

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID:VA241-15-AP-4756

1. **Contracting Activity:** Department of Veterans Affairs, VISN 1, Boston VA Medical Center
2. **Nature and/or Description of the Action Being Processed:**
Purchase of a Volcano CORE Mobile system capable of intravascular ultrasound for use at the Boston VA Medical Center. This purchase includes an initial supply of disposables and an extended service agreement. This will all be under a new contract with Volcano Corporation for a cost of [REDACTED]. This is a firm fixed equipment purchase. The estimated award date is November 16, 2015.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:**
A complete intravascular ultrasound system is required for the accurate assessment of peripheral vessels. The system should be capable of assessing the morphological and geographical features of plaque within a vessel. By having accurate information about the dimensions of the lumen and plaque within, the selection of what stent to use and where to place it can be made with a higher degree of certainty as compared to the methods which are currently employed. Furthermore, this technology can be used to assess the efficacy of stent placement and deployment, both immediately after placement and months down the road.
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):**
Volcano IVUS technology offers the most versatile range of applications when performing vessel assessment. This highly specialized imaging technology is the only IVUS on the market to offer solid state imaging technology which: has a larger field of view, is faster, more reliable, capable of plaque characterization, and results in artifact free images. Volcano offers .014, .018 and .035 wire platforms to visualize essentially all vessels. This is the only system to offer iFR technology which is capable of assessing the blood flow within a vessel across a plaque lesion allowing for optimal stent selection. iFR is a form of frequency flow reserve (FFR) technology which

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

traditionally requires the administration of a hyperemic agent such as adenosine. Volcano's iFR technology does not require this medication and simplifies the clinical workflow. This system's versatility allows for improved access to patient care and the potential for further expansion. Volcano is also the system used at other sites within the VISN. VISN standardization allows for the potential of a consolidated support program in the future allowing for more efficient allocation of resources. Staff familiarity with the device will allow for better patient care and decreases the chance of a use error. Further, Volcano is the only potential vendor which is on the list of "Vista Imaging Approved DICOM Modality Interfaces."

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

Market research on available intravascular ultrasound imaging systems was conducted to evaluate all potential sources capable of meeting the medical center's needs. There are only two manufacturers of an IVUS and it is clear that Volcano offers the superior product.

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

There are currently two intravascular ultrasounds on the market, the Boston Scientific iLab and the Volcano Corporation CORE Mobile System. Market research indicates that both of these systems are closely matched in their listed price, \$175,000 for the iLab and \$199,000 for the CORE. These prices are solely for the cart. The added iFR modality, control pad, initial supply of disposables, and extended service agreement are not factored in. The Volcano device is justified as being more expensive due to the fact that it features the iFR modality and solid state imaging. These two features greatly improve the quality of the clinical procedure along with reducing the risk of an error. iFR modality allows the clinician to assess the intraluminal pressure without having to administer adenosine. Solid state imaging does not utilize any moving parts. It has a faster imaging speed, is more reliable, removes the need for catheter flushing, and reduces maintenance needs. Additionally, the local clinical end users are experienced operating the CORE system and will be less prone to a use error. A use error could result in litigation which would easily cover the difference in the costs of these two comparable devices. As such, the cost for the highly specialized Intravascular Ultrasound is considered fair and reasonable to the Government.

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

Market research was conducted via several internet searches and review of industry databases and third party resources such as MD Buyline and ECRI Institute. The research revealed that Volcano's equipment is the only option offering solid state imaging and iFR technology. Volcano is the clear market leader offering superior performance, versatility, reliability, and customer service according to the sources listed above.

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


It was determined that the Volcano IVUS is the only sufficient equipment, being that this is the brand currently being utilized. Purchasing the same equipment will allow for cost savings when purchasing the consumables.

10. 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:

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

Barriers to competition will be removed when this equipment reaches the end of its life.

- 11. 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.



Scott Kinlay, MBBS PhD
Director, Cardiac Catheterization Lab
VA Boston Healthcare System

11/15/2015


Date

12. 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.

Heather N.
Hampton
225727

Heather Hampton
Contracting Officer
NCO1


Digitally signed by Heather N. Hampton 225727
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11/12/2015

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

William A
Nalls 253622

William Nalls
Division One Chief
NCO 1


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