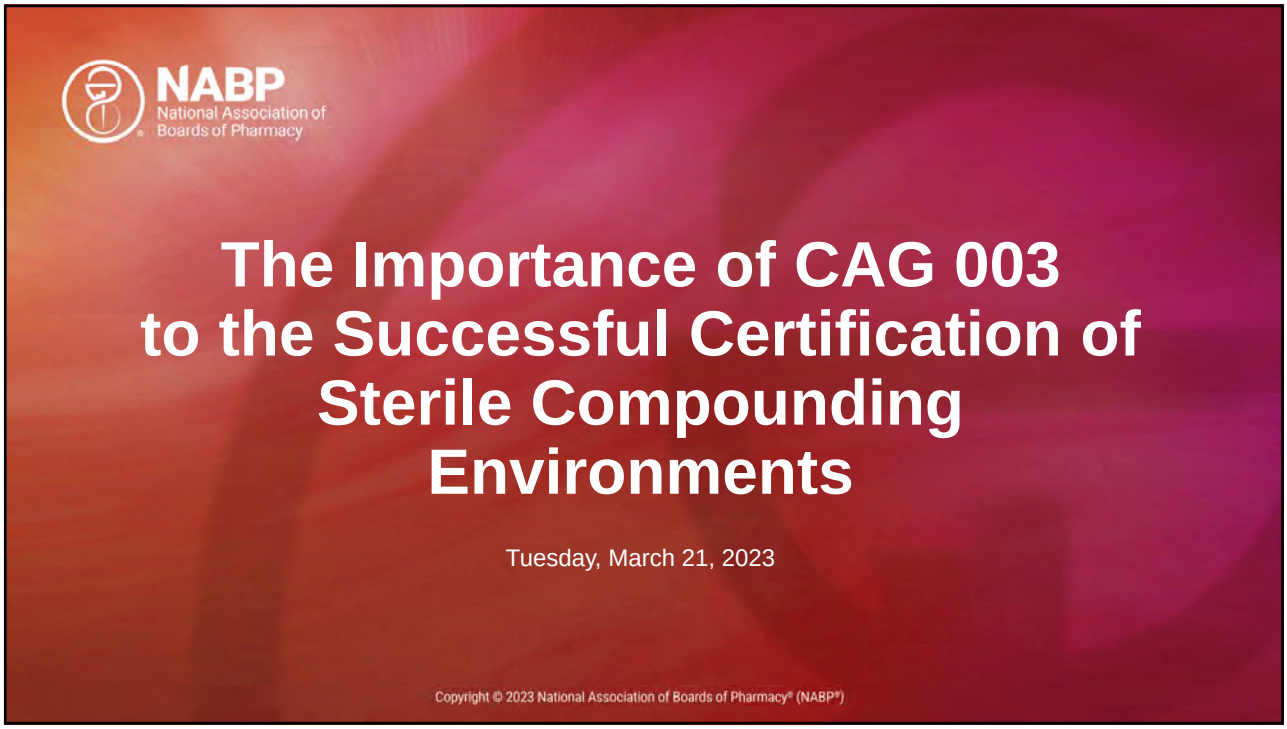

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The handout for today's presentation can be found at:

www.nabp.pharmacy/webinar

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Financial Disclosures

Our speakers Lewis Exner and Abby Roth declare that they do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Additionally, NABP staff involved in the planning of this activity do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE Program within the past 24 months.

All relevant financial relationships have been mitigated.

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NABP National Association of Boards of Pharmacy

The Importance of CAG 003 to the Successful Certification of Sterile Compounding Environments

Lewis Exner
Director of Field Operations
Controlled Environment Consulting

Abby Roth, CMQ/OE
Owner/Microbiologist
Pure Microbiology

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The Importance of CAG 003 to the Successful Certification of Sterile Compounding Environments

Lewis Exner, Controlled Environment Consulting

Abby Roth, Pure Microbiology

NABP National Association of Boards of Pharmacy

CETA Controlled Environment Testing Association

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Learning Objectives

After this webinar, the learner will be able to:

- Recall the Controlled Environment Testing Association's (CETA's) goals and mission.
- Explain the benefits of certifying sterile compounding facilities according to CETA Application Guide (CAG) 003.
- List the essential components of a certification report.

