Pharmacy Environmental Monitoring (EM) Implementation Toolkit

How to Use This Toolkit

The purpose of this document is to aid pharmacy departments in the initial steps required to insource an environmental monitoring (EM) program. While outsourcing EM to an external company and laboratory might seem easier, it is typically in the pharmacy department's best interest to insource this type of program. Pharmacies that insource EM typically report significant cost reduction. Some pharmacies might be deterred to sample beyond a particular frequency when outsourcing EM due to the potentially high cost of outsourcing. Performing EM at an appropriate frequency provides pharmacies the information necessary to maintain compounding and clean room environment best practices, and ultimately maintains safety and quality for patients receiving compounded sterile products (CSP).

There are many components to a fully-fledged EM program. These programs require cross-functional relationships (e.g. laboratory, pharmacy, infection control) to account for various program components. Additionally, pharmacy departments are required to manage equipment that might be new to the department. Competencies to ensure pharmacy personnel are appropriately competent in all facets of the program are necessary. Finally, pharmacies will want to consider what outcomes and corrective action information they want to report to interested stakeholders. The above information is covered in this toolkit and will hopefully aid you in your decision-making and implementation of your own program.

Contents

Clean Room Sampling Maps and Sample Site Rationale

General Overview

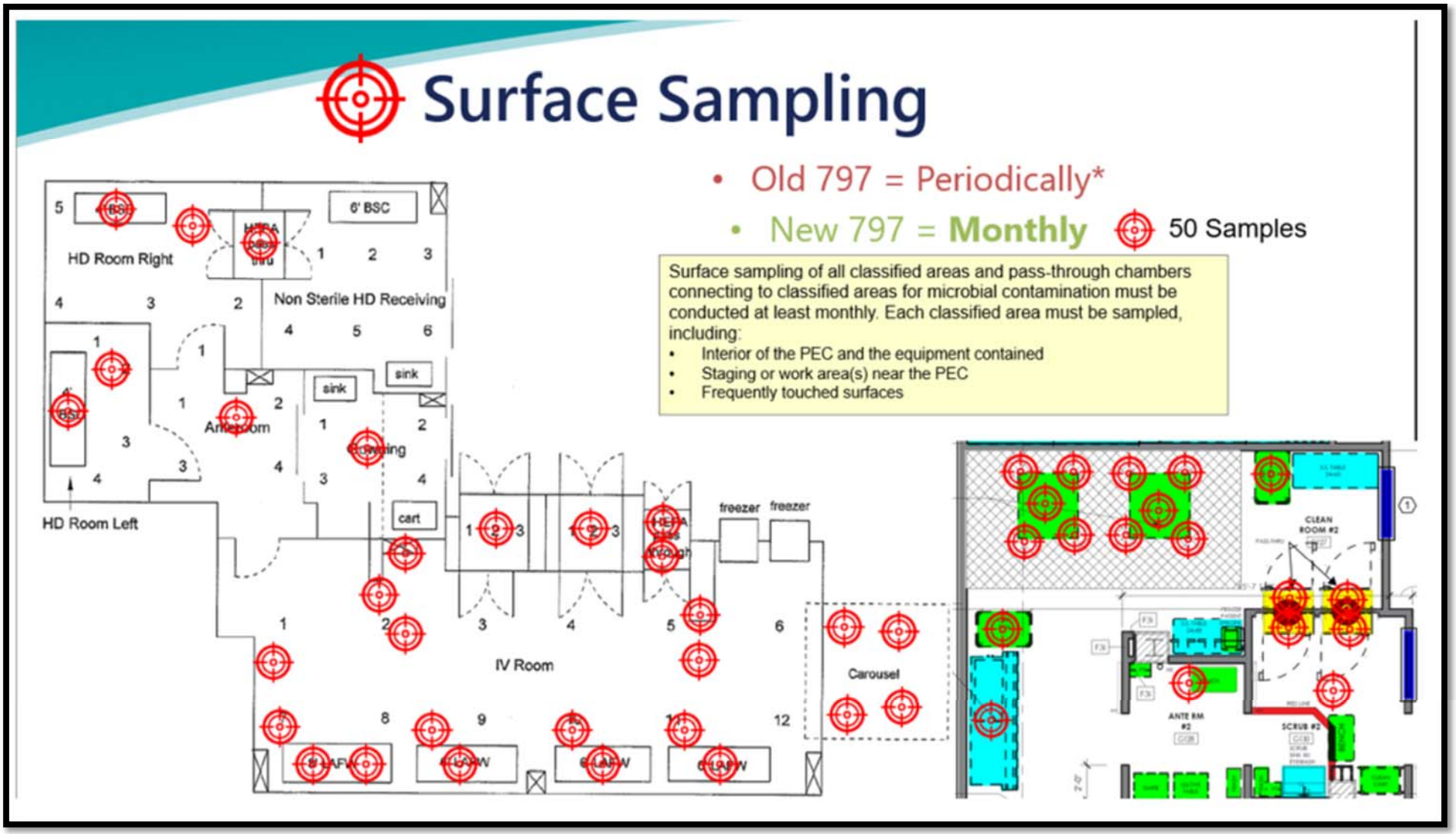
Each pharmacy clean room intended for the compounding of sterile products should maintain a sampling map that directs the activities of the individual responsible for EM.

Ideally, a high quality EM clean room map features the following

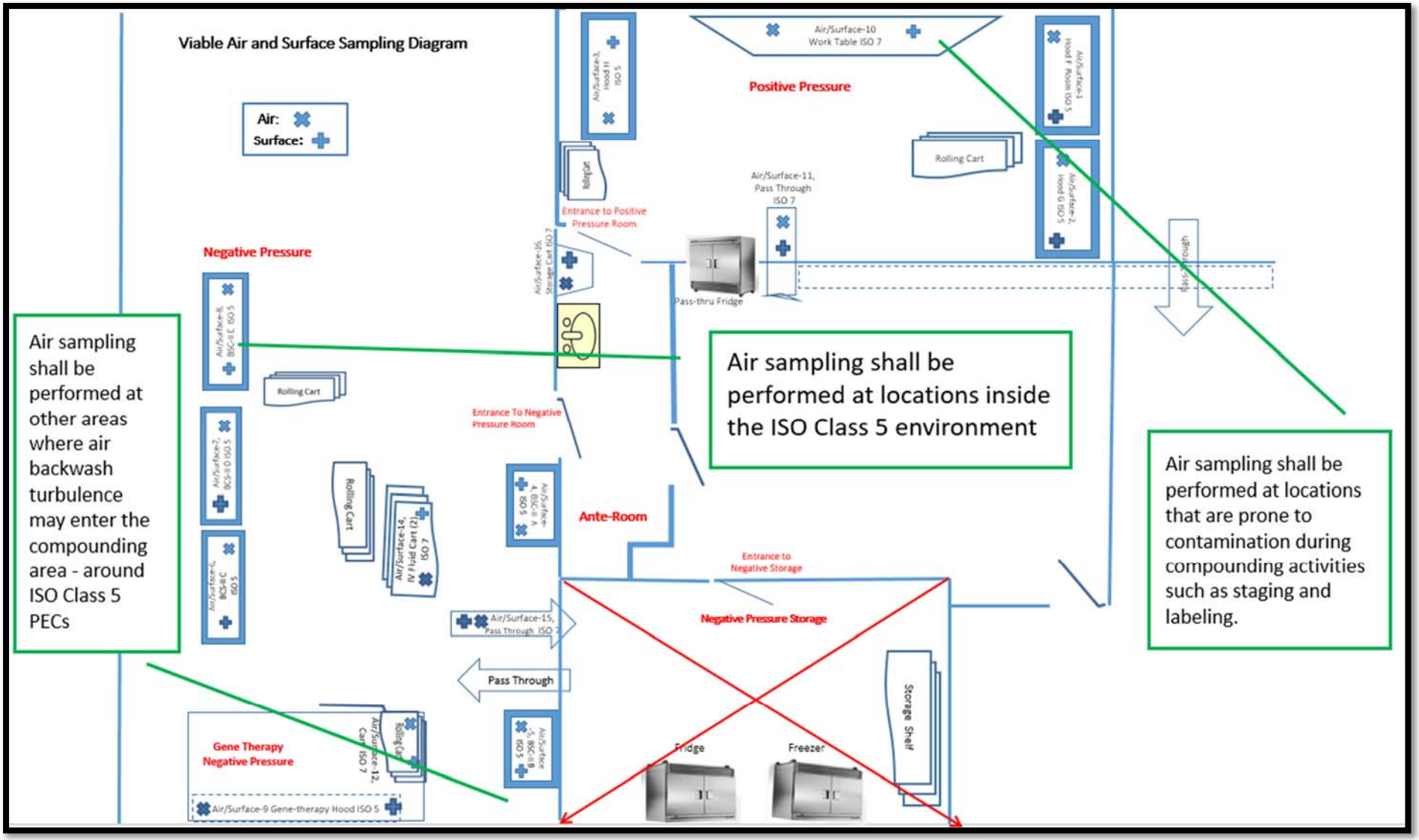
- Locations of primary and secondary engineering controls
- Locations of lines of demarcation (dirty/clean, hazardous/non-hazardous)
- Locations of tables, chairs, inventory racks, workstations and any other standard equipment
- Locations of required air and surface samples that must be obtained
- A key/ table that identifies sample number, describes location, and action levels

Finally, it might also be useful to describe the *purpose* of each sample taken. This will force the pharmacy to be intentional about why certain locations are sampled and others are not. Examples of clean room sampling maps developed by various health systems, along with sample site rationale for some of the examples, are included in the following pages.

