CETA
Controlled Environment Testing Association

PERFORMANCE REVIEW

THE JOURNAL OF THE
CONTROLLED ENVIRONMENT TESTING ASSOCIATION

SUMMER 2024

CETA
Controlled Environment Testing Association

In This Issue

President's Message

Lewis Exner, Controlled Environment Consulting, LLC

I would like to start out by saying that time seems to speed up each year that passes by. It is hard to believe that the Annual Conference was 2 months ago. **I want to thank all the attendees at the Annual Conference along with all the sponsors and exhibitors.** Without each one of you, we would not be able to have the educational experiences at the conference.

I am glad this year was a lot less smoky than the 2021 conference in Reno. The weather was great and allowed for some awesome sightseeing for those that wandered outside the resort. The Conference started off on Friday, April 19, 2024, with the CNBT Practical Exam for those who either needed to retake their exam or take it for the very first time. The CETA Series was held on Friday afternoon, and this was the very first time that we have had several paths to follow, depending on your level and industry knowledge. The following was offered on Friday afternoon: Garbing and Glove Fingertip Testing, EM Sample Plan Creation, Micro/Facility Excursion Investigations, Primary versus Secondary BSC Testing, Certification Testing Order, Measuring Airflow/K Factor, Troubleshooting, Injection Ports, CETA Application Guides, and Fume Hood and CVE Testing.

Saturday morning started with the CNBT Written Multiple Choice Exam. Those not taking the exam could attend the Platinum Sponsor Updates by NuAire and Esco followed by numerous manufacturing updates by ClorDiSys Solutions, Thermo Fisher Scientific, LabConco, Lighthouse Worldwide Solutions, and TEC Services. Again, I want to thank all the sponsors and manufacturers for supporting CETA and contributing to the Annual Conference.

Saturday afternoon was the second day of the CETA Series presentations which included some of the same presentations from Friday and the infamous peanut butter & jelly sandwich SOP presentation! For the individuals that wanted to learn about geothermal technology, the resort gave a tour of their geothermal system right within the resort. This tour was also offered on Monday afternoon.

On Saturday evening, we held CETA's first New Member Reception for all our newly joined members. Others could attend the NSF Steering Committee Meeting. The evening concluded with the opening reception showcasing all of our awesome exhibitors.

The official Conference opened on Sunday morning with Leslie Mackay's President's Address. Thank you, Leslie, for all you have done for CETA during this past year. It is truly appreciated. The first

CONTINUED ON NEXT PAGE

PRESIDENT'S MESSAGE CONT.

presentation was on Annex 1 by Gordon Farquharson. He gave some great insight into the thoughts behind the Annex.

This was followed by Rolinda Bailey with a presentation on risk assessment. This turned out to be a great interactive presentation keeping the audience alert and attentive. Mike Turnure presented on IQ/OQ/PQ. He discussed the requirements for performing the qualifications which are above and beyond typical certification tests. Chris Rowe gave an update on the CNBT program, showing that it is thriving and has become a great program for CETA. Upon conclusion of the presentations, individuals were offered different opportunities to relax and unwind, including: The Annual Wally Whitt Memorial Golf Tournament, the Wild Burro & Horse Center Tour and the Reno Brewery Tour.

Monday began with a presentation by Gordon Farquharson discussing ISO TR 14644-21:2023. Todd Urton discussed the Tag Committee which helped us understand his role with this seat representing CETA. He was also able to help us understand acronyms within our industry. David Phillips described the new CETA Research Grant Program that I am extremely excited about and look forward to seeing through its initial implementation. Shawn Windley gave a great presentation regarding how HEPA filters are made and had some fantastic videos within the presentation. Following lunch, Neil DiSpirito discussed issues within the pharmaceutical industry regarding pharma law. With USP being a big part of most certifiers' business, the presentation on EM Sampling Competency, by Josh Erickson was very enlightening and put my mind at ease knowing that certifiers are competent in performing the EM sampling. The Annual Conference presentations were concluded with Natalie Miranda-Bachman discussing EM sampling challenges that certifiers face while serving their customers.

There were four CAG committees that met after the meeting concluded (CAG-002, CAG-005, CAG-012, and CAG-015), all having different agendas.

Monday evening wrapped up with the Annual Banquet which included some great food, drinks and CETA's first ever cornhole tournament. Four sets of custom boards were awarded to the first and second place teams. I want to thank the sponsors of the cornhole boards, and also Wag-N-Bag for making the custom boards and running the tournament.

There were many members that signed up for the different committees that will be started up in the very near future. The CETA Board is in the process of selecting the individuals for each of these committees and will be in touch shortly.

I would like to thank membership, exhibitors, and sponsors for all of their support and contributions. CETA would not exist without all of you, and I look forward, and am very excited, to move the organization forward during the next year. ■

CETA
Controlled Environment Testing Association

UPCOMING 2024 EXAM DATES

Raleigh, NC

Testing Date:
Friday, August 9

Registration closes Friday, July 19th

Webster, TX

Testing Date:
Saturday, September 14

Registration closes Friday, August 23

This is a private but open exam administration.
Anyone may register, but additional fees will apply.

St. Louis, MO

Testing Date:
Friday, October 18

Registration closes Friday, Sept. 27

No registrations will be granted following the registration cutoff date.
We apologize for any inconvenience.

A MESSAGE FROM THE PAST PRESIDENT

Dear CETA Members,

As I transition into the role of CETA's Past President, I want to take a moment to express my gratitude to each of you. Serving as President was both an honor and a privilege, and our collective achievements over the past year have been incredibly rewarding.

During the Annual Conference, elections for the CETA board were completed, with openings for two certifiers. I would like to thank everyone who ran for these positions. If you were not elected, please don't let that discourage you from running again or joining one of our new committees. By getting involved, you will have the opportunity to:

- Influence the direction of CETA
- Connect with industry professionals who share your enthusiasm for certification and this association
- Benefit from continuous learning and staying up to date with industry standards
- Gain recognition for your contributions and become a trusted voice in the CETA community

CETA is a strong organization because of the distinct individuals who volunteer their time and expertise. Your involvement is crucial to our continued success and growth.

Additionally, I would like to extend my thanks to Kim Coughlin for her years of dedicated service. Kim served as CETA President, CNBT Board Chair, and as a member of the CNBT committee. Her contributions have been invaluable.

I am also pleased to welcome Dan Valesquez to the board. Dan will be serving as the board liaison to CETA's new grant committee. Additionally, Jeremy Mahurin was re-elected to the board and will once again collaborate with Abby Roth on next year's CETA Series.

Lew Exner is now CETA's President, and judging by the outstanding Annual Conference he organized, I am confident he will excel in this role. David Phillips has moved into the position of President Elect and Annual Conference Chair, while David Wasescha is our new Secretary/Treasurer.

Thank you all for your continued support and dedication to CETA. I look forward to seeing you all in Orlando for the 2025 Annual Conference. ■

Leslie MacKay
CETA Past President

CETA has several committees dedicated to the improvement and maintenance of organizational programs, documents, and products. Please click through the links below to learn more about each committee.

Education & Training Committee

Internal Infrastructure Committee

Industry Impact Committee

Membership Committee

Research Grant Committee

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Purpose

The primary method of determining the face velocity of a Class II Biosafety Cabinet (BSC) has been the Direct Inflow Measurement (DIM) device since 1992. This method was confirmed to be the most repeatable method available in 2002. Since 1992, general practice has been to only use this method when there is at least 18 inches of clearance at the leading edge of the DIM. There is no consensus between practitioners as to where that required distance came from; therefore, we aim to determine whether the 18-inch distance from a DIM intake to obstruction is truly integral to accurate measurement of Class II BSC air intake velocity. An additional goal is to determine whether alternative DIM mounting methods, which would decrease the overall DIM length, result in reproducible and comparable intake volume measurements when compared to the traditional mounting method.

Questions:

> How does the distance between an obstruction and the front intake area of a BSC affect the flow rate of air through the front intake area with a DIM installed?

