CETA Application Guide
CAG-014

Airflow Visualization Study

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Revised March 2022.

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Foreword

The Controlled Environment Testing Association (CETA) is an international organization. One of CETA's objectives is to promote quality assurance through the review of existing standards and the development of new methodologies. One of the main vehicles for obtaining this goal is our CETA Application Guides. The CETA Application Guides have proven to be an immeasurably valuable tool to a wide variety of professionals in our industry. They have been used by many safety professionals, industrial hygienists, facility engineers and quality control personnel.

The standards and other documents normatively referenced, in whole or in part, in this CETA Application Guide are indispensable for its use and application. The content of this CAG has its origin in material found in these reference documents. Preparation and development of these guides are the outcome of work completed by technical committees that are formed by the CETA Board of Directors.

Abstract

Airflow visualization studies completed in sterile compounding facilities should be performed in a consistent manner and in such a way that the tests are easily repeatable and well understood by the compounding facility and certification company. CAG-014 provides guidance, methodology and industry best practices applicable to airflow visualization studies in primary engineering controls and cleanrooms.

1 Introduction

Primary and Secondary Engineering Controls used for sterile compounding require airflow patterns to be visualized. The rooms and equipment can then be studied to determine whether they are operating correctly. The Designated Person can visualize whether the device is being used effectively. Airflow Visualization Studies (AVS) should be performed in a consistent manner and in such a way that the tests are easily repeatable. This guide provides an outline of best practice and troubleshooting through AVS testing.

2 Scope

The testing procedures listed in this guide are intended to be used in sterile compounding facilities seeking compliance to USP chapters <797>, <800> and <825>. This guide references minimum current industry-accepted best practices to perform Airflow Visualization Studies and properly document the results.

The definitions, acceptance criteria and minimum requirements listed in this document are based on USP <797>, <800> and <825>.

2.1 Limitations

This document's focus is on sterile compounding facilities although some of the test procedures listed may be useful in other industries.

Individual inspectors may have preferences for AVS that may differ from this document and must be followed. For example, to provide unedited raw footage.

3 Target Audience

This document is intended for anyone that will oversee, collect, edit, review or interpret airflow visualization study videos in a sterile compounding setting.

4 References

For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

4.1 Reference Documents

ISO 14644-1: Cleanrooms and associated environments - Part 1: Classification of air cleanliness by particle concentration (2015). International Organization for Standardization (ISO), Geneva, Switzerland.

NSF/ANSI 49 Biosafety Cabinetry: Design, Construction, Performance and Field Certification. NSF International (NSF), Ann Arbor, MI, US.

USP General Chapter <797>: Pharmaceutical Compounding - Sterile Preparations (2021). United States Pharmacopeia, Rockville, MD, US.

USP General Chapter <800>: Hazardous Drugs - Handling in Healthcare Settings (2019). United States Pharmacopeia, Rockville, MD, US.

USP General Chapter <825>: Radiopharmaceuticals - Preparation, Compounding, Dispensing and Repackaging (2019). United States Pharmacopeia, Rockville, MD, US.

4.2 Cited Bibliography

The following documents are cited in the guide. They may be obtained from the source of the publication.

IEST-RP-CC006.3: Testing Cleanrooms (2004). Institute for Environmental Standards and Technology (IEST), Schaumburg, IL, US.

5 Nomenclature

The terms and definitions here are intended to clarify generally accepted industry positions or to provide specific guidance as needed to understand the testing requirements of this application guide. Where applicable, industry positions have been used in full or in part to define processes.

Adverse Air Currents - Air currents that adversely affect the HEPA filtered unidirectional air flow of a buffer area/room or primary engineering control.

Airlock - A space with interlocked doors constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lesser-controlled area.

Ante Area/Ante-room - An ISO Class 8 (or cleaner) room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The ante-room is the transition room between the unclassified area of the facility and the buffer room. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas.

Aseptic Processing - A method by which separate, sterile components (e.g., drugs, containers, or closures) are brought together under conditions that maintain their sterility. In most cases, the components can be purchased as sterile. Nonsterile components can be separately sterilized prior to combining (e.g., by membrane filtration, autoclave).

As-Built Conditions - Condition where the cleanroom or clean zone is complete with all services connected and functioning but with no equipment, furniture, materials or personnel present.

At-Rest Conditions - Condition where the cleanroom or clean zone is complete with all normal equipment and supplies used for compounding installed and operating, but with no personnel present (see static conditions).

AVS - Airflow Visualization Study (see Visual Smoke Study for SECs and Dynamic Airflow Smoke Pattern Test for PECs)

AVS Output Manifolds - Diffusers remote to the visible medium source intended to release the medium in a method appropriate to the airflow visualization test being performed.

Backstreaming - Airflow currents that travel in the opposite direction (upstream) of the HEPA filtered unidirectional airflow due to the turbulence created by an object within the airstream.

Biosafety Cabinet (BSC), Class II - A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.

Buffer Area/Room - An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the ante-room.

Classified Area - An area that maintains an air quality classification based on the ISO standards (see also the definition for ISO class).

Compounded Sterile Preparation (CSP) - A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.

Compounding - The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication.

Compounding Area - The area where compounding is occurring (i.e., a cleanroom suite, inside the perimeter of the SCA, or CSCA).

Compounding Aseptic Containment Isolator (CACI) - A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.

Compounding Aseptic Isolator (CAI) - A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

CETA - Controlled Environment Testing Association

Critical Area - An ISO Class 5 environment.

Critical Site - A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, and beakers) or openings (e.g., opened ampules and needle hubs) that are exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.

Direct Compounding Area (DCA) - A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Designated Person(s) - One or more individuals assigned to be responsible and accountable for the performance and operation of the compounding facility and personnel in the preparation of CSPs.

HEPA-Filtered Air - The air exiting the HEPA filter in a unidirectional air stream also known as first air.

Dynamic Airflow Smoke Pattern Test - A PEC test in which a visible medium (smoke source), which is close to neutrally buoyant, is used to observe air patterns within the unidirectional space

(i.e., the DCA) under dynamic operating conditions (see Dynamic operating conditions). This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see Visual Smoke Study).

Dynamic Operating Conditions - Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

First Air - The unobstructed air exiting the HEPA filter in a unidirectional air stream.

High-efficiency Particulate Air (HEPA) Filtration - Being, using, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

HVAC - Heating Ventilation and Air Conditioning

ISO - International Organization for Standardization

ISO Class - An air-quality classification from the International Organization for Standardization 14644-1.

Laminar Airflow System (LAFS) - A device or zone within a buffer area that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.

Laminar Airflow Workbench (LAFW) - A device that is a type of LAFS which provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.

Pass-through - An enclosure with sealed doors on both sides that should be interlocked or procedures in place to assure only one door is opened at a time. The pass-through is positioned between two spaces for the purpose of minimizing particulate transfer while moving materials from one space to another.

Primary Engineering Control (PEC) - A device or zone that provides an ISO Class 5 air quality environment for sterile compounding.

Restricted-access Barrier System (RABS) - An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

Secondary Engineering Control (SEC) - The area where the PEC is placed (e.g., a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

Short Circuit (airflow) - An airflow pattern where ceiling or high wall room return grills directly draw HEPA filtered air in from the ceiling HEPA filtered supply source(s) bypassing the required room airflow mixing to meet the required ISO room classification.

Simulated Compounding - Compounding performed by a trained pharmacy technician or pharmacist which replicates the typical compounding procedures performed in the compounding facility but does not utilize active pharmaceutical ingredients.

State of Control - State of control is the practice of controlling variables to achieve the expected results. For the purposes of sterile compounding facility certification, a state of control is achieved when critical parameters used to achieve an appropriate environment for sterile compounding are managed and under control. Adequate HEPA filtered air is supplied to the room or PEC and the cleaner space is protected from less clean spaces by overpressure or displacement airflow.

Static Conditions - See At-Rest conditions

Total Work Area - The area inside the workstation between the sidewalls, horizontal flow diffuser or rear wall, ceiling top or bottom of the downflow diffuser, and top of the work surface. The total work area definition is applicable only for purposes of design and construction and for testing.