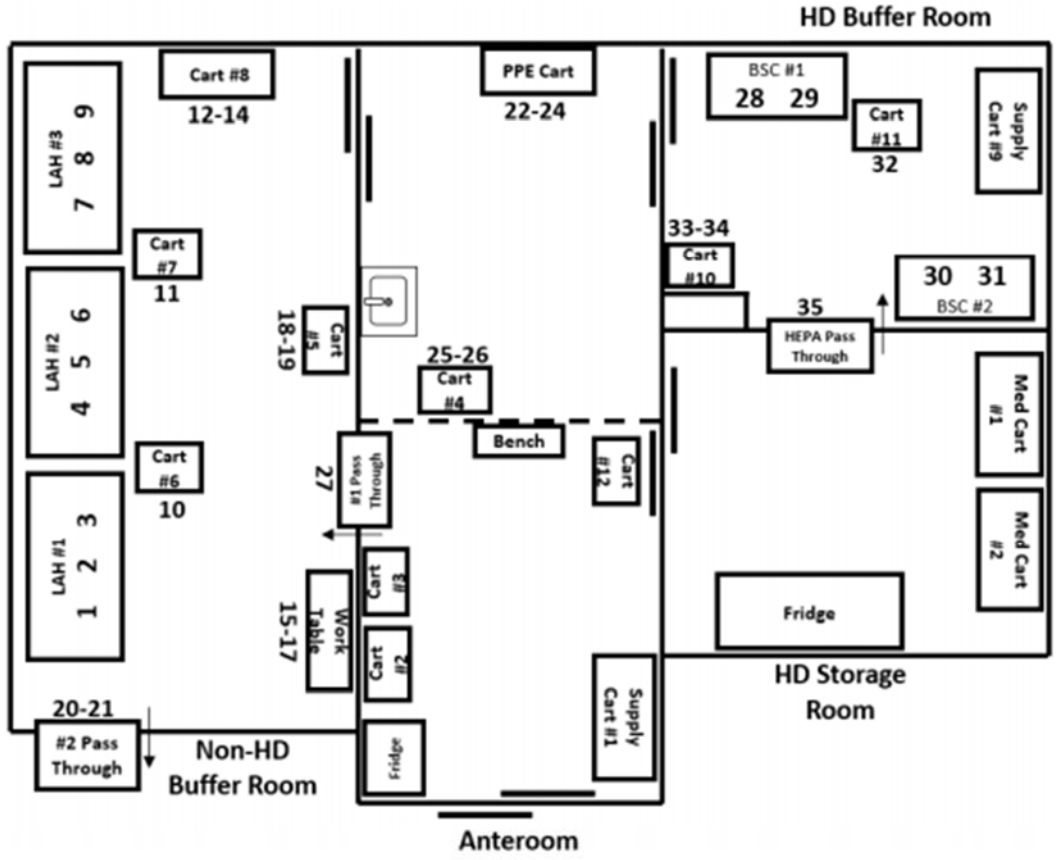
EM Sampling Map Example #1: Surface Sample Sites with Numbered Ceiling HEPA Filters



EM Sampling Map Example #2: Air and Surface Sample Sites with Visual Aids

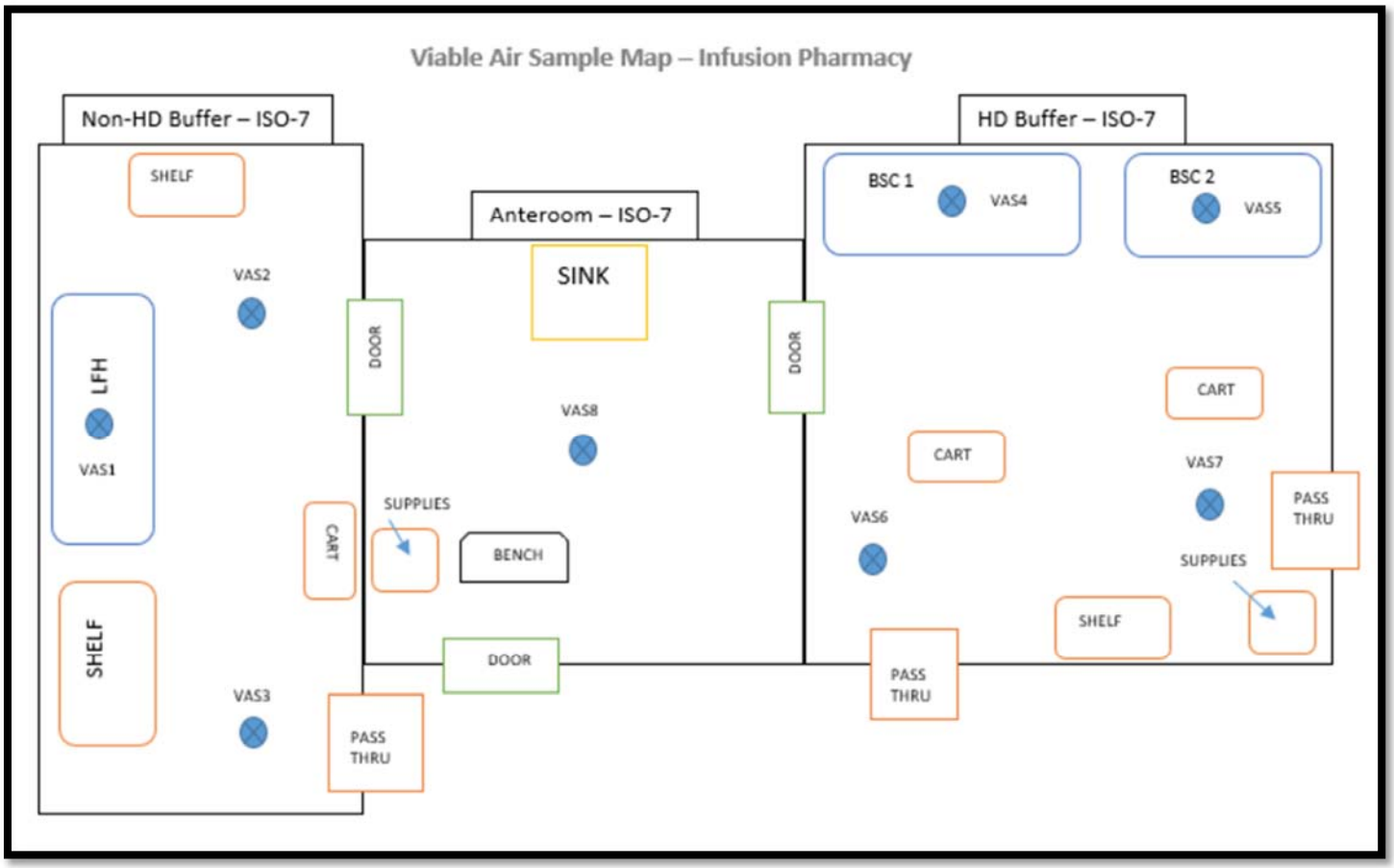


EM Sampling Map Example #3: Surface Samples with Location Detail and Action Levels



Sample Number	Location	Description	Action Level
1	Non-HD Buffer Room	LAH 1, left side, center	>3 CFUs
2	Non-HD Buffer Room	LAH 1, middle, center	>3 CFUs
3	Non-HD Buffer Room	LAH 1, right side, center	>3 CFUs
4	Non-HD Buffer Room	LAH 2, left side, center	>3 CFUs
5	Non-HD Buffer Room	LAH 2, middle, center	>3 CFUs
6	Non-HD Buffer Room	LAH 2, right side, center	>3 CFUs
7	Non-HD Buffer Room	LAH 3, left side, center	>3 CFUs
8	Non-HD Buffer Room	LAH 3, middle, center	>3 CFUs
9	Non-HD Buffer Room	LAH 3, right side, center	>3 CFUs
10	Non-HD Buffer Room	Supply Cart 6, top shelf, center	>5 CFUs
11	Non-HD Buffer Room	Supply Cart 7, top shelf, center	>5 CFUs
12	Non-HD Buffer Room	Cart 8, top shelf, left side, center	>5 CFUs

EM Sampling Map Example #4: Viable Air Sample Sites with Rationale



Pharmacy Sample Site Rationale for EM Sampling Map #4

VAS1 (LFH):
In this ISO 5 environment, critical sites are exposed to “first air” from the HEPA filter creating essentially a particle free, unidirectional airflow. It is important to maintain this environment to protect the integrity of the product during the compounding procedure.

VAS2 (Non-hazardous buffer room):
This sample captures anything that might be a result of the ongoing personnel activity and prep work in this area.

VAS3 (Near non-hazardous buffer room pass thru):
Materials introduced to the ISO 7 room are wiped down with a disinfectant and passed from non-ISO-classified space. Despite the positive pressure from the clean room, we want to be sure this site is regularly monitored for any environmental disturbance.

