

STATEMENT OF WORK:

1. Title of Project: FY16 Hood Inspections for Pharmacy Service and Laboratory Service
2. The Contractor shall:
 - a. Provide all labor, tools, travel and equipment
 - b. Be accredited to biologically and mechanically inspect and certify the hoods as listed below located at the Lebanon Veterans Affairs Medical Center (LVAMC), 1700 South Lincoln Avenue, Lebanon, PA 17042. Minimum of one (1) sample per location plus one (1) control sample.
 - c. Ensure certification of Laboratory hoods complies with Laboratory Ventilation Hood Performance Checks Guidance. Appendix A (See policy directive in Appendix A; attached).
 - a. Face velocity 75 to 125 feet/minute (fpm), optimum flow 100 fpm, with sash at max open position or designated sash height stop levels, i.e. 50% opening.
 - b. Each individual flow reading should be +/- 10% of the average reading.
 - c. Maximum face velocity 125 fpm.
 - d. High toxicity and radiation face velocity should be 125 to 150 fpm.
 - e. The hood fixed continuous airflow monitoring device shall be verified with face velocity data.
 - d. Ensure all preventative maintenance, non-viable & viable air sampling meets criteria stated in Pharmacy Service Memorandums 719-37, 719-40 and 719-41 (Appendix B, C and D). (See policy directive in Appendix B, C, and D; attached).
 - e. Be able to certify in accordance with the USP 797 guidelines <http://www.usp.org/store/products-services/usp-compounding-compendium>: ISO Class 5: not more than 3520 particles 0.5 micrometers and larger size per cubic meter of air for CAI
 - f. Be able to certify Baker Glove Boxes.
 - g. Ensure routine certification procedures will meet or exceed current and applicable local, state and/or federal pharmacy laws.
 - h. Ensure certification of Laboratory hoods complies with Occupational Safety and Health Administration 29CFR1910.1450.
https://www.osha.gov/pls/oshaweb/owares.do_search?p_doc_type=STANDARDS&p_search_type=StandTextPolicy&p_search_str=1910.1450
 - i. Ensure preventive maintenance meets local VA guidelines: All equipment within the Medical center shall be documented in the AEMS/MERS system, including ventilation hoods, for documented preventive maintenance checks. Each piece of equipment shall have attached a PM program regardless of who performs the PM (e.g. maintenance mechanic or vendor). If a vendor completes the PM procedure the work order shall be closed out as such. There is no acceptable alternative to documenting PMs in the AEMS/MERS (VA work order system).
3. Equipment and Requirements:
 - 1) **Pharmacy:**
 - a. Barrier Isolator, Manufacturer Baker, Model Number SS603 ST, Serial Number 85322 (inpatient) B17, Room 138B, In-Patient Pharmacy, Baker, Model SS603ST, SN 85322, PMI# 6640-9083, ISO Class 5
 1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
 2. Two (2) biological viable air samplings are required per year

3. Preventive maintenance: All polyester pre-filters accessible in CAI will be removed and vacuumed to remove dust, debris and particles once monthly by Pharmacy Service
 4. Viable air sampling:
 - a. Air fungal
 - b. Air bacteria
 5. Non-viable particle sampling - Tests required by CETA compounding isolator testing guide CAG-002-2006 Rev. 08-Dec-2008:
 - c. Airflow test (main and pass through chambers)
 - d. Chamber Pressure Test
 - e. HEPA Filter Integrity Test
 - f. Airflow Smoke Pattern Test
 - g. Preparation Ingress and Egress Test
 - h. Particle Count Tests
 6. Labor to replace filters if necessary for proper hood operations. Filters at VA expense
 7. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair
- b. Barrier Isolator, Manufacturer Baker, Model Number CS 500, Serial Number 86013 (chemotherapy), B17, Room 457, Chemo: Baker, Model CS500, PMI # 6640-9084 Type, Other, ISO Class 7. Chemo hood testing must meet manufacturer's specifications maintained by Pharmacy and/or AC Shop.
1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
 2. Two (2) biological viable air samplings are required per year
 3. Preventive maintenance: All cleaning will be performed by Pharmacy Service
 1. Viable air sampling:
 - a. Air fungal
 - b. Air bacteria
 2. Non-viable particle sampling- Tests required by CETA compounding isolator testing guide CAG-002-2006 Rev. 08-Dec-2008:
 - a. Airflow test (main and pass through chambers)
 - b. Chamber Pressure Test
 - c. Site Installation Assessment Tests
 - d. HEPA Filter Integrity Test
 - e. Particle Containment Integrity and Enclosure Leak Test
 - f. Airflow Smoke Pattern Test
 - g. Preparation Ingress and Egress Test
 - h. Particle Count Tests
 3. Labor to replace filters if necessary for proper hood operations. Filters at VA expense
 4. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair
- c. LabConco Protector Laboratory Hood, Catalog # 2247400, Serial # 110643965, B17, Room 138B, Labconco Catalog # 2247400, Serial # 110643965, PMI # 6640-0021. Class 1 biosafety cabinet to meet manufacturers specifications