> Does the skirt used with the DIM device affect its accuracy relevant to the method of DIM installation used by NSF when the listed intake velocities are established? Will the same readings be measured when using a variety of skirts: "biobag" skirt, no skirt, or a 12" x 48" skirt?

> Does the distance between the obstruction and front intake area affect the differential pressure between the interior and exterior of the biosafety cabinet?

Hypotheses:

If the distance between a wall and the front intake area of a BSC decreases to below 18 inches, then airflow rate through the front intake area would decrease due to the obstruction. If that 18-inch clearance can be reduced, the use of a DIM device, which is the primary and most repeatable testing method, would be feasible for more field applications.

If the DIM device were to be assembled with a variety of skirts which help funnel air into the meter, there should be little to no observed difference in the readings in a scenario where all other independent variables are the same. If no difference is observed, this would make the DIM device more feasible and accessible in field applications.

If the distance between an obstruction and the front intake area of a BSC decreases to below 18 inches, and the velocity is affected, then the change in differential pressure across the biosafety cabinet is expected to be directly proportional through some square-rooted functional form to the change in velocity, that is $\frac{V_f}{V_i} \sim \sqrt{\frac{P_f}{P_i}}$ which is derived from the relationship between linear velocity and velocity pressure of air at standard conditions.

Experimental Design:

The experiment was conducted using a NUAIRE NU-540-400 Class II Type A2 BSC with a Shortridge Instruments flow hood kit attached to the front intake area. A voltmeter was connected to the main blower as a means of measuring the voltage at every reading to be able to determine if voltage variation is present and has any effect on reading variation. Additionally, a hydraulic lift fitted with two 96" x 48" sheets of 1/4" pine plywood fastened together with three pine boards running across the back and drywall screws was used to create a 96" x 96" artificial wall capable of moving varying distances from the leading edge of the flow hood. The method outlined above was used at CEC to eliminate any potential of perturbing the flow hood or biosafety cabinet, while maintaining a large flush face to avoid air moving from around the back of the obstruction. A series of readings were taken with the artificial wall placed at each of the varying distances from the DIM. The DIM was set to "Auto-Read" mode to allow a smooth collection of data without possible perturbations to the meter setup itself. In addition to the mode, we ran a short process to determine when balanced readings can be obtained through the Auto-Read mode. In addition to airflow measurements, we recorded voltages and the differential of pressure from the inside to outside of the biosafety cabinet at each stage of the data collection.

As a means of process qualification, we recorded a series of readings through the DIM in Auto-Read mode to determine the number of bad reads, or a measurement taken before proper stabilization of the DIM. This process was done five times, and the number of bad reads was averaged and rounded up to be conservative with the meter. Through five of these tests, we found that only the first readings are to be discarded at each stage due to DIM reading stabilization.

The independent variables for the experiment were the distance of the artificial wall from the leading edge of the

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

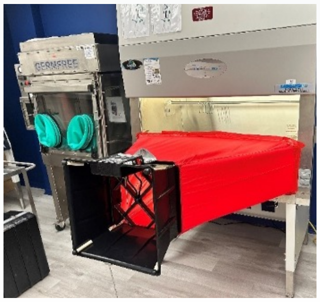
Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

flow hood, blower voltage, cabinet mode (run/calibration), and which, if any, skirt is attached. The two dependent variables were the volumetric rate at which air enters the BSC front access opening and the differential in pressure between the workspace of the cabinet and the room. Additionally, all sets of testing were done in both calibration mode and run mode to determine if any difference is observed.

Pictures documenting the data collection set-up and process are shown here.

Front side of the (wall) artificial obstruction, side facing the cabinet.

Back side of the (wall) artificial obstruction, side facing away from the cabinet.

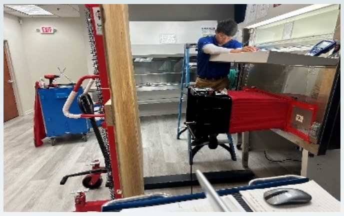


12" x 48" Capture Skirt Configuration

10" x 24" (Biobag) Capture Skirt Configuration

The three flow hood configurations used in this experiment, as well as the method they were connected to the biosafety cabinet.

The set-up used for measuring the differential of pressure between the interior and exterior of the biosafety cabinet. Arrow indicates across the interface at which the pressure differential was measured.



DC Voltages of the blower were measured and recorded alongside the volumetric flow rate and pressure differential at each step in the procedure.

How the obstruction was used to simulate various distances between the front intake opening and a wall. The yellow arrow represents where the corresponding distance was measured.

Materials:

- 1 – Artificial wall made from the following materials:
    - o 2 – 1/4" x 48" x 96" Construction grade pine plywood sheets
    - o 3 – Eight foot long 1" x 4" Pine boards
    - o 12 – GripRite #6 x 1-5/8" Drywall Screws
    - o 2 – National Hardware N100-362 - 5/16" x 1-1/8" Stainless steel rope loop
    - o 4 - Generic Plastic Zip Ties

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

- 1 – Dayton: 2000lb capacity hydraulic forklift
- 1 – Fluke: 323 True RMS Clamp DC Voltage Meter
- 1 – Air Intake Measurement Flow Hood:
  - o 1 – Shortridge Instruments: Airdata multimeter ADM-870C | Electronic micromanometer | Model: ADM-870C | Serial No.: M19140 | Calibrated on: 02 MAR 2023 | Calibration due: 02 MAR 2024
  - o 1 – Shortridge Instruments: Bio Hood Series 8400 Frame
  - o 1 – Shortridge Instruments: Bio Hood Support Kit
  - o 1 – Shortridge Instruments: 10" x 24" Capture Skirt | Commonly referred to as "Biobag".
  - o 1 – Shortridge Instruments: 12" x 48" Capture Skirt
- 1 – TSI Manometer | Model: 9565P| Serial No.: 9565P1729024 | Calibrated on: 16 JUN 2023 | Calibration Due: 16 JUN 2024
- 1 – NUAIRE: Class II Type A2 BSC | Model: NU-540-400 | Series: 5 | Serial No.: 194499101519
- 4 – 9" x 12" Acrylic panels
- Stucco Tape
- Rubber Tube

Procedure:

1. A 1/4" x 96" x 96" artificial wall was assembled by putting two sheets of plywood together and securing from behind with planks using the following materials:
   a. Two sheets of 48" x 96" x ¼" pine plywood.
   b. Three boards of eight foot long 1" x 4" pine wood.
   c. Drywall Screws
   d. National Hardware N100-362 Stainless Steel Rope Loops (5/16" x 1-1/8")
2. The wall is then fastened upright to a hydraulic lift using plastic zip ties and set aside for later.
3. Assemble DIM device in desired configuration for current test on biosafety cabinet.
   a. "Biobag" Skirt: The Shortridge Instruments flow hood with "biobag" skirt and micromanometer were assembled and secured to the front intake area of the NUAIRE BSC. BSC is then further sealed using acrylic panels and stucco tape around the perimeter where the flow hood meets the biosafety cabinet and cabinet sash.
   b. 12" x 48" Skirt: The Shortridge Instruments flow hood with the 12" x 48" skirt and micromanometer were assembled and secured to the front intake area of the NUAIRE BSC. BSC is then further sealed using stucco tape around the perimeter where the flow hood meets the biosafety cabinet and cabinet sash.
   c. No Skirt: The Shortridge Instruments meter frame was propped within the sash opening and further sealed using acrylic panels and stucco tape around the perimeter where the frame meets the biosafety cabinet and cabinet sash.
4. The BSC is then turned on and allowed to complete its warmup cycle.
5. Set up the required independent variables as desired for current testing set on the biosafety cabinet.
   a. Make sure biosafety cabinet is in the proper mode for the desired test (Run/Calibration)
   b. Set blower voltage to desired value (Low blower speed ≈ 6.0 Volts; High Blower Speed ≈ 8.0 Volts)
6. After powering up the micromanometer, the hydraulic lift is first placed 48 inches from the top legs of the capture hood frame.
7. The first reading is discarded as a bad reading due to adjustments and stabilization in the micromanometer.
8. Five readings are recorded at each distance.
9. Average the five readings taken then round the answer to the nearest integer. This is the final value used for each distance.
10. The hydraulic lift is then brought closer to the opening of the capture hood at varying distances (48", 36", 24", 18", 12", 6", 2"). Repeat from step 8 until at 2" from the biosafety cabinet. After collecting data for 2" from the biosafety cabinet, move to step 11.
11. Upon completion of the testing set with given independent variables, continue by starting from step 4 as needed.

