ANNEX 4

PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR PRESSURE SWING ADSORPTION (PSA) AND VACUUM SWING ADSORPTION (VSA) OXYGEN GENERATOR PLANTS AND RELATED SERVICES FOR ONSITE GENERATION OF OXYGEN 93% FOR MEDICINAL USE

This Annex provides offerors with the product(s) specifications and Technical Requirements for the procurement of the commodities requested as part of this solicitation.

1. Product Technical Specifications and Service Requirements

Please see the following technical specifications and service requirements for the PSA and VSA oxygen generator plant(s) with cylinder filling station, service agreement(s), warranty, proprietary consumables and durables (if any), including consumables / durables as needed for this procurement.

Table 1: PSA or VSA oxygen generator plant with cylinder filling station		
1	System Overview	● Oxygen generator unit with: oxygen analyser for medical application, oxygen tank (receiver/buffer tank) with bacterial inlet filter. ● Oxygen cylinder filling station with booster compressor.
2	Detailed requirements	● Uses pressure swing adsorption (PSA) or vacuum swing adsorption (VSA) technology to produce Medical Grade Oxygen 93, defined by USP as follows: *Oxygen produced from air by molecular sieve process. Contains not less than 90.0 % V/V and not more than 96 % O2 V/V, the remainder consists of mostly argon and nitrogen.* ● Provides piped in continuous flow oxygen for healthcare facility. ● Generates a minimum 300 LPM +/- 20%. ● Capability to fill oxygen cylinders in addition, minimum of 10 cylinders (size H), with high pressure manifold, cylinder connecting hoses and steel rack with safety chains. ● Easy to install, preassembled and skid-mounted or containerized. ● Feed compressor. ● Oxygen concentration monitor with +/- 1% accuracy. ● Continuous display of the oxygen concentration and pressure. ● Continuous output flow to cover up specified output. ● Continuous output pressure of 300-600 kPa / 3 – 6 bars / 44-87 psi. ● A gauge or sensor located between the output oxygen and the line pressure control to monitor the output pressure. ● External air dryer with capacity sized to manage compressor output.

Annex 4 – Product Specifications and Technical Requirements

<table>
<tr><td>3</td><td>Control panel / user interface</td><td>

Clearly visible, digital display, in English and/or Spanish, Portuguese, Tajik or French for at least:

Oxygen concentration [%]
Oxygen production trending [Nm3/hour]
Output pressure
System status, including current maintenance need
Cumulative hours of operation (digital or analogue meter)

Audible and visual alarms for:

High temperature
Low/high pressure (ex., output pressure < 3 bar / 44 psi)
Low oxygen concentration (<90%)
Power failure; system failure
Second/reserve source active
Air dryer pressure dew point (>3°C)

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<tr><td>4</td><td>Spare parts</td><td>

Propose spare parts list per recommended preventative maintenance program clearly defined in a disaggregated list comprising part numbers, descriptions, and unit cost, as well as indicating manufacturer/brand/model specifics (e.g. for circuit breaker, printed circuit board, sieve beds, compressor components, valves, wheels, motor capacitor, analyser, etc.).

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<tr><td>5</td><td>Power supply,
(*voltage, frequency and plug variations across the countries)</td><td>

Electrical source requirements: Frequency; Voltage; and Plug type based on country/setting of use as follows:

<table>
<tr><th>Focus Country</th><th>Frequency</th><th>Voltage</th><th>Plug Type</th></tr>
<tr><td>Afghanistan</td><td>50Hz</td><td>220V</td><td>C/F</td></tr>
<tr><td>Ghana</td><td>50Hz</td><td>230V</td><td>D/G</td></tr>
<tr><td>Haiti</td><td>60Hz</td><td>110V</td><td>A/B</td></tr>
<tr><td>Kenya</td><td>50Hz</td><td>240V</td><td>G</td></tr>
<tr><td>Malawi</td><td>50Hz</td><td>230V</td><td>G</td></tr>
<tr><td>Mozambique</td><td>50Hz</td><td>220V</td><td>C/F/M</td></tr>
<tr><td>Nigeria</td><td>50Hz</td><td>230V</td><td>D/G</td></tr>
<tr><td>Tajikistan</td><td>50Hz</td><td>220V</td><td>C/F/I</td></tr>
</table>

Variable Speed Drive, optional.

