

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval  
For  
Other Than Full and Open Competition**

1. **Contracting Activity:** Department of Veterans Affairs, VISN 18, Mesa CCA for Southern Arizona VA Health Care System (SAVAHCS) a Justification and Approval for Other Than Full and Open Competition. Transaction Number: 678-12-3-071-0139.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for one s5i Imaging System considered to be medical equipment. This JOFOC comes as a result of a current requirement at SAVAHCS, from Volcano Corporation. This Point of Care system is used by the Imaging Department to manage the cardio/vascular diagnostic testing and Quality Control (QC) results. The Southern Arizona VA Health Care System requires this equipment to maintain patient care standards for a firm-fixed price of \$135,300.00 to be delivered by May 01, 2012.
3. **Description of Supplies/Services Required to Meet the Agency Needs:** The following services are required by the SAVAHCS. The following medical equipment is required by the SAVAHCS. This unit is an ultrasound system which utilizes catheters for the purpose of measuring the diameter of the blood vessel, assessment of the lumen area, degree of stenosis, and to visualize dissections or tears in the vessel wall. This unit is essential in today's cardiac cath. lab and radiology interventional labs. The s5i allows for multiple user interfaces, providing control for the IVUS system from both the area of the sterile field and the adjacent control room. Images can be viewed simultaneously from multiple vantage points with-in the lab area. The system is completely DICOM and supported by VISTA/IMAGING. This software allows the end user to monitor tests done at the point of care and to enhance image diagnosis performed at the Southern Arizona VA Health Care System 3601 S. 6th Avenue, Tucson, AZ 85723. Equipment will include:
  - a. s5i Imaging System s5i CPU w/DVD Burner, Operator's manual, power transformer, cable pre-install kit, two (2) standard s5i controllers and one (1) bedrail mount, 19" NEC monitor kit, phased array PIM body, DICOM network connection, chromaflow functionality
  - b. VH IVUS End User License Agreement included
    - Three (3) Year VH IVUS Software Support Agreement
  - c. s5 FFR Option: Includes PIMffr and PIMffr Cable
  - d. Optional Full Protection Extended
    - Service Agreement. List Price:
    - \$10,300.00 Multiple Year or Multi-Unit
    - Coverage: \$8,300.00 per year/per unit
  - e. Special features included
    - Chroma flow Imaging and
    - Virtual Histology (VH)

- f. Standard training, instruction, and consultation for the customer required for the use of the s5i Imaging System

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

- ( 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 Corporation, Inc has exclusive rights to produce, distribute and maintain the medical equipment called s5i Imaging Systems . No dealers qualify to work on and maintain the product; furthermore, the product can be interfaced with Vista/Imaging. The medical equipment has a special feature that no other source can provide which is Chroma flow Imaging and Virtual Histology (VH). Volcano Corporation owns the Patent Rights to S5i Imaging System to include the required features; therefore Volcano Corp is the only vendor qualified to service and sell S5i Imaging System and no other supplies or services will satisfy Agency Requirements per FAR 6.302-1.

**6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable.** Research on GSA eBuy revealed no qualified sources; furthermore, competition was not sought for this acquisition from these mandatory sources. Full and Open competition will not be sought. The equipment is required by the SAVAHCS due to a previous purchase from Volcano Corporation for S5i Imaging System. The S5i Imaging System package is the only that will fulfill customer's need. Boston Scientific and Siemens Medical have similar machines but do not have the special features which are Chroma flow Imaging and Virtual Histology (VH) when compared to the S5i System; furthermore, the time and money used to coordinate and schedule training, certification and testing of critical medical personnel at the SAVAHCS will be wasteful. The time needed to re-train employees on a new equipment brand other than S5i Imaging System will also affect quality of patient care. Initial installation and setup from a new contractor will cost the government four (4) times more money when compared to Volcano Corp to include supply chain to remove and replace ware of daily part will be an extra \$100,000.00 per year for different brand machine(see BPA VA258-BP-0102). An intention to award Other Than Full and Open Competition Synopsis will be posted to FedBizOpps (FBO) (per FAR 5.2021).

Other Actions: N/A

**7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The price offered by Volcano Corp., is the same rate for all of its Government clients and is reasonable when compared to market prices and market ranges for similar services and supplies from other sources. The price given is comparable to past procurement for the same or equal product under the following PO see VA678-C00289, VA678-C00289. Finally, the cost for S5i Imaging System maintenance is fair and reasonable based on the information presented above (FAR 6.303-2(a)(7)).

