

Attachment 2: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS
Determination to Solicit from a Single Source
Spectranetics CVX-300 Laser

1. **Contracting Activity:** Department of Veterans Affairs, VISN 06, Hunter Holmes McGuire Richmond, VA VAMC (Station 652).
2. **Nature and/or Description of the Action Being Processed:** The Richmond, VA VAMC requires the procurement of a premium maintenance and service contract for the Spectranetics CVX-300 Laser (PO 652-C40018) (EE# 816233396, Serial Number 1459). This medical device is a highly specialized system designed and used to extract adhered pacemaker leads from within entrapped vessels and arteries. Using this device enables physicians to remove these leads without subjecting the patient to major open chest surgery. It is imperative this device is fully functional at all times due to the emergency need for its use. This is the only device at this medical center of its kind and no other device can be used for this application.

Vendor shall provide semi-annual scheduled preventative maintenance (PM) for the equipment as coordinated with Biomedical Engineering. Work shall be completed during normal working hours of 8:00am – 4:30pm Monday through Friday, excluding Federal Holidays, and for emergency calls as needed.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Richmond, VA VAMC requires a preventative maintenance and service contract for the Spectranetics CVX-300 Laser for scheduled periodic maintenance, inspections, and as-needed services. Premium service covers preventative maintenance, diagnostic and corrective actions needed to support the laser system to include all travel, labor, and parts necessary. Contractor is to provide phone support during normal business hours. The premium service contract is to include unlimited support requests. On-site support is covered during normal working hours of 8:00am – 4:30pm Monday through Friday, excluding Federal Holidays, and is to include all labor, travel, and parts/material costs. On-site service requests are unlimited through the premium service contract. PMs will be scheduled during normal working hours of 8:00am – 4:30pm Monday through Friday, excluding Federal Holidays. Scheduled PM service will be provided per the following frequency: semi-annually (every 6 months) in April and October. Scheduled PM service will be provided at equal intervals during the contract term.

This medical device is a highly specialized system used in emergency cardiac procedures. The requested vendor (Spectranetics) is the Original Equipment Manufacturer (OEM) of this device and is the only vendor capable of performing full repair services and PM/calibrations. The OEM utilizes highly specialized, proprietary components available only to the OEM, and requires very specialized test equipment to calibrate the laser. Calibration and test equipment are not available to any other vendor. The contract is to cover the base period from 1 January 14 to 31 December 14 and will include four option years.

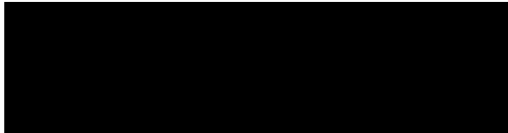
4. **Statutory Authority Permitting Other than Full and Open Competition:**
 - () (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
 - () (2) Unusual and Compelling Urgency per FAR 6.302-2;
 - () (3) Industrial Mobilization, Engineering, 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;
- (X) (8) Soliciting from a single source per FAR 13.106-1(b).

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This medical device is a highly specialized system designed and used to extract adhered pacemaker leads from within entrapped vessels and arteries. Using this device enables physicians to remove these leads without subjecting the patient to major open chest surgery. It is imperative this device is fully functional at all times due to the emergency need for its use. This is the only device at this medical center of its kind and no other device can be used for this application. The requested vendor (Spectranetics) is the OEM of this device and is the only vendor capable of performing full repair services and PM/calibrations. Additionally, the OEM utilizes highly specialized components available only to the OEM, and requires very specialized test equipment to calibrate the laser. Calibration and test equipment are not available to any other vendor.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Efforts were made to investigate the availability of this service by other vendors, however this service remains limited to Spectranetics due to the proprietary nature of components available only to the OEM for repairs and the specialized test equipment required to calibrate the laser.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price quote provided by the contractor will be compared with any previous pricing and other similar items to determine that the price is fair and reasonable.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The previous requirement, VA246-P-0545 was solicited from a single source under FAR 13.106 (see attached Justification and Approval). Additionally, the undersigned Contract Specialist contacted Spectranetics to confirm the proprietary nature of the software, hardware and maintenance of the CVX-300 Laser System. Connie Cooper, Field Service Department, confirmed that their company is the only authorized company to perform maintenance and the parts and software utilized by the CVX-300 Laser System are proprietary (reference attached Memorandum for Record submitted by Spectranetics). As such, no further market research was conducted and intent to sole source was not posted on Federal Business Opportunities (FBO). The determination to solicit to a single source will be posted to FBO for 10 days as required by the Veterans Affairs Procurement Manual.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** This service is limited to Spectranetics as the CVX-300 Laser System is a patent and copyright protected high technology medical device with proprietary software controlling the operation of the laser system. Additionally, Spectranetics technicians are the only technicians certified to perform maintenance and/or specific repairs to this unit.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Reference section 8 above.
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:**
National Contracting Office 6 and the Hunter Holmes McGuire Veterans Affairs Biomedical

Department will continue to evaluate the marketplace to determine if there are new entrants who are qualified and capable of providing this type of complex repair and maintenance.

12. **Requirements Certification:** I certify that the requirement outlined in this determination is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in this determination, are accurate and complete to the best of my knowledge and belief.



Biomedical Engineer
Richmond VAMC

12/4/2013
Date

13. **Determination in accordance with FAR 13.106-1(b):**

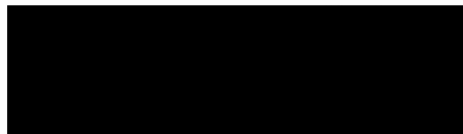
- a. **Contracting Specialist's Determination:** I certify that the foregoing Determination is accurate and complete to the best of my knowledge and belief.



Contract Specialist
Network Contracting Office (NCO) 6 – SAO East

20 Nov 13
Date

- b. **NCM/PCM (Required \$3K and above):** I certify the determination meets requirements for soliciting from a single source.



Services Team Lead
Network Contracting Office (NCO) 6 – SAO East

11/26/13
Date