

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 8, Bay Pines Healthcare System (516) Biomedical Engineering 138M, "Justification for Other Than Full and Open Competition" due to proprietary rights to service the deionization system. Purchase Request VA2237 No. 516-13-1-5105-0020.
2. **Nature and/or Description of the Action Being Processed:** Siemens Industry, Division of Water Technologies has proprietary rights to the servicing of the deionization system. The new firm fixed price contract will include 4 Option Years in addition to the Base Year. The new contract has been identified as contract number VA248-13-C-0069.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Proprietary service to the deionization system and regeneration of the hemo dialysis tanks. Services include tank replacement, monthly loop sanitation, water quality verification, membrane replacement, calibration, functional checks, inspections, and sample collections on the hemo dialysis water purification system. Serial No: 062394-04. The manufacturer, Siemens, Inc. provided a letter attesting to proprietary rights to the service of this highly specialized medical equipment. The period of performance if all option years are exercised is October 2012 to September 30, 2017.
4. **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;
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** This hemo dialysis water purification system is highly specialized medical equipment. No other contractor is allowed to service the deionization system. The assets must be controlled and regenerated through the Siemens Class II Registered Medical facility. Siemens quality program is compliant with the FDA Quality System Regulations (21 CFR, Part 820). Other equipment vendors provide a reverse osmosis unit that may be 510K registered. However, all of the other components are not registered. This may result in inferior components used in the materials with the possibility for performance shortfalls, quality issues, unreliability, and shorter longevity. This procurement for service and regeneration will not be competed because only an authorized Siemens dealer is allowed to service the equipment without warranty issues. This equipment is essential to the Government. Siemens, Inc. is the only firm capable of meeting the needs described in sections 1-4 without the Veterans Health Administration experiencing substantial duplication of cost that cannot be expected to be recovered through competition, and resulting in unacceptable delays in fulfilling the Governments requirements.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**
A "Special Notice" posts to Federal Business Opportunities on December 17, 2012; VA248-13-I-0451.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The anticipated cost to the Government is considered fair and reasonable because the current quote was compared with last year's purchase order; VA516-C20008. The cost of this service maintenance agreement is comparable in price to one year ago. The requirements under FAR 6.303-2(a)(7) have been satisfied.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section VI above, market research in accordance with FAR Part 10, was conducted by special notice, advising industry of the pending acquisition and soliciting inquiries from interested parties to determine if sources capable of satisfying the agency's requirements exist or if services are available that will satisfy the agency's needs. The manufacturer has provided a statement of proprietary rights to the service maintenance on this equipment. The cost of this service maintenance contract is comparable in price to service maintenance agreements for Government owned hemodialysis equipment.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** The requirements under FAR 6.302-1(b)(2) and 6.303-2(a)(9)(i) have been satisfied and supporting statements were previously documented; see Sections 1-8 of this document.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section VI above.
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:** Since this service is proprietary, there will be no further actions taken to foster competition for future acquisitions of the services being acquired. The only potential actions that could be undertaken to remove the barriers to competition would be to purchase new equipment which is not in the best interest of the Government. Approval is required for the planned duration of the life of the contract, which is five years.
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.


Eileen M. Blair
Biomedical Engineering (SBESS)
Bay Pines VA Healthcare System (516)

14 Dec 12
Date

13. 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.



Contracting Officer
Bay Pines VA Healthcare Center


Date

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.



Acting Site Team BP Supervisor
Services and Commodities
Bay Pines VA Health Care System


Date

- c. **SAO (If over 500K):** I certify the justification meets requirements for other than full and open competition.

Name
Director
Service Area Office, East

Date

- d. **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 (if over \$10million) or approve (\$500K to 10 million) for other than full and open competition.

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

Date

- e. **VA Deputy Senior Procurement Executive Approval (over \$10 million but 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
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

Date

- f. **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
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs

Date