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using the 10" x 24" skirt (Biobag):

Biobag Skirt - Low Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	335	334	334	332	331	333	4 | 0.12 %	6.0	0.005
36"	334	337	335	335	333	335	4 | 0.12 %	6.0	0.004
24"	335	329	334	333	338	334	9 | 0.27 %	6.0	0.004
18"	336	331	335	334	336	334	5 | 0.15 %	6.0	0.004
12"	340	338	336	337	335	337	5 | 0.15 %	6.0	0.004
6"	338	334	339	346	343	340	12 | 0.35 %	6.0	0.005
2"	346	318	320	336	342	332	28 | 0.84 %	6.0	0.017

Table 1.A

Biobag Skirt - High Voltage - Calibration Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	357	355	354	359	358	357	5 | 0.14 %	8.0	0.004
36"	357	360	359	360	361	359	4 | 0.11 %	8.0	0.004
24"	365	357	358	356	355	358	10 | 0.28 %	8.0	0.004
18"	359	360	360	357	359	359	3 | 0.08 %	8.0	0.004
12"	362	362	360	356	358	360	6 | 0.17 %	8.0	0.003
6"	366	368	365	364	365	366	4 | 0.11 %	8.0	0.004
2"	368	350	349	348	364	356	20 | 0.56 %	8.0	0.015

Table 1.B

Biobag Skirt - Low Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	336	335	333	335	334	335	3 | 0.09 %	5.9	0.003
36"	332	335	334	335	333	334	3 | 0.09 %	6.0	0.003
24"	335	337	332	338	334	335	6 | 0.18 %	6.0	0.003
18"	334	336	338	336	335	336	4 | 0.12 %	5.9	0.003
12"	333	332	338	335	337	335	6 | 0.18 %	5.9 +/- 0.1	0.003
6"	343	344	339	343	340	342	5 | 0.15 %	6.0	0.004
2"	324	315	336	328	308	322	28 | 0.87 %	6.0	0.013

Table 1.C

Biobag Skirt - High Voltage - Run Mode - 18JUL2023

Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	354	356	358	359	360	357	6 | 0.17 %	8.0	0.004
36"	353	357	351	356	358	355	7 | 0.2 %	8.0	0.004
24"	358	357	362	358	360	359	5 | 0.14 %	8.0	0.003
18"	363	361	360	361	358	361	5 | 0.14 %	8.0	0.004
12"	359	357	356	359	357	358	3 | 0.08 %	8.0	0.003
6"	367	366	368	365	368	367	3 | 0.08 %	8.0	0.004
2"	371	363	354	339	330	351	41 | 1.17 %	8.0	0.014

Table 1.D

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using the 12" x 48" skirt:

12" x 48" Skirt - Low Voltage - Calibration Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	327	327	322	324	326	325	5 | 0.15 %	6.0	0.004
36"	326	324	328	326	328	326	4 | 0.12 %	6.0	0.004
24"	326	326	327	326	327	326	1 | 0.03 %	6.0	0.005
18"	329	327	325	325	327	327	4 | 0.12 %	6.0	0.004
12"	329	327	329	333	332	330	6 | 0.18 %	6.0	0.004
6"	334	335	335	332	336	334	4 | 0.12 %	6.0	0.005
2"	343	329	328	332	338	334	15 | 0.45 %	6.0	0.029

Table 2.A

12" x 48" Skirt - High Voltage - Calibration Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	360	358	361	359	359	359	3 | 0.08 %	8.0	0.004
36"	360	364	362	367	367	364	7 | 0.19 %	8.0	0.004
24"	365	363	366	363	367	365	4 | 0.11 %	8.0	0.004
18"	371	368	367	367	365	368	6 | 0.16 %	8.0	0.004
12"	369	366	367	368	371	368	5 | 0.14 %	8.0	0.004
6"	374	369	364	371	372	370	10 | 0.27 %	8.0	0.005
2"	374	363	342	346	353	356	32 | 0.9 %	8.0	0.029

Table 2.B

12" x 48" Skirt - Low Voltage - Run Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	326	326	327	325	323	325	4 | 0.12 %	5.9 +/- 0.1	0.005
36"	323	329	324	326	327	326	6 | 0.18 %	5.8	0.005
24"	330	327	322	326	329	327	8 | 0.24 %	5.9	0.005
18"	330	327	331	330	333	330	6 | 0.18 %	5.9 +/- 0.1	0.005
12"	328	326	323	327	330	327	7 | 0.21 %	5.9	0.004
6"	335	333	333	337	333	334	4 | 0.12 %	5.9	0.005
2"	340	340	343	337	344	341	7 | 0.21 %	5.8	0.009

Table 2.C

12" x 48" Skirt - High Voltage - Run Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	365	363	364	360	364	363	5 | 0.14 %	8.0	0.005
36"	359	365	364	361	359	362	6 | 0.17 %	8.0	0.004
24"	362	361	363	360	363	362	3 | 0.08 %	8.0	0.005
18"	363	360	360	361	366	362	6 | 0.17 %	8.0	0.004
12"	370	366	368	371	370	369	5 | 0.14 %	8.0	0.004
6"	372	371	369	367	371	370	5 | 0.14 %	8.0	0.005
2"	348	352	380	361	365	361	32 | 0.89 %	8.0	0.028

Table 2.D

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Presenting of Data:

The data was recorded and organized into the tables on the next several pages, grouped by a variety of parameters for clarity. Additionally, some figures were assembled using statistical properties derived from each data set:

Data collected using no skirt:

No Skirt - Low Voltage - Calibration Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	337	340	339	332	333	336	8 | 0.24 %	6.0	0.002
36"	336	333	330	337	337	335	7 | 0.21 %	6.0	0.002
24"	334	330	338	336	334	334	8 | 0.24 %	6.0	0.002
18"	335	337	329	333	337	334	8 | 0.24 %	6.0	0.003
12"	338	338	329	328	337	334	10 | 0.3 %	6.0	0.002
6"	340	339	340	339	342	340	3 | 0.09 %	6.0	0.003
2"	372	351	363	359	359	361	21 | 0.58 %	6.0	0.011

Table 3.A

No Skirt - High Voltage - Calibration Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	358	357	355	356	356	356	3 | 0.08 %	8.0	0.003
36"	355	355	356	360	358	357	5 | 0.14 %	8.0	0.003
24"	353	347	346	353	353	350	7 | 0.2 %	8.0	0.004
18"	356	359	353	355	350	355	9 | 0.25 %	8.0	0.004
12"	357	357	360	360	363	359	6 | 0.17 %	8.0	0.003
6"	362	362	359	363	362	362	4 | 0.11 %	8.0	0.004
2"	391	388	394	391	378	388	16 | 0.41 %	8.0	0.015

Table 3.B

No Skirt - Low Voltage - Run Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	335	336	336	337	338	336	3 | 0.09 %	6.0	0.003
36"	335	341	339	336	336	337	6 | 0.18 %	6.0	0.003
24"	336	338	336	338	335	337	3 | 0.09 %	6.0	0.003
18"	334	333	341	337	343	338	10 | 0.3 %	6.0	0.003
12"	334	334	334	335	336	335	2 | 0.06 %	6.0	0.003
6"	332	341	337	338	342	338	10 | 0.3 %	6.0	0.003
2"	364	370	364	364	360	364	10 | 0.27 %	6.0	0.015

