Biosafety Cabinets

Function & Certification

International High Containment Workshop
May 10-15, 2009

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Introduction

- Learning Objectives
- Definition
- Regulations/Standards
- Categories/Classes of BSCs
- Performance Verification
- Hands-on Certification Project

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Learning Objectives

- Identifying the different types of BSC's and how they function.
- Determining which BSC is correct for given applications.
- Understanding what is involved and required to perform an Annual Certification.

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What is a Biosafety Cabinet (BSC)?

- A Ventilated Cabinet or enclosure
- Uses directional Air flow and HEPA filters to provide:
  - Personnel protection
  - Environmental protection
  - Usually provides product protection

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Regulations / Standards

- National Sanitation Foundation
- NSF Standard 49 (NSF/ANSI 49-2002)
  - Covers Class II Cabinets only
- Available from: http://www.techstreet.com
- Many BSC's in use today are covered under NSF 49 (1992)
- New cabinets are covered under NSF/ANSI 49-2002

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Categories

Biosafety Cabinets are generally broken down into three categories:

CLASS I
CLASS II (A1, A2, B1, B2)
CLASS III

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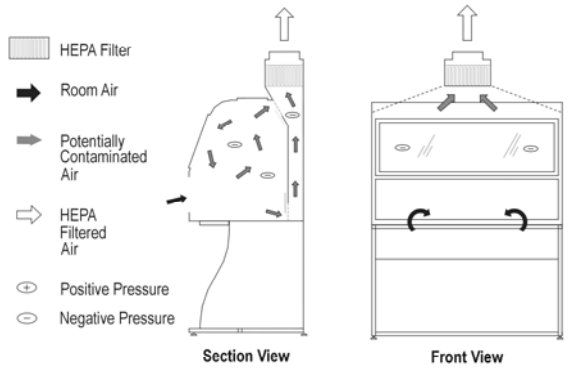
Class I Biological Safety Cabinet

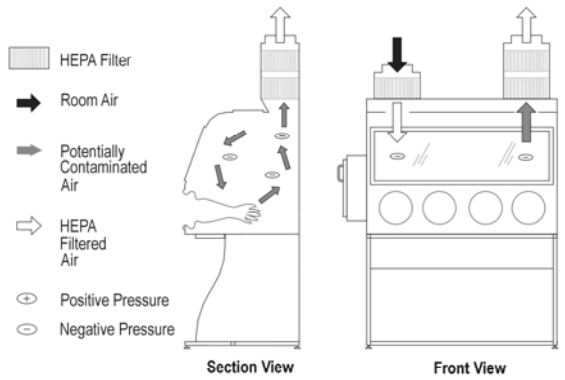
- Provides personnel and environmental protection, but not product protection
- Exhaust air is HEPA filtered, and is not recirculated
- Suitable for work where product protection is not important.
- Similar in construction to a chemical fumehood, but the exhaust air is HEPA filtered



Class I Biological Safety Cabinet

Class III Biological Safety Cabinet

- Totally enclosed ventilated cabinet
- Gas tight construction
- Work in BSC is done through gloves
- Supply air is drawn in through a HEPA filter
- Exhaust air is double HEPA filtered, or single HEPA filtered and incinerated



Class III Biological Safety Cabinet

CLASS II Biological Safety Cabinets

- Provides personnel, environmental, and product protection
- Inward airflow provides personnel protection
- Downward flowing HEPA filtered air provides product protection
- HEPA filtered exhaust air provides environmental protection