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<tr><td>6</td><td>Operational requirements</td><td>

Capable of supplying the specified oxygen concentration continuously in ambient temperature from 10–40 °C (and in some instances from 40 – 45°C), relative humidity from 15-95%, preferably simultaneously, and elevation from 0 to 1000 m, minimum. Some PSAs will need to operate at elevations up to 3000 m.
Capable of being stored continuously in ambient temperature from 10–40°C, relative humidity from 15–95%, and elevation from 0 to 1000 m, minimum. Some PSAs will need storage at elevations up to 3000 m.

Annex 5 requests pricing based on the operational requirements listed above, with the understanding that operation and storage at differing elevations and/or above 40°C and/or relative humidity above 95% may require additional components within the relevant PSA or VSA plant.
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<tr><td>7</td><td>Product labelling</td><td>

Electrical power input requirements (voltage, frequency and socket type)
Manufacturer serial number for tracking/inventory management
Labelling as required to meet U.S./international safety standards for medical O2 systems
Designating required environmental conditions for storage and operation (e.g. temperature, pressure, light, humidity)

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8	Warranty	Bidder to offer standard warranty period and terms, and extended warranty to address the below. These details are requested within Annex 5.
9	Facility/site requirements	1. The manufacturer shall perform a risk analysis complying with the requirements of EN ISO 14971 Medical devices; Application of risk management to medical devices, taking into account the device and its installation, control, supervision, and use. 2. Supplier will be responsible for equipment installation and installation qualification. 3. Where oxygen 93 is manufactured on site, the supply system shall undergo a formal validation program to demonstrate that it is fit for purpose. 4. Supplier will be responsible for training staff. 5. Supplier will be responsible for providing technical support for initial site documentation for regulatory approval.

Table 2: Service agreement conform contract		
1	Pre-installation requirements	**Manufacturer must explicitly provide the minimum operating requirements within the following aspects of the health facility:** ● Acceptable mains capacity. ● Appropriate connections/adaptors. ● Compatibility with back-up power supply (e.g. generator). ● Infrastructure requirements for outdoor or indoor operation e.g. roofing, ventilation, air conditioning, room and floor load requirements.
2	Requirements for commissioning	● DAP 2020 INCOTERMS. ● Note and report any signs of external or internal damage upon plant delivery. ● Verify oxygen concentration, flow and pressure level meets specifications when device is operational. ● Verify operation of oxygen analyser and all alarms, including power failure alarms. ● Verify automatic switch to secondary supply when failure, if applicable. ● Additionally, any other standard manufacturer commissioning protocols. ● Conformity of installation shall be verified by manufacturer's authorized local agent.
3	User and Maintenance training	**Manufacturer and/or authorized local service agent must explicitly indicate the following maintenance routines to match the dedicated staff capabilities within the health facility:** ● Cleaning routines of the PSA or VSA plant considering the electrical safety precautions. ● Cleaning routines for the filters, if applicable (i.e. reusable). ● Testing of alarms. ● Testing of operating pressures. ● Testing of oxygen concentration.

		• Frequency of the recommended maintenance routines (e.g., minor service after 150 operating hours, major service after 500 operating hours). • Safety precautions on management of oxygen. • Maintenance tasks required to be carried out by manufacturer's authorized local agent. • Additionally, any other standard manufacturer service routines not covered above.
4	Maintenance agreement during warranty period	Preventative maintenance parts and kits during warranty period must be included. The manufacturer shall define the costs for preventative and corrective maintenance and spare parts for a period of a least 3 years from date of installation. **Manufacturer must propose the maintenance routines and the predetermined system for procuring spare parts that are brand/model related.**

2. Conformity with Quality and Products Standards

Offerors and the products presented and delivered must fully comply with the following eligibility requirements:

2.1. Manufacturer(s) shall conform to the quality standards set by the International Organization for Standardization and/or the US FDA Quality System Regulations or shall have a valid GMP certificate. Manufacturer must be quality assured with valid certifications like ISO 13485:2016 and other ISOs as described below. A copy of the manufacturer(s) certifications(s) must be provided.

