

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

LIMITED SOURCES JUSTIFICATION

ORDER >\$3,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 504-14-1-980-0002

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: General Electric Company dba GE

Manufacturer/Contractor POC & phone number: Phil.Goodridge@ge.com 610-731-1527

Manufacturer /Contractor Address: 3000 N. Grandview Blvd., Waukesha, WI 53188-8161

Dealer/Rep address/phone number: Mark Meng, GE Product Sales Specialist; 7275 FM 2164; Sanger, TX 76266; 940-255-9856; mark.meng@ge.com

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
Amarillo VA Health Care System
6010 Amarillo Blvd
Amarillo, TX 79106-1991
SAO West NCO 18 El Paso

VISN:

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

An Amarillo VA Health Care System limited sources procurement with GE via their National Acquisition Center (NAC) High Tech Medical Equipment (HTME) Contract V797P-6019B for High Level Disinfection Units for ultrasound transducers. The purpose of this procurement is to purchase a high level disinfectant (Trophon EPF System) capable of performing automated high level disinfection of rectal ultrasound probes. The Urology department uses rectal 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. The Amarillo VA Health Care System 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 Advancing Safety in Medical Technology (AAMI) / US Food and Drug Administration (FDA) Reprocessing Summit. The report can be found below:

<http://www.aami.org/htsi/reprocessing/>

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The Amarillo VA Healthcare System located in Amarillo, TX requires a transducer disinfection system specifically the Nanosonics Trophon EPR system. The transducer disinfection system utilizes hydrogen peroxide in a self-contained system with associated chemical indicators, a printer and a mobile cart that meets all FDA and CDC guidelines for high level disinfection of validated SonoSite C8 Rectal Ultrasound probes. The company known as General Electric Company is the exclusive distributor of the Trophon EPR System. The Trophon is on the VA NAC Contract V797P-6019B. Nanosonics' unique patented disinfection technology generates a hydrogen peroxide mist ensuring high-level disinfection. Trophon EPR achieves high-level disinfection of the probe – including the shaft and handle – in just seven minutes, maximizing your productivity. Unique sensor technology validates each disinfection cycle is completed as specified. The in-process chemical indicator provides further assurance of high-level disinfection. Small quantities of water and oxygen are generated as primary by-products. There are no toxic wastes or residues. The disinfection cycle takes place in a fully automated, closed system, so no one is ever exposed to toxic, harmful chemicals. The recyclable cartridges can be disposed with standard waste. The Trophon EPR system and process are compatible with most ultrasound probe sizes, shapes, and materials.

- PN E8350NA – Trophon EPR - \$9,360.00
- PN E350NJ – Trophon Sonex HL 6 Bottles/Box (80 ml bottles) - \$552.00
- PN 8350NC – Trophon Chemical Indicator - \$80.00
- PN 8350NH – Trophon Cart - \$1,360.00
- PN 8350PA – Trophon Printer - \$799.20

(b) ESTIMATED DOLLAR VALUE: \$12,151.20

(c) REQUIRED DELIVERY DATE: October 1, 2014

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

Market research indicates that GE is the sole distributor of the Nanosonics Trophon EPR Transducer High Level Disinfection System in the United States. There is no alternative transducer disinfection system that neither meets the criterion nor comes close to offering similar advantages and is FDA approved.

☒ A patent, copyright or proprietary data limits competition. The proprietary data is:
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)
Market research indicates that the transducer disinfection system manufactured by Nanosonics Limited has a unique patented disinfection technology that generates a hydrogen peroxide mist that ensures high-level disinfection.

☐ These are “direct replacements” parts/components for existing equipment.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

The transducer disinfection system is validated to disinfect the SonoSite C8 Rectal Ultrasound probes.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

A Delivery Order will be placed against NAC HTME contract V797P-6019B. While this contract is not on FSS schedule, the prices have been pre-negotiated by the NAC, and therefore deemed fair and reasonable.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Market research indicates that GE is the sole distributor of the Nanosonics Trophon EPR Transducer High Level Disinfection System in the United States. There is no alternative transducer disinfection system that neither meets the criterion nor comes close to offering similar advantages and is FDA approved. The transducer disinfection system manufactured by Nanosonics Limited has a unique patented disinfection technology that generates a hydrogen peroxide mist that ensures high-level disinfection. This transducer disinfection system is FDA approved under K501(k) number K103059.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

GE has successfully provided these products to other VA medical centers. They are the only vendor that can provide the Nanosonics Trophon EPR system in the United States.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

As part of their mission, the Sterile Processing Service and Biomedical 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 disinfection products available, a competitive solicitation will be posted.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*



SIGNATURE

January 14, 2014

DATE

Julia Lynch Chief, Sterile Processing Service

Amarillo VA Health Care System (504)

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



CONTRACTING OFFICER'S SIGNATURE

January 22, 2014

DATE

Carlos Jaquez, Contracting Officer

SAO West, NCO 18, El Paso

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



Digitally signed by
ross.brown@va.gov
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DATE

For: Sabrina J Smith
NCO 18 Director of Contracting