VAS4 (BSC 1):
In this ISO 5 environment, critical sites are exposed to “first air” from the HEPA filter creating essentially a particle free, unidirectional airflow. It is important to maintain this environment to protect the integrity of the product during the compounding procedure.

VAS5 (BSC 2):
In this ISO 5 environment, critical sites are exposed to “first air” from the HEPA filter creating essentially a particle free, unidirectional airflow. It is important to maintain this environment to protect the integrity of the product during the compounding procedure.

VAS6 (Near hazardous buffer room pass thru):
Materials introduced to the ISO 7 room are wiped down with a disinfectant and passed from non-ISO-classified space. Despite the positive pressure from the clean room, we want to be sure this site is regularly monitored for any environmental disturbance.

VAS7 (Near hazardous buffer room pass thru):
Materials introduced to the ISO 7 room are wiped down with a disinfectant and passed from non-ISO-classified space. Despite the positive pressure from the clean room, we want to be sure this site is regularly monitored for any environmental disturbance.

VAS8 (Ante room):
1-2 people perform hand hygiene and garbing at any one time in this area. The transfer of waste containers, such as the sharps containers, also takes place in the marked “dirty” section of the room.

Viable Air and Surface Sampling Procedure

General Overview: Air Sampling Operating Procedure

Insourcing environmental monitoring can be beneficial to any department but the procedures around the testing are just as beneficial. A designated person should be trained to understand all aspects of environmental monitoring and setup procedures. The following is an example of a standard operating procedure for performing air sampling. A standard operating procedure (SOP) discusses the conditions under which the testing will occur, when testing will occur, what products will be used to do the testing, a step-by-step procedure, and what to do with the results.

Process Overview

Air sampling shall be performed semiannually during normal working hours under dynamic conditions as part of facility recertification or as needed following construction or repair. Other conditions for viable air sampling from USP 797 include, certification of new facilities, servicing of facilities and equipment, identified end product problems, and patient infections suspected to be related to compounded sterile preparations.

One Thousand Liters Collected at Each Sample Site Using:

- Large Volume Air Sampler:
    - Manufacturer: (selected manufacturer here)
    - Model Number:
    - Serial Number:

- Plates To Be Used:
    - Tryptic Soy Agar (TSA)
    - Malt Extract Agar (MEA)

Preparation, Labeling, and Incubation of Plates:

1. Plates will be stored in the fridge until ready for use
2. A control plate will be sampled from each lot number
3. Sites to be tested will be selected from each institution and will be reflected on the site-specific plan and map
4. Air will be collected during regular compounding activities under dynamic conditions
5. Sampling will be done from cleanest to dirtiest (Example: ISO 5 » ISO 7 » ISO 8)
6. Plates will be labeled using preprinted clear labels with area date, time, and testing location
7. Plates will be returned to the lab for growth and assessment
8. Incubation to be done at the lab
    - TSA (Bacteria) incubated at 30-35°C for 2-3 days
    - MEA or other suitable fungal media incubated at 26°-30°C for 5-7 days
9. Colony Forming Units (CFU) will be evaluated by USP 797 recommendations below
10. Table 2 Recommended Action Levels for Microbial Contamination[1]

Classification of Air Samples

- ISO Class 5
- ISO Class 7
- ISO Class 8
- CFU per cubic meter [1000 liters] of air per plate

Action Levels, Documentation, and Data Evaluation

- Designated person will be notified of all results
- Any CFU count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location
- Re-sampling shall be done within 3-5 business days of positive air sample. Competent microbiology personnel shall be consulted if air re-sampling exceeds action level
- Administrative Director and Hospital Infection Control will be notified with any sample that exceeds the action level

General Overview: Surface Sampling Operating Procedure

The surface sample operating procedure example shows similar information. It discusses how and how often surface sampling will be completed. The standard operating procedure then discusses the products obtained for testing as well as a step-by-step procedure. It also outlines what to do with the results of the test.

Process Overview

Each pharmacy shall be sampled semiannually or as needed to check for bacterial and fungal growth. Sampling will be performed on all ISO areas to evaluate facility cleaning procedures and personnel competency. Surface sampling shall be done at the conclusion of compounding. The contact plate method for assessment will be used.

Agar Plates to Use for Sampling:

- Tryptic Soy Agar (TSA) (bacterial growth) plate (size 24-30 cm^2)
- Malt Extract Agar (MEA) (fungal growth) plate (size 24-30 cm^2)
- Plates will be incubated and read by the IVC compliance technician

Preparation, Labeling, and Incubation of Plates:

1. Plates will be stored in the refrigerator until ready for use
2. A control plate will be sampled from each lot number
3. Plates will be labeled with preprinted clear labels and include time, date, and sampling location
4. Sampling will be done from cleanest to dirtiest (Example: ISO 5 » ISO 7 » ISO 8)
5. Incubation to be done at the pharmacy and read by IVC compliance technician
    - TSA (Bacteria) incubated at 30-35°C for 2-3 days
    - MEA or other suitable fungal media incubated at 26°-30°C for 5-7 days

Surface Collection Method

1. Gently touch the sample area with the agar surface and roll the plate across the surface to be sampled
2. The contact plate will leave a growth media residue
3. Immediately after sampling a surface with the contact plate, the sampled area shall be cleaned with an approved germicidal detergent to clean any residue left by the agar plate.
4. Next, thoroughly wipe the area with a non-shedding wipe soaked in 70% sterile isopropyl alcohol
5. Media plates will be recovered, secured with paraffin film or similar material, inverted, and incubated at the temperatures indicated above

*Table 4 Recommended Action Levels for Microbial Contamination

Classification	Colony Forming Units per plate (CFU)
ISO Class 5	> 3
ISO Class 7	> 5
ISO Class 8	> 100

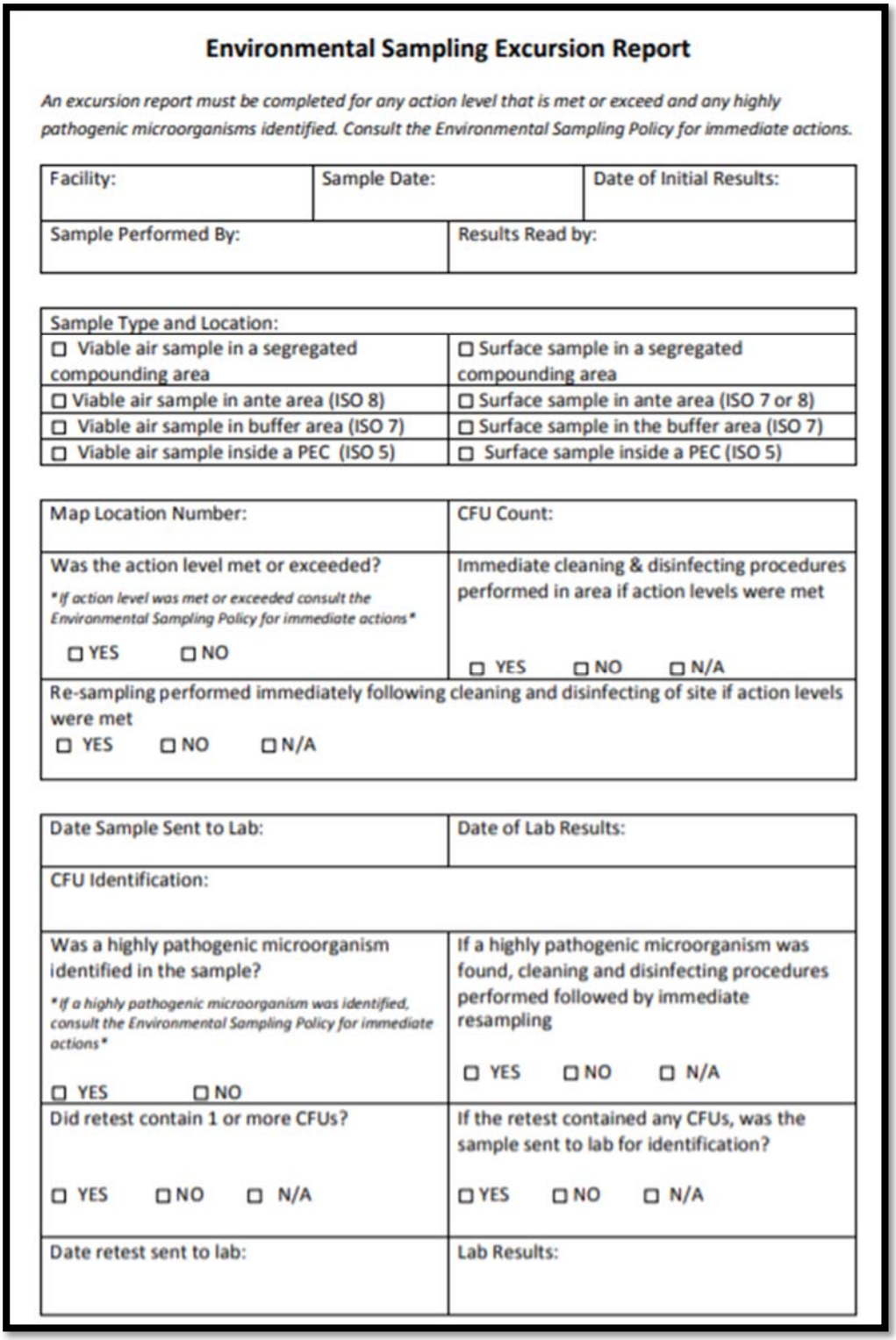
Interpretation of Results

1. Designated person will be notified of all results
2. Any CFU count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location
3. Re-sampling shall be done within 5 days of positive sample
4. Competent microbiology personnel shall be consulted if re-sampling exceeds action level
5. Administrator and Hospital Infection Control will be notified with any sample that exceeds the action level

