

Ventilated Workstation Manual for AFB Smear Microscopy



**MANUFACTURING, VALIDATION,
AND USER GUIDE**

**A VALIDATED, INEXPENSIVE
LABORATORY WORKSTATION**



International Union Against
Tuberculosis and Lung Disease
Health solutions for the poor



Preface

AFB-smear microscopy is still the primary test to provide rapid detection, diagnosis, and monitoring of the treatment of tuberculosis in much of the world, especially in those countries with the highest burden of disease. An important component of effective TB control programs is making AFB-smear microscopy accessible to the population so that symptomatic persons can be rapidly diagnosed for treatment, and to prevent transmission in the community. There are tens of thousands of smear microscopy centers around the world and many are located in small clinics or hospitals. Preparation of the smear directly from sputum specimens is usually performed on the open laboratory bench. With good microbiological techniques and adequate ventilation, the risk of infection is considered to be minimal. However, quality of results may be compromised when laboratory workers reduce the level of manipulation required to obtain a high quality smear out of concern for the generation of potentially infectious aerosols.

AFB microscopy laboratories require adequate ventilation to minimize the occupational risk of infection. However, this is difficult to achieve in many settings where facilities have limited airflow; where climate limits the use of open windows; and where mixing fans may be ineffective in maintaining directional airflow. Almost 35 years ago, Smithwick and Kubica at the U.S. CDC provided drawings and directions for construction of an “inexpensive Class I negative pressure BSC” intended to be used for handling a range of microbiological specimens (Smithwick, unpublished data). Using these and other plans developed by public or commercial entities, several exhaust cabinets of various designs have been fabricated and are found in use globally in TB and other laboratories. However, many of these exhaust cabinets have not been validated against performance specifications and can pose increased risk due to a false sense of safety. Commercially produced biosafety cabinetry or microbiological safety cabinets built to exacting performance standards are available but not affordable or appropriate for this particular purpose, and validation and maintenance are problematic in resource-limited laboratory systems. There is broad agreement among laboratory experts of the need for an inexpensive ventilated cabinet that can be produced according to validated specifications and made available as an option for technicians preparing AFB smears.

This guide provides specifications for the manufacture of a ventilated workstation (VWS) that has been validated¹. The VWS is a partially-enclosed workspace from which air is drawn inward, away from the user and exhausted outside of the laboratory. The purpose of the VWS is to provide a safe work environment when preparing sputum smears for AFB staining or sample manipulations that inactivate sputum specimens for automated molecular testing systems e.g., GeneXpert MTB/RIF Assay from Cepheid (Padmapriya *et al*, 2010).

This Guide should not be interpreted as new guidance on risk related to the preparation of AFB smears, but rather another option for providing a safe laboratory work environment. The VWS is inexpensive to build and requires minimal maintenance.

The project to design, test, and produce the VWS and VWS guide was conceived and approved through the Global Laboratory Initiative (GLI) Working Group of the Stop TB Partnership, WHO, The Union, FIND, CDC, and partner organizations. This project was funded by USAID and CDC through a cooperative agreement with APhL. We are most grateful for the engineers and experts from Germfree and The Baker Company who freely contributed their facilities and expertise to develop prototypes, conduct validations, and provide design drawings and validation reports for this guidance document. The goal of this guidance document is to provide countries with public domain specifications to allow local manufacture of VWSs and encourage regional manufacturers to develop these products for a potential global market of thousands of smear microscopy centers.

John Ridderhof, Pawan Angra, and Ralph Timperi

1. See validation report in section 5.4.

Acknowledgements

The Ventilated Workstation (VWS) project is a combined effort on the part of many organizations and individuals who have contributed to the content and development of this guidance document. We acknowledge the members of the initial workgroup that convened in Atlanta, USA in September 2009 and other key individuals who readily volunteered to contribute time and materials for the development of this document. We sincerely appreciate the contributions of Keith Landy from Germfree and David Eagleson from The Baker Company for their unconditional support in constructing and validating the prototypes and providing the design specifications. It is our sincere hope that this document will be helpful for manufacture and validation of the VWS and for performing periodic validations.

CONTRIBUTORS:

Pawan Angra*
(CDC, Atlanta, GA, USA)

Shanna Nesby
(CDC, Atlanta, GA, USA)

Gerrit Coetzee
(NHLS, Johannesburg, South Africa)

Linda Parsons
(CDC, Atlanta, GA, USA)

David Eagleson
(The Baker Company, Sanford, ME, USA)

John Ridderhof*
(CDC, Atlanta, GA, USA)

Knut Feldman
(FIND, Geneva, Switzerland)

Ron Smithwick
(Independent TB Consultant, Atlanta, GA USA)

Paula Fernandes**
(APHL, Washington, USA)

Rudolph Stotz
(CDC, Atlanta, GA, USA)

Chris Gilpin
(WHO, Geneva, Switzerland)

Ralph Timperi*
(APHL, Washington, USA)

Khye Seng Goh
(Institut Pasteur de Guadeloupe, French West Indies)

Sean Toney
(CDC, Atlanta GA, USA)

Paul Jensen
(CDC, Atlanta, GA, USA)

Kenneth Ugwu
(Health Canada, Ottawa, Canada)

Scott Kreitein
(CUH2A, Atlanta, GA USA)

Steve Williams
(NSF/ANSI, Ann Arbor, MI, USA)

Keith Landy
(Germfree Company, Ormond Beach, FL, USA)

Lucy Maryogo-Robinson
(APHL, Washington, USA)

*Project leads and coordinators

**Writer-editor

Table of Contents

CONTENTS	
Preface	1
Acknowledgements	2
Table of Figures	5
List of Tables	5
List of Acronyms	6
1. Background	7
1.1. Rationale	7
1.2. Introduction to the VWS	8
1.3. Warnings	8
1.4. Bibliography	9
2. Manufacturer's Manual	10
2.1. Purpose	10
2.2. General Characteristics of the VWS	10
2.3. Materials	11
2.3.1. Design Specifications Part 1: The Cabinet	11
2.3.2. Design Specifications Part 2: Fan, Ducting and Damper	11
2.3.2.1. Air flow and Static Pressure Specifications for the VWS	11
2.3.2.2. Fundamentals of Exhaust System	11
2.3.2.3. Duct Design and Fan Criteria	12
2.3.2.4. Fan Selection	15
2.4.2.5. The Damper	16
2.4.2.6. Fan Location	16
2.4. Assembly	16
2.4.1. Cabinet Assembly Protocol	16
2.5. Installation	16
2.5.1. Placement of the VWS	16
2.5.2. Assembly and Installation of Ductwork	18
2.5.3. Installation of the Exhaust Fan	19
2.6. Electrical Safety and Wiring	19
2.7. Post-assembly Quality Control Checks	20
2.8. Validation	20
2.9. Service and Maintenance	20
2.10. Bibliography	20
3. Validation Manual	21
3.1. Purpose	21
3.2. Background	21
3.3. Introduction to Validation Requirements	21
3.4. Validation Protocols	22
3.4.1. Light Intensity Test Using a Light Meter	22
3.4.2. Light Intensity Test by Eye	23

3.4.3.	Noise Level Test Using Sound Meter	23
3.4.4.	Noise Level Test by Ear	24
3.4.5.	Vibration Test Using Vibration Analyzer	24
3.4.6.	Vibration Test by Eye	25
3.4.7.	Stability	25
3.4.8.	Inflow Velocity (restricted access / 100mm [4 in] method)	26
3.4.9.	Direct Inflow Measurement (DIM)	28
3.4.10.	Airflow Smoke Test	29
3.5.	Bibliography	30
3.6.	Appendices	31
V1.	Validation Checklist / Logbook	31
V2.	Reference Values	31
4.	User Manual	32
4.1.	Operation	32
4.1.1.	Starting up	32
4.1.2.	Working at the VWS	32
4.1.3.	Shutting Down	33
4.2.	Daily Airflow Checks	33
4.2.1.	Air Flow Measurement Equipment (Anemometer)	33
4.2.1.1	Measuring the intake velocity in the VWS	33
4.3.	Cleaning	34
4.4.	Monthly Checks	34
4.4.1.	Visual Integrity Check	34
4.4.2.	Airflow Check	34
4.4.3.	Smoke Test	34
4.4.3.1.	Smoke Test Equipment	35
4.4.3.2.	Smoke Test Protocol	35
4.5.	Safety Procedures	35
4.5.1.	When to stop Using the VWS	35
4.5.2.	What to do During Sudden Loss of Power or Spill	35
4.5.3.	Cleaning up Spills inside the VWS	36
4.5.3.1.	Materials required	36
4.5.3.2.	Protocol	36
4.6.	Servicing, Maintenance and Repair	36
4.7.	Bibliography	37
4.8.	Appendices	38
U1.	Daily Checklist	38
U2.	Monthly Checklist	39
5.	Main Appendices	40
5.1.	Glossary	40
5.2.	VWS Frequently Asked Questions	41
5.3.	CAD Drawings For Cabinet Construction	44
5.4.	Prototype VWS Test Report	55

TABLE OF FIGURES

Figure 1. Ventilated Workstation (VWS)	8
Figure 2. The VWS Assembled and Installed	10
Figure 3. Diagram showing appropriately-installed VWS in the laboratory	13
Figure 4. Diagram showing VWS in the laboratory with external discharge structure	13
Figure 5. Typical fan curve	15
Figure 6. Joining the sides to the base	17
Figure 7. Joining the back to the base and sides	17
Figure 8. Attaching the window	17
Figure 9. Exhaust duct collar space	17
Figure 10. Attaching the baffle	17
Figure 11. External light source	17
Figure 12. Placement of VWS in the laboratory	16
Figure 13. Another way of placing the VWS in the laboratory	18
Figure 14. Placing damper and attaching duct (A and B)	18
Figure 15. Attaching flexible and hard duct (preferable option) to the damper (A and B)	19
Figure 16. Wiring diagram for lights and the fan	20
Figure 17. Light intensity test - placing the probe 1	22
Figure 18. Light intensity test - placing the probe 2	22
Figure 19. Light intensity test – placing the probe 3	22
Figure 20. Noise level test	23
Figure 21. Vibration test – placing the probe 1	24
Figure 22. Vibration test – placing the beaker	24
Figure 23. Stability test – applying pressure	25
Figure 24. Stability test – ensuring return to 90 degrees	25
Figure 25. Inward airflow test using cardboard insert	26
Figure 26. VWS with cardboard markings	26
Figure 27. Attachment of the DIM flow hood to the VWS	28
Figure 28. The DIM flow hood attached to the VWS	29
Figure 29. Inflow velocity readings on the DIM flow hood	29
Figure 30. Airflow smoke test – external perimeter	29
Figure 31. Airflow smoke test – internal perimeter	30
Figure 32. Positioning the anemometer to measure airflow	33

LIST OF TABLES

Table 1. Required standards for VWS components	10
Table 2. Recommended duct diameter sizes and their associated static pressure losses.	12
Table 3. Example calculation: the required airflow rate from Figure. 3.	14

List of Acronyms

AFB	Acid-fast Bacilli
ANSI	American National Standards Institute
APHL	Association of Public Health Laboratories
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
BSC	Biological Safety Cabinet
CAD	Computer-aided Design
CDC	Centers for Disease Control and Prevention (USA)
cfm	cubic feet per minute
CLR	Centerline radius
dBA	Decibel (using the "A" weighting scale)
DHHS	Department of Health and Human Services (USA)
DIM	Direct inflow measurement
ft	foot/feet
fpm	Feet per minute
GLI	Global Laboratory Initiative
h	Hour
HEPA	High Efficiency Particulate Air
Hz	Hertz
I-P	Inch-Pound system of units
in	Inches
in ²	Square inches
in w.g.	Inches water gauge
kHz	Kilohertz
The Union	International Union Against Tuberculosis and Lung Disease
lx	Lux
m	Meter
m/s	Meters per second
m ²	Square meters
m ³ /s	Cubic meters per second
mm	Millimeter
mL	Milliliter
min	Minute
<i>M. tuberculosis</i>	<i>Mycobacterium tuberculosis</i>
NB	<i>Nota Bene</i> (Note Well)
NSF/ANSI 49	National Sanitation Foundation International/American National Standard 49
Pa	Pascal
rms	Root Mean Square
s	Second
SI	Système international d'unités (international system of units)
SOP	Standard Operating Procedure
TB	Tuberculosis
TBCAP	Tuberculosis Coalition for Technical Assistance
VWS	Ventilated Work Station
w.g.	Water Gauge
WHO	World Health Organization

1. Background

1.1 RATIONALE

The procedure of sputum-smear preparation for AFB-smear microscopy has the potential to generate infectious aerosols. The infective dose of *M. tuberculosis* is low and sputum specimens from patients with TB are potentially infectious. The preparation of sputum smears poses an uncertain risk of exposure to TB bacilli (Menzies & Joshi, 2007; Kim *et al.*, 2007). However, this risk is less than that of exposure from, care of, or specimen collection from an infectious TB patient (Reid, 1957). Because the risk of exposure in smear preparation is low, the general safety recommendation is to perform smear preparation on an open bench near an open window or in an area that uses an extraction fan for ventilation (World Health Organization, 2004). WHO and The Union recommend the preparation of smears in a ventilated environment with directional airflow (World Health Organization, 2009). Attaining adequate ventilation, however, is difficult in settings where facilities have limited mechanical or natural ventilation. Since the majority of smear preparation is done at the peripheral level of health networks, it is not feasible to have HEPA-filtered biosafety cabinetry or microbiological safety cabinets (from herein termed “biological safety cabinet” or “BSC”). BSCs require continual monitoring and yearly maintenance by qualified personnel. Maintenance is expensive and furthermore, it can be difficult to find suitably qualified personnel (Enarson, Rieder, Arnadottir, & Trebucq, 2000). Poorly maintained BSCs give a false sense of security.

This guideline provides specifications for a ventilated workstation (VWS) that has been validated, is inexpensive to manufacture and requires minimal maintenance.

The VWS is a partially-enclosed workspace from which air is drawn inward, away from the user and exhausted outside of the laboratory. The purpose of the VWS is to provide a safe work environment when preparing sputum smears for AFB staining or sample manipulations that inactivate sputum specimens for automated molecular testing systems e.g., GeneXpert MTB/RIF Assay from Cepheid. Complete sample inactivation study for GeneXpert MTB/RIF Assay has been demonstrated and published (Padmapriya *et al.*, 2010).

The VWS should **never** be used for procedures that increase the risk of generating aerosols including: decontamination or concentration of sputum samples involving centrifugation or vortexing and handling of solid or liquid cultures. Use of the VWS should not replace attention to careful technique to minimize risks and assure high quality smears. Similar to the WHO’s recent Infection Control Guidelines and biosafety principles, use of the VWS is one engineering solution that should be used in addition to administrative precautions such as having patients collect specimens outside of the laboratory (World Health Organization, 2009).

Detailed specifications were developed during the research and design of prototype VWSs. These were determined from the testing of the final prototype VWS by two US manufacturers of safety equipment (The Baker Company, Sanford, ME.; Germfree, Ormond Beach, FL.). The plans and specifications for the VWS are provided without charge for the purpose of production and manufacture by knowledgeable and experienced medical or laboratory equipment manufacturers. The manufacturer should validate several VWS units to assure the quality of the production before they are distributed, and periodically thereafter. Users must validate VWS performance on-site prior to use.

