



"Lab Ventilation: How to Evaluate Effectiveness".

Enclosure Overview, Selection, Setup, Certification, Troubleshooting, and Maintenance



Who We Are



- Located in Leland, NC
- Approx 55,000 sf facility
- All under one roof
 - Sales
 - Design
 - Manufacturing
 - Assembly
 - Validation

The Issue



- Many jobs contain aspects involving inhalation hazards
- Materials may be toxic or have pharmacological activity (APIs, HPAPIs)
- Can cause maladies
 - Cancer
 - Mesothelioma
 - Silicosis



Solving The Issue



- Remove people from the process (automation)

- Use Proper Personal Protective Equipment
 - PAPR, Face Masks, etc.



- Provide Primary Engineering Control (PEC)
 - Fume Hood
 - Powder Enclosure



Engineering Controls

- Airflow is the Enemy
(Uses Much Energy)
- Airflow is Our Friend
(Provides Protection if
Properly Engineered)



Powder Handling – Open Face



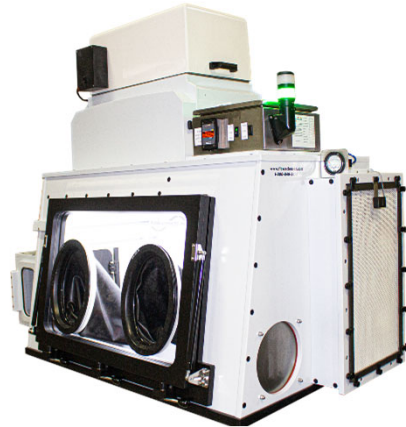
<https://www.labconco.com/category/glove-boxes-powder-containment/specialty-enclosures>



<https://www.nuaire.com/products/containment-ventilated-enclosures>

Common Primary Engineered Controls for APIs

Closed - Gloveboxes



<https://www.labconco.com/category/glove-boxes-powder-containment/glove-boxes-gas-purifiers>

Common Primary Engineered Controls for HPAPIs

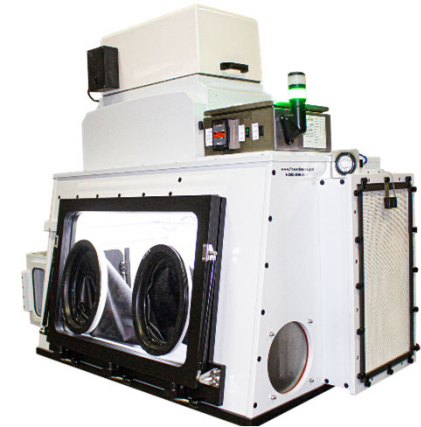
Gloveboxes – Inert Atmosphere



<https://www.labconco.com/category/glove-boxes-powder-containment/glove-boxes-gas-purifiers>

Common Primary Engineered Controls for
Atmospherically Sensitive Materials

Selecting the Correct Enclosure



How do I know which PEC I should use?

Risk Assessment

The best kept secret in containment procurement

Every single containment solution, from every single any manufacturer, works 100% of the time until you add:

1. People
2. Process
3. Product
4. Facility
5. Budget



What is Control Banding?

Everyone has one

'Simple' system for defining hazard of powders

Based on variety of factors, including toxicity, physical properties, route of exposure, etc.

Common terms are Occupational Exposure Band (OEB) or Occupational Health Category (OHC)

