Statement of Work (SOW) for VAS-02 ECH Vacuum System TurboMolecular Pump

Abstract or description:

Statement of Work (SOW) to govern the procurement, fabrication, testing, and final deliverables for the VAS-02 ECH Vacuum System TurboMolecular Pumps.
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<td>v0.0</td>
<td>OBSOLETE (In Work)</td>
<td>18 Apr 19</td>
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| v1.0   | OBSOLETE (Revision Required) | 15 Nov 19 | 1. CLEANED UP FORMATTING AND GRAMMAR  
2. INCORPORATED COMMENTS FROM QA AND SYSTEMS ENGINEERING RELATED TO QUALITY PLAN FOR COTS VS BESPOKE ITEMS  
3. ADDED COMMENTS FROM I&C RELATED TO EMC TESTING AND VALIDATION |
| v2.0   | OBSOLETE (Revision Required) | 02 Dec 19 | 1. Corrected spelling and grammar mistakes  
2. Added requirement that list of cutting/cleaning fluids be presented at project kick-off and approved at that time  
3. Removed language allowing seller to propose a Contractor Release Note (CRN) template |
| v3.0   | OBSOLETE (In Work) | 04 Dec 19 | 1. UPDATED SCOPE STATEMENT TO SHOW A COTS OR A MODIFIED COTS SOLUTION IS EXPECTED AND ADDED ITER CLASSIFICATIONS  
2. UPDATED REFERENCES TO INCLUDE LATEST DOCUMENT REVISION  
3. CHANGED ‘WORK TASKS’ TO ‘PERFORMANCE REQUIREMENTS’  
4. ADDED REQUIREMENTS TO KICK OFF MEETING TO INCLUDE CONFIRMATION OF CUTTING FLUIDS, PUMP VOLUME, CONTROLLER SIZE, OUTLINE OF PACKAGING/HANDLING PROCESSES, TESTING INSPECTION PLAN, QUALITY PLAN.  
5. UPDATED LANGUAGE ON MANUFACTURING AND FABRICATION  
6. MOVED TRANSPORTATION INTO SECTION 5 AND COMBINED WITH SHIPPING DOCUMENTATION AND LOADING.  
7. UPDATED DELIVERABLES TO INCLUDE ONLY CABLING AND CONTROLLERS NEEDED FOR VALIDATION |
| v4.0   | OBSOLETE (Approved) | 26 Dec 19 | 1. CHANGED REFERENCES TO ‘MIP’ TO ‘IP’  
2. UPDATED GRAMMAR/SPELLING  
3. ADDED DISCUSSION OF MANUFACTURING DOSSIER TO KICK OFF MEETING  
4. ADDED INSPECTION PLAN FOR BESPOKE ITEMS IF APPLICABLE AS A DOCUMENT DELIVERABLE |
| v4.1   | CURRENT (Approved) | 06 Jan 20 | 1. CHANGED REFERENCES TO ‘MIP’ TO ‘IP’  
2. UPDATED GRAMMAR/SPELLING  
3. ADDED DISCUSSION OF MANUFACTURING DOSSIER TO KICK OFF MEETING  
4. ADDED INSPECTION PLAN FOR BESPOKE ITEMS IF APPLICABLE AS A DOCUMENT DELIVERABLE |
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1 INTRODUCTION

ITER is an international research project with a programmatic goal of demonstrating the scientific and technological feasibility of fusion energy for peaceful purposes. The ITER device is being designed by the European Union, India, Japan, the People’s Republic of China, the Republic of Korea, the Russian Federation, and the United States. The European Union is the host party for the ITER facility which is being constructed in Cadarache, France. The ITER Organization Central Team (IO) is responsible for the final design, performance parameters, procurement specifications, schedules, integration management, systems engineering, and component assembly, installation, testing, and commissioning. Governing regulations, codes, and standards for the design and construction of all ITER components are determined by the European Union and France. The US portion of ITER is managed by the US ITER Project Office (USIPO) which is hosted by Oak Ridge National Laboratory (ORNL) under contract with UT-Battelle (hereinafter referred to as the “Company”), and located in Oak Ridge, Tennessee. Responsibility for operating the completed ITER facility will belong to the IO.

