

Attachment 1: Request for Limited Sources Memo Format

LIMITED SOURCES JUSTIFICATION

**ORDER >\$3,000
FAR PART 8.405-6**

2237 Transaction # or Vista Equipment Transaction #: 630-11-4-4281-0037 (INSERT)

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in par. 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source: Provide original manufacturer's name for material or contractor's name for service. (If a sole source manufacturer distributes via dealers, ALSO provide dealer information.)

Manufacturer/Contractor: Pentax

Manufacturer/Contractor POC & phone number: (201) 571-2300

Mfgr/Contractor Address: 3,Paragon Dr, Montvale, NJ, 07645-1782

Dealer/Rep address/phone number: _____

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs
VISN 3 Network Contracting Office
(10N3/NCO)
130 W. Kingsbridge Road
Bronx, NY 10468

VISN: 3

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

1. The Department of Veterans Affairs Network, VISN 3 Network Contracting Activity (10N3/NCA), 130 W. Kingsbridge Road, Bronx, New York 10468 has received a requirement to lease Medical Scopes and Related Equipment signed by the Medical Services at:

- I. Brooklyn VAMC
- II. New Jersey Healthcare VAMC

In accordance with FAR 8.405-6(b)(1), FAR 8.402(f), and FAR 6.302-1 we seek to use limited sources on GSA and sole source open market items to create a Blanket Purchase Agreement (BPA).

2. Negotiation shall be conducted to procure a lease with Pentax America Inc. per the VHA directive listed below to standardize the leasing of endoscopes to one manufacturer per site.
3. VISN3 intends to negotiate a lease agreement with Pentax America to provide the following equipment in an effort to standardize Gastrointestinal Endoscope equipment and repair services by replacing the Pentax scopes currently owned by the VISN3 sites listed above with brand-new

leased equipment. No used of equipment of any kind will suffice.

4. The proposed contract vehicle shall be a BPA based on Pentax current mandatory FSS schedule with a period of up to 3 years.
5. The intention of this standardization effort is twofold,
 - I. first to avoid viral outbreaks (as has happened before), under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
 - II. Secondly, to achieve the goal of establishing locally standardized GI endoscope inventories without incurring expense beyond that absolutely necessary.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

- I. The VA of New York and New Jersey (VISN3) is required to lease Pentax medical scopes and related equipment to include: EGD endoscopes, enteroscopes, colonoscopes, sigmoidoscopes and duodenoscopes (ERCP endoscopes).
- II. The majority of the procurement will be purchased through the mandatory FSS schedule.
- III. Note: Those few items not on the Pentax FSS schedule will be added to the BPA pursuant to FAR 8.402(f). The total value of the items is \$209,934 (base + 2 option yrs)
- IV. Pentax is only the source that meets the requirements to implement the mandated directive to standardize scopes and repair services via a leasing agreement.
- V. The following list below are the items that are on FSS contract:

Pentax	Site	Models	Qty
On FSS	NJ	EG-3870OUTK	1
		EG-3670URK	1
		ED-3670TK	1
		EPK-I	2
		NDS26HD	3
		EC-3890LI	5
		EC-3490LI	1
		EG2790I	4
	BK	EC-3890TLK	1
		EPK-I	1
		VSB-3430K	1
		EC-3490Li	1
		ED-3490TK	1
		EC-3890Li	2

(b) ESTIMATED DOLLAR VALUE: \$635,415

(c) REQUIRED DELIVERY DATE: as soon as possible

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE. (CHECK ALL THAT APPLY AND COMPLETE)

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.). Describe in detail why only this suggested source can furnish the requirements to the exclusion of other sources.

1. Under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
2. The agency's minimum needs may only be satisfied by a supply or service that is unique and available from only one responsible source.
3. Pentax scopes characteristics are unique to Pentax. Pentax is the appropriate distributor of these items to Government Accounts. It is in the best interest of the Government to purchase these items from one manufacturer.
1. Per VHA Directive 2009-004 and VHA Handbook 1761.1, a needs assessment survey was completed by each facility. The assessment determined that the facilities listed in Section 1 above have purchased significant and current-generation GI endoscopic equipment from Pentax
4. Purchasing universal alternatives would cause issues with standardization which would cause issues with cleaning and decontamination of these instruments.

This would cause serious bodily damage and harm as it did in viral outbreaks in Tennessee, Georgia and Florida which prompted the creation of the standardization procedures above.

Thus Pentax is the only contractor that can provide the necessary items and services to meet the needs of the facilities listed in Section 1 in VISN3. All items leased must be compatible with existing Pentax equipment.

☐ A patent, copyright or proprietary data limits competition. The proprietary data is: _____
(If FAR 8.405-6(a)(2)iii before posting. Do not include specific proprietary data. Only mention the type of equipment, procedure, etc. to show that proprietary supplies or services are being procured.)

☒ These are "direct replacements" parts/components for existing equipment.

1. The goal of the VHA initiative is move every VISN from owned scopes to leased scopes. So

the leased scopes will be direct replacements for existing owned equipment.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

2. The Pentax equipment sought under this lease, and the service rendered, must be compatible in all aspects (form, fit and function) with the existing Pentax system presently installed.

3. The newly procured equipment must be compatible with the presently owned capital equipment, software and accessories.

☐ The new work is a logical follow-on to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original order must not have been previously issued under sole source or limited source procedures.