1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
2. Perform airflow smoke patterns
3. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair

2) **Laboratory:**

- a. Fume Absorber, Manufacturer Labconco, Serial Number 160728750, B1, Room 042, Histology Lab, Labconco, Model 3955200, SN 160728750.
 1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
 2. Labor to replace filters if necessary for proper hood operations. Filters at VA expense
 3. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair.
- b. Chemical Fume Hood, Manufacturer Shandon, Model Number LIP9700, Serial Number 40893-43, B1, Room 042, Histology Lab, Shandon Lipshaw, Model 9700, grosslabsenior, SN 40893 -43, PMI# 6640-9049, Type is Chemical Fume Hood
 1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
 2. Labor to replace filters if necessary for proper hood operations. Filters at VA expense
 3. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair.
- c. Class II Biosafety Cabinet, Manufacturer Baker, Model Number SG403, Serial Number 79071, B1, Room 3, Microbiology: Baker, Model SG403, PMI # 6640-9069, Type is Class II, A2, BSC
 1. Two (2) mechanical inspections/certifications per year, when device is relocated, or when service is performed.
 2. Labor to replace filters if necessary for proper hood operations. Filters at VA expense
 3. Preparation and submission of written reports containing findings, certification, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair.

5. Inspection Timeframe: Inspections are required every six months. The first inspection/certification shall be performed during the month of July, and the second inspection/certification shall be performed during the month of January. All items listed above shall be inspected/certified in a single day. The contractor is to preschedule a date for the certification.

6. Inspection and Preventative Maintenance Hours:

- a) Pharmacy: Work shall be performed Monday through Friday, excluding Federal holidays, during the afternoon and evening hours, beginning no earlier than 1:00 pm.
- b) Laboratory: Work shall be performed Monday through Friday, excluding Federal holidays, between the hours of 8:00 am and 4:00 pm.
 - a. Histology lab inspection/certification shall be performed in the morning.
 - b. Microbiology/Laboratory inspection/certification shall be performed in either the morning or afternoon.

8. Contractors coming on station will be required to stop by the Police office to register before beginning any work in the Lebanon VA Medical Center.

9. Documentation: The Contractor shall prepare and submit a written report containing findings, certifications, recommended repairs with justifications, and cost estimates of any recommended maintenance and repair. In addition to one (1) hard copy of the report, the Contractor shall also provide one (1) electronic copy. A report is required after each visit. Any repairs that are needed to bring the item up to certification are not part of this Contract.

- 1. Air flow face velocity data in fpm required for performance checks include:
 - a. Pass or Fail
 - b. minimum flow
 - c. maximum flow
 - d. average flow
 - e. date conducted
 - f. velometer type and serial number
 - g. Name of individual
- 2. Post the latest air flow data at the hood (include a, b, c, d, and e above)
- 3. Retain copies of all air flow data
- 4. Retain copies of calibration certifications for velometer

10. Schedule of inspection/certification shall be coordinated after contract award. All work shall be performed by competent, experienced personnel qualified to work on the specified equipment in accordance with manufacturer recommendations and VA specifications. The Contractor shall make sure all manufacturer specifications and VA specifications are met. Upon request, the Contractor shall provide factory training certificates/competencies for all technicians assigned to service the specified equipment, in accordance with The Joint Commission (TJC) and the College of American Pathologists (CAP). If requested, such certificates/competencies are to be submitted to the Pharmacy Service and to the Laboratory Service.

