Update: Ventilated Workstation for Smear Preparation

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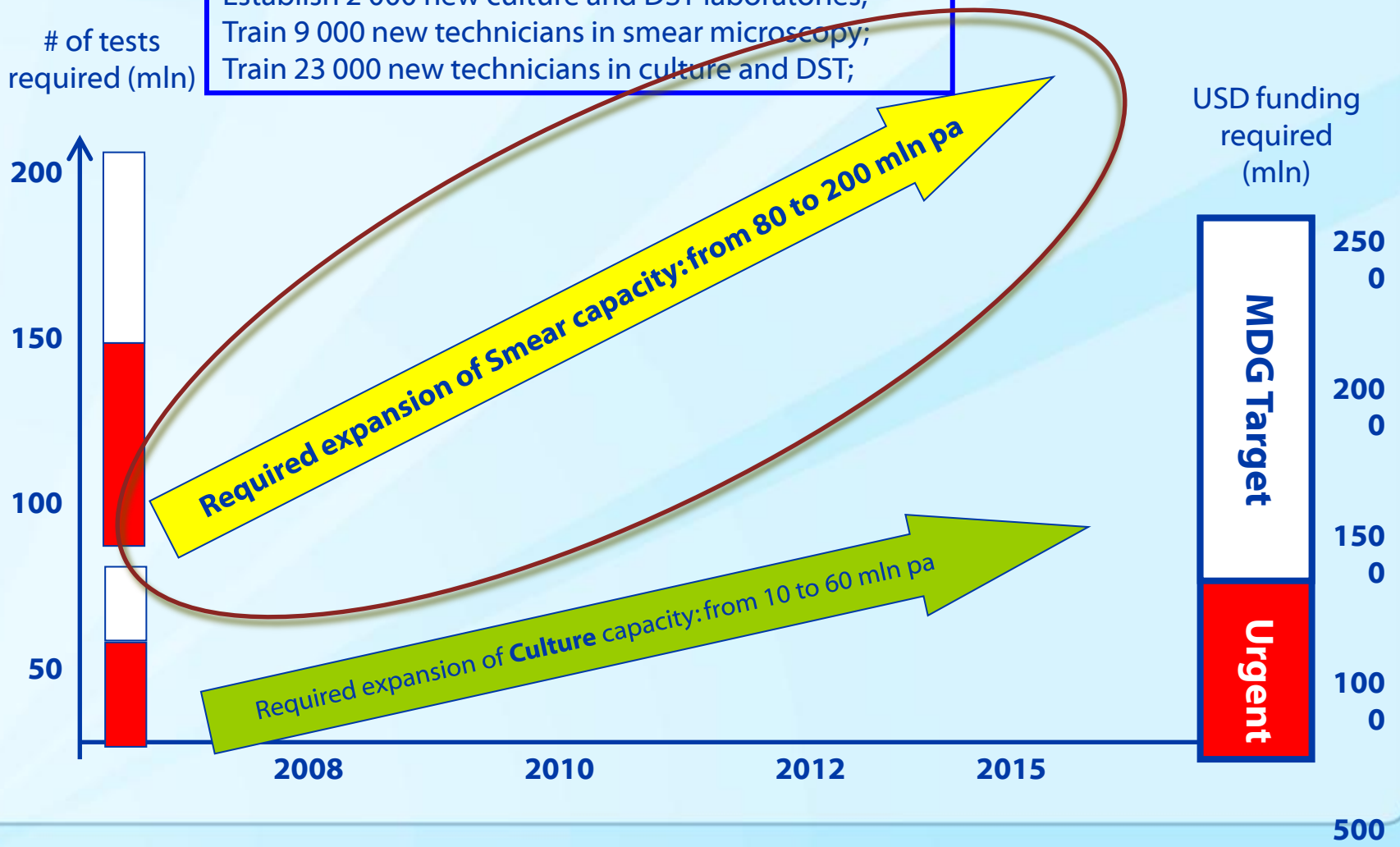
CDC

GLI meeting Oct 05, 2010

To reach MDG targets, a global capacity need of **120 million smears, 60 mlllion cultures** and **6 million DST investigations** must be met by 2015, requiring at least **1 billion USD** investment in laboratory infrastructure and annual variable cost

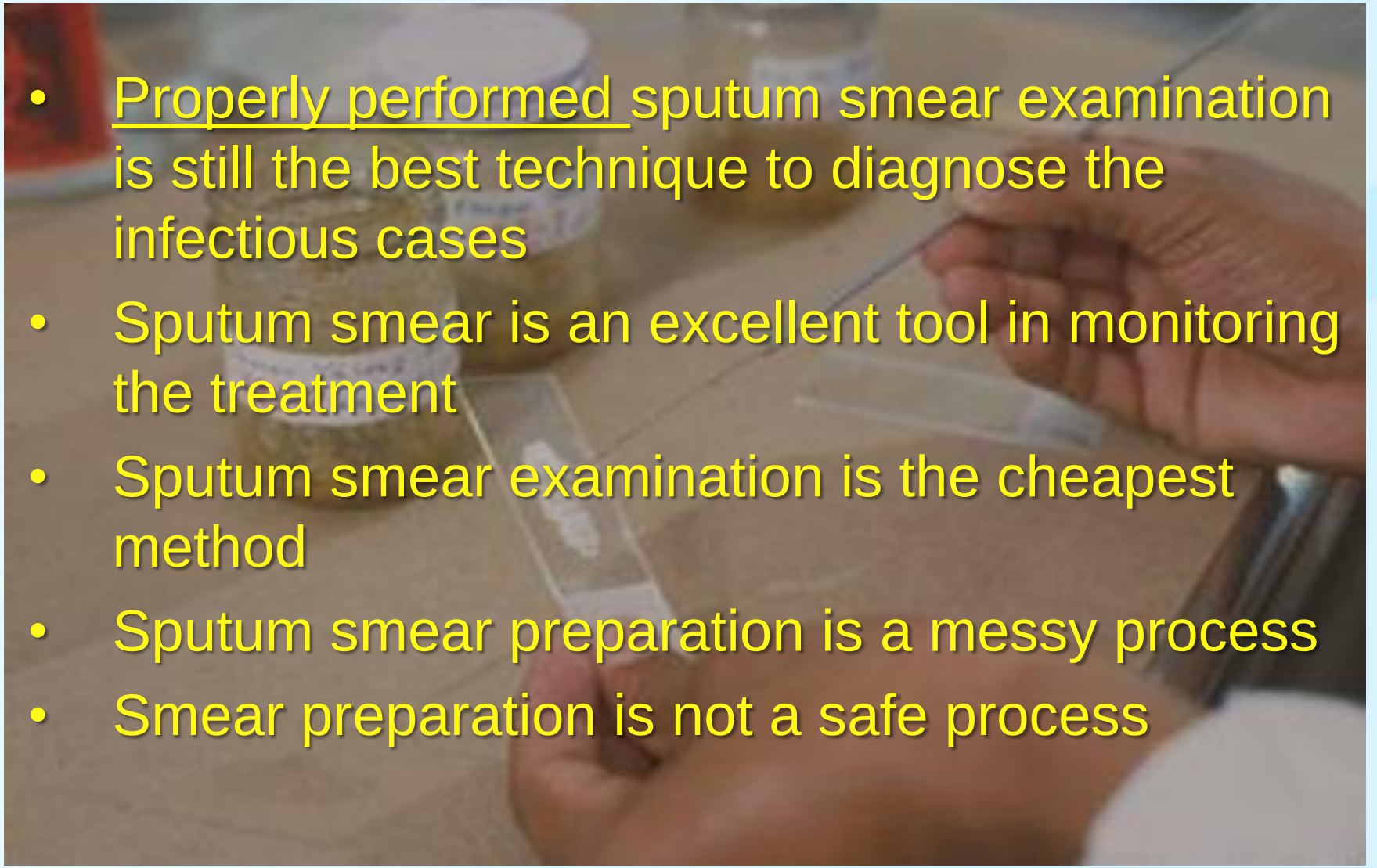
Establish 5 000 new microscopy laboratories;
Establish 2 000 new culture and DST laboratories;
Train 9 000 new technicians in smear microscopy;
Train 23 000 new technicians in culture and DST;



Outline

- Background
- The Ventilated Workstation Document
  - Manufacturing Process
  - Validation
  - User Manual
  - Prototype Validation
- Future Plan

Background



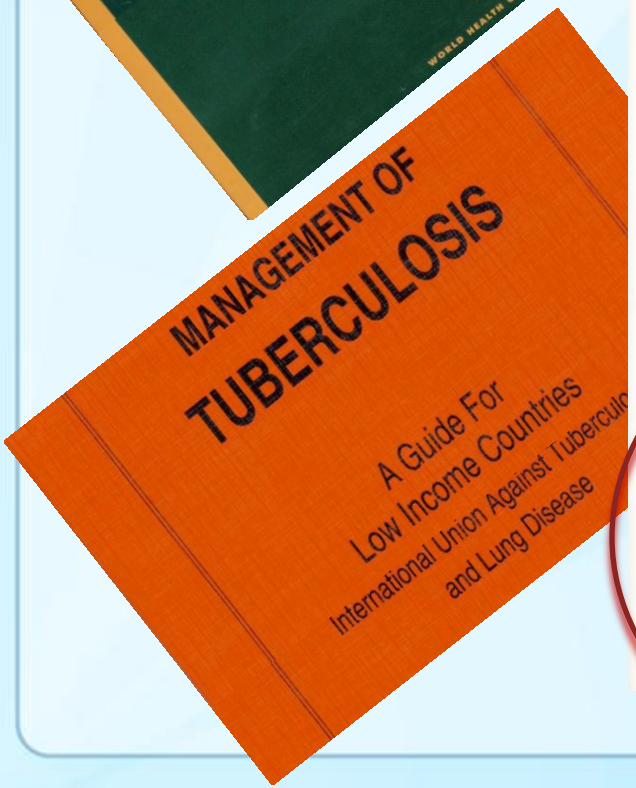
- Properly performed sputum smear examination is still the best technique to diagnose the infectious cases
- Sputum smear is an excellent tool in monitoring the treatment
- Sputum smear examination is the cheapest method
- Sputum smear preparation is a messy process
- Smear preparation is not a safe process

Risk

5.2 Safe handling of specimens

Transmission of *M. tuberculosis* results essentially from infectious aerosols, ie. droplet nuclei of 1-5µm in diameter containing tubercle bacilli, sufficiently small to reach lung alveoli and initialise an infection.

Infection control in the microscopy laboratory must aim at reducing the production of aerosols. Good ventilation is necessary for the protection of laboratory staff from infectious airborne nuclei. A simple way to ensure ventilation and directional airflow is by properly placed windows and doors.



8. BIOSAFETY IN THE TB MICROSCOPY LABORATORY

8.1 General aspects

Laboratory workers are responsible for their own safety and that of their co-workers. Transmission of *Mycobacterium tuberculosis* results essentially from micro-aerosols, i.e., tubercle bacilli contained in droplet nuclei, 1 to 5 microns in diameter, which are sufficiently small to reach lung alveoli, yet sufficient large to adhere to the lining of the lung alveoli.