Common Clean Room Pathogen Information	
Microorganism	**Potential Source of Contamination**
Staphylococcus or Micrococcus	Typical skin flora. Issue could be personal habits or gowning and garbing practices.
Gram negative rods	Water condensation, leaking, non-sterile aerosols
Bacillus species	Dust, dirt, floor traffic, possible air handling
Molds	Influx of unfiltered air, mold from street clothing, mold-contaminated cardboard, water reservoir (i.e. incubator humidification system)
Yeast	Possible outdoor air influx, clothing-borne (especially in late Summer/Fall)
Diphtheroids or coryneforms	Poor air conditioning leading to personnel sweat and discharge from gowns

General Overview: Environmental Sampling Excursion

The Environmental Sampling Excursion report provides detailed information around any non-compliance resulting from the environmental testing. It allows formal documentation around where the non-compliance occurred, lab results of growth, possible sources of contamination and corrective actions. This form can easily be filled out and supplement the testing reports to see the actions taken.



Environmental Sampling Excursion Report

An excursion report must be completed for any action level that is met or exceed and any highly pathogenic microorganisms identified. Consult the Environmental Sampling Policy for immediate actions.

Facility:	Sample Date:	Date of Initial Results:
Sample Performed By:	Results Read by:	

Sample Type and Location:	
☐ Viable air sample in a segregated compounding area	☐ Surface sample in a segregated compounding area
☐ Viable air sample in ante area (ISO 8)	☐ Surface sample in ante area (ISO 7 or 8)
☐ Viable air sample in buffer area (ISO 7)	☐ Surface sample in the buffer area (ISO 7)
☐ Viable air sample inside a PEC (ISO 5)	☐ Surface sample inside a PEC (ISO 5)

Map Location Number:	CFU Count:
Was the action level met or exceeded? **If action level was met or exceeded consult the Environmental Sampling Policy for immediate actions** ☐ YES ☐ NO	Immediate cleaning & disinfecting procedures performed in area if action levels were met ☐ YES ☐ NO ☐ N/A
Re-sampling performed immediately following cleaning and disinfecting of site if action levels were met ☐ YES ☐ NO ☐ N/A	

Date Sample Sent to Lab:	Date of Lab Results:
CFU Identification:	
Was a highly pathogenic microorganism identified in the sample? **If a highly pathogenic microorganism was identified, consult the Environmental Sampling Policy for immediate actions** ☐ YES ☐ NO	If a highly pathogenic microorganism was found, cleaning and disinfecting procedures performed followed by immediate resampling ☐ YES ☐ NO ☐ N/A
Did retest contain 1 or more CFUs? ☐ YES ☐ NO ☐ N/A	If the retest contained any CFUs, was the sample sent to lab for identification? ☐ YES ☐ NO ☐ N/A
Date retest sent to lab:	Lab Results:

Environmental Sampling Excursion Report

Possible Source(s) of Contamination:

Corrective Actions Taken:

All results and corrective actions must be reviewed by the pharmacy manager and the compounding program manager.

(Signature and Date of Review)	*(Signature and Date of Review)*
Program Manager – Pharmacy Compounding	**Pharmacy Manager**

Establishing a Baseline for New Environmental Monitoring

General Overview

A baseline study for viable environmental sampling should be performed to establish normal or expected results for sampling locations. This process will help identify any abnormal results for the specific sampled location during ongoing sampling, even if an excursion has not occurred.

For new primary engineering controls or newly constructed or remodeled secondary engineering controls, a baseline study of the viable air particles should be established to determine normal or expected sampling results.

For new equipment that would be considered a high touch surface within the secondary engineering control (such as the workbench of the primary engineering control, worktables, carts, touch screen, etc.) a baseline study of the surface sampling should be established to determine normal or expected results for those testing locations.

Process Overview

Baseline sampling should be conducted on a weekly basis for at least four consecutive weeks or more. Sampling should occur during normal operating conditions to trend results and establish a baseline for each sampling site.

- Preliminary results for the weekly baseline sampling are to be documented after the completion of the appropriate incubation period for each sample. The attached baseline report will be used to document initial CFU counts.
- All growth must be sent to a microbiology lab, regardless if the sample reached or exceeded the established action level, for identification to at least the genus level.
- Lab results for each sampling location must be documented and retained with the baseline-sampling document for the applicable sampling site.
- Any excursion, such as an above action CFU result or identification of a potentially highly pathogenic microorganism, is to be documented from the beginning of the excursion through remediation
- All baseline sampling documents for each sampling site must be kept with the baseline sampling document and retained as a permanent environmental monitoring record
- After completion of the baseline study, ongoing environmental sampling must occur monthly

Environmental Sampling 4 Week Baseline Study

Fill out the table with preliminary results for weekly baseline testing after each appropriate incubation period is complete. Immediate action is required if the action level is met or exceeded. All growth must be sent to lab for identification, and lab reports must be retained with the baseline study documents. After the 4-week baseline testing is complete, sampling will be performed every 3 months for surface sampling and every 6 months for viable air sampling.

Baseline testing results and other related documents must be reviewed by the Pharmacy Manager and the Compounding Program Manager. After review, Managers are to sign below.

Facility:	Start Date:	End Date:
Sampling Map Location Number:	Sample Type: ☐ Viable air sample ☐ Surface sample	Sample Location: ☐ Anteroom (ISO 7) ☐ Anteroom (ISO 8) ☐ Buffer room (ISO 7) ☐ PEC (ISO 5)

Action Level for Sampling Location: >____ CFUs

Week	Sample Date and Time	Agar Lot #	Sample Results (CFUs)	Date of Results	Action Required
1					
2					
3					
4					

_____ _____

(Signature and Date of Review)
Program Manager – Pharmacy Compounding

(Signature and Date of Review)
Pharmacy Manager

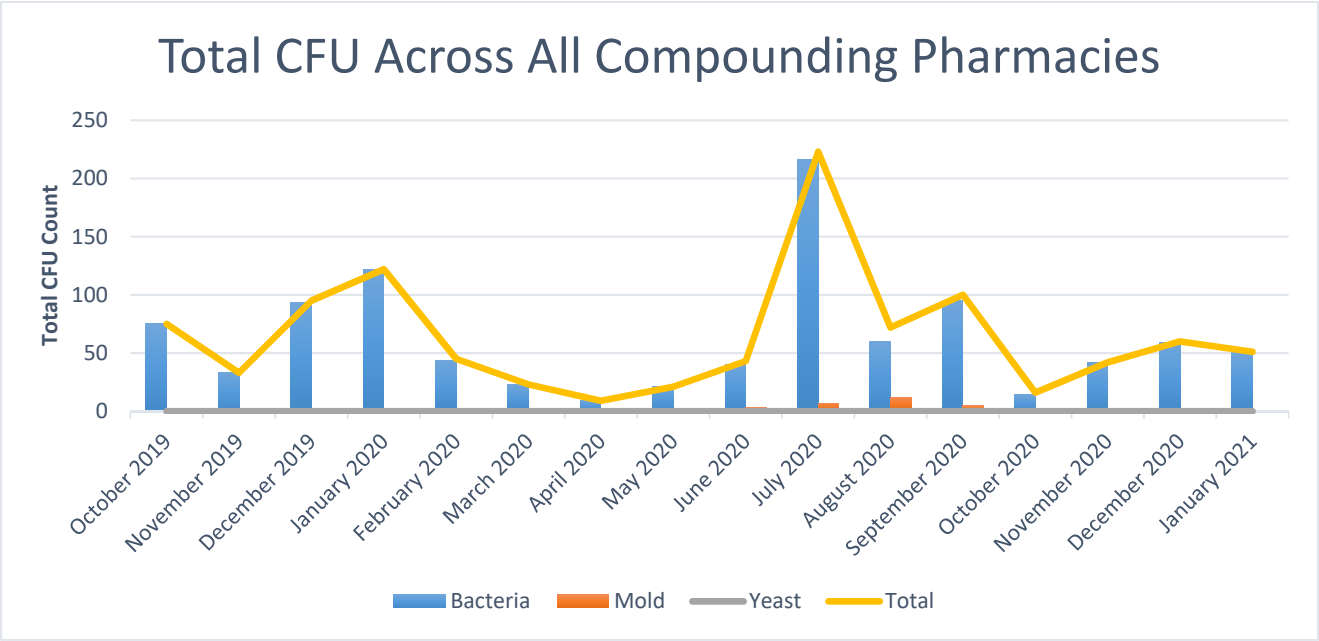
Considerations for Meaningful Trending of Results

