

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Organization:** 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 and services signed by the Medical Services at:
 - a. Brooklyn VAMC
 - b. New Jersey Healthcare VAMC

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

Negotiation shall be conducted to procure a lease with Pentax Medical Company per the VHA directive listed below to standardize the leasing of endoscopes to one manufacturer per site.

VISN3 intends to negotiate a sole source lease agreement under the authority of FAR 603.2-1, with PENTAX Medical Company, 3 Paragon Dr., Montvale, NJ, 07645-1782, 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.

The proposed contract vehicle shall be a BPA based on Pentax's current mandatory FSS schedule with a period of up to 3 years.

The intention of this standardization effort is twofold, 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.

Secondly, to achieve the goal of establishing locally standardized GI endoscope inventories without incurring expense beyond that absolutely necessary.

In addition, substantial savings in operating expenses can be realized going forward if we "right-size" the equipment inventory at each facility in consideration of anticipated case load. This standardization effort provides a natural opportunity to realize these savings.

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

The VA of New York and New Jersey (VISN3) requires the leased procurement of Pentax's medical scopes including related equipment and repair services to include: EGD endoscopes, enteroscopes, colonoscopes, sigmoidoscopes and duodenoscopes (ERCP endoscopes).

The majority of the procurement can be purchased through the mandatory FSS schedule. Though,

approximately forty percent of the requirement shall require an open market purchase. Pentax is only the source that meets the requirements to implement the mandated directive to standardize scopes via a leasing agreement.

The following list below are items that are NOT on FSS schedule:

Pentax	Site	Models	Qty
Non-FSS		EC-3870CIK	1
		EG-3870CIK	1
		NDS24HD	6
		BO232	2

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):

The agency's minimum needs may only be satisfied by a supply or service that is unique and available from only one responsible source. The equipment being added to this BPA under this modification is required for the proper use and function of these medical endoscopes. These endoscopes within this BPR have many proprietary features which require the use of these open market items.

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.

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. 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.

B. 6.302-1 -- Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements.

(a) Authority.

(1) Citations: 10 U.S.C. 2304(c)(1) or 41 U.S.C. 253(c)(1).

(2) When the supplies or services required by the agency are available from only one responsible source, or, for DOD, NASA, and the Coast Guard, from only one or a limited number of responsible sources, and no other type of supplies or services will satisfy agency requirements, full and open competition need not be provided for.

(i) Supplies or services may be considered to be available from only one source if the source has submitted an unsolicited research proposal that --

(A) Demonstrates a unique and innovative concept (see definition at 2.101), or, demonstrates a unique capability of the source to provide the particular research services proposed;

(B) Offers a concept or services not otherwise available to the Government; and,

(C) Does not resemble the substance of a pending competitive acquisition. (See 10 U.S.C. 2304(d)(1)(A) and 41 U.S.C. 253(d)(1)(A).)

(ii) Supplies may be deemed to be available only from the original source in the case of a follow-on contract for the continued development or production of a major system or highly specialized equipment, including major components thereof, when it is likely that award to any other source would result in --

(A) Substantial duplication of cost to the Government that is not expected to be recovered through competition, or

(B) Unacceptable delays in fulfilling the agency's requirements. (See 10 U.S.C. 2304(d)(1)(B) or 41 U.S.C. 253 (d)(1)(B).)

(iii) For DOD, NASA, and the Coast Guard, services may be deemed to be available only from the original source in the case of follow-on contracts for the continued provision of highly specialized services when it is likely that award to any other source would result in--

(A) Substantial duplication of cost to the Government that is not expected to be recovered through competition, or

(B) Unacceptable delays in fulfilling the agency's requirements. (See 10 U.S.C. 2304(d)(1)(B).)

(b) *Application.* This authority shall be used, if appropriate, in preference to the authority in 6.302-7; it shall not be used when any of the other circumstances is applicable. Use of this authority may be appropriate in situations such as the following (these examples are not intended to be all inclusive and do not constitute authority in and of themselves):

(1) When there is a reasonable basis to conclude that the agency's minimum needs can only be satisfied by --

(i) Unique supplies or services available from only one source or only one supplier with unique capabilities; or,

(ii) For DOD, NASA, and the Coast Guard, unique supplies or services available from only one or a limited number of sources or from only one or a limited number of suppliers with unique capabilities.

