JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1

(OVER MICRO-PURCHASE THRESHOLD($3K) BUT NOT EXCEEDING THE SAT ($150K))

IAW FAR13.104, COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW FAR13.106-1(b), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW FAR13.106-3(b)(3),COs are required to include additional statements ***explaining the absence of competition*** (see 13.106-1 for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW FAR13.106-3(b)(3). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER:	**1A. PROJECT/TASK NUMBER**	**1B. ESTIMATED AMOUNT:**
VA256-18-AP-0898		$28,364.98

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

The vendor will provide Overton Brooks VA Medical Center Pharmacy with Medium Risk Validation for 30 employees to include training, written test, media-fill and 1 set of viable fingertip sampling per person/per hand for medium risk for our annual testing.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

Aseptic Enclosures is capable of meeting the timeframe of the OBVAMC without further interruption to Patient care. Of the vendors contacted, they were the only one that was able and willing to provide the service in the timeframe requested.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

The justification rationale is based on FAR Part 13.106-1(b) urgency. It is clinically imperative that the Pharmacy continue the preparation of IV admixtures of simple to complex compounded IV preparations (e.g. large volume and piggyback solutions with additives. Any delay or lapse in production of these compounded IV preparations increases the possibility for injury or reduction in the quality of medical care available to our nation's veterans. This creates the utmost compelling urgency, justifying other than full and open competition.

Change in procedures per Memo dated March 20, 2018 from Acting Assistant Deputy Under Secretary for Health for Clinical Operations indicates the following: If a VA facility laboratory does not have processes in place to conduct USP <797> compliant GFT and MFT testing for personnel involved in the preparation of CSPs, the VA medical facility director must immediately establish a contract with a qualified vendor to perform the required GFT and MFT tests. Prior to this Memo, we had every intention of doing our own media fill and fingertip testing ourselves as we have been doing over the past year. And, we had every intention of doing the annual media fill and fingertip testing ourselves until this memo was released. We just happen to have done our fingertip testing and media fill testing in April of 2017 which puts us in an emergent need of having ours done starting April 16, 2018.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED: We conducted a search of the Vendors who can provide the education and appropriate testing and made contact with them to assess whether they would have the capabilities to take on an emergency contract with the VA to meet our needs. Aseptic Enclosures was contacted and the rep determined the company would be able to perform the needed work.

6. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Signature: Leslie Robinson **Date:** March 29, 2018
Name: Leslie Robinson
Title: **Contracting Officer**
Facility: **NCO (16)**

Department of Veterans Affairs

Memorandum

Date: MAR 20 2018

From: Acting Assistant Deputy Under Secretary for Health for Clinical Operations (10NC)

Subj: Compounded Sterile Preparations (CSPs): Glove Fingertip Sampling (GFT) and Media Fill Test (MFT) Procedure Testing Requirements

To: Veterans Integrated Network (VISN) Directors (10N1-23)

1. The preparation and handling of compounded sterile preparations (CSPs) is a fundamental part of pharmacy practice. The United States Pharmacopeia (USP) Chapter 797 (USP <797>) defines standards for the competency evaluation of garbing and aseptic work practice of personnel who prepare and handle CSPs. The glove fingertip sampling (GFT) and Media Fill Test (MFT) procedures require sampling that includes incubation of the samples at an appropriate temperature for a specific time period that is conducive to multiplication of microorganisms.

2. It has come to my attention that not every VA medical facility has a process in place to conduct the GFT and MFT testing, required by USP <797>, to ensure personnel that prepare CSPs have the appropriate competencies.

3. If a VA medical facility laboratory does not have processes in place to conduct USP <797> compliant GFT and MFT testing for the personnel involved in the preparation of CSPs, the VA medical facility director must immediately establish a contract with a qualified vendor to perform the required GFT and MFT tests. This is an interim measure until a permanent plan is put in place over the coming months.

4. If there are any questions about the GFT and MFT testing required by USP <797>, please contact Puri Subramaniam, PharmD at puri.subra@va.gov.

Teresa D. Boyd, D.O.