2 SCOPE

This statement of work (SOW) defines the activities to be performed by the Seller, consisting of the manufacture, testing, preparation of required documentation packages, and packaging, and preparation for shipment for the magnetically shielded turbo molecular pumps for use in the ECH (Electron Cyclotron Heating) Waveguide Vacuum System. These pumps shall be integrated into the ECH Waveguide vacuum pumping groups upon delivery to the IO site. The pump covered under this Statement of Work (SOW) and their associated technical specification [3.1.1] are expected to be either a commercially available solution, or a commercially available pump that has an external magnetic shield integrated into the final configuration, and compliant with the Safety Important Classification (Non-SIC), Quality Classification (QC-3) and the Vacuum Quality Classification (VQC-3) requirements of the component.

3 APPLICABLE DOCUMENTS

3.1 Standard and Requirements

3.1.1 “Technical Specification for VAS-02 ECH Turbo Molecular Pump (US_D_22PNT5, v7.2)

3.1.2 “ITER Vacuum Handbook” (ITER_D_2EZ9UM, v2.5)

3.2 US ITER Documents, Procedures, and Forms

3.2.1 Requirements for Producing a Quality Plan (ITER_D_22MFMW v4.0)

3.2.2 Quality Plan Template for Suppliers and Subcontractors (US_D_23EG78, v1.4)

3.2.3 Deviation Request Procedure (US_D_22A94F v3.6)
3.2.4 Deviation Request Form (US_D_22C9DT, v2.0)
3.2.5 Nonconformance Reports Procedure, (US_D_22GMTF v9.3)
3.2.6 Non-Conformance Report Form (ITER_D_A6HRLB, v2.1)
3.2.7 Contractor Release Note Procedure (US_D_22NEFV v2.0)
3.2.8 Contractor Release Note Template (US_D_2299UW v4.0)
3.2.9 Requirements for Producing an Inspection Plan (ITER_D_22MDZD, v3.7)
3.2.10 Manufacturing and Inspection Plan (MIP) Template (US_D_22NBD3, 4.0)

4 PERFORMANCE REQUIREMENTS

4.1 Performance Requirement 1 – Project Planning and Schedule

4.1.1 Project Kick-Off Meeting

a. The Project Kick-Off 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 Kick-Off Meeting is to meet the principal participants and to ensure the scope and expectations of the subcontract are understood.

b. The Seller shall provide the company with a complete list of all fluids used in the machining and cleaning of the pump as well as confirmation that they are approved for use for the associated vacuum quality classification (VQC 3) in Appendix 4 of the ITER Vacuum Handbook [3.1.2]. If the Seller uses a fluid as part of their standard processes which is not listed in Appendix 4, the Seller shall request permission in writing prior to the Project Kick-Off meeting. The Company shall provide a response to be included in the approved meeting minutes.

c. The Seller shall provide confirmation of dimensions and cubicle installation requirements in terms of rack unit “U” with one “U” equaling 44.45mm (1.75 inches). A standard 482.6mm (19 inch) rack will be used to house the controllers.

d. As part of the initial proposal during the call for tender phase, the Seller shall provide confirmation that the proposed pumping solution space reservation does not exceed the requirement in Section 4.9 of the technical specification [3.1.1]. The Seller shall also provide the weight of their shielded turbomolecular pump. Seller shall confirm weight and required space volume during the Project Kick-Off Meeting.
e. Additionally, Seller shall provide the company with an outline of their prepackaging, handling, and storage methods and show compliance with Section 2.2 of the ITER Vacuum Handbook (Post Cleaning Handling of Vacuum Components) [3.1.2] for the appropriate vacuum quality class (VQC 3).

f. Discussion topics at the Project Kick-Off Meeting shall include:
   - Contents of the Procurement Package
   - Overview of the Technical Specification [3.1.1]
   - Discussion of any requirements outside of the Seller’s commercially available offering.
   - Overview of Testing/Inspection Plan and requirements including proposed location and method for magnetic field and EMC validation testing.
   - Overview of Quality Plan(s)
   - Contents of the Manufacturing Dossier

   g. If requested, the Seller shall arrange for a tour of the facility where the equipment will be manufactured and were validation testing occurs.

h. The Seller shall prepare the Project Kick-Off Meeting Minutes within 5 working days of the meeting.