1.2 INTRODUCTION TO THE VWS

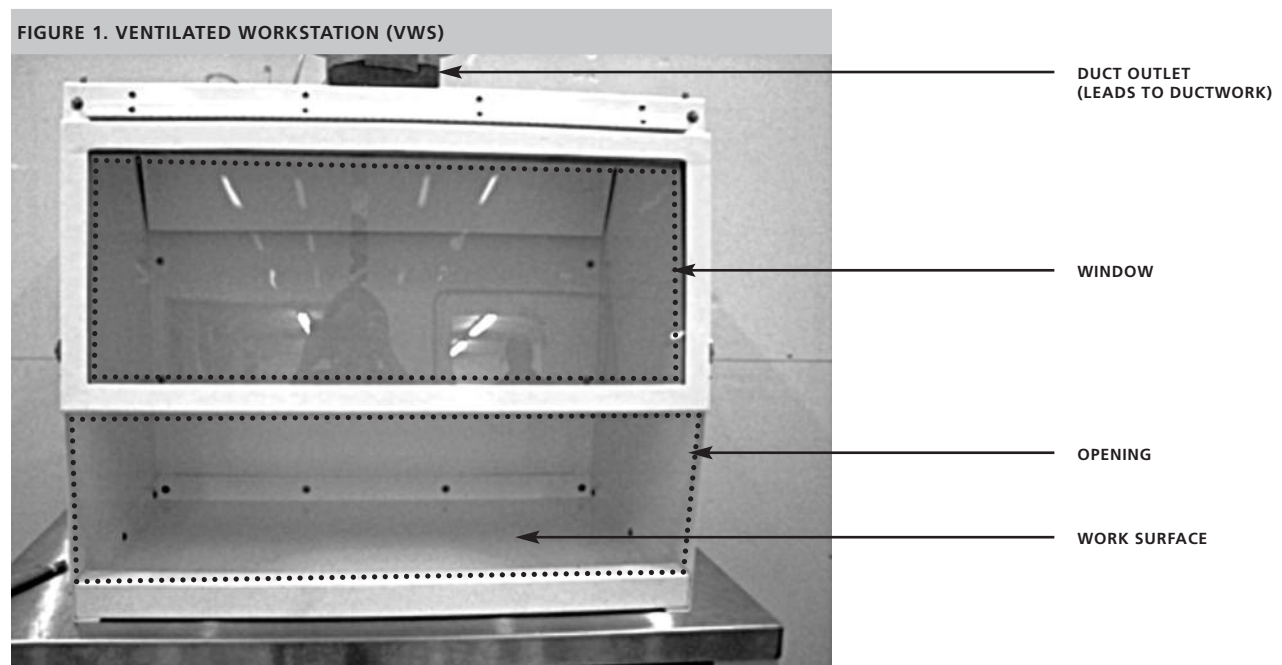
The VWS is a cabinet with an opening for personnel, specimen, and equipment access as well as a viewing window (see figure 1). The viewing window can be opened to allow for access to clean and maintain the cabinet interior.

The VWS is designed to be placed on a sturdy laboratory workbench surface. Once installed, proper operation of the VWS must be validated by qualified personnel. If the VWS is moved or repaired, re-validation is required to ensure the work environment is safe.

1.3 WARNINGS

- The VWS is not a biological safety cabinet and is not designed for procedures that increase the risk of generating aerosols including: decontamination or concentration of sputum samples involving centrifugation or vortexing, and handling of solid or liquid cultures.
- The VWS has not been reviewed or validated for microbiological purposes other than for the preparation of sputum smears for AFB staining.
- The VWS must be installed and validated by qualified personnel². Failure to properly install and validate the VWS can compromise safety.
- Only qualified personnel may move or repair the VWS.

VWS constructed by different manufacturers may use various, but acceptable, construction materials. It is important to follow the specific cleaning guidelines recommended by the manufacturer to ensure cabinet longevity.



2. The qualification of VWS personnel will need to be defined by a national authority. See section 5.2: Frequently Asked Questions for more details.

1.4 BIBLIOGRAPHY

Enarson, D. A., Rieder, H. L., Arnadottir, T., & Trebucq, A. (2000). Management of Tuberculosis: A guide for low income countries. International Union Against Tuberculosis and Lung Disease.

Germfree, Ormond Beach, FL. (n.d.). Retrieved January 2011, from <http://germfree.com/>

Kim, S. J., Lee, S. H., Kim, I. S., Kim, H. K. & Kim, S. K. (2007). Risk of occupational tuberculosis in National Tuberculosis Programme laboratories in Korea. *International Journal of Tuberculosis and Lung Disease*, 11(2), 138–142.

Menzies, D. & Joshi, R. (2007). Risk of tuberculosis infection and disease associated with work in health care settings. *International Journal of Tuberculosis and Lung Disease*, 11(6), 593–605.

Padmapriya, P. B., Sivasubramani, S. K., Blakemore, R., Boehme, C., Perkins, M. D., & Fennelly, K. a. (2010, Oct). Containment of bioaerosol infection risk by the Xpert MTB/RIF assay and its applicability to point-of-care settings. *Journal of Clinical Microbiology*, 48(10), pp. 3551-3557.

Reid, D. D. (1957). Incidence of tuberculosis among workers in medical laboratories. *British Medical Journal*, 10-14.

Smithwick, R. W. (Unpublished data). A simple, inexpensive biological safety cabinet for use in developing nations.

The Baker Company, Sanford, ME. (n.d.). Retrieved January 2011, from <http://www.bakerco.com/index.php>

World Health Organization. (2004). *Laboratory biosafety manual (3rd ed)*. Geneva: WHO.

World Health Organization. (2009). *WHO policy on TB infection control in health-care facilities, congregate settings and households*. Retrieved from WHO policy on TB infection control: http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf

2. Manufacturer’s Manual

2.1 PURPOSE

The purpose of the “Manufacturer’s Manual” is to provide standard instructions and protocols for manufacture, installation and validation of a VWS using basic mechanical and electrical procedures and widely available materials. The manufacturer should validate several VWS units to assure the quality of production before they are distributed and periodically, thereafter.

2.2 GENERAL CHARACTERISTICS OF THE VWS

The purpose of the VWS is to provide a safe work environment when preparing sputum smears for AFB staining, especially in settings where adequate natural or mechanical ventilation cannot be achieved.

Figure 2 shows an installed VWS. It is a rectangular cabinet with top, sides and base; a front angled viewing screen; a front opening for access; and a baffle and exhaust collar in the cabinet roof for connecting to a duct. It is designed to be placed on top of a sturdy laboratory workbench and in an appropriate part of a laboratory where the exhaust duct can be safely attached to an extractor fan at or near the outer wall.



FIGURE 2. VWS ASSEMBLED & INSTALLED

TABLE 1 REQUIRED STANDARDS FOR VWS COMPONENTS		
COMPONENT	MATERIAL	GUIDELINES
Cabinet	16 gauge or heavier Grade 304 / 316 stainless steel (0.0598 in/1.52 mm), or epoxy/powder coated galvanized steel (0.0635 in/1.613 mm); or 14 gauge or heavier epoxy/powder coated aluminum (0.0641 in/1.628 mm)	Must be resistant to corrosive chemicals
Window	Polymethyl-methacrylate (PMMA) glass (also known as acrylic, polycarbonate, Perspex® or Plexiglas®) or tempered/toughened glass	Must be resistant to corrosive chemicals
Fan		Must be sized to meet volumetric airflow rate specifications
Damper	Galvanized metal (or other non-flammable material)	Must be sized according to size of ductwork in order to minimize transitions
Duct / exhaust pipe	Galvanized metal or flexduct (flexible duct)	Must be sized to fit fan in order to achieve volumetric airflow rate specifications. Must be without holes or rust. Minimize sharp turns or elbows
Electricals	Copper wiring	According to local code
Fasteners	Galvanized or stainless steel	Corrosion proof

2.3 MATERIALS

All construction materials must be non-porous and resistant to acids, alcohols, bleach³, stains and abrasives that are used in the laboratory. Metals must be coated to ensure resistance to bleach solutions if that is used regularly to decontaminate work surfaces. Requirements for construction materials are shown in Table 1.1.

2.3.1. DESIGN SPECIFICATIONS PART 1: THE CABINET

Detailed Computer-Aided design (CAD) drawings for cabinet construction are shown in Appendix 5.3. These drawings should be used to cut, bend and join the materials for fabrication of the VWS. Assembly of VWS is described in section 2.4.

2.3.2. DESIGN SPECIFICATIONS PART 2: FAN, DUCT AND DAMPER

2.3.2.1. Airflow and Static Pressure Specifications for the VWS

Inflow Velocity: 0.35 – 0.55 meters per second (m/s) or 69-108 feet per minute (fpm)

Volume of air: 0.0813-0.1277 cubic meters per second (m³/s) or 172-272 cubic feet per minute (cfm).

Static pressure: 200 Pascal (Pa) or 0.803 inches water gauge (in w.g.)

Note that the above specifications are assuming a workstation with dimensions matching those in the VWS plans herein.

Other dimensions for the workstation and its access opening have not been validated.

2.3.2.2. Fundamentals of Exhaust System

The VWS functions similar to an exhaust hood or canopy hood typically found in commercial kitchens, paint shops and other areas where it is important to send air captured by a hood to the outdoors. For proper operation of the VWS, room air needs to be drawn into the front opening located below the view window, and then this air needs to be ducted and discharged to the outdoors. Fan selection for operation of the VWS is based on two requirements: the volumetric flow of air (m³/s or cfm) and the total static pressure of the system (Pa or in w.g.). The design volumetric airflow rate at which air enters the VWS is 0.0813-0.1277 m³/s (172-272 cfm).

Note. This volumetric airflow rate range is the acceptable range for the VWS described in this document but the higher limit (0.1277 m³/s or 272 cfm) must be used when making the fan selection for any room or building location. This volumetric airflow rate range will be a constant when making the fan selection for any room or building location.

The total static pressure acting on the system required to move 0.0813-0.1277 m³/s (172-272 cfm) of air to the outside discharge point of the building will be different for each room or building location. This static pressure must be calculated for each and every VWS installation. The total static pressure of the system is determined by adding all the individual static pressure losses required to move the volume of air through the entire system. The total static pressure must be determined by adding static pressure losses of the following components of the system together:

- VWS estimated hood static pressure is 200 Pa or 0.803 in w.g. (this is constant).
- Length of duct
- Duct diameter
- Turns and bends of duct
- Duct transitions (e.g., to and from fan and damper)
- Weather (rain) cap

³ Bleach commonly refers to household bleach which is an approx. 10% sodium hypochlorite solution. A dilution of household bleach with water (1 part bleach plus 4 parts water) is effective against many bacteria and some viruses, and is often the disinfectant of choice in cleaning surfaces in hospitals and laboratories. The solution is corrosive, and needs to be thoroughly removed afterwards, so the bleach disinfection should be followed by an ethanol or ethanol/water rinse

2.3.2.3. Duct Design and Fan Criteria

The duct will connect the VWS with the fan. The fan should be located at the discharge end of the duct system at or near the outer wall of the building.

A properly designed duct system is more energy efficient thus allowing for selection of a fan with lower electrical power requirements. In general, the duct should be as straight as possible with few bends (e.g. no sharp bends or mitered elbows). Material for the duct should have smooth interior walls. The ventilation system will be more efficient with a larger diameter duct. A duct with a diameter smaller than 125 mm should not be used. Some recommended duct diameter sizes and their associated static pressure losses are listed in Table 2.

The duct should be sturdy and well supported so that it will not break apart and assembled so that air leakage is minimized. At the discharge end of the duct, a weather (e.g. rain) cap which has a minimal static pressure loss should be used. Flap type weather cap should be avoided as it builds up static pressure (Figure 4). This weather cap requires a screen to keep insects and birds out of the duct system.

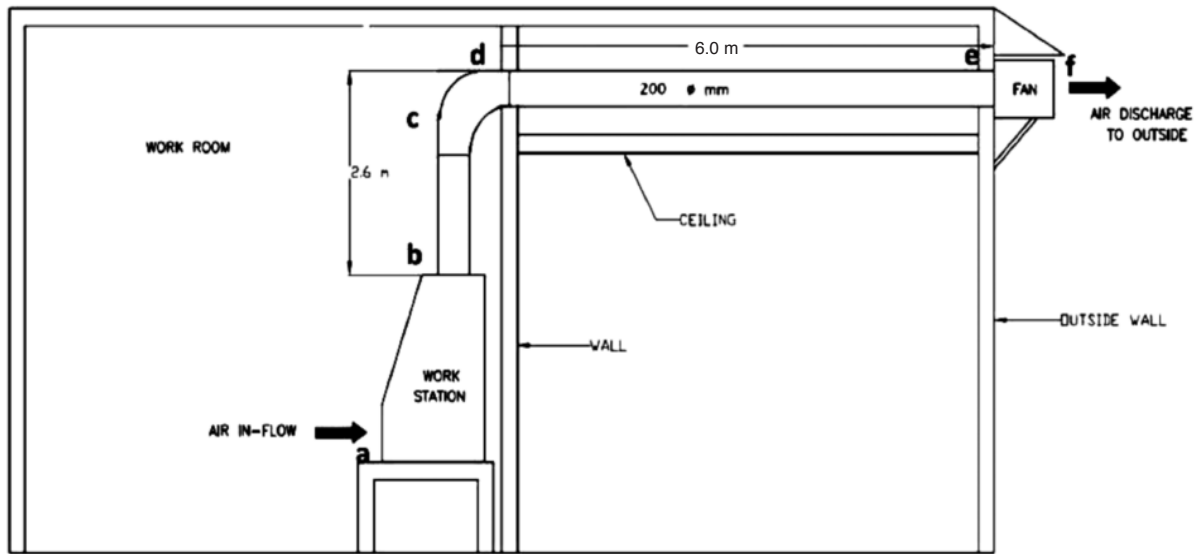
TABLE 2. RECOMMENDED DUCT DIAMETER SIZES AND THEIR ASSOCIATED STATIC PRESSURE LOSSES (GERMFREE, ORMOND BEACH, FL.).

Duct Diameter (SI w/ I-P. Conv.)		Duct Area		Airflow Rate		Duct Velocity		Velocity Pressure		Loss per 1m duct length		Loss per 90° 2.0 dia. R	
				Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)		
"A"				"B"				"C"		"D"		"E"	
(mm)	(in)	(m²)	(in²)	(m³/s)	(cfm)	(m/s)	(fpm)	(Pa)	(in H₂O)	(Pa)	(in H₂O)	(Pa)	(in H₂O)
125	4.9	0.0123	0.1321	0.1238	267	10.1	2018	61.2	0.2538	11.7	0.0147	16.5	0.0685
150	5.9	0.0177	0.1902	0.1238	267	7.0	1401	29.5	0.1224	4.6	0.0059	8.0	0.0330
200	7.9	0.0314	0.3382	0.1238	267	3.9	788	9.3	0.0387	1.1	0.0014	2.5	0.0105
250	9.8	0.0491	0.5284	0.1238	267	2.5	504	3.8	0.0159	0.3	0.0004	1.0	0.0043
Duct Diameter (SI w/ I-P. Conv.)		Duct Area		Airflow Rate		Duct Velocity		Velocity Pressure		Loss per 1' duct length		Loss per 90° 2.0 dia. R	
				Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)	Max (0.55 m/s)	Max (108 fpm)		
"A"				"B"				"C"		"D"		"E"	
(mm)	(in)	(m²)	(in²)	(m³/s)	(cfm)	(m/s)	(fpm)	(Pa)	(in H₂O)	(Pa)	(in H₂O)	(Pa)	(in H₂O)
127	5	0.0127	0.1364	0.1238	267	9.8	1955	57.5	0.2382	10.8	0.0136	15.5	0.0643
152	6	0.0182	0.1963	0.1238	267	6.8	1357	27.7	0.1149	4.3	0.0054	7.5	0.0310
203	8	0.0324	0.3491	0.1238	267	3.8	763	8.8	0.0363	1.0	0.0013	2.4	0.0098
254	10	0.0507	0.5454	0.1238	267	2.4	489	3.6	0.0149	0.3	0.0004	1.0	0.0040

LEGEND:

SI w/ I-P. Conv.	SI units with Imperial conversion	mm	Millimeter
dia. R.	Diameter radius	in	Inches
m/s	Meters per second	Pa	Pascal
fpm	Feet per minute	m	Meter
m ³ /s	Cubic meters per second	m ²	Square meters
cfm	cubic feet per minute	in ²	Square inches

FIGURE 3. DIAGRAM SHOWING APPROPRIATELY-INSTALLED VWS IN THE LABORATORY

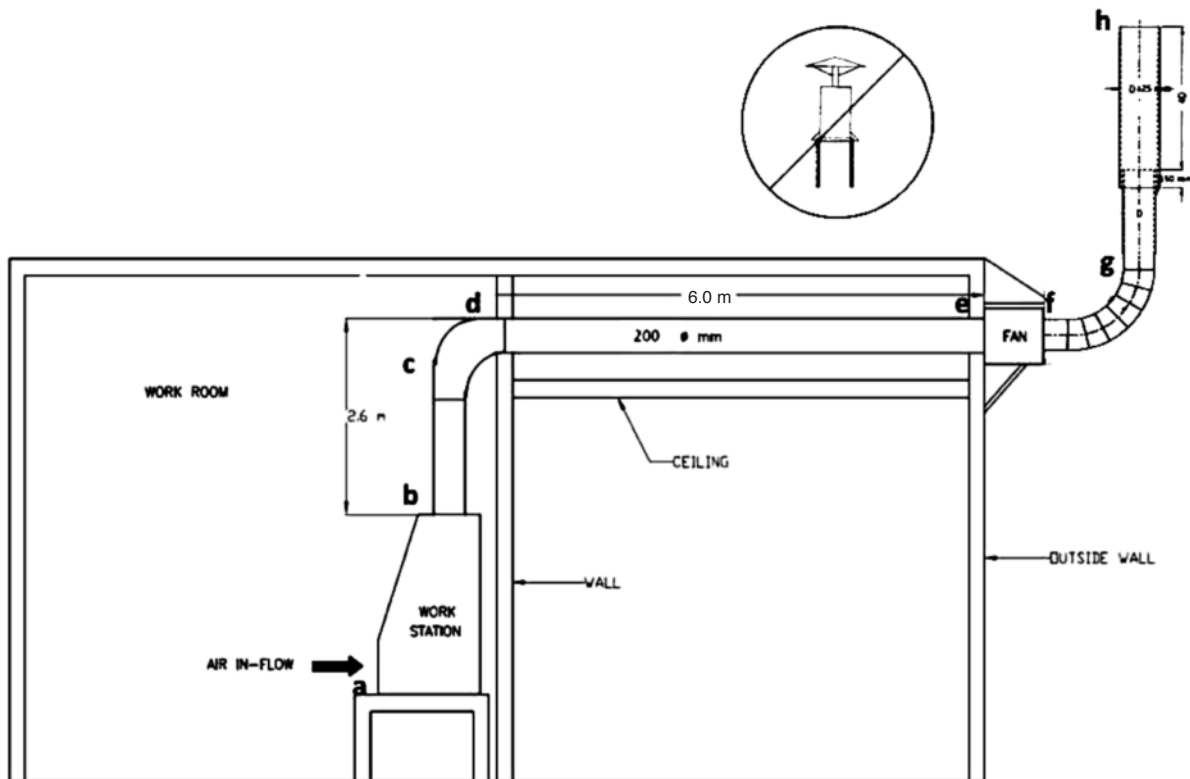


c-d elbow: CLR=1

(CLR = Centerline Radius = Radius from reference point to center of duct/elbow)

Components corresponding to calculations in Table 2 are labeled A-E

FIGURE 4. DIAGRAM SHOWING APPROPRIATELY-INSTALLED VWS IN THE LABORATORY



c-d elbow: CLR=1

f-g elbow: CLR = 2

(CLR = Centerline Radius = Radius from reference point to center of duct/elbow)

Components corresponding to calculations in Table 2 are labeled A-E. (Flap type weather cap should be avoided as it builds up static pressure.)

