

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA261-18-AP-0069

1. **Contracting Activity:**

The Department of Veterans Affairs, VISN 21 Network Contracting Office 21, VA Southern Nevada Healthcare System (VASNHCS), North Las Vegas VA Medical Center is submitting a justification for other than full and open competition to enter into a firm fixed price (FFP) contract for maintenance and repair services in support of Steris Instruments and Sterilizers. 2237# 593-18-1-8075-0002.

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

The Contractor shall provide maintenance and repair services for the Government owned Steris Instruments and Sterilizers. A firm fixed price contract is contemplated for award to Steris IMS, 3316 2nd Avenue North, Birmingham, AL 35222. This procurement shall be conducted in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.0501 Special Document Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using format of FAR 6.303-2. The period of performance for this new firm-fixed price contract shall begin on 04/01/2018 and shall end on 03/31/2019, however this contract shall include three, one-year options.

Base Year	04/01/2018 - 03/31/2019	\$129,030.00
Option Year 1	04/01/2019 - 03/31/2020	\$135,482.00
Option Year 2	04/01/2020 - 03/31/2021	\$142,256.00
Option Year 3	04/01/2021 - 03/31/2022	\$149,369.00
Total		\$556,137.00

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

The Department of Veterans Affairs requires the procurement of instrumentation and sterilizer repair and maintenance services at the Las Vegas Medical Center. **Per Centers for Disease Control (CDC) Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008**

- a. **Category II recommendation:** to inspect equipment surfaces for breaks in integrity that would impair either cleaning or disinfection/sterilization. Discard or repair equipment that no longer functions as intended or cannot be properly cleaned, and disinfected or sterilized.
- b. **Category 1B recommendation:** Provide comprehensive and intensive training for all staff assigned to reprocess semi-critical and critical medical/surgical instruments to ensure they understand the importance of reprocessing these instruments. To achieve and

maintain competency, train each member of the staff that reprocesses semi-critical and/or critical instruments as follows:

- i. provide hands-on training according to the institutional policy for reprocessing critical and semi-critical devices;
- ii. supervise all work until competency is documented for each reprocessing task;
- iii. conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); and
- iv. review the written reprocessing instructions regularly to ensure they comply with the scientific literature and the manufacturers' instructions

Vendor will provide preventative maintenance, specialty repair and services to include but not limited to Case Carts; IV Poles; Mayo Stands; Back Tables; General Stainless Equipment (Rolling Stock); and sterilizer chambers. At least 97% of all work will be done on-site at VA Southern Nevada Healthcare System via a mobile service. The remaining 3% may need to be serviced in the Lab to ensure proper repair. Technical staffs must be certified from an accredited instrument repair technician certification; certification by either the International Association of Healthcare Central Services Materials Management (IAHCSCMM) or the Certification Board for Sterile Processing and Distribution (CBSPD). Contractor to also provide In-service education to SPS staff on issues such as cleaning, care and handling. Instrumentation supplies and equipment must be maintained to ensure an acceptable level of safety and quality at the hospital facility. Sterilizers are vital to the Healthcare Facilities as they are needed to sterilize medical equipment for clinics and surgeries. A firm fixed price contract is needed to maintain the equipment to prevent delays in patient treatment and to comply with federal and state laws.

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;

FAR13.5 Simplified Procedures for Certain Commercial Items: *The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by for restricting competition on this procurement via FAR 13.106-1(b)(2).*

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** Steris IMS is the original equipment manufacturer (OEM) of the Sterilizers and holds the proprietary rights to all equipment parts and hardware. A third-party vendor exists, but are not capable of performing maintenance and repair service of the equipment. Many of the third parties would subcontract the maintenance and repair portion of the contract to Steris or another large business and charge a 13% to 25% premium for program management (i.e. contract administration). Furthermore, third party vendors must be able to access parts within twenty-four (24) hours to ensure there is no delay in sterilizing the equipment. Any delay would impact patient care, by cancelling appointments and surgeries due not having sterilized equipment. Equipment must be sterilized to comply with

