

Attachment B: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

Contracting Activity: Department of Veterans Affairs, VISN 04, VA Pittsburgh Healthcare System, University Drive Division. 2237#646-12-4-222-1088

Nature and/or Description of the Action Being Processed: Sole Source Award to Merit Medical Systems, Inc.

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

Amount \$57,600

Statutory Authority Permitting Other than Full and Open Competition: 41 USC 253 (c) (1), as implemented by FAR 6.302-1.

- (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;

Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

It is essential to purchase the Merit Systems, Inc.'s FDA approved Tracheobronchial Stents (Product No.'s 90129-207; 209; 210; 211; 213; 215; 204; 205; 201; 202; and 217), which are Implants that the VA considers Prosthetics, since the VA's existing Stock of similar Stents used for similar procedures were discovered to be expired, and since the VA prefers a FDA approved Stent.

In addition, per VAAR 806.302-5 (b) (1), the Department of Veterans Affairs has authority under 41 USC 253 (c) (5) and 38 U.S.C. 8123 to purchase prosthetic appliances without providing for full and open competition. Therefore, award will be made to Merit Medical Systems, Inc. on a Sole Source basis.

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

N/A. (Per above authority).

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

The prices quoted by Merit Medical Systems are fair and reasonable, since their charge of \$2,400 each, is the same as they charged a private Hospital on 5/14/2012, and \$100 less, than the \$2,500 each what they charged the VA in Indianapolis, PA. (See Support Documents in the Contract file under S23).

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

Market research was conducted to determine if the items were commercial items, and since the items have been sold in the Commercial Marketplace and to the US Government, the items are considered commercial items.

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

Merit Medical Systems, Inc. is the sole exclusive seller of their Stents in the U.S. (See Support Document in the Contract File under P03).

The VA needs to purchase these Stents ASAP, since their current Stents are expired and are no longer FDA approved and in the meantime would have to fee base out patients until they can obtain unexpired and FDA approved Stents.

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

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:

NA. (See above referenced authority). The Agency can assure expiration dates are checked frequently and although not required by law, could put Purchase Requests in far enough in advance to allow time for competition, should there be more than one source and there is no essential features of the Stents being purchased that cannot be found in similar products.

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.

(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)

Lisa Mincone
Name: Lisa Mincone
Title: Inventory Management Specialist
Department/Facility:

7-13-12
Date

Approvals in accordance with FAR 6.304:

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

Ronald Mazzei
Name: Ronald Mazzei
Title: Contract Specialist
Facility: HJ Heinz

7/13/12
Date

VISN/PCA QA: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Name Date
Title
Facility

NCM/PCM: I certify the justification meets requirements for other than full and open competition.

John A. Pasulnik for
Name Date
Network Contract Manager
VISN/PCA

7/13/12

SAO: I certify the justification meets requirements for other than full and open competition.

Name Date
Director

Service Area Office, East

VHA 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 recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

Norbert Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

VA Deputy Senior Procurement Executive Approval (over \$10 not exceeding \$50 million): 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.

Iris B. Cooper Date
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

VHA Senior Procurement Executive Approval (over \$50 million): 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.

Jan R. Frye Date
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs