DESCRIPTION / SPECIFICATION / WORK STATEMENT

STATEMENT OF WORK PART A – GENERAL INFORMATION

A.1 INTRODUCTION: This requirement is for testing and certification of all National VA Office of Emergency Management (OEM) mobile Pharmacy Pod's primary engineering controls (PECs) and secondary engineering controls (SECs) used for preparation of Compounded Sterile Preparations (CSPs). PECs include a biological safety cabinet (BSC), laminar airflow workstations (LAFW) also commonly referred to as Laminar Flow Hoods and may contain a compounding aseptic containment isolator (CACI) and compounding aseptic isolator (CAI). SECs include a non-hazardous Segregated Compounding Area (SCA) and hazardous Containment Segregated Compounding Area (C-SCA). Testing and certification will be completed in accordance with United States Pharmacopeia (USP) Chapter <797> and Chapter <800> guidelines and the Controlled Environmental Testing Association (CETA) Application Guides (CETA CAGs).

A.2 BACKGROUND: VA is pursuing nationwide contract for standardizing PEC testing for each OEM Pharmacy Pod deployment pursuant to USP Chapter <797>, USP Chapter <800> and CETA CAG standards using CETA Certified National Board of Testing (CNBT) certified individuals and companies to establish consistent PEC certification procedures. Although USP <797> states that certification procedures "such as" those outlined CAG-003-2006 shall be performed, OEM will be requiring that CAG-003-2006 be used in lieu of any other "such as" procedures that may exist.

The USP establishes standards for compounding area designs, environmental monitoring, and competencies for the preparation, handling, and storage of CSPs. The Joint Commission (TJC) Accreditation Manual for Home Care, effective January 13, 2018, established new Medication Compounding (MC) standards for non-sterile and sterile compounded preparations which are based on USP standards. The Food and Drug Administration (FDA) has the authority to inspect VA medical facilities under the Draft Guidance on "Insanitary Conditions at Compounding Facilities" which was published in November 2020.

Certification procedures defined in CETA CAG-003-2006 shall be performed by a CETA CNBT certified testing individual no less once a year or up to 6 times a year whenever the OEM Pharmacy Pod is relocated, altered, or has major service to the PEC(s) or SEC(s).

A.3 SCOPE OF WORK:

A.3.1 NSF 49 Field Testing Requirements for Biological Safety Cabinets
The contractor shall certify all Class II biosafety cabinets to the current version (2016 or higher) of NSF/ANSI 49, Annex F specifications. All equipment used to certify biological safety cabinets shall have National Institute of Standards and Technology (NIST) traceable or comparable calibration certification. Any unit that fails to meet NSF 49 specifications shall be clearly marked with a sign that will notify pharmacy staff that the unit is out of order until further

notice. In addition, any failures shall be reported directly to identified point(s) of contact (POC) as soon as practicable.

For each PEC passing the required certification tests, the contractor will supply the unit with a certification sticker with the following information:

- Company name and address
- Unit make, model and serial number
- Report number
- Location
- Certification date
- Recertification date
- Technician signature

A.3.2 PEC Testing and Certification

The contractor shall test and certify each PEC to the most current version of IEST RP CC002 (Unidirectional-flow, clean-air devices) and to the manufacturer's specifications. The contractor shall use a NIST traceable or comparable calibrated piece of equipment to perform all testing. The contractor shall report each individual face velocity reading and the average of those readings, the downstream concentration reading of the HEPA filter leak test and the results of the induction leak test and back streaming test. Any failures shall be reported directly to the identified site point of contact(s) as soon as practicable.

Horizontal laminar flow hoods shall be certified according to The Institute of Environmental Sciences RP-CC-002 Testing Laminar Air Flow Devices. All certifications for Biological Safety Cabinets (BSCs) must be accomplished in accordance with the most current National Sanitation Foundation/American National Standards Institute (NSF/ANSI) Standard 49 Class II (laminar flow) Biosafety Cabinetry. The list of tests includes, but is not limited to:

- HEPA filter leak test
- Cabinet leak test
- Inflow velocity test to include exhaust airflow volume rate
- Airflow Smoke pattern test
- Electrical leakage and ground circuit resistance and polarity tests
- Lighting intensity test
- Vibration test
- Noise level test
- Ultraviolet (UV) lamp test if applicable

Laminar Flow Hoods certifications must be accomplished in accordance with the most current version of the National Sanitation Foundation/American National Standards Institute (NSF/ANSI) Standard 49 Class II Biosafety Cabinetry, Annex F, test method A-D, 1992 or most current issue.