Generally, higher the number, the more hazardous the material

Used for powders in laboratories and small development operations

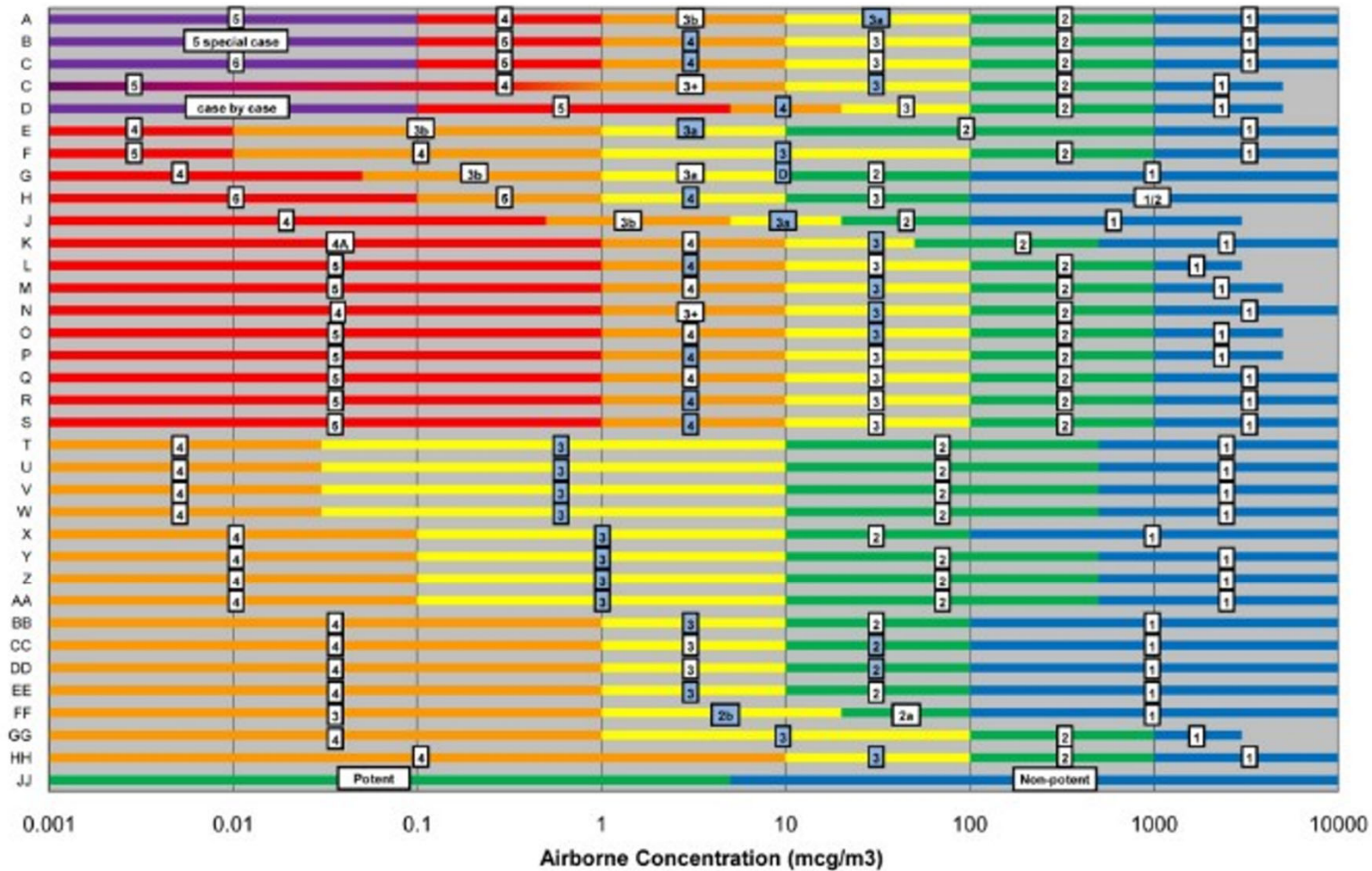
No consistency across the pharma world

Large ranges, so often not very useful in enclosure selection

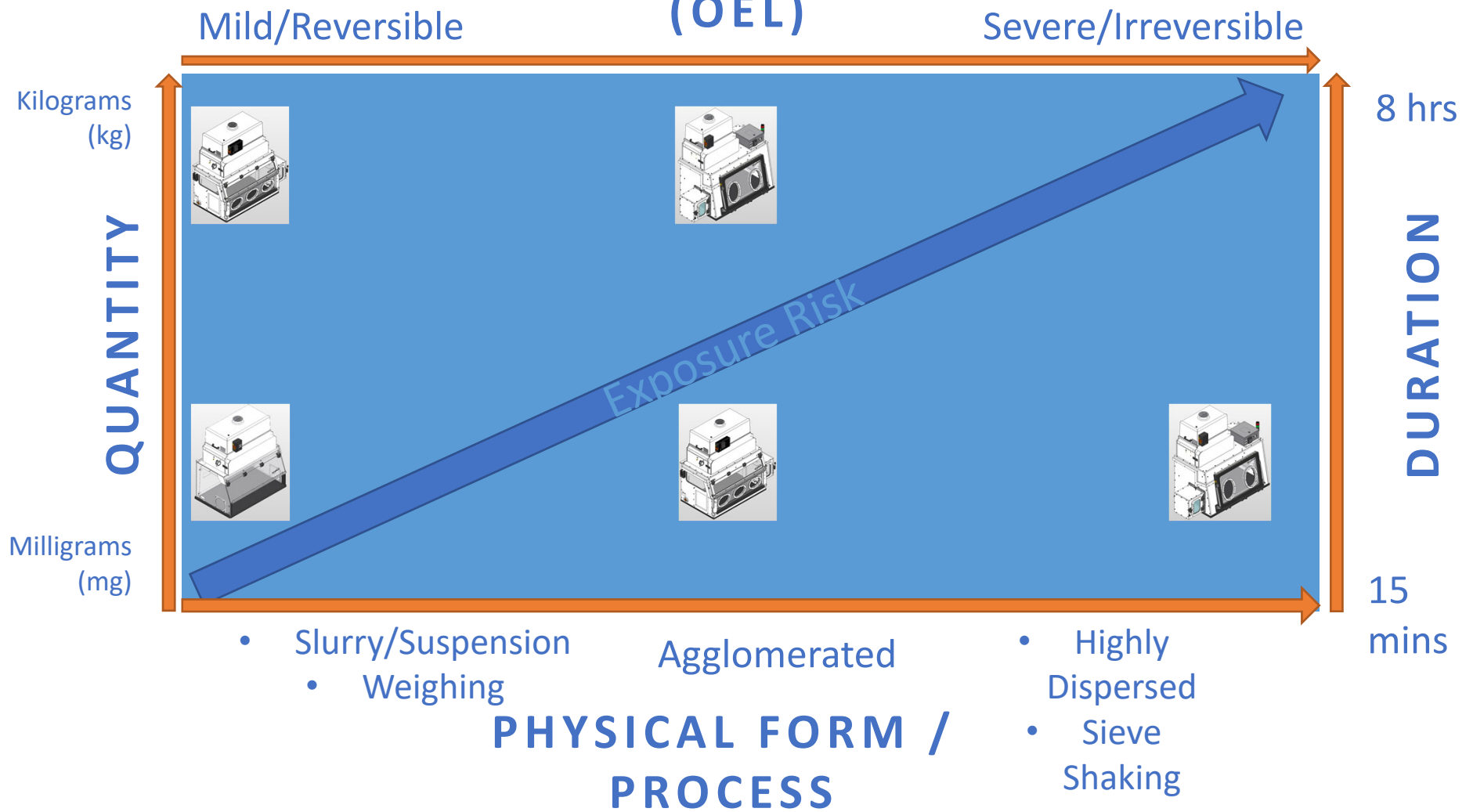
What is The Problem With Control Banding?



