ANNEX 4

PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR MEDICAL GRADE OXYGEN

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

1. Product Description

No.	Product Category	Item Description	Unit of Measure	Quantity
1	Medical Gas	Medical Grade Oxygen (liquid oxygen)	Cubic Feet	As per Annex 1, Pricing Quotation
2	Medical Device	Cryogenic vessels (i.e. Vacuum Insulated Evaporator(s) (VIEs); Bulk tank(s))	Each (capacity expressed in Kg)	As per Annex 1, Pricing Quotation
3	Medical Device	Cylinder Manifold System	Each	As per Annex 1, Pricing Quotation

2. Conformity with Quality and Products Standards

Pharmaceuticals and medical devices procured using US Government funds under GHSC-PSM are restricted commodities and must comply with the guidance as indicated under ADS 312 from the United States Agency for International Development (USAID) Global Health Bureau. The vendor guarantees that the offered items are compliant with the USAID guidance for Pharmaceuticals ADS 312. (https://www.usaid.gov/sites/default/files/documents/312.pdf).

Offerors and the products presented and delivered must fully comply with the eligibility and QA requirements specified in the table below. In certain pre-defined situations, GHSC QA staff may be able to recommend a waiver of some of the requirements.

Item	Eligiblity Criteria	QA Requirements
Medical Grade Oxygen (liquid oxygen)	(a) Product shall have evidence of USAID recognized SRA approval; for US FDA cleared producs manufacturer shall provide evidence of manufacturing establishment registration with the US FDA. (b) Evidence of product's registration, clearance and/or approval issued by the National Regulatory Authority of the exporting country or the country of intended use (i.e. importing country).	Medical Grade Oxygen is an essential medicine and is regulated as a finished pharmaceutical product. Medical Oxygen must be manufactured (e.g., processed, filled, transfilled, mixed, purified, separated, cascaded, transferred, packaged, and distributed) using CGMP. • Supplier (when not the same as the manufacturer or distributor) shall have a valid quality management certification like ISO 9001:2015 or ISO 13485:2016 or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certifications(s) included. If a documented Quality Management System is not available past performance or other alternative means may be considered. • Manufacturer shall have a valid GMP Certificate or equivalent • Product shall meet USP or Eur Ph standards: – USP: ≥ 99.0% by volume of O2 – Eur Ph: ≥ 99.5% by volume of O2 • Adequate label for storage container, including "Oxygen", lot number, manufacture date and expiration date. Label shall state if Oxygen was produced by the air-liquefaction process. Where it is piped directly from the cylinder or storage tank to the patient point of use, adequate label label each outlet "Oxygen". • Container connections shall be appropriate for Oxygen. Adaptors shall not be used to connect containers to patient use supply system piping or equipment.

		• A certificate of analysis shall be provided for each lot supplied. • A safety sheet for medical grade liquid oxygen shall be provided
Mobile and fixed cryogenic vessel destined for Liquid Oxygen transportation and storage (e.g. road tanks, bulk storage tanks, Vacuum Insulated Evaporators, etc.)	Cryogenic vessels shall meet national and international regulations including but not limited to IMDG, ADR-RID- US DOT, CSC, or equivalent [1].	Medical Grade Oxygen can be stored in a variety of containers. Liquid Oxygen referred to in this RFQ shall be transported in mobile cryogenic vessel and stored in fixed cryogenic vessel specifically designed for medical grade liquid oxygen. • **Mobile (transportable) cryogenic vessel:** A mobile thermally insulated container designed to contain liquefied or cryogenic gases. The gas is removed in liquid form. It is filled in the filling area of the pharmaceutical establishment, then transported to the site of utilisation. • **Fixed (static) cryogenic vessel:** A static thermally insulated container designed to contain liquefied or cryogenic gases. The gas is removed in gaseous or liquid form. • Manufacturer shall have valid QMS: ISO 9001:2015 or ISO 13485:2016 Manufacturer Certificate or equivalent or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certifications(s) included. A copy of the manufacturer(s) certifications(s) must be provided.