For each PEC passing the required certification tests, the contractor will supply each unit with a certification sticker with the following information:

- Company name and address
- Unit make, model and serial number
- Report number
- Location
- Certification date
- Recertification
- Technician name and signature

A.3.3 Viable and Non-viable Particle Counts

For the PECs, non-viable particle counts samples will be collected and viable samples may be collected. When the viable sample work order is submitted, they will be collected for each device (both bacterial and fungal) for the air and surface in accordance with USP <797>. Refer to the description of these tests in the section A.3.5.3 and A.3.5.4 for details.

A.3.4 USP<800> Testing for mobile Pharmacy Pod Containment-Segregated Compounding Area

The contractor will provide comprehensive room testing and certification services once a year and up to 6 times a year:

- Airflow profiling and uniformity testing
- Room pressurization monitoring (negative pressure in range of 0.01-0.03 w.c.)
- Temperature and Humidity monitoring
- Air pattern analysis
- Environmental Sampling -Viable surface and air impaction when requested
- Written Report

A.3.4.1 Air Changes per Hour (ACPH)

The contractor shall calculate the total room volume for the C-SCA. A sketch of the room with dimensions, exhaust/supply diffuser locations and equipment locations shall be included in the report. The report provided will specify flow rates detailing returns and supply that were obtained during the testing. The contractor shall calculate air changes per hour (ACPH) for the C-SCA and include their findings in the report. The air changes per hour must not be less than 12 ACPH. In the event the C-SCA does not meet USP<800> requirements for ACPH the identified site POC(s) shall be informed immediately.

A.3.4.2 Pressure Requirements

The contractor shall include in their report differential pressure readings from the C-SCA room to all surrounding areas. The report shall indicate whether the room is required to be a negative or positive pressure room per USP<800>. The contractor shall report all pressures to an accuracy of 0.0001" water column (4 decimal places). Pressure differentials will be reflected on a report showing the sketch of the room(s). The pressure for the C-SCA shall have negative pressure within a range of 0.01-0.03 w.c.

A.3.4.3 Viable Environmental Sampling within the PEC's

- The contractor shall perform viable environmental (air and surface) sampling when requested for fungi and bacteria using high volume impaction samplers to conduct the sampling.

- Air sampling: A sufficient volume of air (1000 liters) shall be tested at each location in order to maximize sensitivity. Samples of less than 1000 liters will not be acceptable.
- Surface Sampling: The contractor shall perform surface samples for bacteria using Tryptic Soy Agar (TSA) contact plates and Malt Extract Agar (MEA) or Sab DEX contact plates for sampling of fungi. Surface sampling will be performed at the end of the day.
- Any laboratory results equal to or greater than the action levels will require notification to the POC(s) immediately upon receipt of results.
- Reports to include at a minimum:
    - Date and time sampling was taken.
    - Environmental sampling reports will contain both the quantitative number of bacterial/fungal isolates as well as the species grown.
    - Media lots used for samples
    - Comments indicating when dynamic conditions were used
    - Certificates of analysis of media used
    - Sketch identifying location of each sample obtained

A.3.4.4 Nonviable Particle Testing within the PEC's

The contractor shall perform environmental nonviable particle testing once a year up to 6 times per year. The contractor shall derive the minimum number of sampling locations using Annex A in the ISO 14644-1.2 standard. Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following:

- ISO Class 5: not more than 3520 particles 0.5 μm and larger size per cubic meter of air for any area primary engineering control (BSC or LAFW).

Report Requirements: All of the following information should be included in the report for clean room certification. Pass/Fail notifications must be included on a per-test basis where applicable.

- Executive summary or summary of findings.
- Location
- Room type (e.g. SCA or C-SCA)
- Date of testing
- Date of next required certification
- Standards used to test room
- Notes
- Room sketch (location of supply/exhaust diffusers, equipment, room dimensions)
- Total room area and volume
- Room humidity and temp
- Air changes per hour
- Pressure differential
- Nonviable particle counts
- Viable particle count analysis when requested
- Picture of viable particle test location in room

A.3.4.5 Report Distribution

The contractor will immediately notify identified points of contact with any results indicating failure. A formalized written report including all required aspects specified in this Statement of Work will be provided in a timely manner with receipt by identified points of contact no more than 14 days from certification evaluation.

All completed reports will be provided via email to VHAPBMPharmacyCompliance@va.gov.

Contractor will be notified by facility where the Pharmacy Pod is deployed of any updates to identified points of contact on an as needed basis.

Testing Frequency:

- Certification procedures defined in CETA CAG-003-2006 shall be performed by a CETA National Board of Testing (CNBT) certified testing individual/company no less than once a year or whenever the OEM Pharmacy Pod is relocated, altered or when major service to the sterile compounding PEC(s) or SEC(s) is performed.
- Environmental sampling (air and surface) will be completed as requested up to 6 times a year (more frequent testing may be requested if required to assess corrective actions associated with prior negative results).

