

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval for Other than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 11, Danville Medical Center located at 1900 East Main Street, Danville, IL 61832-5100. The Requesting Activity, Danville Biomedical Engineering, has submitted VA Form 2237# 550-14-4-936-0513 in the amount of \$416,022.23 for this request.
2. **Nature and/or Description of the Action Being Processed:** A sole-source contract (base year plus 4 option years) with Olympus America, Inc. for the leasing, maintenance and repair of Endoscopy and Urology equipment for the VA Illiana Health Care System, Danville, IL. Contract will be a new, firm-fixed price contract.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** Endoscopy and Urology equipment, manufactured by Olympus America, Inc. to include: Flexible Video Ureterscopes, Flexible Video Cystoscopes, Resectoscopes, Rigid Cysto Set, Camera Heads, Light guides and sources as well as Video Processors and associated and accessories for this equipment. Services to be included as part of this acquisition is maintenance and repair services conducted by the Original Equipment Manufacturer, Olympus America, Inc.

The total estimated cost, inclusive of options, is \$2,092,440.00. The period of performance for this resulting contract will be a base year, effective no later than September 30, 2014, with four (4) one (1) year option periods. The final estimated contract end date is September 2019.

The equipment to be purchased through this acquisition includes:

<u>QUANTITY</u>	<u>EQUIPMENT DESCRIPTION</u>
Two (2)	Slim Flexible Video Ureterscope
Four (4)	Video System - Advanced HDTV Video Processor
Four (4)	Light Source
Four (4)	Light Guide
Four (4)	High Definition Autoclavable Camera Head
Ten (10)	Cysto-Nephro-Video scope
Two (2)	Dual Channel semi rigid ureterscope
Ten (10)	High-Definition, Narrow Band Imaging Gastroscope
Two (2)	Dual Channel semi rigid ureterscope,
One (1)	Super Slim Flexible Uretero-Reno Fiberscope
Two (2)	Ultra-slim video Gastroscope
One (1)	Dual channel therapeutic Gastroscope
One (1)	Therapeutic video Duodenoscope
Two (2)	Resectoscope Set
Four (4)	Rigid Cysto Sets
Thirteen (13)	Sterilization Tray w/mat for Flexible Scopes
One (1)	30 Watt G Laser, "table top" model
One (1)	K10021612 Workstation
Six (6)	Monitor
Four (4)	Color Video Printer
Two (2)	Standard Cart
Four (4)	Sterilization Tray
One (1)	Generator
Two (2)	CO2 Regulator
Two (2)	Pump

Eight (8)	Cables
Two (2)	Workstation

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

- (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):

VA Illiana currently operates using Olympus Endoscopy/Urology equipment in four different areas of the hospital. This request is for upgraded models of the same equipment currently in use. The 190 series requested are HD (high definition) models. This equipment operates using a "unique tower" which allows all Olympus endoscopic equipment to operate from the same source and eliminates the need for multiple towers to operate each piece of equipment. In addition our staff in Urology, Endoscopy, the OR and Sterile Processing is all trained to operate and reprocess Olympus equipment.

The purchase of any other system would require the facility to replace existing components and/or add additional manufacturer's systems in order to operate. These include leak testers, EndoFlush machines, Medivator processing blocks, numerous consumable products unique to each system and any other manufacturer provided components. The estimated cost to replace these components from another manufacturer is estimated to cost \$1,100,000.00, exclusive of consumable products, in addition to the lease of the scope equipment. The lease of the upgraded Olympus equipment is compatible with our existing infrastructure and Endoscopy equipment and therefore would not require additional purchases or components. These components would allow us to advance our commitment to provide the highest quality of care in the safest medical treatment environment possible.

In addition to the need for acquiring additional support equipment should Olympus equipment not be provided, substantial investment in end-user training from direct care providers to processing personnel would be required. In addition to this training, standard operating procedures and processes for processing (cleaning) would have to be amended to reflect manufacturers' use and processing recommendations and requirements to ensure patient safety standards in order to meet the requirements to standardize Reusable Medical Equipment (RME) and their cleaning Standard Operating procedures as required in Veterans Health Administration Directive 2009-004 released February 9, 2009. These procedures, captured in interactive format IVN (Interactive Visual Navigation), developed by the VA Veterans Engineering Resource Center (VERC) in collaboration with Wayne State University, would have to be rewritten. At the time of the drafting of this justification, 24 different standard operating procedures would have to be re-written, and 30 personnel trained on those new procedures. Over two years of effort has been spent on these Interactive processes (IVN) in order to verify the cleaning process of the equipment in accordance with manufacturer's guidelines. An exact cost to reprogram IVN with non-Olympus equipment SOPs, train new personnel, and ensure functionality of the system could not be determined at the time of drafting this justification, but the Requesting Activity estimates the cost to easily exceed \$1M, nearly half the value of this five (5) year acquisition.