☐ An urgent and compelling need exists, and following the ordering procedures would result in unacceptable delays.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

1. The FSS Schedule pricing for leasing equipment is considered fair and reasonable.
2. The final cost for the FSS items to VISN3 is fair and reasonable as it will be less than or equal to the FSS Schedule pricing.
3. In addition, those few items not now on the FSS schedule (which are anticipated to be on the FSS schedule in the near future), are next generation items and when compared to items of current and previous generations of same equipment that have already been deemed fair and

reasonable by the NAC, they are in themselves reasonable and competitively priced within the market.

4. As a result, this overall procurement strategy represents the best value to the United States Government.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

1. The market research conducted consisted a special notice (12/12/2011) and pre-solicitation notice (1/19/2012) posted to fbo.gov.
2. Currently, the sites own the scopes, and will have to replace and dispose of outdated equipment, and move all current generation equipment to a leasing agreement.
3. Pentax was found to be the appropriate distributor of these items to Government Accounts.
4. Pentax was found to be the only company that leases new Pentax equipment.
5. One response was received to the special notice and the pre-solicitation. It was from Medical Optics, an endoscope repair company. According to the information provided "they can provide all labor, parts, tools, equipment, materials, transportation and services necessary to provide preventative maintenance services of medical devices."
6. Since Medical Optics cannot provide leasing for the new Pentax scopes VISN3 requires, they were deemed to have insufficient capabilities to meet VISN3 requirements.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

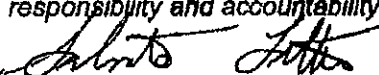
1. This request is pursuant to the authority of FAR Part 8.405-6(b)1, FAR Part 8.402(f), and FAR Part 6.302-1(a).
2. Under 8.405-6(b)1, the use of limited sources procedures for FSS schedules may be used when only one source is capable of responding due to the unique or specialized nature of the work. The sites listed in Section 1 above require the leasing of numerous medical scopes and related equipment for the gastroenterology department. In the past, these sites had simply purchased this equipment but due to standardization and technology demands, they must now lease their equipment.
3. Under VHA Directive 2009-004 and VHA Handbook 1761.1, VHA authority has mandated that standardization of equipment, processes and procedures be implemented immediately to ensure patient safety and health.
4. Under 8.402(f), an ordering activity for convenience, may add items not on the Federal Supply Schedule to a BPA based off of an FSS contract under certain conditions.
 - I. The add-on must comply with all publicizing and competition requirements of the FAR, including FAR part 5, 6, 12, 13, 14, and 15.
 - II. In the interest of convenience these items should be added to this BPA pursuant to 8.402(f) and for the reasons stated below.

5. FAR Part 6.302-1(a) allows for the procurement of items through other than full and open competition; applicable when the agency's minimum needs may only be satisfied by a service that is unique and available from only one responsible source. Many of the required scopes may only be purchased through open market procedures. There are competing companies that can provide other scopes, but due to standardization requirements referenced above, only Pentax scopes can be purchased due to their leasing options. The requirement shall be posted as other than full and open competition which will not allow other contractors to reply to the solicitation.

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

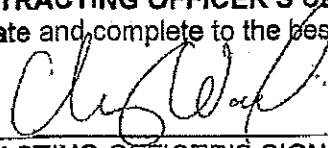
1. This procurement involves replacing owned scopes with leased scopes that include a warranty period in conjunction with and/or followed by a repair service period which may become able to be competed amongst eligible repair companies.
2. This action is the result of a VHA standardization effort and VISN3 is not attempting to circumvent the competitive market.. Our facilities have been supported by Pentax for many years and maintaining continuity while adopting VHA Standards will provide a seamless transition in providing exemplary care to our patients.

(9) 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. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. (This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)

		<u>3/22/2012</u>
SIGNATURE	DATE	
<u>Salvatore Tatta</u>	<u>CBME</u>	<u>Biomedical Engineering</u>
NAME	TITLE	SERVICE LINE/SECTION
<u>Bronx VAMC</u>		
FACILITY		

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(d):

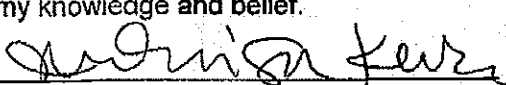
a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



CONTRACTING OFFICER'S SIGNATURE 3/22/2012 DATE

NAME AND TITLE VISN3 FACILITY
Christopher Ward, Contract Specialist

c. NCM/PCM/DESIGNEE: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

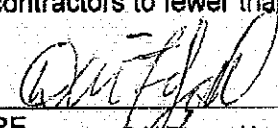


SIGNATURE 3/22/2012 DATE

NAME VISN 3 NCM/PCM
D. M. Fitzgerald

HIGHER LEVEL APPROVAL (Required For orders over \$500,000):


e. SAO: I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.



SIGNATURE D. M. Fitzgerald DATE 2 APR 12
Director, SAO East

NAME
DIRECTOR, SAO EAST

f. VHA HCA REVIEW AND APPROVAL (over \$500,000 to \$10 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4.



NAME DATE 5/29/12
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

g. **VA Deputy Senior Procurement Executive Approval (\$10 million not to exceed \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for restricting consideration of the Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4

N/A

IRIS B. COOPER
Deputy Senior Procurement Executive (DSPE)

DATE

h. **VHA Senior Procurement Executive Approval (over \$50 million):** I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

N/A

JAN R. FRYE
Deputy Assistant Secretary
Office of Acquisition and Logistics
Senior Procurement Executive (SPE)

DATE