

Chapter VI: Other Than Full and Open Competition (OFOC) SOP
Attachment 3: Request for Sole Source Justification Format >\$150K

DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)

1. **Contracting Activity:** Department of Veterans Affairs, Miami VA Healthcare System, NCO-8, Site Team Miami, Purchase Request: 546-15-2-122-0012
2. **Nature and/or Description of the Action Being Processed:** The Miami VA Department of Surgery requires full time on site endoscopic maintenance/repair/certification services inclusive of all parts which are limited to Karl Storz for OEM. This action is estimated at \$281,000.00 per year with an estimated five year total of \$1,405,000.00. It will be a new firm fixed priced contract. This request is for Miami VA owned Karl Storz equipment through on site Karl Storz technicians/experts/engineers. This document is for the justification and approval of a contract award on a limited sources basis as only one source is capable of providing the supplies or services required at the level of quality required for OEM certified services/repairs/parts; due to the unique and highly specialized items being limited to Karl Storz. Through previous history of market research as well as solicitations previously processed this requirement has been deemed a sole source to Karl Storz.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** A full time Karl Storz OEM certified for OEM services/supplies engineer will work on site. The Karl Storz technician requires specific training and certification on all Storz endoscopic equipment. Contractor shall provide maintenance/certification services in accordance with manufacturer's specifications. The contractor shall provide: expert video / equipment maintenance, inspection, function and supply checks, transport and set up to enhance video / equipment on-time availability and preparedness for quick OR turn-over, OR assignment changes and peak surgical volumes. Provide rapid response for inter-operative technical support for video / equipment operation and troubleshooting to reduce delays due to common function / setting adjustments, potential malfunctions or user error and technical support events to provide education to VA staff. Provide proactive proper care and handling, transport, storage, reprocessing and sterilization process / practice guidance and video / equipment, endoscopic and instrumentation inspection, testing, preventive maintenance and minor repair duties. Ensures video / equipment, endoscopes and instrumentation are efficiently managed and properly maintained to achieve standard of care and patient safety priorities, operational efficiency goals, and asset longevity, minimizing damage risks / events and reducing repair / replacement expenses. Provides all inspection, testing, preventive maintenance and minor repair services including related supplies and replacement parts at no additional cost. Reports are routinely provided to indicate savings achieved through the program, education and training of staff, process improvements and damage frequency. Ensures that the equipment functions in conformance with manufacturer specifications and the latest published editions of NFPA-99, OSHA, and CDRH. This includes performance standards and specifications of the Karl Storz scopes. Repair service shall be provided to diagnose and correct equipment malfunctions. Repairs consist of returning a failed component or system to full operational capacity. Repair service may also include exchanging the scope or cleaning, adjusting, replacing parts, or sending to OEM for overhaul repair. All required parts will be furnished by the vendor. On site engineer shall provide pre-paid and pre-addressed next day P.M. freight stamps to send the flexible scope to the contractor for repair. The contractor will return the repaired flexible scope to the VA next day P.M. prepaid. The on-site endoscopic specialist is prohibited from performing or participating in direct patient contact, opening of sterile

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supplies, handling of any prescription or non-prescription medication for any purpose, advising staff or surgeons on the use of any medical devices in a medical procedure and sterilizing any instrument or device or validating the sterility of any instrument or device. For repair and exchange maintenance services, Karl Storz does mention an exclusive small business partner that is a verified SDVOSB, L1 Enterprises. A subcontracting plan will be required to be submitted by Karl Storz.

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;

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

Only One Responsible Source (FAR 6.302-1) – This requirement for endoscopes require Karl Storz OEM certified supplies/services, which to date, other firms are not capable of meeting the needs of the Government. Per market research, as well as the previously issued solicitation VA248-15-Q-0294, it is clear Karl Storz does not provide their certification/parts to any firms outside of their network. The use of such descriptions in the acquisition is essential to the Government's requirements, thereby precluding consideration of a product manufactured by another company. Accordingly, Karl Storz is the only firm capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing unacceptable delays in fulfilling its requirements.

