



DEPARTMENT OF VETERAN AFFAIRS
Office of Acquisition and Logistics
National Acquisition Center
P.O. Box 76
Hines, IL 60141

Justification for an Exception to Fair Opportunity
FAR 16.505(b)(2)(i)(B) – Only one capable source

(1) Identification of the agency and the contracting activity.

This Justification for an Exception to Fair Opportunity is on behalf of VISN 23, Omaha VA Medical Center (Omaha VAMC) located in Omaha, NE and will be executed by the Department of Veterans Affairs National Acquisition Center (NAC – 36A797) located in Hines, IL.

(2) Nature and/or description of the action being approved.

This activity intends to issue a sole-source delivery order against Indefinite Quantity contract SPE2D1-19-D-0018 awarded to Medtronic, Inc. ("Medtronic") to purchase a FDA certified Portable Fluoroscopic System (Port C-Arm) capable of expanding the OR staff's ability to perform spinal surgery/diagnosis through the use of 3D imaging provided by the Medtronic O-Arm's integration with the existing Medtronic Stealth Navigation System currently owned and in operation at the Omaha VAMC.

(3) A description of the supplies or services required to meet the agency's needs, including the estimated value.

The VAMC needs an O-Arm capable of interfacing with the existing Medtronic Stealth Navigation System in order to perform spinal surgeries and diagnoses. This order will include an O-Arm base unit consisting of a complete multidimensional surgical imaging system capable of interfacing with the current VA-owned Stealth Navigation System, advanced configurations for viewing images in high definition, and a printer option. The total estimated value of this order is \$532,848.00.

(4) An identification of the exception to fair opportunity (see 16.505(b) (2)) and the supporting rationale, including a demonstration that the proposed contractor's unique qualification or the nature of the acquisition requires use of the exception cited. If the contracting officer uses the logical follow-on exception, the rationale shall describe why the relationship between the initial order and the follow-on is logical (e.g. in terms of scope, period of performance, or value).

This order will be issued on a sole-source basis in accordance with Federal Acquisition Regulation (FAR) 16.505(b)(2)(i)(B) as only one source can provide the supplies at the level of quality required. Only Medtronic, the original equipment manufacturer (OEM) of the existing navigation system and of the required O-Arm system, can provide the necessary hardware, software, and training required by the facility. The Medtronic navigation system was originally procured through the open market in August of 2014 in the total amount of \$335,476.23 under contract VA26314C0138. By purchasing a new O-Arm through the OEM of the current navigation system, the VA avoids several months of delays for time to

plan, solicit, procure, and have the new system delivered. The VA also saves hundreds of thousands of dollars by using the current navigation system in lieu of purchasing a new one to interface with a new Portable C-Arm. The OEM is the only vendor able to provide the requested O-Arm capable of interfacing with the Stealth Navigation System due to the proprietary nature of the system. The OEM is the only organization capable of owning trade information on the system and therefore, is the only one qualified to offer this system.

(5) A determination by the Contracting Officer that the anticipated cost to the Government will be fair and reasonable.

All items to be purchased as part of this order are currently on contract SPE2D1-19-D-0018. The quoted price for each item is at or below the contract price, and pricing has been determined fair and reasonable at the contract level.

(6) Any other facts supporting the justification.

None

(7) A statement of the actions, if any, the agency may take to remove or overcome any barriers that led to the exception to fair opportunity before any subsequent acquisition for the supplies or services is made.

This Portable C-Arm requirement was solicited in September of 2018 under Request for Quote (RFQ) 36A79719Q0002. All current contract holders of the Joint Defense Logistics Agency (DLA) Troop Support and the Department of Veterans Affairs National Acquisition Center (VA NAC) Radiology and Imaging Systems Program were provided with a copy of the solicitation and given the opportunity to provide an offer for this requirement. Only one quote was received, and the offered system was determined unacceptable because it failed to meet several critical technical requirements included in the solicitation for the required system. Market research revealed that Medtronic offers an O-Arm system capable of meeting all technical requirements and of interfacing with the current Stealth Navigation System at the Omaha VAMC. Other C-ARM technologies are available in the marketplace; however, they do not possess the ability to capture 3D images and integrate them with the Medtronic Stealth Spinal Navigation System owned by the Omaha VAMC.

All prospective delivery orders are competed among all contract holders. Once an order is placed for proprietary equipment, it is generally not possible to compete follow-on acquisitions for upgrades because the system to be upgraded is proprietary in nature. Future requirements will be handled on a case-by-case basis and all attempts will be made to provide fair opportunity to all schedule holders when appropriate.

(8) The contracting officer's certification that the justification is accurate and complete to the best of the contracting officer's knowledge and belief.

By signing this justification, the Contracting Officer hereby certifies that the justifications are accurate and complete to the best of their knowledge.

- (9) Evidence that any supporting data that is the responsibility of the technical or requirements personnel (e.g., verifying the Government's minimum needs or requirements or other rationale for an exception to fair opportunity) and which form a basis for the justification have been certified as complete and accurate by the technical or requirements personnel.**

By signing this justification, the requiring activity hereby certifies that the justification is accurate and complete to the best of their knowledge.

- (10) A written determination by the approving official that one of the circumstances in (b)(2)(i)(A) through (F) of this section applies to the order.**

Based on the information contained herein, a determination has been made that this requirement meets the exception at FAR 16.505(b)(2)(i)(B). Only one source can provide the required supplies.

CERTIFICATION AND APPROVAL

TECHNICAL/REQUIREMENTS CERTIFICATION:

Pursuant to FAR 16.505(b)(2)(ii)(B)(9), I certify that any supporting data that is my responsibility and which forms a basis for the justification is complete and accurate to the best of my knowledge and belief.

James N. Mohr
VISN 23
Facility Biomedical Engineer

CONTRACTING OFFICER CERTIFICATION:

Pursuant to FAR 16.505(b)(2)(ii)(B)(8), I certify that the justification is complete and accurate to the best of my knowledge and belief.

Michael A. Sands
Contracting Officer
VA National Acquisition Center – Hines
High-Tech Medical Equipment Ordering Division

Reagan P. Criddle
VA National Acquisition Center – Hines
Chief, High-Tech Medical Equipment Ordering Division