Unidirectional Airflow - Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.

Visual Smoke Study - A test, used in non-unidirectional ISO Class 7 and ISO Class 8 cleanrooms, in which a visible source of smoke, which is close to neutrally buoyant, is used to verify an absence of stagnant airflow where particulates can accumulate. This test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see Dynamic airflow smoke pattern test). This test is done when an ISO Classified room has ceiling mounted air returns. It only needs to be done when the room is first commissioned and again when any changes to the room configuration which may affect the room's performance are made.

Work Zone - The space within the total work area where the user can perform the process, identified by the manufacturer and airflow visualization studies as appropriate for user activities to maintain product protection.

6 Materials and Equipment

A visual medium (smoke) must be chosen that will demonstrate variations in airflow patterns, and will not affect the airflow direction in any way, or mask smaller eddy currents within the smoke plume due to excessive or inconsistent smoke output.

AVS output manifolds for proper smoke diffusion in rooms, a manifold should be selected based on the type of smoke and output velocity and the video to be collected.

A video recording device.

Stand or tri-pod. For securing video recording devices and/or output manifolds.

Materials needed for simulated compounding (to be provided by the pharmacy).

7 Precautions/Safety

7.1 Precautions

Observe all facility safety signage, personal protective equipment requirements and facility procedures. Ensure safety data sheets are readily available for products used in the certification process.

Smoke detectors in the vicinity of the AVS must be placed in test mode to limit issues caused by smoke alarms.

Irritation to the personnel performing operational/dynamic simulations from the visible medium should be considered.

8 Procedures

It is crucial to identify any local regulation or enforcement variances on any aspects of AVS services. Items with a higher likelihood of variance include; frequency of each type of test, video type, recording style, and final product editing.

The visible medium source should be as close to neutrally buoyant as possible. Water based vapor generators such as CO^2 and liquid nitrogen create a fog that is heavier than air and do not always provide for an accurate representation of the actual air patterns. These smoke sources also diffuse rapidly in ambient air, making identification of stagnant air, or delayed re-entrainment to the critical zones difficult to accurately identify.

8.1 SEC Airflow Visualization Studies (AVS) - Visual Smoke Studies

HVAC systems, equipment, and PECs throughout the suite must be operational and within design parameters prior to beginning AVS.

8.1.1 SEC Ceiling Exhaust/return Air Vent AVS Testing Procedure

Low wall returns are required unless an AVS is completed proving HEPA filter supply air does not immediately get evacuated to the high/ceiling return (short circuiting) prior to diluting into the room, bypassing its ability to mix with room air properly. Each room supply must prove that it does not short circuit into a high exhaust/return (including PEC intakes) and the characteristics of visible smoke must dilute into the room. Visible smoke is injected into the room at the supply diffuser and should flow downward to work height typically 48” (122 cm) from the floor or 12” (30 cm) from work surfaces.

8.1.2 SEC Room AVS Best Practices

In addition to the previous two tests, there are other AVS tests that can be performed on SEC rooms as a Best Practice and/or a troubleshooting method for loss of state of control. Additional AVS testing can be a tool for the certifiers and the facility staff to get a better understanding of how the SEC is operating compared to the design intent.

When performing AVS in unidirectional cleanrooms, IEST-RP-CC006.3 section 6.5 can be used to provide methodology and pass/fail testing criteria.

When performing AVS in turbulent flow cleanrooms, there are several areas of focus as listed below.

Video recordings should be from an angle that captures the greatest deflection of the trailing smoke pattern.

8.1.3 Ceiling Supply HEPA Filter(s)

This test is performed to allow the airflow patterns of the room to be visualized as the air enters the room through the supply HEPA filter(s). Air patterns are monitored as they move through the room to the exhaust source. Smoke should be released into the room at the face of the supply HEPA filter and monitored as it flows throughout the room. Testing should be performed and documented for each ceiling supply HEPA filter.

