



DEPARTMENT OF THE NAVY
NAVSUP FLEET LOGISTICS CENTER NORFOLK
1968 GILBERT STREET SUITE 600
NORFOLK VA 23511-3392

IN REPLY REFER TO
240A
28 JUN 2016
J&A# 16013

**JUSTIFICATION AND APPROVAL (J&A)
FOR OTHER THAN FULL AND OPEN COMPETITION**

1. Identification of Agency and Contracting Activity:

Requiring Activity: Commander Officer
Naval Medical Center Portsmouth (NMCP)
Materiel Management Department
Contracting Division, Bldg #250
54 Lewis Minor Street
Portsmouth, Virginia 23708

Contracting Activity: Commanding Officer
NAVSUP Fleet Logistics Center Norfolk
1968 Gilbert Street
Norfolk, Virginia 23511-3392

Requisition Number: N0018317RQBL003

2. Description of the Action Being Approved:

The ultimate objective and goal of this procurement is to provide for the continuation of the highest quality patient care through the award of a sole-source, firm fixed price contract to Haemonetics Corporation for donor blood collection bags. The bags are necessary to collect, store, and filter blood by the Naval Medical Center, Portsmouth (NMCP). FLC Norfolk plans to issue a sole-source request for quotation (RFQ) to Haemonetics Corporation for the drop shipment of collection bags required by NMCP. This requirement will be awarded subject to FAR Subpart 13.5 "Simplified Procedures for Certain Commercial Items."

3. Description of Supplies/Services:

This requirement is a follow-on for the drop shipment delivery of Leuko-Reduction Filter Whole Blood collection bags with Sterile Air Venting Elimination (SAVE) Systems for NMCP to be delivered the first working day of each month. The Haemonetics Leuko-Reduction Blood Donor Bag System is a CP2D/AS-3 double blood bag unit with an in-line filter and sample diversion pouch for collection of 450 ml of blood and preparation of red blood cells and plasma with pre-storage leukocyte reduction. These products will be used for whole blood collection from blood donors. The placement of a firm fixed price contract is anticipated. Support is currently being provided under sole source contract N00189-15-P-1282 issued to Haemonetics Corporation, which is set to expire on 30 September 2016. The period of performance is a base year beginning 01 October 2016 through 30 September 2017. The estimated period of performance and dollar value for this procurement is \$ [REDACTED]

4. Identification Of Statutory Authority:

The statutory authority for this action is Section 41 USC 1901(e)(2) - a sole source acquisition under the authority of the simplified procedures for certain commercial items, as implemented by FAR 13.501(a).

5. Rationale Justifying Use of Cited Statutory Authority:

Food and Drug Administration (FDA) license 0635 is an FDA approved license that has been granted to NMCP, within this license are the procedures and measures used for blood collection at the facility. Haemonetics Corporation is the sole manufacturer and distributor of the Leuko-Reduction Whole Blood Collection System with the in-line filter, item #726-92, blood donor bag used in this collection process. This system is designed for the collection of one unit of whole blood and the subsequent storage of blood components. The Leuko-Reduction Donor Bag System is the only bag certified for use by the Food and Drug Administration under license number 635 at NMCP. A different type of bag would require NMCP to go through a re-validation study to ensure that the products collected and processed are leukoreduced to FDA and AABB (American Association of Blood Banks) standards as required by license 0635, which would be a duplication of costs. Re-validation would include collection of a FDA approved amount of whole blood for testing and undergo the FDA validation process. This re-validation process would shut down blood collection for 4 to 6 week. Impact to the Government as a result of any deviation would be significant delays in providing health care or force a shutdown of donor collections by the FDA, jeopardizing the lives of many in need of this whole blood product.

Furthermore, another bag would also require NMCP to perform new training, create new Standard Operation Procedures (SOP) for the Command, and update all forms and processes related to blood collection at NMCP.

6. Description of Efforts Made to Solicit Offers from as Many Offerors as Practicable:

Market research conducted via telephone to known sources found that the suggested vendor is the only one capable of fulfilling the minimum needs of the government for a dual collection system with an in-line WBF filter with the required features, which are unique to this particular bag. This requirement will be synopsisized and the solicitation will be posted on the Navy Electronic Commerce Online (NECO) website.

7. Determination of Fair and Reasonable Cost:

The Procuring Contracting Officer will make a determination of fair and reasonableness of price based upon price analysis in accordance with FAR 13.106-3.

8. Actions to Remove Barriers to Future Competition:

For the reasons set forth in Paragraph 5, FLC Norfolk is unable to compete these types of supplies at this time due to current FDA regulations. If another potential source emerges, they will assess whether competition for future requirements is feasible. All future requirements will be handled on a case-by-case basis. NMCP will continue attending conferences and researching trade publications in search of alternatives to these items meeting FDA certifications. Currently, Haemonetics Corporation remains the only known source capable of meeting the Navy's minimum needs.

9. CONTRACTING POINT OF CONTACT:

The point of contact at NAVSUP Fleet Logistics Center Norfolk is Contract Specialist Donna Curry (757) 443-1256; donna.curry@navy.mil.