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

Previous market research efforts yielded insufficient results when attempting to find certified OEM Karl Storz servicers. In addition solicitation VA248-15-Q-0294 was issued on GSA Ebuy on 03-11-2015 and FBO on 03-31-2015 which revealed that there were no possible Karl Storz OEM offerors. A clarification of the only offer submitted revealed the contractor could not meet the Governments performance work requirements. This further confirms the authority of 10 USC 2304(c)(1), regarding the capability of industry to meet the Government's need.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable: Prior to contract award, the Government will determine the price to be fair and reasonable based upon historical data from past procurements and current commercial prices for similar maintenance and repair services. Further, as the VHA uses Karl Storz nationally in its effort to standardize equipment, historical contract pricing will be obtained through review of FPDS-NG utilized for comparison and developing the negotiation strategy. Upon receipt of proposals, the Contracting Officer will negotiate with the contractor to arrive at a price determined to be fair and reasonable and in the best interest of the Government. A contract will not be awarded until the price has been determined fair and reasonable.

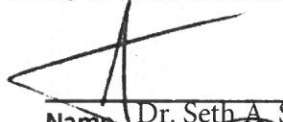
8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted: Market research found Karl Storz is the manufacturer of the equipment and the only company with factory specialized technicians to work on the Smart OR1

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system and the only company authorized to operate Karl Storz proprietary functional design. Karl Storz is the only company with systems engineers and sales representatives that have been factory trained and certified to service all Karl Storz equipment. In addition Karl Storz has a strict warranty policy that states any work, replacement, reinstall, code modification/upgrade, or repair performed on Karl Storz video and integration components by parties other than Karl Storz factory trained technicians will void both the standard and extended service warranties on the smart OR 1 system.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** RME requirements set forth by VA Directive 2009-31 and 2009-004 which mandates that Sterile Processing Services standardize medical equipment to the maximum extent practical to meet standardization requirements are also indicated. The facility has already incurred costs with meeting this standardization to the OEM thus will incur more costs in the remote possibility of changing the current systems in place. Manufacturers of current sterilizers and high level disinfectant machines can only validate such methods of sterilization and disinfection if endoscopes have been repaired and maintained to OEM specifications and repaired using OEM replacement parts. Karl Storz is the only contractor that can provide the highly specialized equipment and service needed to compliment the VA's currently owned systems.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** One (1) offer was received via the previous solicitation, however upon clarification, it was determined the offerer could not provide OEM parts per the Government's requirement.
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:** Until the Government progresses to utilization of a variety of scopes, or additional Karl Storz qualified service providers are incorporated into the marketplace to support the Government's requirement, requests for procurement of Karl Storz Endoscopes, request for service/repair will require a sole source justification.
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.

(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)


Name Dr. Seth A. Spector
Title Chief of Surgery
Facility Miami VA Healthcare System

8/26/15
Date

13. **Approvals in accordance with the** *This part if filled out by Contracting Staff as part of the Justification*

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

Dian E. Williams 116158

Digitally signed by Dian E. Williams 116158
DN: cn=Dian E. Williams, o=Internal, ou=People, email=Dian.E.Williams@va.gov, c=US
Date: 2015.08.27 13:45:51 -0400

Dian E. Williams
Contracting Officer
NCO-8, Site Team Miami

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

DONNETTE A. NYLAND
137908

Digitally signed by DONNETTE A. NYLAND 137908
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=donnette.nyland@va.gov, cn=DONNETTE A.
NYLAND 137908
Date: 2015.08.27 11:03:20 -0400

Name
NCO/PCO 08 Director of Contracting or Designee
Facility

Date

- c. **SAO (If over 650K):** I certify the justification meets requirements for other than full and open competition.

TERRY L.
SPITZMILLER 394683

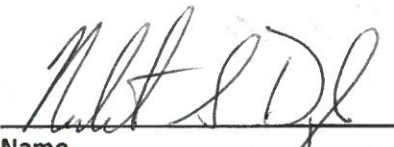
Digitally signed by TERRY L. SPITZMILLER 394683
DN: dc=gov, dc=va, o=internal, ou=people,
0.9.2342.19200300.100.1.1=terry.spitzmiller@va.gov,
cn=TERRY L. SPITZMILLER 394683
Reason: I agree to specified portions of this document.
Date: 2015.09.14 16:39:53 -0400

Name
Director, Service Area Office, East

9/14/2015

Date

- d. **VHA HCA Review and Approval:** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (if over \$12.5 million) or approve (\$650K to 12.5 million) for other than full and open competition.


Name
VHA Head of Contracting Activity (HCA)

9/15/15
Date