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Self-Assessment Questions

1. **Which CETA Application Guide (CAG) describes the certification testing procedures for a sterile compounding cleanroom suite?**
   a. 002
   b. 003
   c. 008
   d. 009
2. **Which test is required for the certification of a laminar airflow workbench (LAFW)?**
   a. Backstreaming
   b. Ingress and egress
   c. Particle containment
   d. Airflow containment verification
3. **Which reporting element should be included in the certification report?**
   a. Condition of the biological safety cabinet
   b. Age of the equipment used for testing
   c. Explanation of the test procedure
   d. Time it took to complete testing

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What is CETA™ Controlled Environment Testing Association ?

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Controlled Environment Testing Association

- Nonprofit organization
- Dedicated to creating an industry of highly qualified, knowledgeable certification professionals to service
  - healthcare
  - life science
  - other industries

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Yesterday

- Established in 1992
- Goals
  - Promote quality assurance in the controlled environment industry
  - Educate industry professionals
  - Work with government and regulatory agencies

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Today

- Hosts conferences and educational series
- Publishes a semiannual journal
- Drafts and maintains the CETA Application Guides (CAGs)
- Offers credentials to industry professionals through the CETA National Board of Testing (CNBT)

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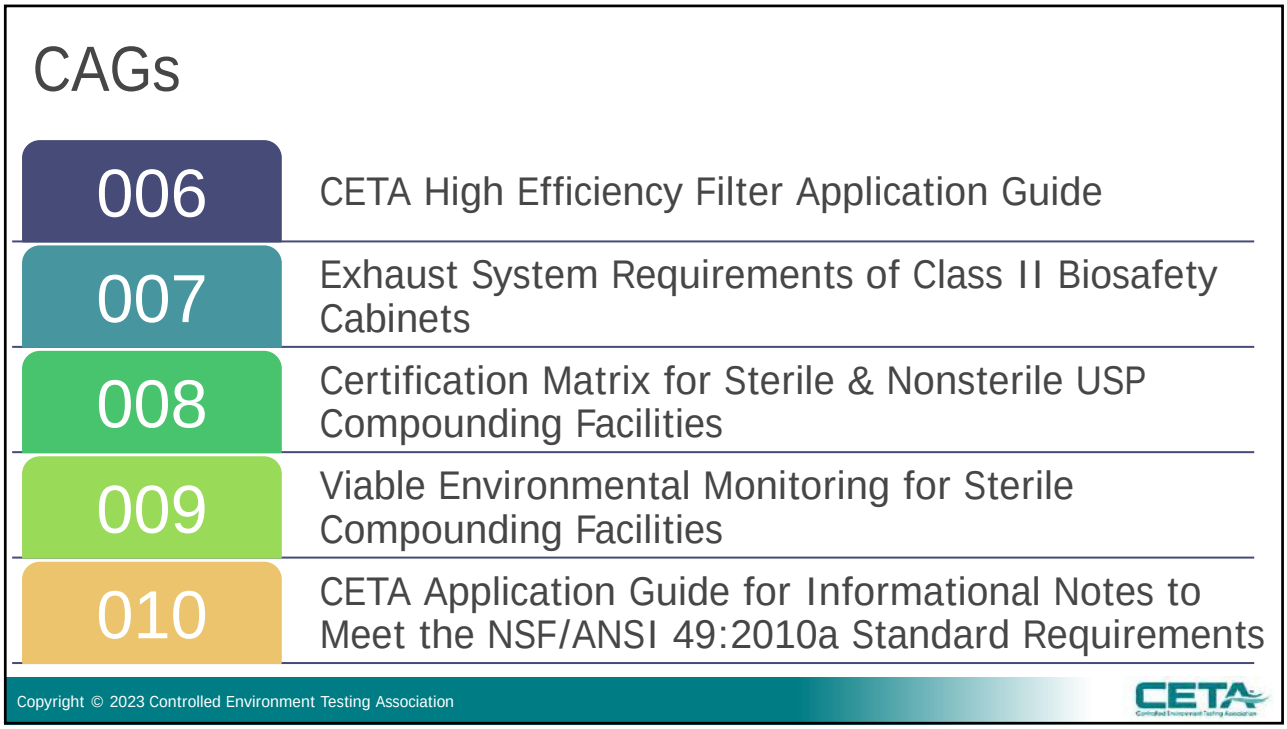
CAGs