Infection control in the laboratory must aim at reducing the production of aerosols. Good ventilation is necessary for the protection of the laboratory staff from airborne infectious droplet nuclei. An easy way to ensure ventilation and directional airflow is by judiciously locating windows and doors so that airborne particles are blown away from the laboratory worker (see Figure 4). Where electricity is available, extractor fans can be used to remove air from the laboratory.

until torn. This improper use affords a sense of false security and carelessness that often impacts negatively on the biosafety conditions of the laboratory – contaminated gloves are used to handle or to operate laboratory equipment that would otherwise never become contaminated. As the use of gloves is impractical in most settings where this guide will be used, soaking hands in 70% alcohol followed by washing with a detergent solution, rinsing with water and drying with paper, is highly recommended.

Wearing conventional surgical masks does not significantly reduce the risk of infection by aerosol inhalation. The emphasis again is to be placed on the reduction of aerosols produced during laboratory procedures by adopting and strictly enforcing Good Laboratory Practices.[8]

Eating, drinking and smoking are not permitted in the laboratory.

Open the Window ?

Place	Max (°C)	Min (°C)	Conditions
Cairo	43	8	Extreme hot
Delhi	46	-1	April-Aug (Extreme hot)
Almaty	27	-14	Nov-March (Extreme cold)
Addis Ababa	25	5	Mornings are cold
Bamako, Mali	47	26	Extreme hot
Calcutta	44	13	Extreme hot
Cuzeco, Peru	29	-1	
Djebiuti	47	23	Extreme hot
Guaymas, Mexico	47	13	Extreme hot
Irkutsk, Russia	20	-26	Extreme cold (Sept-May)

Solutions

In addition to good laboratory practices

- Design laboratories to address ventilation and climate issues
- Buy BSC for smear microscopy
  - Expensive, requires periodic certifications
  - (HEPA filter maintenance otherwise ‘false sense of security’)
- Alternate cabinet which is suitable for smear preparation

Smithwick's Cabinet

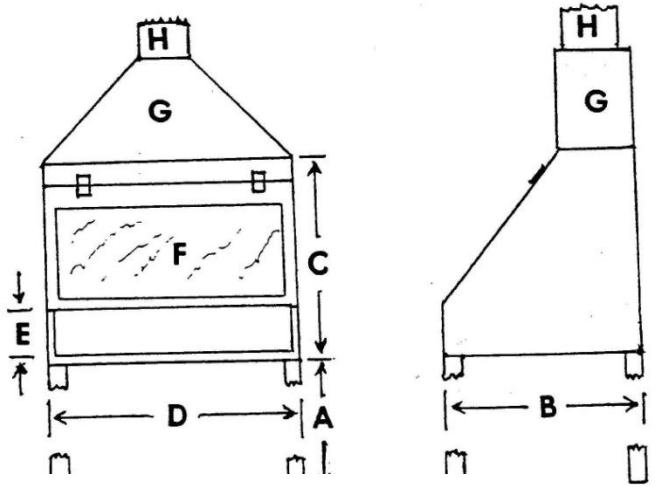
A Simple, Inexpensive
Biological Safety Cabinet
For Use in Developing Nations

by

R. W. Smithwick and G. P. Kubica

Mycobacteriology Laboratory
Respiratory Diseases Branch
Division of Bacterial Diseases
Center for Infectious Diseases
Centers for Disease Control
Atlanta, Georgia 30333
USA

Figure 2. Schematic diagram of a BSC.



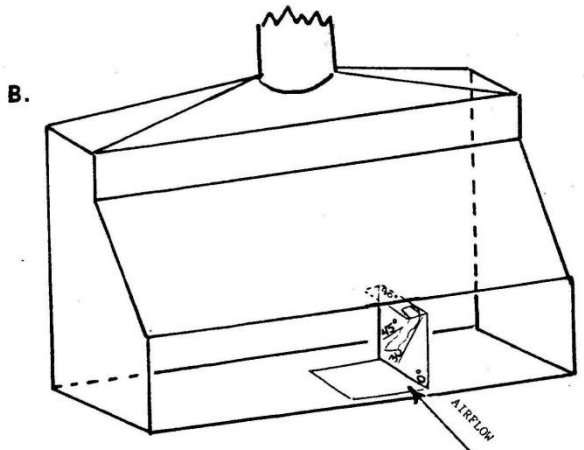


Figure 3. A simple airflow gauge: A. Close-up drawing of construction; B.Placement in BSC for airflow check (see text for details).

Observations

Feasibility Meeting

Held at CDC on March 12, 2009; Attended by safety and laboratory experts from CDC, APHL, and CU2HA.

- Balancing need and unintended messages about AFB smear microscopy: simple cabinets are not the only solution!
- Appropriate use versus non-appropriate use of simple cabinets
- Not intended for TB culture, TB DST and other infectious organisms
- Alternate uses for routine microbiology
- A guideline is not a standard therefore manufacturer and local certification may not be available

Outcome

1. Design a simple workstation cabinet to perform smear microscopy, minimal maintenance, no HEPA filter, and develop a guidance document with performance specifications to fabricate ‘Fan Box’ under local conditions.

2. Specification document could be a mix of European Standards, ASHRAE guidelines. WHO, ABSA, and CLSI should be involved in the writing of this guidance document.

3. General consensus to invite manufacturer of bio-safety cabinets and fume hoods in subsequent discussions.

4. A final consensus meeting of experts to discuss the nomenclature of ‘the box’, global standards, general safety practices, prototypes, and validation.

