

**DEPARTMENT OF VETERANS AFFAIRS**

**Justification and Approval (J&A)  
For  
Other Than Full and Open Competition (>\$150K)**

**Acquisition Plan Action ID: VA256-16-AP-0311**

1. **Contracting Activity:** Department of Veterans Affairs, Network Contracting Office 16, Michael E. DeBakey VA Medical Center.

Requisition Number: 580-16-1-167-0012

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

**FAR13.5 Test Program:** This procurement is for Berchtold Surgical Boom and Light Systems in accordance with FAR 13.5 Test Program for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.

Proposed award for this procurement is a new, firm-fixed price contract to Stryker Communications.

3. **Description of Supplies/Services Required to Meet the Agency's Needs** The Michael E. DeBakey VA Medical Center is constructing two (2) new hybrid operating rooms (OR) and one general operating room. The proposed action is for the purchase, delivery, and installation of Berchtold Operating Room Chromophare® Surgical Lighting and TeleTom® Equipment Management Systems, which will require some renovation, customized to the operating room layout and design as determined by the Architect and Clinical staff, in the two (2) hybrid operating rooms and one new general operating room. FBO Notice VA256-16-Q-0212 will be posted for notification of the Government's intent to sole source a new firm fixed priced contract to Stryker Communications.

**Equipment Cost** [REDACTED]

**Installation Cost -** [REDACTED]

**Renovation Services Cost -** [REDACTED]

Estimated delivery is May 2016.

The systems will include the following:

***NOTE: See attachment for a complete list of equipment and quantities required.***

**Stryker Berchtold LED Lights, Flat Panel Arms & Shield Mounts**

- Non-array based light heads with 104 LED's per light
- Surgical lighting using precision beam technology with 650 overlapping beams of light

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

- 47" depth of field for best in class shadow resolution
- Top tier laminar flow compliance – lighting meets SWKI 5 standards
- Ingress protection from dust & water – IP 53 certified
- 4 adjustable color temperature settings – light can be set to 3500K, 4000K, 5000K and 5500K color temps
- A single spindle in the ceiling (non-tandem mounted) supporting a Surgical light with 1600mm top arm, a shield mount with 1500mm top arm, and a flat panel arm with 1400mm top arm which accommodate the reach necessary to position all 3 around the table while staying clear of the no-fly zone provided by the imaging vendor as specified by the architect
- A single spindle in the ceiling contains a surgical light as well as a video / power arm which has the ability to also provide high voltage and low voltage data access in the field without the presence of an equipment boom.

**Booms**

- True all electric braking – no compressed air or nitrogen gas for pneumatic braking necessary
- Certified to UL 1047 standards
- Fully isolated power system – both KEZR and KEXS standards
- Booms combined with surgical lights, monitor arms, and shields attached to single spindle in the ceiling (non-tandem mounted)
- Anesthesia and Equipment booms must have 1300mm top arms to accommodate no-fly zone of imaging vendor as specified by architect (in the prior 2 years of design meetings that we had)

**Turnkey Installation**

- The vendor must coordinate their turnkey installation efforts with the general contractor for the 2 hybrid operating rooms, as well as the general contractor for the general operating room and facilities management project manager.

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

FAR 13.5 Test Program: The authority for applying the Commercial Test Program of FAR 13.5 is (Section 4202 of the Clinger-Cohen Act of 1996) and is implemented for restricting competition on this procurement via FAR 13.106-1(b)(2).