001	CAG for the use of Compounding Aseptic Isolators in Compounding Sterile Preparations in Healthcare facilities
002	CETA Compounding Isolator Testing Guide
003	CETA Certification Guide for Sterile Compounding Facilities for USP Compliance
004	Biological Decontamination and Disinfection of Accessible Surfaces in Biosafety Cabinets
005	Servicing Hazardous Drug Compounding Primary Engineering Controls

12


CAGs
006
CETA High Efficiency Filter Application Guide
007
Exhaust System Requirements of Class II Biosafety Cabinets
008
Certification Matrix for Sterile & Nonsterile USP Compounding Facilities
009
Viable Environmental Monitoring for Sterile Compounding Facilities
010
CETA Application Guide for Informational Notes to Meet the NSF/ANSI 49:2010a Standard Requirements
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CETA

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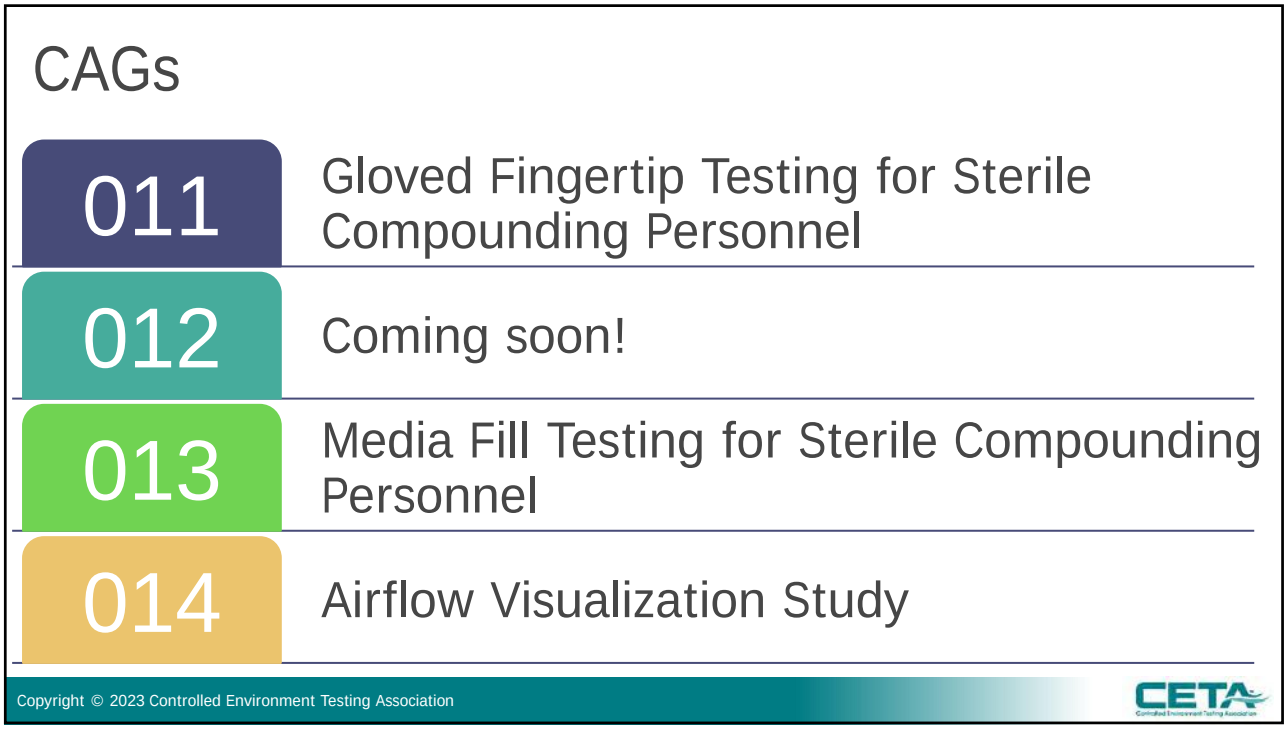
CAGs
011
Gloved Fingertip Testing for Sterile Compounding Personnel
012
Coming soon!
013
Media Fill Testing for Sterile Compounding Personnel
014
Airflow Visualization Study
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CNBT Credentials

- Sterile Compounding Facilities
- Fume Hood
- Cleanroom Testing

Visit www.cetainternational.org to search for CNBT credentialed certification professionals.