federal and state laws. If the Sterilizer is inoperable or breaks, it would result in considerable costs to the Government for a replacement, take up to twelve (12) months to install and more time to train staff. Furthermore, improper maintenance or repair by another vendor may lead to voiding any warranties, delay of patient treatment and an increase of patients trying to obtain appointments at clinics. Steris technicians are certified by the Certification Board for Sterile Processing and Distribution (CBSPD), as required by the SOW (copy of certificate filed in contract briefcase). In addition, a sources sought notice was posted to see which businesses are interested in performing the services. 2 small business sources responded, Pacific Monarch and Advanced Endoscopy Devices. A solicitation was posted allowing the small businesses to participate and provide a quote response. However, upon review of Pacific Monarch's quote response, they did not address the technical evaluation factors listed in the solicitation, nor did they provide evidence that their technicians were certified by either the International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD). In addition the quote was received late from Pacific Monarch after the 2PM PST deadline. The quote response received from Advanced Endoscopy Devices addressed some of the evaluation factors, however they did not provide evidence that their technicians were certified by either the International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD) as required by the SOW. In addition, their total price quote was significantly higher than the Independent Government Estimate at \$1,988,901.00. The IGCE is at \$712,972.20. This price quote was not fair and reasonable. This solicitation was posted on GSA e-Buy and FBO with the same interested parties. An interested SDVOSB firm reached out from Sustainment Technologies stating they partner with Steris IMS. However, when requesting a quote submission, the representative from Sustainment Technologies advised they would not be submitting a quote. Email correspondence filed in contract briefcase. The amount of time spent reprocurring the requirement has placed an undue delay in getting the services awarded, which now makes this an urgent requirement as the instruments and sterilizers are vital to the Healthcare Facilities as they are needed for clinics and surgeries. If the instruments are not maintained and sterilized, this will greatly impact patient care.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A sources sought notice (36C26118Q0014) was placed on www.fbo.gov on October 5, 2017 requesting interested parties to provide a response. 2 small business GSA sources responded, Pacific Monarch and Advanced Endoscopy Devices. A solicitation was then posted on GSA eBuy on November 29, 2017 allowing the small businesses to participate and provide a quote response. However, upon review of Pacific Monarch's quote response, they did not address the technical evaluation factors listed in the solicitation, nor did they provide evidence that their technicians were certified by either the International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD). The quote response received from Advanced Endoscopy Devices addressed some of the evaluation factors, however they did not provide evidence that their technicians were certified by either the International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD) as required by the SOW. In addition, their total price quote was significantly higher than the Independent Government Estimate at \$1,988,901.00. The IGCE is at \$712,972.20. This price quote was determined not to be fair and reasonable. This solicitation was reposted on FBO on January 23, 2018 with the same interested parties responding to the solicitation. Once again, the evaluation factors were not entirely addressed and pricing was not fair and reasonable. In addition the quote was received late from Pacific Monarch after the 2PM PST deadline. An interested SDVOSB firm reached out from Sustainment Technologies stating they partner with Steris IMS. However, when requesting a quote submission, the representative from Sustainment Technologies advised they would not be submitting a quote. Email correspondence filed in contract briefcase. The amount of time spent reprocurring

the requirement has placed an undue delay in getting the services awarded, which now makes this an urgent requirement as the instruments and sterilizers are vital to the Healthcare Facilities as they are needed for clinics and surgeries. If the instruments are not maintained and sterilized, this will greatly impact patient care. This equipment must remain in optimum working condition to avoid delay in patient treatment. Any delay would cause cancellation of surgeries and clinic appointments. Contractors must be able to obtain the OEM parts to ensure there is no delay in the event of equipment failure. This requirement is needed to ensure the equipment is maintained and sterilized for patient healthcare.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated total dollar amount of this procurement is for a base plus three (3) option years. The Contracting Officer relied on the healthcare facilities Independent Government Estimate (IGE) and the quotes provided from the solicitations to determine fair and reasonable pricing. The IGE was significantly lower than the quotes received from Advanced Endoscopy Devices who provided a thorough technical response, however failed to provide evidence that their technicians were certified by either the International Association of Healthcare Central Services Materials Management (IAHCSCMM) or the Certification Board for Sterile Processing and Distribution (CBSPD). Therefore, the pricing from Steris has been determined fair and reasonable to the Department of Veterans Affairs.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**

As described in Section 6 above, in accordance with FAR Part 10, market research was conducted through GSA, SBA, Vet Biz, and FBO via Sources Sought announcement and posting the solicitation on GSA e-Buy and FBO advising industry of the pending acquisition and soliciting quotes from interested parties. It was determined that contractors are not capable of providing the services, and/or do not hold the required certifications accredited by either the International Association of Healthcare Central Services Materials Management (IAHCSCMM) or the Certification Board for Sterile Processing and Distribution (CBSPD); and/or cannot provide the services at a fair and reasonable price. I also researched on FBO and found a similar acquisition from VISN 22, which was recently sole source to Steris on November 8, 2017. I contacted the procuring office Contracting Officer, and the CO confirmed the requirement was sole source to Steris, Contract# 3626218C0009 for 1 base year amounting to \$150,505.42.

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

Sole Source award to Steris IMS is the only logical choice as the instruments and sterilizers are OEM and only certified Steris technicians are capable of providing the maintenance and repair services. Steris technicians are the only technicians who have provided evidence of credentials certified by the Certification Board for Sterile Processing and Distribution (CBSPD). A copy of the technician's certificate is filed in the contract briefcase.

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

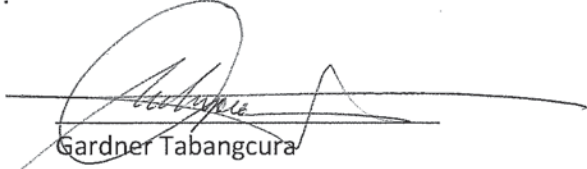
See section 6 above.

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:**

Overcoming barriers of competition is not feasible at this time, as no other vendors are fully capable or certified to provide parts or servicing. The contracting officer will resolicit the requirement when its time to renew the services to determine if other sources will be capable at that time. It may best approach for the interested companies to ensure their technicians are fully certified by either the

International Association of Healthcare Central Services Materials Management (IAHCSMM) or the Certification Board for Sterile Processing and Distribution (CBSPD). In the future, the requesting service shall research similar systems and equipment from other companies who will have the ability to access licensing, software updates and parts; therefore, competition cannot be realized 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.


Gardner Tabangcura
Assistant Chief, Sterile Processing Service (SPS)
VA of Southern Nevada Healthcare System

28 MAR 2018
Date

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

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

Parvinder S. Brar 747434
Digitally signed by Parvinder S. Brar
747434
Date: 2018.03.28 10:04:19 -07'00'

Parvinder Brar
Contracting Officer
NCO 21

Date

- b. **Director of Contracting /Designee (Required over \$150K but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.

MARK J.
MIKUS 140783
Digitally signed by
MARK J. MIKUS 140783
Date: 2018.03.28
10:39:40 -07'00'

Mark J. Mikus
NCO 21 Branch Chief

Date