

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA263-16-AP-5218

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: Waters Technologies Corporation

Manufacturer/Contractor POC & phone number: Kari Schlicht 800-252-4752

Mfgr/Contractor Address: 34 Maple Street, Milford, MA 01757

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

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network 23 Contracting Office (NCO23)

4801 Veterans Drive

Saint Cloud, MN 56303

VISN:

23

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

A firm-fixed price delivery order to Waters Technologies to add an additional benchtop tandem quadrupole API mass spectrometer analyzer and high pressure liquid chromatography system (LC-MS/MS) which will be utilized for Drugs of Abuses testing at the Minneapolis VA Health Care System.

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

A benchtop tandem quadrupole API mass spectrometer analyzer and high pressure liquid chromatography system which will be utilized for Drugs of Abuses testing. To include the following:

1 each- Waters TQ Detector, IVD, product # 176850019IVD

1 each- Nitrogen Generator NM32L, product # 186005664

1 each- Power Supply, Uninterruptable 5.2KV, product # 725000473

1 each- Printer, HP Laser Jet, P3015dn, 110 Volt, product # 668000275

1 each-Implementation Kit, product # 720002242EN

(b) ESTIMATED DOLLAR VALUE: \$322,574.75

(c) REQUIRED DELIVERY DATE: 60 Days ARO

(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.

The Minneapolis VA Toxicology laboratory currently has 4 LC-MS/MS systems purchased from Waters Corporation dating back to 2008. These instruments are used to detect and identify presence of drugs in patient's urine and blood samples. 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 8 or 9 different individuals and therefore they rely on consistency of protocols and the ease of use of these protocols, similar to the operation in a factory. There are a number of companies which manufacture LC-MS/MS systems. While the hardware manufactured by all the companies is pretty compatible, the key to the ease of use of the system is the software on the systems which drive the operation of the instrument. Every manufacturer has different software and these are totally different. It takes a very long time (months) to train individuals to become familiar with the operation of the software which drives competent use of the LC-MS/MS system. Furthermore, the hardware components and maintenance protocols and schedules are very different.

Given this background and the work environment in the Toxicology laboratory, we are require the purchase a fifth system from Waters Technology Corporation for the following reasons:

1. The laboratory will need to train 8-9 individuals and then maintaining their competency on a totally different system than the 4 other systems in the laboratory would be costly.
2. Lack of compatibility of our methods if we have 4 systems from one manufacturer and 1 other system from a totally different manufacturer separate validations protocols will be needed. In addition, protocols are re-validated yearly, so the separate validation for a LC-MS/MS instrument from a different manufacturer would require an additional re-validation.
3. The laboratory will have to maintain a separate parts inventory if a different system is procured.

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 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:

The Minneapolis VA Health Care Systems already has 4 LC-MS/MS systems purchased from Waters Corporation, and this request is to purchase an additional LC-MS/MS systems. A purchase of another 4 LC-MS/MS systems that is from a different manufacturer will require the laboratory to train staff on two separate system, have two set of protocols for these types of tests, utilize two software packages depending on the instrumentation that was used for the testing, perform annual re-validation on two separate systems. Whereas purchasing an additional system from Waters Technologies Corporation will no additional training, protocols, additional software, or re-validation.

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

The LC-MS/MS system from Waters Technologies Corporation is available on FSS Schedule GS-07F-0559X.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

None.

(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:

If in the future another LC-MS/MS systems is needed, the government will perform market research to determine if the same barriers remain, and if this can be done through a competitive procurement.

(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.)*

Renee E. Burke
331253

04/18/2016

Renee Burke
Supervisor of Special Diagnostics Testing
Minneapolis VA Health Care System

DATE

(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: OFOC SOP](#):

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

04/18/2016

Andrea Harter
Contracting Officer
NCO 23-St. Cloud

DATE

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

04/18/2016

Jennifer Myers-King
Branch Chief
NCO 23

DATE