Scope of Work

Pharmacy IV Prep Area Microbiological Monitoring for USP 797 Compliance

***\*Note that this sample has been revised from the source document on the Government Point of Entry as necessary to align formatting and applicable FAR procedures.\****

**1. Background:** The Ralph H. Johnson Veterans Affairs Medical Center (RHJ VAMC) has a pharmacy on the first floor with a cleanroom suite consisting of two ISO Class 7 buffer rooms, one ISO Class 7 chemotherapy anteroom, and one ISO Class 8 anteroom. Within the buffer rooms include three ISO Class 5 cabinets: two Laminar airflow workbenches (LAFWs) in the main buffer room and one Class II Biologic Safety Cabinet (BSC) in chemotherapy buffer room. Microbiological sampling of IV hoods (ISO Class 5), buffer rooms (ISO Class 7) and anterooms (ISO Class 8) is required by United States Pharmacopeia, chapter 797: *Pharmacy Compounding – Sterile Preparations* (USP 797), VHA Directive 1108.12: *Management and Monitoring of Compounded Sterile Preparations*, and VA information letter 10-2006-008. Additionally, the RHJ VAMC is undergoing construction for a new cleanroom suite that will add one additional ISO Class 5 Class II BSC. Anticipated completion of the new cleanroom suite is Fall 2020. The sampling strategy recommended by the revised 2019 USP 797 should be followed for all air and surface samplings for bacterial and fungal growth.

The revised 2019 USP 797 recommends volumetric air sampling of all classified areas using an impaction device at least every 6 months. The revised 2019 USP 797 also recommends surface sampling of all classified areas and pass-through chambers connecting classified areas to be conducted at least monthly. According to USP 797, fungi and bacteria are not expected to be present in ISO Class 5 areas. The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained.

**2. Scope:** The contractor shall perform volumetric active air sampling of all classified areas using an impaction device and must be conducted in each classified area **quarterly** for fungi and bacteria at selected sampling sites. The following requirements must be met when performing air sampling:

* Sampling is conducted during dynamic operating conditions.
* Avoid disturbing unidirectional airflow, when conducting sampling of a primary engineering control (PEC).
* Follow all manufacturer’s instructions for operation of the active air sampling device, including placement of media.
* Use of high volume sampling pumps capable of achieving and maintaining the required flow rate of 28 liters per minute and impaction samplers to conduct the sampling. A sufficient volume of air (> 1000 liters) shall be tested at each location in order to maximize sensitivity.
* A general microbial growth media that supports growth of bacteria and fungi must be used. The contractor shall use Tryptic Soy Agar (TSA) contact plates for bacteria samples and Malt Extract Agar (MEA) or sabouraud dextrose agar (SDA) contact plates for fungal samples.
* Certificated of Analysis from the manufacturer must verify that the media meets the expected growth promotion, pH, and sterilization requirements.
* The media devices must be retrieved and covered, at the end of sampling
* Samples must be incubated in an incubator, at temperatures that will promote growth of bacteria and fungi.
* The incubator temperature must be monitored during incubation, either manually or by continuous recording device.
* Invert the TSA contact plates and incubate at 30-35 degrees Celsius for no less than 48 hours. Record the total number of discrete colonies of microorganisms on each media device as colony forming units (cfu) per cubic meter of air.
* Invert the MEA or SDA contact plates and incubate at 20-25 degrees Celsius for no less than 5 days. Record the total number of discrete colonies of microorganisms on each media device as colony forming units (cfu) per cubic meter of air.

The contractor shall perform surface sampling of all classified areas and pass-through chambers connecting to classified areas for microbial contamination **monthly** for fungi and bacteria at selected sampling sites. The following requirements must be met when performing surface sampling:

* Surface sampling is performed at the end of compounding activity or shift, but before the area has been cleaned and disinfected.
* Surface sampling devices must have a raised convex surface.
* A general microbial growth media that supports growth of bacteria and fungi must be used. The contractor shall use TSA contact plates for bacteria samples and MEA or SDA contact plates for fungal samples. The growth media must be supplemented with neutralizing additives to neutralize the effects of any residual disinfecting agents.
* Sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult to reach locations.
* Certificated of Analysis from the manufacturer must verify that the media meets the expected growth promotion, pH, and sterilization requirements.
* When performing the surface sampling, using a rolling motion, firmly press the media surface onto the surface to be sampled. Cover each surface sample device at the end of each sampling.
* After surface sampling, the sampled area must be thoroughly cleaned and disinfected by the contractor with RHJ VAMC approved cleaner and 70% isopropyl alcohol (IPA), in accordance with RHJ VAMC policy.
* Samples must be incubated in a calibrated incubator at temperatures that will promote growth of bacteria and fungi.
* The incubator temperature must be monitored during incubation, either manually or by continuous recording device.
* Store media devices during incubation in a manner to prevent condensation from dropping onto the agar and affecting the accuracy of the cfu reading.
* Incubate the surface sample TSA contact plates and incubate at 30-35 degrees Celsius for no less than 48 hours. Record the total number of discrete colonies of microorganisms on each media device as colony forming units (cfu) per cubic meter of air.
* Incubate the surface sample MEA or SDA contact plates and incubate at 20-25 degrees Celsius for no less than 5 days. Record the total number of discrete colonies of microorganisms on each media device as colony forming units (cfu) per cubic meter of air.