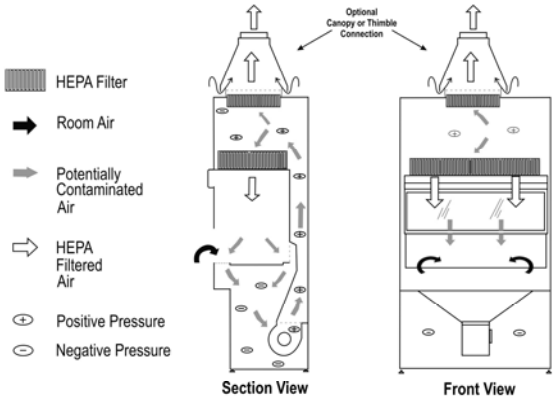
CLASS II Biological Safety Cabinets

- Class II cabinets are divided into 4 sub-categories depending on it's design:
  - Class II Type A1
  - Class II Type A2
  - Class II Type B1
  - Class II Type B2

Class II type A1

(Class II type A under NSF49-1992)

- Face velocity = 75 fpm (minimum average)
- HEPA filtered down flow air (Supply)
- HEPA filtered Exhaust
  - May exhaust back into laboratory
  - May exhaust directly outdoors through a canopy (Thimble)
- May have positive pressure contaminated ducts that are not surrounded by negative pressure plenums



Class II Type A1 Biological Safety Cabinet

Class II type A2

(Class II type A/B3 under NSF49-1992)

- Face velocity = 100 fpm (minimum average)
- HEPA filtered down flow air (Supply)
- HEPA filtered Exhaust
  - May exhaust back into laboratory
  - May exhaust directly outdoors through a canopy (Thimble)
- May NOT have positive pressure contaminated ducts unless they are surrounded by negative pressure plenums

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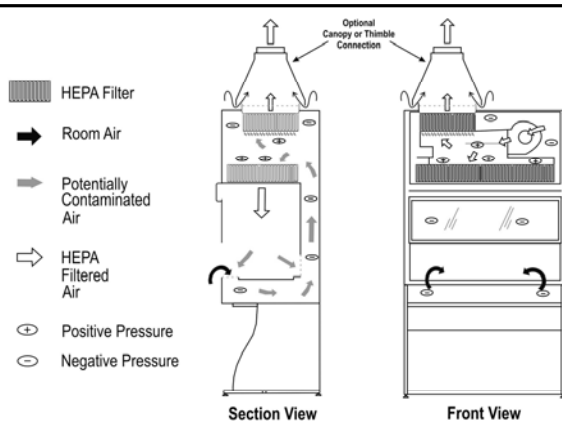
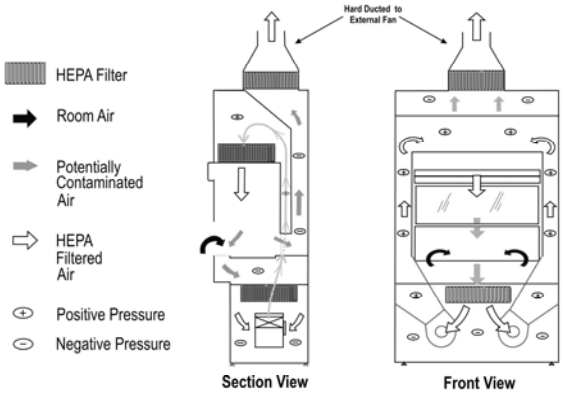


Class II Type A2 Biological Safety Cabinet

Class II type B1

(Class II type B1 under NSF49-1992)

- Face velocity = 100 fpm (minimum average)
- HEPA filtered down flow air (Supply)
- HEPA filtered Exhaust
  - Some air is recirculated within the cabinet
  - Exhaust must go directly outdoors
- May NOT have positive pressure contaminated ducts unless they are surrounded by negative pressure plenums

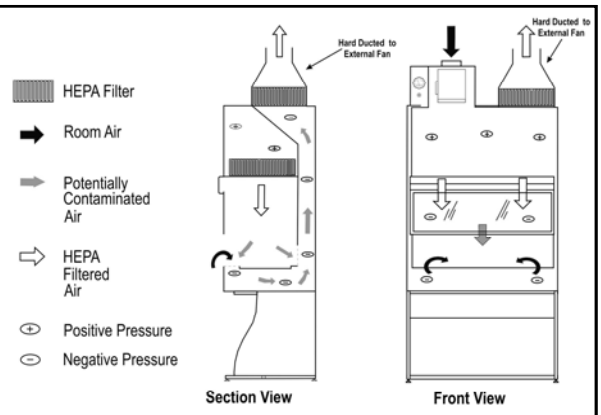


Class II Type B1 Biological Safety Cabinet

Class II type B2

(Class II type B2 under NSF49-1992, AKA: "total exhaust")