11. Handling of Laboratory specimens: Contractor shall complete the specimen processing within 24 hours and shall deliver them back to the LVAMC within that same 24 hour period. In the event of weekend or Federal National Holiday, return deliveries shall occur on the next business day. The National Holidays are as follows:

New Year's Day	January 1
Martin Luther King's Birthday	Third Monday in January
President's Day	Third Monday in February
Memorial Day	Last Monday in May
Independence Day	July 4
Labor Day	First Monday in September
Columbus Day	Second Monday in October
Veterans Day	November 11

Thanksgiving Day
Christmas Day

Fourth Thursday in November
December 25

12. Performance Period: The Government is requesting one base period of one year and four option periods of one year.

Base Period:	
Option Period 1:	
Option Period 2:	
Option Period 3:	
Option Period 4:	

Subject: Laboratory Ventilation Hood Performance Checks Guidance

Importance: High

In recent AWEs several issues have been identified in reference to laboratory hood ventilation checks (Clinical and Research) performed by VA Medical Center HVAC shops and contractors. To correct those issues, this email will serve as guidance. Send this to your Laboratory Safety Committee, and VA Medical Center HVAC shop, and Laboratory Department Head.

NOTE1: If a hood is not operating within hood performance check below or manufacturer design parameters, take it out of service. Post a sign on the hood sash with the sash lowered if the hood is out of service.

NOTE 2: All equipment within the Medical center shall be documented in the AEMS/MERS system, including ventilation hoods, for documented preventive maintenance checks. Each piece of equipment shall have attached a PM program regardless of who performs the PM (e.g. maintenance mechanic or vendor). If a vendor completes the PM procedure the work order shall be closed out as such. There is no acceptable alternative to documenting PMs in the AEMS/MERS (VA work order system).

HOOD PERFORMANCE CHECK:

1. Face velocity 75 to 125 feet/minute (fpm), optimum flow 100 fpm, with sash at max open position or designated sash height stop levels, i.e. 50% opening.
2. Each individual flow reading should be +/- 10% of the average reading.
3. Maximum face velocity 125 fpm.
4. High toxicity and radiation face velocity should be 125 to 150 fpm.
5. The hood fixed continuous airflow monitoring device shall be verified with face velocity data.

EXPERIMENT WORK PRACTICES IN HOOD:

1. Keep all apparatus at least 6 inches back from the face of the hood. You may provide a stripe in the hood as a reminder.
2. Keep all apparatus at least 6 inches in front of the lower baffle. You may provide a stripe in the hood as a reminder.
3. Do not use lab hood for storage.
4. The sash should be at the lowest height as feasible when working in the hood.

DOCUMENTATION (INTERNAL OR VENDOR PROVIDED):

5. Air flow face velocity data in fpm required for performance checks include:
 - a. Pass or Fail
 - b. minimum flow

- c. maximum flow
 - d. average flow
 - e. date conducted
 - f. velometer type and serial number
 - g. Name of individual
- 6. Post the latest air flow data at the hood (include a, b, c, d, and e above)
 - 7. Retain copies of all air flow data
 - 8. Retain copies of calibration certifications for velometer

REFERENCE:

ACGIH Industrial Ventilation: A Manual of Recommended Practice
Occupational Safety and Health Administration 29CFR1910.1450

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Pharmacy Service Memorandum 719-37

**LEBANON VA MEDICAL CENTER PHARMACY
PREVENTATIVE MAINTENANCE****1.0 Definition and Purpose:**

This document outlines the requirements and process for performing regularly scheduled maintenance on all classified cleanroom environments and equipment that supports its operation. All equipment maintenance and/or testing will be consistent with manufacturer's recommendations.

2.0 Policy:

- 2.1 All CAI hood pre-filters, if accessible, will be vacuumed on a monthly basis during non-production times.
- 2.2 All classified cleanroom environments and equipment that support its operation will be tested and re-certified by qualified individuals at a minimum of every 6 months, whenever the device and/or room is relocated, or when service is performed. Documentation shall be kept on file.
- 2.3 Certification that each ISO Class 5 area meets guidelines for total particle counts must take place every 6 months and whenever the PEC is relocated. Tests are performed by qualified personnel using state-of-the-art equipment. Documentation is kept on file. Threshold for total particle count follows threshold requirements set forth in USP 797.
 - 2.3.1 ISO Class 5: not more than 3520 particles 0.5 micrometers and larger size per cubic meter of air for CAI
- 2.4 Routine certification procedures will meet or exceed current and applicable local, state and/or federal pharmacy laws.