- ( X ) (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):**

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

- a. The Michael E. DeBakey VA Medical Center is not seeking competition for this procurement because the required items are part of an ongoing project for the construction and renovation of the operating rooms at the Medical Center.
- b. The Michael E. DeBakey VA Medical Center is currently using the Berchtold lighting systems in its operating rooms. The configuration is similar to current surgery suites at the VA Medical Center and will ensure a seamless transition for the facility's surgeons when performing surgery for VA beneficiaries.
- c. In order to maintain consistency in all OR suites and not compromise patient care, all of the OR's are being fully integrated with the same video equipment and lighting to ensure continuity for the surgeons and anesthesiologist as well as provide optimal patient safety. To date, several boom systems have been installed by Stryker Communications and market research has been conducted to determine that Stryker Communications is the only source that provides this specific lighting/boom system meeting the customized specifications for the operating rooms. There are no other equal products on the market capable of conforming to the specifications per the architect design of the new operating rooms. The design included specific requirements for the lights and booms, such as a "no fly zone". This technology is proprietary to Stryker Communications.
- d. The placement of the lighting system was configured during the design of the operating rooms specifically for Berchtold equipment to ensure that the location and motion did not conflict with other equipment in the rooms as the booms cannot be considered without also considering lights, flat panel monitors and integration of audio-visual components. Between the surgical lights to support open procedures, the no-fly zone, all the anesthesia equipment, and the dual imaging monitors being mounted on booms, was all included in complex planning of the construction of these operating rooms.
- e. TELETOM® Equipment Management System employs a unique modular approach with the platform system. The boom is offered with only one size service module, but with multiple platform systems which all connect to that same service module. This allows for quick conversion (for example, from a three to four platform system) with no recertification of gas and electric services needed. This ability for a quick, economical adaptation helps eliminate costly downtime and makes it easy to upgrade the boom with new equipment.
- f. The Stryker/Berchtold lighting and boom system allows the removal of all cords from the floor reducing trip/fall hazards and provides a system to safely house the integration and video cables that are being installed as part of the overall OR video integration project. The new lighting does not heat tissue area as quickly as halogen lighting and provides a cooler work environment for patient and staff. The Berchtold Surgical Lights boast four color temperature settings, full 360 degree rotation and Precision Beam Technology(TM) that focus 650 beams of overlapping light into one homogenous column, creating ideal light quality and shadow prevention. They also provide energy efficiency to facility as halogen requires replacement after 1000 hours vs LED's which last for 60,000 hrs. All other OR suites have the new LED lights which may improve surgical outcomes through better visibility.

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

g. The Berchtold's line of equipment management systems will provide a flexible platform to support the equipment needs of the operating rooms. Configurable art sets, service heads, and mounting options will provide customization for the unique room designs.

h. Stryker's authorized general contractors will perform all pre-installation renovation work.

i. The Berchtold systems will provide a comprehensive light and boom network that will be utilized in the operating rooms shown in Item 3. These suites have specific applications and procedures which will rely on the Berchtold lighting and boom systems to function.

j. The previous requirement was awarded to Berchtold, a small business, after approval of the justification for other than full and open competition by the Deputy Director of Contract. This justification referenced by the customers indicates that a justification (not available) for the sole source procurement from Berchtold for boom system was approved during the 2012 OR Expansion planning phase.

k. Integration of another manufacture system other than the Berchtold would potentially increase cost in renovation changes to meet the existing requirements currently in place. In addition, using other systems that are not Berchtold products could damage the existing systems, void the warranty, and delay the activation of the OR thus, directly impacting patient care.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** In order to maintain consistency in all OR suites and not compromise patient care, all of the OR's are being fully integrated with the same video equipment and lighting for standardization, integration, training, and continuity. To date, several boom and light systems have been installed by Stryker/Berchtold Corp at the Michael E. DeBakey VA Medical Center in accordance with the architectural design of the operating rooms. Therefore, no other offers are being solicited because Stryker/Berchtold equipment is already being used in the OR renovation project at the Michael E. DeBakey VA Medical Center. The operating rooms have been customized for the Stryker/Berchtold equipment.

A Notice of Intent to award a Sole Source contract to Stryker Communications will be posted to FEDBIZOPPs. The award synopsis will be posted to FEDBIZOPPs.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The Contracting Officer considers the anticipated cost to the Government will be fair and reasonable based on a comparison of the costs on past procurements history for the same or like items since the OR expansion and video integration project began in 2012. These past procurement prices and other VA Medical Center historical pricing will be used to assist the Contracting Officer in making a determination of pricing fair and reasonableness. On past procurement of the booms and lights, the Government has received a substantial cost reduction compared to what is offered to public entities.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Since approval of the Michael E. DeBakey VA Medical

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

Center's Operating Room expansion/video integration project inception, the Medical Center has purchased several Stryker/Berchtold lighting and boom systems. In order to maintain consistency and not compromise patient care we are requesting upgrade to the existing lighting system to be identical to the other OR suites. Stryker/Berchtold is the sole manufacturer of these systems and they are not available from other distributors.

The Contracting Officer conducted market research which revealed other sources of similar equipment. An internet search revealed TRUMP Medical Systems provides a line of equipment booms; STERIS Corporation offers ceiling systems with single or double arms in lengths and the STERIS Harmony EMS system; Getinge USA offers a wide range of OR Room systems with over twenty-five different arm systems; Skytron offers the Ergon 3 booms that provides four arms from one mount as well as other arrays of equipment carrier systems.