STATEMENT OF WORK PART C – SUPPORTING INFORMATION

C.1 Place of Performance: The testing requirements will be for one OEM Pharmacy Pod that will require certification testing to be completed at any destination in the United States or Puerto Rico where it may be deployed.

Specific OEM Pharmacy Pod PEC and SEC Information:

	1	2
Physical Location	SCA	C-SCA
Manufacturer	Germfree	Germfree
Model Number	BZ3-SSRX	BBF-3SSRX
Serial Number	3S-15-BH-20252	3S-15-BR2-20253
Make	LAFW	Class II Type A2
EE#	NA	NA

Sterile Compounding Rooms:

- Non-Hazardous SCA (unclassified air)
- Hazardous C-SCA (unclassified air), however, must meet USP <800> ACPH and negative pressure requirements.

Changes to PEC(s) or SEC(s) will be communicated in a timely manner to contractor and facility, costs will be adjusted accordingly based on these changes. Contractor to provide unit based costs for services to allow for adjustments in equipment.

C.2 Period of Performance: Contract period is from date of award for five (5) years. Performance is to begin 15 calendar days from date of award.

C.3 Special Considerations:

C.3.1 Contractor Furnished Materials:

- All materials and tools to complete the work identified.
- Contractor to ensure all staff that perform on-site testing arrive wearing non-shedding clothing.
- Contractor to ensure all staff performing these tests will be trained in and wearing the appropriate personal protective equipment (PPE) prior to accessing the PEC.
- Contractor shall ensure personnel conducting these tests have been appropriately trained and have documented competency (which shall be made available upon request).

C.3.2 Government Furnished Materials and Services:

- The Government will provide all necessary personnel protective equipment (PPE) required for contractors on site.
- The Government will provide oversight and verification of contractor personnel completion of donning of PPE and hand hygiene prior to testing/sampling.
- The Government will, on rare occasion, provide office or meeting space to discuss test results, projects, or plans.
- May also provide desk phone service as needed.

C.3.3 Qualifications of Key Personnel: VA OEM is seeking a qualified contractor that meets the following specifications:

- Provide three references showing the completion of at least 3 jobs of similar size and scope at other facilities located throughout the United States.
- All certifications must be signed by an NSF 49 certified technician. A copy of NSF 49 certifications must be attached to the bid documentation for any technicians that will be performing the work.
- All PEC and SEC performance testing must be supervised by a technician with a CETA National Board of Testing (CNBT) certification. A copy of the certification must be attached to the bid documentation for the supervisor or project manager of the team that will be performing work at the facility.
- Provide AIHA accredited laboratory certification for all USP<797> viable sampling analysis. Certification must be attached with bid documentation.
- Provide copy of clean room certification report for evaluation.

C.3.4 Security Requirements: There are no security requirements required for this work, as samples are retrieved by the vendor and a test report is received in return.

C.3.5 Additional Considerations

The contractor (or Representative) shall contact the VA identified POC(s) to schedule work and prior to the beginning of work. Scheduling of work will be at the direction of facility identified POC(s) to ensure services are incorporated into current facility certification cycles.

Local facility POC(s) will provide the contractor with additional facility specific procedures which include check in and check out procedures; contractor badging requirements; parking procedures; and any additional facility specific procedures. The contractor will be expected to adhere to those procedures. Services are to be performed with 3 days of request due to the necessity of this unit to be deployed to areas of expedient need. Contractors that are willing to perform after-hours or weekend work should include this information in their bid documentation. If a contractor is willing to perform services after 4:00pm EST or on weekends or federal holidays this service must be included within the bid pricing as no extra charge. The ability to perform work after hours is not required; however, preferences will be given to contractors that offer flexible work hours.

C3.6 Invoicing

Payment will be made monthly in arrears, invoices will be prepared by the Contractor, and submitted through Tungsten Network (formerly known as OB10) http://www.tungstennetwork.com/us/en/. A properly prepared invoice shall contain:

- Invoice Number and Date
- Contractor's Name and Address
- Accurate Purchase Order Number
- Supply or Service provided
- Period Supply or Service Provided
- Total Amount Due

Contractor questions about the e-invoicing program (Tungsten Network), contact information is as follows:

- Tungsten e-Invoice Setup Information: 1-877-489-6135
- Tungsten e-Invoice email: VA.Registration@Tungsten-Network.com
- FSC e-Invoice Contact Information: 1-877-353-9791
- FSC e-invoice email: vafsccshd@va.gov

Web Address: HTTP://WWW.FSC.VA.GOV/EINVOICE.ASP

The contractor will provide an electronic copy of each invoice to the identified POC(s) referenced in A.3.5.6

C.3.7 Liable Insurance Requirements: None