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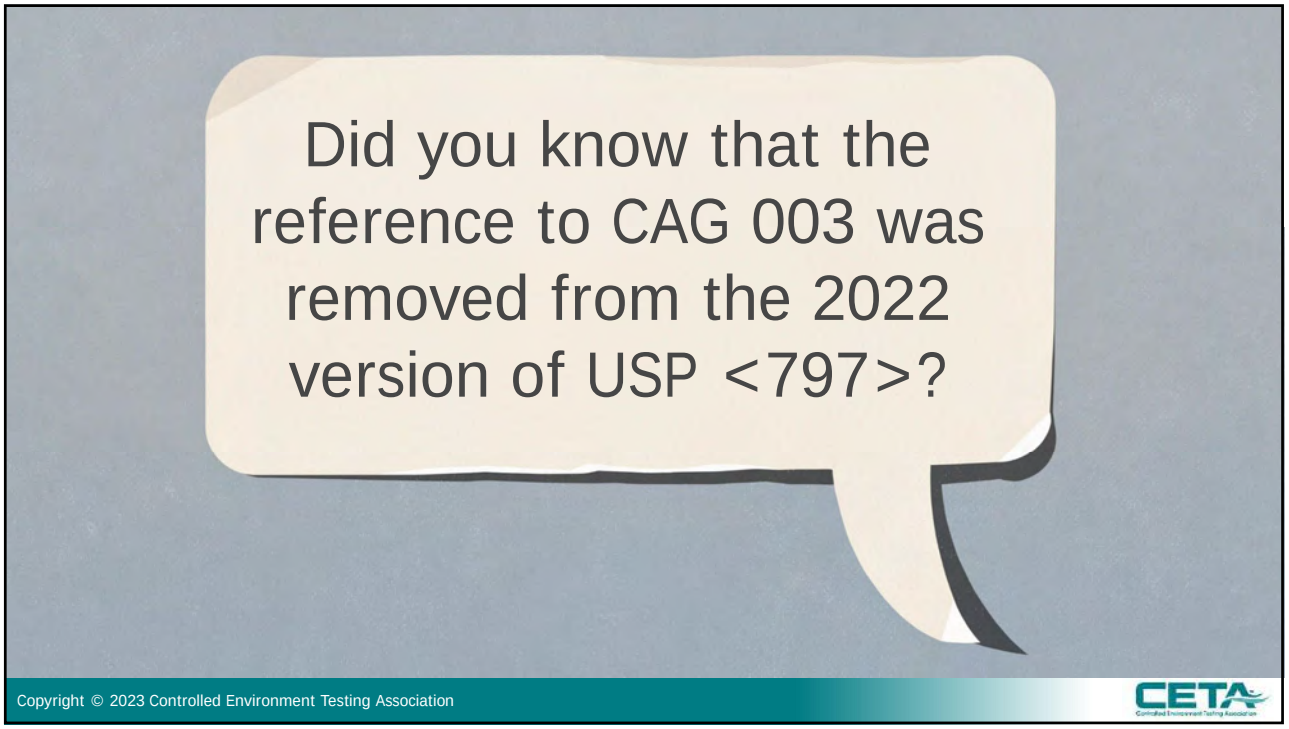

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What USP <797> Says

"Before a compounding area is used to compound either Category 1, Category 2, or Category 3 CSPs, it must be independently certified using the requirements in this chapter and when applicable, manufacturer specifications."

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Why This Is Concerning

- Allows certification vendors to test how they want
- Designated person needs to better understand all the different standards and industry guidance documents related to certification

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Benefits of Requiring Testing to CAG 003

1. Well-defined and industry-accepted test procedures
2. Consistent testing from company to company
3. Inclusion of necessary certification tests not listed in USP <797> specific to PECs

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Certification doesn't have to be scary!

