

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

2237 Transaction # or Vista Equipment Transaction #: 678-15-2-047-0393

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: Provide *original manufacturer's* name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, *ALSO* provide dealer information.)

Manufacturer/Contractor: Abiomed, Inc

Manufacturer/Contractor POC & phone number: Diane Welsh, 978-646-1467, dwelsh@abiomed.com

Mfgr/Contractor Address: 22 Cherry Hill Drive, Danvers, MA 01923

Dealer/Rep address/phone number: N/A

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

VISN 18 Network Contracting Office (NCO)

Phoenix Contracting Office

777 E Missouri Ave, #300

Phoenix, AZ 85014

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

This justification to limit sources comes as a result for the EMERGENCY acquisition of Impella CP Catheters for Southern Arizona Veterans Affairs Health Care System (SAVAHCS) Surgical Department to continue using existing Automated Impella Controller (AIC) equipment. During the weekend of February 21-22, 2015 the facility had a larger than average numbers of patients come in requiring emergency catheterization depleting hospital and surrounding facilities inventory. The disposable catheterization kits are required during an emergency when patients are noted with severely clogged arteries which could cause impending heart attack, stroke, or death.

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

Supplies required to meet the agency's need are quantity twelve (12) of item number 0048-0003 Impella CP Catheter (AIC)

(b) ESTIMATED DOLLAR VALUE: \$301,882.56

(c) REQUIRED DELIVERY DATE: Overnight delivery February 24, 2015

(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 has determined that the required catheters are proprietary to Abiomed on the Abiomed Automated Impella Controller (AIC) that SAVAHCS owns and operates. No other device will work with the AIC. Previous purchases and existing mandatory use federal supply schedule contracts support the unavailability of competition.

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.)

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 twelve (12) of item number 0048-0003 Impella CP Catheter are single use catheters required to continue using the Automated Impella Controller (AIC) (emergency heart pump) that SAVAHCS owns and operates. Should SAVAHCS be unable to continue to purchase the single use supplies, the equipment would rendered inoperable and patient care would be severely impacted.

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. N/A

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

During the weekend of February 21-22, 2015 the facility had a larger than average numbers of patients come in requiring emergency catheterization depleting hospital and surrounding facilities inventory. The disposable catheterization kits are required during an emergency when patients are noted with severely clogged arteries which could cause impending heart attack, stroke, or death.

(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:

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 2: Request for Limited Sources Justification Format >\$150K

Approval of this justification to limit sources to the above referenced manufacturer/contractor to purchase the required 12 catheter Kits represents the best value to the government in accordance with FAR 8.404 (d) and 2.101 as it allows the continued use of SAVAHCS's existing equipment without the unacceptable delays and added expense of acquired new equipment, supplies, and additional training.

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

Querying the Government wide database of contracts and other procurement instruments intended for use by multiple agencies available at www.contractdirectory.gov found that there are other VHA's or other governmental agency purchases of items or services for the Impella Catheters. Searches for "impella catheter" found one small business NAC Federal Supply Schedule (FSS) holder, Government-Wide Acquisition Contracts (GWAC), Multi-Agency Contracts, Other Indefinite Delivery Contracts (IDC), Basic Ordering Agreements (BOA), or Blanket Purchase Agreements (BPA) awarded by many Federal Agencies leading to procurement of this product.

Market Research was conducted in accordance with FAR 10.002, 8.002, and VAAR 808.002 yielding Item 0048-0003 Impella CP Catheter is only available via mandatory source federal supply schedule V797D-30214 between Abiomed, Inc and Veteran Affairs National Acquisition Center valid until August 14, 2018.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

N/A

(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:

Continue to work with the manufacturer to allow authorized resellers or distributors via the federal supply schedule program or med/surg prime vendor program.

(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.)*

Tim Harris

Digitally signed by Tim Harris

DN: c=US, cn=Tim Harris,
o=SAVAHCS, ou=Logistics

Date: 2015.03.04 16:08:40 -07'00'

Tim Harris
Supervisory Supply Management Specialist

Date

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
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(10) APPROVALS IN ACCORDANCE WITH THE VHAPM, Volume 6, Chapter VI: OFOC SOP

a. **Prepared by:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

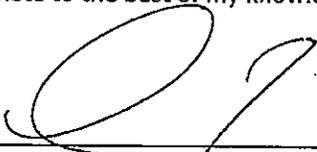
David W. Hetterly
641408

David Hetterly
Contract Specialist

Digitally signed by David W. Hetterly 641408
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=david.hetterly@va.gov,
cn=David W. Hetterly 641408
Date: 2015.03.04 16:10:36 -07'00'

Date

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

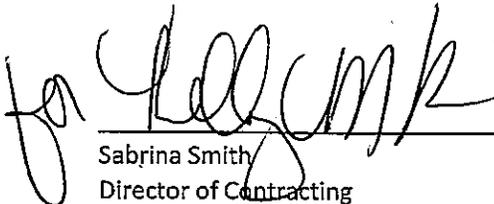


Douglas Crowley, Supply Branch 1 Supervisor
Contracting Officer

3/5/2015

Date

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



Sabrina Smith
Director of Contracting
VISN/PCA 18

3/19/2015

Date

Kelly M. Dodson
Division Chief 11