

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. Contracting Activity:

Veteran Health Administration (VHA)
Service Area Office (SAO) – East
323 North Shore Drive, Suite 500
Pittsburgh, PA 15212

Requiring Activity:

James J Peters VAMC, NCO3
130 West Kingsbridge Rd
Bronx, NY 10468

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

2237 Number: 526-13-3-2213-1313

This is a request for Other Than Full and Open Competition for a Firm Fixed Price Contract for a unique Solar Gastrointestinal High Resolution Manometry (GI HRM) System in accordance with FAR 6.302-1. This purchase is in direct connection with the ongoing research in the National Center of Excellence for the Medical Consequences of Spinal Cord Injury.

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

A solar GI HRM system, the most advanced HRM system available to date, measures both function and pressure throughout the GI tract, including the colon. The system operates with a solid state catheter which contains pressure channels ranging from 24-36 channels. The system is designed to monitor, measure, and analyze colonic motility utilizing a solid state pressure catheter. This system is designed specifically to capture, analyze, and report pressure changes in the colon, which allows researchers to monitor colonic motility as well as improve testing for diagnostic purposes to detect colonic disorders. The research staff is primarily focused on how physical activity alters colonic function and motility in a patient population that has known bowel dysfunction as a result of a spinal cord injury (SCI). The solar GI HRM system would allow our staff to monitor the changes in pressure both before and after physical activity and observe the effects that physical exercise might have on improving colonic motility and reducing the symptoms of neurogenic bowel. This equipment is required in direct connection with the ongoing research in the National Center of Excellence for the Medical Consequences of Spinal Cord Injuries. The entire solar GI HRM system includes the following: hardware: safety module, remote, U2M 5P, CIM-AUX, option key, cables, clamps, and manuals; Software: MMS investigation and diagnostic, SSP Solar GI, SGI HRM, SSP-9PROT, SSP QM,

SGI/COLON; a Dell desktop computer, 20inch display with an arm and HP Deskjet printer; and a 14F HRM Colonic Catheter 36 pressure, 4cmx20 channels, 2cmx16, L6 lumen.

The estimated aggregate cost of this equipment is \$ 49,958.00.

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):

Medical Measurement System (MMS) is among the top leading companies in the world for designing, manufacturing, and distributing medical diagnostic equipment for multiple medical fields including gastroenterology. MMS has utilized the concept and innovation of high resolution manometry, which measures intraluminal pressure activity in the gastrointestinal tract, to develop state of the art software and systems to improve diagnostic techniques. The company is the sole provider of this solar GI HRM system, which is necessary in accurately observing real time colonic motility during physical activity. This ability to observe colonic motility has not been previously studied and as a result would lead to a deeper and more reliable understanding of colonic motility during physical activity in a patient population that has known GI disorders and dysfunction on account of having a spinal cord injury.

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

This is a proprietary system manufactured by Medical Measurement Systems USA. An intent to sole source was posted to FBO on 06/02/14 and closed on 06/06/14. No responses were received, further confirming that Medical Measurement Systems USA is the only source capable of satisfying this requirement.

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

The list price for our second system described herein is \$49,958.00. The list price is the same price that is offered to other customers in the commercial marketplace. The Contracting Officer will request an additional discount prior to contract award.

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

While MMS is the Manufacturer, additional distributors were sought during market research resulting in only one other vendor, Ardmore Healthcare. Upon requesting an informal quote, the research office was informed that this vendor is not located in the US and furthermore, does not have distributing rights in the United States.

An intent to sole source was posted to FBO on 06/02/14 and closed on 06/06/14. No responses were received, further confirming that Medical Measurement Systems USA is the only source capable of satisfying this requirement.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Medical Measurement Systems USA is the only company available to produce a solar GI HRM system that is compatible to study colonic motility. There were no additional vendors that manufacture this product, which makes Medical Measurement System the sole provider of this high resolution manometry technology for diagnosing and monitoring disorders in gastroenterology, particularly colonic motility.

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

None. An intent to sole source was posted to FBO on 06/02/14 and closed on 06/06/14. No responses were received, further confirming that Medical Measurement Systems USA is the only source capable of satisfying this requirement.

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:

This is a proprietary system manufactured by Medical Measurement Systems USA. No other sources can manufacture or distribute this system. The Research Office will continue to survey the market for other sources that can provide similar equipment for future acquisitions.

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.

13. Approvals in accordance with FAR 6.304

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.