Example: The total pressure loss of the system can be calculated using data in Table 2. Follow the steps associated with table 2 using data from your installation to calculate the **total static pressure**. Table 3 shows the calculation example for Figure 3. Table 3 provides the required **airflow rate** for installed duct diameter. These values are needed for fan selection.

TABLE 3. EXAMPLE CALCULATION: THE REQUIRED AIRFLOW RATE FROM FIGURE. 3.					
STEP		SI		I-P	
1	Duct Diameter (Column "A")	150.00	mm	6	in
2	Volumetric Airflow Rate (Column "B")	0.1238	m ³ /s	267	cfm
3	Velocity Pressure (Column "C")	29.5	Pa	0.1149	in H ₂ O
4	Friction losses per unit of duct length (Column "D")	4.6	Pa	0.0054	in H ₂ O
5	Elbow Pressure Losses (Column "E")	8.0	Pa	0.0310	in H ₂ O
6	VWS Estimated Hood Static Pressure (Section: 2.3.2.2)	200	Pa	0.8029	in H ₂ O
7	Enter total length of straight ductwork	6.00	m	20.00	ft
8	Pressure losses for straight ductwork (#4 x #7)	27.6	Pa	0.1080	in H ₂ O
9	No. of 90° Elbows, Entries, and/or Special Fittings	6	#	6	#
10	Total Fittings Pressure Losses (#5 x #9)	48.0	Pa	.1860	in H ₂ O
11	Total Ductwork SP Loss (#8 + #10)	75.6	Pa	0.2940	in H ₂ O
12	Cumulative Static Pressure (#6 + #11)	275.62	Pa	1.0969	in H ₂ O
13	Total Static Pressure	276	Pa	1.10	in H ₂ O
14	Volumetric Airflow Rate from Column "B" (multiply m ³ /s x 1000 for L/s)	0.1238 (125.8)	m ³ /s (L/s)	267	cfm

Calculations:

1. Enter the diameter of the installed ductwork
2. Enter the Volumetric Airflow Rate for the appropriate diameter from Column "B"
3. Enter the Velocity Pressure from Column "C"
4. Enter the calculated Friction Loss per unit of duct length from Column "D"
5. Enter the Elbow / fixture loss calculation from Column "E"
6. The fixed estimate for losses internal to the VWS is listed in line item #6
7. Enter total length of straight duct in system. This includes ductwork before and after the fan
8. Calculate the pressure losses for the straight ductwork by multiplying the length of straight duct (#7) by the pressure loss per unit length of duct (#4)
9. Enter the number of elbows, fixtures and fittings on line #9. This includes the entire system (before and after the fan).
Mitered elbow should be counted as 2 radiused elbows. Rain caps, transitions, and dampers should be counted as 1 each fixture.
10. Calculate the pressure losses due to fixtures by multiplying the number of fixtures (#9) by the pressure loss per fixture (#5)
11. Determine the total ductwork static pressure loss by adding line #8 and #10.
12. Calculate the Cumulative Static Pressure by adding the Total Ductwork Static Pressure (#11) and the estimated VWS internal losses (#6)
13. The calculated Total Static Pressure is 247 Pa or 1.097 in H₂O
14. From table 1 for 150 mm diameter duct the Volumetric Airflow Rate is 0.1238 m³/s (123.8 L/s) or 267 cfm

Line 13 and 14 are used as criteria in fan selection from fan curves.

2.3.2.4. Fan Selection

The fan must not be selected or purchased until duct diameter has been determined, static pressure calculations are completed, and mounting location and brackets have been reviewed.

The inlet and discharge sides of the fan must be able to have the appropriate duct collars attached. These collars must be sized to provide for a smooth flow of air from the inlet and outlet and not block the inlet and discharge area of the fan. The fan must have mounting brackets and fasteners for the location in which it will be placed.

Many types of fans will be suitable for use with the ducting of the VWS.

Forward curve and backward incline are examples but the selection should be based on availability, replacement and service in the area.

The most important characteristic to understand when making a fan selection is the relationship or performance of the fan with different volume flows (m^3/s or cfm) and static pressure loss (Pa or in w.g.). Most commercially available fans will provide this information called a “fan curve”. Fans that do not provide this information should be avoided.

After calculating the static pressure loss variables as described under Duct Design, the next step would be to submit the static pressure loss and volumetric airflow rate to a fan supplier or distributor for fan selection. This selection will be made reviewing the fan curve from many fans available. Figure 5 is a typical fan curve which shows the fan performance verses the static pressure. A fan should be selected if the performance curve intersects the total static pressure curve at our desired volumetric airflow rate and total static pressure as shown below.

To use a fan curve, the relationship between static pressure loss and volumetric airflow rate is required. Since the volumetric airflow rate of $0.1257 \text{ m}^3/\text{s}$ (267 cfm) has been determined, the chart will be used to determine the total static pressure loss.

Many fans are available with different speed settings or can be installed with a variable speed drive. The latter option gives the ability to adjust the speed at which the fan is operating, thus controlling the inflow velocity. If a filter is added to the ventilation system, it will cause an increase in resistance as it loads and a reduction in the volumetric airflow rate and inflow velocity. Thus, it is recommended that the VWS be used without any filter in the ventilation system.

FIGURE 5. TYPICAL FAN CURVE.

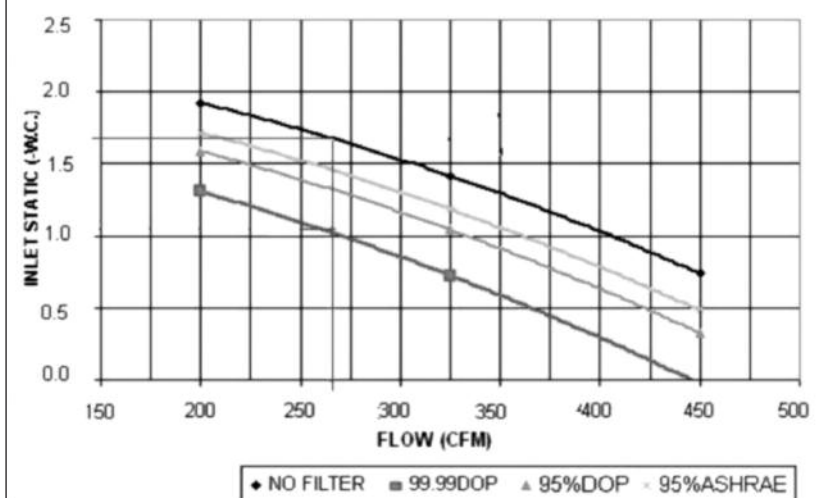


Figure 5 illustrates the relationship between inlet static pressure (in w.g.) and airflow (CFM). The fan manufacturer will provide a fan curve (do not purchase fans from manufacturers who do not provide fan curve information). In the case of the VWS, it is appropriate to use the “NO FILTER” line (the top line).

2.3.2.5. The Damper

An adjustable damper should be placed at the top of the VWS and the duct should connect to this. The damper will allow for adjustment to the exhaust system in the event that the fan is oversized. The adjustable damper can be a butterfly type and should be the same diameter of the duct.

2.3.2.6. Fan Location

The fan and discharge location of the air should be positioned away from a gathering point or sitting area of people. The fan should also be located in a protected covered area.

2.4. ASSEMBLY

2.4.1. CABINET ASSEMBLY PROTOCOL

- a. Place base on temporary work surface away from wall
- b. Attach left and right side using fasteners (Figure 6). **NB. The sides are placed on the outside of the base.**
- c. Attach the rear wall on the outside of the base (Figure 7)
- d. Attach top [with hinged window already affixed] (Figure 8)
- e. The inside of the cabinet should now look like this [inside view of VWS] (Figure 9)
- f. Attach top baffle (Figure 10)
- g. Attach light housing. If light is inadequate, an additional external light source can be attached from the top of the window as shown in figure 11. **NB. It is preferred to wire the light so that it is linked to the motor-blower. This way the motor-blower can only operate when the light is on and vice versa. (See the wiring diagram figure 16).**

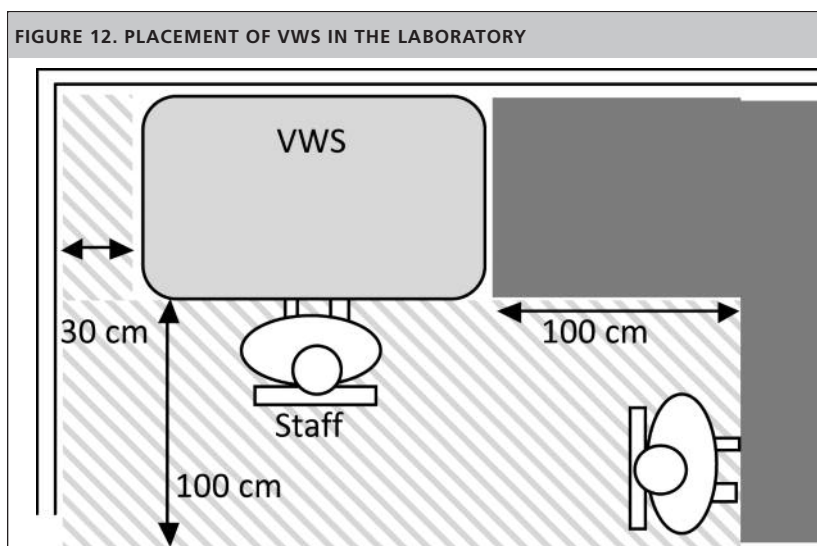
2.5. INSTALLATION

The correct placement of the VWS is important to ensure personnel and public safety. Be sure to read the following sections on placement and installation of duct and exhaust fan before beginning the installation process. The internal placement of the VWS is dependent upon its connection to the exhaust.

2.5.1. PLACEMENT OF THE VWS⁴

The following guidelines pertain to the placement of the VWS unit inside the laboratory:

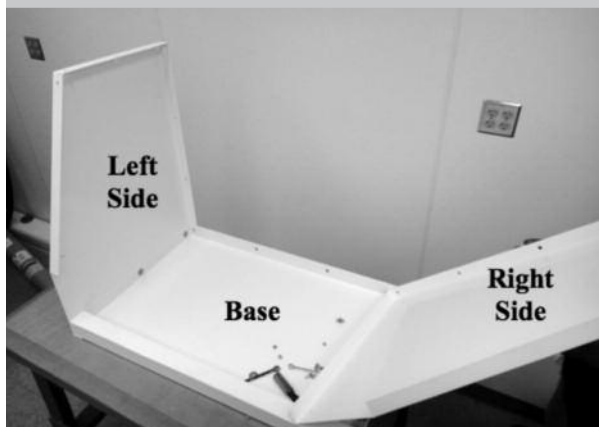
- a. Place the VWS on a sturdy laboratory work bench away from heavy equipment that may cause excessive vibration.
- b. There must be an undisturbed space of 100 cm (39 in) around the front of the VWS.
- c. Place the VWS at least 30 cm (12 in) from adjacent walls and 100 cm (39 in) from adjacent perpendicular benches.



⁴ These requirements are taken/adapted from: British Standards Institute (2005), Memarzadeh, *Methodology for Optimization of Laboratory Hood Containment* (1996) and Division of Technical Resources (2010).

CABINET ASSEMBLY PROTOCOL

FIGURE 6. JOINING THE SIDES TO THE BASE



- a. Place base on temporary work surface away from wall
 b. Attach left and right side using fasteners (Figure 6).
 NB. The sides are placed on the outside of the base.

FIGURE 7. JOINING THE BACK TO THE BASE AND SIDES



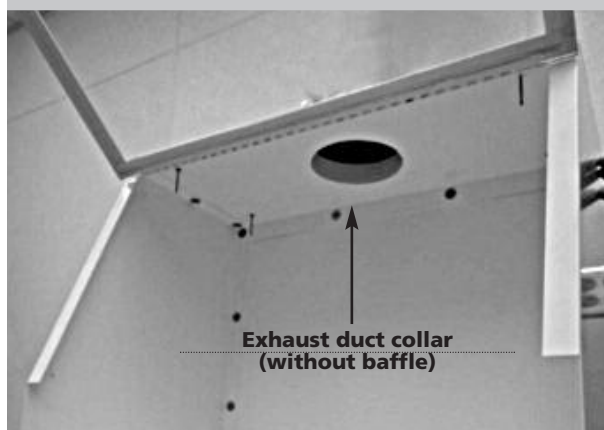
- c. Attach the rear wall on the outside of the base (Figure 7)

FIGURE 8. ATTACHING THE WINDOW



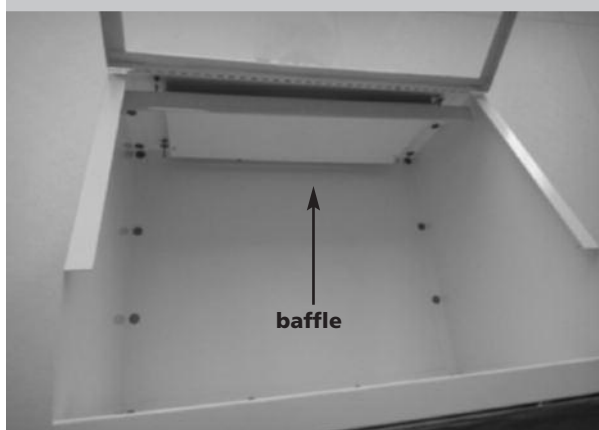
- d. Attach top [with hinged window already affixed] (Figure 8)

FIGURE 9. EXHAUST DUCT COLLAR SPACE



- e. The inside of the cabinet should now look like this [inside view of VWS] (Figure 9)

FIGURE 10. ATTACHING THE BAFFLE



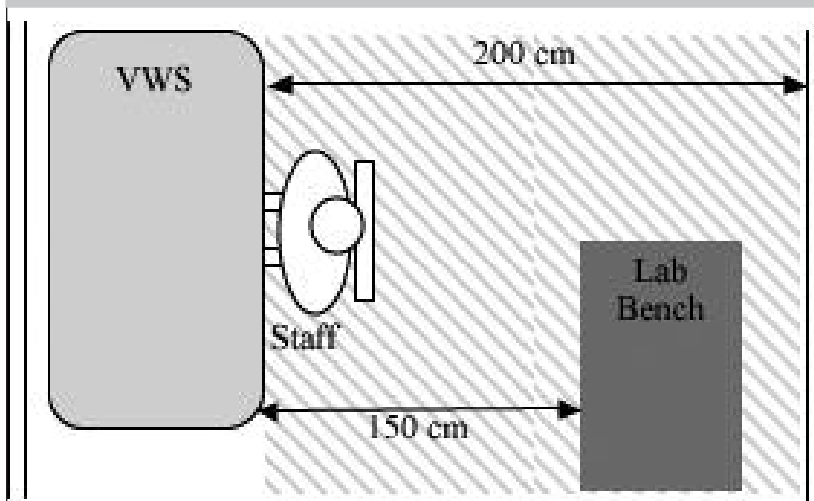
- f. Attach top baffle (Figure 10)

FIGURE 11. EXTERNAL LIGHT SOURCE



- g. Attach light housing. If light is inadequate, an additional external light source can be attached from the top of the window as shown in figure 11.