Everyone has one



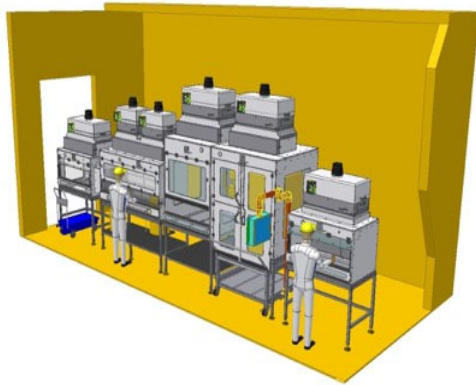
HEALTH HAZARD (OEL)



When 'Standard' Solutions Don't Work



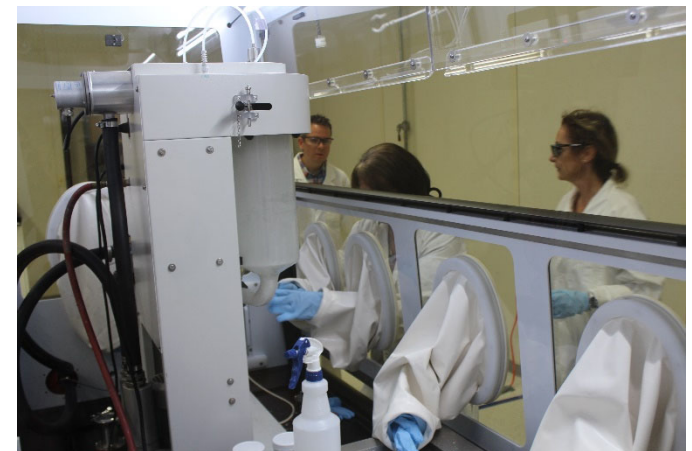
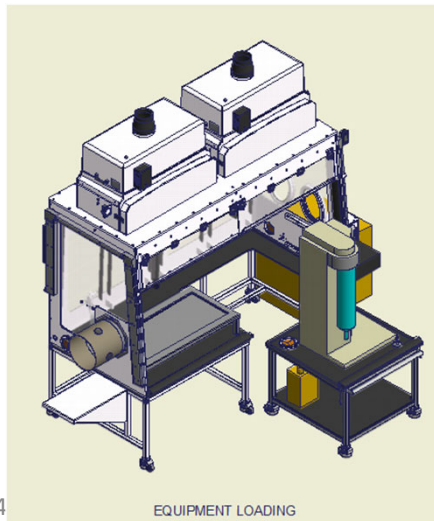
Customization



Engineering

Manufacturing

Performance Verification

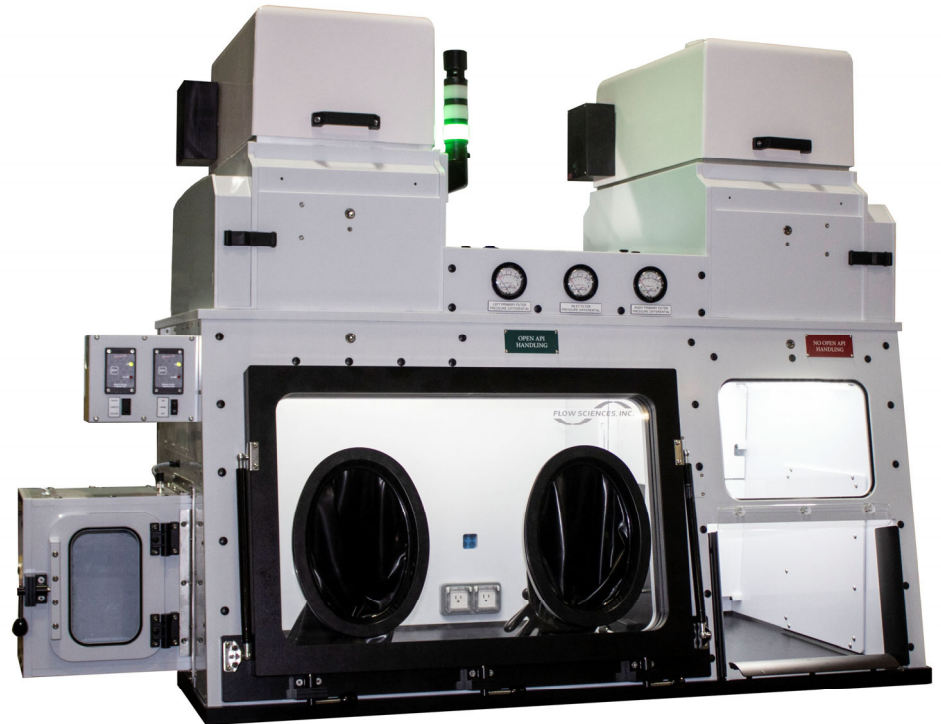


When 'Standard' Solutions Don't Work



Case Study - Design

- Personnel Protection
- OEB 5 compounds ($<30 \text{ ng/m}^3$)
- CPT – 10 ng/m^3
- Weighing and dissolution of 10s grams powder
- Short duration of task ($\sim 30 \text{ min}$)
- Ventilated area for secondary cleaning



