

STATEMENT OF WORK

1. General

1.1 The purpose of this solicitation is to establish a committed source of supply of medical-grade liquid bulk oxygen for the Department of Veterans Affairs (VA), Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX, facility included in the solicitation. The contractor shall provide a contractor-owned tank with an appropriate back-up system (i.e. reserve tank or cylinder bank) and liquid bulk oxygen.

1.2 The quantities are estimates of the facility's annual requirements for the Michael E. DeBakey Veterans Affairs Medical Center, Houston, TX. There is no express or implied guarantee that these quantities will be purchased. The contract period for the base contract awarded under this solicitation will be from date of award through a one year period with four option periods, if exercised by the government. Please note that contracts that include the installation of contractor-owned equipment will include a 30 day transition period at the beginning and end of the contract period. (paragraph 5.1).

1.3 Contracting Officer Representative (COR) will be assigned upon contract award for this ordering facility. The COR is responsible for contract administration issues such as ordering and providing specific delivery instructions. A letter of delegation that outlines the COR's specific responsibilities will be provided to the contractor and COR at the time of contract award. Within 15 days after notification of contract award, the contractor shall meet with the COR to ensure mutual understanding of facility requirements relating to the ordering method and specific details of any delivery instructions.

1.4 Prior to first filling and yearly thereafter, contractor must perform in-service training to include the following facets for contractor owned and government owned systems: the refill procedure, any preventive maintenance support requirements that may be needed from the medical center systems, and an explanation of all the volume alarm and low pressure set-points. The contractor will provide written procedures and training for VA staff for protocols to accomplish emergency shutdowns or other sudden, unplanned termination of the refilling process. Contractor will provide 24/7 emergency contact name(s) and telephone number(s).

1.5 Prior to first filling and at least yearly thereafter, and thereafter, alarm set-point testing and written verification must be presented through the use of a qualified third party expert per [NFPA 99 Standard for Health Care Facilities 2015 Edition](#) for contractor owned and government owned systems. Any code deficiencies in the Medical Center's existing system, as defined by NFPA 50 "Bulk Oxygen System", must be identified by the contractor. A detailed explanation of these deficiencies must be presented in writing to the COR. Receipt of this written explanation must be signed for by the COR.

1.6 Prior to first filling, and thereafter, the contractor must verify, in writing, the accuracy of all gauges on contractor owned tanks. If the gauge(s) are government owned, contractor will provide, if requested after award, a written proposal with price to verify accuracy of the

gauge(s). The Government may choose to exercise this option at its desire.

2. Acronyms

2.1 This section lists acronyms that are used in this Statement of Work and other parts of the solicitation.

CCF – 100 cubic feet

CF – Cubic feet

CGA – Compressed Gas Association

CGMP – Current Good Manufacturing Practices

CO – Contractor owned

COR - Contracting Officer Representative

DOD – Department of Defense

DOT – Department of Transportation

FDA – U.S. Food & Drug Administration

GO – Government owned

IHS – Indian Health Service

NFPA – National Fire Protection Association

OGA – Other Government Agency (Other than VA)

OSHA – U.S. Department of Labor, Occupational Safety and Health Administration

USP – United States Pharmacopeia

VA – Department of Veterans Affairs

3. Government-Furnished Property

3.1 The solicitation schedule will identify the bulk oxygen storage tank(s) at each facility as being either **GO** (Government Owned) or **CO** (Contractor Owned). Government owned bulk oxygen storage tanks and appurtenances will be maintained by and at the expense of the Government in a manner that will insure compliance with applicable regulations, standards and normal good practices.

3.2 Government facility shall provide a suitable location and foundation for the installation of the contractor owned bulk oxygen tank(s). Additionally, facility shall provide access to an electrical power source and hook-up to a facility-maintained alarm system. The contractor shall perform the hook-up of contractor owned equipment to the facility-maintained alarm system.