Experts' Meeting

Expert Consultation: Developing specifications for TB smear Preparation cabinets was held at CDC, September 15-16, 2009.

Attendees: CDC, WHO, FIND, APHL, Health Canada, CU2HA, NHLS South Africa, Germfree, NSF.

- Types of fabrication materials
- Ergonomics
- Electric components
- Design
- Validation of prototypes

Recommendations

New name: **Ventilated Workstation (VWS)**

- Make prototypes and validate using NSF 49 guidelines
- Write document
- Define Intended use of cabinet
- Components to specify:
  - Materials
  - Design and dimensions
  - Fan and ducting
- Fan selection
- Fabrication and installation
- Validation
- Guidance document: Manufacturer manual, validation, and user manual (daily operation, cleaning and maintenance)

Prototypes

- Germ Free constructed prototypes
  - Initial validation
- The Baker Company performed complete validation
- Based upon the validation results prototype design perfected and revalidated
- Guidance document was written

What is in the Document?

VENTILATED WORKSTATION

For AFB Smear Microscopy

Manufacturing, Validation and User guide.

LOGO CDC | LOGO WHO | LOGO APHL

Contents

1. **Background:** Rationale, introductions, warnings
2. **Manufacturer's Manual:** General characteristics of the VWS,
    1. Manufacturing process, materials, design specifications
    2. Fan, ducting and damper, air flow and static pressure specifications, duct design and fan selection criteria.
    3. Assembly, post-assembly QC Checks, validation, placement of VWS
    4. Assembly and Installation of ductwork and exhaust fan
3. **Validation Manual:** Validation protocols (inflow velocity, airflow smoke test, light Intensity, noise level tests)
    1. Validation checklist / logbook and reference values
4. **User Manual:** Daily airflow checks, cleaning, safety procedures
5. **Main Appendices:** List of acronyms; CAD drawings for VWS construction; prototype validation test report

Component Standards

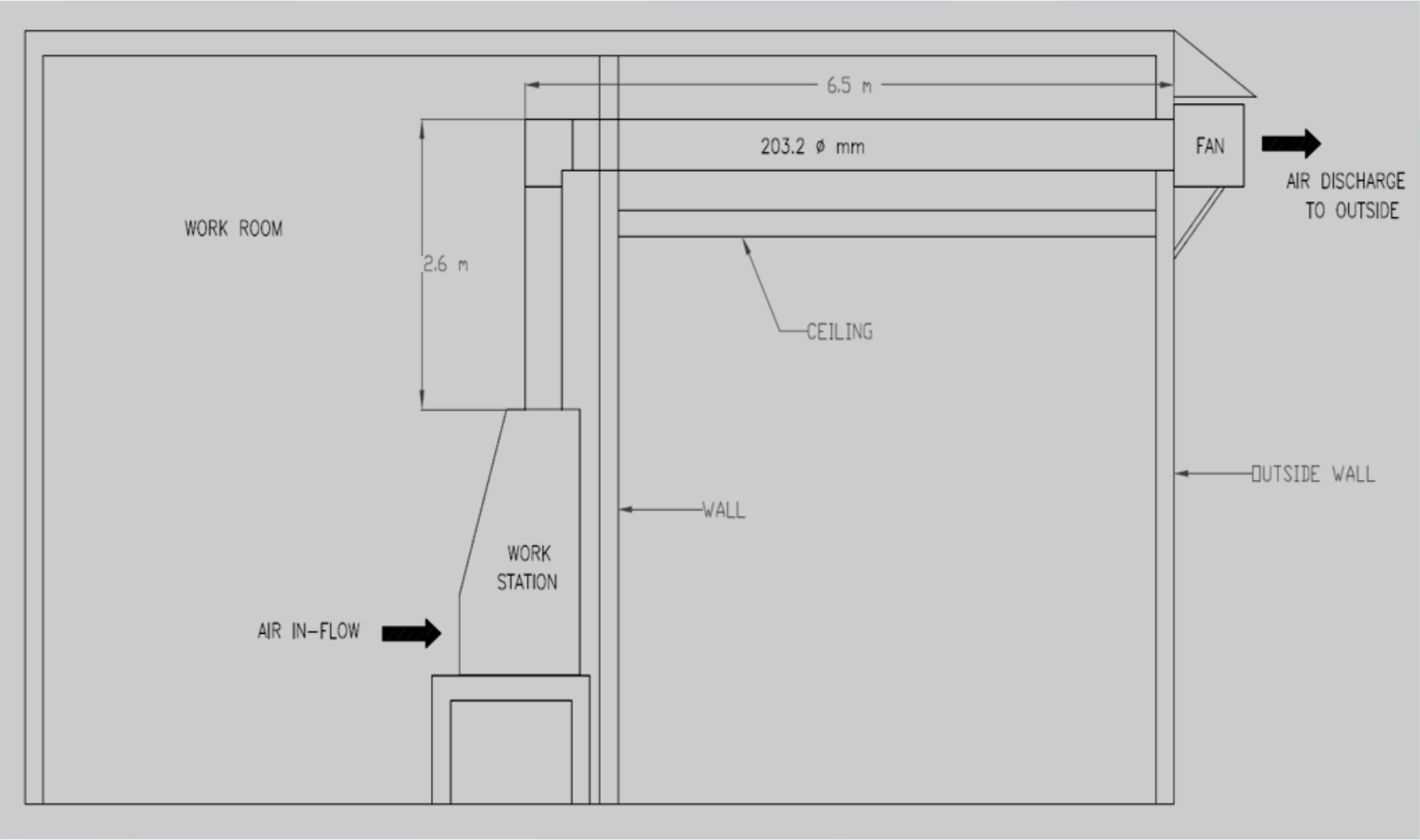
Component	Material	Guidelines
Cabinet	Grade 304 / 316 stainless steel or epoxy-coated aluminum	Must be resistant to corrosive chemicals such as bleach, acid and phenolic compounds that are frequently used in the laboratory
Window	Polymethyl-methacrylate (PMMA) glass (also known as acrylic, perspex or plexiglas) or tempered/toughened glass	
Fan		Must be brand new.
Damper	Galvanized metal	Must be new
Ductwork / exhaust pipe	Galvanized metal	Must be appropriate size to fit fan. Must be rigid without holes or rust. No sharp turns or L-bows.
Electricals	Copper wiring	According to local code
Fasteners	Galvanized or stainless steel	Rust proof

