

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION
LYNDON B. JOHNSON SPACE CENTER

RECOMMENDATION AND DETERMINATION TO SOLICIT FROM ONE SOURCE

Pursuant to 10 U.S.C. 2304(c)(1) and
Federal Acquisition Regulation 6.302-1

Justification for other than Full and Open Competition (JOFOC)

This justification provides the rationale for contracting by other than full and open competition for the acquisition of an additional Spectral Domain (SD) retinal Optical Coherence Tomography (SD OCT) devices manufactured by Heidelberg Engineering in order to complement the suite of Heidelberg devices recently procured for Medical Operations and ISS. The total estimated cost of the additional OCT device for use at NASA Johnson Space Center effort is ~\$166,000 and the estimated period of performance or lead-time for delivery is 8/20/13 – 9/30/13.

This recommendation is made pursuant to FAR 6.302-1(a)(2)(ii)(A), for the acquisition of supplies or services determined to be reasonably available from only one source. Awarding to any other source would result in substantial duplication of cost to the Government that is not expected to be recovered through competition. Competition is impractical for the following reasons:

Over the past year, the Biomedical Research and Environmental Sciences Division at NASA JSC procured, modified, tested, and certified the commercial off the shelf Heidelberg SD OCT for flight eye examinations. Additional units were procured for use in the JSC clinic for pre and post-flight exams. This OCT was launched on ATV4 in June 2013 and is currently being used on the International Space Station (ISS).

The concern of vision problems spurred the Human Research Program (HRP) to initiate multiple vision related research studies, many of which depend on OCT imagery. The suite of devices procured by ISS is insufficient to support the numerous HRP studies so an additional unit is being procured. This unit will be used by research scientists to obtain ground data complementary to that already being collected during medical exams. Therefore, it is imperative that the research device be the same make and model as the clinical and flight units previously purchased by HRP. For this reason, HRP requires Heidelberg Engineering for their knowledge of Optical Coherence Tomography device.

Commercially known as the Spectralis OCT, this ophthalmic imaging device is used for detailed medical examinations of the back of the eye. This imagery is an enormous improvement in the quality and resolution of ocular imagery over what was previously obtained. It will be used to quantify the ocular structure changes and resulting vision decrements observed in long-term spaceflight crewmembers. The vision risk has recently risen to be one of the top risks of human spaceflight so the ISS Program Office charged

the medical operations team with overhauling the vision testing previously performed. The OCT development was put on the fast track per program direction.

At the direction of the ISS Program Office, JSC's Space and Life Sciences Directorate performed a market survey in late 2011, identifying seventeen (17) candidate OCT devices. This market survey was presented to the ISS Medical Authority in October 2011, and from the published specifications, three (3) of the candidates were identified as meeting (or being able to meet with software-only upgrades) the clinical requirements for NASA's OCT project. These three are:

- Heidelberg Engineering *SPECTRALIS OCT 2-mode*
- OptoVue *iVue*
- Zeiss *Cirrus HD-OCT*

Following the market survey, technical discussions with the manufacturer and in-person demonstrations of each of the three devices were conducted. These meetings led to the disqualification of two of the candidates using the criteria below.

- **Technical Compatibility**
The *iVue* is not compatible with the Operations Concept developed by NASA, as it does not include a patient-specific retinal registry/memory feature. The lack of this feature means that all operations will require two crew members, and each exam will require more time than the ISS Program has made available for this hardware.
- **Economically justified based on tooling, qualification, or other cost.**
The *Cirrus* contains a fully-integrated Windows PC that cannot be de-integrated. Even if hardware procurement costs are equivalent, the Bioastronautics cost of certification of this unit is predicted to be 70-90% higher than that of the *SPECTRALIS* or *iVue*, both of which can be operated using an existing on-board ISS computer. Therefore, it is economically prohibitive to pursue the *Cirrus*.

Based on this market survey, it was determined that the Heidelberg Engineering could provide the SD OCT which meets HRP requirements. The Heidelberg SD OCT is a sole source for which there is no alternative data for HRP's medical research..