

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) 16
Division II Services Team B
400 Veterans Avenue
Biloxi, MS 39531-2410

Agency:

Department of Veterans Affairs, VISN 16
Gulf Coast Veterans Health Care System
400 Veterans Avenue
Biloxi, MS 39531-2410

2237: 520-15-1-076-0014

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

This sole source request ensures the facility maintains compliance with reprocessing procedures, national standardization and manufacturer integrity of the Getinge sterilizers, washers and water filtration systems.

This requirement is for the PM&R of the Getinge Sterilizers.

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

The Gulf Coast Veterans Health Care System in Biloxi, MS has a requirement for preventive maintenance and repair of the Getinge Sterilizers manufactured by Getinge. The Getinge sterilizers use steam sterilization technology. Preventive maintenance service includes replacement of all wearable parts, system calibration, and system diagnostics. The systems have proprietary components which require service through a Getinge Technical Resources Support Manager. All labor, time, and materials for corrective maintenance are required. Approximate cost per year is ~~\$50,472.00~~. Base ~~(\$50,472.00)~~ plus 4 option periods at ~~(\$50,472.00)~~ each total: ~~\$202,360.00~~

The equipment is located at the Biloxi VA Medical Center:

Brand	Model	Serial #	Location
Getinge	6930AMPS	98C59159	Biloxi, MS VAMC
Getinge	Castle7600	KC03A067	Biloxi, MS VAMC
Getinge	8666	0627020-0608	Biloxi, MS VAMC
Getinge	533HC	07K08083	Biloxi, MS VAMC
Getinge	633HC	URA012838	Biloxi, MS VAMC
Getinge	633HC	URA012836	Biloxi, MS VAMC
Getinge	633HC	URA012837	Biloxi, MS VAMC
Getinge	HS-450 WATTS R	6450229	Biloxi, MS VAMC
Getinge	CAS-45	GC-33244-W12	Biloxi, MS VAMC
Getinge	CAS-45	GC-33245-W12	Biloxi, MS VAMC
Getinge	CAS-45	GC-33246-W12	Biloxi, MS VAMC
Getinge	HS-4800FT WATT	124800239	Biloxi, MS VAMC

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):**

Getinge is the only known FDA approved vendor that can supply Preventive Maintenance services on the Getinge Systems.

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

A sources sought synopsis, VA256-14-I-1381 was issued on 12 Aug 2014, to gain knowledge of potential qualified sources and their size classification (hubzone, 8(a), small, small disadvantage, or Service Disabled Veteran or Veteran owned small business) relative to NACIS 811219 (size standard of \$20.5 Million). The synopsis resulted in no responses.

The synopsis identified that Network Contracting Office (NCO) 16, was in the process of seeking sources for a potential contractor to provide maintenance for Government-owned Getinge Sterilizers for a base year and four each one-year option periods, which are planned to begin on or about October 1, 2014.

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

The estimated value of this solicitation to include base period and the four each, one year option periods is ~~\$20,000,000~~. Based on market research and comparison of pricing among other VA's the contracting officer believes Getinge pricing will be fair and reasonable. Getinge holds a VA federal supply schedule awarded by the National Acquisition Center (NAC). The contracting officer also believes Getinge would not jeopardize their corporate governance by offering unfair or unreasonable pricing. However, a complete analysis of all costs or a price analysis will be fully utilized prior to award of the contract.

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

Market Research revealed no SDVOSB, VOSB, or small businesses authorized or capable of providing the preventative maintenance and repair. Historically, the services have been provided Getinge. Getinge is the OEM and has proprietary ownership of all hardware, software and firmware. A sources sought was issued on 12 Aug 2014 and closed 15 Aug 2014, resulting in no responses.

A search of the VETBIZ database using the keyword "Getinge Sterilizers" and NACIS code 811219 revealed 2 SDVOSB and 2 VOSB owned enterprises; however, none of these firms are authorized nor have the capability to perform the services.

A search of the SBA's dynamic small business database using the keyword "Getinge Sterilizers" and NACIS code 811219 revealed no small businesses.

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

Getinge USA Service is the sole-source for OEM trained and certified technicians to perform scheduled and unscheduled maintenance on Getinge equipment listed previously. Getinge USA Service also provides the only certified Operator, First Response, and Bio-Med training on Getinge equipment.

The VA's Sterilizers (manufactured by Getinge USA, Inc.) are under a limited manufacturer's warranty for 15 years from the date of purchase. Under Getinge's Limited Equipment Warranty, Paragraph 3.0 (g), "installation, maintenance, or repair of the Equipment performed by other than Getinge or a service provider authorized by Getinge" will void any Getinge equipment under warranty. We confirmed with our Getinge representative that they do not subcontract any of their maintenance or repair work to any other company.

In Jun 2009, the VA was criticized by lawmakers for putting more than 10,000 former patients at risk and causing a national scare over botched colonoscopies. The VA Office of Inspector General published report No. 09-01784-146 "Use and Reprocessing of Flexible Fiber-optic Endoscopes at VA Medical Facilities" and the VA Secretary at the time, Eric Shinseki, stated he would discipline staffers due to the significance of the event. Also, in 2009, the Department of Veterans Affairs received \$26 million worth of new sterilizing equipment to help in reprocessing endoscopes and other reusable medical devices (RME).

VHA Directive 2009-004, "Use and Reprocessing of Reusable Medical Equipment (RME) in Veterans Health Administration Facilities" requires that RME reprocessing SOPs reflect manufacturers' instructions. In addition, VHA Directive 2009-031, "Improving Safety in The Use Of Reusable Medical Equipment Through Standardization Of Organizational Structure And Reprocessing Requirements" para. 4d(5)(b), states that independent repair maintenance contracts or in-house service agreements need to be executed in order to ensure adherence with current manufacturers' maintenance and repair guidelines. Reprocessing of RME is a serious concern. Therefore, it would only make good business sense that the PM&R service be provided by the manufacturer capable of meeting FDA standards of approval to avoid repeating an episode of disaster.

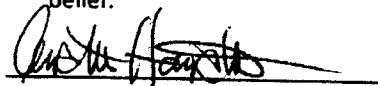
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

"See Section VI 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:

Full and open competition can be sought when the hardware and software required for the equipment are no longer proprietary.

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.



Austin Hampton
Clinical Engineer
Gulf Coast Veterans Health Care System

8/15/2014

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.

windell.lance@va.gov

Digitally signed by windell.lance@va.gov
DN: cn=windell.lance@va.gov
Reason: I am the author of this document
Date: 2014.08.15 13:31:38 -05'00'

Windell Lance
Contracting Officer
Network Contracting Office (NCO)16
Division II Services Team B
(Biloxi Medical Center, Biloxi, MS)

Date

- b. **P&C:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

bennett.smith2@
va.gov

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Date: 2014.08.18 10:55:16 -05'00'

Bennett Smith
Chief, Division II Services Team B
Network Contracting Office (NCO)16
(Biloxi Medical Center, Biloxi, MS)

Date

- c. **NCM/PCM/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

aaron.villalpando@va.gov
v

Aaron Villalpando
Director of Contracting
Network Contracting Office 16

Date