- Face velocity = 100 fpm (minimum average)
- HEPA filtered down flow air (Supply)
- HEPA filtered Exhaust
  - No recirculation
  - Must exhaust directly outdoors
- May NOT have positive pressure contaminated ducts unless they are surrounded by negative pressure plenums



Class II Type B2 Biological Safety Cabinet

Performance Verification

- NSF 49 contains 2 sets of tests
- First set is found in Annex A
  - Very detailed and exhaustive
  - These are the tests that the manufacturer has to pass in order to have a BSC listed by NSF
  - These tests are conducted by NSF

Performance Verification

- Second set of tests found in Annex F
- Known as "Field Tests"
- Also know has "Annual Certification"
- Intended to ensure that BSC's are operating as designed, and that personnel, environmental, and product protection are still in place

How Often Do We Certify?

- Required:
  - At least annually
  - When HEPA filters have been changed
  - When BSC has been relocated
  - When internal parts are repaired
    - Blower motor
    - Speed control

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Who should Certify

- NSF International Biohazard Cabinet Field Certifier Accreditation program.
  - 3.5 hr Written exam
  - 9 hr practical exam
- Most facilities in the U.S. and Canada recommend NSF accredited certifiers to do annual certification of BSC's

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Instrumentation

- NSF requires accredited certifiers to use calibrated equipment.
- Must be calibrated annually
- Must produce copies of calibration certificates to NSF every year
- Certificates must be NIST traceable (National Institute of Standards and Technology)

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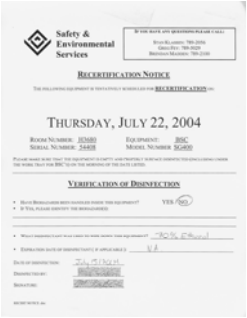
First Things First

- Make sure the cabinet is safe for the certifier.
- BSC must be surface disinfected with a suitable disinfectant
- If possible seek the advice of a biosafety officer.
  - Does the BSC need to be decontaminated?
  - Is the disinfectant appropriate for the biohazards in the BSC

Sign-off Sheet

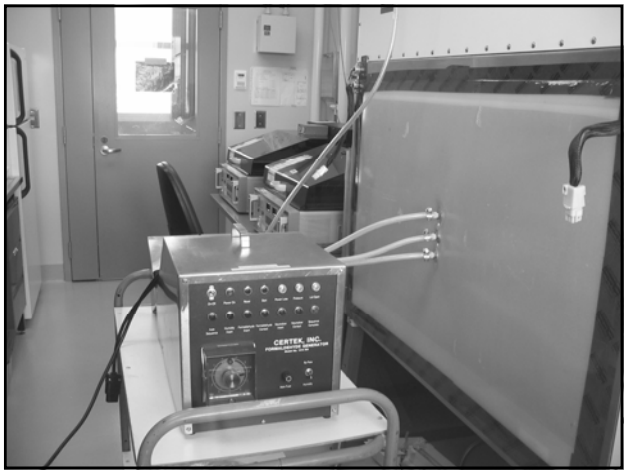

Safety & Environmental Services

RECERTIFICATION NOTICE

THURSDAY, JULY 22, 2004

ROOM NUMBER: H3680 EQUIPMENT: BSC
SERIAL NUMBER: 54408 MODEL NUMBER SG400

VERIFICATION OF DISINFECTION



Gather Information

- Need to know:
  - Down flow set point
  - Downflow measurement method
  - Inflow set point
  - Inflow measurement method

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Gather Information

- Manufacturer is often the best place to start.
  - Manual
  - Technical support

