

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition
FAR 6.302-1

1. Contracting Activity: Department of Veterans Affairs, VISN 10, Network Contracting Activity for the Cincinnati, Cleveland and Dayton Medical Centers 539-11-4-220-0120

2. Nature and/or Description of the Action Being Processed: Negotiation shall be conducted to procure a lease with Olympus American Incorporated. Circumstances require that this be done without the benefit of full and open competition. In accordance with FAR 6.302-1, the VA will create a Task Order to sole source open market Endoscopes.
Open Market: \$149,111.88

3. Description of Supplies/Services Required to Meet the Agency's Needs: The VISN 10 Network Contracting Activity requires the lease and maintenance procurement of Olympus American Inc's medical scopes and related equipment. The majority of it can be purchased through the mandatory FSS schedule. Though, approximately thirty-one percent of the requirement shall require an open market purchase. This brand/type of scope is necessary in order to meet the agency's requirement of standardization of Endoscopes as these facilities currently have Olympus brand scopes. Standardization is important as the correct care and cleaning of the scopes is essential to ensure patient safety, and having different brands will put patients at risk due to the need to clean each brand differently. Leasing these scopes is important to ensure continuation of patient care and the continued support to clinical services.

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):

FAR Part 6.302-1(a) allows for the procurement of items through other than full and open competition; applicable when the agency's minimum needs may only be satisfied by a service that is unique and available from only one responsible source. VISN 10 requires the leasing of numerous medical Endoscopes and related equipment for the Gastroenterology Department. To maintain sufficient quantities of working scopes the VISN 10 Medical Centers have purchased and repaired this equipment on an as needed basis. Currently Olympus America Endoscopes have been the majority type of scope being utilized at three of VISN 10's Medical Centers. Per VHA Directive 2009-004 Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities and VHA Handbook 1761.1 Standardization of Supplies and Equipment, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health. In addition, the December 10, 2010 memo from the Deputy Undersecretary for Health Operations and Management (DUSHOM) (10N) outlines guidance for VHA standardization of Endoscopes (WebCIMS No.451818). This memo states that the Integrated Product Team established in 2010 has deemed leasing to be the preferred method of procurement to achieve standardization as it presents the VA the ability to standardize with greater efficiency, be flexible with new technology and accurately predict future maintenance costs and that Medical Centers should immediately pursue agreements with one of three FSS contractors. With the majority of the Endoscope within

VISN 10 being manufactured by Olympus America the VISN has determined that it would be in its best interest in supporting the standardization directive to procure the required scopes that are not on Olympus America's FSS contract using Open Market Sole Source Procedures. Additionally, the guidance is recommending that leasing be the preferred method of procurement and only Olympus America has an approved leasing schedule. Since Olympus is the only contractor to provide leasing for these scopes, they offer a truly unique product as the sole responsible source.

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

The mandated VHA National Standardization of Endoscopes initiative requires the leasing and repair services of GI Endoscopic equipment to one of the three manufacturers (Olympus, Pentax or Fujinon). The GI departments throughout Network 10 are currently utilizing VA owned Olympus Endoscopic Equipment. Standardization to one manufacturer will enhance the safety and quality of patient care by reducing the variability in the number of different processes required for endoscope setup and reprocessing, thus reducing the potential for error. Network 10 had received special funding for fiscal year 2011 supporting the mandate to comply with standardization and to ensure the most recent technology is being utilized in GI Endoscopic equipment. The VHA National Acquisition Center has issued a mandatory National Leasing Agreement to Olympus of America, Inc. for VHA facilities to comply with the National Initiative.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The anticipated cost of this procurement presented by Olympus American, Inc is fair and reasonable to the Government based on using service estimates, and previous purchasing history of prices.

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 Market Research, various VA and Federal Supply Contracts were reviewed. GSA and the internet were also researched. The majority of the required scopes will be procured off Olympus America's FSS contract, and because of the need to match the existing scopes, other company's scopes were not considered. Each brand of scope requires different cleaning and disinfecting techniques. To mix brands of scopes within a facility increases the risk for processing errors and is a potential risk to patients. Past incorrect processing of endoscopes at VA medical centers have resulted in patients being exposed to HIV, Hepatitis and other contagious diseases. Furthermore, VISN 10 Network Contracting must standardize their equipment according to VHA Directive 2009-004 and VHA Handbook 1761.1.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: None. See Items 5 above.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: There are no other sources that have expressed an interest to date.

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:

Alternate sources have been given consideration. This procurement involves changing technology in scope procurements and maintenance. Future requirements for this service cannot be accurately predicated at this time.

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.

Karen S. Williams 9-6-2011
SIGNATURE DATE
Karen S. Williams Network 10 Material Manager Logistics
NAME TITLE SERVICE LINE/SECTION
VISN 10
FACILITY

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.

Ronald T. Heigmann 9/12/2011
CONTRACTING OFFICER'S SIGNATURE DATE

Ronald T. Heigmann C.O. Network Contracting Activity (C)
NAME AND TITLE FACILITY

b. VISN/PCA QA (Required \$3K and above): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. *This signature may be the VISN NCM/PCM if the Contracting Officer and Contracting Supervisor is the same individual.


SIGNATURE

9/12/2011
DATE

Joseph L. Boggs
NAME AND TITLE
JOSEPH L. BOGGS
QUALITY ASSURANCE COMPLIANCE
VISN 10

c. NCM/PCM: I certify the justification meets requirements for other than full and open competition.


Name

9/12/2011
DATE

TERRY L. SPITZMILLER
NETWORK CONTRACT MANAGER
NETWORK CONTRACTING ACTIVITY 10
VA HEALTHCARE SYSTEM OF OHIO