A search on GSA eBuy resulted in 48 contractors on Schedule 65 II A, Medical Equipment and Supplies, Category A-80 – Lights, Surgical, Ceiling and Surgical Stand. Forty-three of the forty eight are small businesses of which Berchtold is one of the small businesses.

A search of VetBiz resulted in 38 vendors.

An SBA Search using NAICS Code 339113, keywords, surgical boom, resulted in "zero" firms in the Economic Groups of Veteran, SDV, HUBZone Certified, SDB Certified, 8(a) Certified, and Woman or Women Owned.

However, since the construction project for the construction/renovation of the Michael E. DeBakey VA Medical operating rooms is already underway and the designs for the operating rooms are customized for Stryker/Berchtold equipment, it was not feasible to consider other manufacturers of surgical boom and lighting systems for this requirement.

In fulfillment of the operating rooms' construction, a requirement for installation of customized boom systems was procured for the Michael E. DeBakey VA Medical Center on 21 July 2014 at a cost of \$485,354.88, Purchase Order VA256-14-C-0184/580-A40323. The pricing difference in the current acquisition requirement and the previously awarded Purchase Order No. 580-A40323 is the scope of work and amount and type of equipment required. The operating room equipment is specific to surgeries performed in that particular operating room. The previous requirement was awarded to Berchtold, a small business, after approval of the justification for other than full and open competition by the Deputy Director of Contract. This justification referenced that a justification (not available) for the sole source procurement from Berchtold for boom system was approved during the 2012 OR Expansion.

In September 2014 a sole source Purchase Order, No. VA256-14-P-4132, was awarded to Karl Storz Endoscopy-America, Inc. in the amount of [REDACTED] for HD Video Integration Systems for 8 operating rooms. Included in this acquisition was the procurement of Berchtold equipment - boom additions in Rooms 1, 10, and 11, which was at a cost of [REDACTED]; OR #5 Flexmove Room at a cost of [REDACTED]; Flat Panel Arm Upgrade Rooms 2, 3, 9, and 12 at a cost of [REDACTED]; the Services costs was [REDACTED]. The total cost of the Berchtold equipment for the operating rooms was [REDACTED]. The pricing difference in the current requirement and Purchase Order Number VA256-14-4132 is that the previous requirement included HD Video Integration Systems for eight (8)

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

operating rooms and the surgical booms and lighting systems. The current requirement is for only the booms and lighting system 3 operating rooms.

Although, Skytron offers the ERGON 3 Booms, the operating rooms were design for use of the Stryker/Berchtold booms and lighting system. The number of light heads, weight of attachments, dual arm weight capacity, and arm reach for the ERGON 3 Booms and Stryker/Berchtold booms and light differ.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Since approval of the OR expansion/video integration project inception the hospital has purchased several of the Berchtold lighting and boom systems from Stryker Communications. In order to maintain consistency and not compromise patient care we are requesting upgrade to the existing lighting system to be identical to the other OR suites. There is no other equal product capable of transforming to the established, customized specifications, and the warranty on current Stryker/Berchtold equipment would be void. This technology is proprietary to Stryker Communications. In addition, Berchtold is the manufacturer of the required lighting and boom system and has unique installation requirements that only Stryker Communications can provide.

The Berchtold TeleTOM® Equipment Management Systems are custom-figured to enhance a specific environment. Since all units will share one compact, flexible, interchangeable suspension system, future upgrades and technology transitions will be easy and risk free.

Stryker Communications is the only firm capable of providing the boom and light systems required for these operating rooms without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition.

Any further delay in procuring this equipment will result in delays in the current OR construction project at the Michael E. DeBakey VA Medical Center and will result in added costs for those delays.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Stryker Communications, 1410 Lakeside Parkway, Flower Mound, TX, (PH – 1-877-789-8106).
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:** Due to currently installed equipment and design specifications, there are no other sources the facility can seek out at this time. For future requirements, the Agency will conduct market research during the construction design stage so that consideration may be made of all possible sources for equipment purchases that are part of a major construction project prior to finalizing the construction procurement.
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.

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

\_\_\_\_\_  
[Redacted Signature]

\_\_\_\_\_  
Date

13. Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.

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

\_\_\_\_\_  
[Redacted Signature]

3/22/2016  
\_\_\_\_\_  
Date

\_\_\_\_\_  
[Redacted Signature]

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
[Redacted Signature]

\_\_\_\_\_  
Date

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

\_\_\_\_\_  
[Redacted Signature]

\_\_\_\_\_  
Date