

Chapter VI: Other Than Full and Open Competition (OFOC) SOP  
Attachment 3: Request for Sole Source Justification Format >\$150K

DEPARTMENT OF VETERANS AFFAIRS

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

1. Contracting Activity:

Department of Veterans Affairs  
VISN 1  
1400 VFW Parkway  
West Roxbury VA Medical Center

The purchase request number is 523-16-2-7811-1322.

2. Nature and/or Description of the Action Being Processed: Contract for custom Perfusion kits. Items being ordered are Custom Packs made specifically for Cardiac Surgery to insure the Perfusion team at the West Roxbury MA campus can provide to the Dr.'s, to place a patient on lung and heart bypass during Cardiac surgery. Perfusion also provides blood filtration for other caseloads such as Vascular and General Surgery. This contract will be a firm fixed price, with a base year and 4 options years. The total approximate value is: This is a Brand Name Justification only. TF

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

Cardmedia tubing packs/heparin bonded are required when conducting cardio pulmonary bypass and provide cardiac and pulmonary support for the patient. The technique administers low doses of heparin bonded circuits to provide high quality medical care to the patient. These supplies and accessories are used in all open heart cases. Through clinical market research it was determined that Cardmedia tubing packs/heparin bonded can only be purchased from Medtronic or their distributors.

The MPS Cardioplegia Delivery Set is a brand name that we need to acquire because we currently own the Quest MPS console equipment, and these are the only supplies that will work with this equipment.

The CDI Blood Parameter Monitoring System 500 (CDI System 500) with Sensor is the only product of this type in the market. It is used as part of the Custom Packs because it continuously measures and calculates vital blood parameters during cardiopulmonary bypass. This product provides the Cardiac surgeons and Perfusionists information to improve patient care during surgery. The CDI System equipment is also currently owned by the VA.

The Haemonetics Cell Saver is the only brand that will suffice because it is the only product that is used with the Elite Autotransfusion System that we currently own. These supplies and accessories are used in all open heart cases along with some vascular and abdominal surgery cases.

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4. Statutory Authority Permitting Other than Full and Open Competition:

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-19
- (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):

The VHA brand name products above have been approved by physicians, as in their clinical judgment the brand name product will provide a better therapeutic outcome for patients' recovery.

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

The following requirement was posted to the FBO to allow for vendors to compete. A Sources Sought Notice was posted to FBO and the results are listed below in item #10. TF

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

The West Roxbury VA Medical Center anticipates the cost to the Government will be fair and reasonable based on competition and comparison to recent prices paid.

A Request for Quote will be posted to FBO to promote competition and procure the items needed at the best prices. TF

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

After searching NAC & GSA, there are no available contracts for any of the items requested.

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:

A Sources Sought Notice was posted on FBO and 5 responses were received.

1. LogMet Solutions, SDVOSB
2. Manus Medical, SDVOSB
3. Veterans Healthcare Supply Solutions, SDVOSB
4. Invosurg, not showing in SAM
5. CardioPulmonary Services, Small-Business.

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:

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At this time, the physician has stated the above mentioned brand name products are the only brands that will meet the specific needs of the patients, however, we are still competing this amongst distributors.

- 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.

*Melissa Williams*  
Name: Melissa Williams  
Title: Inventory Management Specialist  
Facility: Boston VA Health Care System

*7/6/16*  
Date: *7/6/16*

- 13. **Approvals In accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP. This part if filled out by Contracting Staff as part of the Justification**

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

Tammy A Fox 706200

Digitally signed by Tammy A Fox 706200  
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0.9.2342.19200300.100.1.1=tammy.fox@va.gov, cn=Tammy  
A Fox 706200  
Date: 2016.07.14 09:17:09 -04'00'

Tammy A. Fox  
Contracting Officer  
NCO1

Date

- b. **Procurement Analyst: Concur/ Non-Concur**

Gary W Dilk  
231297

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0.9.2342.19200300.100.1.1=gary.dilk@va.gov,  
cn=Gary W Dilk 231297  
Date: 2016.07.14 10:50:03 -04'00'

Gary Dilk  
NCO1

Date

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

Gerald F. Jacobs  
668993

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0.9.2342.19200300.100.1.1=gerald.jacobs@va.gov,  
cn=Gerald F. Jacobs 668993  
Date: 2016.07.14 11:17:43 -04'00'

Gerald Jacobs  
Director of Contracting NCO1

Date

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- d. VHA SAO 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 \$13.5 million) or approve (\$700K to 13.5 million) for other than full and open competition.

**JOSEPH MALETTA**  
**1347841**

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0.9.2342.19200300.100.1.1=joseph.maletta@va.gov,  
cn=JOSEPH MALETTA 1347841  
Date: 2016.07.28 12:46:14 -04'00'

Joseph Malatta  
SAO East Director/VHA Head of Contracting Activity (HCA)

Date