Recommended Ducts and Associated Pressure Losses

Table -A

Duct diameter Round (mm)	Airflow volume l/s	(Pa) Loss per 10 m of duct length	(Pa) Loss per 90 degree bend	(Pa) Loss per 45 degree bend
"A"	"B"	"C"	"D"	"E"
152.4	141	60	21.6	5.5
203.2	141	12.5	6	1.5
254	141	5	3	0.8

Duct and Fan


6.5 m
203.2 ø mm
FAN
AIR DISCHARGE
TO OUTSIDE
WORK ROOM
2.6 m
CEILING
OUTSIDE WALL
WALL
WORK
STATION
AIR IN-FLOW

Fan Selection

Step No.	Step	Column “F”	Column “G”
1	Enter Duct Diameter "A" from table A		
2	Enter Total Length of Duct in m		
3	Multiply by equivalent amount in column "C" oftable A		
4	Divide By 10		
5	Enter number of bends/ elbows		
6	Multiply by equivalent amount in column "D"(if 90) or "E"(if 45) of table A		
7	Loss in Workstation is 200 Pa (fixed)		200
8	Add up all values in Column G of this chart.		
9	Calculate 20 % of Line 8		
10	Add Line 8 & 9 together to get the Total Pressure (Pa)		

Fan selection should be based upon airflow (l/s) and total static pressure loss in the system

Drawings

Ventilated Workstation

The design of the Ventilated Workstation allows for options in the method to manufacture and the selection of materials to be used. The following items are important for proper Ventilated Workstation operation:

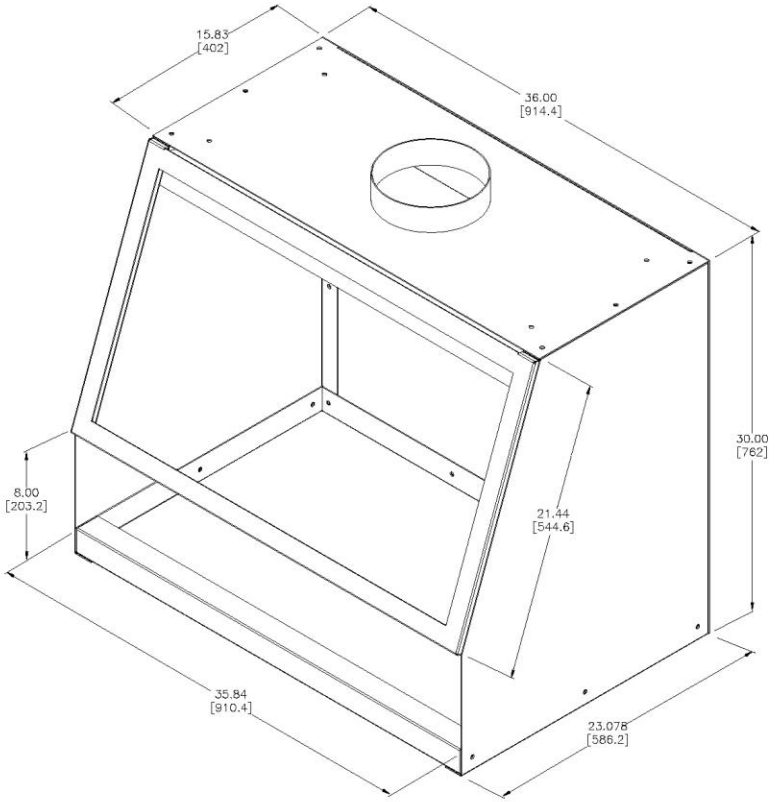
The front inward airflow opening dimensions must be maintained.

The baffle design and where it is placed at the inside top of the workstation must be maintained.

The selection of material for the cabinet must be able to withstand bleach. Aluminum or sheet metal can be used but it must be properly coated with epoxy paint or equal. Stainless steel can also be used but it is not ideal for use with bleach.

