

DEPARTMENT OF VETERANS AFFAIRS

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

Acquisition Plan Action ID: VA701-17-AP-9054

1. Contracting Activity:

Department of Veterans Affairs, VISN 19, VA Rocky Mountain Regional Medical Center

2. Nature and/or Description of the Action Being Processed:

This is a brand name justification for a requirement that will be awarded as a new "Firm Fixed Price" purchase order in accordance with Federal Acquisition Regulation (FAR) Part 13.5 to upgrade a pre-existing GE Healthcare CardioLab system to a GE Healthcare ComboLab system. In addition, this requirement includes the purchase of one (1) new ComboLab System, one (1) new MacLab system to accommodate all hemodynamic and electrophysiology recording for the invasive cardiology department and Software and Administrative Licenses for the MacLab and ComboLab

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

Brand Name: GE Healthcare System upgrade to CardioLab / ComboLab

Brand Name: GE Healthcare MacLab 696

Brand Name: GE Healthcare ComboLab 696

Brand Name: GE Software and Administrative Licenses MacLab/Combolab

ESTIMATED DOLLAR VALUE: \$792,874.64

REQUIRED DELIVERY DATE: Within 60 days after receipt of order (ARO)

Upgrade a pre-existing GE Healthcare CardioLab system to a GE Healthcare ComboLab system. In addition, this requirement includes the purchase of one (1) new ComboLab System, one (1) new MacLab system to accommodate all hemodynamic and electrophysiology recording for the invasive cardiology department and Software and Administrative Licenses for the MacLab and ComboLab.

4. Statutory Authority Permitting Other than Full and Open Competition:

FAR13.5 Simplified Procedures for Certain Commercial Items: Authority for restricting competition under simplified acquisition procedures is 41 U.S.C. 1901, as implemented by FAR 13.5.

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above:

The ComboLab System manufactured by GE Healthcare is the only system capable of combining electrophysiology (EP) recording and hemodynamic monitoring in one footprint. This allows the EP

procedure room to be used for Cath procedures without any changes to hardware, technology, or clinical procedures. This also reduces clinical variation from each invasive cardiology room, limiting the risk of user errors.

The current Medical Center in Denver, CO has the GE Healthcare CardioLab, and has been used for Electrophysiology recording since 2010. The data from these studies is required for comparisons for futures procedures at the new VA Rocky Mountain Regional Medical Center. Without historical clinical data, clinical decisions will be impacted, and may lead to delay of care. To ensure raw data is available in the new campus, the GE Healthcare System will need to be installed to complete the migration.

According to the cost estimates, if the VA purchased the Electrophysiology recording system (CardioLab, ~ \$135,000) separate from the Hemodynamic monitoring system (MacLab, or equivalent, ~\$139,000) that need to be installed in the EP lab and Hybrid OR rooms, the cost is about \$50,000 more for each room. The total impact of an equipment only acquisition is about \$100,000. There would also be additional costs for maintenance and operations resulting from running two systems versus running one system.

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

In the market research phase, the clinical subject matter experts, Ms. Cathy Clark, Invasive Cardiology Nurse Manager; and Dr. Paul Varosy, Director of Cardiac Electrophysiology, were consulted in regards to the functions needed in the new space. Their expertise in the field was also utilized to determine what products are available in the market. With their aid in the research, it was determined that the GE Healthcare ComboLab is the only system that can combine the functions necessary for both an EP lab space and Cardiac Cath Lab space.

The Contracting Officer contacted GE Healthcare and requested a list of authorized vendors of this brand name equipment. GE provided a list of authorized vendors which included two (2) veteran-owned-small businesses (VOSB); TrillaMed, LLC and ALKO Enterprises, Inc.

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

Anticipated costs for all items to be procured with this system are estimated in accordance with the terms and conditions of the VA NAC and DLA Troop Support Contract, V797H-17-D-0025 and SPE2D1-18-D-0015.

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

Clinical subject matter experts were consulted for the market research of electrophysiology recording systems and hemodynamic systems available in the market. It was determined that only one (1) brand name Original Equipment Manufacturer (OEM) would be able to migrate the current clinical data, and also ensure that one system would be installed in the EP and Hybrid OR rooms.

The two (2) VOSB vendors found during market research are authorized dealers/distributors to the OEM and are referenced in section 6 above. Both vendors confirmed they have the capability to provide the requested brand name items and have proof of their manufacturer authorized dealership.

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

Not applicable as this is a brand name justification. This acquisition will be set aside for VOSB concerns in accordance with 38 U.S.C. 8127 (i)(2) and VAAR Part 819.7006(a)(1).

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

TrillaMed, LLC (CVE Verified SDVOSB)
ALKO Enterprises, Inc. (CVE Verified VOSB)

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:

Not applicable as this is a brand name justification; not a justification for other than full and open competition. There are two (2) VOSB concerns available for competition in accordance with 38 U.S.C. 8127 (i)(2) and VAAR Part 819.7006(a)(1).