FIGURE 13. ANOTHER WAY OF PLACING THE VWS IN THE LABORATORY.



- d. Ensure the VWS is at least 100 cm (39 in) from an opposing wall.
- e. The VWS should be at least 150 cm (59 in) away from opposing benches (and doorways) or areas with occasional traffic.

2.5.2. ASSEMBLY AND INSTALLATION OF DUCT

The VWS unit must be placed inside the laboratory according to the guidelines in section 2.5.1 and the requirements for placement of the exhaust fan (section 2.5.3).

- a. Place damper on top of exhaust collar
- b. Fasten damper with screws
- c. Tape/seal damper with metal duct tape
- d. Adjust damper to be fully open NB. Ensure arrow is pointing in the correct direction (direction of airflow)

FIGURE 14. PLACING DAMPER AND ATTACHING DUCT

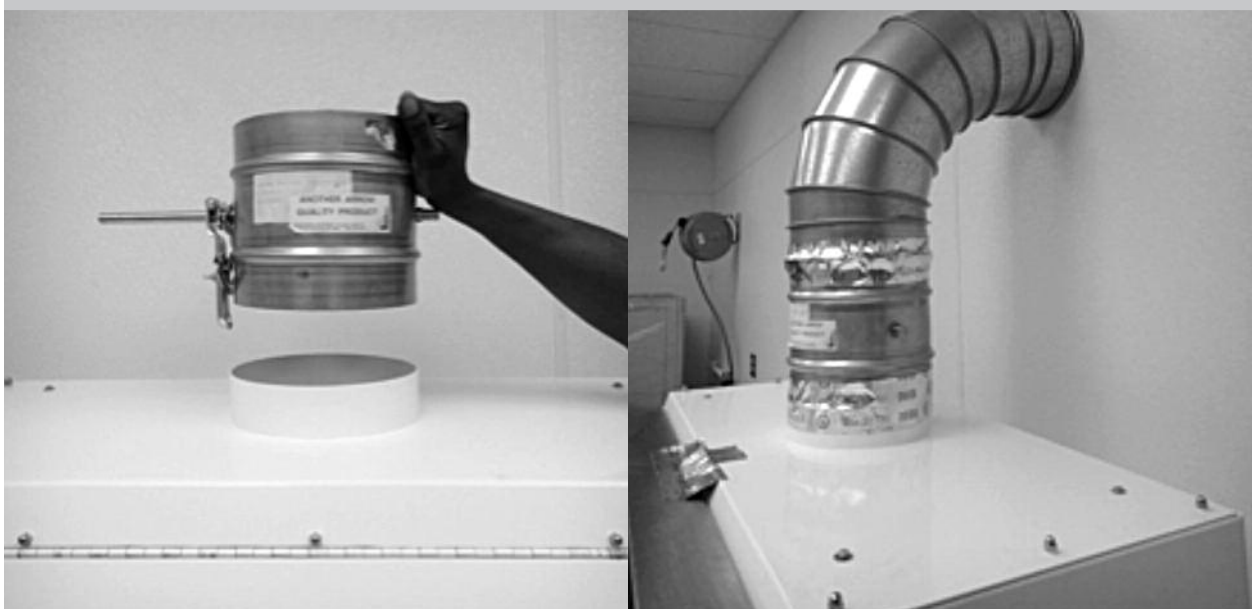
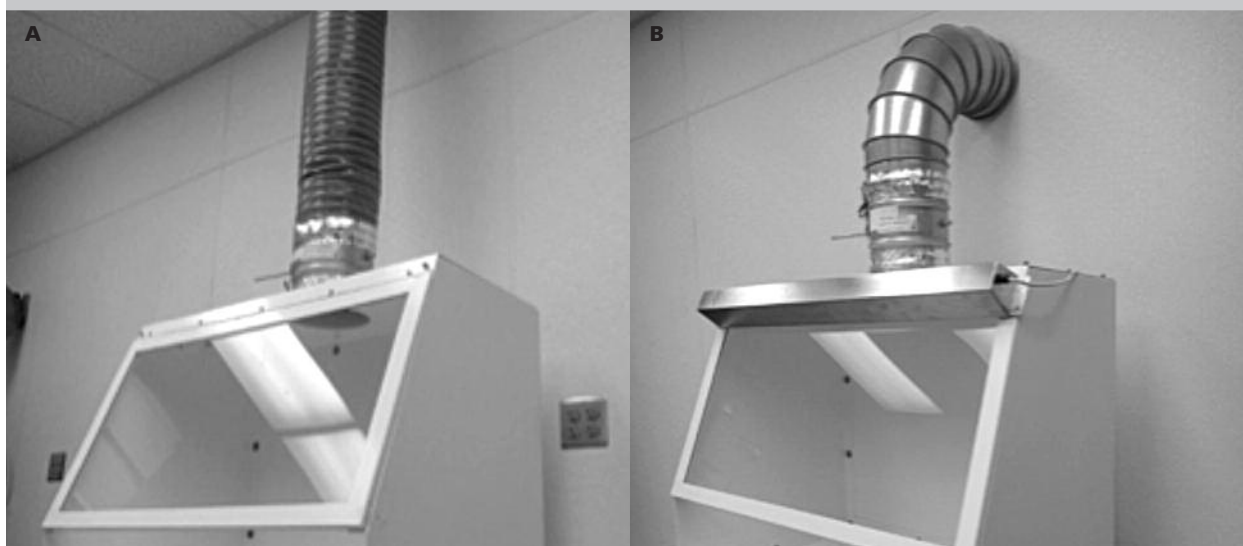


FIGURE 15. ATTACHING FLEXIBLE (A) AND HARD DUCT (B) TO THE DAMPNER**A. Option for installing flexible duct:**

- a. Attach flexible duct to top of damper
- b. Slip over cabinet duct collar and clamp or tape on damper

B. Option for installing rigid duct⁵:

- a. Use a wall to the rear of the VWS to fix rigid duct

2.5.3. INSTALLATION OF THE EXHAUST FAN

The fan should be located at or near the outer wall and should be supported by a sturdy stand or bracket. The fan and air duct should have weather cap and bird protector installed. The duct should discharge the air away from people and in open space. The fan should also be located in a covered protected area.

2.6. ELECTRICAL SAFETY AND WIRING

The use of high quality electrical cable and components meeting the local code are imperative for the safety of the user and longevity of the equipment. Figure 16 displays the wiring diagram for the VWS lights and blower.

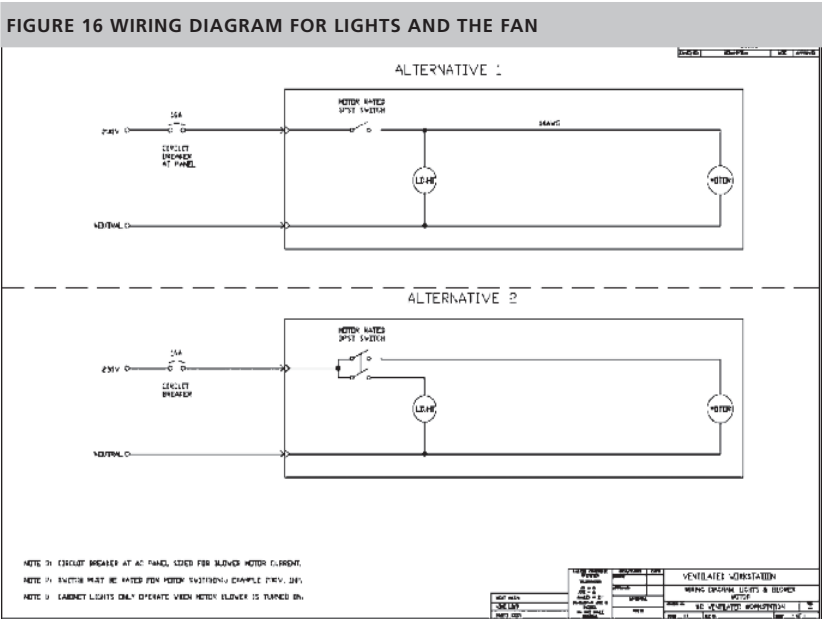
Electrical wiring for the light source should be firmly attached to the VWS; and the appropriate casing should be used for the fan. It is preferable to use the laboratory power switch to control the light and fan. Alternately, an electrical switch box can be mounted at the top of the VWS.

A light source can be mounted externally on the top of window panel and tightly fixed with screws or clamps. If the light source is desired to be mounted inside the VWS, it can be tightly screwed either inside the window or onto the baffle. A small hole in the side panel can be made and a rubber bung should be used to pass the wire and to seal the hole. The hole can also be sealed with, e.g. caulking or electrical tape.

5. Preferred option with CLR>2

2.7. POST-ASSEMBLY
QUALITY CONTROL CHECKS

- 1. Inspect and check that all the components conform to the specifications described in the design materials section.
- 2. Ensure that assembly of VWS conforms to the design.
- 3. Inspect thoroughly that there are no visible spaces or gaps at the edges.
- 4. Ensure that the window is clear and see through.
- 5. Turn on and off the electrical switches to ensure the turning on and off of light and fan.



2.8. VALIDATION

Validation is required after manufacture, installation and repair. Please refer to the Validation Manual (Chapter 3) for testing protocols.

2.9. SERVICE AND MAINTENANCE

The VWS is designed to perform with minimal need for servicing and maintenance. Appropriate use and cleaning is essential to ensure the longevity of the VWS (see sections 4.3 and 4.4 of the User Manual). Proper installation and user training is key to ensure safety.

VWS manufacturers must provide contact details to the laboratory personnel at each site and be able to provide follow-up servicing, training and repair where required.

2.10. BIBLIOGRAPHY

British Standards Institute. (2005). *Microbiological safety cabinets: recommendations for cabinet installation: BS 5726:2005*. London: British Standards Institute.

Division of Technical Resources. (2010). Placement of a biological safety cabinet in the laboratory. News to Use: Design Requirements Manual, 1(3).

Germfree, Ormond Beach, FL. <http://germfree.com/>

Memarzadeh, F. (1996). *Methodology for Optimization of Laboratory Hood Containment*. Bethesda: National Institutes of Health.

3. Validation Manual

3.1 PURPOSE

The purpose of this document is to guide manufacturers, installation engineers and members of regulatory bodies on the requirements and procedures for validating the ventilated workstation (VWS).

Important: This document is specifically designed for validation of the VWS. It does not provide guidance for validating any other safety devices including BSCs, laminar flow, clean benches and fume hoods.

3.2. BACKGROUND

The VWS, when designed and built to the exact specifications detailed in the “Manufacturers’ Manual”, should conform to the quality standards of the prototype. The design, fabrication, and installation of the prototype VWS has been validated according to the protocols detailed within this manual.

It is necessary for the manufacturer to validate every manufactured VWS due to variations in component parts and specific site installation requirements.

3.3. INTRODUCTION TO VALIDATION REQUIREMENTS

Each VWS design is validated for all tests described within the Validation Manual. After installation and repair, the required validation tests include:

- Inflow velocity
- Airflow smoke test

It is essential to record the date, evaluator initials and validation test results immediately in the validation checklist / logbook provided (see appendix V1). All results must be recorded, even those falling outside of the passing range. All failing test results, observations and corrective actions must be recorded.

Each protocol describes a test based on an international consensus standard. The majority of tests require special measuring devices. In some cases, alternative testing protocols have been suggested in case measuring equipment is unavailable at the manufacturing site or testing laboratory. The alternative protocols do not employ standardized equipment; therefore, it is important to note that many are not based on consensus standards. Despite this, these tests will ensure proper functioning of the VWS. The exceptions are the tests critical to ensuring adequate inflow velocity and protection to the user. For these, the testing laboratory or manufacturer must be in possession of an airflow meter and a safe source of generating smoke. Cigarette and other tobacco products are prohibited in the laboratory.

The validation equipment must be well-maintained and periodically calibrated. The validation equipment should always be used according to the manufacturer’s instructions.

3.4. VALIDATION PROTOCOLS

3.4.1. LIGHT INTENSITY TEST USING A LIGHT METER⁶

3.4.1.1. Purpose

The VWS is designed to permit light to illuminate the work area at sufficient levels for procedures to be conducted within. This test determines the light intensity on the work surface of the VWS in lux (lx).

3.4.1.2. Apparatus

A photoelectric illumination (light) meter accurate to $\pm 10\%$. The illumination meter shall be calibrated in accordance with the manufacturer's instructions.

3.4.1.3. Protocol

- a. Measure out and place light meter probe in the geometric center of the VWS work surface (inside black dotted circle).
- b. Allow photoelectric illumination meter to stabilize and record the reading.
- c. Measure out and place light meter probe 300 mm (12 in) to the right of the geometric centre (shown by black dotted circle) of the VWS work surface.
- d. Allow photoelectric illumination meter to stabilize and record the reading.
- e. Measure out and place light meter probe 300 mm (12 in) to the left of the geometric centre (shown by black dotted circle) of the VWS work surface.
- f. Allow photoelectric illumination meter to stabilize and record the reading.
- g. Complete the light intensity section on the worksheet (Appendix V1).

3.4.1.4. Interpretation of results

Calculate the mean of the three readings. The mean of the lighting intensities should be a minimum of 650 lx (60 ft-candles). No individual reading should be below 430 lx (40 ft-candles).

FIGURE 17. LIGHT INTENSITY TEST—PLACING THE PROBE 1



FIGURE 18. LIGHT INTENSITY TEST—PLACING THE PROBE 2

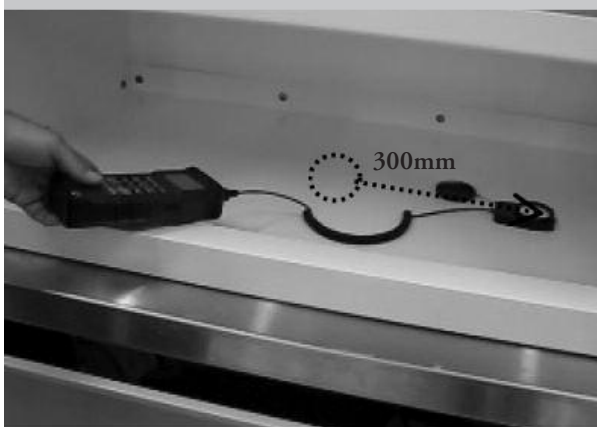


FIGURE 19. LIGHT INTENSITY TEST—PLACING THE PROBE 3



⁶ Adapted from EN 12469, Annex A.2 and NSF/ANSI 49, Annex A.4

3.4.2. LIGHT INTENSITY TEST BY EYE

3.4.2.1. Protocol for light intensity test without light meter.

- Place a piece of hand written or printed white paper (92 brightness) with black fonts (Times New Roman) of font size 12 (without bold or italics) on the surface of the cabinet.
- Complete the light intensity test by eye section on the worksheet (Appendix V1).

3.4.2.2. Interpretation of results

There should be ample light in the cabinet to read the writing easily.

3.4.3. NOISE LEVEL TEST USING SOUND METER⁷

When connected to a suitable exhaust system, the VWS should not produce any excessive noise such as to interfere with work.

3.4.3.1. Purpose

This test provides a uniform method for measuring the noise level produced by the VWS when functioning at normal operating airflow.

3.4.3.2. Apparatus

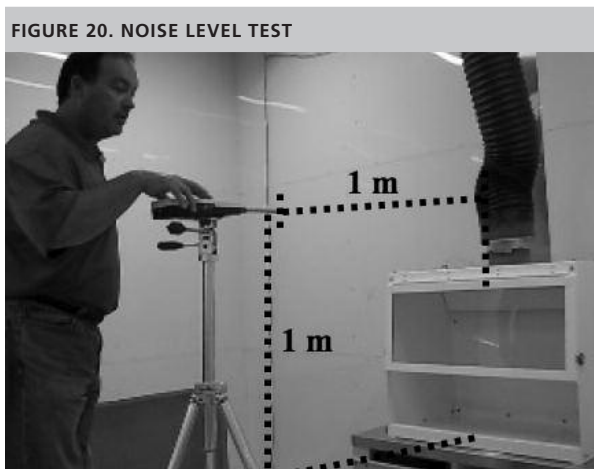
The sound meter should meet the following requirements: minimum accuracy of ± 1 Decibel (dBA), resolution of 1 dBA, range of 50 to 100 dBA and using the “A” weighting scale set up according to the manufacturer’s instructions.

