JUSTIFICATION AND APPROVAL
FOR A LIMITED SOURCE AWARD UNDER A FEDERAL SUPPLY SCHEDULE

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
260 Industrial Way West
Eatontown, NJ 07724

2. Description of Action:

The proposed sole source action is for a two year Firm-Fixed Price effort for the upgrade of Minneapolis VA Health Care System's (MVAHCS) current hemodynamic monitoring system with GE Healthcare (GE), 3000 N. Grandview Ave, W-443, Waukesha, WI 53188.

3. Description of Supplies or Services:

The Hemodynamic Monitoring System is a Food and Drug Administration (FDA) approved medical device. This invasive cardiology information system integrates physiological monitoring parameters, specialized electro-physiology recording and stimulation, and other procedure documentation capabilities into one comprehensive hardware and software solution. The current hemodynamic monitoring system owned and operated at MVAHCS is the MacLab system made by GE. The MacLab system was purchased in 2006. The proposed action will provide an upgrade to the existing MacLab system, required for the MVAHCS Invasive Cardiology department in the Cardiac Catheterization Labs (Cath Labs) and Cardiac Electro-Physiology Labs (EP Labs). The Hemodynamic Monitoring System Upgrade project is comprised of one new GE ComboLab, hardware and software upgrades to the two existing GE ComboLabs and one existing Mac-Lab and server equipment, additional GE compatible components and accessories, database migration services, clinical and technical training, interface development to the VA's electronic medical record (CPRS/VISTA), and installation services. The total estimated value of the proposed action is [redacted] The period of performance is two years from date of award.

4. Statutory Authority:

Federal Acquisition Regulation (FAR) Part 8.405-6(a)(1)(i)(B), Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized.

5. Rationale Supporting Use of Authority Cited Above:

GE is the exclusive provider of the products, expertise, and services required for this project. MVAHCS currently has three cardiac catheterization and electrophysiology suites, and is adding a fourth suite (electrophysiology) in 2013. An additional hemodynamic monitoring unit with both CathLab and EP Lab functions is required

for the new electrophysiology suite. The three existing suites house the existing ComboLabs and Mac-Lab, and the new ComboLab will be installed in the fourth suite. Only GE's ComboLab unit will be able to function with the three existing units as a hemodynamic monitoring system. Additionally, all components of the system must be the same revision level to function properly, which is why the upgrade of existing labs is required. The upgrades required affect the MacLab hardware and servers, requiring an upgrade of the GE proprietary MacLab software and the Microsoft Operating System to be installed. In addition, the MacLab hardware and software being upgraded contains MVAHCS specific data, which include patient data/past procedures, facility developed product and supply lists, user profiles, and other information. Therefore, database migration services are a critical requirement in the upgrade of this system. GE has the technical expertise to migrate the existing MacLab database in a timely and accurate manner. Only GE components and accessories can meet VA's requirements because this is a FDA approved medical system entirely designed, and specifically configured, to be compatible with only GE provided hemodynamic monitoring system components. Additionally, a non GE vendor cannot provide installation services for the MacLab. Only GE personnel have access to training and knowledge to complete installation, initial configuration, and set up of the MacLab system. Furthermore, only GE personnel have access to the service keys/tool required to control and configure the MacLab software. This effort also includes clinical and technical training. Only GE can provide this training because GE employs subject matter experts that have prepared curriculum, technical literature, service keys, and other accessories needed for ongoing training and competencies associated with the MacLab equipment. GE has also developed VA-specific competencies to ensure VA staff use their systems correctly. Finally, only GE can provide interfacing to VistA. GE has already been approved and certified by VA for their Clinical Procedures, the software package designed to work as an interfacing tool between the MacLab system and VistA.

6. Efforts to Obtain Competition:

Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Governments' requirements. There is no competition anticipated for this acquisition. In accordance with FAR 5.301 and 8.405-6(a)(2), this action will be synopsized at award on the Federal Business Opportunities Page and the justification will be made publicly available. Any proposals that are received shall be evaluated.

7. Actions to Increase Competition:

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research:

Market research has been conducted by MVAHCS clinical and technical staff on an ongoing basis from January 2012 to the present. A multidisciplinary team comprised of clinical and technical stakeholders from Cardiology, Biomed, IT, Clinical Application Coordinators, and the Primary Care leadership have been engaged in vendor presentations and on-site demonstrations with GE, Philips Medical, and Bard CR. The team has also conducted system configuration reviews with all three companies to assess/determine utility, data, cyber security, power, VISTA interface, and other site planning requirements. The team has also reviewed product literature and benchmarking with other VA community peers as well as reviewed ECRI Institute product comparison documentation. The MacLab system has products and features which are unique to GE. For example, MacLab provides CathLab and EP Lab functions (i.e., ComboLab) within the same device, while other manufacturers provide these functions in separate devices.

The Philips invasive cardiology information system is also highly proprietary. However, Philips provides only the CathLab (physiological monitoring and invasive cardiology information system function) and is not compatible with MacLab equipment. EP Lab recording functions would need to be provided by a second vendor (i.e., GE or Bard CR) to match the equipment requirements for MVAHCS.

The BARD CR does not provide an invasive cardiology information system; Bard CR provides only the EP Lab recording and stimulation components. The invasive cardiology information system and physiological monitoring components required would need to be provided by a second vendor (i.e., GE or Philips). Limited BARD CR components are compatible with GE MacLab.

Based on all of these market research efforts, the Government's technical experts have determined that only GE's MacLab system can meet all of VA's needs.

9. Other Facts:

None.