4. Contractor-Furnished Equipment

4.1 For contractor owned tanks, the contractor shall provide, install and maintain bulk oxygen tank(s) with appropriate back-up system(s). Through the duration of the contract, the contractor shall be liable for the integrity, suitability, and safety of contractor owned tank(s) that will insure compliance with applicable regulations, standards and normal good practices. The tank capacity and reserve system shown in the schedule are minimum capacities required by the using facilities. Manifold, cylinders for the reserve supply, liquid converter, alarm switch, regulator,

valves, level indicator, and any other devices or connections required for proper tie-ins with the facility's gas system shall be furnished by the contractor, without cost to the Government. The manifold or liquid converter shall deliver gas at a pressure and rate of flow adequate to supply the system. Each liquid oxygen storage container shall have an outlet that allows access for testing the purity of the oxygen.

4.2 All equipment and materials required to perform on the contract (other than what is specifically listed in section 3, Government-Furnished Property) shall be provided by the contractor. Contractor owned equipment shall be installed, inspected, and maintained by the contractor without additional cost to the Government (i.e., all installation, inspection, and maintenance costs shall be included in the contract's monthly equipment rental fee). Contractor owned equipment shall be kept in good operating condition and appearance, in accordance with applicable regulations, standards and normal good practices. The contractor shall be provided reasonable access to the bulk oxygen systems for this purpose.

5. Installation of Contractor-Owned Equipment

5.1 Unless otherwise directed by the using facility, contractor owned equipment shall be installed by the effective date of the contract, October 1, 2015, and shall be connected to the medical gas system on that date; provided that the contractor shall be allowed a maximum of thirty days after receipt of notice of award to complete installation. If the contractor's equipment replaces equipment already in use, the exchange of equipment shall be accomplished without interruption of gas supply to the using facility. Contractor installed equipment shall remain the property of the contractor and shall be removed upon termination of the contract, when directed by the ordering facility and in full cooperation with the succeeding contractor so as to avoid interruption of gas supply.

5.2 Upon expiration or termination of the contract and if the contractor is not awarded a follow-on contract, the contractor shall remove contractor owned equipment at no cost to the Government. To permit orderly transition from one contractor to another, the contractor shall continue to honor the contract's monthly equipment rental fee and bulk oxygen contract price for scheduled expiration of the contract period, unless transition from one contractor to another is completed prior to transition period. For any partial month, the contractor shall prorate the monthly equipment rental fee accordingly. The contractor shall continue to provide and maintain its equipment during this transition period.

5.3 No guarantee is given or implied that data included in the schedule regarding contractor owned equipment currently located at the facilities is complete and accurate as to the factors affecting the cost of furnishing and installing the required contractor owned tanks and appurtenances. **Offerors are strongly encouraged to visit the facility sites prior to submitting a quote** and take other steps as may be reasonably necessary to ascertain the nature and location of the work, and the general and local conditions which can affect the work or the cost thereof. Failure to do so shall not relieve offerors from the responsibility of estimating properly the difficulty and cost of successfully performing the work. A Site Visit can be arranged by contacting Mr. Barton at phone number (713) 794-7878 or Mr. Aguilar at phone number (713) 794-7593.

5.4 All contractor owned equipment shall be installed in accordance with NFPA 50: Standard for Bulk Oxygen Systems at Consumer Sites, 2001, NFPA 99 Standard for Health Care Facilities, 2002 Edition, and FDA's Current Good Manufacturing Practices (CGMP) Regulations. The contractor shall comply with all OSHA standards and applicable safety requirements, including proper signage and use of personal protective equipment.

6. Delivery of Medical Liquid Bulk Oxygen

6.1 Bulk oxygen is ordered by and delivered to the individual ordering facility. Information regarding unique delivery requirements is included in the solicitation schedule.