3.4.3.3. Protocol

- Turn on the VWS and lights.
- Set up sound meter 1 m (39 in) from the front center and 1 m (39 in) above the VWS work surface (as indicated by the black dotted lines in Figure 20)⁸.
- Wait for sound meter to stabilize. Measure and record noise level in dBA.
- Turn off VWS and lights and measure background noise level.
- Record background and VWS noise level results on the worksheet.
- Complete the noise level section of the worksheet (Appendix V1).

3.4.3.4. Interpretation of results.

The noise level in front of the VWS should not exceed 67 dBA when the ambient sound level is 57 dB or less. If the background noise level is more than 57 dBA, the reading should be corrected according to tables provided in the sound meter operator’s manual.



7. Taken/adapted from NSF/ANSI 49 – 2008.

8. Taken/adapted from EN12469.

3.4.4. NOISE LEVEL TEST BY EAR

3.4.4.1. Protocol for noise level test without sound meter.

- Turn on blower and lights.
- Sit at VWS with second person situated 1 m (39 in) away to the side.
- Testers should be able to hear one another when speaking in their normal voice.
- Turn off blower and lights and notice ambient/background noise level as above.
- Complete the noise level by ear section of the worksheet.

3.4.4.2. Interpretation of results

A normal talking voice should be audible 1 m (39 in) from the tester while he/she is seated facing the front of the VWS. The background noise level must be addressed if a normal talking voice cannot be heard when the VWS is switched off.

3.4.5. VIBRATION TEST USING VIBRATION ANALYZER⁹

When connected to a suitable exhaust system, the VWS should not vibrate excessively such as to interfere with procedures.

3.4.5.1. Purpose

This test determines the amount of vibration in the VWS cabinet when operating under normal airflow conditions.

3.4.5.2. Apparatus

A vibration analyzer with a minimum reliability of 1.0×10^{-4} in (2.5×10^{-6} m) rms (root mean square) amplitude of displacement or the ability to detect differences of this magnitude, set up in accordance with manufacturer's instructions.

3.4.5.3. Protocol

- Turn on blower and lights.
- Place the vibration analyzer probe at the geometric centre of the VWS work surface (indicated by black dotted circle in Figure 21).
- Wait for vibration analyzer to stabilize. Measure and record net displacement (in or m rms amplitude) on the worksheet.

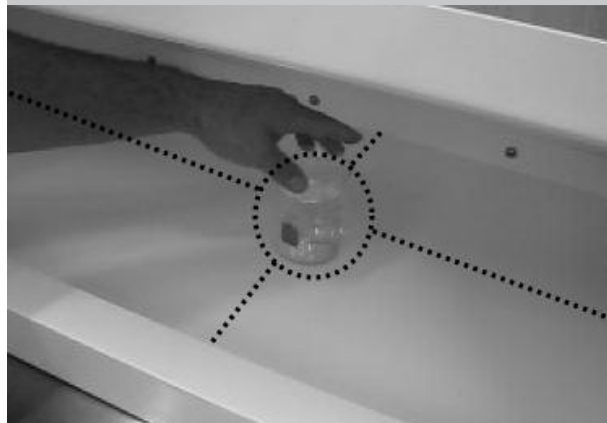
3.4.5.4. Interpretation of results.

The net displacement shall not exceed 2×10^{-3} in (5×10^{-5} m) rms amplitude at frequencies between 10 Hz and 10 kHz in the center of the work surface when the cabinet is operating at the design volumetric airflow rate.

FIGURE 21. VIBRATION TEST – PLACING THE PROBE 1



FIGURE 22. VIBRATION TEST – PLACING THE BEAKER



9. Taken/adapted from NSF/ANSI 49, Annex A.5

3.4.6. VIBRATION TEST BY EYE

3.4.6.1. Protocol for vibration test without vibration analyzer.

- Turn on blower and lights.
- Place a 200 ml beaker of water (about ½ full or containing 100 ml) in the geometric center of the work surface (indicated by the black dotted circle in Figure 22).
- Look for rippling on the water surface.
- Record observations on the worksheet (Appendix V1).

3.4.6.2. Interpretation of results

The surface of the water should be still. Ripples are an indication of too much vibration in the cabinet.

3.4.7. STABILITY¹⁰

The cabinet shall be designed and constructed to resist deflection under applied forces and resist deflection of the work surfaces under load.

3.4.7.1. Purpose

This test is recommended to be performed at the local manufacturing facility to ensure that the materials used to construct the VWS are sturdy.

3.4.7.2. Apparatus

Carpenter's square for measuring right angles.

3.4.7.3. Protocol

- With the blower and lights turned off, place the square against the right hand side of the VWS.
- Holding the square steady with the left hand, apply pressure to the top of the VWS with the right hand until the unit has displaced 20-30 mm (0.8-1.2 in). NB. There will be some movement in the VWS however, the unit should not displace easily (Figure 23).
- Hold the unit in the displaced position for a few seconds and then let go. Remember to keep hold of the square in its original position (Figure 24).
- Repeat steps 'c' and 'd' on the left hand side of the VWS.
- Record observations on the worksheet (Appendix V1).

3.4.7.4. Interpretation of results.

The left and right hand sides of the VWS should return to a 90 degree angle (against the square) after pressure is released.

FIGURE 23. STABILITY TEST – APPLYING PRESSURE

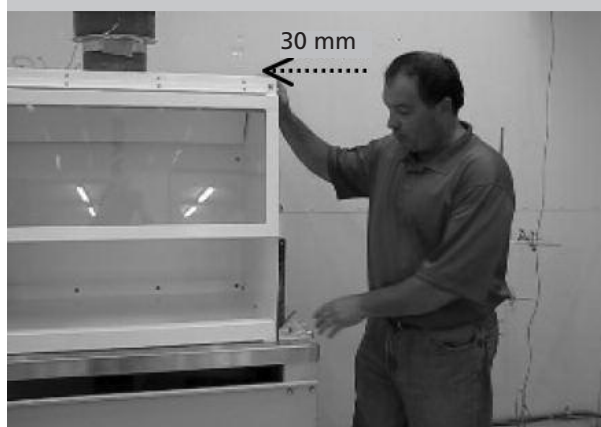


FIGURE 24. STABILITY TEST – ENSURING RETURN TO 90 DEGREES

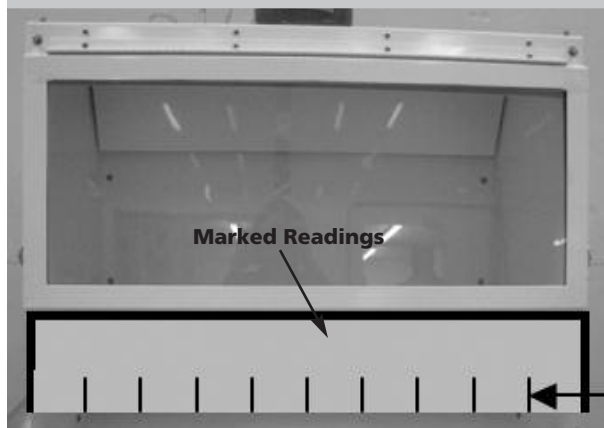


10. Taken/adapted from NSF/ANSI 49, Section 6.8

FIGURE 25. INWARD AIRFLOW TEST USING CARDBOARD INSERT



FIGURE 26. VWS WITH CARDBOARD MARKINGS



3.4.8. INFLOW VELOCITY¹¹ (RESTRICTED ACCESS /100 MM [4 IN] METHOD)

Determination of the air inflow velocity through the work access opening is one of the most important validation tests. This test verifies the correct amount of air is being pulled through the VWS by the extractor fan. Incorrect inflow velocity may lower the level of protection to the worker.

3.4.8.1. Purpose

The purpose of this test is to demonstrate that the VWS is capable of achieving the required inward airflow (as validated to provide containment).

3.4.8.2. Apparatus

A hotwire anemometer with a suitable range and sensitivity should be used, and should be calibrated according to manufacturer's recommendations. In addition, a flat sheet of cardboard (or hardboard) and tape are required.

3.4.8.3. Protocol

- Cut and tape in place a rectangular piece of cardboard 150 mm x 900 mm (6 in x 36 in) long to fit into the top of the 250 mm x 900 mm (10 in x 36 in) access opening. This will leave an opening along the bottom edge of approximately 100 mm x 900 mm (4 in x 36 in) for an open area of 0.09 m² (1 ft²) (Figure 25).
- Measure and mark along the 100 mm (4 in) opening, 9 readings, starting 50 mm (2 in) from the left sidewall with 100 mm (4 in) spacing. The 9 readings, starting from the left side of edge of the 100 mm (4 in) opening measure: 50 mm (2 in), 150 mm (6 in), 250 mm (10 in), 350 mm (14 in), 450 mm (18 in), 550 mm (22 in), 650 mm (26 in), 750 mm (30 in), and 850 mm (34 in) (Figure 26).
- Turn on the blower and lights.
- Place the hotwire anemometer probe tip filament center along the line of the 100 mm (4 in) opening, with the probe tip oriented upward.

11. Adapted from EN 12469

- e. The probe should be held against the bottom edge of the work station opening, oriented in a vertical, upward position, with each of the 9 readings taken 50 mm (2 in) up from the bottom edge of the work station or half way up in the vertical plane of the 100 mm (4 in) opening. Measurements are taken with reference to the center of the filament probe located near the end of the probe tip.
- f. For each reading, hold the probe for a minimum of 10 seconds and record the average velocity reading measured for that location (in meters per second).
- g. Record observations on the worksheet (Appendix V1).

3.4.8.4. Calculations

Fixed parameters for the designed VWS and opening:

$$\text{Area}_{\text{Restricted Access}} = \text{Length} \times \text{Height}$$

$$\text{Area}_{\text{Restricted Access}} = \mathbf{0.10\ m \times 0.90\ m = 0.09\ m^2}$$

$$\text{Area}_{\text{Design Access}} = \text{Length} \times \text{Height}$$

$$\text{Area}_{\text{Design Access}} = \mathbf{0.25\ m \times 0.90\ m = 0.225\ m^2}$$

Measured average airflow from anemometer: Velocity (m/s)

$$\text{Volumetric Airflow Rate (Q}_{\text{Restricted Access}}) = \text{Velocity} \times \text{Area} = \text{Velocity} \times \mathbf{0.09\ m^2}$$

$$\text{Velocity}_{\text{Calculated for design Access}} = \text{Q}_{\text{Restricted Access}} / \text{Area}_{\text{Design Access}}$$

Example:

Suppose average measured inflow velocity through the restricted access = 0.95 m/s

$$\text{Q}_{\text{Restricted Access}} = 0.95\ \text{m/s} \times \mathbf{0.09\ m^2} = 0.0855\ \text{m}^3/\text{s} \text{ Or } = 181.2\ \text{cfm}$$

$$\text{Velocity}_{\text{Calculated for design Access}} = \text{Q}_{\text{Restricted Access}} / \text{Area}_{\text{Design Access}}$$

$$\text{Velocity}_{\text{Calculated for design Access}} = 0.0855\ \text{m}^3/\text{s} / \mathbf{0.225\ m^2} = 0.38\ \text{m/s} \text{ Or } = 74.8\ \text{fpm}$$

Conclusion: Both total volumetric airflow rate and the calculated inflow velocity are within the design standards; however, they are near the lower limit.

3.4.8.5. Interpretation of results.

The average inflow air velocity for the VWS should not be less than 0.35 m/s (69 fpm). No individual measurement should differ from the mean by more than +/- 0.1 m/s (20 fpm). The fan should be adjusted and test repeated until the average calculated inflow velocity is between 0.35 – 0.55 m/s (69-108 fpm).

3.4.8.6. Volumetric Airflow rate Adjustments

Adjust the inflow velocity by increasing or decreasing the exhaust volumetric airflow rate. If the average inflow velocity is too low, increase the exhaust flow. If the average inflow velocity is too high, decrease the exhaust volumetric airflow rate. **Adjustments may be made by changing the fan speed, by adjusting the damper, or both.** Repeat until the proper inflow velocity from the measurements and calculations has been obtained.

3.4.9. DIRECT INFLOW MEASUREMENT (DIM)¹²

3.4.9.1. Purpose

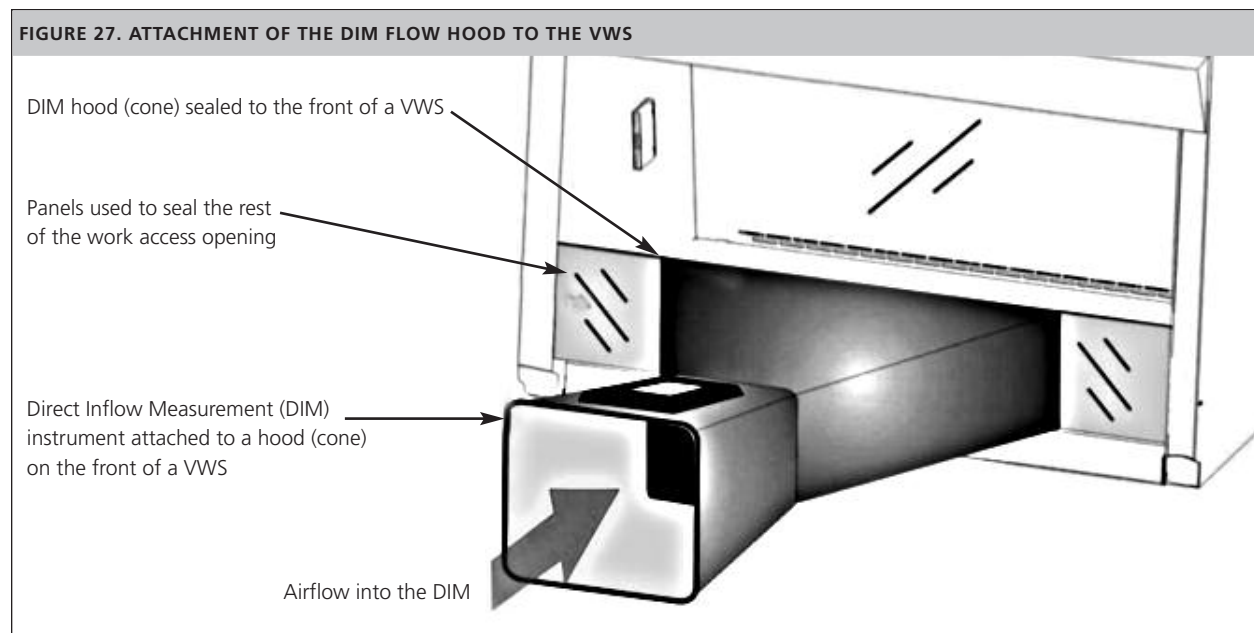
This test determines the measured and calculated inflow velocity through the work access opening and the calculated exhaust flow volume rate. A minimum of five individual volumetric readings shall be taken and averaged using a direct reading instrument. It may be used in place of the restricted access method shown in section 3.4.8. Either method may be used.

3.4.9.2. Apparatus

The direct inflow measurement (DIM) instrument shall be used to obtain direct measurement of inflow volume. An instrument with an accuracy of $\pm 3\%$ of reading $\pm 0.003 \text{ m}^3/\text{s}$ ($\pm 7 \text{ ft}^3/\text{min}$) shall be used for this test. An example of an acceptable instrument is a calibrated, NIST traceable flow hood.

3.4.9.3. Protocol

- Tape the DIM instrument flow hood to the center of the front opening of the ventilated workstation. Seal the open areas on either side of the capture hood portion of the DIM as necessary. Tape and simple closure panels (paper, cardboard, or wood) could be used for sealing (Figure 27).
- The VWS exhaust blowers must remain in operation during testing. Take at least five readings, and average them to determine inflow volume rate. Care should be taken not to restrict the airflow through the instrument intake area (i.e. do not stand directly in front of the DIM flow hood while performing the measurements (Figure 28)).
- Calculate the average inflow velocity in meters per second (or feet per minute) by dividing the average inflow volume rate in cubic meters per second (cubic feet per minute) by the work access opening area in square meters (square feet) (Figure 29).
- Include the following in the reported data: individual inflow volume rate readings, average inflow volume rate, work access opening dimensions and area, average inflow velocity.