Case Study - Results

Task	Quantity (Open Handling)	Result
Weighing	10g (n=6)	ND
Cleaning 1	N/A (n=6)	ND
Cleaning 2	N/A (n=6)	ND
Pour Test	50g (n=3)	ND
Cleaning	N/A (n=3)	ND
Spill (GB)	5g (n=1)	ND
Spill (Open)	5g (n=1)	ND



When 'Standard' Solutions Don't Work



- CQ18032
- Pills, coated and uncoated
- CPT – 1 $\mu\text{g}/\text{m}^3$
- 30kg
- Vibratory Feeder
- Bottle filling line



When 'Standard' Solutions Don't Work



Task	Quantity (Open Handling)	Result
Dispensing	25kg (n=6)	ND
Cleaning 1	N/A (n=6)	ND
Feeder	25kg (n=6)	ND
Filling Head	25kg (n=6)	ND



When 'Standard' Solutions Don't Work

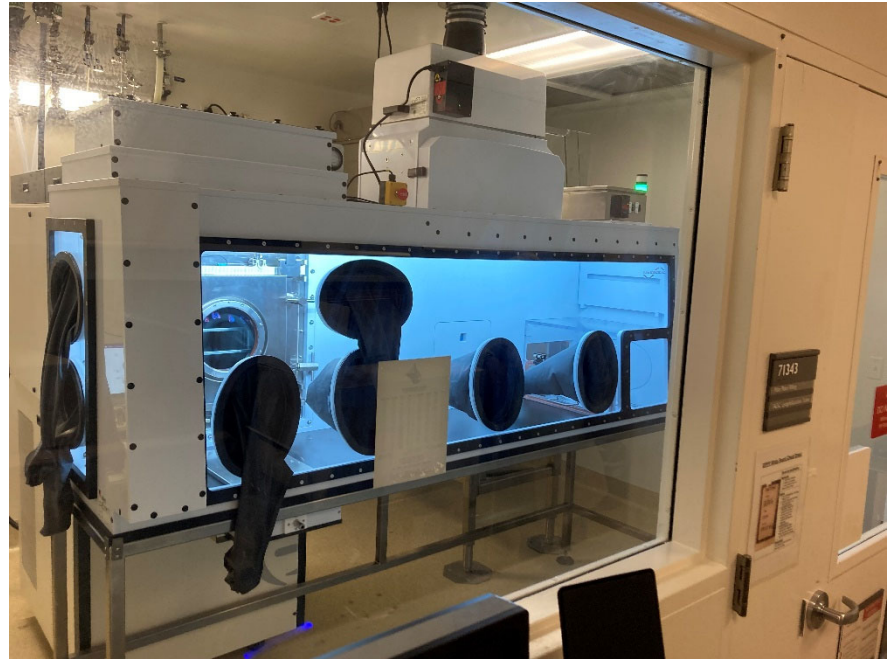


- CQ14602
- Buchi B290 Spray Dryer
- CPT – 1 $\mu\text{g}/\text{m}^3$
- Multi g
- Spray Dryer
- Disassembly of glassware, cleaning, etc.



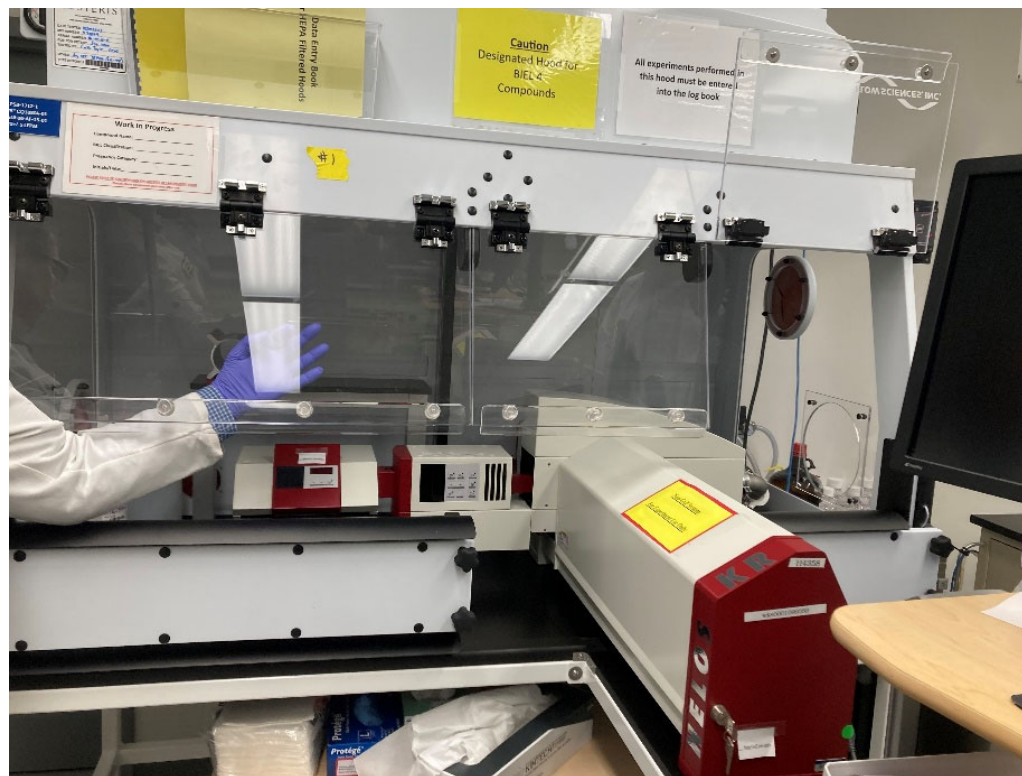
Task	Quantity (Open Handling)	Result
All (Personal)	50g (n=6)	<0.655ng/m ³
All (Area)	50g (n=6)	<1.288ng/m ³

