

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA255-17-AP-2702

1. Contracting Activity: Department of Veterans Affairs, VISN 15;

a. Kansas City Medical Center
4801 E. Linwood Blvd
Kansas City MO. 64128-2226
ATTN: Pharmacy

b. 2237 Assigned – 589-17-2-1792-0088

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

This requirement is for the purchase and installation of three(3) EDU conversion exhaust kits in the Mobile Isolation Chambers (MIC) to bring the MICs into compliance with USP 797 standards in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2. This requirement is a new contract to modify the MICs units. This contract will be A Firm Fixed Price Contract.

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

The exhaust and sterilization equipment to meet compliance and enhance cleaning of the MIC units are the bulk of the purchase, the startup and training for using and maintaining the new equipment is also listed as a line item. The delivery date will be coordinated by the Kansas City VAMC upon award, to determine the most appropriate installation and training times based on vendor availability and IV Room workflow to avoid interruptions or delays to patients receiving IV Therapy. The preferred delivery date would occur before April 1, 2017.

The specific models in use are the MIC Single and MIC Dual systems that can be found on the vendor's website (<http://www.mic4.com/products/>). The exhaust system must meet USP 797/USP 800 standards for sterile/non-sterile compounding of hazardous (oncology) agents and shall not void any of the Manufacturers warranties. USP standards can be accessed for reference from the following site: <http://www.usp.org/frequently-asked-questions/pharmaceutical-compounding-sterile-preparations>.

- a. 1 x negative pressure external venting kit compatible with MIC brand isolation chambers (estimated at \$4,800.00 each)
- b. 3 x internal MIC EDU internal chamber cleaning systems (estimated at \$55,000.00 each)
- c. 1 x training session for new equipment (estimated at \$3,500.00 each)

Total estimated cost: \$173,300.00

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):

Only One Responsible Source IAW FAR 6.302-1(a)(2)(ii) – Containment Technologies Group is the manufacturer and supplier of the MIC units and the EDU conversion kits required to bring the MICs into compliance with USP 797 standards.

Goss Service Associates, LLC is the authorized distributor and servicer for parts and services under the MIC units. The Kansas City VAMC MIC Units are currently maintained and certified under contract **VA255-15-P-0711**, by Goss Service Associates, LLC. Accordingly, Goss Service Associates, LLC is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

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

1) *The manufacturer was contacted to determine if there was a list of available sources that;*

a. *Are authorized resellers of the EDU Conversion Kit provided by Containment Technologies Group.*

i. *There are women owned small business resellers/installers that are certified (See item #5 above)*

ii. *The manufacturer is a women owned small business manufacturer*

b. *Offer a similar EDU Conversion Kit that could be used on the MIC Units currently in use.*

i. *There are no know alternate conversion kits that can be used on the current MIC Unit.*

2) *A sources sought was posted from 03/08/2017-03/14/2014 Federal Businesses Opportunities (FBO) to seek out potential;*

a. *Vendors*

b. *Optional Exhaust conversion kits from other manufacturers that could be used to meet the requirements set forth in USP 797 on the current MIC unit manufactured from Containment Technologies Group.*

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** IAW Far 6.303-2(b)(7) the price quoted is considered fair and reasonable. The EDU Conversion Mobile Isolation Chamber (MIC) pricing is in-line with Historical pricing data reported in FPDS and is considered fair and reasonable. This will be a firm fixed price contract no cost or price analysis is required.

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

As described in item #6 above, a sources sought was posted to FBO to identify any potential authorized distributors or alternate external venting systems that could be used on the Mobile Isolation Chamber currently in use at the Kansas City VAMC. No one other than those vendors noted in item # 6 above responded.

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

See Item # 5 above;

- 1) Containment Technologies LLC - Manufacturer
- 2) Goss Service Associates LLC – Authorized Distributor

10. **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:**

This is a one-time requirement to bring MIC into USP 797 Compliance Standards.

11. **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.

Stephen E
LaCerte 386267

Digitally signed by Stephen E LaCerte
386267
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=stephen.lacerte
@va.gov, cn=Stephen E LaCerte 386267
Date: 2017.03.21 10:25:34 -05'00'

Name

Date

Title

Facility

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

Larry M.
Zaritz 184054

Digitally signed by Larry M. Zaritz 184054
DN: dc=gov, dc=va, o=internal,
ou=people,
0.9.2342.19200300.100.1.1=larry.zaritz@v
a.gov, cn=Larry M. Zaritz 184054
Date: 2017.03.21 10:38:26 -05'00'

Name

Date

Title

Facility

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

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

Paul A. HEMENWAY
653155

Digitally signed by Paul A. HEMENWAY 653155
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=paul.hemenway@va.gov,
cn=Paul A. HEMENWAY 653155
Date: 2017.03.22 11:17:11 -05'00'

Name

Date

NCO/PCO XX Director of Contracting or Designee
Facility