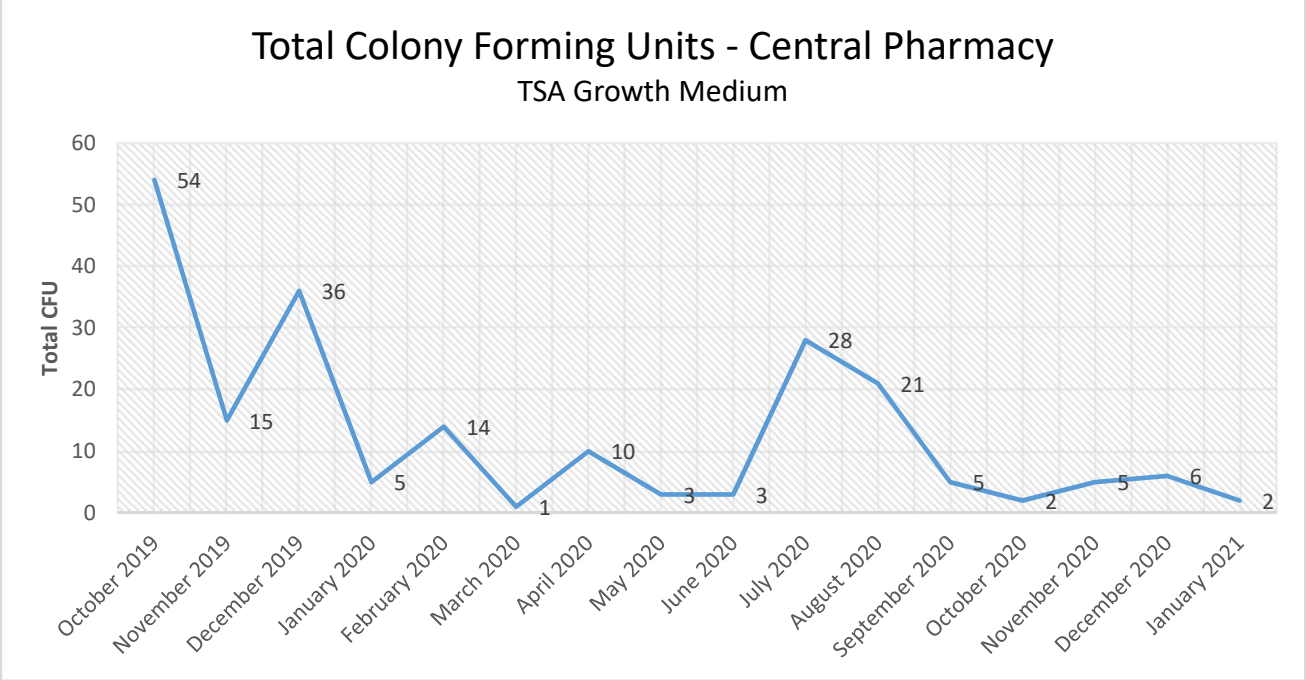
General Overview

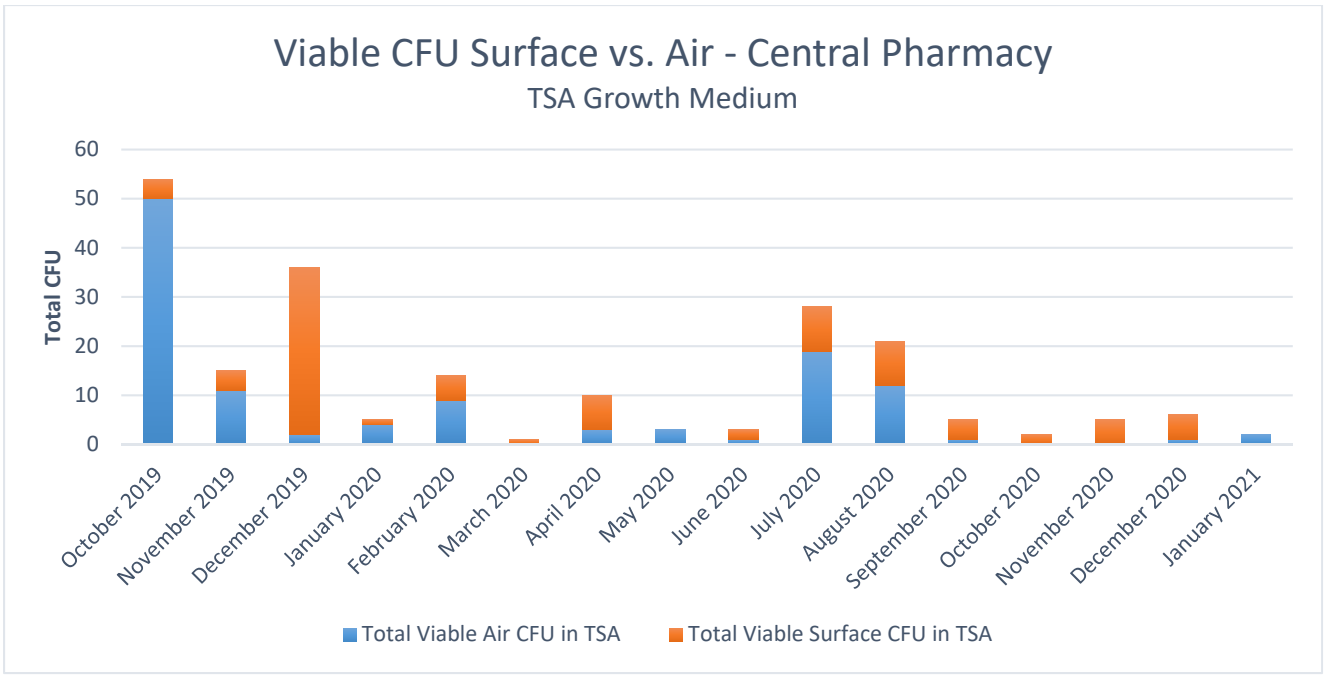
A hallmark of a strong EM program is measurement of progress in order to continuously improve compounding conditions, and effectively correct excursions. The below information is meant to highlight how some pharmacies track microbial growth to inform corrective action. These data also serve to inform interested parties (e.g. infection prevention) of EM program progress and outcomes.

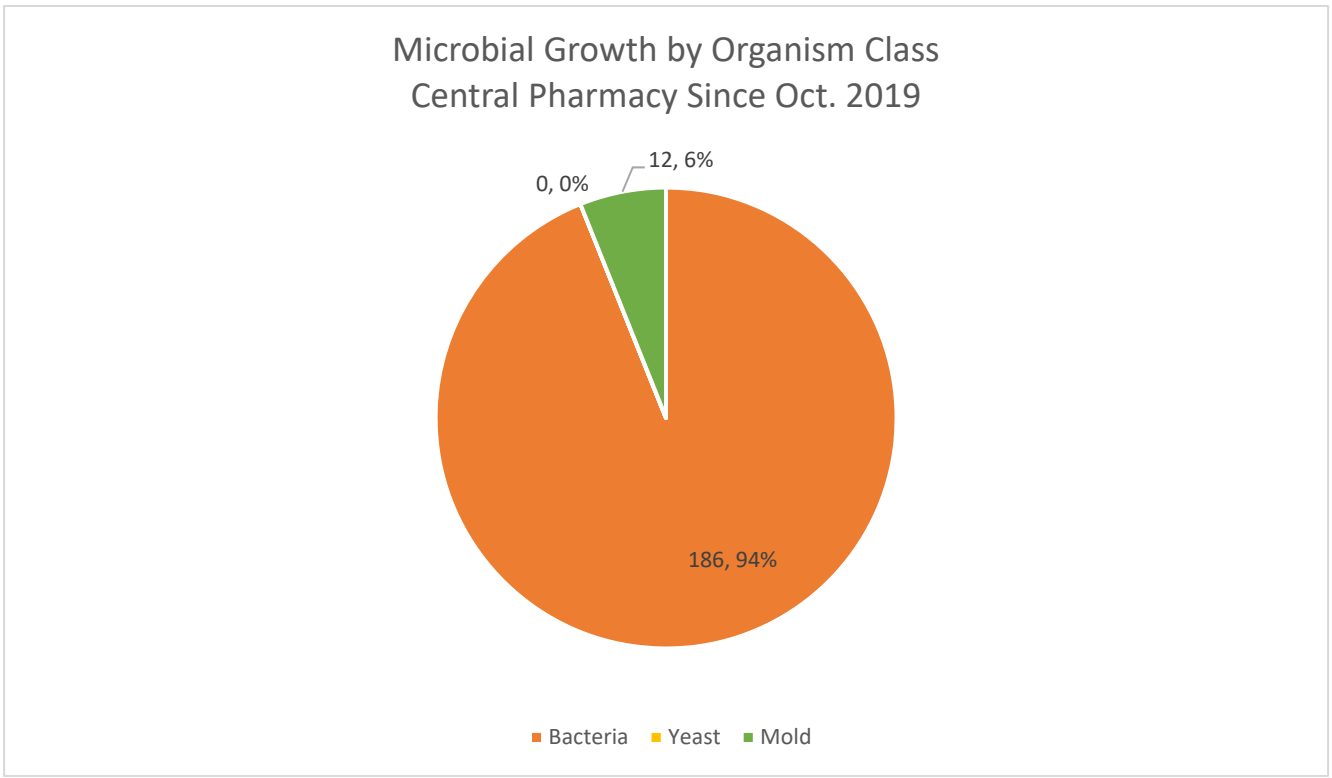
Metrics to consider using during your tracking efforts are below. These can be incorporated into a dashboard or other visual aid tool if this benefits decision making at your organization. The below information is recommended based on monthly sampling. Sampling can occur more or less frequently, so reporting metrics should be adjusted as needed. The below is not an all-inclusive list, but some ideas to begin tracking and trending EM results in a spreadsheet or other database tool.