When 'Standard' Solutions Don't Work



Lyostar-4 integrated with Flow Sciences Glovebox and Baker BSC
Replacing similar setup with a Lyostar-2
Containment required for initial setup – 50 ng/m^3
Results – 12 ng/m^3

When 'Standard' Solutions Don't Work



Sympatec instruments integrated with Flow Sciences open-faced enclosures
Example of putting the 'business end' in containment

STEP 1 – INSTALLING THE ENCLOSURE

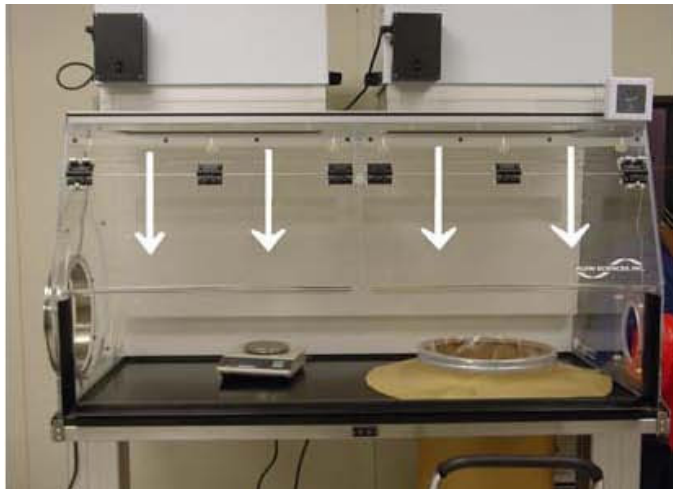
- Location, Location, Location
 - Avoid high traffic areas
 - Avoid locations below AC vents
 - Avoid locations near to exhaust vents
 - Avoid having enclosures at 90° to each other
 - Ensure that you have all the parts that were shipped with the unit
 - Refer to manuals / certification guidelines for proper setup of enclosure

Installation

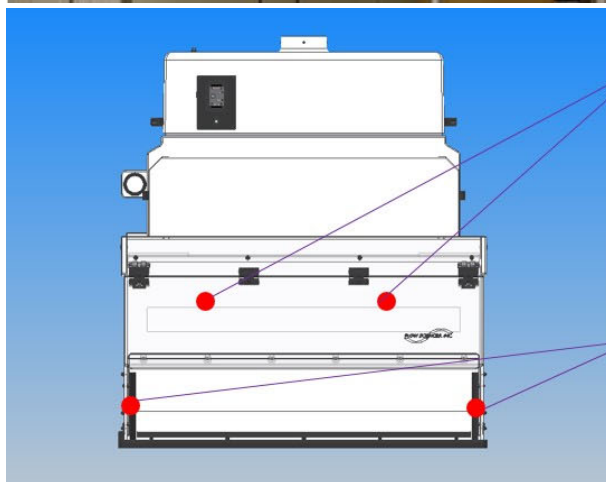
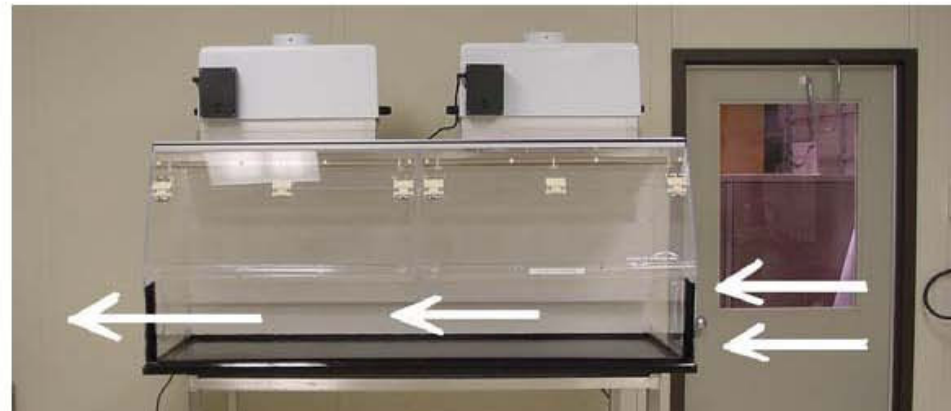