4.1.2 Project Schedule

   The Seller shall prepare a Project Schedule which outlines, at a minimum, all tasks, meetings, deliverables, milestones, and Control Points. The US ITER Technical Project Officer (TPO) has the option to add additional items to the Project Schedule.

4.1.3 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.

4.1.4 Project Plan

   a. The Seller shall prepare a Project Plan that integrates each element of subcontract management into a concise written document.

   b. The Project Plan shall identify the Seller’s key personnel in this project and describe their individual roles and responsibilities.

   c. The Project Plan shall include the proposed Project Schedule.
4.1.5 Progress Meetings

a. If the Project Kick-Off meeting confirms the pumping solution is entirely made from the Seller's standard product line, then the Seller shall provide the company written notification when production of the pumps and related hardware begins and ends.

b. The USIPO shall reserve the right to schedule progress meetings as needed to discuss any potential problems, resources, technical issues, contractual issues, or to discuss testing and validation if required.

c. The Seller shall prepare and send minutes of any teleconferences and meetings to the TPO for review and approval within 5 business days.

d. A progress meeting shall occur to coincide with both the commencement and completion of the testing.

4.2 Performance Requirement 2 – Manufacturing and Fabrication

4.2.1 Commercial Off-the-Shelf items

If the requirements in this SOW and its applicable technical specification can be satisfied via the Seller's commercially available components, then at a minimum, the manufacturer's cut sheet and a Certificate of Conformance shall be supplied and included as part of the manufacturing dossier.

4.2.2 Inspection Plan for Bespoke Items

Any fabrication processes needed outside of the Seller's standard manufacturing and fabrication processes shall be documented and provided to the Company prior to commencement. The Company shall give approval of the proposed operations before implementation.

Any drawings or quality documentation needed to facilitate the incorporation of a bespoke solution shall be provided and approved by the Company prior to commencement. An Inspection Plan (IP) [3.2.3] will need to be generated for any bespoke operations, and the associated drawings included therein.

The IP shall serve as the document of record for assurance of compliance with the terms of the technical specification, this statement of work, and the approved quality plan.
a. The Seller shall prepare the IP and submit it to the Company for approval. Manufacturing may not begin until written notice is received that the IP has been approved by the Company.

b. The requirement for an IO specific 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.

c. The IP shall list the sequence of manufacturing operations encompassing additional bespoke items and range from review/approval of drawings, verification of materials, manufacturing, inspection and testing, as well as packaging for delivery. It will be used to monitor quality control and inspection reports.

d. The Seller shall include Control Points in the IP. The Company will add any Control Points needed to the IP and will 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 [3.2.10].

e. A list of all cutting fluids, cleaning agents, and prepackaging storage methods shall be attached to the IP to show compliance with the ITER Vacuum Handbook [3.1.2].

4.3 Performance Requirement 3 – Testing and Validation

4.3.1 Mechanical Testing

The Seller shall submit a Testing and Validation Plan to show compliance with all elements of the pump technical specification [3.1.1]. This plan must be approved by the Company before any testing and validation operations can be commenced. The Seller shall indicate whether compliance with the listed technical requirement shall be validated via historical data, a product information sheet, or through first article testing.

The Seller shall fabricate a first article of the turbomolecular pump and verify its performance via the approved Testing and Validation Plan prior to commencement of the remaining pumps.