3.0 Materials and Equipment:

- 3.1 Various air filters based on the equipment used

4.0 Procedure:

- 4.1 All classified environments and equipment must be tested and certified prior to performing any validation procedures or patient-specific prescription compounding.
- 4.2 It is the responsibility of the Inpatient Pharmacy Supervisor to insure that all classified environments and equipment are certified, maintained and operating properly.
- 4.3 The Inpatient Pharmacy Supervisor will be responsible for maintaining an environment and equipment maintenance schedule to insure compliance with current and applicable local, state and/or federal laws.
- 4.4 All routine certification and maintenance procedures/processes will be scheduled events and occur during non-peak production hours.
- 4.5 All certification and maintenance procedures/processes must be performed by trained and experienced individuals who can demonstrate proficiency in areas of classified cleanroom environments and equipment or who can demonstrate that they have been trained.

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**LEBANON VA MEDICAL CENTER PHARMACY
PREVENTATIVE MAINTENANCE**

- 4.6 Routine certification and maintenance procedures/processes will be performed and dictated based on equipment within a facility and based on manufacturer's recommendations or current and applicable laws.
 - 4.6.1 Once a month, all polyester pre-filters accessible in CAI will be removed and vacuumed to remove dust, debris and particles. Record maintenance on the Monthly Pre-Filter Maintenance Log.
- 4.7 All certification certificates must be prominently displayed and maintained in a readily retrievable file.
- 4.8 Facility cleaning and environmental procedures and testing must be performed prior to initiating any compounding processes.



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CHIEF OF PHARMACY

Pharmacy Service Memorandum 719-40

LEBANON VA MEDICAL CENTER PHARMACY
VIABLE AIR SAMPLING**1.0 Definition and Purpose**

To outline the procedures utilized to monitor and quantify viable contaminants in the direct compounding area in ISO Class 5 as well as other ISO classified room environments where compounding related activities occur. Viable air sampling is a facility-related metric of the Environmental Sampling Plan (ESP). The objective of viable air sampling (VAS) is to obtain representative estimates of bioburden of the compounding areas. Data are evaluated by pharmacy leadership and while it is important to review all environmental data as sampling occurs, it is essential that data are reviewed over extended periods of time to identify trends that may indicate adverse shifts in the compounding environment.

2.0 Policy**2.1** Viable air sampling must be performed:

- 2.1.1 Initial certification of new equipment or facility
- 2.1.2 After facility or equipment is serviced
- 2.1.3 Every 6 months as part of recertification of equipment and facility
- 2.1.4 When work practice problems are identified or suspected with products or staff

2.2 Viable air sampling will occur under dynamic operating conditions, that is, while compounding and compounding related activity is occurring. This has also been called active air sampling.**2.3** Volumetric air sampling is required in which air sampling is performed using a device that draws a predetermined volume of air onto an agar plate. Gravimetric sampling is not acceptable.**2.4** It is preferred that the device used to perform the volumetric air sampling device use impaction methodology.**2.5** Volumetric Sampling must occur at the following locations:

- 2.5.1 One viable air sample at each discrete primary engineering control (BSC, CAI)
- 2.5.2 One viable air sample is sufficient in each PEC except in the case of PECs that are 8 linear feet or longer. In those cases one (1) viable air sample will be taken for each 4 feet of ISO Class 5 linear compounding surface.
- 2.5.3 Sampling of air in the ISO Class 7 buffer area/cleanroom (i.e. pass through) where air turbulence may be expected

2.6 Air samples must sample volumes of air at least equal to 400 - 1000 liters for each sample.

- 2.6.1 Since ISO Class 5 air conditions are much cleaner with respect to particulates than Classes 7 or 8, it is expected that the contaminates per liter of air are less prevalent than in the air of a Class 7/8 area. With this in mind, the air volume to be sampled within an ISO Class 5 area must be 1000 liters per sample in order to improve the level of detection of particles whereas sample sizes of 400 liters each are acceptable in ISO Class 7/8 areas.

