

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval (J&A)
for
Other Than Full and Open Competition (>\$150K)

Computer Assisted Surgery Specialist Services

Acquisition Plan Action ID: VA263-17-AP-7588

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office-23, 316 Robert St. N., St Paul, MN 55101, Attention: Daniel Vagts, Contracting Officer for Minneapolis VA Health Care System (MVAHCS). 2237#: 618-18-2-4002-0002(vendor: Medtronic Inc., use vendor #52415)

2. Nature and/or Description of the Action Being Processed: Minneapolis VA Health Care System (MVAHCS) requests that other than full and open competition procurement procedures be used in order to establish a sole source contract with Medtronic Inc., 710 Medtronic Pkwy, Minneapolis, MN, for technical support with the Medtronic Stealth Navigation System. Procurement type will be a firm fixed price, Indefinite Delivery Indefinite Quantity (IDIQ) contract. The contract will be awarded on a sole source basis for the technical support of the VA owned Medtronic Stealth Navigation System to assist with complex spine cases. This service is required for patient safety.

FAR 13.5 Simplified Procedures for Certain Commercial Items: This procurement is for computer assisted surgery specialist services in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements.

3. Description of Supplies/Services Required to Meet the Agency's Needs: The Minneapolis VA Healthcare System (MVAHCS) has a requirement for the provision of services of Computer Assisted Surgery Specialist (CASS), also known as a Certified Surgical Technician/Equipment Specialist (CST), to provide technical support for VA Surgeons when they are performing complex neurology, spinal and ENT surgical procedures using the VA owned Medtronic Stealth Navigation System. The surgery specialist will provide their technical expertise and guidance in using the Stealth Navigation System assisting surgeons with navigation solutions for complex computer-assisted surgical procedures to maximize patient safety. Period of Performance: Services are required for a 12-month base contract period with four (4) 12-month option periods. Total IGCE (Base + Option Periods) = \$1,665,292.85. Anticipated start date is May 1, 2018.

4. Statutory Authority Permitting Other than Full and Open Competition: *41 U.S.C 3304(a)(1)* as implemented by *FAR 6.302-1* Only one responsible source and no other supplies or services will satisfy agency requirements. FAR 13.5 Simplified Procedures for Certain Commercial Items: This procurement is for computer assisted surgery specialist services in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority): Medtronic Inc. is the manufacturer and sole supplier of Computer Assisted Surgery Specialists that are trained and certified to provide technical support for use of the Medtronic Stealth Navigation System. Medtronic Inc. holds a patent on this system and no other company has access to their proprietary information.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable: Sources sought notice was published to FBO (Federal Business Opportunities) on August 16, 2017 received zero (0) responses. Past market research has established that Medtronic Inc. is the manufacturer and sole provider of technical staff to assist in the operation of their equipment. The assigned synopsis number for this acquisition is VA263-17-R-0530.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Medtronic Inc. has a printed price list for surgical support services. The price is listed at \$3,500 per single case coverage. On the current VA contract (VA263-16-D-0042, P.O.# 618-C70117) the VA NCO-23 awarded the contract at a price of \$3,200 per surgical case. This is lower than the current printed price of \$3700 that Medtronic Inc. offers to the general public. Therefore, price has been determined fair and reasonable due to printed price list, past procurement history, and current VA contract price. Negotiations will be held with Medtronic Inc. to obtain best possible prices 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: *Per PPM 2016-05, Implementation of the Veterans First Contracting Program as a Result of the U.S. Supreme Court Decision: §8127 is mandatory, not discretionary and its text requires the Department to apply the Rule of Two to all contracting determinations. In order to meet the VA Rule of Two, COs shall review the Vendor Information Pages (VIP) database in accordance with VAAR Class Deviation 810.001-70 to determine if two or more service-disabled veteran-owned businesses (SDVOSBs) and veteran-owned small businesses (VOSBs), in the appropriate NAICS code, are listed as verified in the VIP database.* The Stealth® Surgical Navigation System and the O-Arm® Imaging System were purchased by MVAHCS from Medtronic and installed in the O.R. at the Minneapolis VA Medical Center by Medtronic Inc. The system is proprietary and technical support is not available from any other vendor. Per PPM A search of the Small Business Administration's Dynamic Small Business and GSA e-library Search using search criteria of NAICS – 541690, and using the keywords "Stealth Navigation System" yielded zero (0) results. A search of the Department of Veterans Affairs Vendor Information Pages (VetBiz) using search criteria of NAICS – 541690, and using the keywords "Stealth Navigation System" yielded (1040) businesses. Medtronic holds a patent on these systems and no other company has access to their technical proprietary information.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: The selected source, Medtronic Inc., has historically provided this service for technical support during surgical cases requiring computerized surgical navigation using the Stealth® Surgical Navigation System. Contract #VA263-16-D-0042 for Stealth Navigation Services (was awarded by NCO-23 for these same services and Medtronic Inc. was the only offeror. The Minneapolis VAHCS has also added an O-Arm® Imaging System to the Stealth® Surgical Navigation System.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: None

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: The Minneapolis VAHC has prepared and submitted a procurement package to NCO23 requesting a firm fixed price, IDIQ contract be established for these services.

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.

Lynda S Dent
195967

Digital signed by Lynda S
Dent 195967
Date: 2018.01.12 13:35
+05:00

05-01-2018

Name: Lynda Dent
Title: AO SSC PSL
Facility: Minneapolis VAHCS

Date

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

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

Daniel R. Vagts
381500

Digitally signed by Daniel R.
Vagts 381500
Date: 2018.05.01 11:03:41 -0500

05-01-2018

Name: Daniel Vagts
Title: Contracting Officer
Facility: NCO-23

Date

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

5/03/2018

Date

FOR

Name: Daryl A. Berg
Title: Director of Contracting or Designee
Facility: NCO-23

c. 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 approve for other than full and open competition.

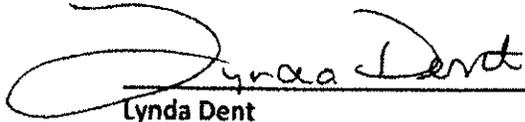
Randy L. Hays
Acting Director, SAO Central
SAO Central Head of Contracting Activity

Date

ACQUISITION PLAN NO:

DESCRIPTION OF THE PROGRAM: Computer Assisted Surgery Specialist to provide technical support for complex surgical procedures using VA owned Stealth® Surgical Navigation Systems

Preparer Signature:


Lynda Dent
AO/COR Surgery & Specialty Care

Date: 8/20/17

Concur / Non-Concur

Daniel R. Vagts
381500
Digitally signed by Daniel R. Vagts 381500
Date: 2018.04.17 07:17:48 -05'00'

Daniel Vagts
Contracting Officer, NCO 23

04-17-2018
Date: _____