12. NSF/ANSI 49, Annex A.9

FIGURE 28. THE DIM FLOW HOOD ATTACHED TO THE VWS



FIGURE 29. THE DIM FLOW HOOD ATTACHED TO THE VWS



3.4.10. AIRFLOW SMOKE TEST¹³

3.4.10.1. Purpose

This test determines that the airflow along the entire perimeter of the VWS work access opening is inward and that there is no escape of air to the outside.

3.4.10.2. Apparatus

A source of smoke should be used to provide visualization of airflow patterns in the VWS. Incense sticks or other small handheld smoke producing items are appropriate. Bear in mind that smoking is never allowed in the clinical laboratory. Cigarette and other tobacco related products are prohibited in the laboratory and must not be used.

3.4.10.3. Protocol

- Turn on blower and lights.
- Run the smoke source slowly along the entire external perimeter, approximately 40 mm (1.5 in) from the VWS work access opening (Figure 30).
- Record any observations on the worksheet (Appendix V1). Particular attention should be paid to corners and vertical edges. No smoke should be refluxed (returned) out of the VWS once drawn in.

FIGURE 30. AIRFLOW SMOKE TEST – EXTERNAL PERIMETER



13. NSF/ANSI 49, Annex A.10 and ASHRAE 110, section 6.1

FIGURE 31. AIRFLOW SMOKE TEST – INTERNAL PERIMETER



- d. Run the smoke source slowly along the internal perimeter, approximately 150 mm (6 in) from behind the VWS work access opening (Figure 31).
- e. Record any observations on the worksheet (Appendix V1). All smoke should be exhausted from the VWS. No visible smoke should flow out of the front of the VWS.

3.4.10.4. Interpretation of results.

When testing the external perimeter of the work access opening, all smoke should be drawn into the VWS. When testing the internal perimeter of the work access opening, no smoke should escape from the VWS into the room. Smoke not sucked into the VWS or escaping from the work access opening is a sign the air inflow velocity is too low. The fan and/or the damper would need to be adjusted to increase the exhaust volumetric airflow rate and the inflow velocity.

3.5. BIBLIOGRAPHY

ASHRAE, Standard 111-2008 Practices for Measurement, Testing, Adjusting and Balancing of Building Heating, Ventilation, Air-Conditioning and Refrigeration Systems. Atlanta (GA); 2008.

ASHRAE, Standard 62.1-2010 Ventilation and Acceptable Indoor Quality. Atlanta (GA); 2010.

European Committee For Standardization (CEN). EN 12469:2000 E. Biotechnology- Performance Criteria for Microbiological Safety Cabinets. Brussels; 2000.

NSF International (NSF); American National Standards Institute (ANSI). NSF/ANSI Standard 49-2009. Biosafety cabinetry: design, construction, performance, and field certification. Ann Arbor (MI); 2008.

3.6. APPENDICES

V1. VALIDATION CHECKLIST / LOGBOOK

Date		VWS ID/Site	Tester Initials	Tester Signature

Test and method used		Readings (shaded areas do not need to be filled)									Mean	Observations and corrective actions	
		1			2			3					
Light Intensity	Light meter	___ lx ___ ft candles			___ lx ___ ft candles			___ lx ___ ft candles			___ lx ___ ft candles		
	By eye	Record observations											
Noise Level	Sound meter	___ dB (background)						___ dB (test)					
	By ear	Record observations											
Vibration	Analyzer	___ in or m rms (indicate whether in or m)											
	Water test	Record observations											
Stability	Using square	Record observations											
Inflow Velocity (restricted access)	Anemometer	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ Av.		
Inflow Velocity (calculated design access)		___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ m/s ___ cfm	___ Av.		
Smoke	Smoke	Record observations											

V2. REFERENCE VALUES

Validation test	Standard Reference	Minimum	Maximum	Corrective Action
Light Intensity	NSF/ANSI 49 - 2009	650 lx (60 ft-candles)	N/A	
Noise Level Test	NSF/ANSI 49 - 2009	N/A	67 dB _A (assuming background <57dB _A)	
Vibration Test	NSF/ANSI 49 - 2009	N/A	5 x 10 ⁻⁵ m rms amplitude at 10 Hz to 10 kHz	
Inflow Velocity (restricted access)	Determined during prototype testing	0.88 m/s (173 fpm)	1.38 m/s (272 fpm)	
Inflow Velocity (design access)	Determined during prototype testing	0.35 m/s (69 fpm)	0.55 m/s (108 fpm)	

4. User Manual

4.1. OPERATION

The purpose of the VWS is to provide a safe work environment for preparing sputum smears for AFB staining or sample manipulations that inactivate sputum specimens for automated molecular testing systems e.g., GeneXpert MTB/RIF Assay from Cepheid (Padmapriya *et al*, 2010).

The VWS should never be used for procedures that increase the risk of generating aerosols including: decontamination or concentration of sputum samples involving centrifugation or vortexing, and handling of solid or liquid cultures. Use of the VWS should not replace attention to careful technique to minimize risks and assure high quality smears. Similar to the WHO's recent Infection Control Guidelines and biosafety principles, use of the VWS is one engineering solution that should be used in addition to administrative precautions such as having patients collect specimens outside of the laboratory (World Health Organization, 2009).

The following steps should be performed before each use of the cabinet. Following these steps will ensure proper VWS operation and equipment longevity:

4.1.1. STARTING UP

- a) Switch on the VWS fan and light.
- b) Check the VWS opening to ensure there are no obstructions.
- c) Allow VWS to run for 5 min before beginning work.
- d) Wipe down the cabinet internal surfaces with a disinfectant (see section 4.3).
- e) Ensure the inward airflow by visual means (see section 4.2).

4.1.2. WORKING AT THE VWS

The following recommendations play a part in worker's safety, comfort and health.

- a) Assemble all items required for smear preparation inside the VWS before starting the work.
- b) Use an adjustable chair or stool with a backrest and ensure sufficient legroom under the VWS.
- c) Sit in a comfortable position with a straight back where the entire work surface can be viewed clearly.
- d) Make sure there is enough light to see the work surface without the need to squint. **It should be possible to read handwritten sample identifiers easily.**
- e) Lay out samples and supplies neatly so that all items can be handled easily and the need to reach across the cabinet is limited. Do not overcrowd or clutter the work surface. **NB. It is important to minimize arm movement in the VWS as this disrupts the flow of air.**
- f) Place items in the VWS so that work flows from 'clean' to 'contaminated' areas. **NB. A small waste bag/container should be placed inside the VWS for collecting contaminated applicator sticks.**
- g) Open one specimen at a time and follow the standard operating procedure for smear preparation.
- h) Prepared smears can be left inside the VWS for drying.
- i) Once the slides are completely dry, bring them outside of the VWS for fixation.
- j) Remove all samples, waste containers and remaining supplies from the VWS.

4.1.3. SHUTTING DOWN

- a) Allow the VWS to run for 5 min after work has been completed.
- b) Remove all materials, specimens and supplies from the VWS. Do not use the VWS to store items.
- c) Wipe down the cabinet internal surfaces with a disinfectant (see section 4.3).
- d) Turn off the VWS fan and light.

4.2. DAILY AIRFLOW CHECKS

An inward airflow check must be performed to ensure the VWS is functioning properly and providing protection to the worker. This could be achieved by taping a thin plastic or paper strip at the top edge of the opening window. The strip would flutter inside the VWS when turned-on. In case of any doubts, airflow checks using an anemometer (see section 4.2.2) must be performed to ensure the directional and sufficient airflow.

4.2.1. AIRFLOW MEASUREMENT EQUIPMENT (ANEMOMETER)¹⁴

An anemometer (either thermal or rotational/vane) is the preferred means to measure the flow of air drawn into the VWS. Inflow checks using swinging vane anemometer could be performed daily.

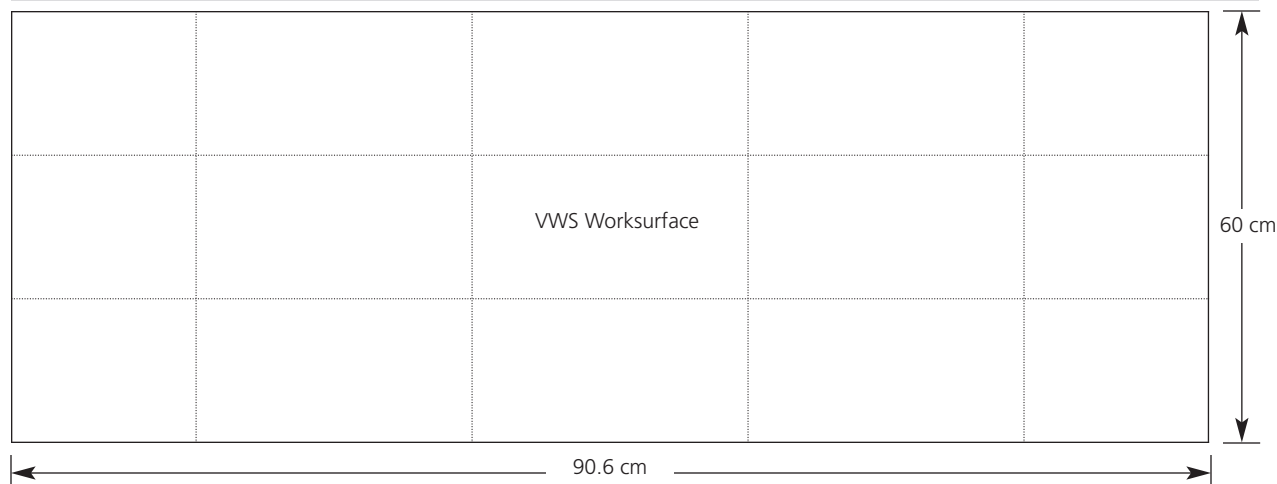
4.2.1.1. Measuring the Intake Velocity in the VWS

The anemometer probe or vane should be placed 5 cm above the lower edge of the front window.

- a) Airflow measurements should be taken at 8 points across the work surface (the intersection of the grid at points 1-8 in Figure 32).
- b) Each measurement should be made for 60 seconds to allow anemometer to stabilize (take an average reading over the 60 s).
- c) Record the results of each measurement on the 'Daily Checklist' in Appendix A.
- d) Take the average of the 8 measurements. The average should be between 0.35 – 0.55 m/s (69-108 fpm).

Warning: Do not use the VWS if the average intake velocity is less than 0.35 m/s or greater than 0.55 m/s. Record the issue on the intake velocity worksheet and contact the laboratory manager, qualified engineer or manufacturer. Retain a record of all contacts made and subsequent steps taken on the worksheet.

FIGURE 32. POSITIONING THE ANEMOMETER TO MEASURE AIRFLOW (THE TUBERCULOSIS COALITION FOR TECHNICAL ASSISTANCE, 2010)



14. Adapted from "Use and maintenance of class I and class II biological safety cabinets," the Tuberculosis Coalition for Technical Assistance (TBCAP).

4.3. CLEANING

- Ensure that disinfectants and cleaning agents are suitable for use on the VWS surfaces and window and biocidal for *M. tuberculosis*. Some of the commonly used disinfectants in laboratory are: 70% alcohol, 5% phenol, and 10% bleach (0.5% sodium hypochlorite).
- The internal surfaces of the VWS should be cleaned at least twice per day. This must be done before beginning work at the start of the day and after finishing work at the end of the day.
- Waste must be removed from the VWS at the end of every day (and periodically throughout the day depending upon workload).
- The VWS cabinet, including window and all other surfaces, should be cleaned and decontaminated with disinfectant.
- Be sure to clean all surfaces, especially under the lip, the work access opening, corners, and baffle (sloped area above internal surface of window).

NB. Bleach solutions may corrode metal surfaces of the VWS and should be followed immediately by wiping with 70% alcohol solution.

4.4. MONTHLY CHECKS

4.4.1. VISUAL INTEGRITY CHECK

The purpose of performing monthly visual integrity checks is to identify any potential structural or mechanical defects that may require attention. These include problems with the exhaust fan or ducting that may lead to excessive noise and vibration. All observations and any steps taken must be recorded on the checklist in Appendix U2.

- Check the workstation internal and external surfaces for cracks, abrasions and corrosion.
- Check the duct (externally) making sure there are no cracks and that the duct appears enclosed around the duct outlet.
- Check the window for cracks and scratches ensuring visibility of the internal work surface is adequate.
- Check to ensure the light is fully functional.
- Check that the cabinet does not vibrate excessively.
- Check the exhaust fan does not make excessive noise.
- Record the results of the visual integrity check on the checklist in Appendix U2.

4.4.2. AIRFLOW CHECK

Monthly airflow checks by using anemometer (see section 4.2) must be performed to ensure the proper inflow velocity. Follow the procedure as described and record results on the worksheet in Appendix U2. If results do not fall within reference values, revalidate according to section 3.4.8.

4.4.3. SMOKE TEST

The smoke test determines that the airflow along the entire perimeter of the VWS work access opening is inward and that there is no escape/reflux of air to the outside.

4.4.3.1. Smoke Test Equipment

A source of smoke should be used to provide visualization of airflow patterns in the VWS. Incense sticks or other small handheld smoke-producing items are appropriate.

4.4.3.2. Smoke Test Protocol

NB. The smoke test (photos shown in section 3.4.10) was performed on a newly manufactured VWS in a clean factory setting. When performing the smoke test in the laboratory setting, always wear personal protective equipment (gloves and lab coat).

- a) Turn on blower and lights.
- b) Run the smoke source slowly along the entire external perimeter, approximately 40 mm (1.4 in) from the VWS work access opening.
- c) Record any observations on the worksheet (Appendix U2). Particular attention should be paid to corners and vertical edges. No smoke should be refluxed out of the VWS once drawn in.
- d) Run the smoke source slowly along the internal perimeter, approximately 150 mm (6 in) from behind the VWS work access opening.
- e) Run the smoke source slowly along the internal perimeter, approximately 150 mm (6 in).
- f) Record any observations on the worksheet (Appendix U2). All smoke should be exhausted from the VWS. No visible smoke should flow out of the front of the VWS.

4.5. SAFETY PROCEDURES¹⁵

Laboratory personnel must follow good laboratory practice all the time. No eating, drinking, and smoking is allowed in the laboratory. Food must not be stored in the laboratory refrigerators. If available, disposable gloves, a laboratory coat and sturdy closed-toe shoes should be worn while working with potentially infectious material. Disposable gloves are for one-time use only and must be taken off at the end of the each work session. Gloved hands, which could spread contamination, must not touch surfaces such as door handles, telephones, pens, and microscope handles.

4.5.1. WHEN TO STOP USING THE VWS

Do not use the VWS in the event of the following:

- If the VWS or laboratory loses power.
- If the daily or monthly checks indicate a problem with airflow.
- If there is a spill inside the workstation.

4.5.2. WHAT TO DO DURING SUDDEN LOSS OF POWER OR SPILL

In the event of sudden power loss or spill:

- a) Close any open sample tube.
- b) Place items towards the back of the workstation (or at the back and away from the spilled material).
- c) If responding to a spill, follow the procedure for clean up (section 4.5.3).
- d) Do not use the VWS until the problem has been resolved (power has returned or spill has been properly cleaned up); however, keep the VWS fan on.

15. Adapted from (U.S. Department of Health and Human Services, 2007)

4.5.3. CLEANING UP SPILLS INSIDE THE VWS

For biohazardous spills within the VWS, clean-up should begin immediately and be performed while the cabinet is running. Disinfectant should be applied in a manner that minimizes generation of aerosols.

Always follow universal safety precautions when handling broken glass containers with or without specimen or other sharps.

4.5.3.1. Materials required

- Absorbent tissue
- Rubber gloves
- Forceps
- Waste bags and containers
- Disinfectant

4.5.3.2. Protocol

- a) Place absorbent tissue over the spill area and apply disinfectant solution liberally.
- b) Pick up contaminated material using forceps and thick rubber gloves and place in an autoclavable container.
- c) Discard contaminated waste in the appropriate manner.
- d) Any laboratory worker in the vicinity of the spill must dispose of their gloves and immediately wash hands and forearms. In case of wounds, cuts or abrasions, medical care should be sought immediately.

4.6. SERVICING, MAINTENANCE AND REPAIR

The VWS is designed to be maintained by the user. The user should perform all daily and monthly cleaning and maintenance checks and keep a record of all results and observation.

Prior to servicing, maintenance or repair, the VWS must be decontaminated by cleaning all surfaces with an appropriate disinfectant (see section 4.5).

Qualified personnel should be contacted in the following circumstances:

- When the average airflow measurement falls below 0.35 m/s (69 fpm) or above 0.55 m/s (108).
- If there are gaps in the joints or severe corrosion of the cabinet.
- If the window is broken or the view of the work surface is compromised such that work cannot be performed with ease.
- If the smoke test results show smoke escaping from the work access opening after being drawn into the cabinet or smoke escapes from another part of the cabinet or duct.
- If the duct has separated from the duct outlet.
- If the duct has cracked or degraded.
- If there is excessive noise or vibration.