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Standards and Guidance Documents

USP <797>
Facilities and engineering controls

CETA CAG 002
Certification testing specific to RABSs

CETA CAG 003
General certification testing guidelines

NSF/ANSI 49
BSC performance and certification

ISO 14644-1
Air cleanliness classification

IEST-RP-CC002
LAFW performance and certification

RABS image courtesy of Contec, Inc.

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USP<797> is not a certification specification.

It simply provides the tests required for chapter compliance.

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Cleanroom Testing

Chapter Required	Industry Practice
• Airflow testing • HEPA filter integrity testing • Total particle count testing • Visual smoke test only if the cleanroom does not have low wall returns	• Room segregation • Temperature and humidity

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PEC Testing

Chapter Required	Industry Practice
• Airflow testing • HEPA filter integrity testing • Total particle count testing • Dynamic airflow smoke pattern testing	• Specific PEC testing

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PEC Specific Tests

LAFW	BSC	CAI/CACI
• Induction Leak • Backstreaming	• Inflow velocity testing (exhaust) • NSF/ANSI 49 airflow containment verification	• Chamber pressure • Ingress and egress • Particle containment

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Reporting Style

- Easy to navigate
- Paginated
- Table of contents
- Date testing was performed

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CAG 003 General Report Elements

- Name, address, and contact information for the certifying organization, also listing key personnel with appropriate accreditations.
- Confirming remark that facility/equipment was tested “in accordance with CETA CAG 003-[Current version].” The most current version of the CAG must be referenced.
- Explanation of test procedure used for data collection and justification for any deviations from established industry practices encountered during the certification process.

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CAG 003 General Report Elements

- The required reporting values listed in each test section of CAG 003.
- A list of test equipment utilized in data collection. List shall include make, model, serial number, and calibration date.
- A copy of the current calibration documentation for each piece of equipment when requested.

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For all tests, the report must include

- Name of the test
- Acceptance criteria
- Pass or fail/results statement

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ISO Classified Turbulent Airflow Area

- All airflow measurements and their corresponding filter or diffuser locations or grid identifications on a diagram
- Room volume
- Average total room airflow volume
- Total air changes per hour of the room (include LAFW and/or non-ducted BSC HEPA exhaust to room, if applicable)
- Any correction factors used or deviations from the primary method

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SEC HEPA Filter Leak Test

- Upstream aerosol challenge concentration
- Method used to report concentration
  - measured
  - calculated
- Maximum leak penetration in percent

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SEC Room Pressure

- Room pressure differential relative to an adjacent room/space
- Compare performance of room pressure monitor
- Whether smoke dispersed at entry doors follows correct direction

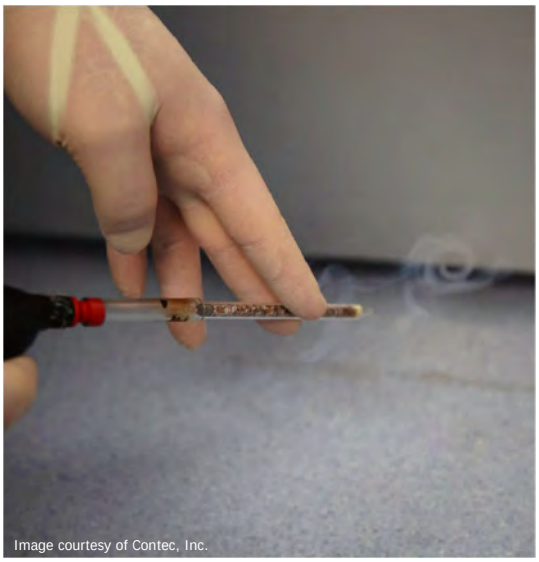

Image courtesy of Contec, Inc.