In addition to the routine air and surface sampling described above, the contractor shall perform ad hoc air or surface sampling at the request of RHJ VAMC. Reason for ad hoc air and surface sampling include, but are not limited to:

* In conjunction with certification of new facilities or equipment
* After servicing of facilities or equipment
* In response to identified problems
* In response to identified trends
* In response to changes that could impact the sterile compounding environment

**3. Task:** An appropriate environmental air and surface sampling plan shall be developed by the contractor for airborne and surface sampling viable particles that is in compliance with the revised 2019 USP 797. The sampling plan must be designed and conducted in a manner that minimizes the chance that the sampling itself will contribute to contamination of the CSP or the environment. Air sampling shall be conducted in each classified area identified by RHJ VAMC during dynamic conditions. Surface sampling shall be performed in each classified area at locations identified by RHJ VAMC at the end of compounding activities or shift. The identified surface sample locations are the interior of the PEC and the equipment contained in it, staging or work areas near the PEC, frequently touched surfaces, and other areas prone to contamination during compounding activities and during other activities such as labeling, gowning and cleaning. The contractor shall perform the following samples:

1. Bacteria air sample analysis
2. Fungi air sample analysis
3. Bacteria surface sample analysis
4. Fungi surface sample analysis
5. Prepare and submit laboratory test

Sample Locations:

Cleanroom Suite

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| **Location** | **ISO Class** | **Sample Type** | **Analysis** |
| PEC, inside LAFW #1, left side | 5 | air/surface | fungi and bacteria |
| PEC, inside LAFW #1, right side | 5 | air/surface | fungi and bacteria |
| TPN Compounder Equipment, inside LAFW | 5 | surface | fungi and bacteria |
| PEC, inside LAFW #2, left side | 5 | air/surface | fungi and bacteria |
| PEC, inside LAFW #2, right side | 5 | air/surface | fungi and bacteria |
| IV Buffer Room, near door | 7 | air | fungi and bacteria |
| IV Buffer Room, worktable | 7 | surface | fungi and bacteria |
| Pass-through, IV Buffer Room to Workroom | 7 | surface | fungi and bacteria |
| Anteroom, worktable inside clean side of line of demarcation | 7 | surface | fungi and bacteria |
| Anteroom, inside of clean side of line of demarcation | 7 | air | fungi and bacteria |
| Workroom, near door | 8 | air | fungi and bacteria |
| Workroom, worktable near door | 8 | surface | fungi and bacteria |
| PEC, inside BSC #1, center | 5 | air | fungi and bacteria |
| PEC, inside BSC #1, left side | 5 | surface | fungi and bacteria |
| PEC, inside BSC #1, right side | 5 | surface | fungi and bacteria |
| PEC, inside BSC #2, center | 5 | air | fungi and bacteria |
| PEC, inside BSC #2, left side | 5 | surface | fungi and bacteria |
| PEC, inside BSC #2, right side | 5 | surface | fungi and bacteria |
| Chemo Buffer Room, near door | 7 | air | fungi and bacteria |
| Chemo Buffer Room, worktable | 7 | surface | fungi and bacteria |

**3.1. Performance**: Perform all microbiological sampling for the RHJ VAMC pharmacy clean room suite in compliance with USP 42 – NF 37 General Chapter 797, *Pharmaceutical Compounding-Sterile Preparations* standards, VHA Directive 1108.12 *Management and Monitoring of Compounded Sterile Preparations,* and VA information letter 10-2006-008.

1. All samples shall be analyzed by a laboratory accredited by AIHA in Environmental Microbiology. Sampling results will be compared to recommendation provided in the revised 2019 USP 797 guidance document. All samples should be brought to the laboratory with minimal delay (e.g. same day or shipped overnight) to prevent potential contamination.
2. Each sampling session will be conducted during normal business hours, Monday thru Friday 8 AM thru 4:30 PM. Each session will be scheduled at least 5 working days in advance and is subject to the workload of the pharmacy and should be coordinated by the Associate Chief, Inpatient Pharmacy. Each session will be scheduled with Christina A. Delp, Industrial Hygienist, who will serve as the contracting officer’s technical representative (COR).
3. For any measured levels of growth for air or surface sampling, an attempt must be made to identify any microorganism recovered to the genius and species level with assistance of a microbiologist.
4. Any laboratory results greater than the action level will require notification of the COR immediately upon receipt of results. Laboratory results of these levels or above will require resampling to be performed after action deemed appropriate by the Associate Chief of Inpatient Pharmacy has been taken to correct the microbiological growth. Resampling for the areas at or above the action levels may be required in as little as 24 hours from notification by the COR.