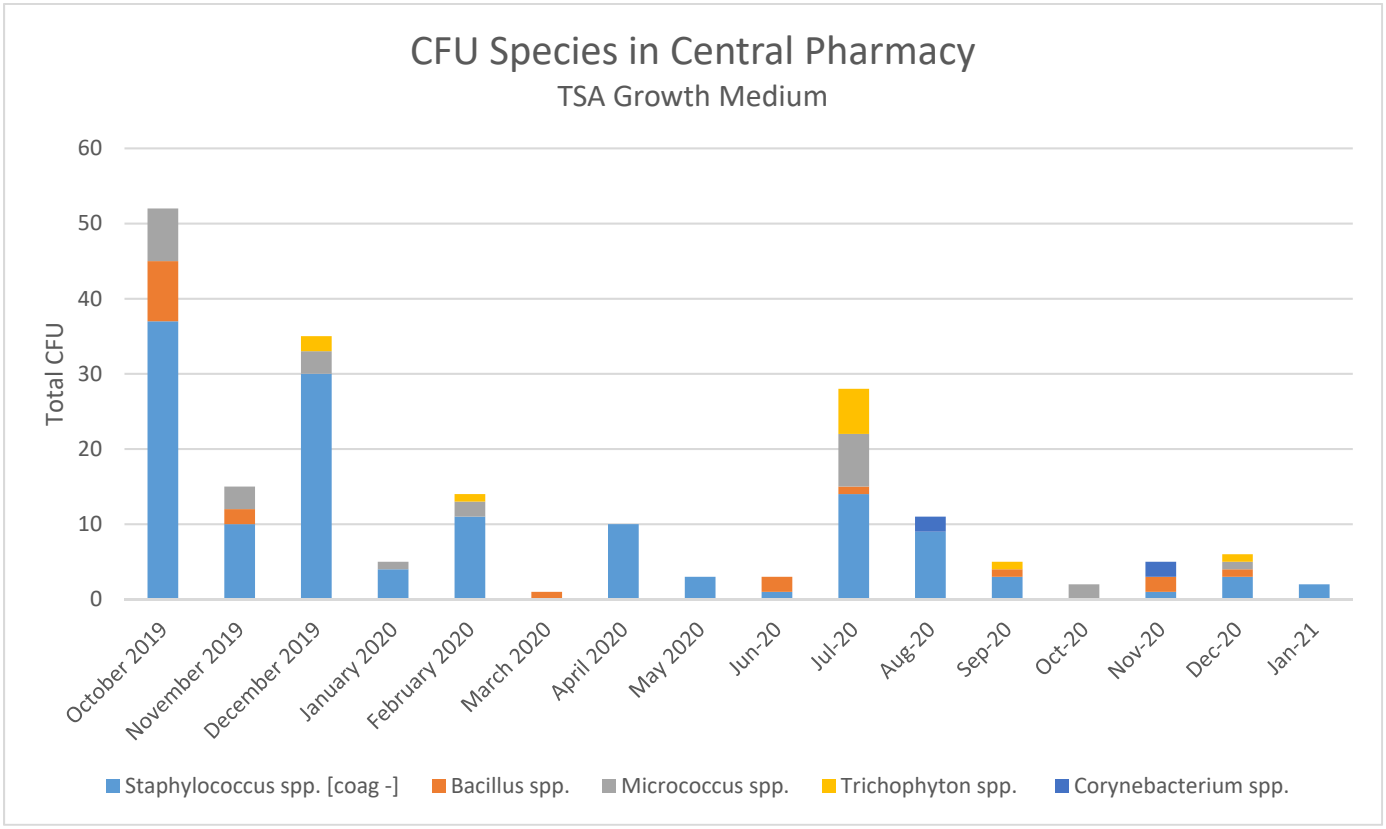
Metric	Description
Total CFU/month All Areas	Sums CFU count across all areas. Does not provide much decision-making capability for individual areas. Does serve as a benchmark to watch seasonal and other trends across enterprise.
Total CFU per Pharmacy per Month	Sums CFU count across each pharmacy. Does not provide much decision-making capability for individual sample locations. Does serve as a benchmark to watch seasonal and other trends for each room.
Total Surface CFU per Pharmacy per Month	Sum of surface CFU count across each pharmacy. Does not provide much decision-making capability for individual sample locations. Does serve as a benchmark to watch seasonal and other trends related to viable surface growth for each room.
Total Air CFU per Pharmacy per Month	Sum of air CFU count across each pharmacy. Does not provide much decision-making capability for individual sample locations. Does serve as a benchmark to watch seasonal and other trends related to viable air growth for each room.
Bacterial vs. Fungal Growth per Pharmacy per Month	Breaks down total CFU growth between two groups. Bacteria and fungus can be compared to understand more vs. less pathogenic organisms by pharmacy at a glance.
Microorganism Genus +/- Species per Pharmacy per Month	Breaks down CFU per pharmacy to the genus +/- species level to understand which areas might be contaminated by varying sources.
CFU Count by Individual Secondary Engineering Control (SEC)	Allows pharmacy to understand if growth is occurring in SECs where more or less activity is occurring. For example, anterooms where gowning and garbing is occurring should exhibit more growth than a positively pressured non-hazardous buffer room.
CFU Count by Individual Primary Engineering Control (PEC)	Allows pharmacy to understand if growth is occurring in PECs. If so, individual PECs can be tracked and trended over time to correlate with employee activity, mechanical issues, or other issues specific to the PEC in question.
CFU Count by ISO Classification	A Pareto Diagram is recommended here. This allows pharmacy to visualize where the majority of growth is occurring based on ISO classification of secondary and primary engineering controls.

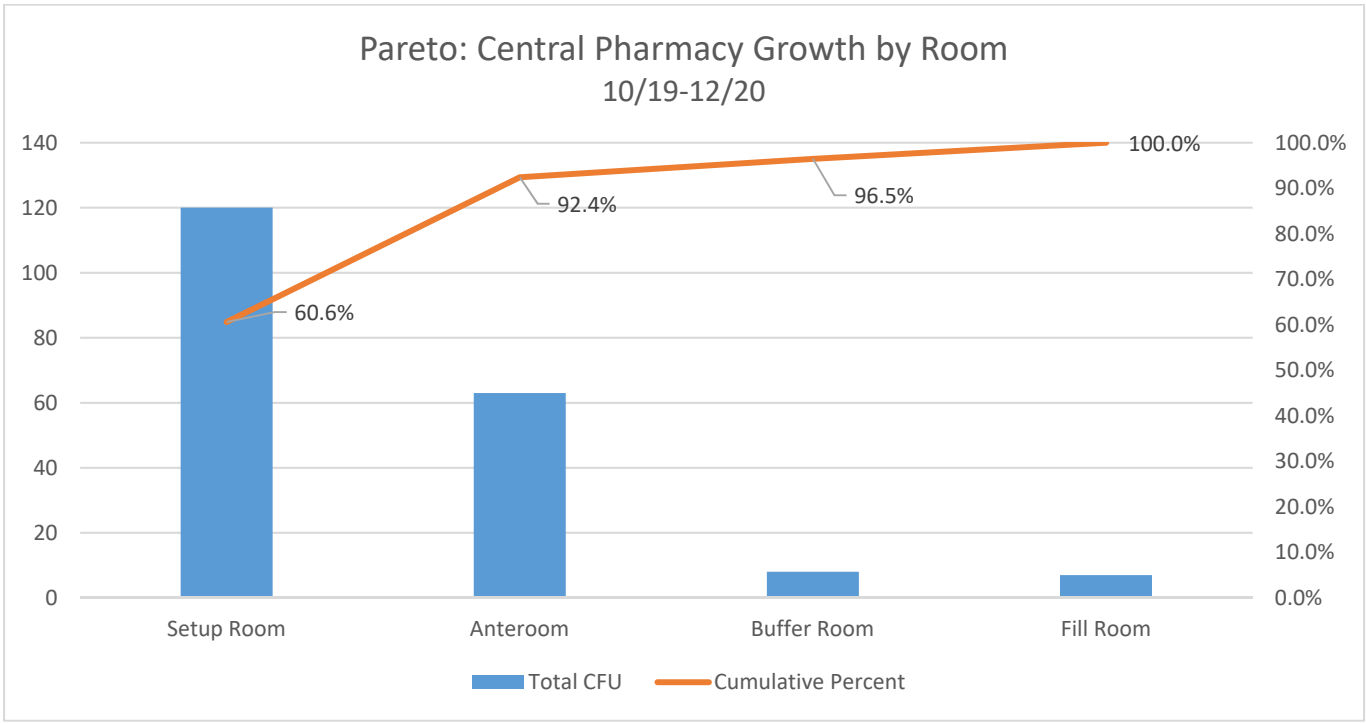

Total CFU Across All Compounding Pharmacies
Total CFU Count
250
200
150
100
50
0
October 2019
November 2019
December 2019
January 2020
February 2020
March 2020
April 2020
May 2020
June 2020
July 2020
August 2020
September 2020
October 2020
November 2020
December 2020
January 2021
Bacteria
Mold
Yeast
Total