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SEC Airborne Total Particle Counting

- Number and year of publication of ISO 14644
  - For example, ISO 14644-1:2015
- Clear identification of the physical location of the cleanroom or clean zone testing, and specific designations for coordinates of all sampling locations
  - A diagrammatic representation can be helpful
- Specified designation criteria for the cleanroom or clean zone, including the ISO Class number, the relevant occupancy state(s), and the considered particle size(s)

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SEC Airborne Total Particle Counting

- Details of the test method used, with any special conditions relating to the test, or departures from the test method, and identification of the test instrument and its current calibration certificate
- The test results, including particle concentration data for all sampling locations

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Other SEC Tests

General Temperature and Moisture

- All measurements and corresponding grid locations

SEC Lighting Level and Uniformity

- All measurements and corresponding room locations
- Overall average lighting intensity

SEC Noise Level

- All measurements (Octave bands or dBA) and corresponding grid locations
- Maximum reading

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Class II BSC Testing

- CAG 003 refers to NSF/ANSI 49 Annex N5 for field certification
- Total Particle Count Testing is described in CAG 003
- Field certification professionals should be accredited by NSF International for certification of Class II BSCs.

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RABS Testing

- CAG 003 refers to CAG 002 for testing Compounding Aseptic Isolators (CAIs) and Compounding Aseptic Containment Isolators (CACIs)
- Total Particle Count Testing is described in CAG 003
- Field certification professionals then use this manufacturer test criteria to field certify performance.

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LAFW Airflow Velocity

- Grid dimensions used
- Distance from screen or diffuser
- Individual velocity readings in the applicable grid
- Overall average of the velocity readings

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CAG-003:2022, 8.4.1: Airflow Velocity Test

Anemometer Mfg.:	TSI	Model:	966
S/N:	P17260084	Calibration Due:	16 Jun 2

Number of Supply Readings Taken:	12

Diagram of Supply Velocity Profile Taken at 6 inches from diffuser screen on a 12-inch grid pattern starting 6" from the walls.

Data points reported in feet per minute (FPM)

			100	90	100	90			
			90	90	100	100			
			100	90	90	90			

Average Velocity			
Acceptable Min (FPM):	90	Acceptable Max (FPM):	110
Average Velocity in FPM (calculated):	94		

Airflow Uniformity			
The individual point readings shall not vary more than	±20%	from the average velocity.	
Minimum Allowed:	71	Actual Minimum:	90
Maximum Allowed:	118	Actual Maximum:	100

Differential Pressure (w.c.):	0.60
	No Change

Velocity Conforms to: Manufacturer's Specifications

Uniformity

Fail Average Velocity

Pass Average Velocity / Fail Airflow Uniformity

Grid dimensions

Distance from screen

Individual readings

Average velocity

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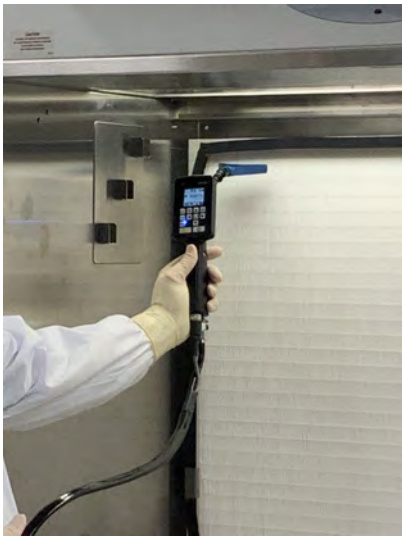
LAFW HEPA Filter Leak Testing



- Upstream aerosol challenge concentration
- Method used to report concentration
  - measured
  - calculated
- Maximum leak penetration in percent

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LAFW Induction Leak/Backstreaming Test

- Source of visual smoke

CAG-003:2022, 8.4.1: INDUCTION LEAK/ BACKSTREAMING TEST

Set particle counter to sample continously. Hold probe in hand and orient into direction of airflow. Take readings at least 1" away from side walls and sample1" downstream of the penetration or seam. During sampling pass a localized visible medium over penetration outside of LAFW.
Using a localized visible medium source scan the plane of the face access opening. Visible medium is positioned 2" outside of the plane of the face opening. Special attention must be given to corners and upper edges of the face opening.
***Equipment: See Total Particle Count Section**

No increase in 0.5 um size particles. No visible medium entering the work zone.