Placement of Enclosure

Shear

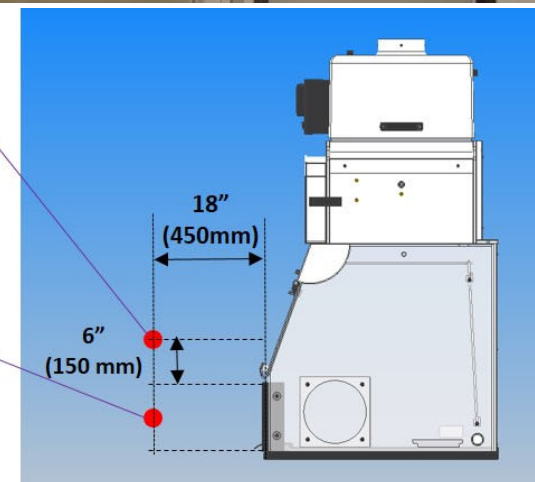


Cross Draft



Recommended Locations
for Shearing Measurement

Recommended Locations
for Cross Draft Measurement



Installation



Primary filter fully seated to rear of BIBO housing



Airflow arrow points toward top

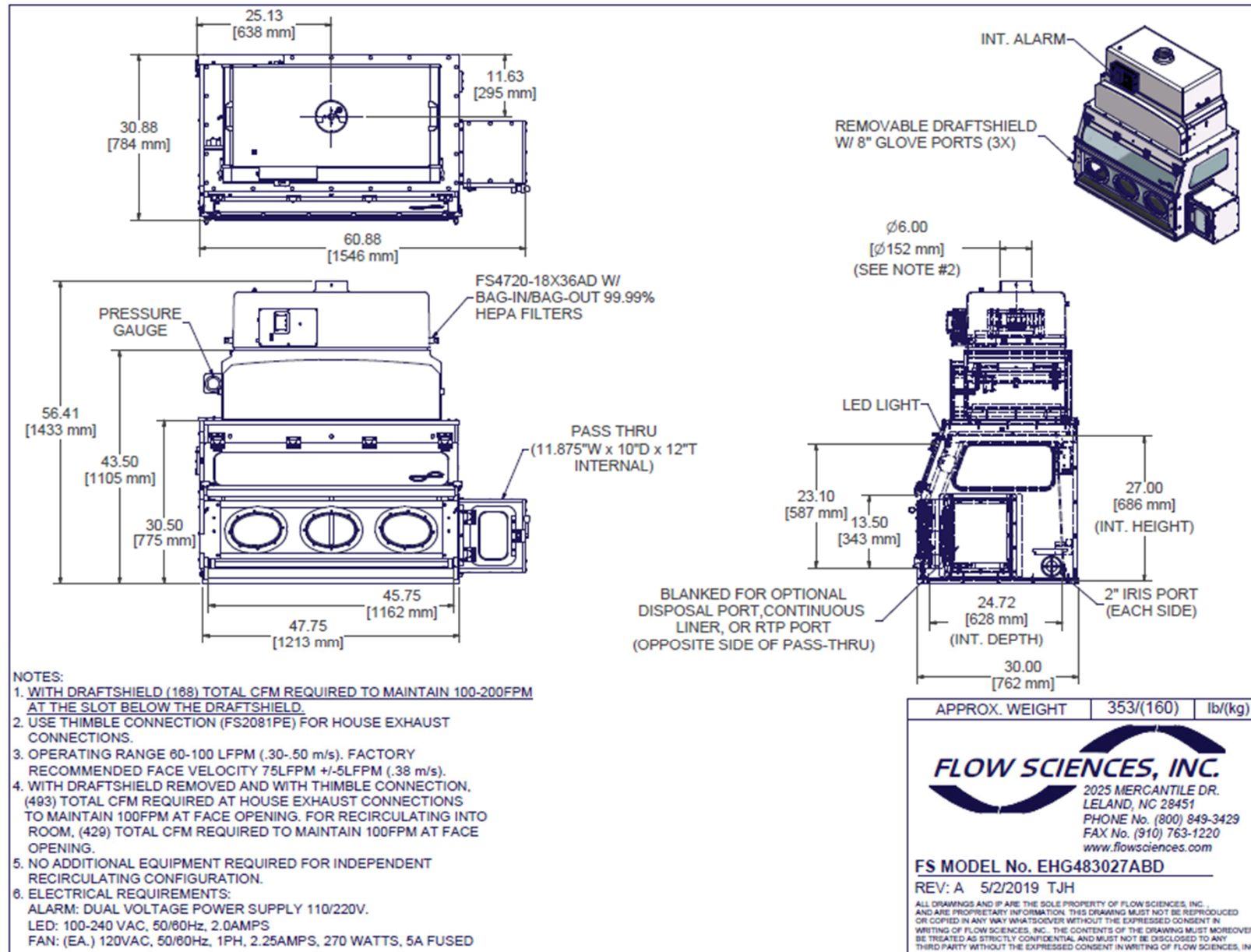


Install the filter bag | Roll bag up into flange | Secure with strap

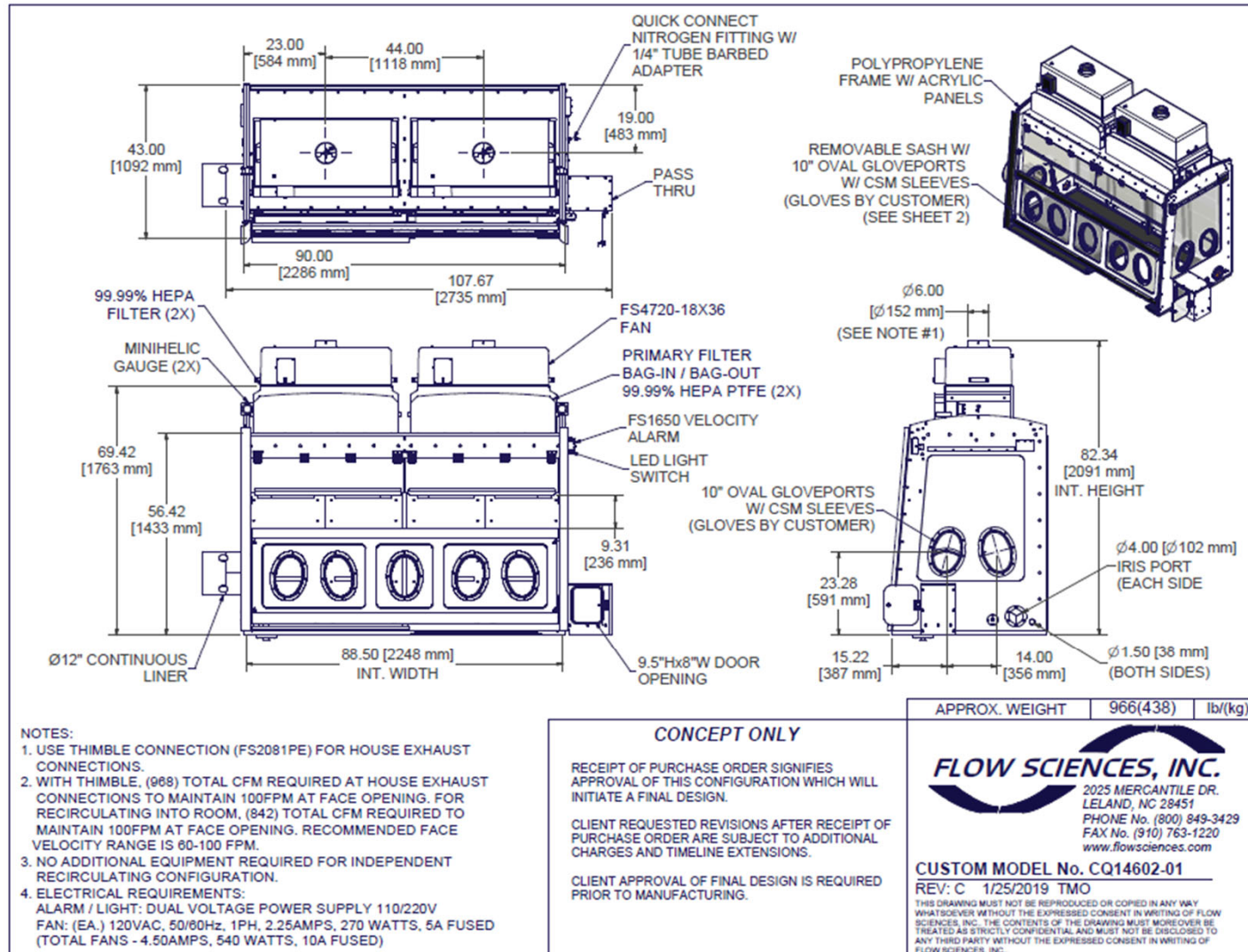
STEP 2 – FINDING THE INFORMATION

- Use enclosure drawing to determine:
 - Recommended face velocity
 - CFM requirements for HVAC
