

**STATEMENT OF WORK**  
**Pharmacy Clean Room, Bio Safety Cabinet and Fume Hood Certifications**  
**Wilkes-Barre Veterans Affairs Medical Center**

**1. General.** Wilkes Bare Veteran Affairs Medical Center (WB VAMC) has a hospital pharmacy that compounds drugs for use in the facility. The pharmacy has two (2) Medium-Risk Level (CSP) compounding rooms (CB-89B, CB-89C: both are ISO 5 rooms) and attached ante room (CB-89A: ISO 7) located within the pharmacy. Additionally the hospital also uses a glove box isolator located in room 4-152, oncology. The intent of this contract is to have a vendor provide the required testing identified in United States Pharmacopeia (USP) Convention Guidance 797 Pharmaceutical Compounding-Sterile Preparations and USP 800. The WB VAMC has an in-house laboratory that has multiple fume hoods or bio safety cabinets located that need to be inspected and certified semi-annually.

**2. Scope.** The scope of work shall generally consist of, but not necessarily be limited to, providing all labor, materials, tools, equipment, permits, testing, trouble shoot and reports required to test, calibrate and certify. The work will be issued via task order. This task order contract is for one base year and four option years.

2.1 Access: The onsite hours of work are from 8:00 AM to 10:00 PM Monday through Friday; any on site work will have to be previously coordinated and approved via email at least 72 hours prior to any testing. Any work determined by the contracting officer's representative (COR) as having a significant impact on the operations of the facility shall be conducted on an after-hours schedule or limited hours schedule. The Vendor shall follow all federal, state, Veterans Affairs and local code/regulations/standards. The work shall be coordinated through the designated COR.

**2.2 Contractor Qualifications/ Requirements :**

- a. The contractor's field personnel shall have training on fundamental practices and precautions with in USP 797 and operation of ISO 5 clean rooms. (e.g. gowning, gloving, and hand washing procedures) The contractor shall have a current National Environmental Balancing Bureau (NEBB) certification and all final reports shall be stamped and signed with NEBB seal.
- b. The contractor shall be ISO 9001 certified, Quality Management System. Contractor shall in coordination with the WBVAMC Safety and Pharmacy develop a "quality control client agreement" constant with the ISO 9001 requirements.
- c. The contractor shall have its own laboratory for growth and testing micro-bacterial samples. The laboratory shall preform batch sampling of all shipments of growing media plates; too confirm that the plates are sterile from the manufacture.
  - a. Contractor shall include in the "quality control client agreement" to have *provide* a sterile control dish, for all on site Biological testing. The proof dish shall be of the same batch as the test plates and handled/stored in the same manner as the test plates. The sterile control dish is to show the media remained sterile and that there was no cross contamination during the handling or lab processing.

- d. The contractor's Fume Hood, Biological Safety Cabinets (BSC) testing personnel shall have certifications showing knowledge on NSF/ANSI-49.
- e. The contractor shall have the capacity to test the clean room HEPA filters at the air handler via large smoke injection machine in addition to hand held wand for filter bypass testing.
- f. The contractor must maintain a file sharing website / web based application that will maintain test results and reports for at least 8months for the government to access and download.
- g. The contractor shall issue a certification certificate (PDF) to show that the VA has passed a specific test with respect to the requirements of USP 797 and or USP 800. The Certificate will show the test date and the expiration date and be signed by the company's quality control department or company officers with the appropriate training/education to make such a declaration. Chemical hoods and BSC in the Lab may have a certification sticker applied directly to the equipment rather than an 8.5 by 11" PDF certificate.

### **3. Task Order Service Schedule**

<b>Price Schedule of Service</b>		
<b>Item #</b>	<b>Description of Service</b>	<b>Location (rooms/space)</b>
1	USP 797 Room AIR testing <sup>Note 1</sup>	Existing Pharmacy clean rooms (CB-89A, 89B, 89C)
2	USP 797 Biological testing <sup>Note 2</sup>	Existing Pharmacy clean rooms (CB-89A, 89B, 89C)
3	USP 797 Room AIR testing (Isolator room) <sup>Note 3</sup>	Existing Oncology / Glove Box Isolator (4-152)
4	USP 797 Biological testing (Isolator & room) <sup>Note 4</sup>	Existing Oncology / Glove Box Isolator (4-152)
5	USP 797 & 800 Room AIR testing <sup>Note 5</sup>	Existing Pharmacy clean rooms (CB-89A, 89B, 89C, HD storage location)
6	USP 797 & 800 Biological testing <sup>Note 6</sup>	Existing Pharmacy clean rooms (CB-89A, 89B, 89C)
7	USP 797 & 800 Room AIR testing (Isolator room) <sup>Note 7</sup>	Existing Oncology / Glove Box Isolator (4-152)
8	USP 797 & 800 Biological testing (Isolator & room) <sup>Note 8</sup>	Existing Oncology / Glove Box Isolator (4-152)
9	USP 797 & 800 Room AIR testing New Clean Rooms <sup>Note 9</sup>	New Pharmacy clean rooms (Not yet constructed, estimated construction in 2019)

