

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 16, Station 502 Alexandria VA Health Care System (VAHCS)

PO# 502-14-1-170-0017

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

This requirement is for the Government-Owned EC-5000 CXIII Laser. Nidek Inc. is the OEM (Original Equipment Manufacturer) and as such owns the proprietary rights to the equipment.

- a. Preventative Maintenance Inspections, Parts, Labor, Technical Assistance and Certification in accordance Nidek Inc. recommendations.
- b. The contractor is responsible for providing and installing manufacture designed and issued filed modifications, safety corrections and revisions for correcting software and equipment deficiencies.

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

Period of Performance:

Base year to start 10/01/13 to 09/30/14; with four (4) option years

Option year (1) 10/01/14 to 09/30/15

Option year (2) 10/01/15 to 09/30/16

Option year (3) 10/01/16 to 09/30/17

Option year (4) 10/01/17 to 09/30/18

Contractor must provide all necessary labor, tools, supplies, travel and parts needed to maintain the listed equipment as described in the SOW (attached), in accordance with the OEM guidelines.

The combined total estimated cost for the base year and four (4) option years is \$192,500.00

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

- (X) (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):

The Nidek EC-5000 laser currently in use at the Alexandria VAHCS was manufactured and installed by the Nidek Inc., the manufacturer of the equipment, who holds all intellectual/proprietary rights to the equipment, associated parts and accessories and its operating system. According to the Nidek Inc. the company does not certify or authorize any third party service provider to maintain products. Nidek Inc. is the only firm capable of providing the OEM certified and authorized services as required by the SOW.

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

As technology becomes available, research will be performed to consider other products that meet or exceed the current requirements. The notice required by FAR 5.201 will be published.

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

One or all Price analysis techniques will be used to verify that the overall price offered is fair and reasonable:

- a. Comparison of previously proposed prices and contract prices with current proposed prices for the same or similar service.
- b. Comparison of proposed prices with independent Government cost estimates.
- c. Comparison of proposed prices with prices obtained for maintenance services on similar medical equipment or prices obtained for other VA contracts for the same equipment.

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

Market research was completed to determine what services were available, which companies provided for them, would they meet the requirements for performing the maintenance that would be required and would there be sufficient vendor support to sustain the equipment. Nidek Inc., as the manufacturer of the equipment, holds all intellectual/proprietary rights to the equipment, associated parts and accessories and its operating system. Nidek Inc. does not OEM certify or authorize any third party service provider in the servicing of its products. At this time, there were no other sources available for competition for this unique purchase request.

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

Biomedical device product manufacturing is heavily regulated industry. The Food and Drug Administration (FDA) is the principal healthcare regulatory authority in the United States, having jurisdiction over medical devices, drugs, biologics, and combination products. The paramount objectives driving policy decisions by the FDA are safety and efficacy of healthcare products. For that reason, the manufacturer of the equipment holds all intellectual/proprietary rights to the equipment, associated parts and accessories and its operating system and does not certify or authorize any third party service provider to maintain its products.

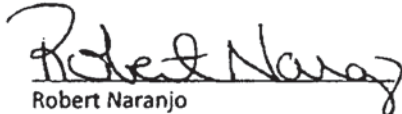
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

See Section 6 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:

See Section 9 above.

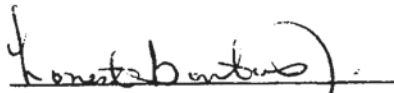
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

  
Robert Naranjo  
Medical Equipment Repairer  
Alexandria VA Health Care System

9-5-13  
Date

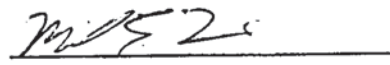
13. Approvals in accordance with FAR 6.304

- a. Contracting Officer's Certification (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
LONEST BONTON JR.  
CONTRACTING OFFICER  
ALEXANDRIA VA HEALTH CARE SYSTEM


9/6/2013  
Date

- b. P&C: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
MICHAEL E. LEWIS  
CHIEF, PURCHASING AND CONTRACTING  
ALEXANDRIA/VA Health Care System  
Network Contracting Office 16

6 Sep 13  
Date

- c. NCM/PCM: I certify the justification meets requirements for other than full and open competition.

  
Aaron Villalpando  
Network Contract Manager  
Network Contracting Office 16

9/6/2013  
Date