Air Sampler Manufacturer's information should be reviewed regarding the following:

- 2.6.1.1 The extent to which the air sampling unit substantially affects (or not) air flow within the ISO Class 5 primary engineering controls.
- 2.6.1.2 The sampling capacity (the number of liters per minute drawn through the sampler and across the media sample) of the unit. The higher the sampling capacity, the shorter the time it will take to sample the predetermined volume needed at each location.

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**LEBANON VA MEDICAL CENTER PHARMACY
VIALABLE AIR SAMPLING**

- 2.6.1.3 Some samplers sample at a high rate such as 180 liters/minute so a 1000-liter sample is obtained in 5.5 minutes whereas other samplers may take much longer. Other air samplers come with dual heads so that one sampling time of 5.5 minutes can sample using both types of media simultaneously (180 liters/minute).
- 2.6.1.4 Faster sample speeds are important to prevent:
- 2.6.1.4.1 Drying of media which can occur as air is drawn across the plate and exposure to air for longer periods of time dries the media and potentially reduces its ability to sustain growth thereby potentially causing false negative findings.
 - 2.6.1.4.2 Prolonged disruption of air flow within the ISO Class 5 direct compounding area.
- 2.7 Two types of growth media must be used for each sample location regardless of compounding risk level as follows:
- 2.7.1 A general microbiological growth medium such as Soybean-Casein Digest medium and
 - 2.7.2 Malt Extract Agar or other media that supports the growth of fungi.
- 2.8 Recommended initial viable air sampling microbial contamination Alert and Action Levels are as follows

Type of Air	Alert Level	Action Level
ISO Class 5 Air	1 CFU per sample	>1 CFU per sample
ISO Class 7 Air	>5 CFUs per sample	> 10 CFUs per sample
ISO Class 8 Air	>50 CFUs per sample	> 100 CFUs per sample

- 2.9 In general, alert levels are generally set at a level approximately 50% of the action level.
- 2.10 Alert levels ensure that a potentially finding or trend is verified after repeat cleaning and sampling prior to the initiation of the more robust and costly activities associated with Action Level triggers.
- 2.11 Alert and Action levels may be re-evaluated after sufficient microbial environmental data has established a baseline for a given ISO classed area at a pharmacy. Limits may not be higher than those set above, but may be lowered.

3.0 General Information

- 3.1.1 Viable Air Sampling is performed by a contracted vendor.
- 3.1.1.1 Ascertain that the device is an impaction device
 - 3.1.1.2 Ascertain the sampling capacity (speed in liters per minute)
 - 3.1.1.3 Ascertain the type of media required so they may be obtained by the pharmacy
 - 3.1.1.4 If the media is provided by the certifying vendor, ascertain that they are kept under proper storage conditions at all times. The vendor should provide proof of annual service according to NIST standards if required by the manufacturer.

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VIABLE AIR SAMPLING

3.1.1.5 Ascertain device calibration requirements and verify that the device is calibrated immediately prior to use.

4.0 Procedures**4.1 Actions to take if results exceed Alert or Action Levels**

- 4.1.1 Report any out of limit results to the Pharmacy Manager or designee immediately.
- 4.1.2 If the results exceed the designated Alert Level (but do not exceed the Action Level), retest the area/s affected.
- 4.1.3 If subsequent results exceed the designated Alert Level for a second time or exceed the designated Action Level at any time, perform cleaning and disinfection activities; Cleaning and Disinfecting of the Compounding Area and retest the area/s affected. If the retested area/s exceeds the:
 - 4.1.3.1 Alert Level again but is below the designated Action Level, perform a three-time cleaning and disinfection procedure and retest.
 - 4.1.3.2 Action Level perform the following:
 - 4.1.3.2.1 Retain the affected plate/s.
 - 4.1.3.2.2 Send the affected plate/s to an appropriately credential laboratory to identify, at least to the genus level, the microorganisms recovered.
 - 4.1.3.2.3 The results of the microbiological examination must be reviewed as it will provide clues as to how the organisms are being introduced, thereby assisting in remediation.
 - 4.1.3.2.4 Any viable air sampling result that either exceeds established Action Levels or exceeds established Alert Levels 2 times in a row, also triggers an immediate re-evaluation of the adequacy of:
 - 4.1.3.2.4.1 personnel work practices including employee hand washing/garbing and aseptic technique procedures;
 - 4.1.3.2.4.2 cleaning procedures,
 - 4.1.3.2.4.3 other operational procedures such as material handling,
 - 4.1.3.2.4.4 air filtration efficiency within the aseptic compounding location, and
 - 4.1.3.2.4.5 other physical plant or work practice controls as determined to be applicable by pharmacy leadership.
 - 4.1.3.2.5 This investigation is documented on the *Facility and Personnel Environmental Sampling Action Report* and the source of the contamination is sought.
 - 4.1.3.2.6 The affected area will receive a three time cleaning and the viable air sampling repeated.
 - 4.1.3.2.7 Should an area continue to fail, it is the responsibility of the Pharmacy Manager to seek guidance appropriate sources to assist in determining additional corrective actions which may include but are not limited to prohibition of compounding