(2) The existence of limited rights in data, patent rights, copyrights, or secret processes; the control of basic raw material; or similar circumstances, make the supplies and services available from only one source (however, the mere existence of such rights or circumstances does not in and of itself justify the use of these authorities) (see Part 27).

(3) When acquiring utility services (see 41.101), circumstances may dictate that only one supplier can furnish the service (see 41.202); or when the contemplated contract is for construction of a part of a utility system and the utility company itself is the only source available to work on the system.

(4) When the agency head has determined in accordance with the agency's standardization program that only specified makes and models of technical equipment and parts will satisfy the agency's needs for additional units or replacement items, and only one source is available.

(c) *Application for brand name descriptions.* An acquisition that uses a brand name description or other purchase description to specify a particular brand name, product, or feature of a product, peculiar to one manufacturer does not provide for full and open competition regardless of the number of sources solicited. It shall be justified and approved in accordance with FAR 6.303 and 6.304. The justification should indicate that 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. See 5.102(a)(6) for the requirement to post the brand name justification. (Brand-name or equal descriptions, and other purchase descriptions that permit prospective contractors to offer products other than those specifically referenced by brand name, provide for full and open competition and do not require justifications and approvals to support their use.)

(d) *Limitations.*

(1) Contracts awarded using this authority shall be supported by the written justifications and approvals described in 6.303 and 6.304.

(2) For contracts awarded using this authority, the notices required by 5.201 shall have been published and any bids, proposals, quotations, or capability statements must have been considered.

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

A special notice, VA243-12-I-0427 was posted on fbo.gov on December 12, 2011 stating VISN3s intention of sole sourcing this requirement.

A pre-solicitation notice, VA24312Q0640, was posted on fbo.gov on January 13, 2012 stating VISN3s intention of sole sourcing this requirement.

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

The estimated total cost of the open market items to be added to the BPA is \$209,934.00 which includes the base period and all option years.

The quote is considered fair and reasonable price and offers the best value to the United States Government based on using service estimates and previous purchasing history of prices. In addition, when compared to items of previous generations and like quality that have been deemed fair and reasonable by the NAC (FSS Schedule), these items only command a small price premium of about 10-15% due to their cutting edge technology.

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

The market research conducted consisted of a needs assessment survey, and a special notice and pre-solicitation posted to fbo.gov.

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.

Per VHA Directive 2009-004 and VHA Handbook 1761.1, for health and safety purposes, a needs assessment survey was completed by each facility to determine the state of the scope inventory. The assessment determined that the facilities listed in Section 1 above have purchased significant and current-generation GI endoscopic equipment from Pentax. Pentax is the appropriate distributor of these items to Government Accounts. Pentax was found to be the only company that lease new Pentax equipment.

One response was received to the special notice. 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. "

Since Medical Optics cannot provide leasing for the new Pentax scopes VISN3 requires, they were deemed to have insufficient capabilities to meet VISN3 requirements.

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

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).

- A. 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.
- B. 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. 1) The add-on must comply with all publicizing and competition requirements of the FAR, including FAR part 5, 6, 12, 13, 14, and 15. In the interest of convenience these items should be added to this BPA pursuant to 8.402(f) and for the reasons stated below.
- C. 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.

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

Medical Optics, 10320 West McNab Road, Tamarac, Florida 33321

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:

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.

In addition, this procurement shall be in the form of a Blanket Purchase Agreement, should a future contractor pose better pricing and exceptional lease terms, the Government may always opt out the proposed BPA and create a new BPA with other contractors to fulfill this need.

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.

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Salvatore Tatta
Name: Salvatore Tatta
Title: Chief, Biomedical Engineer
Facility: James J. Peters VAMC

2/10/12
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.

Chris Ward
Name
Title **CHRISTOPHER WARD**
Facility **VISN3 CONTRACTING OFFICE
SPECIAL PROJECTS COORDINATOR**

2/10/12
Date

b. **VISN/PCA QA:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

N/A

Name
Title
Facility

Date

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

M Pringle
Name *Myrmanus Pringle*
Acting Network Contract Manager
VISN/PCA X

2/16/12
Date

d. **SAO:** I certify the justification meets requirements for other than full and open competition.

N/A

Name
Director
Service Area Office, East

Date