10	USP 797 & 800 Biological testing New Clean Rooms <sup>Note 10</sup>	New Pharmacy clean rooms (Not yet constructed, estimated construction in 2019)
11	USP 797 & 800 Professional consultation (1 Man-days)	WBVAMC - TBD
12	USP 797 & 800 Professional consultation (2 Man-days)	WBVAMC - TBD
13	Preform analysis to determine species of CFU found during Biological testing	Contractor Lab
14	Certification of Fume Hood	WBVAMC - TBD
15	Certification of Biological Safety Cabinet	WBVAMC - TBD
16	Repair filter, gasket or fan motor on Hood or BSC	WBVAMC - TBD

**Note 1 -797 Room AIR testing** includes but not limited to the following: Shall test and validate the number of air changes per hour through the rooms, test and validate that the hood and room exhaust provide a unidirectional/laminar air flow as required to prevent contamination, inspect HVAC filter assembly for air bypass issues that would cause contamination (smoke injection to be done at the AHU), differential pressure testing/monitoring, particulate air sampling, testing the BSCs and hood (inside clean room) to certify that the units meet the original manufactures specifications and for air flow velocity, installation, aerosol leak, smoke pattern test, noise, ultraviolet light, down flow velocity profile, inflow velocity (with & without reduced opening) and airborne particle count. The contractor shall preform Hood /BSC certification / test as prescribed by NEBB, NSF, ANSI publications and standards. The intent of this "797 room AIR" section is to test and meet all of the USP 797 requirements for physical safety standards to include air particle counts.

**Note 2 - USP 797 Biological** testing includes but not limited to the following: Shall develop a sample plan in coordination with the VAMC but not less than 16 wipe samples and 6 viable air samples in the pharmacy clean rooms (e.g. a minimum 16(wipe) and 6(air) samples to be split among the 3 rooms dependent on the sample plan). The contractor shall provide sterile control dish to demonstrate that no cross-contamination during processing (one wipe and one air). The intent of this "797Biological testing" section is to test and show that the facility meets all of the USP 797 requirements for Pharmaceutical Compounding-Sterile Preparations with respect to Biological sampling.

**Note 3 -797 Room AIR** (Isolator room) testing includes but not limited to the following: Shall test and validate the number of air changes per hour through the room, test and validate that the hood and room exhaust provide a unidirectional/laminar air flow as required to prevent contamination, inspect glove box filter assembly for air bypass issues that would cause contamination, differential pressure

testing/monitoring, particulate air sampling, testing the glove box isolator to certify that the units meet the original manufactures specifications and for air flow velocity, installation, aerosol leak, smoke pattern test, noise, ultraviolet light, down flow velocity profile, inflow velocity (with & without reduced opening) and airborne particle count. The contractor shall preform glove box isolator certification / test as prescribed by NEBB, NSF, ANSI publications and standards. The intent of this "797 room AIR (Isolator room) " section is to test and meet all of the USP 797 requirements for physical safety standards as it relates to the formulation of hazardous drugs in a glove box isolator.

**Note 4 - USP 797 Biological (Isolator room) testing** includes but not limited to the following: Shall develop a sample plan in coordination with the VAMC but not less than 4 wipe samples and 2 viable air samples in room 4-152. The contractor shall provide sterile control dish to demonstrate that no cross-contamination during processing (one wipe and one air). The intent of this "797 Biological testing (Isolator room)" section is to test and show that the facility meets all of the USP 797 requirements for Pharmaceutical Compounding-Sterile Preparations with respect to Biological and contamination sampling.