 - Electrical requirements
 - Other components that need to be certified

Finding the Information



Finding the Information



SHEET 1 OF 6

STEP 3 – SET THE DESIRED VELOCITY

- Using information from drawing, determine face velocity needed
- Using fan speed controller, set face velocity
- Connect house exhaust (if needed) and adjust extraction system flow to correct level
- Ensure alarm light turns green
- Check alarm function by blocking airflow across sensor

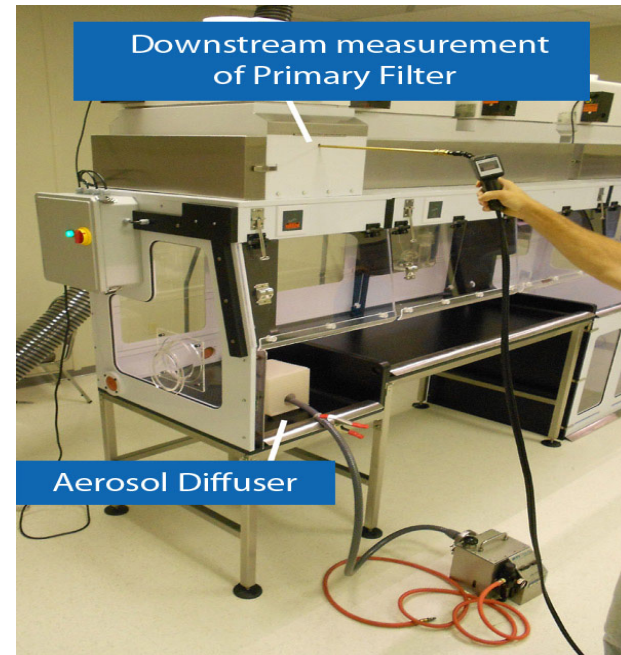
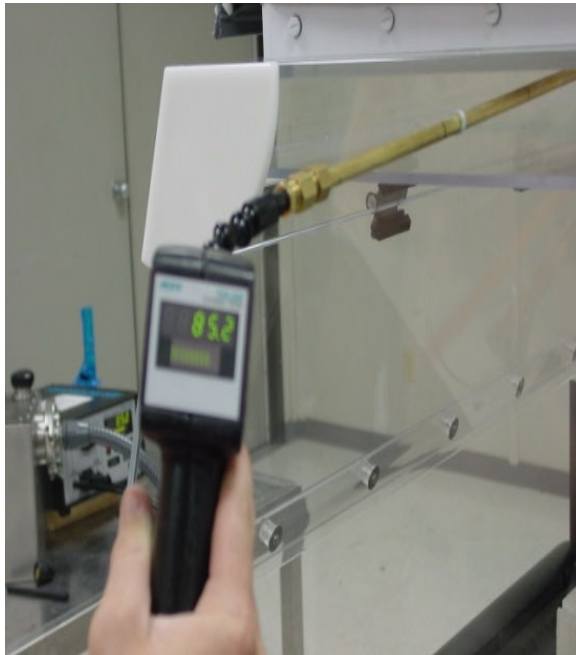
STEP 4 – CERTIFICATION