Introduce smoke in a manner that does not create additional adverse air currents (for example, currents that would be created by a technician on ladder). An output manifold may be necessary for this test. The use of strong directional lights or lasers may aid in recording the results as listed in section 8.3.5. Special focus should be paid to areas of delayed purge (stagnant air) and those areas must be suggested for inclusion in the environmental monitoring plan.

8.1.4 Exhaust/return Vents

This test is performed to allow the airflow patterns of the room to be visualized as the air exits the room through the exhaust/return vents. Testing should be performed and documented for each exhaust/return vent.

Smoke can be released at the face of the exhaust/return vent. The smoke source is then moved away from the vent to determine the area of capture. Smoke can also be released and monitored as it moves towards the exhaust/return vent.

The focus is to ensure the vent captures as designed. Introduce smoke in a manner that does not create additional adverse air currents. A diffuser or output manifold may be necessary for this test. The use of strong directional lights or lasers may aid in recording the results as listed in section 8.3.5.

Where exhaust/return vents are designed to evacuate particulate from a mechanical source (such as a refrigerator) the vent should prove it operates as intended.

Where an exhaust/return vent is not showing sufficient capture, an investigation should take place to determine whether the HVAC system requires rebalancing, the exhaust vent should be resized, or whether the vent should be capped off to facilitate easier cleaning.

8.1.5 Pass-throughs & Airlocks

This test is performed on Pass-throughs & airlocks between any classified area and an area of lesser air quality. This test should be performed as-built and under dynamic operating conditions. During the dynamic operating condition test the

materials typically used in the pass-through or airlock present and transferred as usual.

Fill pass-through or airlock with smoke from the lesser air quality area and observe what happens when the door to the classified area is opened. Ensure manufacturer recommended purge times are used before opening inner doors.

If smoke enters the classified area, verify it does not contact critical areas (such as sterile staging, prep or storage areas). Smoke cascading into or onto these areas is unacceptable.

Where smoke cascades into critical areas an investigation should take place to determine whether the HVAC system requires rebalancing, or other mechanical adjustments.

8.1.6 SEC Airflow Visualization Studies (AVS) Reporting and Documentation

A video recording is the method of AVS documentation. A video recording allows for future review and training purposes. The certification report should refer to the video file.

Some inspectors will be looking for a continuous video with no editing so they can be sure mistakes have not been edited out. If editing, ensure raw footage is also included.

These details should be included at the start of filming:

- Date
- Facility name and site location
- Room name and test being performed
- Operational state (as-built, at-rest, dynamic / operational)
- Number of (if any) compounding technicians present in room
- AVS should be reviewed with the Designated Person to ensure the process was carried out properly.
- AVS should be reviewed by the compounding facility supervisors so they can determine optimal operating set-ups based on airflow patterns within the space.
- AVS should be viewed by compounding personnel just prior to each semiannual media fill test to ensure staff are up to date on the latest methods used to provide proper contamination control.

8.1.7 SEC Airflow Visualization Studies (AVS) Frequency

AVS for high wall/ceiling return/exhaust air vents shall be performed at least once, and repeated any time changes to the room are made.

The remainder of the SEC AVS tests listed in section 8.1, do not have a required test frequency. They are useful in troubleshooting or confirming initial functionality.

8.2 PEC Airflow Visualization Studies (AVS) - Visual Smoke Studies

PECs must be operational and certified prior to beginning AVS.

8.2.1 As-Built PEC AVS Objective

To be completed when the PEC is clean and empty but all manufacturer supplied components and any permanently installed items in place.

The as-built test is to determine if the device is performing as designed. It ensures that unidirectional airflow is sufficient to sweep away particulate at the work area and to identify adverse air currents. This test will establish the Direct Compounding Area (DCA).

8.2.2 As-Built PEC AVS Procedure

Visible medium to be released 1 inch (2.5 cm) from PEC diffuser in a pattern that covers the entire face of the diffuser. Identify and document areas free of adverse air currents, that can be established as the direct compounding area. First Air must be demonstrated through the direct compounding area. Areas of adverse air currents should be discussed with the Designated Person. Examples of non-unidirectional airflow currents would be downstream of an oversized HEPA filter patch, downstream of an IV bar, or a corner/side of the work area with limited HEPA filter coverage.