The VWS can only be repaired by qualified personnel. The user should not attempt repair. The VWS should be re-validated (inflow velocity and airflow smoke test) after major repair of the cabinet, replacement of a panel or window, duct and fan (including component parts). Validation must be performed by qualified personnel.

4.7. BIBLIOGRAPHY

Padmapriya, P. B., Sivasubramani, S. K., Blakemore, R., Boehme, C., Perkins, M. D., & Fennelly, K. a. (2010, Oct). Containment of bioaerosol infection risk by the Xpert MTB/RIF assay and its applicability to point-of-care settings. *Journal of Clinical Microbiology*, 48(10), pp. 3551-3557.

The Tuberculosis Coalition for Technical Assistance. (2010). TB Diagnosis Tools. Retrieved from TB|CTA: <http://www.tbcta.org/Library/>

U.S. Department of Health and Human Services. (2007). Biosafety in microbiological and biomedical laboratories. 5th. Washington, District of Columbia, USA: U. S. Government Printing Office.

World Health Organization. (2009). WHO policy on TB infection control in health-care facilities, congregate settings and households. Retrieved from WHO policy on TB infection control.: http://whqlibdoc.who.int/publications/2009/9789241598323_eng.pdf

4.8. APPENDICES

U1. DAILY CHECKLIST					
DATE:				SITE:	
ROOM:				VWS:	
DAY	STAFF INITIALS	CLEANING (WRITE YES/NO)		AIRFLOW VISUAL CHECK (WRITE YES/NO)	OBSERVATIONS / COMMENTS
		PRE-WORK	POST-WORK		
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

U2. MONTHLY CHECKLIST					
DAY:	MONTH:			YEAR:	
SITE:	ROOM:			VWS:	
NAME:				SIGNATURE:	
INTEGRITY CHECKLIST (VISUAL)					
CHECK	RESULT (CIRCLE ALL THAT APPLY)				COMMENT
Internal surface	OK	Cracks	Abrasions	Corrosion	
External surface	OK	Cracks	Abrasions	Corrosion	
Duct	OK	Cracks	Degradation	Other	
Window	OK	Cracks	Scratches	Degradation	
Light	OK	Flicker	No light	Other/Comment	
Vibration	No vibration	Vibration			
Noise	No noise	Noise			
Smoke Test	PASS	FAIL			
INFLOW VELOCITY AND DIRECTION (USING ANEMOMETER)					
POSITION	RECORDED INFLOW VELOCITY (M/S OR FPM)				COMMENT
1					
2					
3					
4					
5					
6					
7					
8					
Total					
Average	(total/8)				

5. Main Appendices

5.1 GLOSSARY

Baffle | A static device inside and near the roof of the VWS that regulates the flow air.

Biological Safety Cabinet | A self-contained enclosure that provide protection for personnel, environment and/ or products against hazardous microorganisms. Also known as microbiological safety cabinet or biosafety cabinet.

Damper | A bladed device that can be opened or closed to regulate airflow through a duct system.

Duct | Tubing (may be rigid or flexible) that connects the VWS from the exhaust collar in the cabinet roof to the extractor fan in the wall. Also known as ductwork.

Duct Static Pressure | The pressure acting on the walls of a duct. (technically, it's the total pressure minus the velocity pressure).

Exhaust Collar | The opening in the roof of the VWS to which the duct is attached.

Fan Curve | Diagram giving the pressure/volume characteristics of a fan, and often the power required by the fan.

Intake Velocity | The rate of air intake through the VWS access opening (measured in m/s or fpm).

Motor-blower | The exhaust fan motor.

Refluxed | Air escaping out of the VWS back into the room rather than being draw out through the exhaust.

Total Static Pressure | In ventilation applications, static pressure is usually the difference between the absolute pressure in an exhaust system and atmospheric pressure, such that static pressure less than atmospheric pressure is termed "negative static pressure" and static pressure above atmospheric pressure is termed "positive static pressure."¹³

Total Static Pressure loss | Sum of static pressure losses (negative) before and after the ventilator.

Validation | A series of tests carried out on each manufactured VWS to ensure minimum requirements of personnel protection are attained.

Velocity | A vector measurement that specifies the time rate of change of displacement and direction; i.e., the first derivative of the displacement with respect to time¹⁶.

Water Gauge | Inches of Water Gauge (in. w.g.) – A unit of pressure equal to the weight of a column of liquid water one inch high at 20° C (1 in. w.g.=0.036 psi).

16. Source: The Baker Company (<http://www.bakerco.com/glossary.html>)

5.2 VWS FREQUENTLY ASKED QUESTIONS

1. What is the ventilated workstation?

The VWS is a partially-enclosed workspace from which air is drawn inward, away from the user and exhausted outside of the laboratory.

2. Is it a bio-safety cabinet?

The VWS is not a biological safety cabinet. It has not been constructed nor tested to the same standards.

3. What is the use of ventilated workstation?

The purpose of VWS is to provide a safe work environment when preparing sputum smears for AFB staining.

4. Does it replace Good Laboratory Practices?

No, the VWS does not replace good laboratory practice.

5. Does it provide worker safety?

Yes, along with good laboratory practices a well maintained VWS provides worker safety.

6. Does it provide product protection?

No, the VWS does not provide product protection.

7. What samples can be processed in it?

The purpose of the VWS is to provide a safe work environment when preparing sputum smears for AFB staining or sample manipulations that inactivate sputum specimens for automated molecular testing systems. Complete sample inactivation for a rapid PCR based method has been published (Padmapriya *et al*, 2010).

8. Can it be used for other sample manipulations?

The VWS should never be used for procedures that increase the risk of generating aerosols including: decontamination or concentration of sputum samples involving centrifugation or vortexing, and handling of solid or liquid cultures. It should never be used for culture or manipulation of cultures that may be growing *M. tuberculosis*.

9. Can it be used for initial TB culture?

The VWS cannot be used for initial TB culture.

10. Can it be used for other bacterial cultures?

The VWS has not been designed for manipulating bacterial cultures.

11. Can it be used for making smears from TB cultures?

No, the VWS should never be used for making smears from TB cultures.

12. Can it be used for performing TB drug susceptibility testing?

The VWS should never be used for performing TB drug susceptibility testing on liquid or solid cultures.

13. Does it mean that making smears from sputum specimens on an open bench is dangerous?

Making smears on an open bench does not carry an increased risk for transmission of TB provided good laboratory practice is observed and the space has adequate natural ventilation with directional airflow away from the worker. However, if such practices cannot be observed, the risk of exposure may be increased.

14. We are making sputum smears on open benches for many years. What is the need for ventilated workstation now?

The World Health Organization supports the preparation of sputum smears for AFB staining on the open bench and emphasizes the importance of using good laboratory practices to ensure personnel safety. The World Health Organization also offers advice on laboratory work flow and ventilation. The VWS expands the range of primary safety barriers available to health workers and offers a safe alternative to laboratories where adequate ventilation is not available or possible.

15. Can smears be made from the sputum specimens on the open benches if there is a power failure?

Yes, as long as good laboratory practices and directional airflow away from the worker are ensured.

16. Is it battery operated?

The current model is based upon regular power. However, the use of battery depends upon the fan. As long as the fan can be validated in providing adequate airflow, it can be operated by battery.

17. How many persons can work in it?

Only one person can use it at a time.

18. Where can I get the VWS?

You should contact your local or regional manufacturer. If you do not currently have a local or regional manufacturer, you can provide this manual to companies with the capacity to fabricate the VWS¹⁷.

19. What is the assurance that locally made ventilated workstation will provide safe work environment?

As long as the local manufacturer follows the design and validation instructions correctly, the VWS will provide a safe work environment.

20. Does the VWS require regular monitoring?

Yes, there are very important daily and monthly checks that must be performed. The results of these checks must be recorded along with any actions taken.

21. Does the VWS require periodic validation?

The VWS only requires validation after manufacture, installation and major repairs (see section 4.6.). Users must check and maintain the VWS according to the instructions for daily checks (see section 4.2.) and monthly checks (see section 4.4.).

22. Who can perform the validation?

Validation of the VWS is relatively simple. However, it should only be performed by personnel trained by the manufacturer or in line with the requirements of the national body concerned with laboratory equipment. Each country or region will need to set the competency standard.

23. Who can repair the ventilation workstation?

Repair of the VWS should only be performed by personnel trained by the manufacturer or in line with the requirements of the national body concerned with laboratory equipment. Each country or region will need to set the competency standard.

17. No commercial manufacturers were available at the time of this manual going to press. It is intended that the VWS Manual be shared with potential national and international manufacturers so that VWSs may be provided as demand grows.

24. How it can be cleaned?

The VWS can be cleaned by surface wipe by using appropriate disinfectant.

25. Does it require decontamination prior to repair?

Yes, a thorough cleaning of internal surfaces by surface wipe method with appropriate disinfectant is required prior to repair.

26. Can open flame be used inside the ventilated workstation?

No, the VWS is used for preparing and drying sputum smears only. Open flames could interfere with airflow and cannot be used inside the VWS.

27. Where can I get more information on ventilated workstation?

You can get more information by contacting CDC: wwwn.cdc.gov/dls/ila/default.aspx,
APHL: www.aphl.org/AboutAPHL/publications/Pages/default.aspx or GLL: www.stoptb.org/wg/gli/

28. Is there any cost to the guidance document?

No, the guidance document is free.

29. Can I make the ventilated workstation for profit?

There are no restrictions on making the VWS for profit.

30. How much does the VWS cost?

The VWS design specifications were developed so that each unit could be made at minimum cost. It is not possible to give an accurate figure for cost as input materials, labor and shipping (not to mention inflation over time) vary greatly from country to country.

5.3 CAD DRAWINGS FOR CABINET CONSTRUCTION

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:

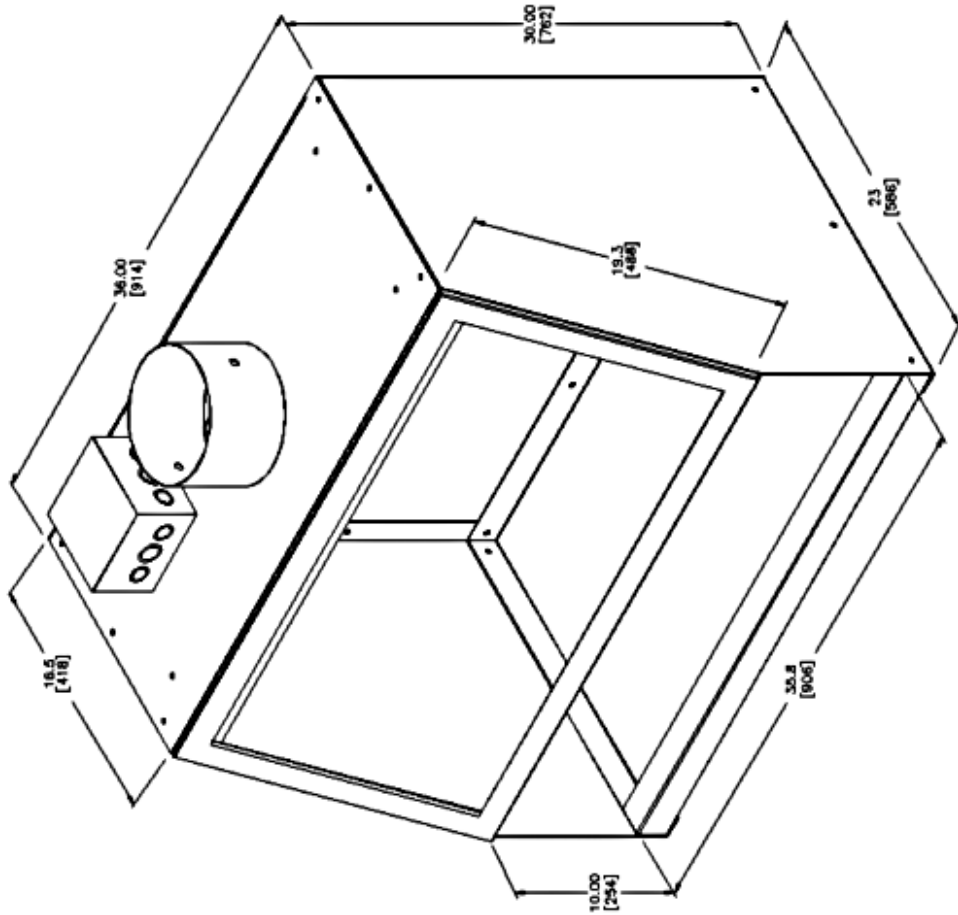
The front inward airflow opening dimensions must be maintained.

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

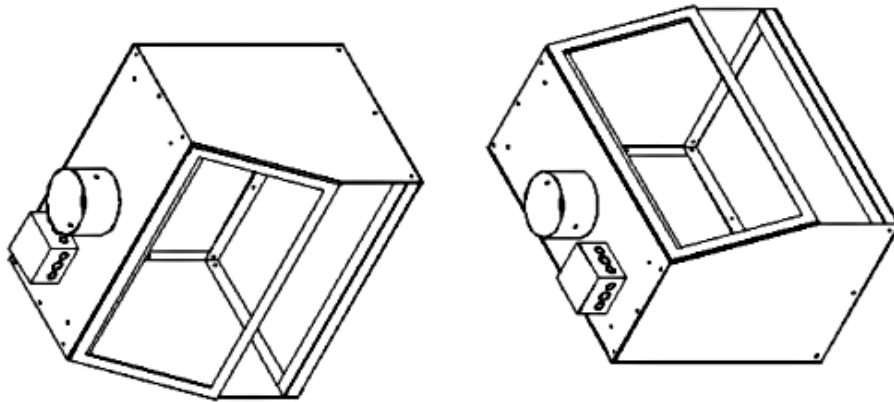
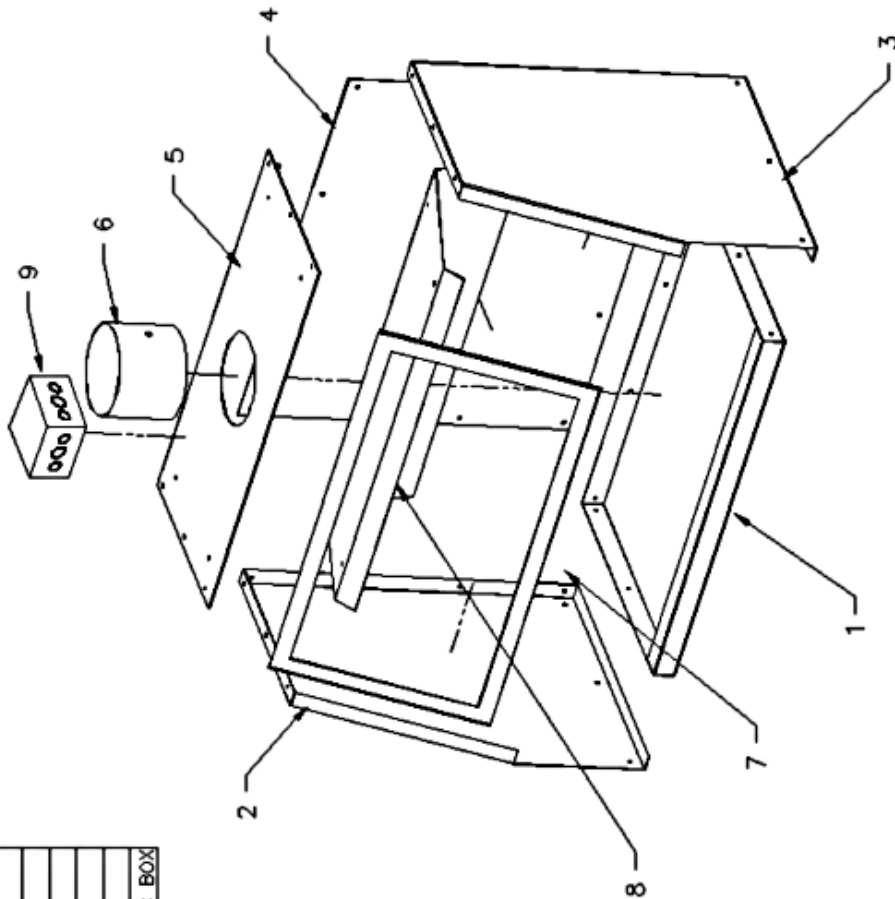
The selection of material for the cabinet must be able to withstand bleach. Aluminum or sheet metal can be used but it must be properly coated with epoxy paint or equal. Stainless steel can also be used but it is not ideal for use with bleach.

