China, EURATOM (for the European Union and Switzerland), the Republic of India, Japan, the Republic of Korea and the Russian Federation. DIPLOMATIC SHIPMENT on behalf of the ITER Organization. FOR DUTY-FREE CUSTOMS CLEARANCE.

- Consignor (Seller’s name, address, and contact information)

ii. Itemized packing list on Seller’s letterhead detailing the following at a minimum for each package:

- Subcontract Number
- Package number (sequential number assigned to each package.
- Package type (e.g., wooden crate, item on pallet, etc.)
- Seller’s equipment/component identification number(s)
- ITER Equipment Identification Number(s) (if applicable)
- Item Description
- Quantity of each item
- Gross Weight (kg)
- Net Weight (kg)
- Dimensions (cm)
- Volume (m3)
- Special Handling Instructions
- Storage Instructions (e.g., indoor, conditioned space)

iii. Declaration of Integrity

- The undersigned hereby certifies that the components and package(s) described on this Packing List meet the contractual requirements except for any approved deviations and NCRs specified in the associated documentation.

NOTE: The invoice, packing list and other documents, where appropriate, must be acceptable to the country's Customs agency. The LSP shall review submitted documents and request amendments where required. If amendments are requested, Seller must update and submit revised documents within seven days.

- iv. Export Control License(s) or other authorized documents if required.
- 3. Pre-Shipment Package No. 3
 - a. Pre-shipment deliverable package #3 is to be provided no later than two weeks prior to the planned date of shipment.
 - b. The pre-shipment deliverable package #3 shall contain the following items:
 - Evidence of appropriate proof testing and certification for any custom lifting apparatus that will travel with the item and be utilized during loading and unloading operations.
- 4. Pre-Shipment Package No. 4
 - a. Pre-shipment deliverable package #4 is to be provided no later than one week prior to planned date of shipment.
 - b. The pre-shipment deliverable package #4 shall contain the following:
 - Any remaining information needed to facilitate the appropriate completion of transport documents such as bills of lading or air waybills.
 - Data elements and authorizations (e.g., shipper's letter of Instruction, power of attorney) required for LSP submission of electronic filings in the automated export system when necessary.
 - Dangerous goods declaration if required for transport.
- 5. Package Marking
 - a. The Seller is required to mark each package with the following:
 - Subcontract number
 - Delivery address
 - Consignor (Seller's name, address, and contact information)
 - Package number (as identified on the packing list)
 - ITER Equipment Identification Number(s) (if applicable)
 - Gross Weight (kg)
 - Net Weight (kg)
 - Special Handling Instructions
 - Lifting/Lashing/Jacking points
 - Center of gravity (in 3 dimensions)

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6. Deviations from Planned Date of Shipment

Seller shall immediately notify the TPO and PO, in writing, of any actual or potential change to the agreed-upon date of shipment.

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7. DELIVERABLES

7.1 Hardware

Table 2: List of Hardware Deliverables

Hardware Deliverable Identifier	Analysis Station	PNI
HD1	EP11 Analysis Station	I00DFBTC6
HD2	LP12 Analysis Station	I00SNA7UN

7.2 Documentation

Table 3: Document Deliverables

Document Delivery Identifier	Document Name	Referred Section
DD1	Quality Plan	Task 1. Quality Plan
DD2	Project Plan	Task 2. Project Management
DD3	Project Kickoff Meeting Minutes	Task 3. Kickoff Meeting & Progress
DD4	Progress Meeting Notes	Progress Meetings
DD5	Preliminary Design and Analysis	Task 4. Design and Analysis
DD6	Magnetic Shielding Design and/or Testing	Task 5. Magnetic Shielding Design, Testing
DD7	Final Design and/or Testing	Task 6. Final Design and/or Testing
DD8	Inspection Plan	Task 7. Inspection Plan
DD9	Validation Plan	Task 8. Validation Plan
DD10	Manufacturing and Fabrication Drawings	Task 9. Manufacturing Drawings for Fabrication
DD11	Manufacturing Documentation	Task 10. Manufacturing Procedures for Fabrication
DD12	Material Certifications and Receiving Inspection Reports	Task 11. Material Procurement
DD13	MRR Documentation	Task 12. Manufacturing Readiness Review
DD14	Package Design Documentation	Task 13. Fabrication
DD15	Acceptance and Inspection Test Plan	Task 14. Inspection and Testing
DD16	Pre-shipment Transportation Documentation	Task 15. Preparation for Transportation and Packaging
DD17	Deviation Requests (if applicable)	Task 16. Documentation
DD18	Non-Conformance Reports (if applicable)	Task 16. Documentation
DD19	Manufacturing Dossier	Task 17. Data management

7.3 Quality Assurance

1. Quality Program
2. Quality Plan
3. Inspection Plan
4. List of Qualified Personnel
5. Software control and Validation Program
6. Deviation Requests
7. NCRs
8. CRN

7.4 Project Management

9. Meeting Minutes
10. Monthly report and schedule
11. List of deliverables

7.5 Materials Procurement

12. Raw material Type 3.1 certificates
13. COTS Type 2.1 certificates

7.6 Manufacturing Readiness Review

14. Manufacturing Drawings
15. Manufacturing procedures
16. Inspection Procedures
17. Cleaning Procedures
18. Testing Procedures
19. Personnel Qualification Records

7.7 Fabrication

20. CRN
21. CoC
22. Manufacturing dossier

7.8 Transportation

23. Package design documentation
24. Pre-shipment transportation documentation

7.9 Manuals

25. Manuals and procedures for installation, maintenance, and inspection