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| **Sample Type** | **Location** | **ISO Class** | **Action Level** |
| Air Sample | Inside PEC (LAFW or BSC) | 5 | >1 cfu/m3 |
| Air Sample | Buffer Room or Chemo Anteroom | 7 | >10 cfu/m3 |
| Air Sample | Anteroom | 8 | >100 cfu/m3 |
| Surface Sample | Inside PEC (LAFW or BSC) | 5 | >3 cfu/device |
| Surface Sample | Buffer Room or Chemo Anteroom | 7 | >5 cfu/device |
| Surface Sample | Anteroom | 8 | >50 cfu/device |

Note 1: If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each device media.

Note 2: Action level for fungi and bacteria

Note 3: cfu/m3 = colony forming unit per cubic meter (1000 liter) of air per plate

**4. Reports:** A written report will be issued for each sampling session and an electronic copy via e-mail provided to COTR, within 10 days of the receipt of laboratory results. Each session’s report will include at a minimum:

* Date and time of sampling
* Name and signature of Certified Industrial Hygienist performing the sampling
* Date samples received to laboratory
* Date samples analyzed
* Name and signature of Lab Manager (or other approved signature)
* Date reported
* Name and signature of Certified Industrial Hygienist preparing the report
* Narrative of work practices used
* Results of sampling
* Location where samples were collected, including diagram of sampling locations
* Narrative interpretation of laboratory results
* Recommendations based on the results of the sampling
* Any limitations with sampling methods, analysis, or results.
* Comparison chart or table showing results of all quarterly sampling by date and sample location
* Laboratory results
* Closed chain of custody.

The following documentation must be available at request of the COTR or Associate Chief of Inpatient Pharmacy, via email, within 5 days of the request:

* Certificate of Analysis from the manufacturer verifying that the air and surface sampling media devices used meet the expected growth promotion, pH, and sterilization requirements.
* Incubator temperature monitoring log for the duration of air and surface sampling incubation period.
* Service and calibration records for all equipment used during air and surface sampling collection and incubation.

**5. Personnel Qualifications:** This sampling shall be performed and the report prepared by an Certified Industrial Hygienist (CIH) certified by the American Board of Industrial Hygiene (ABIH). Testing personnel are trained in proper operations of the air and surface sampling equipment to ensure accurate and reproducible sampling. Per revised 2019 USP 797, an effective microbiological air and surface monitoring program identifies quality trends over time. The contractor needs to be familiar with the RHJ VAMC pharmacy cleanroom suite and has access to past microbiological air and surface sampling results.

**6. Contractor Qualification:**  Thecontractor shall have at least 3 year of successful Veterans Affairs experience in conducting USP 797 pharmacy cleanroom sterile environment sampling in a tertiary or higher level medical center. Due to the timeliness of sampling, ad hoc sampling, and possible resampling, the contractor must be able to facilitate unplanned sampling or resampling based on unacceptable results within 24 hours of request. To minimize the risk of contamination and to prevent delays in reporting, the samples must be shipped overnight to the AIHA certified environmental microbiology laboratory for receipt the next morning and immediate incubation.

The contractor shall provide two comparable example projects to demonstrate experience with similar work. Example project information should include the type/number of hoods/rooms work experience conducted over the past 5-10 years, as well as specific information on the type and size of facilities where work was performed, and the services provided. Experience shall be verified by having at least two pharmacy clean room references forwarded directly to the contracting officer.

**7. Equipment:** Contractor shall utilizing appropriate air sampling pumps that are capable of achieving and maintaining the required flow rate of 28.3 liters per minute (LPM), Anderson N-6 impactor or equivalent, Tryptic Soy Agar (TSA) and Malt Extract Agar (MEA) plates or Sabouraud Dextrose Agar (SDA), and appropriate sterile sampling swabs or equivalent. All air sampling devices must be serviced and calibrated as recommended by the manufacturer.

**8. Place of Performance:** Ralph H. JohnsonVA Medical Center Charleston, 109 Bee Street, Charleston, SC 29401.

**9. Period of Performance**:

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| 2020 (Base year) | 1 August 2020– 31 July 2021 |
| 2021 (Option year 1) | 1 August 2021– 31 July 2022 |
| 2022 (Option year 2) | 1 August 2022– 31 July 2023 |
| 2023 (Option year 3) | 1 August 2023– 31 July 2024 |
| 2024 (Option year 4) | 1 August 2024– 31 July 2025 |

**10. Contract Performance Monitoring:**

The government reserves the right to monitor services in accordance with Performance Based Matrix.

**11. Invoices:**

Payment will be made upon receipt of a properly prepared detailed invoice, prepared by the Contractor, validated by the Contracting Officer’s Technical Representative (COTR), and submitted to VA FSC, P. O. BOX 149971, AUSTIN, TX 78714.

A properly prepared invoice will contain:

* Invoice Number and Date
* Contractor’s Name and Address
* Accurate Purchase Order Number
* Supply or Service provided
* Total amount due

**12. Records Management Language for Contracts**

The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].
9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.