Table 3.C

No Skirt - High Voltage - Run Mode - 18JUL2023									
Distance (Inches)	DIM Readings (CFM)						Range (CFM)	Accessory Readings	
	1	2	3	4	5	AVG	Δ | %AVG	Volt (DC)	ΔP (in. w)
48"	360	356	357	359	360	358	4 | 0.11 %	8.0	0.003
36"	357	356	351	358	355	355	7 | 0.2 %	8.0	0.003
24"	351	354	354	357	355	354	6 | 0.17 %	8.0	0.003
18"	356	358	362	361	360	359	6 | 0.17 %	8.0	0.003
12"	356	355	357	358	362	358	7 | 0.2 %	8.0	0.003
6"	361	356	355	363	356	358	8 | 0.22 %	8.0	0.003
2"	396	403	386	395	405	397	19 | 0.48 %	8.0	0.016

Table 3.D

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Comparing the airflow volume averages by flow hood configuration:

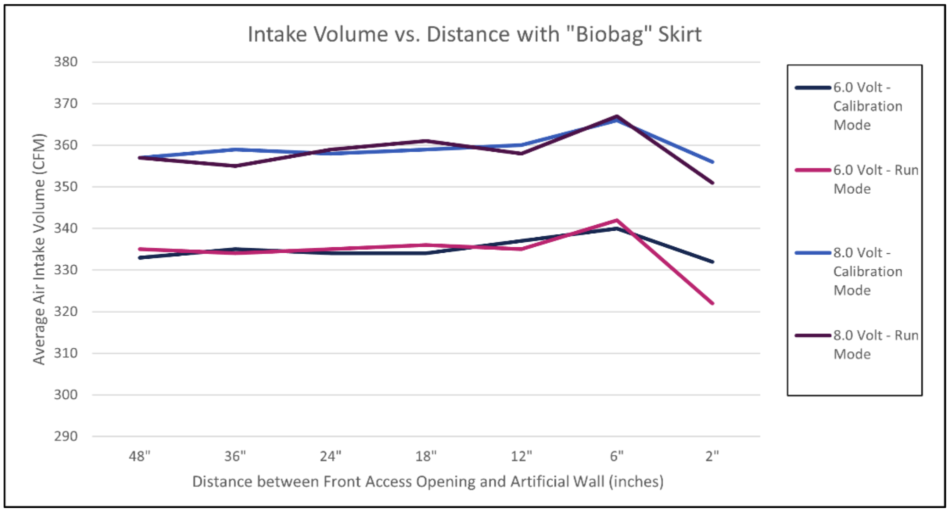


Figure 1:
10"x24" (Biobag) Skirt

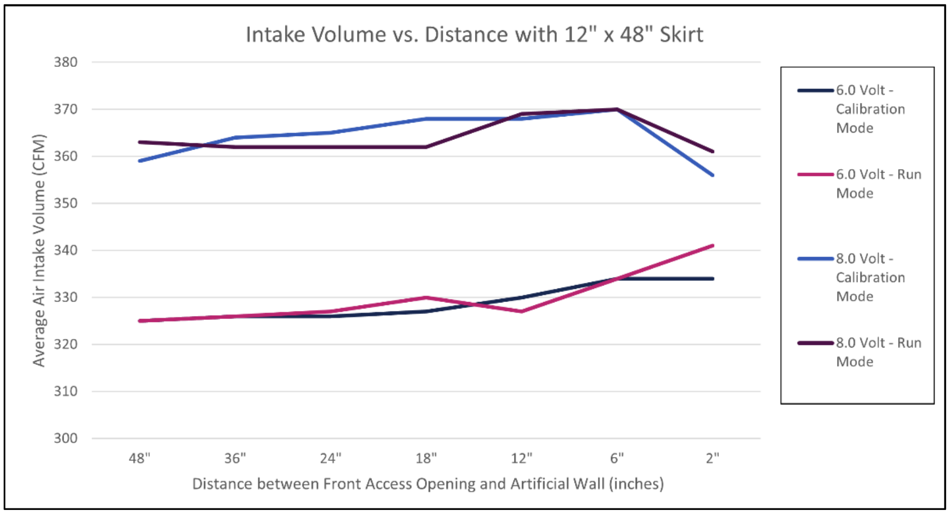


Figure 2:
12"x48" Skirt

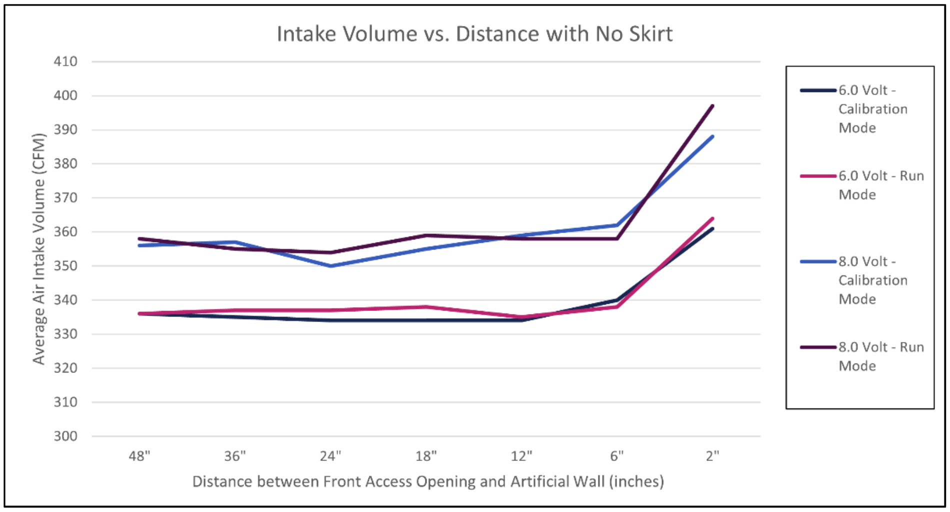


Figure 3:
No Skirt

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

Data Analysis:

The experiment went as expected with no unusual events that would have introduced error. The volumetric flow rate of air entering the biosafety cabinet was recorded in cubic feet per minute on Tables 1-3. The average intake volume is an arithmetic mean across all readings at the same distance from the wall. These averages are the values that were further used in the remaining figures. Aside from the intake volume, two accessory readings were taken to document the DC voltage across the blower at each stage, as well as the differential of pressure from the workspace of the biosafety cabinet to the exterior. All this data was taken from the original twelve tables and further used to draw an analysis on the effects of an obstruction at various distances from the front access opening of the biosafety cabinet.

Arguably the most important metric to determine whether a difference occurs at various distances of an obstruction is the average airflow intake volume for the cabinet under a variety of circumstances. This is obvious as it is the property one is directly interested in when using a flow hood for testing intake velocity on a biosafety cabinet. This data was assembled into Figures 1-3 based on the flow hood skirt configuration used for testing. In all three figures, there is a fair consistency in airflow volume until the obstruction comes within six inches of the biosafety cabinet. In the cases when a skirt was used, an upward trend is observed at six inches, but then takes a sharp drop at two inches to levels below the previous average. This behavior is not observed in the case when no skirt was used; From six inches and closer, a strictly increasing monotonicity can be observed in the data indicating a constant increase in the rate of change for the data starting at two inches. By only considering the case most applied by field technicians will apply (Biobag), there is no overwhelming evidence to indicate that a biosafety cabinet needs more than six inches of clearance at the front access opening for proper function.

The averages were grouped by the configuration of the flow hood used for taking readings, and further separated by the set voltage of the blower and the operation mode which the biosafety cabinet was set to: Calibration or Run. In Figures 1-3, these values were all regrouped to visualize how they compare with the rest of the testing of similar configurations. Through application of the continuity equation, it can be determined that there must be an increase in linear velocity at the flow hood, and subsequently at the intake of the biosafety cabinet since the cross-sectional area remains constant throughout the duration of the experiment.