6.2 The contractor shall deliver medical-grade liquid oxygen within the time-frame specified in the schedule. The time-frame identified may be either the number of calendar days after receipt of the Government's order, the specific days of the week for delivery, the specific time intervals between deliveries, a specified reorder point, or other specified ordering and delivery methods. If the time frame for contractor delivery is not identified in the facility requirements, the contractor must provide 24-hour notice prior to delivery or upon mutual agreement between the facility and contractor, alternate ordering/delivery methods such as pre-scheduled deliveries, calling for tank level readings, installing a telemetry unit, etc. may be arranged. If for any reason the contractor is unable to delivery at the agreed upon day or time, the contractor will provide 24-hour notice to the COR, so that the facility can initiate an alternate backup action. In accordance with VHA Patient Safety Alert dated April 5, 2004, all deliveries must be monitored by a qualified and trained technical representative that will be designated by the facility. Contractor will be provided with names and contact information of primary and back-up facility representatives. This applies to all deliveries regardless of time or day of execution.

6.3 Tanks(s) will be filled to maximum functional capacity at each refilling procedure unless otherwise specified in the facility requirements or as agreed upon in a written document signed and dated by the COR.

6.4 At the time of each delivery, contractor must provide a legible signed and dated written document that identifies the tank level prior to fill, the level after fill, and the quantity delivered. This document must be counter-signed by the facility representative supervising the delivery.

6.5 Emergency delivery will be provided within 24 hours after receipt of Government notification. Contractor must respond to the facility by either telephone or email within one hour to confirm receipt of emergency notification to ascertain the nature of the emergency. Emergency status is determined by the Government. Facility Representative shall notify the contractor when conditions warrant, such as an actuated main bulk tank low level alarm, imminent alarm condition, or system leak. Failure of the contractor to remain current with agreed delivery schedule and requirements does not constitute an "emergency" for purposes of charging an emergency delivery fee.

7. Quality Assurance Specifications and Requirements

7.1 All medical gas manufacturers and fillers of medical gases must be registered with FDA as drug manufacturers. All oxygen shall be manufactured, processed, packed, transported, and stored according to FDA's Current Good Manufacturing Practices (CGMP) regulations, and all labeling shall comply with FDA's labeling regulations (21 CFR Part 201).

7.2 All liquid bulk oxygen delivered under the contract shall be medical-grade and shall meet or exceed the standards cited in the current edition of the United States Pharmacopoeia/National Formulary (U.S.P.).

7.3 A valid certificate of analysis shall be provided with each delivery of liquid oxygen. The certificate shall include, at a minimum:

- a) Supplier's name and complete address
- b) Name of the Product (i.e. Oxygen U.S.P.)
- c) An Air Liquefaction Statement where appropriate
- d) Lot number or other unique identification number
- e) Actual analytical results for full U.S.P. monograph testing. (A statement that only states that the product meets the minimum purity of 99.5%, etc. is not acceptable.)
- f) Test method used to perform the analysis. (A statement such as "Meets U.S.P. specifications" is not acceptable; nor would "Tested via Servomex" be acceptable since the specific model number is not provided.)
- g) Signature of authorized supplier representative and date.

7.4 Material Safety Data Sheets shall be provided to the facility COR upon request.

7.5 A copy of all inspection reports shall be provided to the facility COR upon the completion of any contractor owned or government owned bulk oxygen system inspections that are required by regulation.

7.6 All contractor owned equipment shall be maintained or repaired in accordance with NFPA 50: Standard for Bulk Oxygen Systems at Consumer Sites, 2001 and FDA's Current Good Manufacturing Practices (CGMP) Regulations.

8. Applicable Regulations & Standards

The following is a list of some of the regulations and standards that are applicable to this contract. The list is not comprehensive, and the contractor is responsible for ensuring that all products, equipment and services provided under the contract are in compliance with applicable Federal, state, and local regulations. If applicable, the editions in effect as of the date of this solicitation are listed. Contractor is responsible for remaining compliant with any future revisions that are effective at the time of contract performance.