The Company reserves the right to witness any of the tests listed in the Seller’s approved Testing and Validation Plan. Written notification of testing period and location shall be provided to USIPO no later than 8 weeks prior to testing.
4.3.2 **Electromagnetic Compatibility Validation**

The Seller shall perform electromagnetic compatibility (EMC) on a first article unit in accordance with the requirements contained in Section 4.14 of the technical specification [3.1.1].

All EMC testing shall be conducted by an independent test laboratory that has been assessed and accredited in accordance with ISO 17025.

The Seller shall submit test plans developed for EMC testing to the Company for review and approval prior to conducting the ECM tests.

The Seller shall submit the final EMC test results to the Company for approval prior to producing additional units.

If modifications are required to the vacuum pump design during production, the Seller will repeat the EMC testing on the new design. If the Seller believes that the modifications do not warrant repeating the EMC tests, they will provide the Company with a comprehensive description of the changes and technical justifications for not redoing some/all the tests in a format as directed by the Company. If the Company does not agree, the Seller will repeat the EMC tests on the new version.

4.4 **Performance Requirement 4 – Documentation**

The following documentation shall be issued to the USIPO for approval prior to shipment of the pumps:

4.4.1 **First Article Testing and Validation Report**

The Testing and Validation Plan described in Section 4.3, shall be completed and approved by the USIPO certifying all requirements of the technical specification [3.1.1] have been successfully met. This document is to be submitted for approval to the USIPO, and then the approved document shall be returned to the Seller for inclusion in the Manufacturing Dossier [4.4.4].

4.4.2 **Contractor Release Note:**

Each delivery of hardware to the ITER site shall have a Contractor Release Note [3.2.7]. The Contractor Release Note (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.

USIPO is responsible for obtaining IO approval. The equipment shall not be delivered until the CRN has been accepted. A standard form [3.2.8] is available from the Company for documenting the CRN, but the Seller may propose an equivalent format, which must be accepted by the IO Quality Division. The Seller shall not submit the Contractor Release Note until all manufacturing and validation testing operations are complete. Once approved, the CRN shall be returned by the USIPO to the Seller for inclusion in the Manufacturing Dossier [4.4.4].

4.4.3 Certificate of Conformity

The Seller shall prepare a Certificate of Conformity for the turbomolecular pumps. The Certificate of Conformity shall state that the items meet all requirements defined in the technical specification [3.1.1] and this statement of work. The designated POC shall submit the completed Certificate of Conformity to the TPO. Once approved, the Certificate of Conformity shall be returned by the USIPO to the Seller for inclusion in the Manufacturing Dossier [4.4.4].

The Seller may use any suitable format for the Certificate of Conformity. At a minimum, the Certificate of Conformity shall include:

• Manufacturer’s details (name, address, etc.)
• Item identification details (model, serial number, etc.)
• Declaration that the equipment meets the applicable requirements (specifically list requirements documents)
• Any standards the item complies with
• Signature of Sellers’s authorized representative.

4.4.4 Manufacturing Dossier

A manufacturing dossier shall be compiled containing, at a minimum, any Deviation Requests [Section 5.5] or Non-Conformance Reports [Section 5.6] generated by the vendor, the component information as specified in Section 4.2, a copy of the completed Testing and Validation Plan in Section 4.3, any drawings generated in the course of this project, and completed copies of the Contractors Release Note [Section 4.4.2] and the Certificate of Conformity [Section 4.4.3]. Manufacturing Dossier shall also include a copy of the CE Certification certificate for the pumps as well as any manuals which
accompany the pump (i.e., operation, maintenance, installation, etc.) in both English and French.

4.5 Performance Requirement 5 – Data Management

4.5.1 Language and Units

All documentation required for operations, installation, and maintenance shall be provided in both the English and French languages. All correspondence, test reports, and documents required per this SOW and the associated technical specification, shall be provided in English. All dimensions and parameters shall be reported in SI units (e.g., mm, kg, N, MPa, °C) as the primary units.