2.2. Product (or applicable components) shall have evidence of (a) US FDA Clearance and manufacturer shall provide evidence of medical device establishment registration with the US FDA **or** (b) CE Mark (USAID Recognized SRA)* Certificate. In case the aforementioned are not available, a clarification should be submitted by the offeror and a Free Sale Certificate (or equivalent) shall be provided.

2.3. Product shall conform to the applicable conformance standards:

- ISO 7396-1: Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.
- ISO 8573-1: Compressed air – Part 1: Contaminants and purity classes.
- ISO 8573-2: Compressed air – contaminant measurement – Part 2: Oil aerosol content.
- ISO 8573-4: Compressed air – contaminant measurement – Part 4: particle content.
- ISO 5011: Inlet air cleaning equipment for internal combustion engines and compressors – performance testing.
- ISO 21969: High pressure flexible connections for use with medical gas systems.

- All pressurized vessels to be:
  - Designed according to Pressurized Equipment Directive (PED) or American Society of Mechanical Engineers (ASME) VIII, or equivalent
  - Certified Pressurized Equipment Directive (PED) or American Society of Mechanical Engineers (ASME) III, or equivalent
  - Cleaned according to ISO 15001, ASTM G93, or equivalent

*R*ecognized stringent regulatory authorities (SRA): U.S. Food and Drug administration (USFDA), Japanese Ministry of Health, Labor, and Welfare (MHLW), also represented by the*

Pharmaceuticals and Medical Devices Agency (PMDA); European Medicines Agency (EMA) and member states admitted to the European Union (EU) prior to 1996 Hague Convention (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and United Kingdom); SwissMedic; Health Canada; and Australia Therapeutic Goods Administration (TGA).

3. Lead Time

Please provide the estimated lead time.

4. Post-Acceptance inspection

Each product delivered to GHSC-PSM shall comply with all product specifications and test procedures (when applicable) specified through the life cycle.

GHSC-PSM reserves the right to sample from and perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services continue to conform to the prescribed requirements after product acceptance. In the event, products are determined to not be fully compliant, the Offeror shall be required to remedy any defects or faults.

5. Product documentation

Manufacturer shall provide documentation for all components, equipment, instrumentation and materials used in the entire oxygen 93 supply system, including but not limited to the following (see below). If some documentation is not available to be submitted with the proposal, the Supplier must identify such documentation and provide when the documentation would be available (e.g. ready for shipment, installation, etc.) for submission.

- Pressure testing certificates for all pressure equipment, in accordance with relevant standards and country regulations.
- Evidentiary documentation of current and valid Manufacturer QMS and ISO certification by internationally recognized standardization bodies
- Manufacturer's product reference number and product description
- Certificate of conformance CE Mark (SRA), US FDA clearance (PMA/510K) or other when specified above in "Conformity with Quality and Product Standards".
- Contact details of manufacturer, and authorized distributors (if applicable), and local service agent.
- Recommended storage and transportation conditions
- When applicable, country product registration or import permit to the country of destination.
- Certificate of quality, calibration and inspection (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language)
- User manual, detailing (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language):
    - Specific protocols for operation
    - List of equipment and procedures required for cleaning, disinfection
    - Troubleshooting, calibration, and routine maintenance
- Service manual (Printed and electronic copies, in English, and translated into French, Spanish, Tajik and Portuguese language).
- Certificate of cleaning for oxygen service in accordance with EIGA Doc 33 *Cleaning of*

Equipment for Oxygen Service Guideline, or equivalent for the relevant equipment, piping and instrumentation.