Q=V*A (Continuity Equation)

Fluid Volume Rate=Linear Velocity *Cross-Sectional Area

It can be determined that the linear velocity of air entering the biosafety cabinet must be affected when considering this equation with our results, specifically increasing as the wall is brought closer. Due to the fixed cross-sectional area programmed in the flow hood, there is only one logically relevant reason this could have occurred; an increase in the linear velocity of the air entering the cabinet. There is data that shows an undeniable increase in the differential pressure, which theoretically would encourage air to pass through the flow hood at an increased rate. However, we could not find any proportionality between the increase in differential pressure and the increase in intake volume to confirm this to be the entire cause of increase.

As far as how the distance between an obstruction and the front access opening of the biosafety cabinet affects the differential pressure across the biosafety cabinet, our data from Tables 1-3 clearly indicates an increase in the pressure differential as the obstruction got closer to the front access opening. This is evident in every single testing set-up that was performed. While there was minor variability as the obstruction came closer, the minimum increase in pressure observed at two inches was 80% whereas the maximum increase was a staggering 625%. However, a chart detailing the correlation coefficient between the airflow volume and the pressure was assembled and included below as Figure 7.:

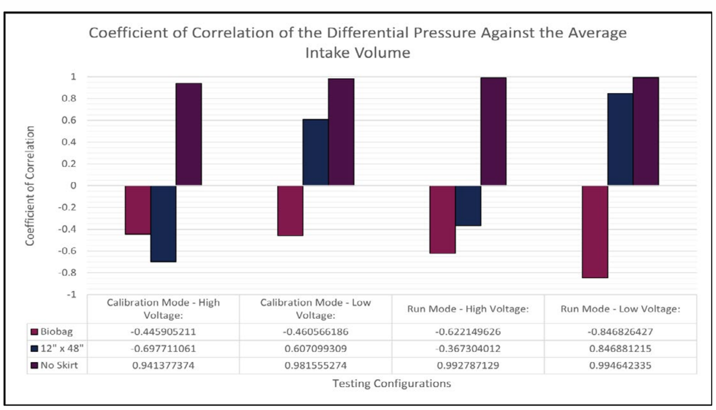


Figure 7: Coefficients of correlations across data sets.

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

A coefficient of correlation is a numeric value between -1 and 1 which indicates how similarly two sets of data change, where 1 means the sets trend identically, and -1 implies the two sets trend in opposing directions, and 0 means no common trend. Intuitively, one would expect to see all the correlation coefficients very close to 1, indicating a high correlation, because of a fluid's affinity to flow from higher to lower pressure regions, given that the interior of the cabinet is at a lower pressure than the environment outside of the cabinet. However, only the flow hood without a skirt has a high correlation, indicating that the set-up without a skirt was the only setup in direct noncompliance with Bernoulli's Principle which states an increase in the speed of a fluid occurs with the increase in static pressure. While Bernoulli's Principle is commonly applied to a closed fluid duct, consider the entirety of the cabinet and flow hood set-up to act as the hypothetical fluid duct since the cabinet should be completely contained everywhere between the air intake point and the air exhaust point. Instead of coefficients close to 1, most of the relevant points have a negative correlation, otherwise implying that the air intake rate and the differential pressure across the cabinet are inversely proportional.

Another aspect of our data that can be analyzed is the standard deviation across each series of testing. These values were all collected and presented in Figures 4-5. Figure 4 simply shows the standard deviation across all data collected, whereas Figure 5 shows the same, but with all data from two inches omitted. Standard deviation can be thought of as a metric for how similar, or tight a set of data is. In our application, a higher standard deviation means a larger variation in the readings, whereas a lower standard deviation means all the readings were very close to the average. For our sake, as low of a standard deviation as possible is desired, which correlates to all our readings being tight. Looking at Figure 4., an observed low standard deviation in the experiments using the various skirt configurations. However, when the skirt was removed our standard deviation took a significant rise. This indicates to us that the measurements are much more stable and vary less when a skirt is used to funnel the airflow into the biosafety cabinet. Although there is no current metric to determine when the standard deviation is too high, a configuration with a skirt would statistically perform more favorably compared to one without the skirt.

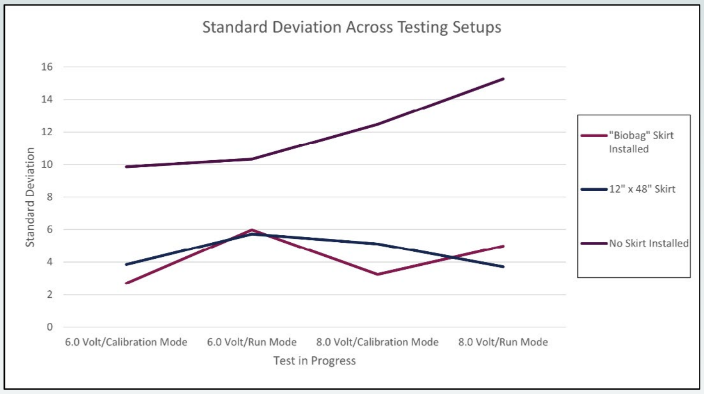


Figure 4: Standard Deviations of each cabinet mode/configuration.

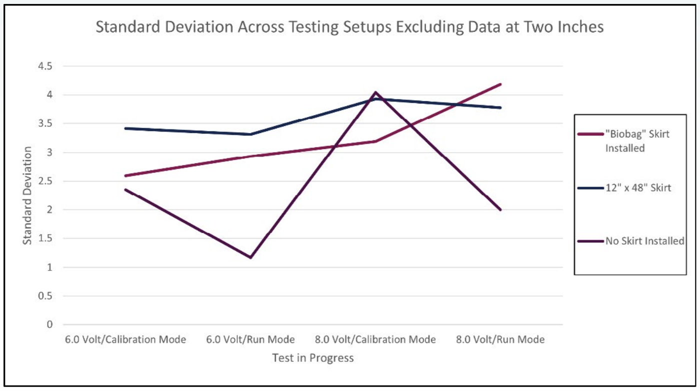


Figure 5: Standard Deviations of each cabinet mode/configuration excluding all data from two inches.

Finally, in Figure 5., all data from two inches was omitted because of the amount of outlying data recorded out of curiosity to see how the standard deviation curves change. When comparing Figures 4 and 5, the curves fit much more tightly together in the figure excluding the data from two inches, as well as a noticeably lower standard deviation across the board. This figure denotes that the data collected at two inches does not fit our set well at all, implying that the next closest distance (six inches) is where the accuracy in readings is maintained at a variety of distances.

An initial hypothesis regarding this testing was that as the blower speed increased, the standard deviation of the testing session would increase allowing for acceptance of a larger range of readings. However, Figure 4 directly contradicts this hypothesis. The figure shows a beginning trend of increasing the standard deviation as blower speed increased, but the trend became inconsistent as there are multiple tests done at 6.0 Volts which return a standard deviation closer to those returned with a blower set at 8.0 Volts. However, as

CONTINUED ON NEXT PAGE

AN ANALYSIS OF REQUIRED SPACING AT THE FRONT INTAKE AREA OF CLASS II BIOLOGICAL SAFETY CABINETS CONT.

Crosby Ravert, Robert Timer, Lewis Exner, Adam Costa, Anh Huynh, Jason Scrafano, and James T. Wagner

mentioned above, it seems to be the skirt which had the biggest effect on standard deviation. This figure does well to refute the previous conjecture, as well as invalidate any notion of acceptance with a two-inch clearance.

