

Attachment 2: Request for Sole Source Memo Format

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval**

**For**

**Other Than Full and Open Competition**

**1. Contracting Activity:** Department of Veterans Affairs, VISN 03, NCO3.

2237 transaction number **630-13-4-3901-0049** – for the purchase of eleven (11) GE Trophon EPR units complete with all necessary accessories for the function of the units. The items are being requested at the following VISN 03 locations:

- a. VA New York Harbor:
  - i. Manhattan campus: 2 units
  - ii. Brooklyn campus: 2 units
- b. VA New Jersey Healthcare System: 2 units
- c. VA Northport Medical Center: 2 units
- d. VA Bronx / John J Peters Medical Center: 2 units
- e. VA Hudson Valley Healthcare System: 1 unit

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

A VISN3-wide sole source procurement with GE Healthcare via their NAC HTME Contract (V797P6019B) for High Level Disinfection Units for Ultrasound Transducers.

The purpose of this project is to acquire units capable of performing automated high level disinfection of endocavitary ultrasound probes at the five facilities of VISN 3.

The Radiology departments at each of the five facilities in VISN use endocavitary ultrasound probes in routine clinical examinations. These probes require high level disinfection after each examination. The current process of high level disinfection is time consuming, requires extensive staff training and staff performed quality control, and utilizes chemical disinfectants which have the potential for toxic exposure to staff members.

VISN 3 seeks to replace this process with a more time efficient, automated high level disinfection system which uses nontoxic materials in accordance with the priority goals from the AAMI/FDA Reprocessing Summit. The report can be found here

[http://www.aami.org/htsi/reprocessing/pdfs/2011\\_Reprocessing\\_Summit\\_publication.pdf](http://www.aami.org/htsi/reprocessing/pdfs/2011_Reprocessing_Summit_publication.pdf)

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

- A. High Level Disinfectant(HLD) Unit for Ultrasound probes

- a. Capable of performing automated HLD for endocavitary ultrasound probes that meets all FDA, Joint Commission, and VHA guidelines
  - b. Suitable for use in intermediate and low level disinfection of non-endocavitary probes
  - c. Hydrogen peroxide based system with cartridge style replacement
  - d. ISO 9001 compliant
  - e. Fully automated HLD process
  - f. HLD cycle time less than 10 minutes
  - g. Integrated quality assurance sensor
  - h. Chemical indicator system
  - i. Probe manufacturer documented compatibility with all endocavitary probes currently in use within VISN 3
- B. Delivery: Vendor shall deliver all High Level Sterilization Units for Ultrasound Transducers within 45 days of award.
- C. Training: Vendor shall provide sufficient training for at least two SPS personnel at each of the five VISN 3 facilities.
- D. Purchase of future High Level Disinfection Units for Ultrasound Transducers: within one year of the award, any facility in VISN 3 may purchase any number of additional High Level Disinfection Units for Ultrasound Transducers at a cost per unit at or below the original awarded price. Each newly purchased unit will be delivered and installed within 45 days of purchase.

The contractor shall also conduct the following tasks:

- 1. Delivery of all required High Level disinfection Units for Ultrasound Transducers within 45 days of award
- 2. Completion of training of at least two SPS personnel at each VISN 3 facility within 90 days of award
- 3. Specifications: see above "Requirements"

#### **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):**

General Electric Healthcare is the sole manufacturer and distributor of the Trophon EPR Transducer High Level Disinfection System. There is no alternative Disinfection System that meets VISN 3's criterion, nor comes close to offering similar advantages.

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

Market research was conducted to see if there were other vendors that were capable of meeting the needs of the SOW.

A special notice was published to fbo.gov seeking sources capable of meeting the requirements.

A Google search on Transducer high level disinfection systems was conducted in order to find other sources.

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

Purchase will be via NAC HTME contract# V797P6019B. While this contract is not on the FSS schedule, the prices have still been prenegotiated by the NAC, and therefore deemed fair and reasonable.

**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 see if there were other vendors that were capable of meeting the needs of the SOW. No sources were found.

A special notice was published to fbo.gov seeking sources capable of meeting the requirements. There were no responses.

A Google search on Transducer high level disinfection systems was conducted in order to find other sources. No sources were found.

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

N/A

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

GE Healthcare

**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:**

As part of its mission, VISN 3 Radiology and Biomed departments regularly monitor the marketplace for new technology, products and services that would be beneficial to our Veterans. Any subsequent acquisitions will take into account this up-to-date knowledge of the marketplace, and if there are new, better and/or more cost effective radiology disinfection products available, we will compete the solicitation.

**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.



Name Irina Belets

Title: Biomedical Engineering

Facility: VISN 03 VAMC-NYHHS Brooklyn Campus

June 25, 2013

Date

**2. 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.

**Ward, Christopher A.**

Name: Christopher Ward

Title: Specialized Team Coordinator

Facility: NCO3

Digitally signed by Ward, Christopher A.

DN: cn=Ward, Christopher A.,

email=Christopher.Ward@va.gov, o=Veteran Affairs

Date: 2013.08.06 09:59:51 -04'00'

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

Jadwiga M Kustra 175043

Digitally signed by Jadwiga M Kustra 175043  
DN: dc=gov, dc=va, o=Internal, ou=people,  
ou=2342, 1.2.840.100.1.1=jadwiga.kustra@va.gov, cn=Jadwiga M Kustra  
175043  
Date: 2013.08.06 12:37:52 -04'00'

Acting for Yolanda Borges  
Network Contract Manager  
NCO3

Date

Ms. Jadwiga Kustra, DNCM, NCO 3

- c. **SAO (If over 500K):** I certify the justification meets requirements for other than full and open competition.

N/A

Name

Director

Service Area Office, East

Date

- d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$10million) or approve (\$500K to 10 million) for other than full and open competition.

\_\_\_\_\_  
Name N/A  
Chief Procurement and Logistics Officer  
VHA Head of Contracting Activity (HCA)

\_\_\_\_\_  
Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$10 million but not exceeding \$50 million):**  
I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

\_\_\_\_\_  
Name N/A  
C. FORD HEARD  
Deputy Senior Procurement Executive (DSPE)  
Office of Acquisition and Logistics  
Department of Veterans Affairs

\_\_\_\_\_  
Date

- f. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

\_\_\_\_\_  
Name N/A  
Jan R. Frye  
Deputy Assistant Secretary for Acquisition and Logistics  
Senior Procurement Executive (SPE)  
Department of Veterans Affairs

\_\_\_\_\_  
Date

**13.**