- Certificate of calibration for instrumentation including transmitters, analysers.
- Process and instrument diagram.
- Equipment lay out.
- General piping arrangement.
- Electrical/control wiring diagrams
- Sequence of operation, including system controls and interlocks
- Installation manual.
- Operating and maintenance manuals.
- Equipment specifications (including compressors, blowers, filters, dryers, refrigerators, vessels, absorber vessels).
- Piping and fitting specifications.
- Pressure regulators and safety valve specifications.
    - Instrumentation specifications, including pressure and temperature gauges, temperature/flow/pressure transmitters, including oxygen analysers, carbon monoxide/carbon dioxide analysers, differential pressure analyser.
- Performance test of the PSA or VSA unit(s) including certificate and testing report.
- Hazard review.
- SDS - Safety data sheets for the material used.

6. Shipping Specifications

Plant to be skid-mounted or containerized to facilitate rapid installation.

Please provide a Packing List with items, weights and dimensions per pallet (as applicable) as well as a Detailed Packing List with aggregate quantities per item, weights and dimensions as well as shipping conditions applicable to the items (i.e. temperature control, special instructions around loading, or hazardous goods declarations) and all batch numbers and quantities. A Detailed Packing List template may be provided to the Supplier. Supplier is required to comply with packaging and shipping instructions related to the INCOTERM.

The supplier will identify cargo with dangerous / hazardous characteristics and, if applicable, provide details around transportation limitations and packing requirements that suit the appropriate mode of transport. At this point, GHSC-PSM should be alerted for actions and or direction on next steps. The Safety Data Sheet (SDS) shall be provided for these commodities. Any products with hazardous/dangerous characteristics should be packaged / palletized separately so as not to impact the mode of shipment. Where applicable, suggestions should be offered to GHSC-PSM around packing and mode of transport. Combinations of dangerous goods should be packed in a fashion best suited to the correct mode of transport for the quantities or characteristics and to ensure that these are segregated as necessary on the shipping documentation and mode of transport e.g. where flammable solids and flammable liquids are ordered together, these should be split and assigned new packing lists wherein acceptable quantities should be further aligned.

7. Packaging and Packing

The products to be supplied under a contract resulting from this solicitation will be packed and protected to prevent damage or deterioration during transportation and storage. The box will

be manufactured of a standard heavy-duty material appropriate for the destination countries where high heat and humidity is prevalent, that will withstand export handling and rough treatment, and help ensure the quality of the product. Individual boxes and shipping cartons (tertiary packaging) must be shrink wrapped on all sides in order to protect the goods from water damage during transit time. The supplier shall be required to remedy any defects or faults, and Chemonics will not be responsible for any additional costs

8. USAID Marking Requirements

Chemonics reserves the right to require USAID marking as below: The Manufacturer(s) will be responsible for ensuring that all export shipping cartons, whether shipped from the United States or from any other source country, carry the official USAID emblem.

Emblems will be affixed by metal plate, decal, stencil, label, tag, or other means, depending upon the type of commodity or export shipping carton and the nature of the surface to be marked. The emblem on each export-shipping carton will be affixed in a manner which assures that the emblem will remain legible until the carton reaches the consignee. The size of an emblem will vary depending upon the size of the commodity and the size of the package or export-shipping carton. The emblem will, in every case, be large enough to be clearly visible at a reasonable distance.

Emblems will conform in design and color to samples available from USAID and can be found at: http://www.usaid.gov/branding/.

Emblems will be obtained by the Manufacturer(s) at its expense in the quantity and type required. The Manufacturer(s) will be required to affix USAID emblems in accordance with the marking requirements stated above.

A list of the emblem suppliers can be found at: http://www.usaid.gov/branding/suppliers.

9. Innovation

- ### Bar coding

  Not applicable for this procurement.

- ### EDI (Electronic Data Interchange)

  Not applicable for this procurement.

- ### Vendor Management Inventory

  Not applicable for this procurement.

- ### Global Trade Item Number (GTIN)

  Please see the Global Standards Section of Annex 1 – Basic Ordering Agreement Template with Terms and Conditions for requirements.