

JUSTIFICATION AND APPROVAL
FOR OTHER THAN FULL AND OPEN COMPETITION

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

2. Description of Action: The proposed action is for a firm-fixed-price (FFP) contract for TeraRecon iNtuition 9000 3D and 4D visualization software, hardware, and onsite training with Circle Cardiovascular Imaging cmr42 Cardiac Magnetic Resonance Imaging (MRI) software for use at the Palo Alto VA Medical Center (VAMC). The solicitation will be issued on an unrestricted basis on the Federal Business Opportunities (FedBizOpps) website. Delivery shall be 30 days from receipt of contract while the period of performance for the hardware and software warranty shall be 48 months from activation of software.

3. Description of Supplies or Services: As imaging technology continues to advance, the detail of what can be seen continues to improve. One effect of imaging in more and more detail is the accumulation of an unwieldy number of images. It is not uncommon for datasets to contain 4,000 or more images. It is difficult and inefficient to individually evaluate each of those slices. In some cases, such as cardiac rhythm gated examinations of the chest, evaluation of the complete information contained within the datasets is impossible without the use of software that allows for the organized evaluation of the images by different points in the heart cycle. Interventional and surgical planning can be streamlined by advanced visualization software. This occurs not only by aiding the clinician's visualization of the pathology at hand, but by also allowing for collaborative evaluation.

An advanced visualization suite is necessary for the evaluation and display of now relatively routine "gated" studies, which acquire 3D and 4D images of the chest and heart throughout a heartbeat with the ability to view the motion of the object of interest, usually the heart. With this software, the large volume of data acquired with the Computed Tomography (CT) scanner can be evaluated in an efficient fashion with the object of interest demonstrated throughout all time points in the cardiac cycle. In addition, evaluation of the coronary arteries requires advanced 3D and 4D visualization such as curved planar reformations, straightened viewing, diameter measurements, and calcium scoring.

TeraRecon iNtuition 9000 3D and 4D visualization software allows for evaluation of volumetric data sets in an efficient and streamlined fashion, which will improve efficiency overall, and will improve lesion detection and/or characterization. The Circle Cardiovascular Imaging cvi42 imaging software module works directly with the iNtuition 9000 imaging system to provide a comprehensive suite of imaging and diagnostic tools for VA clinicians. Additionally, the iNtuition imaging software includes a hardware

component that provides a “thin client” server technology, allowing the software to be utilized across a wide range of client computers without the need for upgrading these computers, which improves scalability and ease of deployment.

The Clinical Applications Training associated with this procurement shall provide VA clinicians a total of six eight-hour days of onsite training on the clinical applications of the TeraRecon iNtuition 9000 software.

4. Statutory Authority: The statutory authority permitting other than full and open competition is 41 U.S.C.3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) Subpart 6.302-1 entitled, “Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.”

5. Rationale Supporting Use of Authority Cited Above: The challenge of instituting an enterprise wide 3D and 4D advanced visualization solution is that existing computer systems, in general, are many years old. In terms of computing power and random access memory (RAM), this makes a big difference in system capabilities. Advanced 3D and 4D visualization software such as Carestream Health – Image Fusion Suite, Toshiba Vital Images – Vitrea Core and Ziosoft/QI Imaging – Ziostation System that rely on computer power of the “current” computer system do not meet the Government’s requirements as they require upgrading each and every computer that will be running this software. This would limit the use of the system throughout the enterprise to only those computers that have the computing power to run the software.

TeraRecon iNtuition 9000 brand name software is the only 3D and 4D advanced imaging software that utilizes a “thin client” server technology that does all of the high end computing in a central server; as a result, all of the computers in the hospital connected to the server will be able to control and display this data. TeraRecon iNtuition 9000 will obviate the need for procuring and/or upgrading existing computers to run its visualization software, allowing the software to be downloaded onto all of the existing medical center computers. The capability for the software to run on any of the computers already installed throughout the medical center without upgrade is essential for fast, seamless, and affordable installation and will allow for immediate collaborative endeavors with our clinician colleagues. Although other vendors provide similar imaging software, only iNtuition brand name software, through its use of the “thin client” server technology, meets this capability

Circle Cardiovascular Imaging cvi42 software is a cardiovascular post-processing software comprised of multiple modules for viewing and analyzing of cardiovascular magnetic resonance (CMR) and CT images of the cardiovascular system. This software provides additional cardiac imaging capabilities not inherent to the TeraRecon iNtuition 9000 software. Because of the processing and rendering capability of the software, the computers that utilize this software require dedicated graphics cards. This software will only be able to run on the Mac computers currently used in the radiology and cardiology departments, where the use of this software module would be required. Circle Cardiovascular Imaging cvi42 software is the only cardiac imaging software available that is fully compatible with the TeraRecon iNtuition 9000 imaging system and

has the capability to run on the Mac based computers already in use in the VAMC's radiology and cardiology departments.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section of this document. Although the Government is limiting competition as a result of specifying a brand name, competition is expected for the required software, hardware, and training among authorized resellers. Additionally, the ordering activity will make publicly available the justification along with the solicitation in accordance with FAR 6.302-1(c).

7. Actions to Increase Competition: In order to remove or overcome barriers to competition in the future, the program office 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: On June 17, 2012, representatives from the VAMC in Palo Alto, California attended the 14th Annual International Symposium on Multidetector-Row CT in San Francisco. In addition to the information gathered at this event, four companies visited the Palo Alto VAMC to demonstrate how their imaging solutions would work in the VA clinical environment. Additionally, these companies were given the chance to post-process some of the scans that were already performed at the VA to ensure compatibility and prevent their ability to just use pre-rendered and perfect data-sets.

Medical experts from the Palo Alto VAMC, including radiologists, vascular and cardiovascular surgeons, cardiologists and a neurosurgeon, reviewed the capabilities of the following 3D and 4D advanced imaging software: Carestream Health – Image Fusion Suite, Toshiba Vital Images – Vitrea Core; TeraRecon – iNtuition 9000 and Ziosoft/QI Imaging – Ziostation System. The market research revealed that even though all four products provided similar features and functions, only the TeraRecon iNtuition 9000 offered a software based on the “thin client” server technology that could provide the required advanced 3D and 4D imaging without the need for upgrading or replacing of the existing individual computer systems for each end user of this software. The market research verified that the other imaging software solutions would require either the upgrading or replacement of each existing end user computer where the software would be utilized; and therefore, did not meet the Government's requirements.

The market research also indicated that there are currently two cardiovascular MRI imaging software suits that are fully compatible with the TeraRecon iNtuition 9000 3D and 4D advanced imaging environment; Medis Medical – Quantification Software QCA-CMS Solutions and Circle Cardiovascular Imaging – Circle cmr42 Cardiac MRI. These software suites both provide the additional cardiac imaging modules required but only the Circle cmr42 is compatible with the existing Mac based computers used for image reading and evaluation in the radiology and cardiology departments.

Based on the market research the Government's technical experts have determined that TeraRecon iNtuition 9000 advanced 3D and 4D imaging software suite with the

Circle CV Imaging software is the only imaging solution that can meet the Government's requirements.

9. Other Facts: In accordance with Public Law 100-656, all actions over \$25,000 must be entered into the Forecasting of Contracting Opportunities (FCO) database. This procurement has been entered into FCO via the electronic Contract Management System (eCMS).