

Service Area Office, East  
Department of Veterans Affairs  
323 North Shore Drive, Suite 500  
Pittsburgh, PA 15212

Memorandum 2011-003  
December 28, 2010

Attachment A: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 4, James E. Van Zandt VA Medical Center – Station 503

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

Purchase of two (2) Sterrad NX sterilizers for Sterile Processing Services to replace the existing Ethylene Oxide (EtO) Sterilizers. Included should be installation and validation, in-service, and one (1) year warranty.

Background:

Sterilization is currently performed using EtO. Per VHA Directive 2011-015, existing EtO sterilizers are required to have air pollution devices (Abators) installed by October 1, 2014. The projected cost of this equipment is estimated at \$25,000 - \$30,000 plus installation costs. At that point the Medical Center decided to review other alternatives to sterilization of equipment.

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

The Medical Center endoscopes/cystoscopes must be sterilized. Tables 6.1 and 6.2 (attached) show compatible methods that can be used with our existing Olympus scopes. Of the 5 methods shown only EtO and Sterrad NX are sterilizers, while the other three (3) are disinfectants. Between the two (2) remaining, the Sterrad NX is preferred from an environmental stand point because EtO is a proven carcinogen and requires dedicated exhaust and monitoring.

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 Sterrad NX system is the only other system compatible with our existing scopes as stated above and shown on the attached tables 6.1 and 6.2. The benefit is that it is environmentally friendly.

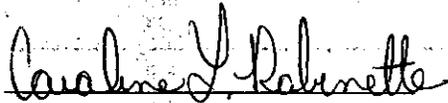
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**  
Sources are limited due to the compatible methods of sterilizing. EtO and Sterrad NX are the only two (2) systems compatible with our existing scopes.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:**  
Pricing was requested for Sterrad NX equipment. The pricing was reviewed by engineering and compared to actual costs for a Sterrad NX 100 system that was recently installed at the Wilkes-Barre VAMC.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:**  
Market Research was conducted to review alternatives to the EtO. The only alternative, as mentioned above, was to purchase the Sterrad system.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** N/A
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** N/A
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:** N/A
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.

  
Name: William Lightner  
Title: Chief Facilities Service  
Facility: VISN 4 VAMC Altoona, PA

4-23-12  
Date

13. **Approvals in accordance with FAR 6.304**

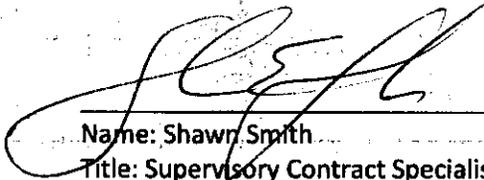
- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Name:  
Title: Contracting Officer  
Facility: VISN 4 VAMC Altoona, PA

5/11/2012  
Date

**One Level above Contracting Officer:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. \*This signature may be the VISN NCM if the Contracting Officer and Contracting Supervisor is the same individual.



Name: Shawn Smith  
Title: Supervisory Contract Specialist  
Facility: VISN 4 VAMC Altoona, PA

5/10/12  
Date

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

\_\_\_\_\_  
Name: David Stout  
Network Contract Manager  
VISN 4 VAMC Altoona, PA

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
Jeffrey R. Ryan  
Director  
Service Area Office, East

\_\_\_\_\_  
Date

### List of compatible methods validated in terms of biological efficacy and material durability

This chart lists those cleaning, disinfection, and sterilization procedures and agents that have been thoroughly tested on components of endoscopes and their accessories.

|   | Steam sterilization (autoclaving) | ETO gas sterilization | 2 to 3.5% glutaraldehyde | 70% ethyl or isopropyl alcohol | Detergent solution | Ultrasonic cleaning |
|---|-----------------------------------|-----------------------|--------------------------|--------------------------------|--------------------|---------------------|
| <i>Disinfectants</i>                              |                                   |                       |                          |                                |                    |                     |
|   |                                   |                       |                          |                                |                    |                     |
|   |                                   |                       |                          |                                |                    |                     |
|   |                                   |                       |                          |                                |                    |                     |
|   |                                   |                       |                          |                                |                    |                     |
|   |                                   |                       |                          |                                |                    |                     |
| Endoscope   |                                   |                       |                          |                                |                    |                     |
| Light guide adapter (MAJ-1413)                    |                                   |                       |                          |                                |                    |                     |
| Rechargeable miniature light source (MAJ-922)     |                                   |                       |                          |                                |                    |                     |
| Channel cleaning brush (BW-15B)                   |                                   |                       |                          |                                |                    |                     |
| Channel-opening cleaning brush (MH-507)           |                                   |                       |                          |                                |                    |                     |
| Forceps/irrigation plug (isolated type) (MAJ-891) |                                   |                       |                          |                                |                    |                     |
| Suction cleaning adapter (MAJ-1077)               |                                   |                       |                          |                                |                    |                     |
| Cylinder plug (MAJ-1940)                          |                                   |                       |                          |                                |                    |                     |
| ETO cap (MB-156)                                  |                                   |                       |                          |                                |                    |                     |

applicable
  not applicable

Table 6.1

**List of compatible methods validated in terms of material durability**

|   | STERRAD® NX™*1 | STERRAD® 50/100S/200*1 |
|---|----------------|------------------------|
| Endoscope   |                |                        |
| Light guide adapter (MAJ-1413)                    |                |                        |
| Rechargeable miniature light source (MAJ-922)     |                |                        |
| Channel cleaning brush (BW-15B)                   |                |                        |
| Channel-opening cleaning brush (MH-507)           |                |                        |
| Forceps/irrigation plug (isolated type) (MAJ-891) |                |                        |
| Suction cleaning adapter (MAJ-1077)               |                |                        |
| Cylinder plug (MAJ-1940)                          |                |                        |
| ETO cap (MB-156)                                  |                |                        |

 compatible     not compatible

Table 6.2

\*1 ASP tests the microbiological efficacy of Olympus products in sterility. As for the microbiological efficacy, contact ASP. Also see the "STERRAD® 50/100S/200/NX™" instruction manual.