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VIALE AIR SAMPLING

activities in the affected area; further sampling, or evaluation and recertification by a qualified vendor/manufacture to determine root cause of the contamination.

- 4.2 Documentation of Viable Air Sampling is found in the Certification Report compiled at each certification/recertification by the Vendor.
- 4.3 Any actions taken are documented on the *Facility and Personnel Environmental Sampling Action Report*.
- 4.4 Surface sample data should be reviewed on a routine basis and analyzed for trends or adverse shifts in environmental bioburden if necessary.



PAUL CARNES, PHARM.D., FACHE
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Pharmacy Service Memorandum 719-41**LEBANON VA MEDICAL CENTER PHARMACY
NON-VIABLE PARTICLE TESTING****1.0 Definition and Purpose**

A non-viable particle is a particle that has no detectable culturable organisms associated with it. In other words these particles do not contain living organisms. Reducing the number of non-viable particles however is critical to reducing bioburden in ISO classified compounding areas since non-viable particles act as a means of transport for microorganisms. Bacteria and other living organisms attach themselves to non-viable particles and can be carried by available air currents, therefore it is important to minimize their occurrence. Non-viable particle testing must be performed at least twice annually during routine certification as a means to verify the proper function of primary engineering controls.

2.0 Applicable Documents

- 2.1 Controlled Environment Testing Association. CETA Certification Guide for Sterile Compounding Facilities
- 2.2 Documentation of semi-annual certification provided by vendor after testing.
- 2.3 Hand Hygiene
- 2.4 Overview of Aseptic Technique

3.0 Policy

- 3.1 Non-viable particle testing is primarily considered a facility related metric component of a comprehensive environmental sampling plan.
- 3.2 Non-viable particle testing occurs in the following areas:
 - 3.2.1 Primary Engineering Controls (LAFWs, BSCs, CAIs and CACIs)
 - 3.2.2 ISO Class 7 buffer area/clean rooms
 - 3.2.3 ISO Class 7/8 ante-area/rooms
- 3.3 Poor work practices can adversely impact non-viable particle counts therefore employees must comply with Hand Hygiene and Overview of Aseptic Technique procedures.
- 3.4 Procedures followed by vendors performing certification must comply with CETA guidelines and manufacturer's recommendations for the specific equipment being used and tested.
- 3.5 Non-viable particle testing is required each time and on such occasions that a primary or secondary engineering control certification/recertification is completed.
- 3.6 The Pharmacy Manager or designee must review in detail the findings of non-viable particle counts as part of the review of the certification findings.
- 3.7 Should the Pharmacy Manager or designee determine that non-viable particle counts in a particular area or PEC demonstrate undesirable trends, it is the responsibility of the Pharmacy Manager to evaluate the need for additional follow up activities such as:
 - 3.7.1 Further investigation of, maintenance or repair of the primary engineering control or secondary engineering control (i.e., particular HEPA filter is damaged).
 - 3.7.2 Evaluation of cleaning and disinfection.
 - 3.7.3 Evaluation of staff work practices.
 - 3.7.4 Retesting.

4.0 Documentation

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NON-VIABLE PARTICLE TESTING**

- 4.1 Documentation of non-viable particle counts is found in the certification report compiled at each certification/recertification by the vendor.
- 4.2 Documentation of any concerns and follow up actions regarding non-viable particle counts is required.



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