Conclusion:

The set of experiments conducted yielded a variety of interesting results. When it comes to using a skirt for airflow intake volume measurement, our data concluded that the skirts are much more favorable in recording data than any configuration without the skirt. Additionally, it can be concluded that the differential of pressure across the biosafety cabinet definitively increases when an obstruction is present at the front access opening, the effects of the change in pressure does not directly affect the airflow as observed in the cases above. In the results, there was no notable change in the air intake rate until the wall came within less than six inches from the biosafety cabinet. In conclusion, a cabinet with an obstruction at six inches would perform similarly enough to a cabinet with an obstruction at eighteen inches to continue safe operations. ■

FINANCIAL REVIEW 2024

CETA Members,

Wow, where has the year gone? It was great seeing so many of you at this year's conference in Reno. The annual conference is always such a great time to connect and learn from the many talented individuals who make up and support our organization. It should not come as a surprise to hear that attendance and feedback were very strong, while our operating costs remained well within budget. And who didn't have a blast at the closing reception/ cornhole tournament!? Already looking forward to next year's meeting in Orlando – hope to see all of you there.

Turning to CETA financials. Those of you who joined the annual business meeting in Reno will recall that the Treasurer/Secretary 'torch' has formally been passed to me by Erin Thane. Erin served as Treasurer/Secretary for the previous two years - a big thanks is owed to her for her service and financial guidance for our organization. Erin led several great financial initiatives, including the dubious task of budgeting as well as setting up our first-ever investments in two CDs.

Looking ahead, we're quite excited about several new initiatives that have been made possible through CETA's healthy and stable financial position. The Board of Directors is continually looking for ways to benefit our membership and industry. One of those initiatives is the funding of CETA's newly-created Grant program. A board vote earlier this year kicked off the program, which allows for funding of unique research projects that seek to address key industry topics that directly benefit our membership and industry. We hope to see many submissions to this unique program.

CETA is also planning to renew our CDs, while also looking at expanding our investment plans to help our money stretch further in support of our annual conference, CNBT, CAGs, and beyond. These programs add tremendous value to our certification community and we continue to grow them every year.

With lots in the works, we hope you will all have a chance to benefit from CETA activities over the course of the next year. And if you have a question or suggestion, be sure to reach out at any time. Thank you all for being an active part of our organization – see you in Orlando! ■

David Wasescha
CETA Treasurer

HEPA – IN THIS ISSUE'S HEPA, WE ASKED 5 QUESTIONS OF CERTIFICATION TECHNICIANS FROM CONTROLLED ENVIRONMENT CONSULTING.

Adam Costa, CNBT
Jason Scrafano
Robert (Bob) Timer, NSF Accredited , CNBT Accredited
Anh Huynh, CNBT

Here's what they had to say!

1. **Many certifiers enter the field without knowing anything about the industry. What is your certification technician "origin story"? How did you get to be where you are today?**

   JASON – I had also not heard of this industry prior, and it only became known to me from a job posting. I went to school and became certified for HVAC/R, but eventually pivoted into jobs focusing on different aspects of air quality. Upon learning about this industry, I thought it would be a good fit for my background and seemed like an interesting and useful field.

2. **As a newer technician, how would you describe the certifier's role?**

   BOB – Ensure that all the PECs and cleanrooms are operating with specifications.

   ANH – Most of the time you feel like a jack of all trades, as you need to bring together theory and practice.

3. **Which is your favorite and least favorite test to perform, and why?**

   ADAM – I don't think I have one test that stands out as a favorite, but my least favorite test would be smoke studies or particle counting.

   BOB – Leak testing of the HEPA filters is my favorite since we are verifying that clean air is being delivered in critical sites or cleanrooms where medicine can be made. USP smoke study of PECs is my least favorite since pharmacy techs don't like doing it with you.

4. **Looking back on the training you received, which test was the hardest to learn/master and why? How could your training have been different to assist in your learning?**

   JASON –The hardest to learn/master, in my opinion, was BSC related testing. This is mainly because there are many types and manufacturers, most of whom require they be tested and/or adjusted in different ways. I am not sure my training could have been any different in a way to help me understand it better in the moment. This is one of those things where you need to see each and every one in the field, as having each iteration in a training area is probably unrealistic.

5. **What advice do you have for certification technicians new to the industry?**

   JASON – Use a notepad app or something equivalent and take notes while in the field. You are going to be absorbing a massive amount of information as someone completely new, and this will save you.

   ANH – Mastering aseptic technique is key to quality work and will provide better peace of mind. While all clients will typically triple clean after you leave a job site, you still do not want to leave anything or take anything with you. Gives a new meaning to "leave work at work."

   BOB – There are a lot of specifications and situations that you will run across. It will take time. Ask other technicians for advice to master the skill.

   ADAM – Absorb all the information you can.

RENO

APRIL 19-22

CETA
Controlled Environment Testing Association

NEVADA
2024 CETA ANNUAL CONFERENCE

Scenes from Reno!

QUICK REFERENCES FOR CETA

Provided by Kyle Mulder

Contact Numbers

NuAire- 800-328-3352
Baker- 800-992-2537
Kewaunee- 704-873-7202 or 704-871-3271
Labconco- 800-821-5525
Thermo- 800-848-3080
Germfree- 800-888-5357
Esco- 215-441-9661
Envirco- 800-884-0002
Airclean- 800-849-0472
Biobase- rd@biobase.cn

Conversions

1 foot (AKA ') = 0.3048 meters
1 inch (AKA ") = 2.54 centimeters
1 square meter = 10.76 square feet
1 square foot = 144 square inches
1 cubic foot = 0.028 cubic meter
1 cubic meter = 35.315 cubic feet
1 cubic foot = 1728 cubic inches
Degree F = (degree C x 1.8) + 32
1 in WC = 1" WG = 249.09 Pa = 0.036 PSI
1 torr = 1 mm HG = 0.535" WC
1 bar = 401.463"WC
1 CFM = 28.317 LPM
TCs: J=Black K=Yellow T=Blue

Equations

Area= length multiplied by width
Patch %= (total area of patches ÷ effective area of filter) move decimal 2 places →for %
Area of a circle= π (3.14) x radius squared (multiply radius by radius first). Radius is ½ the diameter.
Ft² of right-angle triangle= length x width ÷ 2
Volume=length multiplied by width multiplied by height
Q = VxA, air volume = velocity times area
Air changes per hour= (total dominant room CFM x 60) ÷ room ft³
K_V= (air volume ÷ area) ÷ measured velocity = number to multiply measured velocity by
P_T=P_V+P_S total pressure = velocity pressure + static pressure
Velocity from velocity pressure=4005 x $\sqrt{P_V}$
PAO challenge = generator output (standard 13,500 per nozzle)/total CFM per plenum
PC min sample volume = (20÷Largest particle size class limit) x 1,000. or 1 minute and 2 liters, whichever is greater.
Min # of PC locations for >1000 m² rooms= (m²÷1,000) x 27
Volts = current x resistance, V= I x R
RSD is from AVERAGE, not ranges.

Grids

#= number of locations
L= length of area at plane of testing
With vignette (BSC DF, CB);
#=(L-(2x vignette)) ÷ space max) round up+1
Spacing=(L-(2x vignette) ÷ (#-1) round to 0.00"
Without vignette (fume hood, BSC RA);
#=(L÷ space max) round up to whole number
Spacing=(L÷ space max) round to 0.00"

Standards and Procedures

Fume hood: normally 12-18" sash Readings <12" apart equally spaced
-OSHA; 60-100 fpm.
-CAL OSHA; 100 min, no point lower than 70 and must have an airflow monitor. Carcinogenic use requires 150 min with no point lower than 125.
-SEFA; 60-100 fpm, 20fpm "flyers". Cross drafts must be less than 30fpm.
-ANSI/AIHA Z9.5; 80-120 fpm with 20%RSD.
-ASHRAE 110; no velocity spec. Tracer gas with mannequin. 9µL gas inject. Cross drafts at 18" out at sash height. Critical orifice 4 LPM. Gas ejector 12" from walls and 6" behind sash. Gas detector probe 3" from sash 22" up from work-deck. 0.1 PPM common max leakage.
-NIH; 90-120 fpm. Low volume hoods no less than 80.
-NFPA; 80-120 fpm.
-NIOSH; 100-150 fpm.
-ACGIH; 80-100 fpm.
-National research council; 80-100 fpm, 120 recommended for high toxicity, but should not exceed 150 fpm.