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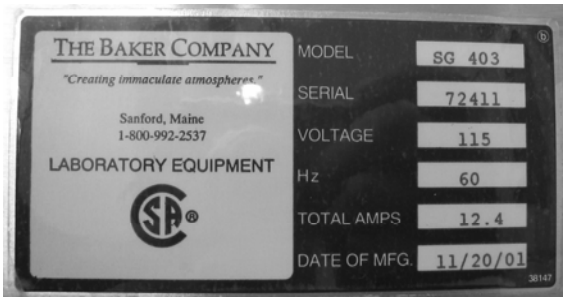

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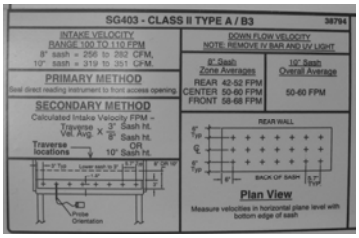
Gather Information

- NSF requires new cabinets to have a label containing certification information



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Gather Information

- NSF publishes current certification information
  - Book format
  - http://www.nsf.org/Certified/Biosafety/
  - Information on older cabinets not available from NSF

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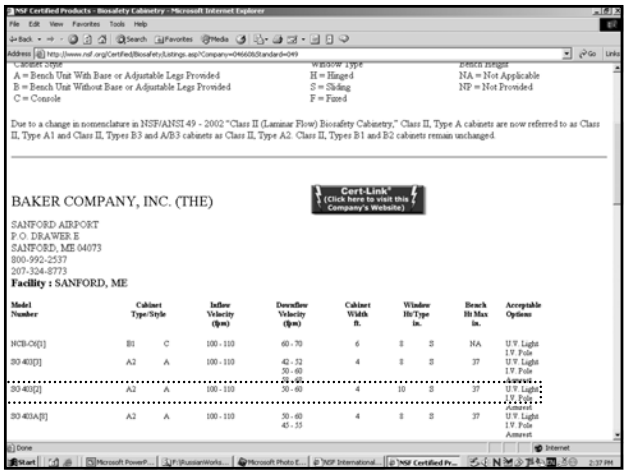

NSF Certified Products - Biosafety Cabinetry - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address http://www.nsf.org/Certified/Biosafety/Listings.asp?Company=046608Standard=049

Cabinet Style	Window Type	Bench Height
A = Bench Unit With Base or Adjustable Legs Provided	H = Hinged	NA = Not Applicable
B = Bench Unit Without Base or Adjustable Legs Provided	S = Sliding	NP = Not Provided
C = Console	F = Fixed	

Due to a change in nomenclature in NSF/ANSI 49 - 2002 "Class II (Laminar Flow) Biosafety Cabinetry," Class II, Type A cabinets are now referred to as Class II, Type A1 and Class II, Types B3 and A/B3 cabinets as Class II, Type A2. Class II, Types B1 and B2 cabinets remain unchanged.

BAKER COMPANY, INC. (THE)

Cert-Link® (Click here to visit this Company's Website)

SANFORD AIRPORT
P.O. DRAWER E
SANFORD, ME 04073
800-992-2537
207-324-8773
Facility : SANFORD, ME

Model Number	Cabinet Type/Style		Inflow Velocity (fpm)	Downflow Velocity (fpm)	Cabinet Width ft.	Window Ht/Type in.		Bench Ht Max in.	Acceptable Options
NCB-O6[1]	B1	C	100 - 110	60 - 70	6	8	S	NA	U.V. Light I.V. Pole
SG 403[3]	A2	A	100 - 110	42 - 52 50 - 60 58 - 68	4	8	S	37	U.V. Light I.V. Pole Armrest
SG 403[2]	A2	A	100 - 110	50 - 60	4	10	S	37	U.V. Light I.V. Pole Armrest
SG 403A[8]	A2	A	100 - 110	50 - 60 45 - 55	4	8	S	37	U.V. Light I.V. Pole Armrest

