

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: VA260-18-AP-3751/648-18-2-9961-0032

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office (NCO) 20 on behalf of the VA Portland Healthcare System.
2. **Nature and/or Description of the Action Being Processed:** This is a new requirement to replace and supplement existing electrosurgical units for the VA Portland Medical Center Operative Care Service. The procurement will be set-aside for SDVOSBs.
FAR13.5 Simplified Procedures for Certain Commercial Items: This procurement is for commercially available medical equipment in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The estimated value of the proposed action is \$348,429.98. This is a brand-name justification for the following:

Valleylab™ FT10 Energy Platform	19 ea
Wolf Bipolar Resection Cable	19 ea
Bipolar Resection Footswitch	19 ea
Monopolar Footswitch	19 ea
Bipolar Footswitch	19 ea
Cart for FT10	19ea
Valleylab Blade Electrode 6.5", 100/Bx	1 bx
Valleylab Blade Electrode 6.5", 50/Bx	11 bx
Blunt Tip Lap Sealer Divider, 6/Bx	2 bx
Curved Large Jaw Open Sealer, 6/Bx	2 bx
Rocker Switch Pencil, 50/Bx	3 bx
Edge Insulated Blade Electrode, 50/Bx	2 bx
Edge Insulated Blade Electrode, 50/Bx	1 bx
Suction Coagulator 6inch 10 Fr, 25/Bx	1 bx
Valleylab Needle Electrode 2.8, 150/Bx	1 bx
10x10mm Dsp Tng Lletz Loop, 10/Bx	1 bx
Valleylab Accessory Holster, 50/bx	1 bx

Biomedical service training

2 ea

4. Statutory Authority Permitting Other than Full and Open Competition: 41 USC §3304(a)(1), as implemented by FAR 6.302-1.

- (x) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

FAR13.5 Simplified Procedures for Certain Commercial Items: The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).

Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority): The Valleylab FT10 Energy Platforms are replacing obsolete Valleylab electrosurgical units. This requirement is for specialized surgical equipment which has been approved for use by the facility Clinical Products Review Committee (CPRC). Per VHA Directive 1761 (1), the CPRC is responsible for reviewing and approving all new Reusable Medical Equipment (RME) prior to their use for direct patient care so that compatibility with current processes and equipment is ensured.

The need for standardizing operative equipment is critical as different models have slightly different operating procedures and user interfaces. A mixture of different models in the operative theater increases the risk of user error, significantly increasing the risk to patient safety. Standardizing operative equipment is a recognized best-practice for reducing the risk of errors, increasing uniformity of practice and patient safety. See Zhang, J. et al., Evaluating & Predicting Patient Safety for Medical Devices with Integral Information Technology, in Advances in Patient Safety: From Research to Implementation, Vol 2: Concepts and Methodology (Kerm Henriksen et al. eds., Agency for Healthcare Quality and Research 2005).

Furthermore, standardization of equipment reduces the overall cost to the Government as it enables the Government to benefit from strategic, centralized procurement of consumables and components. The VA Portland Healthcare System currently uses Valleylab surgical equipment which is proprietary to Medtronic/Covidien. To purchase items from a different manufacturer would require the replacement of ancillary equipment and would represent an excessive duplication of costs to the Government.

5. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Market research identified that there is a NMR class waiver for NAICS 334510, FSC/PSC 6525. Therefore, a search was conducted to determine if there are any authorized retailers of the

required equipment. Market research identified that this equipment is available through SDVOSB OEM authorized sources. An informal sources sought was sent to two SDVOSB firms on July 12, 2018, to determine capability and interest. Both SDVOSB sources replied as interested – each has confirmed that they are OEM authorized distributors. A review of their capability statements and Authorized Vendor Letters indicate that they capable of performing. Therefore, offers will be solicited on FBO as a SDVOSB set-aside IAW 38 U.S.C. 8127.

6. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the Government will be Fair and Reasonable based on competition.
7. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research was conducted to determine if there are any authorized retailers of the required equipment. This includes a search on VIP, strategic source listings, GSA's eLibrary and FPDS for past acquisitions with similar requirements. Market research identified that this equipment is available through SDVOSB OEM authorized sources. As described in Section 5 above, in accordance with FAR Part 10, market research was conducted by soliciting inquiries from interested parties. Two SDVOSB sources indicated interest and confirmed that they are OEM authorized distributors. A review of their capability statements and Authorized Vendor Letters indicate that they capable of performing. Therefore, it is expected that there are two or more verified SDVOSB sources that are able to meet the requirement.
8. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The operating rooms are not designated for use by a single physician or surgical team; physicians schedule the use of one or more rooms as needed and can be working out of any of the suites. Therefore, the VA has a legitimate need to standardize the equipment it uses in the Operative Care Service to achieve the highest possible reliability and effectiveness.
9. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
- | | |
|------------------------------|--------------------------------------|
| Beacon Point Associates, LLC | Veterans Healthcare Supply Solutions |
| 1216 SW 4th Street, Suite 4 | 13949 Alvarez Road, Suite 300 |
| Cape Coral, FL 33991 | Jacksonville, FL 32218 |
| (239) 673-6965 | (904) 638-5519 |
| DUNS: 078717364 | DUNS: 96489983 |
| SDVOSB | SDVOSB |
10. **A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:**
Standardized medical equipment is a bona fide clinical need for patient safety. Future changes in available technologies or standards will require review and approval from the facility Clinical Products Review Committee (CPRC). However, market research will continue to be completed for all subsequent acquisitions to ensure to promote competition from authorized sources.
11. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance,

Other Than Full and Open Competition (OFOC) – Brand Name

which are included in the justification, are accurate and complete to the best of my knowledge and belief.

Gordon Hosoda
Chief, Healthcare Technology Management
VA Portland Healthcare System

Date

12. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

- a. **Contracting Officer or Designee's Certification (required)**: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Jacob P. Jackson
Contracting Officer, Supply Branch II
Network Contracting Office (NCO) 20

Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K)**: I certify the justification meets requirements for other than full and open competition.

Jonathan Jewel
Branch Chief, Supply Branch II
Network Contracting Office (NCO) 20

Date