

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, VISN 08, James a Haley VA Medical Center
NCO 8-Services Team
TDB-0945/673-14-2-046-0402
"Justification for Other Than Full and Open Competition."
Purchase Request (2237) 673-14-2-046-0402

2. **Nature and/or Description of the Action Being Processed:** This is a one-time procurement for the Repair, Calibration, & Preventative Maintenance (PM) of one Omniguide Intelliguide FELS-25A Surgical Laser to include all labor and materials/parts to repair and calibrate/PM on Omniguide Intelliguide FELS-25A laser system, S/N 101187, ID# 88755 (TDB-0945/673-14-2-046-0402) and restore to first class operating condition. Ensure system operates according to manufacturer's specifications.
This procurement will be awarded as a new contract as a firm-fixed-price.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Omniguide is the original equipment manufacturer (OEM) and no other vendors have been found who can perform the required testing and adjustments and obtain the necessary FDA-approved repair parts and proprietary software keys for this type of service.
Total contract value estimated at \$2,995.00.
Estimated period of performance of March 17, 2014.
The laser system is limited and could cause a mistreatment for certain critical surgeries. Patient procedures will either need to be cancelled or sent out to other facilities on fee basis until this system can be returned to full operation. The Omniguide Intelliguide FELS-25A laser system is a highly specialized system with an acquisition value of more than \$69,500. In-house staff does not have the specialized tools and equipment required to perform this critical level of service.

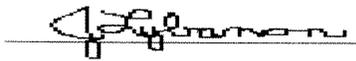
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - () (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - () (3) Industrial Mobilization, Engineering, 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;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The hospital must have functional medical equipment that is used for patient procedures. OEM-Omniguide is the manufacturer and exclusive distributor of this specific patient care equipment. Although there are normally third-party repair companies that can perform repairs on some high-tech medical equipment and systems, there are no third-party repair companies that have been located that can perform work or procure the necessary FDA approved software and repair parts for this level of service on this highly specialized system. Without timely repair of this system, patient procedures would need to be postponed (if clinically possible due to the patients' conditions) or sent to other facilities on fee basis. Non-emergent procedures are already scheduled (including a full schedule daily) and would need to be postponed and rescheduled if possible or sent out. Many medical equipment manufacturers, including Omniguide Surgical Inc. have proprietary service documentation, diagnostic tools, software, and equipment, as well as parts. Third party companies do not have access to these necessary resources and therefore often cannot complete maintenance work on high-tech medical equipment. As equipment ages or becomes more common, manufacturers become less guarded about sharing these resources with competitors. As this state-of-the-art equipment ages, it is likely that there will be some other vendors who may be able to perform maintenance work.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Past efforts to locate third-party vendors who can perform repairs, have the proprietary software, and obtain FDA approved parts on this highly specialized medical equipment have turned up no additional sources other than the OEM.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** IAW FAR 13.106-3(a), the contract specialist anticipates price to be fair and reasonable based on past acquisitions of a similar scope and nature found on www.fbo.gov solicited under NAICS code 811219 Repair and Maintenance/ -- Other Electronic and Precision Equipment Repair and Maintenance. The anticipated price to the Government is \$2,995.00. Price is fair and reasonable in comparison with current market value.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Past efforts to locate third-party vendors who can perform repairs, have the proprietary software, and obtain FDA approved parts on this highly specialized medical equipment have turned up no additional sources other than the OEM. This agency is committed to the competitive spirit of all procurement regulations. It is our policy to seek full and open competition to the largest extent possible while fulfilling the necessary requirements. Three companies (Laser Repair Depot, Evergreen Laser Corp, Dynamic Laser) who perform work of a similar scope and nature were contacted on March 5, 2014 and were unable to service the referenced equipment. Further research done by the Contract Specialist (CS) on GSA Advantage and through a Google/Bing search turned up no further results. Furthermore, a letter from Omniguide Inc. requested by the CS was received 03/14/2014 stating that they have proprietary software that only they are able to use for service of this laser.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** A statement of work has been developed for this procurement (firm-fixed-price repair), but the critical need for these repair services is time-sensitive and delays can have an adverse impact on patient care.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A

11. 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:

The Government shall post a notice on Federal Business Opportunities that permits prospective vendors to submit their respective technical capabilities solely for consideration in future acquisitions for the similar supplies and services.

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

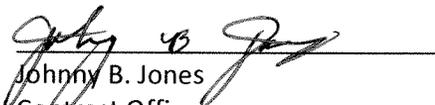


Julie I. Lybanon
Chief, Biomedical Engineering Section
James A. Haley Veterans' Hospital

3/7/14
Date

13. Approvals in accordance with FAR 6.304

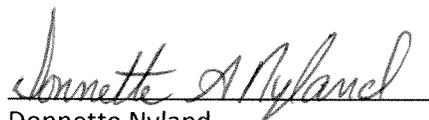
- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Johnny B. Jones
Contract Officer
NCO 8 – Tampa Florida

3/18/14
Date

- b. **Product Line Supervisor (PLS):** I certify the justification meets requirements for other than full and open competition.



Donnette Nyland
Contract Manager/Supervisor
Services Team
NCO 8 – Tampa Florida

3/19/14
Date

- c. **SAO (If over 500K):** I certify the justification meets requirements for other than full and open competition.

Name
Director
Service Area Office, East

Date

- d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$10million) or approve (\$500K to 10 million) for other than full and open competition.

Name
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$10 million but not exceeding \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

C. FORD HEARD
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- f. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date