4.5.2 Company Provided Information

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

4.5.3 Original Copies

The Seller shall keep and maintain the original copies of all signed documents. The Seller shall provide electronic copies of all documentation in searchable Portable Document Format (.pdf). Electronic documents shall be supplied to USIPO using email, USB storage device, or compact disc.

5 TRANSPORTATION

The Seller is required to load items to be transported onto the LSP conveyance (e.g., truck, van, trailer, vessel, ocean container, air freight, rail cart) at the factory. In doing so, Seller shall provide all necessary and customary equipment, personnel, and safety equipment for proper loading into the vehicle. The Seller shall also generate all shipping, packaging, and customs documentation as required by this SOW.

5.1 Packaging, Loading, and Storage

5.1.1 Packaging Design and Marking

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 resulting in nonconformity with applicable requirements. The seller shall provide a Package Design Document which includes the proposed packaging design as well as evidence showing it can withstand air, land, and sea transport.

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)

5.1.2 Storage of finished Products

The Company, at its discretion, may require Seller to postpone the date of shipment by up to sixty (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 sixty (60) days, Seller agrees to good faith negotiation of extended storage terms.

5.1.3 Loading

The Seller is responsible for loading the packaged hardware unto the LSP provided conveyance. Seller shall provide all equipment, personnel, and any custom tooling needed for loading the packaging.

5.2 Creation and Submittal of Pre-Shipment Documentation

NOTE: All documentation must be completed in the English language.

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

5.2.1 Pre-Shipment Deliverable Package No. 1

A pre-shipment Deliverable Package shall be provided by the Seller no later than 10 business days after the Project Kick-off Meeting.

Pre-Shipmemt Deliverable Package #1 is to contain the following items:
1) Written notice of the planned date on which the goods will be packaged and available for shipment.

2) Contact information for Seller’s Shipping/Logistics coordinator.

3) Technical characteristics of the packaged components as follows:
   a. Physical data and drawings showing dimensions, total and distributed weights, center of gravity (in 3 dimensions), shipping orientation;
   b. Address of the location where items are to be picked up by the LSP.
   c. Documentation (e.g., Material Safety Data Sheet) regarding relevant compliance regimes, such as Export Control, Transportation of Dangerous Goods, and Environmental Protection;
   d. Conditions or precautions to be respected when moving, loading/offloading, handling/slinging, and storing/marshaling to include, when required, specific provisions and controls to be performed and recorded while under the control of the LSP;
   e. 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;
   f. Packaging specification including confirmation of compliance with international packing standards (e.g., International Standard for Phytosanitary Measures (ISPM)-15, Conformite Europeenne/CE certification for relevant package lifting appurtenances such as eyes/rings), agree barcoding requirements and regulations relating to packaging materials used. NOTE: All packaging using wood products must comply with the requirements of ISPM-15;
   g. Definition of packaging/frame, when the components are packed or tarped, including any particular procedures for handling, moving, clean-up, maintenance, storage;
   h. Specification for securing and hanging packages/frames including jacking/lifting/lashing conditions, procedures, and acceptable securing points;
   i. Identification of specialized equipment/hardware (e.g., custom lifting fixture) interface requirements between each point of use within the supply chain. 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.

j. Description of Interface between Seller and LSP (e.g., release conditions for loads, Seller’s loading means, etc.);

k. Technical data concerning monitors (e.g., shock, vibration, tilt, acceleration, temperature) utilized to detect events during transit which may cause damage to components.

5.2.2 Pre-Shipment Deliverable Package No. 2

Pre-Shipment Deliverable Package #2 is to be provided no later than ninety (90) days prior to planned date of shipment.

Pre-shipment Deliverable Package #2 is to contain the following items:

1) Written confirmation of the date goods will be ready for shipment or submit revised shipment date for approval.

2) Contact information for Seller’s Shipping/Logistics coordinator

3) Fabrication value of goods (for insurance purposes—should not include destination site support services)

4) Transport drawings with sufficient detail to facilitate lifting/lashing/stowage and approval of the operators (e.g., steamship line, air carrier).