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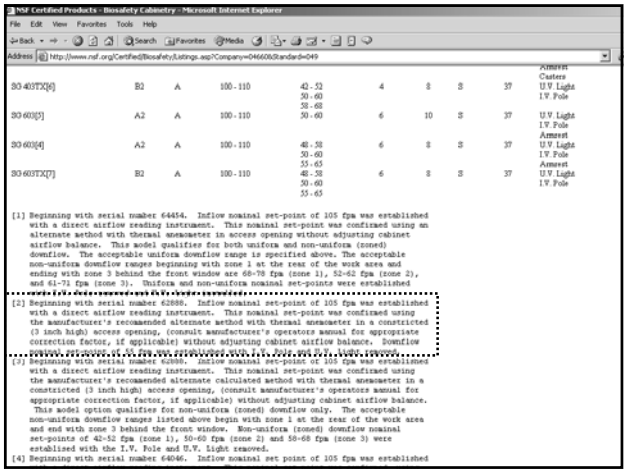

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Address http://www.nsf.org/Certified/Biosafety/Listings.asp?Company=046608Standard=049

									Armrest Casters
SG 403TX[6]	B2	A	100 - 110	42 - 52 50 - 60 58 - 68	4	8	S	37	U.V. Light I.V. Pole
SG 603[5]	A2	A	100 - 110	50 - 60	6	10	S	37	U.V. Light I.V. Pole Armrest
SG 603[4]	A2	A	100 - 110	48 - 58 50 - 60 55 - 65	6	8	S	37	U.V. Light I.V. Pole Armrest
SG 603TX[7]	B2	A	100 - 110	48 - 58 50 - 60 55 - 65	6	8	S	37	U.V. Light I.V. Pole

[1] Beginning with serial number 64454. Inflow nominal set-point of 105 fpm was established with a direct airflow reading instrument. This nominal set-point was confirmed using an alternate method with thermal anemometer in access opening without adjusting cabinet airflow balance. This model qualifies for both uniform and non-uniform (zoned) downflow. The acceptable uniform downflow range is specified above. The acceptable non-uniform downflow ranges beginning with zone 1 at the rear of the work area and ending with zone 3 behind the front window are 68-78 fpm (zone 1), 52-62 fpm (zone 2), and 61-71 fpm (zone 3). Uniform and non-uniform nominal set-points were established

[2] Beginning with serial number 62888. Inflow nominal set-point of 105 fpm was established with a direct airflow reading instrument. This nominal set-point was confirmed using the manufacturer's recommended alternate method with thermal anemometer in a constricted (3 inch high) access opening, (consult manufacturer's operators manual for appropriate correction factor, if applicable) without adjusting cabinet airflow balance. Downflow

[3] Beginning with serial number 62888. Inflow nominal set-point of 105 fpm was established with a direct airflow reading instrument. This nominal set-point was confirmed using the manufacturer's recommended alternate calculated method with thermal anemometer in a constricted (3 inch high) access opening, (consult manufacturer's operators manual for appropriate correction factor, if applicable) without adjusting cabinet airflow balance. This model option qualifies for non-uniform (zoned) downflow only. The acceptable non-uniform downflow ranges listed above begin with zone 1 at the rear of the work area and end with zone 3 behind the front window. Non-uniform (zoned) downflow nominal set-points of 42-52 fpm (zone 1), 50-60 fpm (zone 2) and 58-68 fpm (zone 3) were established with the I.V. Pole and U.V. Light removed.

