

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval
For
Other Than Full and Open Competition**

1. **Contracting Activity:** The responsible agency for this acquisition is the Department of Veterans Affairs, Network Contracting Office 18, and Southern Arizona VA Health Care System (SAVAHCS). The Arizona VA health Care System Facilities proposes to enter into a contract using Other Than Full and Open Competition for the Biomedical Engineering Program Office.
2237 - 678-14-3-125-0628
2. **Nature and/or Description of the Action Being Processed:** This procurement is for a single site. The contract contemplated will be a firm fixed price contract to St. Jude Medical Inc., 1 St. Jude Medical Drive, 1 Lillehei Plaza, St. Paul, MN 55117-1799.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This procurement is to provide comprehensive preventive maintenance services and repairs on Ilumien OCT Imaging System equipment at SAVAHCS. Currently the equipment is located at SAVAHCS. This equipment will require the ongoing maintenance and support to ensure the facilities remain compliant with The Joint Commission (TJC)
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 contractor, St. Jude Medical Inc., is the original equipment manufacturer (OEM) of this bio-medical equipment (Illumien OCT Imaging system, Model: C7XR, S/N: C7XR1102025) in use at SAVAHCS. This medical equipment with its intuitive software manages all tasks associated with running a new high-speed engine that scans at 180 frames per second. Next-generation DOC (drive-motor and optical controller) allows tableside initiation of live view and pullback Intuitive user interface, with Real-time 3D image reconstruction of vessel and lumen. The equipment must undergo periodic validation to assure commissioning and performance qualification, within TJC's Elements of Performance (EC.02.04.01); which requires that the hospital manages medical equipment risks. St Jude Medical Inc. has provided a written statement that they are the only certified contractor to perform maintenance services on the Illumien OCT Imaging OEM instrumentation, through their specialized trained staff.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Market research has revealed no additional sources that are either veteran owned, small business or large. Sources Sought did not yield any large or small business interest.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** St. Jude Medical is the OEM and the only authorized vendor to allowed to perform preventative maintenance on the Ilumien OCT Imaging system, as per the OEM. The anticipated total dollar amount of the proposed acquisition is \$12,000.00. This price is for annual preventive maintenance for a base year plus two additional option years @ \$4000.00 per year. The price quotation from St. Jude Medical Inc. was compared to other 2 other quotes, the Veterans Administration received (at two separate locations) and appeared consistent to what was awarded at the other facilities. This information is what was used was used in determining the price to be fair and reasonable IAW FAR 13.106-3 (2) (ii). The current IGCE is for \$4000.00 and determined fair and reasonable and a price that a practical and knowledgeable person would pay.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** In accordance with FAR Part 10, it directs that market research be conducted on each acquisition appropriate to their individual circumstance. The nature of this acquisition for service on highly technical equipment does not disproportionately inhibit the research. However, given the necessity to have accurate assessments without the miscalculation, is of the utmost magnitude. Precise dispersions of calculations, periodic maintenance of this equipment is both critical and unavoidable. Industry has provided satisfactory understanding of the requirement and assured that the OEM St. Jude Medical Inc., are the only source that are qualified to service this specific equipment. A recent Sources Sought revealed that no other large or small business could provide the essential expertise to render recurring maintenance on the Ilumien system.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The above-mentioned information provided, to include the attached documentation from St. Jude Medical Inc., has determined that there are no other suitable contractors to perform this required service.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
St. Jude Medical Inc.
1 St. Jude Medical Drive
1 Lillehei Plaza,
St. Paul, MN 55117-1799
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 expectations that increased use may generate a consequent decline in equipment pricing, the costs of new equipment will be scrutinized to guarantee the cost effectiveness of prolonged maintenance on the existing equipment. Although other equipment manufacturers may have less restrictive requirements for the maintenance of their equipment, in so doing expanding the viable pool for these services. In order to safeguard that each facility sustains standardization in meeting TJC requirements, any forthcoming requirements for Ilumien OCT imaging equipment will be meticulously assessed to ensure the government is purchasing equipment that meets the facilities minutest needs.

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.



Krista Anderson
Biomedical Engineer
Southern Arizona VA Health Care System

6/5/2014

Date

13. **Approvals in accordance with FAR 6.304**

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



Daniel C. Thiel
Contract Officer
Network Contracting Office (NCO) 18 (SAVAHCS)

Date

- b. **DoC:** I certify the justification meets requirements for other than full and open competition.



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For: Sabrina J. Smith
Director of Contracting
Network Contracting Office (NCO) 18 (SAVAHCS)

Date