[1] IMDG: International Maritime Dangeroud Goods; ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road; RID: Agreements Concerning the International Carriage of Dangerous Goods by Rail (RID); US-DOT: United States Department of Transportation; CSC: Convention for Safe containers

		• A certificate of inspection certifying mobile/fixed cryogenic vessel has been inspected by third-party inspection agency or notified bodies in accordance with applicable regulations and standards shall be provided. • A Cryogenic Vessel(s)) Technical Specifications Datasheet detailing product design specifications (characteristics, material, design scope, capacity and dimensions, working temperature, working pressure, pressure valves, etc.) and applicable directives and standards shall be included • Medical gas mobile and fixed cryogenic vessels (i.e. ISO portable tank) shall comply with the below regulations and standards or equivalent, as applicable: • Product shall comply with relevant QA standards or equivalent as specified. **QA standards:** **General:** o ISO 1496-3:2019 Series 1 freight containers — Specification and testing — Part 3: Tank containers for liquids, gases and pressurized dry bulk o ISO 21010:2017 for Cryogenic vessels – Gas/materials compatibility o ISO 21013-1:2021 for Cryogenic vessels – Pressure-relief accessories for cryogenic service – Part 1: Reclosable pressure relief valves o ISO 23208 for Cryogenic vessels – Cleanliness for cryogenic service **Large transportable vaccum insulated vessels:** o EN 13530-1:2002 - Cryogenic vessels - Large transportable vacuum insulated vessels - Part 1: Fundamental requirements

		○ ISO 20421-1:2019 Cryogenic vessels - Large transportable vacuum-insulated vessels - Part 1: Design, fabrication, inspection and testing ○ ISO 20421-2:2017 Cryogenic vessels - Large transportable vacuum-insulated vessels - Part 2: operational requirements **Static vaccum insulated vessels:** ○ EN 13458-1:2002 - Cryogenic vessels - Static vacuum insulated vessels - Part 1: Fundamental requirements ○ ISO 21009-1:2008 for Cryogenic vessels – Static vacuum-insulated vessels – Part 1: Design, fabrication, inspection, and tests ○ ISO 21009-2:2015 Cryogenic vessels - Static vacuum insulated vessels - Part 2: Operational requirements • **Packaging and Labelling** Specific cryogenic vessels compatible with liquid oxygen shall be used. Cryogenic vessels shall be compliant with applicable United Nations nomenclature: UN 1073: Oxygen, refrigerated liquid (cryogenic liquid), Hazard Class 2.2 and include appropriate labels. ○ Label 2.2 – Oxygen; Non-flammable, non-poisonous gas; ○ Label 5.1 – Oxidizer Product shall be labeled with manufacturer/distributor information. The labelling shall state reserved for medicinal use. Each portable tank must have permanently marked on the metal identification plate the following: ○ owner information (name, registration number); ○ manufacturing information (country, year, manufacturer's name and serial number); ○ approval information (UN symbol, approval country,

		authorized body for approval, design approval number, pressure vessel code, TC IMPACT APPROVED and T code (as applicable); ○ pressures (MAWP, test pressure, intial pressure test date, identification mark of inspector, external design pressure, MAWP for heating/cooling system); ○ temperatures (in °C); ○ materials; ○ capacity at 20°C in liters; ○ insulation; ○ hold times ○ periodic inspections and tests • Adequate directions for use shall be included
Cylinder manifold system	(a) Product shall have evidence of US FDA Clearance (PMA/510K) and manufacturer shall provide evidence of medical device establishment registration with the US FDA or (b) CE Mark (USAID Recognized SRA)* Certificate; for product that are US FDA 510K exempt, manufacturer shall provide evidence of medical device establishment registration.	• Manufacturer shall have valid QMS: ISO 9001: 2015 or ISO 13485:2016 Manufacturer Certificate or equivalent or approved by standards regulatory bodies in country of manufacturer, which bodies must be accredited by or affiliated to standards institutes like ISO, with copy of certifications(s) included. A copy of the manufacturer(s) certifications(s) must be provided • Product shall comply with relevant QA standards or equivalent as specified. **QA standards:** ○ ISO 14971 Medical devices — Application of risk management to medical devices ○ ISO 7396-1:2016 Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (in accordance with) ○ ISO 21969:2009 High-pressure flexible connections for use with medical gas systems ○ ISO 10524-2:2018 Pressure regulators for use with