8.2.3 As-Built PEC AVS Acceptance

The PEC must be capable of establishing and maintaining First Air across the direct compounding area. The test must prove that the PEC provides first air in sufficient velocity to sweep particulate away from the work area and that the PEC is not affected by the surrounding less clean air.

8.2.4 As-Built PEC AVS Frequency

At least once, and repeated any time major modifications to the work area are made to the PEC.

8.2.5 At-Rest/Static PEC AVS Objective

At-rest testing confirms the PEC is properly integrated into the facility and that placement of materials or equipment does not impede the first air in the DCA.

All equipment and supplies that are normally used for compounding must be in place within the PEC.

It must be demonstrated that the DCA has sufficient airflow to sweep contamination away from the critical site when all equipment and supplies are in place. Adverse air currents (such as back streaming, and dead air spots) caused by the placement of equipment and supplies will be addressed and discussed with the Designated Person.

8.2.6 At-Rest/Static PEC AVS Procedure

A visible medium is released across the First Air entrance plane directly upstream of all equipment and materials within work area. It must be proven that air flows directly from the HEPA filter, into the DCA, to the critical site, across the critical site, and then out of the DCA.

A visible medium is released downstream of any equipment and supplies at the access plane to the device to ensure that placement of items does not create an influx of less clean air into the DCA.

8.2.7 At-Rest/Static PEC AVS Acceptance

The PEC must be capable of maintaining First Air across the direct compounding area. It must be proven that First Air flows directly from the HEPA filter, into the DCA, to the critical site, across the critical site, and then out of the DCA.

The placement of equipment and supplies must not cause influx of less clean air, into the DCA.

8.2.8 At-Rest/Static PEC AVS Frequency

At least once, and repeated any time the placement or size/shape of materials or equipment is changed. This includes when items are removed from the overall process.

8.2.9 Dynamic/Operational PEC AVS Objective

This test is performed to ensure that the PEC provides adequate unidirectional airflow to support the aseptic operations performed utilizing first air. The focus of the visible smoke source must be at any/all critical sites once exposed and to identify adverse air currents into the DCA created by excessive movement during the compounding process.

To be completed in the actual conditions in which the engineering control is used. Actual compounding personnel are present and performing the most complex, complete simulated actual operations executed in the PEC, using sacrificial supplies.

8.2.10 Dynamic/Operational PEC AVS Procedure

The visible medium must be discharged as far upstream of the process as possible, ideally at the HEPA filtered air source, in a location that allows for proper visual tracking of the visible medium to the critical site. Every time a critical site is exposed or moved (for example, a vial stopper, needle, syringe connection) it must be within the cascading visible medium, until covered, connected or the manipulation is otherwise completed.

8.2.11 Dynamic/Operational PEC AVS Acceptance

It must be proven that First Air flows directly from the HEPA filter, into the compounding area, to the critical site, across the critical site, and then out of the compounding area. The visible medium must directly contact the critical site first, before any other obstructions from the HEPA filter source/diffuser as it exits the

compounding area. The visible medium must be free of turbulence, refluxing or re-entrainment into compounding area.

8.2.12 Dynamic/Operational PEC AVS Frequency

At least once, and repeated any time changes are made to the compounding process, as well as at any frequency required by regulatory bodies.

8.2.13 PEC Airflow Visualization Studies (AVS) Reporting and Documentation

A video recording is the method of AVS documentation. A video recording allows for future review and training purposes. The certification report should refer to the video file.

Some inspectors will be looking for a continuous video with no editing so they can be sure mistakes have not been edited out. If editing, ensure raw footage is also included.

These details should be included at the start of filming

- Date
- Facility name and site location
- Equipment identification number
- Operational state (as-built, at-rest, dynamic/operational)

AVS should be reviewed with the Designated Person to ensure the process was carried out properly.

AVS should be reviewed by the compounding facility supervisors so they can determine optimal operating set-ups based on airflow patterns within the space.

AVS should be viewed by compounding personnel just prior to each semi-annual media fill test to ensure staff are up to date on the latest methods used to provide proper contamination control.