Clean bench: Grid 6" from sides <12" apart 6-12" off filter (not handheld). Leakage <0.01%
IEST-RP-CC002. 90 ± 10 fpm, or MFR spec

Class 1 BSC (single pass): Grid 6" from sides <12" apart. Normally 75-100 FPM MFR spec is primary. Gross leakage <0.01% or MFR spec
IEST-RP-CC034=basic HEPA leak 0.01% and patches less than 3% total, smaller dimension of patch <1.5". *0.005% is only for Class II hoods.*

Class 2 BSC: MFR spec airflows. No hand-held air measurements, work area empty.
NSF/ANSI 49 Annex N5
Grid is per data plate, if no data plate; downflow 6" from sides <6" apart and sash height (newer than 2002 units normally 4" above sash), **exhaust filter inflow;** 4" from sides <4" apart 4" from filter, **RA** no less than 2 per 12". **Scan HEPA leak;** 2" per second 1" from filter <0.01%, **Duct HEPA leak;** sweep entire duct <0.005%. **B2 interlock;** Shut down total exhaust for alarm 15 second test, then bring back up to supply reactivation and slowly go back to for % drop calc. Must alarm ≤20% of total exhaust. Interlock must activate at same time of alarm **Smoke tests**; Work opening edge retention; 1.5" out around the perimeter of the access opening. No smoke should spill/flow onto/over work tray. View screen retention: 6" up from sash edge 1" inside, no smoke can escape access area or reflux upward. Sash/window seal; along the top of the sash at wiper and along sash sides, no smoke can escape cabinet. Down flow uniformity: 4" up from sash along the center of the work tray no refluxing or dead spots. **Pressure decay;** on any positive plenum adjacent to common space units (A1). Seal off intakes and exhaust. Use drain valve and compressor to increase to 2.00" w.c. hold for 30 minutes, ,10% loss is pass. **Secondary tests (per NSF 49);**
Light; Samples taken 6" from sides and <12" apart on the work deck centerline. Lights and blower off; Lights and blower on; Acceptance criteria: lights on is >45fc greater than background <15fc.
Sound; two readings taken 15" up from work deck, 12" out from leading edge of access opening. First reading with motor off - dbA. Second reading with motor on - dbA. Acceptance criteria: <70dbA after NSF correction factor (0-2=reduce background, 3=-3, 4 or 5=-2, 6-10=-1) with motor on.
Vibration; Two readings taken at geographical center. Motor off - 0.00000" rms. Motor on - 0.00000" rms. Acceptance= <0.002" rms. Your meter will probably require a conversion.
UV Light; Two readings at the center of the work tray. One lights off. One with UV light on and warmed up (wait for reading to level out). Acceptance = >40 microwatts per square centimeter.
GFCI; Ground polarity is correct. Acceptance criteria: Unit trips, but not at 1, 2, or 3 ma gnd.

Isolator/RABS: CAI/CACI
CAG-002 required tests.
Airflow; MFR spec (grid too)
Chamber pressure: unit maintains neg or pos press with each passthrough door open (at a time) and when gauntlets are extended in or out (pressure specific) from sash over 3 seconds.
Site installation; Exhaust alarm function, proper ducting (negative), functional passthrough interlock.
Chamber integrity: outside must fail ISO 8, use Laskin nozzle if needed. Then scan all potential penetrations with particle counter. Acceptance, no penetration fails ISO 5 with probe held 1" away. (CACI only)
Smoke pattern; shows smooth downflow, no refluxing or inward air from penetrations.
Prep ingress egress; probe 6-8" high and 2" in from door path. During passthrough of previously particle saturated tray, counts cannot exceed ISO class 5.
Particle counts: passthrough and main chamber meet ISO 5. Both static and dynamic conditions in the main chamber, static = 5 loc dynamic =1 (per DCA)

QUICK REFERENCES FOR CETA

Provided by Kyle Mulder

Gauntlet breach: (not required), one gauntlet removed, 3 readings center of hole. Acceptance >100fpm (normally).

<u>**ISO 14644-1**</u>: classification of any space See reverse side for min # of locations. 1 count per location minimum 2 liters and 1 minute per count. Locations are set in equally divided sections of the area. Particle counts are the only thing REQUIRED to classify an area. Certifiers do not count as occupants.

Viable Samples/EM:

The sampling plan <u>must</u> be risk based and owned by the user.

Dual media can utilize two TSA plates if approved by the client.

Air: Dynamic requires normal quantities of compounders performing all actions normal in tested area (entry, gowning, staging, media fill).

Surface: Dynamic is after a process and BEFORE cleaning in PECs. Aseptically clean and disinfect surface locations.

Fingertip; Roll each gloved finger pad on media w/o breaking media.

Action levels; Air; ISO 8 >100, ISO 7 >10, ISO 5 >1. Surface; ISO 8 >50, ISO 7 >5, ISO 5 >3.

Equipment

Thermal anemometer (hotwire); dot into the wind, actual absolute pressure (HG) found on Shortridge abs press) and temp when above 1,000ft otherwise 29.92 HG if <1,000 ft.

Capture hood (Flow hood or Balometer): Must seal entire area being tested (not gas tight). Uncorrected for BSCs or exhaust

Particle counter; always read cumulative, particles per cubic meter. Point probe towards airflow in unidirectional devices, otherwise always point up. Locations should be about 6-12" above work areas or about 48" above the floor.

Particle generator: normal output equation is total CFM in plenum challenged divided INTO 13,500 (or actual output of the generator) per nozzle. Step downs are not allowed unless taking upstream readings. Should not be restricted smaller than ½"

Decontamination

Paraformaldehyde: >60% rh >70° F/15° C. Total vol (ft³) x 0.3 = g of PF. Total vol x 0.33 g Amm carb/ 0.48 g Amm bicarb. 6-hour contact 1 hour neutralize. <0.75 PPM PEL

Chlorine Dioxide (bowl/wet); >40% rh. >60° F/15°C. 6.5 packet for <50 ft³, 9.75 for <75 ft³. 2-hour contact (80 minute possible). <2 PPM PEL.

VHP; <30% (<20% ideal) rh. > 86°F/30°C. 1mL per ft³ or 0.5 mL for room and incubator. 1mL of HP = 1.13g. 2-hour contact. <1 PPM PEL-TWA

Passwords/sequences/codes:

DO NOT CERTIFY IN ADJUSTMENT/MANUAL MODES!

↑↑↓↓←→←→BA start

NuAire;

9876 for touch screen

NuAire flag or earth hidden button for triple digital display and incubators.

LED display: Hold silence, press flag, blower start, then up arrow.

Digital display: Silence, enter, up, down

ES series/DC motor; a small button at bottom right of speed control must be pressed till light to adjust speed.

Digital exhaust alarm: Hold up and down arrows to enter cal mode, reset to enter value. Hold down arrow to set low alarm point. Hold up arrow to set high alarm.

Baker;

Dipswitch position: left dipswitch (white switches in blue box of 2 switches) down for manual mode (flashing green light), adjust with potentiometer next to switch, wait 1 minute, put dipswitch back to auto (solid green light)

Multi pot; third pot up from bottom/closest to you turned CW till stop for manual mode, bottom pot is then speed control, wait 1 minute and turn same third pot up CCW to return to auto mode.

Red button: press for blinking green light for manual adjustment, adjust with white screw, wait 2 minutes after adjustment and press red button again for solid green light to return to auto mode.

Labconco;

All units: DFs 4' above sash if data plate is up top, at sash height if data plate by elbows.

Blue Delta w/ switches; Turn off unit, hold silence, turn on unit, unit will start beeping, let go of silence, adjust speed control behind plate on top power box (two blue square buttons). Press silence to exit.

Units after blue Delta; Light, UV, timer, timer, OK.