☑ PASS	☐ FAIL

Comments:	N/A

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PEC Particle Count Testing

- Two types
- At rest
  - Optional
  - Reporting shall be to ISO-14644-1 [2015] section 5.4
- Operational
  - At each critical site
  - To comply with USP <797>

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PEC Particle Count Testing – At Rest

CAG-003:2022, 8.4.2: TOTAL PARTICLE COUNT

Particle Counter Mfg.:	Lighthouse	Model:	Solair 3350
S/N:	180162011	Calibration Due:	14 Jan 2023
Ambient room particle count (room ambient) ppcm:		340	
Sample locations are taken at:		12" from diffuser screen	

Note: All particles 0.5 micron and larger were counted. Readings shown are in particles per cubic meter of air.

(1) 0		(2) 0
	(3) 0	
(4) 0		(5) 0

Particle count locations are identified with number (1) thorugh (5). Room ambient count is identified as (Room Ambient).

ISO Class 5 0.5 um & larger (At-Rest) ISO 14644-1: 2015:

☑ PASS ☐ FAIL

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PEC Particle Count Testing – Operational

Operational Particle Counts

The particle counter isokinetic probe is positioned within 6-12 inches of the product manipulation point. The technician shall simulate compounding operations during the 1-minute sampling period. The reading must not exceed the class limit.

Type of clean zone:	Unidirectional	Occupancy State of Test:	Dynamic
Cleanroom or zone Cleanliness Classification:	ISO 5	Type of Test:	Verification
Particle Class Limit in Particles Per Cubic Meter:	3520	Sample Time (minutes):	1
Measured Particle Size in Microns (and larger):	0.5	Sample Volume (liters):	100
Number of Particle Count Sample locations (L):	1	Number of People in PEC:	1

Sample 1 (PPCM):	0	Sample 2 (PPCM):	N/A

Particle counts meet specifications ISO Class 5 (3520 ppcm @ 0.5um & larger) Operational:

☑ PASS ☐ FAIL ☐ No Test

Comments:	N/A

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CAG 014 Airflow Visualization Study (AVS)

Visual Smoke Study → SEC AVS

Dynamic Airflow Smoke Pattern Test → PEC AVS

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CAG-014:2022, 8.2: Airflow Visualization

This test is performed to verify that airflow smoke patterns demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the Direct Compounding Area (DCA).

ACCEPTANCE: The smoke must flow across the critical sites within the DCA with no turbulence or refluxing present. The airflow crossing the critical sites must be comprised of "First Air" only. Once the airflow exits the critical area it may not re-enter.

Under operational conditions, airflow smoke patterns should demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic (operational) conditions within the unidirectional flow device. The smoke illustrates the importance of proper use of "First Air" in the DCA.

Results

☑ PASS ☐ FAIL ☐ No Test

Smoke source used:	MSA Smoke Ventilation Tube
Comments:	N/A

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Summary

- CETA is dedicated to promoting the quality of the controlled environment industry.
- The removal of CAG 003 from USP Chapter <797> could result in questionable certification of sterile compounding facilities.
- Inspectors, surveyors, and practitioners must know what to look for in a certification report.

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Self-Assessment Question #1

Which CETA Application Guide (CAG) describes the certification testing procedures for a sterile compounding cleanroom suite?

a. 002
b. 003
c. 008
d. 009

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Self-Assessment Question #2

Which test is required for the certification of a laminar airflow workbench (LAFW)?

a. Backstreaming
b. Ingress and egress
c. Particle containment
d. Airflow containment verification

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Self-Assessment Question #3

Which reporting element should be included in the certification report?

a. Condition of the biological safety cabinet
b. Age of the equipment used for testing
c. Explanation of the test procedure
d. Time it took to complete testing

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Contact Information

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- Abby Roth abby@puremicrobiology.com
- Controlled Environment Testing Association
  - www.cetainternational.org
  - info@cetainternational.org

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Q&A

You may use the Questions tool on your screen to submit questions to the presenter.

Our host will read the questions out loud in the order they are received.

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Submit Your CPE Claim

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   If you do not have a login for NABP's CPE submission site, you will need to create an account.
2. Click on the "Live CPE" tab
3. Select the workshop from the Live Meetings and Conferences list
4. Enter the session code provided on the next slide
5. Complete the course and speaker evaluations
6. Select the appropriate credit (pharmacist or pharmacy technician)
7. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
8. Click the claim button

Claims must be submitted by noon on May 20, 2023.

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