

**DEPARTMENT OF VETERANS AFFAIRS**

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

1. **Contracting Activity:** Department of Veterans Affairs  
Network Contracting Office (NCO) 18  
Veterans Integrated System Network (VISN) 18  
Southern Arizona VA Health Care System (SAVAHCS)

NCO 18 proposes entering into a contract using Other than Full and Open Competition for a service agreement with Ethicon US, LLC.

2. **Nature and/or Description of the Action Being Processed:** The NCO 18 Contracting Office proposes a sole source, firm-fixed price contract with Ethicon US, LLC which is the original equipment manufacturer (OEM), and sole firm (see Attachment 1) that is capable of servicing, repairing, supplying replacement parts, and providing a service agreement for the various Advanced Sterilization Products (ASP) used throughout VISN 18 medical facilities. The contract will be base plus two (2) option years, exercised annually on the need of the customer and availability of funds.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This procurement is for the provision of a service agreement for preventative maintenance inspection services for Ethicon US, LLC ASPs currently in use throughout VISN 18 Medical facilities. The units require ongoing maintenance service and support in order to ensure that they remain fully functional and can continue to be used for their intended purposes. The use of these multiple pieces of equipment directly affects patient care.
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):** Ethicon is the OEM, and sole proprietary firm which is capable of servicing, repairing, supplying replacement parts, and providing a service agreement for the ASPs used throughout VISN 18 medical facilities. Ethicon has provided a written statement dated July 30, 2015 confirming that they are the only source certified to perform any maintenance, repair, or other services on their equipment and that all equipment servicing must be performed by OEM certified/trained personnel. Specifically, they state that Ethicon "only authorize servicing by personnel who have been trained and certified by ASP training personnel."

Furthermore, they note that “service attempted or performed by unauthorized personnel will void all ASP warranties and/or service agreements for the specific system in accordance with the provisions of ASP’s product warranty policy and service agreements. In addition, approved and proprietary parts are necessary to service STERRAD® Systems. These parts are only available to ASP authorized personnel.”

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A sources sought notice was posted to FedBizOpps (FBO) for the work associated with this procurement in order to ensure that offers are solicited from any potential sources; no vendors responded to the sources sought. A previous award for the same service within VISN 18 is the following: VA258-13-P-0261; this purchase order was awarded to Ethicon US, LLC after market research revealed that Ethicon was the only source of the required service agreement; this was supported by their statement in an email dated September 6, 2012 that “there are no other companies who service the STERRAD system due to propriety protections.” For this requirement, Ethicon provided a letter dated July 30, 2015 (see Attachment 1) confirming that they are the only source capable of performing the necessary services. Once this confirmation was received, no further efforts to solicit potential vendors were made as Ethicon is the only responsible source for the required servicing, repairing, replacement parts, and service agreement.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The prices proposed by Ethicon for the ASP service agreement are in line with those previously paid to Ethicon by VISN 18 facilities for the same work on earlier requirements. This reinforces the assertion that the anticipated cost of this procurement is considered to be fair and reasonable in accordance with (IAW) Federal Acquisition Regulation (FAR) Part 13.106-3(a)(2)(ii) and 15.404-1(b)(2)(ii). This FAR part states that in order to ensure a fair and reasonable price, a comparison “of the proposed prices to historical prices paid, whether by the Government or other than the Government, for the same or similar items...may be used for commercial items.” The pricing provided for service agreement coverage during the base period and two option years on six (6) ASP units is, on average, slightly lower than the prices paid on the previous purchase order for the same service agreement coverage.

The previous procurement to Ethicon (VA258-13-P-0261) provided service coverage for ASP units located at both the Tucson and Phoenix VA hospitals. The number and type of instruments fluctuated during the three years of coverage but culminated during the second option year with six (6) total instruments at a monthly rate of \$6,289.10. For this anticipated procurement, Ethicon has quoted a base year price for the same six (6) ASPs at a monthly rate of \$6,120.91. The quoted price remains the same during the first option year and increases slightly during the second option year. The average monthly cost for the entire thirty-six (36) months is \$6,202.53. This results in a quote price that is roughly \$86.57 or 1.40% (per year) lower than the price previously paid for the service agreement coverage during the final year of the previous contract.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As stated above, a previous award for the same service within VISN 18 was awarded to Ethicon US, LLC after market research revealed that Ethicon was the only source of the required service agreement. They remain the sole source provider as confirmed by the sole source documentation, dated July 30, 2015, provided by Ethicon. Additional market research performed since the previous award has identified the following:

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Attachment 3: Request for Sole Source Justification Format >\$150K

- A sources sought notice was posted to FBO and resulted in no vendor responses.
- Ethicon US, LLC is the only entity found in an internet search that can provide the services.
- The contractor provided documentation (see Attachment 1) self-identifying Ethicon US, LLC as the only source that can provide these services due to proprietary reasons. They note that Ethicon will “only authorize servicing by personnel who have been trained and certified by ASP training personnel. Training is product-specific and separate training is required for each product model. Authorized service personnel include: trained ASP service employees; trained third party service providers under contract with ASP to provide servicing on our behalf; and customers who have purchased and completed product-specific Biomed Training provided by ASP.” Furthermore, Ethicon goes on to state that “service attempted or performed by unauthorized personnel will void all ASP warranties and/or service agreements for the specific system in accordance with the provisions of ASP’s product warranty policy and service agreements. In addition, approved and proprietary parts are necessary to service STERRAD® Systems. These parts are only available to ASP authorized personnel.”
- Ethicon went on to confirm in an August 14, 2015 email that outside of itself, “there are no companies that are authorized to perform the preventative maintenance.”
- Vista – Proposed price(s) found to be fair and reasonable compared to previous purchase orders.


9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** OEM provided documentation (see attachment 1) stating proprietary reasoning.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** None


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:** Not Applicable

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- 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.

  
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Krista Edwards  
Biomedical Engineer  
SAVAHCS

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August 24, 2015  
Date

  
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Jane Lacson  
Biomedical Engineer  
PVAHCS

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August 24, 2015  
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.

  
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Daniel Thiel  
Contracting Officer  
Network Contracting Office 18, SAVAHCS

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August 25, 2015  
Date

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

**KELLY M.**  
**DODSON 185769**  
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Deputy Director of Contracting  
Network Contracting Office (NCO) 18

Digitally signed by KELLY M. DODSON 185769  
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