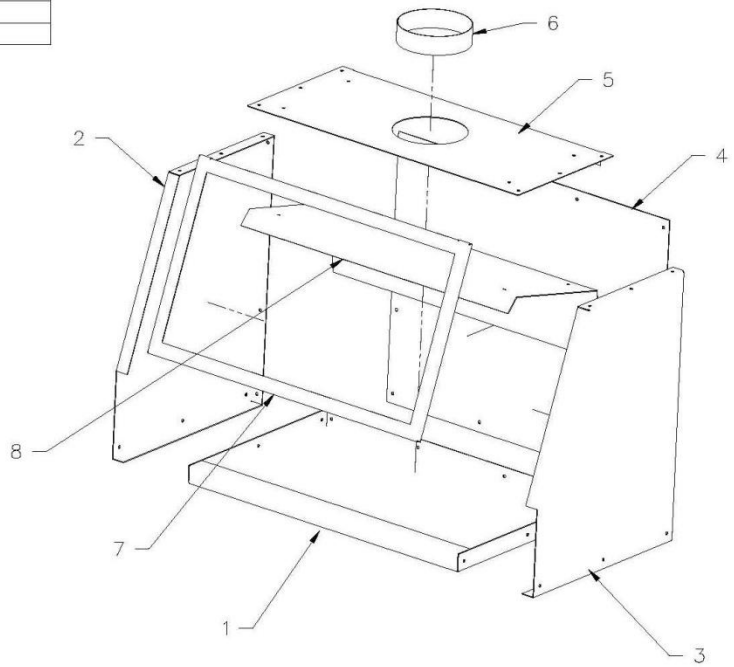
The window can be supplied using glass, acrylic or polycarbonate.

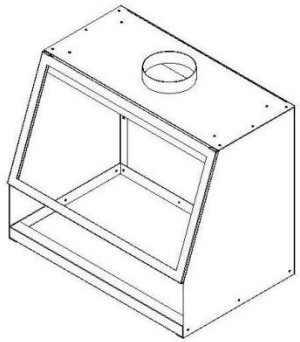
A light housing needs to be attached to the top of the window- on the outside.

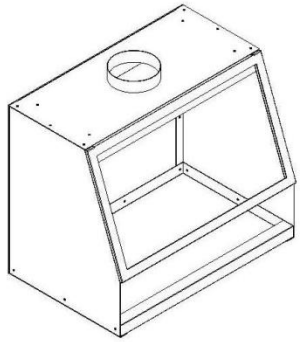


Drawings cont.

BUILD OF MATERIALS	
ITEM #	DESCRIPTION
1	BOTTOM PANEL
2	LEFT SIDE PANEL
3	RIGHT SIDE PANEL
4	BACK PANEL
5	TOP PANEL
6	TOP FLANGE
7	WINDOW FRAME
8	BAFFLE







