

VHAPM Part 819.7007/7008 Sole Source Awards to a Verified Service-Disabled Veteran-owned Small Business/Veteran-owned Small Business

Attachment 1: Request for SDVOSB/VOSB Sole Source Justification Format >SAT

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: VA263-18-AP-7474

1. **Contracting Activity:** US Department of Veterans Affairs, NCO 23, St. Cloud VA Health Care System, 4801 Veterans Drive, St. Cloud MN 56303-2099. Organizational Activity: US Department of Veterans, Minneapolis VA Health Care System, One Veterans Drive, Minneapolis MN 55417.

2237 Number: 618-18-3-040-0256

2. **Nature and/or Description of the Action Being Processed:** To establish a firm fixed price purchase order for the Minneapolis VA Health Care System, Forensic Toxicology Laboratory for a capitol purchase for two (2) new benchtop tandem quadrupole API mass spectrometer analyzer and high pressure liquid chromatography system (LC-MS/MS) testing from Government Scientific Source (GSS). These units will be utilized for Drugs of Abuse testing in the HHS certified NIDA laboratory located at the Minneapolis VA.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** This procurement shall include the instrument (s) (sample manager, column manager, UPLC, TQD), nitrogen generator, workstation, application software (instrument operation/control and sample analysis), monitor, printer, uninterruptable power supply, installation, training, validation of the system, and include a one year warranty.

Estimated Delivery: 60 days ARO

4. **Statutory Authority Permitting Other than Full and Open Competition:** 41 USC §3304(a)(5), 38 U.S. Code § 8127, as implemented by FAR 6.302-5 (Authorized or Required by Statute). COs may use the non-competitive (sole source) procedures authorized in VAAR 819.7007 or 819.7008 up to \$5,000,000. Check the specific VAAR clause used below:
() 819.7007 Sole source awards to a verified service-disabled veteran-owned small business; or
(XX) 819.7008 Sole source awards to a verified veteran-owned small business

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5. **Demonstration that the Contractor's Unique Qualifications and/or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The Minneapolis VA toxicology laboratory is requesting sole source purchase of a LC-MS/MS system from Government Scientific Source (GSS) an authorized distributor for Waters Technologies Corporation. Waters Technology Corporation is the manufacturer of the 'Xevo-TQ-S' instrument. This is a sole source request due to the fact MVAHCS toxicology laboratory already has 5 Waters Tandem LCMS systems in use. This purchase is to replace 2 of the units that are 10 years old, and are in need of constant repairs causing delays in testing as these are the work horses for drug testing in the NIDA laboratory. Staying with the same manufacture will ensure standardization of the system operating systems. If systems were purchased from another vendor, we would have 3 systems with one vendor and 2 systems from another. The laboratory would have to separate validation protocols and develop new methods which is not only time consuming but will be a significant cost in labor and reagents. Protocols are re-validated annually, so the separate validation for a LC-MS/MS instrument from a different manufacturer would be time consuming and add additional unnecessary expenses. There will be less cost and time spent in training personnel in the use of the proposed system as they are already operating with it and the transition would be very quick and seamless. These are very sophisticated pieces of equipment which require many months, if not years of experience to operate. The daily operation of the laboratory is performed by many different individuals and would take an extensive amount of time to get all employees to be competent. By replacing the instruments that are already in place, the Minneapolis VA will not require any site modifications as the present requirements for power, nitrogen and argon gas, or space that is very limited in the NIDA laboratory would be the same. Selecting a new vendor would be an extra financial requirement and a delay in installation due to moving power and creating a new work space. Purchasing Waters LC-MS/MS system would keep the government from experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling the needs of the MVAHCS toxicology laboratory.

The Minneapolis VA toxicology laboratory has a compelling urgency to get this procurement awarded before the FY ends due to funding. The 2 instruments that are being replaced are 10 years old and keep having extensive down time for repair, causing delays in testing. The Minneapolis VA Finance counsel met and awarded the funding to get the new instruments in during the current fiscal year, so MVAHCS does not have to wait another year for purchase. Once the equipment is purchased it takes 3 months to actually get the equipment installed and operational. Due to the new regulations in drug testing of VA employees and the strict monitoring of drugs of abuse, the laboratory cannot wait the extra time for the next fiscal year for the award.