Logic Vue; Light, up, timer, timer, OK

Clean bench & touchscreens; 1925

Thermo;

1300 Series A2; hold silence and light for 10 seconds till beep for service mode before measuring velocities. S1=DF blower, S2=exhaust blower, S3=DF alarm point, S4=inflow alarm point. ON button to save when "set" shows. Silence button to exit service mode. Order: S2, S4 (to note value), S1, S3, reenter/resave noted S4 at the end.

Silence button to exit service mode.

1400 series; Program (arrow pointing right) and hidden button (to the right of silence) simultaneously followed by enter to start CH mode (will show a wrench). Same sequence to exit (faces will appear).

Herasafe; 6363

ESCO;

0009 admin pin

0019 for factory calibration of airflow sensor (when all else fails)

Kewaunee

Interceptor; 9999 and/or 1001

Airclean;

HEPA filter 2 year reset codes;

6 digits; 833673

11 digits; 1B9-CBA4-C014

Or call Airclean

Biobase

Fan speed; settings button, password 1234, first row for fan speed adjustment, second row for pressure display, third row for air display. NSF A unit, while in off hold fan button for 5 seconds and fan speed screen will populate.

Airflow alarms:

TEL 500; Set airflow to alarm point. Hold enter for 5 seconds (lights will flash, and beeping will start). Press and hold both enter and set for 5 second sample time. Two beeps = good cal. ***500 BSC is the same, but at setpoint airflow with internal 80% alarm point.***

TEL 1,000; Hold enter and use +- keys to highlight setup, select calibration, password is 0000. Adjust to match measured airflows at normal and press enter. Lower sash, measure velocities, match reading, press enter. Back to run/setup = good calibration.

Apex 1,000(TSS); Mute button for 3 seconds shows mode (1 LED = mode 1 where unit is calibrated to actual air flows, 2 LED = mode 2 where unit is calibrated to calculated 20% loss). Mute button for 15 seconds turns off buzzer till repeated. Cal button (paperclip button) toggles modes, 5 seconds starts alarm cal, 10 seconds 0s sensor (sensor must be blocked, re-zero is not needed often). To calibrate hold mute for 3 seconds and press cal button to sample.

Lab Crafters Air Sentry: Password is 00000

BSC airflow corrective actions

TYPE	STATUS	OPEN EX DMPR	CLOSE EX DMPR	RAISE MAIN SC	LOWER MAIN SC
A1/A2	Low inflow, good downflow	O		O	
A1/A2	Good inflow, low downflow		O	O	
A1/A2	High inflow, good downflow		O		O
A1/A2	Good inflow, high downflow	O			O
A1/A2	Low inflow and downflow	P	P	Y	
A1/A2	High inflow and downflow	P	P		Y
A1/A2	High inflow, low downflow		Y	P	P
A1/A2	Low inflow, high downflow	Y		P	P
B2	Low inflow, good downflow	Y			O
B2	Good inflow, low downflow	P		Y	
B2	High inflow, good downflow		Y	O	
B2	Good inflow, high downflow		P		Y
B2	Low inflow and downflow	Y		Y	
B2	High inflow and downflow		Y		Y
B2	High inflow, low downflow			Y	
B2	Low inflow, high downflow				Y

Y=Yes

P=Possibly, see other status with post adjustment findings.

O= a possible option

Table 1 — ISO Classes of air cleanliness by particle concentration

ISO Class number (N)	Maximum allowable concentrations (particles/m³) for particles equal to and greater than the considered sizes, shown below[a]					
	0,1 µm	0,2 µm	0,3 µm	0,5 µm	1 µm	5 µm
1	*10*[b]	d	d	d	d	e
2	100	*24*[b]	*10*[b]	d	d	e
3	1 000	237	102	*35*[b]	d	e
4	10 000	2 370	1 020	352	*83*[b]	e
5	100 000	23 700	10 200	3 520	832	d, e, f
6	1 000 000	237 000	102 000	35 200	8 320	293
7	c	c	c	352 000	83 200	2 930
8	c	c	c	3 520 000	832 000	29 300
9[g]	c	c	c	35 200 000	8 320 000	293 000

Table A.1 — Sampling locations related to cleanroom area

Area of cleanroom (m²) less than or equal to	Minimum number of sampling locations to be tested (N_L)
2	1
4	2
6	3
8	4
10	5
24	6
28	7
32	8
36	9
52	10
56	11
64	12
68	13
72	14
76	15
104	16
108	17
116	18
148	19
156	20
192	21
232	22
276	23
352	24
436	25
636	26
1 000	27
> 1 000	See Formula (A.1)

NOTE 1 If the considered area falls between two values in the table, the greater of the two should be selected.

NOTE 2 In the case of unidirectional airflow, the area may be considered as the cross section of the moving air perpendicular to the direction of the airflow. In all other cases the area may be considered as the horizontal plan area of the cleanroom or clean zone.

ALTERNATIVE CLEANROOM CLASSIFICATION PHASES

MATTHEW LEMIEUX, VTG, LLC.

Traditionally, as described by Federal Standard 209 and ISO 14644-1, cleanroom classification phases are defined in three ways.

The first, As Built, means that the cleanroom construction is finished, and the room mechanical systems are operational. However, the room is empty of both client production equipment and operation personnel. In the second phase, At Rest, the as-built cleanroom is populated with client production equipment, which is operational, but client personnel are not present. In the third phase, Operational, the at rest cleanroom is occupied by the expected contingent of client operating personnel. The life science industry prefers two phases, static and dynamic. Static is most closely associated with the at rest phase and dynamic corresponds with operational.

With the customary site complications of equipment installation, hookup, commissioning, qualification, pressure balancing and other occupations, the strict conditions of the various phases are seldom actually present. To address these real-world difficulties, six alternative certification phases are suggested by the author.

1. **Remunerative –** In this mode, the cleanroom contractor is urgently attempting to classify a portion of the project for client turnover before the entire contiguous space is constructed. This is usually attempted with installation of temporary plastic wall barriers. The exterior building shell may be open to the elements and the cleanroom may graciously shelter displaced members of the local fauna, both terrestrial and avian.

2. **Unpressurized –** The cleanroom is to be classified before the air balancing contractor has had the opportunity to final balance the minuscule air pressure differences indicated in the design. This is often due to contractor disagreements concerning responsibility for architectural finish details without which pressurization cannot be achieved. This state is often found contemporaneous with the remunerative state. The general contractor may be clearly seen through the gap in the astragal confidently assuring the certifier that the room has been thoroughly balanced.

3. **Unfiltered –** This situation occurs when job-site pressure mandates the classification of cleanrooms despite knowingly having HEPA filter integrity leaks which have yet to be addressed and remediated. It is essential during this phase that all cleanroom personnel adhere to strict gowning classification protocol and traffic patterns so as not to contaminate the room while the general contractor is removing damaged hepa filter media.

4. **Unsecured –** During this mode, there are un-garbed contractor and client employees entering and exiting the cleanroom spaces during the classification. They often bear cardboard boxes, cutting torches, saws, drills, and surface grinders. It is prudent for the certification technicians to wear OSHA-approved hearing and eye protection during this delicate classification mode.

5. **Janitorial –** The cleanroom cleaning personnel are present in an overcrowded, claustrophobic density and are actively utilizing vacuum cleaners, paper towels, brooms, mops, and bountiful spray IPA bottles. Those certification technicians tragically encumbered by alcohol addiction are judiciously advised to seek out other project responsibilities during this phase.

6. **Helicopter –** During this modality, the ungarbed responsible contractor supervisor personnel and/or client representatives are hovering intrusively around the particle counter inlet sampling probe emphatically gesticulating and conversing with each other whilst eagerly inquiring of the certification technician – "Did we pass?"

In closing, the esteemed editorial board strongly suggested that I emphasize the satirical nature of this submission, prior to publication, lest the suggestions detailed herein be seriously undertaken by the governing bodies.

Controlled Environment
Testing Association
230 Washington Ave., Ext
Suite 101
Albany, NY 12203

CETA OFFICERS AND DIRECTORS