As indicated in Annex 4 of the RFP, Table 1:

**Question 1:** Detailed Requirements, Bullet Point #4: Where it indicates 'minimum of 10 cylinders' (size H), is this a filling quantity per day (24 hours) that would be required?

**Response:** The 10 cylinders filling requirement is per day (24-hour period).

**Question 2:** Spare Parts: Do you require a specific 'spare parts' duration schedule encompassing 1, 3- or 5-year packages for the PSA/VSA oxygen plants?

**Response:** Spare parts duration minimum is 12 months with additional 12-month options up to 5 years.

**Question 3:** Power Supply: Please confirm if ‘each’ of the designated countries listed have both single phase and 3-phase electrical power available on-site. In reviewing the chart, it only indicates single phase power.

**Response:** This information is currently being researched through an initial facility level assessment. Additional information will be shared once those specifications are confirmed.

**Question 4:** In Section 5, Product Demonstration, Bullet Point #4: Do the respective pressure vessels for the PSA/VSA oxygen plants require CE certification/compliance for the 8 countries listed?

**Response:** Yes, 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 for proposed models for the 8 countries listed are required. In the event the aforementioned are not available, a clarification should be submitted by the offeror and a Free Sale Certificate (or equivalent) shall be provided.

**Question 5:** ISO 13485 certifies QM systems for Medical Devices. Do you also require certification of compliance EU Council Directive 93/42/EEC Annex II which certifies the actual Oxygen Generation Plant CE and not just the management systems in place?

**Response:** Both, ISO 13485 certifications and CE mark certification are compliant with EU Council Directive 93/42/EEC Annex II and are required if the Oxygen generation plant is regulated by this EU Directive.

As listed in Annex 4 of the RFP: PRODUCT SPECIFICATIONS AND TECHNICAL REQUIREMENTS FOR PRESSURE SWING ADSORPTION (PSA) OXYGEN GENERATOR PLANTS AND RELATED SERVICES FOR ONSITE GENERATION OF OXYGEN 93% FOR MEDICINAL USE

1.1 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.
1.2 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.

**Question 6:** Do plants need to be prepared for outside installation (with weather protection)? If so, then probably containerized solutions preferable - correct?

**Response:** Yes, in Annex 5 pricing, PSM is asking for offerors to price both containerized and non-containerized solutions. Depending on the facility assessment and situation, it’s very possible a country may require the containerized solution. We’re trying to capture the broadest range of possibilities when a facility is ready to order a PSA/VSA plant.

**Regarding Oxygen Concentrators & PSA/VPSA Plants:**

**Question 7:** BOA No. GHSC-PSM-BOA-2020: At what time should we raise items of negotiation within the contract? We prefer to list our concerns directly with Chemonics/USAID. Is this possible?

**Response:** Offerors may include proposed edits or redlines of the BOA with their offer; however, Chemonics will not address any proposed changes until we negotiate with apparently successful offerors.

**Question 8:** Service: What service shall be included in the price of the units?

**Response:** Please stipulate which RFP section including item number you are referring to.

**Question 9:** Warranty: It is given on parts, labour is not included – do you want labour to be included during the warranty period or should it be quoted separately as part of the “Service Level Agreement”?

**Response:** Provide standard warranty and explain what it covers and what it doesn’t. Anything excluded from your standard warranty may be proposed and priced in your extended warranty or SLA according to your business practice and/or corporate standards.

**Question 10:** Quality Certificates and Docs (see page 46 of Annex 1, BOA) requested in different languages: Official documents are available in ENG only, user manuals are multi-language (ENG, FR, ESP, POR, not available in Tajik). Would Russian language be acceptable for Tajik?

**Response:** If your user manuals are not available in Tajik, then Russian language user manuals are acceptable.

**Question 11:** Technical manual and patient manual requested to be shipped with the unit: we only ship the user manual, both user and tech manuals are available online. We cannot alter the content of the box.

**Response:** Noted.

**Question 12:** Some of the required quality documents may not be made available because protected by copyright or patent, please indicate if accepted.
Response: Please stipulate which RFP section including item number you are referring to and what documentation or quality information you consider to be copyrighted.