**Note 5 - USP 797 & 800 Room AIR testing** includes but not limited to the following: Shall test and validate the number of air changes per hour through the rooms, test and validate that the hood and room exhaust provide a unidirectional/laminar air flow as required to prevent contamination, inspect HVAC filter assembly for air bypass issues that would cause contamination (smoke injection to be done at the AHU), differential pressure testing/monitoring, particulate air sampling, testing the BSCs and hood (inside clean room) to certify that the units meet the original manufactures specifications and for air flow velocity, installation, aerosol leak, smoke pattern test, noise, uv light, down flow velocity profile, inflow velocity (with & without reduced opening) and airborne particle count. The contractor shall preform Hood /BSC certification / test as prescribed by NEBB, NSF, ANSI publications and standards. The contractor shall inspect and certify the HD storage room for proper environmental controls identified in USP 800. The intent of this "797 & 800 room AIR" section is to test and meet all of the USP 797 & 800 requirements for physical safety standards to include air particle counts.

**Note 6 - USP 797 & 800 Biological testing** includes but not limited to the following: Shall develop a sample plan in coordination with the VAMC but not less than 16 wipe samples and 6 viable air samples in the pharmacy clean rooms (e.g. a minimum 16(wipe) and 6(air) samples to be split among the 3 rooms dependent on the sample plan). The contractor shall provide sterile control dish to demonstrate that no cross-contamination during processing (one wipe and one air). The intent of this "797&800 Biological testing" section is to test and show that the facility meets all of the USP 797 & 800 requirements for Pharmaceutical Compounding-Sterile Preparations with respect to Biological and contamination sampling.

**Note 7 -797 & 800 Room AIR (Isolator room) testing** includes but not limited to the following: Shall test and validate the number of air changes per hour through the room, test and validate that the isolator and room exhaust provide a filtered/unidirectional/laminar air flow as required to prevent contamination, inspect glove box filter assembly for air bypass issues that would cause contamination, differential pressure testing/monitoring, particulate air sampling, testing the glove box isolator to certify that the units meet the original manufactures specifications and for air flow velocity, installation, aerosol leak, smoke pattern test, noise, ultraviolet light, down flow velocity profile, inflow velocity and airborne particle

count. The contractor shall preform glove box isolator certification / test as prescribed by NEBB, NSF, ANSI publications and standards. The intent of this "797 & 800 room AIR (Isolator room) " section is to test and meet all of the USP 797 requirements for physical safety standards as it relates to the formulation of hazardous drugs in a glove box isolator.

**Note 8 - USP 797 & 800 Biological (Isolator room) testing** includes but not limited to the following: Shall develop a sample plan in coordination with the VAMC but not less than 4 wipe samples and 2 viable air samples in room 4-152. The contractor shall provide sterile control dish to demonstrate that no cross-contamination during processing (one wipe and one air). The intent of this "797 Biological testing (Isolator room)" section is to test and show that the facility meets all of the USP 797 requirements for Pharmaceutical Compounding-Sterile Preparations with respect to Biological and contamination sampling.

**Note 9 - USP 797 & 800 Room AIR testing New Clean Rooms** includes but not limited to the following: Shall test and validate the number of air changes per hour through the rooms, test and validate that the hood and room exhaust provide a unidirectional/laminar air flow as required to prevent contamination, inspect HVAC filter assembly for air bypass issues that would cause contamination (smoke injection to be done at the AHU), differential pressure testing/monitoring, particulate air sampling, testing the BSCs and hood (inside clean room) to certify that the units meet the original manufactures specifications and for air flow velocity, installation, aerosol leak, smoke pattern test, noise, ultraviolet light, down flow velocity profile, inflow velocity (with & without reduced opening) and airborne particle count. The contractor shall preform Hood /BSC certification / test as prescribed by NEBB, NSF, ANSI publications and standards. The contractor shall inspect and certify the HD storage room for proper environmental controls identified in USP 800. The intent of this "797 & 800 room AIR" section is to test and meet all of the USP 797 & 800 requirements for physical safety standards to include air particle counts.

**Note 10 - USP 797 & 800 Biological testing New Clean Rooms testing** includes but not limited to the following: Shall develop a sample plan in coordination with the VAMC but not less than 20 wipe samples and 10 viable air samples in the pharmacy clean rooms (e.g. a minimum 16(wipe) and 6(air) samples to be split among the 4 rooms dependent on the sample plan). The contractor shall provide sterile control dish to demonstrate that no cross-contamination during processing (one wipe and one air). The intent of this "797&800 Biological testing" section is to test and show that the facility meets all of the USP 797 & 800 requirements for Pharmaceutical Compounding-Sterile Preparations with respect to Biological and contamination sampling.