[4] Beginning with serial number 64046. Inflow nominal set point of 105 fpm was established

Gather information

- CETA (Controlled Environment Testing Association)
  - "Spec Guide for Biological Safety Cabinets"
  - http://www.cetainternational.org

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Mandatory Tests

(Required for "NSF field Certification" sticker)

- **Downflow velocity profile test**
- **Inflow velocity test**
- **Airflow smoke patterns test**
- **HEPA filter leak test**
- **Cabinet integrity tests (A1 cabinets only)**
- **Site installation assessment tests**

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Optional Tests

(Worker Comfort and Safety)

- **Lighting intensity**
- **Vibration**
- **Noise level**
- **Electrical leakage (NSF 49-1992)**
- **Ground circuit resistance (NSF 49-1992)**
- **Polarity tests (NSF 49-1992)**

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Thank You

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Containment Services

IF YOU HAVE ANY QUESTIONS PLEASE CALL:
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GREG FEY: 789-5029
BRENDAN MADDEN: 789-2100
DARYL BOEHM: 784-5930

RE-CERTIFICATION NOTICE

THE FOLLOWING EQUIPMENT IS TENTATIVELY SCHEDULED FOR RE-CERTIFICATION ON:

WEDNESDAY, MAY 13, 2009

ROOM NUMBER: 7269 EQUIPMENT: BSC
SERIAL NUMBER: 123456 MODEL NUMBER: XYZ

PLEASE MAKE SURE THAT THE EQUIPMENT IS EMPTY AND PROPERLY SURFACE DISINFECTED (INCLUDING UNDER THE WORK TRAY FOR BSC'S) BY THE MORNING OF THE DATE LISTED.

VERIFICATION OF DISINFECTION

- HAVE BIOHAZARDS BEEN HANDLED INSIDE THIS EQUIPMENT? YES / NO
- IF YES, PLEASE IDENTIFY THE BIOHAZARD(S):

_____

_____

- WHAT DISINFECTANT WAS USED TO WIPE DOWN THIS EQUIPMENT? _____
- EXPIRATION DATE OF DISINFECTANT (IF APPLICABLE): _____

DATE OF DISINFECTION: _____

DISINFECTED BY: _____

SIGNATURE: _____

Downflow Velocity Profile Test

Purpose:

- To measure the velocity of air flowing from top to bottom inside the cabinet.

Instrument:

- Thermal Anemometer
- Accuracy: +/- 3 fpm (+/- .015 m/s) or 3% of reading, whichever is larger

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Downflow Velocity Profile

- Setpoints given are +/- 5 fpm
  - eg: Setpoint of 65 fpm = 60-70 fpm
- A cabinet can have zones so that the back row, middle row, and front row all have different setpoints.
  - Know as “zoned” cabinets

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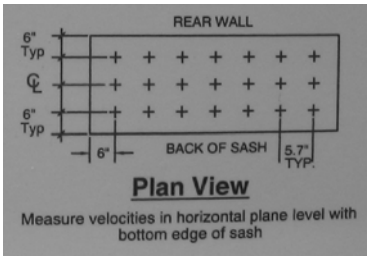
Downflow Velocity Profile

- Work area is divided into a grid pattern



Downflow Velocity Profile

- Readings are taken at sash height
  - (4 inches above sash height for NSF49-2002)
- An average of all readings is calculated
- Individual readings should be within 25% or 16 fpm of the average of all readings (which ever is greater)

Downflow Velocity Profile Test

Inflow velocity test

Purpose:

- To determine the inflow velocity through the work access opening

Instrument(s)

- Direct Inflow measurement (DIM) instrument
- Thermal Anemometer

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Inflow velocity test

Method:

- Usually involves measuring total flow entering the front of the BSC in cubic feet per minute (CFM)
  - Then divide by area of access opening to obtain velocity
- "Approved" method is usually on label, or available from NSF or Manufacturer

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Inflow Velocity Test

- There is usually an "approved" Alternative method.
  - Can involve measuring flow with a thermal anemomoter (The same as the one used in the down flow test)
  - Can sometimes be measured at the exhaust air outlet. (air out = air in)