5) The following business documents (in English language):

a) **Pro-Forma/commercial invoice** on Seller’s letterhead listing at a minimum:
   
   - Subcontract number
   - Description and quantity of goods
   - Value of goods
   - Incoterms 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)

  b) 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)

- **Declaration of Integrity**

  The undersigned hereby certifies that the components and package(s) described on this Packing List meet the contractual requirements with the exception of any approved deviations and non-conformance reports 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 (7) days.

c) Export Control License(s) or other authorized documents if required.

5.2.3 Pre-Shipment Package No. 3

Pre-Shipment Deliverable Package #3 is to be provided no later than two weeks prior to planned date of shipment.

Pre-shipment Deliverable Package #3 is to 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.

5.2.4 Pre-Shipment Package No. 4

Pre-Shipment Deliverable Package #4 is to be provided no later than one week prior to planned date of shipment.

Pre-Shipment Deliverable Package #4 is to contain the following:

1. Any remaining information needed to facilitate appropriate completion of transport documents such as Bills of Lading or Air Waybills.

2. 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 (AES) when necessary


5.2.5 Package Marking

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)

5.2.6 Deviations from Planned Date of Shipment

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

6 QUALITY ASSURANCE

6.1 Conflicts

In the event of a conflict between the Technical Specification [3.1.1] and this Statement of Work, or between either of these documents and a requirement in a specified code or standard, the Seller shall notify the Company’s TPO and PO in writing. The TPO and PO will determine which document takes precedence and advise the Seller accordingly. Failure to notify the Company of any such conflict shall not relieve the Seller of any responsibility to meet all requirements.

6.2 Quality Program

The Seller’s Quality Program shall be implemented and sufficient to ensure that the quality of items produced, or services provided will meet all the requirements as stated in this document and as contracted. The Seller must produce the items or services in accordance with their quality assurance program as identified in their subcontract with the Company. Changes to the program that could affect the items or services must be approved by the Company in advance.

6.3 Quality Plan

6.3.1 Quality Plan Requirements for COTS solution

If the Seller can demonstrably satisfy all requirements of the technical specification and this statement of work, using an existing pump from their standard product line, no ITER specific Quality Plan is required.

6.3.2 Quality Requirements for Bespoke items

If the seller must modify a standard offered pump or develop a pump outside of their current product offering, then an ITER specific Quality Plan must be developed, submitted, and approved for the bespoke items.

If required, the Seller must develop a quality plan that incorporates the requirements per Requirements for Producing a Quality Plan [3.2.1], specifically for the subcontract, identifying how they will fulfill the specific subcontract requirements.
NOTE: This plan is in addition to the pre-established Quality Program of the Seller’s organization as detailed in section 5.2.

Work on the subcontract may not begin until notice is received that the Quality Plan is approved by the Company. The requirement for a subcontract-specific Quality Plan per Requirements for Producing a Quality Plan [3.2.1] shall be flowed down contractually from the Seller to the Sellers 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)].

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 should continue in accordance with the current approved Quality Plan until the revised Quality Plan is accepted.

A standard template, Quality Plan Template for Suppliers and Subcontractors [3.2.2], is available from the Company for documenting the contract-specific Quality Plan, but the Seller may propose to use their own equivalent format.

6.4 Access for Source Surveillance Inspections

As part of the Company’s quality assurance program, source surveillance activities may be conducted at the Seller’s facility or any sub-tier seller facility that the Company determines necessary to ensure quality objectives are met. Representatives of the Company, US Department of Energy, or other ITER-affiliated organizations (e.g., IO) may accompany the source surveillance team as inspectors or observers. Such surveillance may include auditing and monitoring of production processes, in-process inspection and controls, chemical or physical certifications, final inspection and tests, preparation for shipment, and review of certification data. The Seller shall provide the source surveillance team and inspectors, including observers, access to all data and operating areas pertinent to the subcontract without exception. Source surveillance by the Company representatives, source surveillance team, or inspectors shall not constitute equipment acceptance by the Company and shall in no way relieve the Seller of the responsibility to furnish acceptable items.