8.3 Techniques to Aid in Performing AVS

8.3.1 Alternative/Additional Materials for Best Results

Tape measure for scale and material placement reference.

Remote lighting can aid in visibility of smoke in less ideal or lighter background situations.

- Colored gels/lenses can increase the effect of remote lighting
- Often the primary lighting of the area or PEC will need to be turned off to limit diffusion from light colored walls.

Lasers can visually demonstrate lower levels of smoke in areas that are easily seen with the naked eye but would otherwise not be evident in a video record. They are extremely helpful for qualitative recovery testing documentation.

Higher resolution cameras are more effective at capturing trace movement of smoke. However, larger file size can prove a challenge when transferring data.

Camera should be cleanable and shock resistant for use in controlled environments.

Suction cups and magnets are useful for static shots in the PEC.

Camera sticks are often helpful in filming.

Dry erase markers may be helpful to indicate the DCA.

8.3.2 Process Tracking and Angles

Tracking the process

Moving the camera location during the process to ensure each action is within range (normally 6-12 inches or 15-30 cm) will help to achieve unobstructed views of the critical sites.

Multiple shots

After the entire process has been captured on video, capturing each action individually through the entire process can put focus on each step of the manipulation. Each shot is normally taken between 6 and 12 inches (15-30 cm) from the action being performed, with an unobstructed view of smoke passing over critical sites.

Multiple angles

Multiple simultaneous angles can add a level of depth perception to the video making the process simple to view. Top and front angles often limit the obstruction caused by compounder's hands or arms and provide the best views.

8.3.3 PEC Dynamic AVS Focus Point Recommendations

Actions/processes to capture may include but are not limited to the following:

- Opening sterile syringe and placement
- Opening sterile needle and connection to syringe
- Exposing sterile needle and transitions between each action
- Uncapping, wiping and penetrating vial
- Wiping and penetrating bag
- Opening and entering ampules
- Filling vials of dehydrated media for reconstitution and mixing

- Connection of transfer tubing
- Sealing of critical site for delivery
- Bagging the final syringe/bag (HD final product transfer bags to patients)

8.3.4 Common Areas of Concern for AVS

During As-Built/at-Rest testing, closely monitor these areas to establish the DCA:

- Downstream of a lip at the rear (back) of the worksurface in horizontal LAFW
- Downstream of the IV bar
- Around the center of vertical LAFWs and BSCs where the smoke splits front to back
- The perimeter of air diffuser(s) and along walls
- HEPA filter center bars
- Patches from repairing HEPA filter leaks
- Downstream of any equipment or materials placed in the work zone
- Along the work trays/ surfaces in the main chamber of CAI/ CACI's
- Just inside viewscreen on CAI/CACIs

If identified, document the zone(s) of the adverse air currents within the work area that must not be included in the Direct Compounding Area or used for other processes requiring first air.

8.3.5 Filming Tips

Perform a trial run of the compounding procedure prior to taking the actual video.

If the video is blurry, the camera may be focused on the view screen of the PEC. Place the camera inside the PEC for better focus and to reduce reflections.

If the camera must be handheld, steady the hand or arm against a sturdy surface.

Verify what the camera is filming to ensure capture of the focus point.

Verbal explanation can be added to aid review and provide helpful notes during editing and post production.

The use of dry erase markers can be used to outline the DCA.

Ensure adequate quantity of smoke is present before starting to film.

PEC and/or room light can be turned off to aid in visualizing the medium.

When greater contrast of the visible medium is needed, thin plastic (garbage bag) may be applied to smooth surfaces using sterile water or alcohol to create static

cling adhesion. This method is simple to remove and does not cause or cover up adverse air currents as other backdrop methods could.

Diffusion of light is needed for visualization. If background light is insufficient, a mobile light source may be needed to achieve diffusion without causing washout or hot spots in the video.

Colored lights can aid in increasing the visibility of the medium. Colored lights will reflect off of surfaces differently than they will diffuse in the visible medium. Using colored lighting gels over light sources will improve the contrast between the medium and white backgrounds.

9 Addresses and Contacts

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