Title 21, Code of Federal Regulations, Parts 210 & 211 - CGMP regulations for supplying medical grade oxygen.

29 CFR 1910.104 Applies to the installation of bulk oxygen systems on industrial and institutional consumer premises

49 CFR – Transportation

Federal Food, Drug, and Cosmetic Act

NFPA 50: Standard for Bulk Oxygen Systems at Consumer Sites, 2001 Edition

NFPA 99: Standard for Health Care Facilities, 2002 Edition

U.S.P. 23

Density data and volume measurement equivalents published in Compressed Gas Association Pamphlet No. P-6, titled "Standard Density Data, Atmospheric Gases and Hydrogen," shall be used when necessary to convert measurement of gases from one form to another. For example, the following conversion factor shall apply for conversion from gallons to cubic feet.

Calculation based on data in CGA P-6

1 ft³ liquid O₂ = 860.6 ft³ gas (Table 1)

1 ft³ liquid O₂ = 7.48052 gal ((Table 2)

Therefore:

7.48052 gal (1 ft³) liquid O₂ = 860.6 ft³ gas

$$1 \text{ gal liquid O}_2 = \frac{860.6 \text{ ft}^3 \text{ gas}}{7.48052}$$

1 gal liquid O₂ = 115.05 ft³ gas
or more commonly quoted as 1 gal liquid O₂ = 115.1 ft³ gas

9. Contractor Owned Cylinders

9.1 This section applies to all contractor owned cylinders that are provided under this contract as a back-up system to a primary bulk oxygen system.

9.2 Laws and Regulations: Cylinders and other containers for gaseous and liquid forms of gases shall comply with the Department of Transportation specifications and shall be maintained, filled, marked, labeled, and shipped to comply with current and subsequent updates to DOT regulations (Title 49-Transportation, Code of Federal Regulations). Packaging, labeling, etc., for medical gases shall also comply with the Federal Food, Drug, and Cosmetic Act.

9.3 Marking: In addition to marking required by the aforementioned laws and regulations, marking shall comply with American National Standards Z48.1-1954 (R 1971), "Method of Marking Portable Compressed Gas Containers to Identify the Material Contained."

9.4 All unauthorized or inapplicable markings, tags, and labels shall be removed. When shipment is by commercial carrier, shipping tags complying with Federal Standard 123F dated 5/15/91 shall be attached to each cylinder so as to be protected by the valve protection cap. The contract data markings required by the applicable standard shall be applied to one side of the tag and the identification markings on the reverse side. Consignee markings may be omitted when shipment is by contractor's truck.

9.5 Valves: Valves shall comply with Compressed Gas Associates Standard CGA-V-1 (11th Edition, 2003), "Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections." Valve protection caps for cylinders designed to receive such caps shall be securely attached to the cylinders in a manner to protect the valves from injury during transit and delivery to the purchaser's receiving area. Refer to 49 CFR 173.301(g)).

9.6 Color Coding: All cylinders shall be color coded in accordance with the Compressed Gas Association Pamphlet CGA C-9-1988, "Standard Color Marking Of Compressed Gas Containers Intended For Medical Use."

9.7 The contractor shall be responsible for all testing required by regulation of contractor owned cylinders at no additional cost to the Government.

9.8 The bidder's price for the oxygen shall include the furnishing of, at no additional cost, all services which are required at each and every filling of a cylinder to comply with applicable regulations, specifications, and normal good practices. Such services are of the type normally provided in the supply of medical cylinder gases, and shall include, but not be limited to: tags indicating cylinder is "Full," "In Use," or "Empty"; inspection, testing, evaluation, and cleaning services required at each and every filling; pin-indexing, when required, and attachment of Government-furnished warning tags, when required. Attaching of oxygen cylinders to manifold systems, when required, shall also be performed by the contractor at no additional cost. In addition to services listed in this paragraph, the contractor is responsible for all maintenance and testing of contractor-owned cylinders.