To ensure the safety of Company’s representatives and observers that visit the Seller’s facilities, the Seller shall provide relevant information about their facility safety procedures including, for example, safety glasses, hearing and respiratory protection, emergency preparedness, rally point, and general safety rules. Upon arrival, the Seller shall review typical workplace hazards with the representatives and discuss the applicable facility safety procedures.

6.5 Seller-Requested Deviation

The Seller may propose deviations from the specifications, drawings, or other technical or administrative requirements of this procurement, via the Deviation Request Procedure [3.2.3]. Where time is a consideration, the Seller may communicate the proposed deviation directly to the TPO (via e-mail correspondence), with a copy to the Company’s Procurement Officer. The
request should 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 provided to assist the Seller in requesting a Deviation from the company [3.2.4]. The Company’s TPO will evaluate the technical aspects and document a recommendation (cannot be verbal) to the Procurement Officer, 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.

6.6 Seller-identified Non-Conformances

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 follow the US ITER Nonconformance Report Procedure [3.2.5] to control the nonconforming item or process, document the condition and bring the issue to closure.

The Seller shall:

1) Identify and segregate when practical, the non-conforming item,

2) Stop any further work on the item until a decision is made,

3) Provide written notification of the discovered nonconformance and the discovery date (via email, copy of internal NCR form, US ITER NCR form partially filled out) to the TPO, with a copy to the Procurement Officer and QARO, as soon as possible but no longer than five (5) business days from discovery.

4) After the discovery process is complete, provide any additional details, proposed dispositions, and justifications (as necessary) to the Company in a Nonconformance Report using US ITER’s Non-Conformance Report Form [3.2.6].

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 is one that could affect a critical requirement, such as performance, safety, reliability, operability, traceability, interchangeability, or regulatory requirements. Minor nonconformances normally are those with no such impact.

Major Non-Conformance

Nonconformances identified as Major will require completion of a Root Cause Analysis (RCA). Following the RCA, the proposed remedial action for a major nonconformance shall be implemented only after written acceptance from the Company.
**Minor Non-Conformance**

If the Company decides the non-conformance is not a major non-conformance, the Seller shall take actions to resolve the non-conformance within its own quality system. However, the remedial action may only be implemented following written approval by the company.

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 impact 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 & approval matrix) that does not affect the quality of final product.
- Flow controller accuracy range not consistent with manufacturer’s data sheet, but data was correctable after calibration of the device.

### 6.7 Non-Conformance Report

The report should 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 [3.2.6] is available from the Company for documenting the nonconformance.

**NOTE:** The issuance and acceptance of a nonconformance report in no 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.

#### 7 DELIVERABLES

The following deliverables shall be submitted according to a timeframe which supports the approved schedule for this work and subcontract closeout.

**7.1 Hardware**

The hardware to be provided per this SOW are as follows:

a) Eight Magnetically Shielded Turbomolecular Pumps as described in the technical specification.

b) All hardware needed for installation of the pumps (fasteners, clamps, gaskets, flex hoses, etc.) as well as, at a minimum, three additional gaskets of each required size and type.
c) The required controllers and cabling to meet the validation and performance requirements of this SOW and related technical specification.

7.2 Documentation

The documentation deliverables and the corresponding sections of this SOW are:

- First Project Meeting Minutes (Section 4.1.1)
- Project Plan (Section 4.1.4)
- Progress Meeting minutes (Section 4.1.5)
- Inspection Plan for Bespoke Items (if applicable) (Section 4.2.2)
- Test and Validation Plan Proposal (Section 4.3)
- Completed Test and Validation Plan (Section 4.3)
- Contractor Release Note (Section 4.4.2)
- Certificate of Conformity (Section 4.4.3)
- Manufacturing Dossier (Section 4.4)
- Package Design Documentation (Section 5.1.1)
- Pre-shipment Transportation Documentation (Section 5)
- Quality Plan and any Related Documents (Section 6)