It should be noted this justification also includes maintenance and repair service, which currently can be completed by third parties. However, as the VA is leasing these scopes, should the VA send the equipment to third party contractors for maintenance and repair, the manufacturer (Olympus) will void all warranties should the equipment malfunction. Furthermore, when the equipment is sent back to Olympus at the end of the contract, should the equipment contain non-OEM components, the manufacturer will charge the VA to return the equipment to its original condition. Considering all of this, the Contracting Officer has determined it is in the best interest of the Government to include maintenance and repair services as part of this acquisition.

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

Request for Information (RFI) VA251-14-I-0318 was released on Federal Business Opportunities (FBO) website on May 12, 2014 with a close date of May 16, 2014 looking for all available sources for the leasing of gastrointestinal and urological endoscopes with maintenance & repair services. Only Olympus America, Inc. responded to the Sources Sought Notice with an email to the Contracting Officer. No small businesses responded to the FBO Sources Sought. The Requiring Office also provided quotes from Olympus America, Inc.

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

Currently, almost all of the scopes required under this contract can be provided under Olympus America, Inc. Department of Veterans Affairs National Acquisition Center (NAC) contract V797P-2065D. However, maintenance and repair services are not under contract and therefore this acquisition needs to proceed as open market. To assist with determining that the prices for the leased equipment are fair and reasonable, the Contracting Officer will compare the prices quoted to the VA under this solicitation to those established under Olympus's FSS contract, which in accordance with FAR 8.404(d) have previously been determined fair and reasonable by the GSA Contracting Officer. Other price analysis techniques identified in FAR Parts 13 and/or 15 will be used, if necessary, to ensure that the prices are fair and reasonable.

In order to determine price reasonableness and fairness for the maintenance and repair services, the Contracting Officer can make comparison using current contracts in place for maintenance and repair services for endoscopes. NCO 11 has a history of acquiring endoscope maintenance services when medical facilities purchase endoscopes rather than lease, and the cost of these service agreements can be used to determine price reasonableness and fairness. Other price analysis techniques identified in FAR Parts 13 and/or 15 will be used, if necessary, to ensure that the prices are fair and reasonable.

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

As described in Section VI above, market research, in accordance with FAR Part 10, was conducted by release of a sources sought announcement of the FBO, advising industry of the pending acquisition and soliciting inquiries from interested parties. The results of the market research are included in Section VI.

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

The Contracting Officer was provided an email from the Requesting Activity from the only other major endoscope provider known to the Contracting Officer, Pentax Medical. The email from Pentax Medical states they are unable to provide the required urology endoscopes and do not manufacture any of the rigid scopes or accessories. The Contracting Officer believes it is in the best interest of the Government not to split this requirement and therefore considers Pentax Medical unable to satisfy the Government's requirements for this procurement.

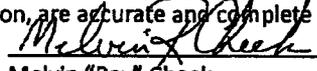
10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

See Section VI 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:

No actions are being taken to remove or overcome any barriers to competition. Barriers to competition include substantial previous investment in training, personnel, and equipment to support the endoscopes and accessories being acquired through this acquisition. Until significant investment is made at the program level to provide additional training and upgrade existing equipment for equipment other than Olympus America, Inc., the barriers to competition will remain as the risk to the VA (lack of training, lack of support equipment, etc.) are substantial.

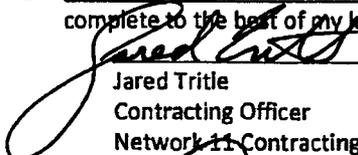
12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and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


Melvin "Ray" Cheek
Chief, Sterile Processing Service
Danville VA Medical Center

8/14/14
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.


Jared Tritle
Contracting Officer
Network 11 Contracting Office

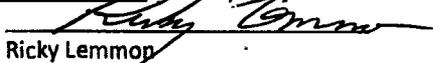
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b. NCM/FCM (Required \$3K and above): I certify the justification meets requirements for other than full and open competition.


Donald R King
Director of Contracting
Network 11 Contracting Office

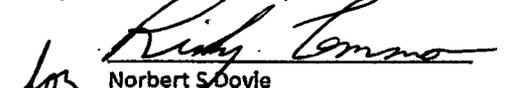
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Date

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


Ricky Lemmon
SAO Director
Service Area Office, Central

8-15-14
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.


for Norbert S Doyle
Chief of Procurement and Logistics
VHA, Head of Contracting Activity (HCA)

8-15-14
Date