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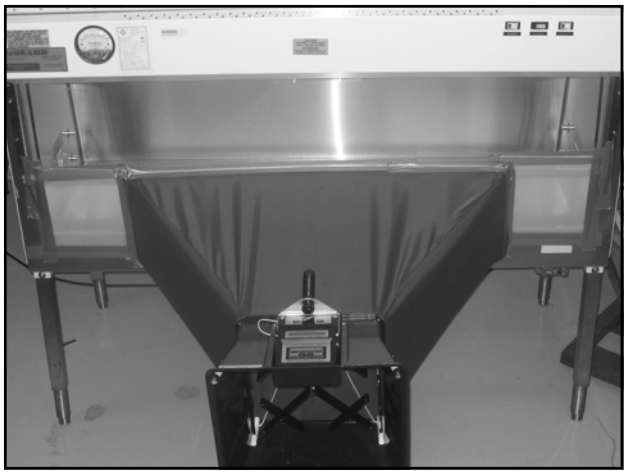

Airflow smoke Patterns test

Purpose:

- **To visualize air flow patterns in and around the BSC**

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Airflow Smoke Patterns Test

Method:

- **A smoke source is needed to "visualize" the air patterns**
- **Several sources available**
  - **CAUTION: Some smoke pencils contain corrosive chemicals, and should be handled with care!**
- **Broken down into 4 specific tests:**

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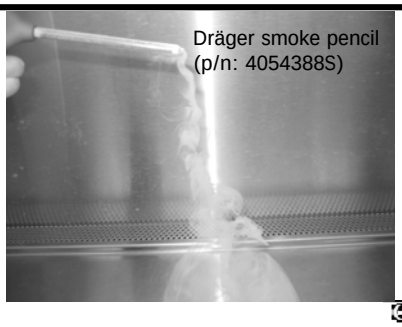
Smoke Source



Smoke Source

Dräger “Flow Check”
(p/n: 6400760)

Smoke Source

#1: Downflow smoke Pattern Test

- Smoke is passed from one end of the cabinet to the other along the centreline of the work surface.
  - 4 inches (10 cm) above the bottom edge of the sash
- Look for: smooth downward flow
- No dead spots or upward flow

Downflow

#2: View Screen Retention test

- Smoke is passed from one end of the cabinet to the other.
  - 1 inch (2 cm) behind glass, and 6 inches (15 cm) up from the bottom of the sash
- Look for: smooth downward flow
- No dead spots
- No smoke leaves the cabinet

Viewscreen Retention test

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#3: Work Opening Edge Retention Test

- Smoke is passed along the entire perimeter of the front opening
  - Approximately 1.5 inches (4 cm) away from the glass.
- Look for:
  - No smoke leaves the cabinet once it has entered the cabinet
  - No smoke is drawn out over the work area.

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Work opening retention test

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#4: Sash / Window Seal Test

- Smoke is passed inside the cabinet along both sides, and top edges of the glass sash.
  - 2 inches (5 cm) from the glass.
- Look for:
  - No escape of smoke from the cabinet

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Sash / Window Seal Test

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HEPA Filter Leak Test

Purpose:

To determine the integrity of supply and exhaust HEPA filters, filter housings and filter mounting frames.

Instruments:

- Aerosol Photometer
- Aerosol Generator of the Laskin Nozzle type

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Aerosol Photometer

Aerosol Generator

HEPA Filter Leak Test

Method:

- **Introduce aerosol upstream of the filter to be tested with the BSC operating.**
- **Determine upstream concentration by measurement or calculation.**
- **Scan filter with probe not more than 1 in (2.5 cm) from filter at a rate of no more than 2 in/s (5 cm/s).**

HEPA Filter Leak Test

Method (continued):

- **If filter cannot be scanned due to BSC design (ie. B2 exhaust) an overall penetration can be taken at a point in the duct work downstream of the filter that provides a well-mixed aerosol.**

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HEPA Filter Leak Test

Acceptance Criteria:

- **Filters than can be scanned:**
  - **Sustained aerosol penetration shall not exceed 0.01% of the upstream concentration.**
- **Filters that cannot be scanned:**
  - **Sustained aerosol penetration shall not exceed 0.005% of the upstream concentration.**

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