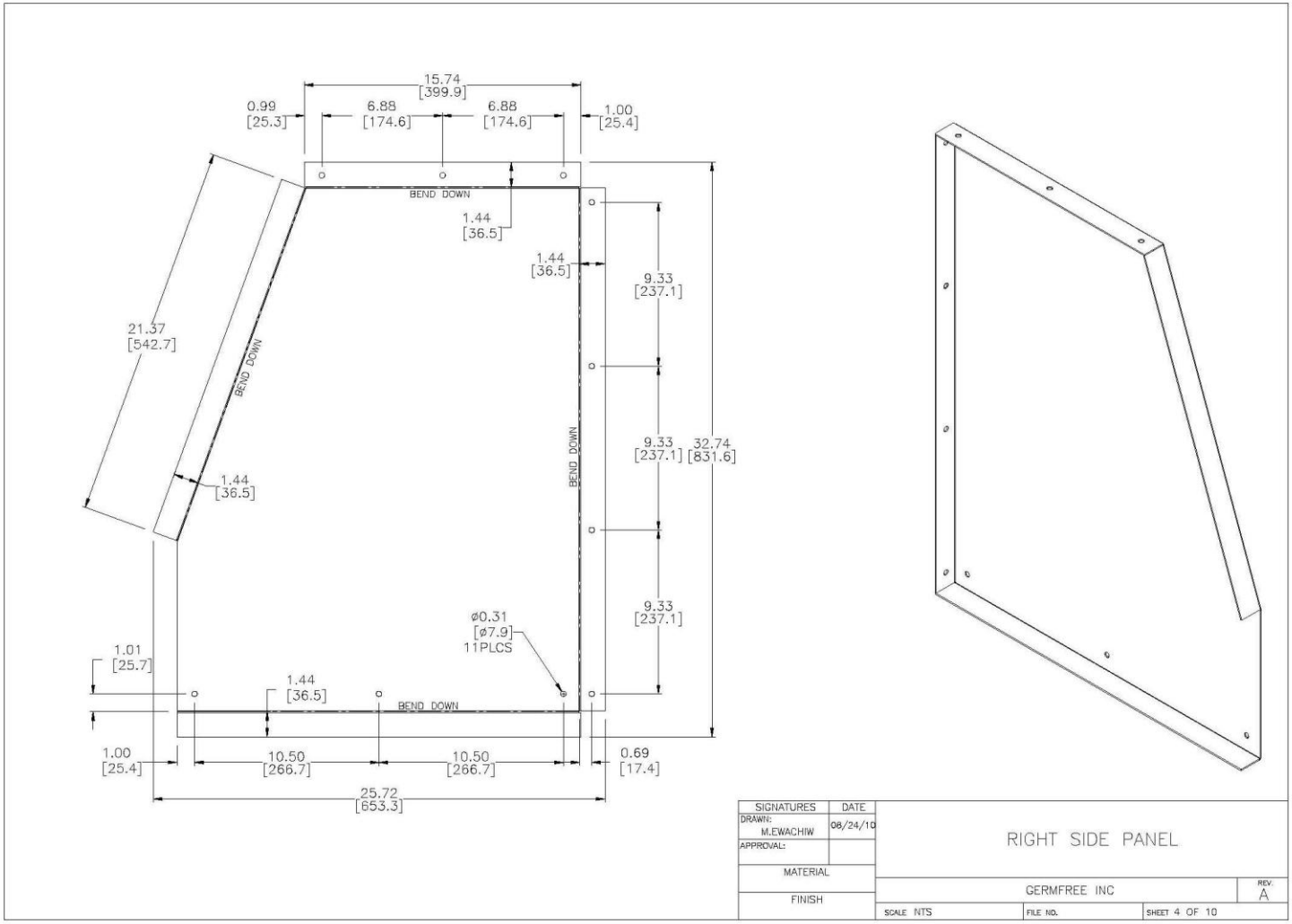
SIGNATURES	DATE
DRAWN: M.EWACHIW	08/24/10
APPROVAL:	
MATERIAL	
FINISH N/A	

VENTILATED WORKSTATION

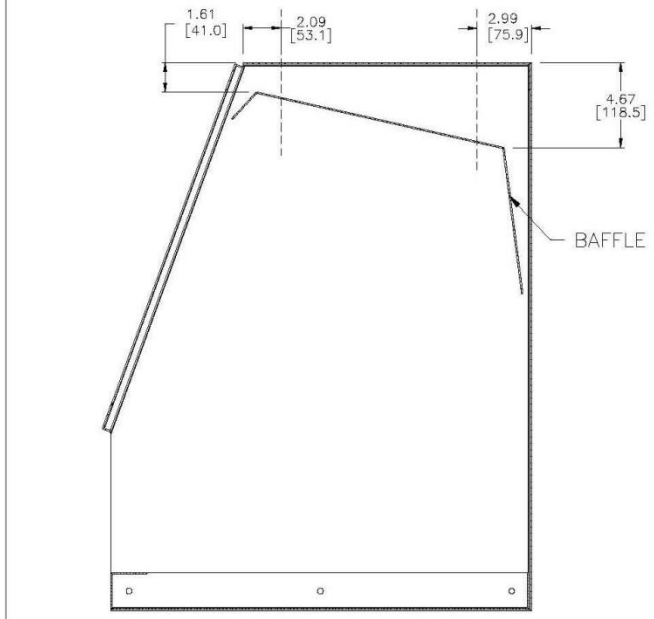
GERMFREE INC — REV. A

SCALE NTS | FILE NO. | SHEET 1 OF 10

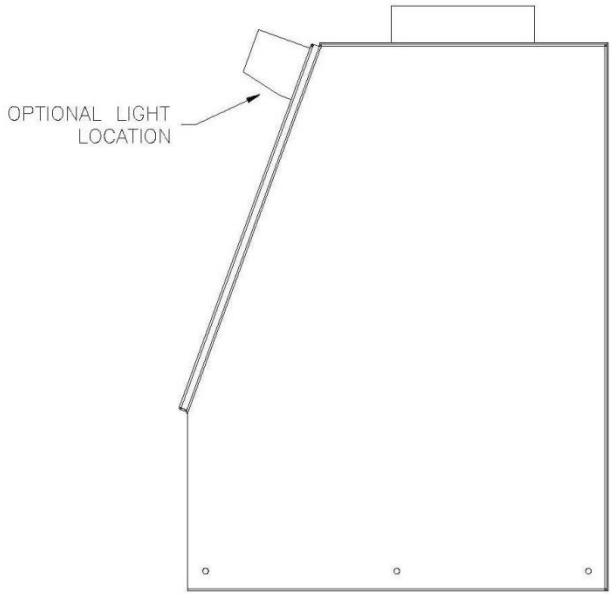
Drawings cont.



Drawings cont.



BAFFLE LOCATION

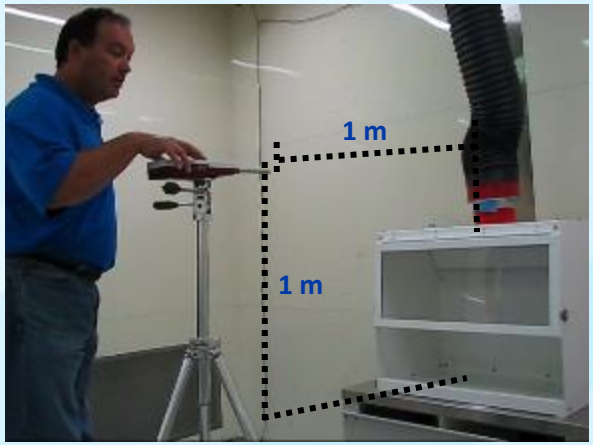


LIGHT LOCATION

SIGNATURES	DATE	BAFFLE/LIGHT LOCATION	
DRAWN: M.EWACHIW	08/24/10		
APPROVAL:			
MATERIAL		GERMFREE INC	REV. A
FINISH		SCALE NTS / FILE NO. / SHEET 10 OF 10	