The Waters TQS-Micro Tandem LCMS have unique technical features that separate it from competitors such as extended mass range, IVD grade, and increased scan speeds. The design of the ion source (orthogonal geometry ion source) provides a very efficient emission of ions of interest and subsequent removal of non-ionized materials. The use of traveling waves reduces the residence time of the ions in the collision cell resulting in multicomponent MRM data acquisition without loss of signal intensity and minimal cross talk between adjacent MRM channels.

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6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The manufacturer to the instrument, Waters Technology (a large business) has indicated that they have a VOSB authorized distributor in Government Scientific Source (GSS). GSS is a verified VOSB on VIP. A VIP search for NAICS 334516 yielded 82 matches, however, a VIP search for the NAICS 334516 and 'Xevo TQ' had no matches.

In accordance with PPM 2016-05, Para 7:

- (i) The number of SDVOSBs and VOSBs reviewed: Only one contractor was contacted because GSS is the only known SDVOSB/VOSB authorized distributor of these instruments.
- (ii) Documentation of the basis of price reasonableness: See Paragraph 7 below.
- (iii) An explanation why only one of the firms can accomplish the requirement: See Paragraph 5 above.
- (iv) An explanation for finding the non-competitive procurement is in the best interest of the government: See Paragraph 5 above.
- (v) An explanation for selection of the contractor, which will allow the approving official to make a reasonable determination regarding whether a non-competitive procurement is appropriate. See Paragraph 8 below.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Once the quote has been received from GSS, pricing will be compared against Waters Technology's GSA contract to ensure pricing is fair and reasonable.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The manufacturer of the instrument (Waters Technology), a large business, has provided written documentation the Government Scientific Source (GSS) is the only SDVOSB/VOSB vendor for Waters and that GSS can distribute the full breadth of their products. GSS is a verified VOSB on VIP. A VIP search for NAICS 334516 yielded 82 matches, however, a VIP search for the NAICS 334516 and 'Xevo TQ' had no matches. Market research was performed by the customer by reading literature and reaching out to vendor sales reps to discuss the different operating systems. It has been determined that it is going to be most advantageous to MVAHCS to purchase two (2) waters LC-MS/MS instruments to replace the current ones. MVAHCS currently has five (5) in use, and the purchase of these two (2) instruments are to replace two (2) of the older ones that are getting old. Other vendors would introduce a new operating system, set up, and cause a lack of compatibility of methods. This would create a signification amount of extra work, extra time every year for having sperate protocols and validations, and could potentially create confusion for the toxicology laboratory staff causing deficiencies in inspections.

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9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** It will be the best use of the government resources to purchase the LC-MS/MS system from Government Scientific Source (GSS), which is an authorized distributor for Waters Technology's instruments/systems. The recurring cost of having to maintain 2 different system from 3 other systems will have a numbers of hidden cost associates with this move as well as labor cost to maintain and operate two separate systems.

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

Waters Technologies Corporation dba Waters Corporation
34 Maple Street
Milford MA 01757

On behalf of their authorized VOSB distributor: Government Scientific Source (GSS)
12351 Sunrise Valley Drive
Reston VA 20191

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:** At this time there is no plan to compete out this requirement as the requested unit by Waters Technology is found to be the only analyzer that is meeting the requirements of the highly specialized NIDA toxicology laboratory. The analyzers must be IVD grade, have a mass rang of 2000 m/z, scanning speeds of 20,000Da/S, mass resolution of 0.5 Da, have dilute and shoot applications, and have ETG and ETS. Every time one or more of these analyzers needs replacement, research will be conducted to see if anyother vendor can meet the needs of the government.

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.

Date

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13. Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:

- 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.

- b. **One Level Above the Contracting Officer (Required over the SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.