Question 13: USAID marking requirements – see Annex 4 Product Specs, page 8: emblems must be obtained and affixed by us at our expenses. Please specify where it must be affixed, i.e. on which packaging (primary or secondary, i.e. boxes or pallets).

Response: Per USAID’s branding and marking requirements a banner must be placed on the pallet, a sticker affixed to the box, and, if it does not impede or interfere with the function of the equipment, a sticker on the equipment.

Question 14: INCOTERMS: please confirm FCA ATL airport or Miami port are accepted, as well as New York airports and port.

Response: Incoterms for PSA/VSA plants is DAP hence the receiving health facility will not take possession of the equipment until it has been installed, commissioned tested, and accepted.

Question 15: In Annex 6 Service Level Agreement: the KPIs are not realistic, i.e. points 2 and 3 are not applicable in countries that are large and lack infrastructures allowing fast transportation. Please consider changing them to days instead of hours Example: point 2 within one working day; point 3 within 5 working days.

Response: Noted. Offeror is requested to negotiate with local agents/service provider and propose reasonable KPIs per country based on your service network/platform capability.

Question 16: Registration: if the registration in a country where it is not necessary becomes mandatory, the Supplier must be given time to adjust and apply for registration. Equally, if a registration expires, Supplier must be granted time to re-register.

Response: Noted. Please indicate countries where proposed models are registered, and any registration expiration dates as applicable. To the extent an offeror’s product is not registered and needs to be registered or re-registered prior to importation, Chemonics/PSM may be able to obtain registration waiver(s) on a case by case basis.

Regarding PSA/VSA Plants, Annex 4:

Question 17: You specify capability to fill minimum 10 oxygen cylinders (size H) but you do not rate of filling in days/hrs/weeks?

Response: The 10 cylinders filling requirement is per day (24-hour period).

Question 18: Regarding oxygen output pressure is any PSA acceptable within the range of 44-87PSIG?

Response: Any PSA can be acceptable if it satisfies other requirements per annex 4.

Question 19: What is the 3 Phase Power Supply available at the Focus Countries listed?

Response: This information is currently being researched through an initial facility level assessment. Additional information will be shared once those specifications are confirmed.
Question 20: Please explain “formal validation program” This refers to the testing element related to commissioning the PSA/VSA plant itself.

Response: The formal validation program will verify that O2 produced meets specifications and the test will be conducted by national regulatory bodies as appropriate.

Question 21: Do you require the capacity of 240-300 LPM of oxygen production to supply oxygen to the central hospital pipeline while simultaneously having the capability to fill oxygen cylinders at a pressure of up to 151 Bar g. at a given flow rate? LPM?

Response: Our specification calls for 300 LPM +-20% therefor the range is from 240 LPM – 360 LPM. The proposed model should have the capacity to use this total oxygen flow to supply the health facility and/or fill cylinders (at a pressure of 150 bar/2200 psi) if the full oxygen flow rate is not used in the health facility. Asynchronous cylinder filling capability is also acceptable.

Question 22: We note that you have included VPSA in your technical requirement. To the best of our knowledge, an oxygen concentrator (PSA) is the only Medical Device sanctioned with a GMDN number and description - not VPSA. The GMDM number and description for the plant in question is for PSA plant – GMDN 57850 – description “Bulk oxygen concentrator system” which refers to a PSA not VPSA – see https://www.gmdnagency.org/Terms/Details/1000059?lang=en

GMDN AGENCY
Term Details
Name: Bulk oxygen concentration system
Definition: A stationary assembly of mains electricity (AC-powered) devices designed to concentrate oxygen (O2) from ambient air and then deliver the concentrated O2, with purity of up to 99.5%, to the hospital medical gas supply system. It may produce high-purity O2 using pressure swinging adsorption (PSA) technology which processes air through internal molecular sieves having a large total surface area to separate nitrogen (N2) from the air. It typically consists of an air compressor, refrigeration dryer, water and oil separators, high pressure O2 pump and various storage tanks. The concentrated O2 is delivered via the medical gas supply system to the user and/or a gas cylinder filling station.