Design Validation

Light intensity test

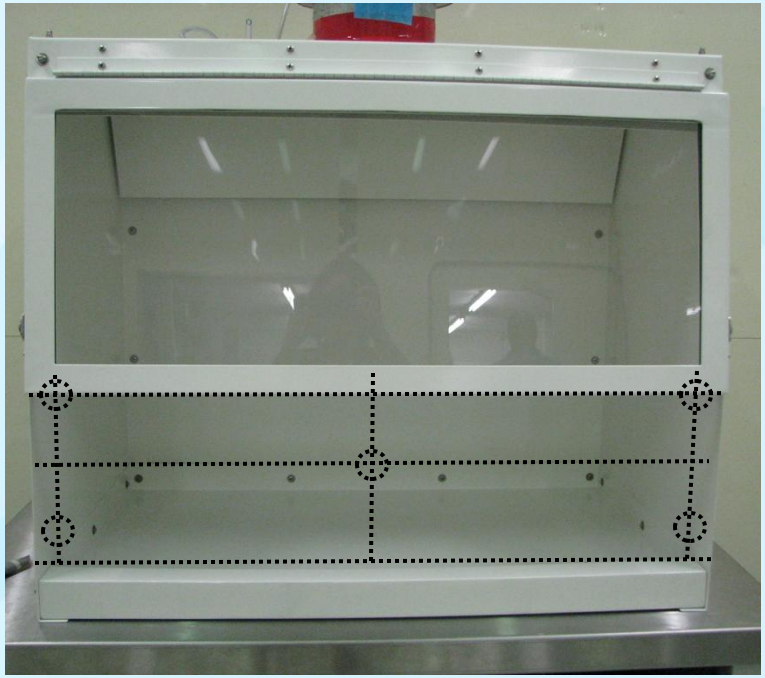


Noise level test

Vibration test

Stability test

Air Inflow Test



Air inflow test at various open sash points

Smoke Test

Smoke inflow test

Smoke outflow test

Microbiological Testing Report

THE BAKER COMPANY

161 Gatehouse Rd., Sanford, Maine 04073 USA

"Creating Immaculate Atmospheres"

Microbiological Testing Report
Ventilated Workstation with a 25.4 cm (10 inch) sash opening

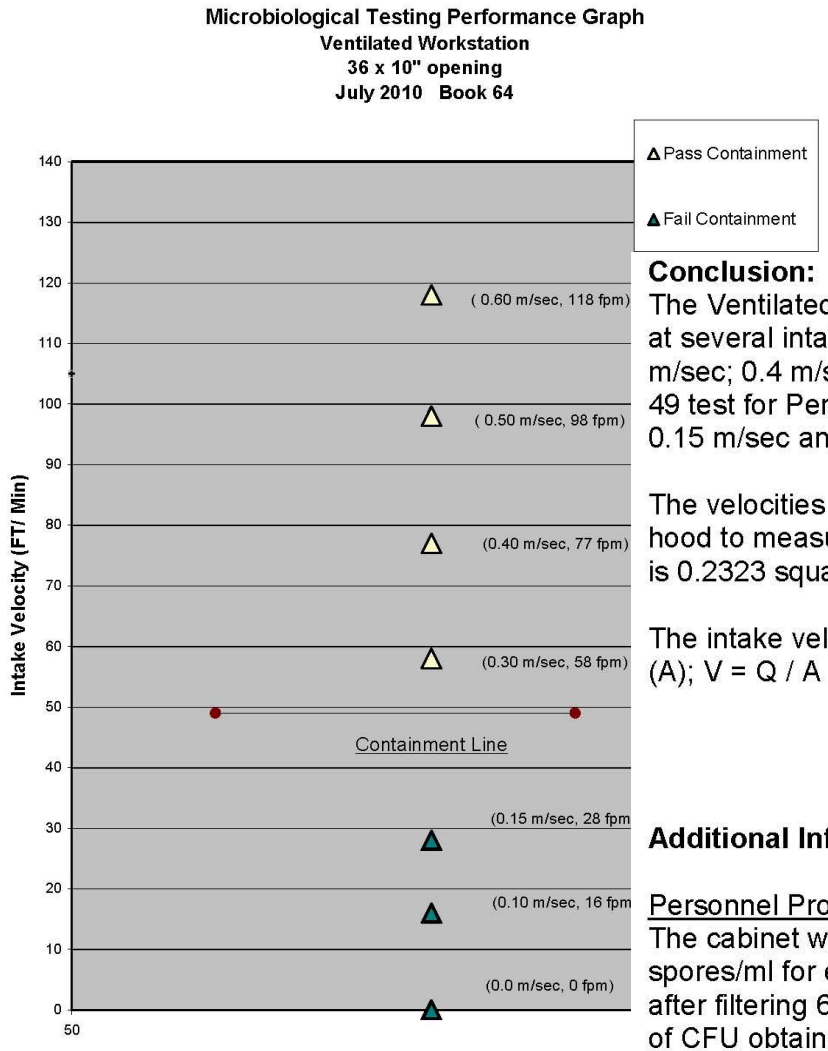
Document Number: BAKT153

August 17, 2010

Martin Rogers
Microbiological Testing Laboratory Manager

Purpose:
To report the results of microbiological testing of a Ventilated Workstation, 25.4 cm (10 inch) sash opening, safety cabinet, manufactured by Germfree.

Microbiological Testing Cont…



Conclusion:

The Ventilated workstation passed the NSF Standard 49 test for Personnel Protection at several intake velocities. The passing intake velocity values are 0.6 m/sec; 0.5 m/sec; 0.4 m/sec and 0.3 m/sec. The Ventilated workstation failed the NSF Standard 49 test for Personnel Protection at intake velocities lower than 0.30 m/sec, including 0.15 m/sec and 0.10 m/sec. (See results graph, last page of this report)

The velocities were calculated using a direct inflow measurement device (DIM) flow hood to measure the intake flow, and dividing by the area of the access opening which is 0.2323 square meters (2.50 square feet).

The intake velocity (V) equals the intake air flow (Q) divided by the access open area (A); V = Q / A

Additional Information:

Personnel Protection Test

The cabinet was challenged with Bacillus Subtillis bacterial spores at 5.0 X 10^6 spores/ml for each test run. The filter count shows the total count of CFU obtained after filtering 6 all glass impingers (AGIs). The Slit sampler count shows the total count of CFU obtained from the 2 slit sampler settling plates combined.

Current Status

- The guidance document is being reviewed by a broader group of experts with a deadline Oct 15, 2010

- Next steps:
  - Clearance
  - Printing
  - Web publishing of the Guidance document and videos

Thank you