

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Procuring Contracting Activity:** Department of Veterans Affairs, SAO Central Region, 708 S. Third Street, Minneapolis, MN 55417 for the Department of Veterans Affairs, Michael E. DeBakey VA Medical Center, 2002 Holcombe Blvd., Houston, TX 77030.
2. **Nature and/or Description of the Action Being Processed:** Justification and approval for Other Than Full and Open Competition for the purchase of on (1) X-Ray Blood Irradiator System, including installation and training, for the Michael E. DeBakey VA Medical Center, Houston, TX per Purchase Requests # 580-13-3-167-0524. Award of a firm-fixed price contract is anticipated. This procurement will proceed on a sole source basis with Best Theratronics, Inc.

The intent of this requirement is to ensure the MEDVAMC maintains the ability to continue to offer Veterans advanced treatment and care as inpatients and outpatient. The Raycell MK2 X-Ray Blood Irradiator is critical blood banking equipment designed specifically for Irradiation of Blood Products. At present we purchase a high volume of irradiated blood products, anywhere from 100-120 units per month, plus platelets. Our supplier cannot deliver irradiated product on a STAT order because of distance limitation.

The Contracting Officer's market research has revealed the following:

- a. Research reflects that Raycell MK2 Irradiator System is currently available by issuing a sole source special notice on FBO and issue a solicitation to Best Theratronics.
- b. There is no need to customize these products to meet the government's requirements.
- c. Research in FPDS was conducted and there are a history of contract to large businesses.
- d. An open market search on FBO was done using "Raycell MK2 Irradiator System" and "X-Ray Blood Irradiator" and no results were given.
- e. GSA advantage was searched and no results were found under: "Raycell MK2 Irradiator System" and "X-Ray Blood Irradiator".
- f. Contractor financing will not be offered within this acquisition due to the nature of what is being requested. These are common use medical systems/ products and availability of the items should be already established through the potential offeror. It is anticipated that the requirement will be fulfilled by issuance of a Sole Source FFP Contract for an award.
- g. At this time, there are no services/ products that will require recovered materials and/or items that are energy efficient. A review of covered product categories on the U.S. Department of Energy website, and the U.S. Department of Agriculture website yielded no matches.
- h. The North American Industry Classification System Codes (NAICS) used for the aforementioned products have historically been 339112 "Surgical and Medical Instrument Manufacturing" with a size standard of 500 employees. It is the Contracting Officer's determination that this NAICS code best describes the required products. Review of the non-manufacture class waiver list indicates that this NAICS code/product description does not qualify for the waiver.
http://www.sba.gov/sites/default/files/09212011_class%20waivers.pdf
- i. Research reflects that the equipment is provided by Best Theratronics, but there is no current GSA/FSS Contract in place with Best Theratronics.
- j. Market research indicated Best Theratronics sells the MK2 Irradiator System to other federal agencies.
- k. Best Theratronics actively markets the Raycell MK2 Irradiator and provides for similar installation and training as requested by VISN 16 in the commercial marketplace.

3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The X-Ray Blood Irradiator System includes the following items:

The system will primarily be used for irradiating blood products. It will make it possible to provide internal blood component irradiation service, capitalizing on internal resource without any inconvenience and discomfort to the

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patients undergoing chemotherapy/radiotherapy. Having an in house internal Irradiator has proven to be safe and feasible, and along with significant cost reduction. The overall time/cost of this procedure was compared with the current procedure, out-sourcing the irradiation of blood components. It can deliver 25Gy dose in approximately 3 minutes. The system shall come with 2.0 litre canister which holds approximately 4 (four) 300ml bags of blood. The system shall have end-of cycle time indicator with audible alarm, dose uniformity -1.5 to 1 maximum, two separate door safety interlocks for the sample chamber. System is mounted on casters (all casters are lockable) and a Safety design that prevents damage to instrument from accidental spillage. The system shall be FDA approved.

The total for all items is \$305,050.00. Delivery is expected within 180 days of the Notice of Award.

4. **Statutory Authority Permitting Other than Full and Open Competition:** FAR 6.302-1(a)(2). The VA's minimum needs can only be satisfied by unique supplies or services available from only one source (41 USC 253 (c)(1)).
5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**
Best Theratronics is currently the only manufacture offering a Raycell MK2 Irradiator System which is FDA approved and meets all of the technology requirements of VISN 16 Pathology and Lab Department at the Michael E DeBakery VA Medical Center. The Raycell MK2 X-Ray Blood Irradiator is critical blood banking equipment designed specifically for Irradiation of Blood Products. Currently, the facility spends over \$15,000.00 per month to irradiate blood products that are needed for Oncology, Liver Transplant and Immunosuppressed patients.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** Considering that the MK-2 X-Ray Blood Irradiator is the only FDA approved operative surgical robotic system available, efforts to include other potential sources has been limited. This action will be synopsisized and published on the Government Point of Entry, FedBizOpps.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** The MK-2 X-Ray Blood Irradiator is currently the only FDA approved X-Ray Blood Irradiator system currently on the market. The Contracting Officer has determined the anticipated cost to be fair and reasonable based on the following information.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** Market research has shown that the identified manufacturer is the sole source for this system.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** There are no other facts supporting the use of Other Than Full and Open Competition.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** This J&A will be posted on FedBizOpps. If responses to the synopsis indicate that additional sources are available, the file will be documented accordingly and the requirement competed among all eligible sources.
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:** None. Until another X-Ray Blood Irradiator system is approved by the FDA, the MK2 X-Ray Blood Irradiator is the only know system capable of meeting the Government's 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.



POC
Molla Shibeshi
Supv Medical Technology, Diagnostic & Therapeutic Care

09/09/2013
Date

13. Approvals in accordance with FAR 6.304

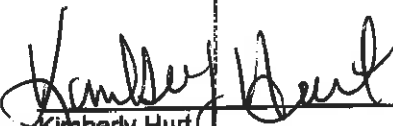
- a. **Contracting Officer's Certification: (required)** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Jennifer Johnson
Contracting Officer
SAO Central Region

Date 9/10/13

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



Kimberly Hurt
Regional Chief Contracting
SAO Central Region

Date 9/10/13