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. No sources are available on GSA. The GSA eBuy FSS has no qualified sources and, research also showed that no NASA\_SEWP contractor has Volcano Corporation products or service as CLINs. Full and open competition is not a good source because no dealer is available. The selection for alternate equipment with minor modification will not work at this time. This procurement award date is projected for April 20, 2012 (See item 6 also). Please see the following Market research information.

Review of Government and/or commercial databases for relevant information. Item is available only from one source.

Review of internet sources. Looked for resources on google.com and technical information from Volcano Corp, Siemens, Boston Scientific Corp, GSA eLibrary, and GSA advantage.

Review of catalogs and other generally available product literature (online and/or in hard copy). Yes,  
<http://www.volcanocorp.com/products/ivus-imaging/s5i-imaging-system.php>  
[https://www.medical.siemens.com/siemens/en\\_US/gg\\_us\\_FBAs/files/brochures/AcuNav/AcuNav\\_8F\\_Flyer.pdf](https://www.medical.siemens.com/siemens/en_US/gg_us_FBAs/files/brochures/AcuNav/AcuNav_8F_Flyer.pdf)  
<http://www.medcompare.com/details/26092/Galaxy-Digital-Imaging-Console.html>  
<http://www.lychron.com/downloads/Galaxy%202%20IVUS%20imaging%20system.pdf>  
<http://www.gsaelibrary.gsa.gov/ElibMain/searchResults.do>  
<http://www.gsaelibrary.gsa.gov/ElibMain/searchResults.do>

Researched the preceding links for information on product and authorized dealer. NO dealers or other sources available on GSA eLibrary.

<http://www.gsaelibrary.gsa.gov/>

Use of source lists for identical or similar items obtained from Government, professional, and/or industry sources. Yes, have researched requested information through GSA advantage and GSA eLibrary.

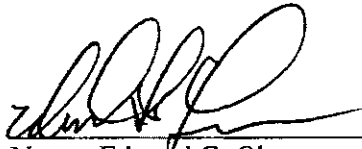
<http://www.gsaelibrary.gsa.gov/ElibMain/searchResults.do>  
<http://www.gsaelibrary.gsa.gov>

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The equipment that is requested on this Justification and Approval is the singular property of Volcano Corp. The time required soliciting, competing, performing source selection; installing and re-train staff will seriously interrupt patient care and facility operations to include costing the VA more resources than necessary for optimal efficiency. In summary, Volcano Corp has patent rights and sole control over software and maintenance for S5i Imaging System (see FAR 6.302-1(b)(2) ).

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A

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:** Full and Open competition has been considered for this procurement and is not a smart business choice considering customer's needs. FBO, NASA\_SEWP and GSA are acceptable sources to seek competition for equipment items.

**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.



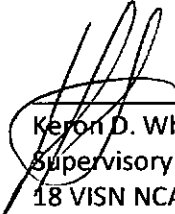
Name: Edward G. Ohnesorgen  
Title: Chief Radiologic Technologist

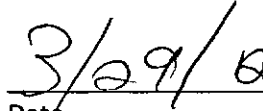
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Date: December 29, 2011

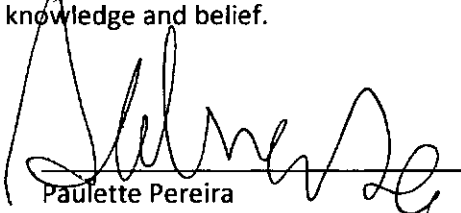
**Approvals in accordance with FAR 6.304**

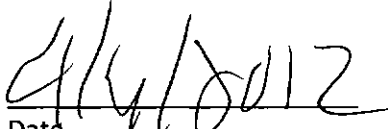
- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
Keron D. White  
Supervisory Contracting Officer  
18 VISN NCA

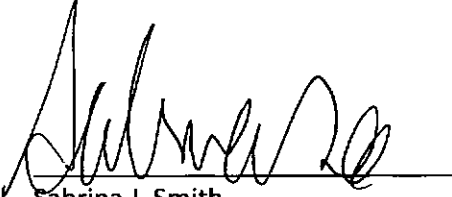
  
Date


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

  
Paulette Pereira  
QA/Compliance Procurement Analyst  
VISN18, NCA 18/SAO-West

  
Date

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

  
Sabrina J. Smith  
Network Contract Manager  
18 VISN

  
Date