Code: 57850
Status: Active
Created Date: 15 Oct 2010
Note that ISO 7396-1: 2016 speaks about concentrator units – which would imply PSA oxygen concentrators – albeit single bed concentrator units and not vacuum pressure swing adsorption units.

Could we please have clarity on the above regarding the validity of VPSA for your requirements, given that there is no GMDN and a subsequent description of the same.

Response: ISO 7396-1:2016 applies to the following different types of oxygen supply systems:

- Supply systems in which all sources of supply deliver oxygen; in this case the concentration of the oxygen will be greater than 99%
- Supply systems in which all sources of supply deliver oxygen 93; in this case the concentration of the oxygen may vary between 90% and 96%
Per our understanding VSA is a slightly different technology from PSA but follows the same principles overall.

Question 23: Requirement in Annex 4 – oxygen generator and booster, is that one system/one line of production?

Response: Yes. The specifications included in Annex 4 refer to a single unit/system.

Question 24: Are facility locations still being discussed, do we only know countries?

Response: USAID is working closely with country Missions to identify recipient facilities and conduct respective facility level assessments. In line with the terms of the RFP, offerors should assume a delivery location within the capital city in each country for the purposes of deriving their proposal. To allow the greatest degree of flexibility with respect to installation costs, annex 5 requests that offerors detail standard installation costs in addition to itemizing hourly labor rates for custom level installs. For custom installation costs it is recommended that offerors indicate what constitutes a custom installation and what assumptions are included.

Question 25: If we give you a general cost for installation and then say there will be additional costs for example for 1-hour drive vs. A 5-hour drive, will that be sufficient?

Response: Offerors should indicate, in appropriate level of detail, what assumptions are factored when deriving standard installation costs versus a custom installation.

Question 26: Do we assume at this stage that the plant room is already there, a suitable location for the equipment is already there? And how will we get things like electrical supply to the equipment?

Response: PSM’s USAID colleagues are conducting facility level assessments with country missions to identify where the plants will be delivered and commissioned. Power and infrastructure requirements are key elements to determine site readiness to receive a PSA/VSA plant. The assumption is that there will be a room or covered space with appropriate flooring to meet the load requirements to house the equipment with adequate power (three phase). Suppliers are responsible for connecting the PSA/VSA plant to the electric panel/source.

Question 27: How will we get it lifted off a truck for instance? Will that be included in PSM’s evaluation as well or are the manufacturers supposed to include that?

Response: The supplier is responsible for off-loading the plant from the truck to include but not limited to coordinating heavy machinery, recruiting labor and other incidentals as necessary to facilitate the process.

Question 28: Annex 4, what is the three-phase power availability? What we see is just the single-phase.

Response: That will be informed through the facility level assessment as noted in response to question no. 26 above.

Question 29: Speed, quality and sustainability are three qualities you will be looking into. How will you assess the sustainability portion? Will you for instance, be looking into power consumption throughout the course of 5 years, the material in which the plant is being made, etc. How will you assess that?
Response: Sustainability will be assessed through three different elements. Total cost of ownership which includes estimated costs over time as presented in the supplier’s offer. Chemonics will also assess the capability of the supplier’s local service provider and have requested references to inform this element. The third will assess suppliers’ past performance in terms of long-term operation.

**Question 30:** Regarding the SLA, during the warranty period typically labor is not included but parts are. So we should price in during the warranty period the ability for our agents to visit the sites, and then after that, there would be a different cost for the service agreement?

**Response:** Offerors should indicate the hourly rates for the different labor categories so those can be pre-negotiated and incorporated into the SLA accordingly.

**Question 31:** Regarding contracts, for example, if the name of the company has a bank account associated with that name, should the name be different from the parent company, but the bank account is the same, is that an issue?

**Response:** Yes, that is an issue since the name on the invoice needs to match the legal name on the BOA, in the Purchase Order and the legal name on the bank account. We can add more than one name as the contracting entity on the BOA.