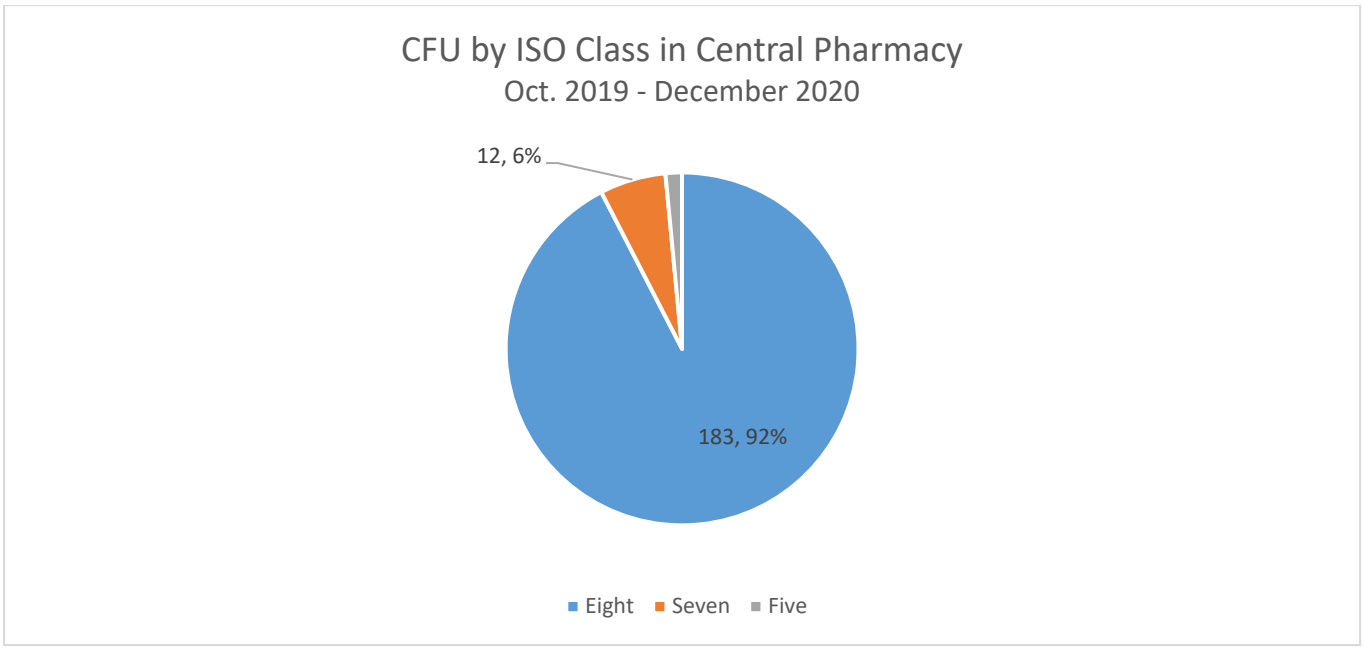

Total Colony Forming Units - Central Pharmacy
TSA Growth Medium
Total CFU
60
50
40
30
20
10
0
54
15
36
5
14
1
10
3
3
28
21
5
2
5
6
2
October 2019
November 2019
December 2019
January 2020
February 2020
March 2020
April 2020
May 2020
June 2020
July 2020
August 2020
September 2020
October 2020
November 2020
December 2020
January 2021


Viable CFU Surface vs. Air - Central Pharmacy
TSA Growth Medium
Total CFU
60
50
40
30
20
10
0
October 2019
November 2019
December 2019
January 2020
February 2020
March 2020
April 2020
May 2020
June 2020
July 2020
August 2020
September 2020
October 2020
November 2020
December 2020
January 2021
Total Viable Air CFU in TSA
Total Viable Surface CFU in TSA


Microbial Growth by Organism Class
Central Pharmacy Since Oct. 2019
12, 6%
0, 0%
186, 94%
Bacteria
Yeast
Mold


CFU Species in Central Pharmacy
TSA Growth Medium
Total CFU
60
50
40
30
20
10
0
October 2019
November 2019
December 2019
January 2020
February 2020
March 2020
April 2020
May 2020
Jun-20
Jul-20
Aug-20
Sep-20
Oct-20
Nov-20
Dec-20
Jan-21
Staphylococcus spp. [coag -]
Bacillus spp.
Micrococcus spp.
Trichophyton spp.
Corynebacterium spp.


Pareto: Central Pharmacy Growth by Room
10/19-12/20
140
120
100
80
60
40
20
0
100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
60.6%
92.4%
96.5%
100.0%
Setup Room
Anteroom
Buffer Room
Fill Room
Total CFU
Cumulative Percent


CFU by ISO Class in Central Pharmacy
Oct. 2019 - December 2020
12, 6%
183, 92%
Eight
Seven
Five

Relationship with Internal or External Clinical Laboratory Service

General Overview

A pharmacy department's EM program can greatly benefit, both financially and operationally, from an effective relationship with an internal clinical laboratory. An effective laboratory-pharmacy relationship consists of aligned incentives to minimize costs, reduced turnaround times for microorganism culturing and/or results interpretation compared to a large for-profit vendor, and microorganism expertise. If an internal clinical laboratory is not available, an external laboratory for results interpretation could be an effective option if service levels are adequate, and pricing is competitive.

An internal laboratory will be incentivized to minimize charges for results interpretation to the pharmacy department, and offer transparency in pricing beyond what an external, for-profit laboratory might offer. Additionally, a laboratory might have additional buying power for growth media compared to a pharmacy. This could reduce plate pricing, and an internal laboratory service would be incentivized to pass along the savings achieved through this buying power. The pharmacy department should ensure the internal laboratory is capable of interpreting and processing cultured media.

Internalizing an EM program should result in improved turnaround times for microbial growth results, which should result in quicker implementation of corrective action plans, if needed. Either pharmacy or a clinical laboratory can incubate growth media. If pharmacy incubates growth media, then transitions to an internal clinical laboratory for results interpretation, pharmacy has the opportunity to know colony forming unit (CFU) counts at the earliest opportunity. Whether an internal or external laboratory is used for results interpretation, turnaround expectations should be established up front. If a contract is utilized for an external clinical laboratory, penalties for longer than expected turnaround times could be instituted to incentivize strong service.

Process Overview

Establishing a relationship with a clinical laboratory requires pharmacy to connect with laboratory leadership and explain the service rationale and expectations. If an internal laboratory is available, it will be critical to convey the benefit to the organization from perspectives of compounding safety, cost reduction, and operational efficiency.

Once a relationship is established with the laboratory, it will be important to set up a sustainable process. Identification of a pharmacy technician to own the process, types and quantities of plates desired for sampling, cost centers to utilize for internal billing are all necessary steps. Finally, it might take some education of laboratory leadership about how these orders might be treated, since clinical laboratories might be more accustomed to filling orders for studies. The documents on the following pages are examples of how a standard process might be established with forms that fit a lab's workflow:

Clinical Laboratories

Special Studies Requisition

CLIENT ID #5025

Pharmacy Cleanroom – Plate Pickup

THIS REQUISITION MUST ACCOMPANY EACH SAMPLE

P.I.:
Study Coordinator:
Responsible for Invoices:

CLIENT5025	PLATE_CHARGE	MRN: S043954
Subject ID LAST	**Subject ID FIRST**	

01 / 01 / 2021
Date of Birth (MM/DD/YYYY)

☒ **Not known**
Sex

Pharmacy Instructions

1. When more plates are needed, go to the Micro Lab, present this requisition, and collect the plates.

Floating 3 CRA/Microbiology Instructions

1. CRA – do not process this requisition. Send directly to Micro lab.
2. Microbiology Lab – In **SoftLab Order Entry**, access patient **CLIENT5025, PLATE_CHARGE** (MRN S043954). Create a new stay, and enter the following information:
   a. Attending Dr.:
   b. Ward:
   c. Reg. by:
3. Enter the test code checked in the table below. Save the record. This will charge the Pharmacy account for the plates we are providing to them for this study. Provide CRA with this requisition to scan into SoftMedia.
4. Provide the pharmacist with the following materials:

Hardy #	Quantity	Name
P34	**3** x 10 plates	TSA, Lectin Tween 15 x 65 mm Contact plate
W41	**2** x 10 plates	TSA, Lectin Tween 15 x 10 mm , deep fill.

