

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA248-15-AP-12119

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, Orlando, VA Medical Center  
675-16-1-2555-0007

2. **Nature and/or Description of the Action Being Processed:**

This is a request for other than full and open competition for the procurement of continued prevention and corrective maintenance for STERRAD® sterilization systems from Advanced Sterilization Products (ASP), a division of Ethicon, Inc. which is a Johnson & Johnson company.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:**

The Orlando VA Medical Center currently requires preventive and corrective maintenance services for the following STERRAD® sterilization system for the Lake Baldwin (5201 Raymond Street, Orlando), Daytona (551 National Healthcare Drive, Daytona) and Viera (2900 Veterans Way, Melbourne) Out Patient Clinics (OPC):

STERRAD NX  
STERRAD® 100NX

ASP is currently the only authorized agent to provide services for these sterilizers. These systems are utilized to sterilize medical instruments and equipment for routine and emergency medical care. The proposed contract action will provide all labor, parts and travel required to provide semi-annual preventive maintenance service as well as on-call as needed corrective maintenance and repair services. The base year period of performance will be November 1, 2015 through October 31, 2016. The contract will include four (4) 12 – month option periods concluding on October 31, 2020.

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;

**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 STERRAD® sterilization systems utilize a patented, proprietary, low-temperature hydrogen peroxide plasma technology that sterilizes medical instruments and devices. This technology is an alternative to Ethylene oxide (EtO) which had been used widely prior to the development of the STERRAD® technology. The STERRAD® systems were originally purchased for the Orlando VA Medical Center through the mandatory NAC Contract. The initial warranty was in place and additional service contract was negotiated by the NCO-8 contract, which ended 30 Sep 2015.

The STERRAD® systems currently in place at the Orlando VA Medical Center (valued at approximately \$800,000 less depreciation) are approximately 2-4 years old, and have an estimated useful life of fifteen years each, meaning that the remaining useful life is between eleven to twelve years. Orlando VA Medical Center plans to continue usage for the next five years and is likely to continue usage for the life span of these sterilizers. Servicing the systems requires both adequate training and the ability to provide replacement parts. ASP will not sell parts for the STERRAD® systems to anyone who has not undertaken their official training course in Irvine, CA, which costs between \$22,000.00 and \$24,000.00. Moreover, their technicians are legally bound by a non-competitive agreement which prohibits them from servicing the STERRAD® systems independently of ASP. Additionally, an RFI was posted to FBO for 14 days and no responses were received from any potential sources. Because of these factors, there are no known providers of STERRAD® system maintenance service outside of ASP. Moreover, Orlando VA has not sent a VA member to STERRAD® training nor does it have any immediate plans to do so.

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

Market Research sources:

- GSA eLibrary – Johnson & Johnson (ASP) only have contracts for purchase of equipment with initial warranty maintenance. There are GSA ASP contracts for maintenance of STERRAD® products.
- Google (maintenance for STERRAD®) – Searched the WEB and there are no companies listed who stated that they repair and/or maintenance STERRAD® sterilizers.
- Contacted company who maintains other brand sterilizers and they stated that they are not permitted/trained to maintenance the STERRAD®. They are considering sending personnel to training but not at this time.
- Posted a Sources sought Notice on FedBizOpps on 09/22/2015 requesting firms with interest and certifications to service STERRAD Sterilization Systems to respond to my sources sought notice. The close date was 10/06/2015. No responses were received.
- Surveyed SDVOSB database – there were no companies who were qualified to maintenance/repair STERRAD®.

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

The anticipated price to the Government is \$26,184.00 for the base period. The independent government cost estimate (IGCE) estimated a 10% increase per year for this contract. The total cost for the base and 4 option

years is estimated \$151,867.20. Prior to award, the contracting officer will determine the fairness and reasonableness of these prices on the basis of comparison to established contracts for the same service with other VA medical centers and/or other federal customers as well as comparisons to standard commercial rates.

**8. 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 identify alternative service providers, other than ASP who were licensed to perform maintenance on the STERRAD® systems. In addition, the contracting officer contacted ASP and asked if there were any other companies licensed to fix their STERRAD® equipment or if they partnered with a SDVOSB to service their equipment. They stated that, although they partner with SDVOSB and have a GSA contract for the end item sales, they do not have any small business partners at this time. Additionally, they are the only source for service for the STERRAD® equipment.

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In light of the above research and the lack of alternative service providers, it was determined that no alternatives currently exist as previously outlined in Paragraph 5.

**9. Any Other Facts Supporting the Use of Other than Full and Open Competition:**

None

**10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**

Advanced Sterilization Products (ASP), a division of Ethicon, Inc., which is a Johnson & Johnson Company

**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:**

Research was done by the VISN to determine alternate equipment that can be purchased. It was determined that a prospective competing sterilization product, the STERIZONE®125L+ sterilized by TS03, has been identified. This system used similar low temperature technology to sterilize medical equipment. The government end users have been notified of this equipment. Other sites are using this equipment; however, the Orlando equipment is only 2-4 years. It would not be cost-effective at this time to purchase new equipment to replace at this time. Additionally, the contracting officer spoke with one SDVOSB contractor and they stated that

they are trying to work with ASP so that they can get the training to fix the STERRAD® systems. They stated that this is a timely process and many take up to a year or more.

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.

  
Adam Reveile  
Supervisor, BME  
Orlando VAMC

10/19/2015  
Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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

  
Marie E. Smith  
Contracting Officer  
Network Contracting Office-8 (Orlando)

Digitally signed by MARIE E SMITH 250710  
DN: dc=gov, dc=va, ou=internal, ou=people,  
o=9.2342.19200300.100.1.1=marie.smith4@v  
.gov, cn=MARIE E SMITH 250710  
Date: 2015.10.19 14:31:46 -0400

10/19/2015  
Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

\_\_\_\_\_  
Dennis Bleckley  
Deputy Director of Contracting  
Network Contracting Office-8

\_\_\_\_\_  
Date