		medical gases — Part 2: Manifold and line pressure regulators OR ○ ISO 10079-3:2022 Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source ○ ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications ○ Conforms to ISO, NFPA, and/or CGA standards, and/or UL or CSA approved. ○ Cleaned according to ISO 15001:2010 Anaesthetic and respiratory equipment — Compatibility with oxygen, ASTM G93, or equivalent • A Product Technical Specifications Datasheet detailing product design specifications (characteristics, material, design scope, parts, etc.) and applicable directives and standards shall be included • Product shall be labeled with manufacturer/distributor information and part identification number; lot number and expiration date required when applicable • Adequate directions for use shall be included. • A certificate of conformance shall be provided for each product procured.

3. Quality Assurance Provision

According to GHSC-PSM Standard General Contract Terms and Conditions as to this solicitation.

4. Pre-Acceptance Sampling and Testing requirements

When applicable, offeror shall coordinate with GHSC's quality assurance contractor, Global Health Supply Chain Program - Quality Assurance (GHSC-QA) implemented by FHI360 (ghsc-qa-orders@fhi360.org), who will implement inspection, sampling, quality assurance testing and acceptance within the terms and conditions outlined below.

4.1. Sampling requirements

GHSC-QA reserves the right to sample from the Manufacturer's facility and to perform or cause to be performed any of the tests and inspections set forth in this purchase description to assure that supplies and services conform to the prescribed requirements.

4.2. Test method

When required, product will be tested in accordance with established GHSC-QA protocols. The manufacturer will be requested to provide the specifications and test methods utilized for product release. In instances when a method transfer is required, manufacturer will be requested to provide for method transfer and routine test reference substances required for performing the laboratory QC tests.

4.3. Lot disposition

Where testing is not required, it is not applicable. Product is released per manufacturer specification where applicable.

4.4. Manufacturer Furnished inspection data

When applicable, Manufacturer shall provide a summary of the final inspection results for each lot available for delivery under this contract prior to shipment to GHSC-PSM. Individual test reports shall be maintained by the Manufacturers, and shall be made available for inspection by GHSC-QA.

5. Post-Acceptance inspection

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

GHSC-QA 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.

6. Product documentation

The following product documentation is required as part of this solicitation: Completed Annex 4: Medical Gas: Technical Questionnaire. Offerors shall submit the completed questionnaire in accordance with the instructions provided in *Supplement 1: Instructions for Creating and Submitting Technical Documentation to FHI 360*. Additional documentation may be requested.

The following product documentation is requested and shall be provided as part of the procurement process:

- A certificate of analysis for each lot of the medical gas supplied, a certificate of inspection/conformance of the container(s) used for transportation and storage of medical gas and a certificate of conformance for each cylinder manifold system shall be provided, as specified in product quality standards section.

7. Shelf Life

Goods with a Shelf Life must be freshly manufactured within the past 12 months, and thus have maximum possible shelf life. Goods with a maximum possible shelf life of less than 24 months shall have at least 85% of shelf life remaining when delivered. Goods with a maximum possible shelf life of more than 24 months shall have at least 24 months, or 85%, of shelf life remaining whichever is longer, when delivered.

No Goods will be accepted which do not comply with 7.1 requirements unless Chemonics has agreed in writing to different requirements, in which case the Goods must strictly comply with those modified requirements. The period of warranty referenced in Section VI for all goods with a shelf life shall be no less than the minimum Shelf Life of the Goods.

8. 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 cryogenic containers used for the transport and storage of product must be manufactured with appropriate materials for the destination countries where high heat and humidity is prevalent withstand export handling and rough treatment and help ensure the quality fo the product. The responsibility of periodic inspections, maintenance and adequate quality of the cryogenic containers in use lies with the supplier. The supplier shall be required to remedy any defects, faults and Chemonics will not be responsible for any additional costs

9. 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.