- Verify that airflow (face velocity) is correct, and that grid is balanced
- Verify that filter is installed and sealed correctly (if installed)
- For any style enclosure, refer to manual and/or certification guidelines for relevant standards required for certification

Certification



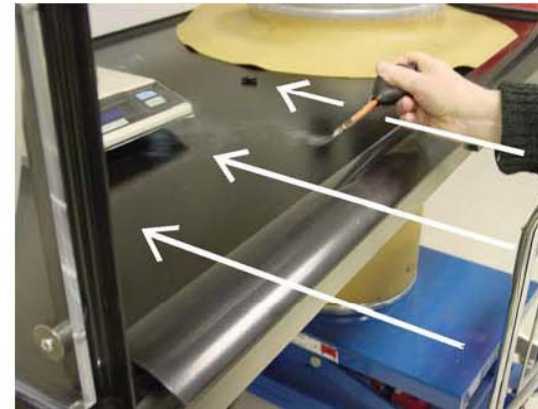
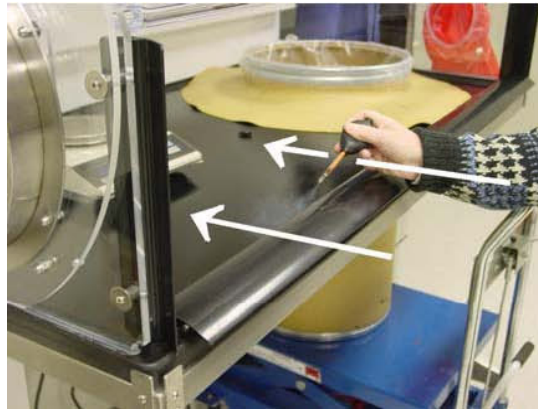
Aerosol Challenge



Certification



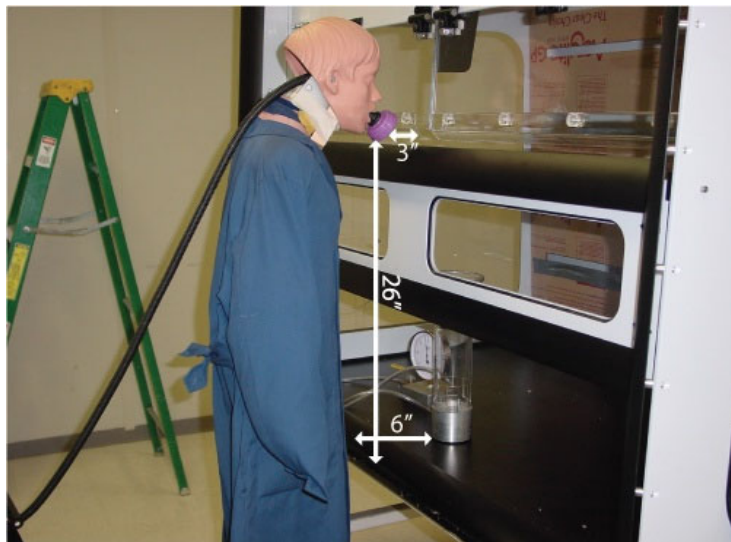
Flow Visualization - Optional



Certification



Tracer Gas - Optional

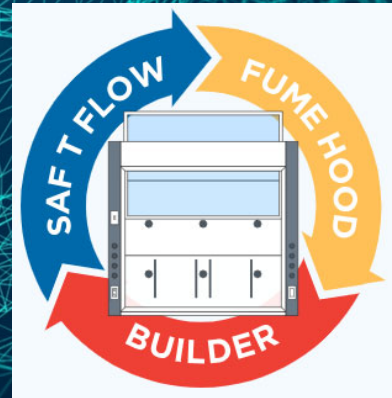


Refer to latest version of ASHRAE-110 standard for acceptable values of tracer gas outside enclosure

STEP 5 – RE-CERTIFICATION

- Verify that airflow (face velocity) is correct, and that grid is balanced
 - Adjust fan speeds if required
 - Ensure alarm function by blocking airflow across sensor
- Verify that filter is installed and sealed correctly (if installed)
- For any style enclosure, refer to manual and/or certification guidelines for relevant standards required for re-certification

FLOW SCIENCES, INC.





Q&A