	Soft Mnemonic	Test name
☒	**HCHG2**	Charge for micro plates

Clinical Laboratories
Special Studies Requisition

CLIENT ID #5025

Pharmacy Cleanroom – Sample Submission

THIS REQUISITION MUST ACCOMPANY EACH SAMPLE

P.I.:
Study Coordinator:
Responsible for Invoices:

Subject ID LAST	**Subject ID FIRST**

01 / 01 / 2021	☒ **Not known**	QC
Date of Birth (MM/DD/YYYY)	Sex	Specimen Source

Pharmacy Instructions

1. For **EACH PLATE** submitted for work up, complete all fields in the above section.
   Label the plate with the same Subject ID listed on this requisition. All plates and requisitions must be labeled.
2. Bring plates and requisitions to Floating 3 Microbiology Lab.
3. Results will be faxed upon completion to

Floating 3 CRA/Microbiology Instructions

1. CRA – bring specimens and requisitions directly to Microbiology.
2. Microbiology – create a new patient using the Client ID and patient identifiers provided in the above section.
3. Order the test below; for source enter **QC**

	Soft Mnemonic	Test name
☒	**CXMSC**	Culture Miscellaneous

List of EM Competencies for Program Participants

Volumetric Air Sampler Competency

Date:

Trainee: **Trainer:**

Sampling Device: volumetric air sampling device

Approved Audience: Pharmacists and Pharmacy Technicians
Approved Trainer: Program Manager – Pharmacy Compounding
Frequency: Once

Component I – Review of Training Materials

	Date Complete
Has reviewed and understands the user manual for the sampling device	_____

Component II – Preparation

	Initial when competency demonstrated	
	Trainee	Trainer
Prior to sampling, verifies that the battery is charged enough to sample the volume of air and the number or sites to be sampled	Initial	Initial
Demonstrates how to turn the unit on	Initial	Initial
Demonstrates correct procedure for programming volume of air to be sampled	Initial	Initial
Sanitizes contact plate housing head using sterile 70% IPA by spraying the alcohol for approximately 30 seconds at a distance of 30 cm while the instrument is running (must be performed in the PEC)	Initial	Initial
Removed stainless steel sampling head and wipes the contact plate housing down with a sterile 70% alcohol wipe	Initial	Initial
Prior to sampling, verifies that the battery is charged enough to sample the volume of air and the number or sites to be sampled	Initial	Initial
Inserts contact plates into the plate holder of the sampler and removes the lid of the contact plate without contaminating the plate's surfaces	Initial	Initial
Places the lid of the contact plate face down on a clean wipe	Initial	Initial
Attaches the sterile aspirating head to the unit correctly without touching any surface of the head except the sides	Initial	Initial

Component III – Sampling Procedure

Turns the sampler on, verifies volume of air to be sampled again and begins sampling	Initial	Initial
At the end of the sampling cycle, removes aspirating head without touching any surface except the sides and without contaminating the contact plate	Initial	Initial
Replaces the lid on the contact plate and removes contact plate from sampler	Initial	Initial
Understands that the exterior and interior surfaces of the aspirating head must be sanitized between each sample site using a sterile 70% alcohol wipe	Initial	Initial
Understands that a new disposable sampling head must be used for each separate room (secondary engineering control)	Initial	Initial
Understands that if sampling must occur both in the PEC and the secondary engineering control that the PEC is located in, the same sampling head may be used, but the PEC must be sampled first	Initial	Initial

Component IV – Calibration of Air Sampler

Understands the sampler must be calibrated by an authorized vendor every 12 months	Initial	Initial
Understands that calibration records must be kept onsite for the life of the air sampler	Initial	Initial

_____

Trainee Sign & Date

I am competent with the operation of the volumetric air sampler

_____

Trainer Sign & Date

Trainee is competent in the use of the volumetric air sampler

Equipment List

Setting up to insource EM will require the purchase of new equipment. Some of this equipment may require large capital purchases and require advance planning within the institution's purchasing process. Examples of equipment used at one institution is listed below. Depending on the number of clean rooms being serviced, two air samplers may be beneficial. This is because accrediting bodies may require yearly recalibration leaving an institution without an air sampler while undergoing recalibration. A second air sampler will allow for operations to continue. Another recommendation for equipment depending on sampling volume is to have two incubators as there may be samples that need to be within two temperature ranges (30-35°C and 26°-30°C) at the same time.

Air sampler:

  - Manufacturer:
  - Model Number:
  - Detector Mfr: Flow System
- Air Sampling Plates:
  - Tryptic Soy Agar (TSA)
  - Malt Extract Agar (MEA)
- Refrigerator for plate storage prior to use
- Clear labels
- Surface Sampling Plates
  - Tryptic Soy Agar (TSA), size 24-30 cm^2
  - Malt Extract Agar (MEA), size 24-30 cm^2
- Non-shedding wipes
- 70% sterile isopropyl alcohol
- Paraffin film
- Incubator
- Continuous temperature monitoring system for both incubators and refrigerators

Compendium of Industry Resources

Environmental Monitoring Resource Guide		
The following is a list of resources to aid in the development of a site's cleanroom environmental monitoring plan. This includes standards, regulations, continuing education, and other helpful guides.		
Abbreviations: • **IEST**: Institute for Environmental Services and Technology • **ISO**: International Organization for Standardization • **USP**: United States Pharmacopeia		
Resource	**Details**	**Link**
USP Standards		
USP <797> Pharmaceutical Compounding - Sterile Preparations	See the sections on 'environmental quality and control' and 'Viable and Nonviable Environmental Sampling (ES) Testing' for specifics related to environmental monitoring program in controlled environments.	https://www.usp.org/
USP <800> Hazardous Drugs - Handling in Healthcare Settings	See the section on 'Environmental Quality and Control' for specifics around environmental wipe sampling for HD on surfaces and locations where this should occur.	
USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments	This best practice guide provides comprehensive information on the importance of a microbiological evaluation program for controlled environments and gives specifics on the design and implementation of an environmental monitoring program.	
CETA Standards		
CETA CAG-003: Certification Guide for Sterile Compounding Facilities	A guide to establish an industry-based minimum set of criteria appropriate for performance evaluation and certification of facility and environmental controls used for compounded sterile preparations. It is intended to assist compounders, facilities managers and certification professionals in determining appropriate tests and procedures to be employed on the various engineering controls.	www.CETAinternational.org
CAG-008: Secondary Engineering Controls	Provides a matrix for reviewing the certification of secondary engineering controls used in sterile compounding facilities designed to comply with USP <797>. The guide provides specific information on each type of test (e.g. airflow, HEPA filter integrity, smoke pattern tests, particle counts, temperature, humidity, etc.)	
CETA CAG-009: Viable Environmental Sampling & Gowning Evaluation	Provides an industry-based methodology for complying with the environmental sampling requirements addressed in USP <797> and <825>. It is intended to assist in determining appropriate procedures, which will establish a	

	unified approach for testing sterile compounding facilities, and utilizes traditional microbiological methods as indicated in the standards.	
ISO Standards		
ISO 14644-1: Cleanrooms and associated controlled environments - Classification of air cleanliness by particle concentration	The standard defines the performance of a cleanroom environment with respect to the total particulates per unit volume and the total particulate counts allowed to meet the defined air quality classifications.	https://www.iso.org/standard/53394.html
ISO 14644-2: Cleanrooms and associated controlled environments - Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Specifies minimum requirements for a monitoring plan for cleanroom or clean zone performance related to air cleanliness by particle concentration, based upon parameters that measure or affect airborne particle concentration.	https://www.iso.org/standard/53393.html
IEST Standards		
IEST-RT-CC006: *Testing Cleanrooms*	Covers testing methods for characterizing the performance of cleanrooms. It is intended to assist planners, designers, manufacturers, and customers in preparing detailed specifications for cleanroom procurement and for assuring cleanroom operational compliance. The test methods may also be used or adapted for periodic monitoring of cleanroom or clean zone performance.	https://www.iest.org/Standards-RPs/Recommended-Practices/IEST-RP-CC006
IEST-RP-CC013: Calibration procedures and guidelines for select equipment used in testing cleanrooms and other controlled environments	Covers procedures for calibrating and verifying equipment used in characterizing cleanrooms and for determining intervals of calibration. The RP includes general procedures for calibrating photometers, aerosol generators, and anemometers. Where available, references for calibrating other instruments are provided.	https://www.iest.org/Standards-RPs/Recommended-Practices/IEST-RP-CC013
IEST-RP-CC014.1: *Calibration and Characterization of Optial Airborne Particle Counters*	Covers procedures for calibrating and characterizing the performance of optical particle counters (OPCs) that detect and measure the size of single particles in air and other gases. These procedures are intended for use by OPC manufacturers, specialized test houses, and OPC users who maintain calibration and testing facilities to determine the sizing and counting accuracy of these instruments.	https://www.iest.org/Standards-RPs/Recommended-Practices/IEST-RP-CC014
FDA		

FDA 2004 *Guidance for Industry Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Guide*	Provides guidance on CGMP practices for aseptic processing facilities. Has specific information on personnel qualification, cleanroom design, process design, quality control, environmental monitoring, and review of production records. Section 'A' of this guidance document has detailed information on an environmental monitoring program, including writing a program, establishing levels and a trending program, disinfection efficacy, monitoring methods, surface monitoring, active air monitoring, and passive air monitoring.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/sterile-drug-products-produced-aseptic-processing-current-good-manufacturing-practice

Suggested Reading

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3. Settineri F. Managing Environmental Monitoring Excursions. Pharmacy Purchasing & Products. November 2016: 20-22
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6. Sutton S. Critical Components of Effective Environmental Monitoring. Pharmacy Purchasing & Products. March 2015: 20-24
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