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

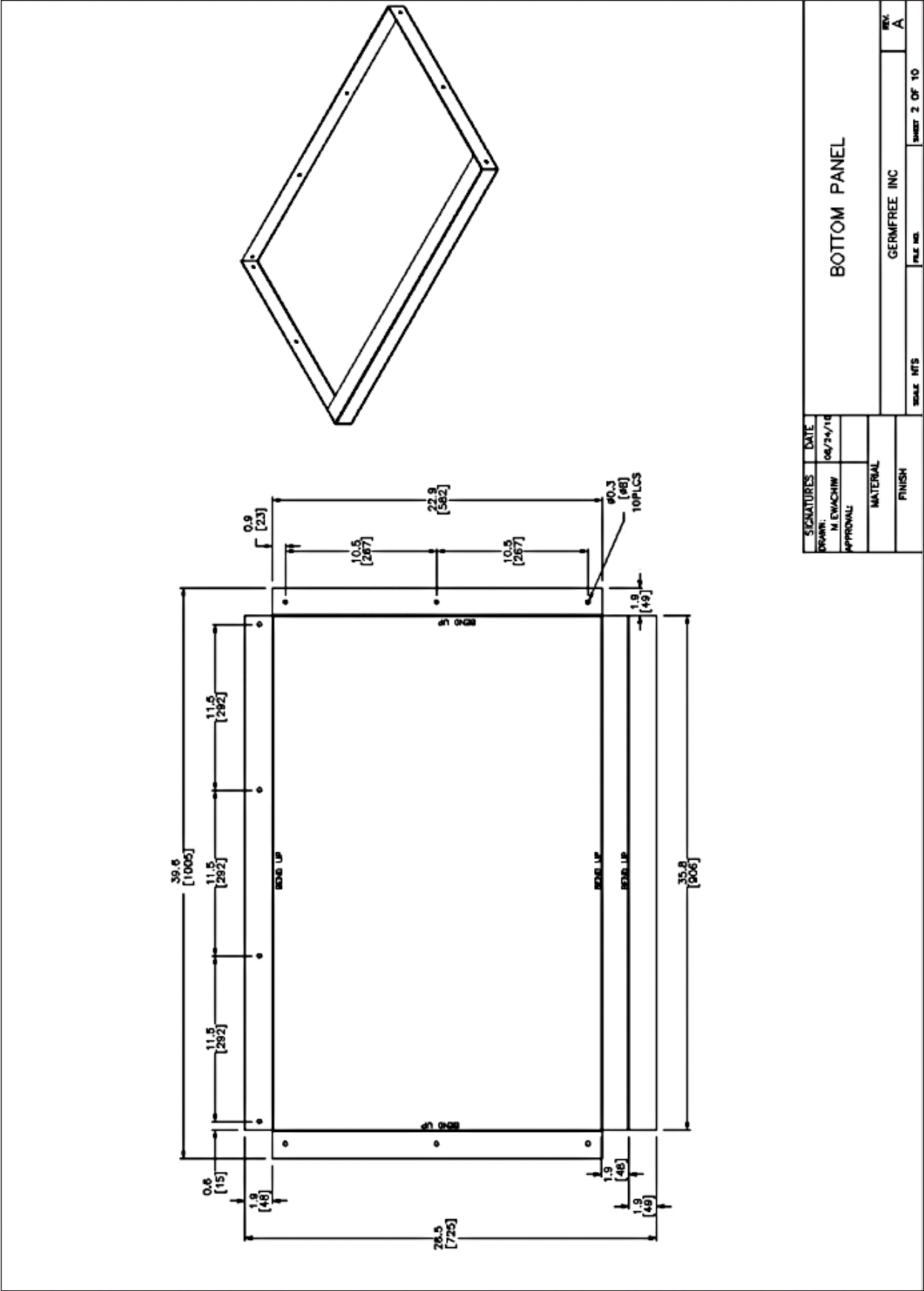
A light housing needs to be attached to the top of the window- on the outside.

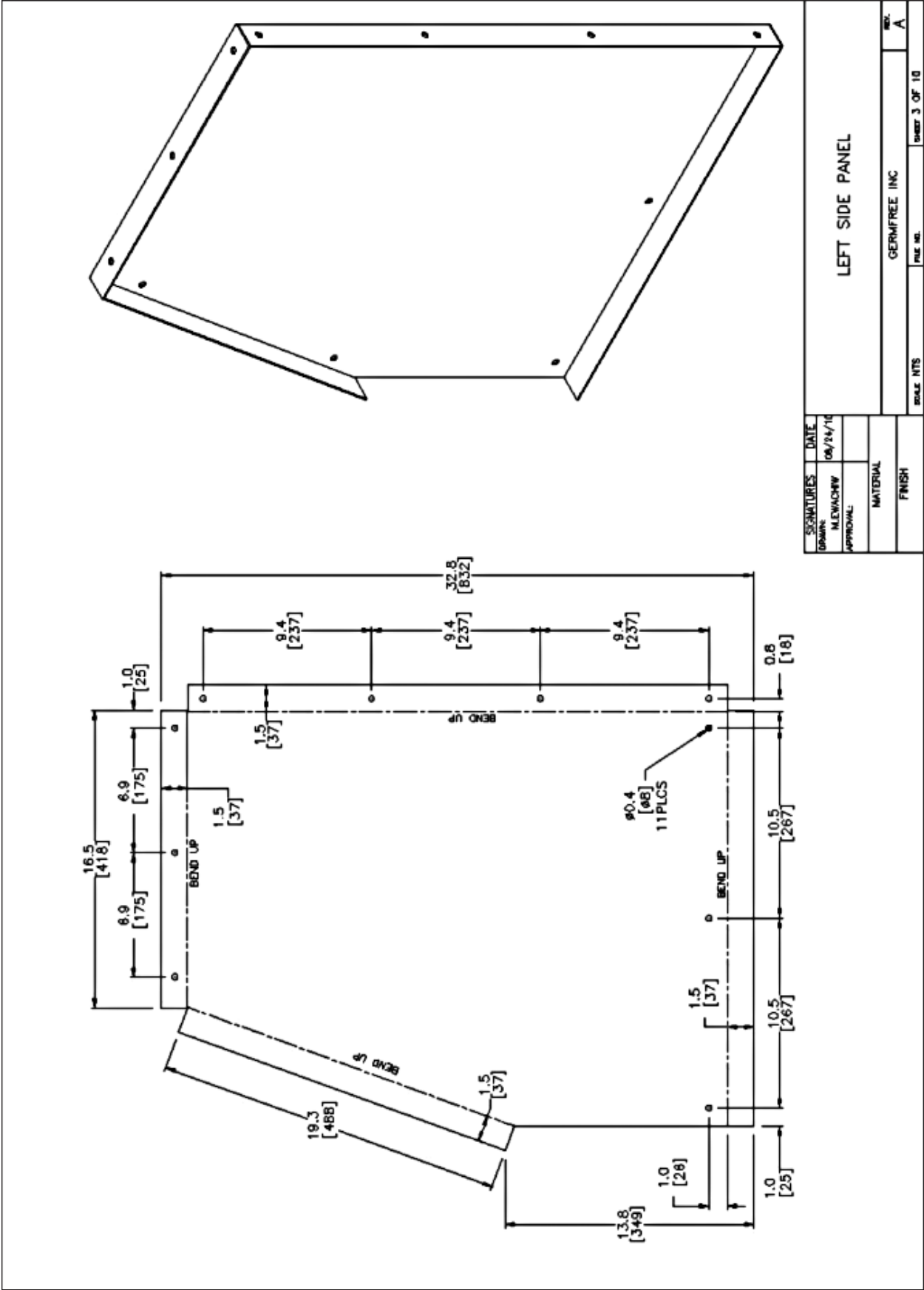


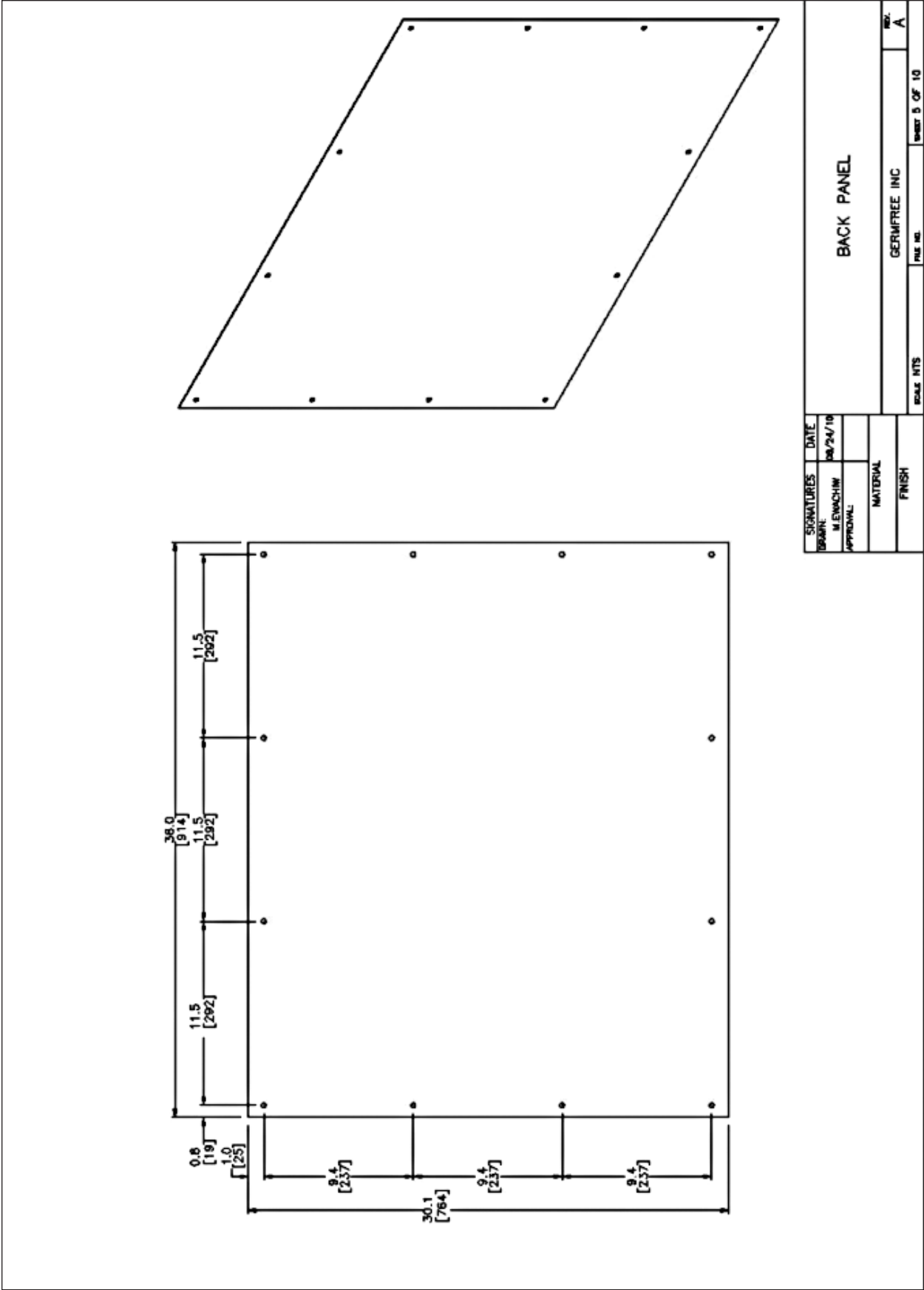
BUILD OF MATERIALS	
ITEM #	DESCRIPTION
1	BOTTOM PANEL
2	LEFT SIDE PANEL
3	RIGHT SIDE PANEL
4	BACK PANEL
5	TOP PANEL
6	TOP FLANGE
7	WINDOW FRAME
8	BAFFLE
9	ELECTRICAL JUNC BOX

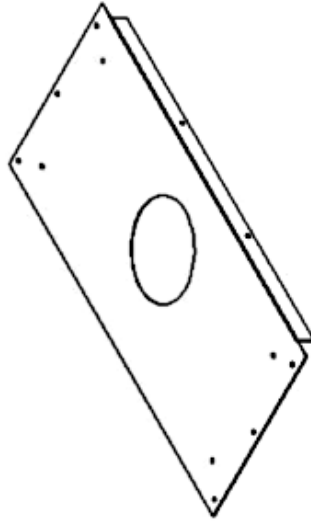


SIGNATURES		DATE
DRAWN: M. LEWACH		08/24/10
APPROVAL:		
MATERIAL		
FINISH		N/A
SCALE: NTS		FILE NO.
GERMIFREE, INC.		SHEET 1 OF 10
REV. A		





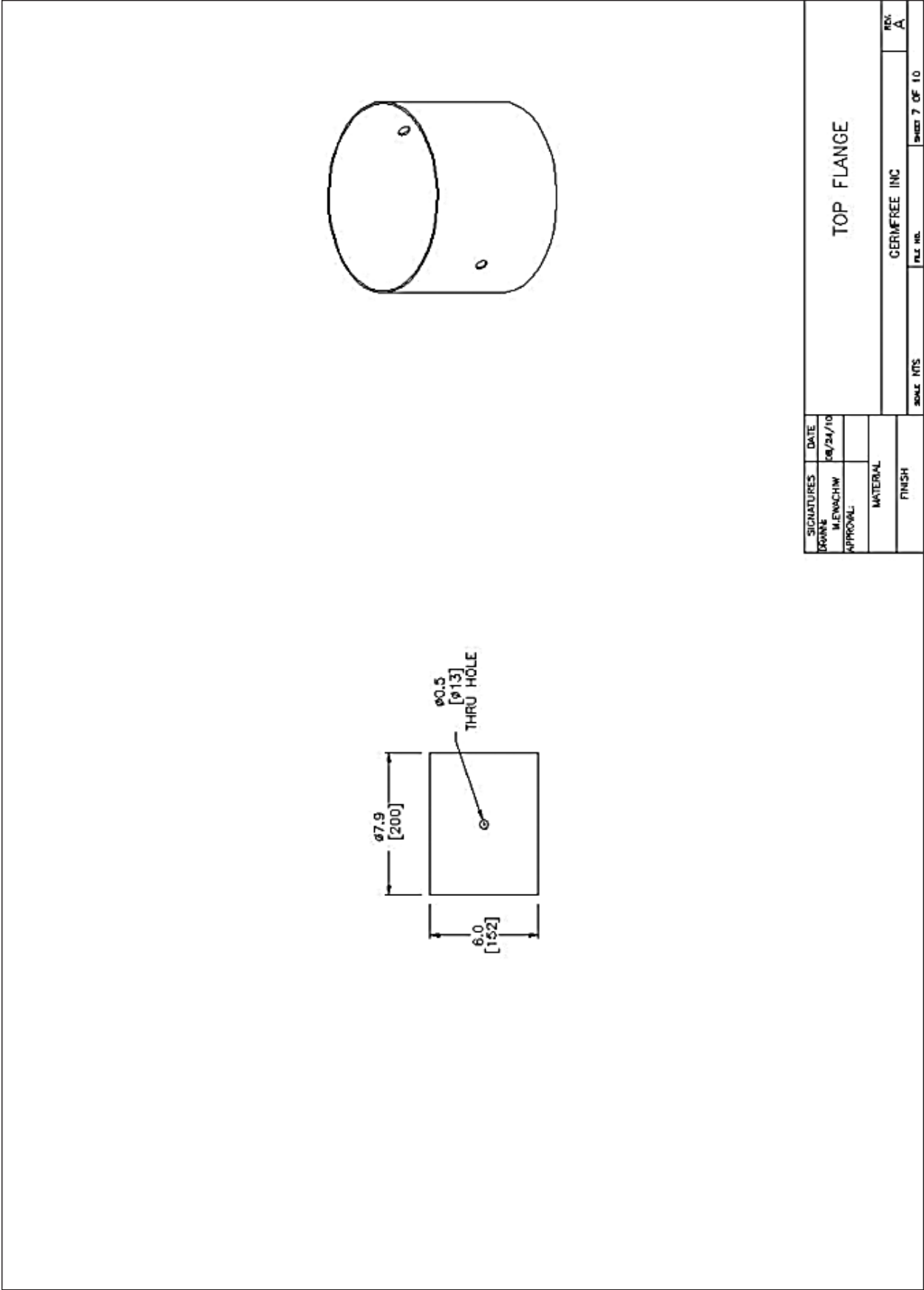




SIGNATURES	DATE
DRAWN	08/24/10
CHECKED	
APPROVAL	
MATERIAL	
FINISH	

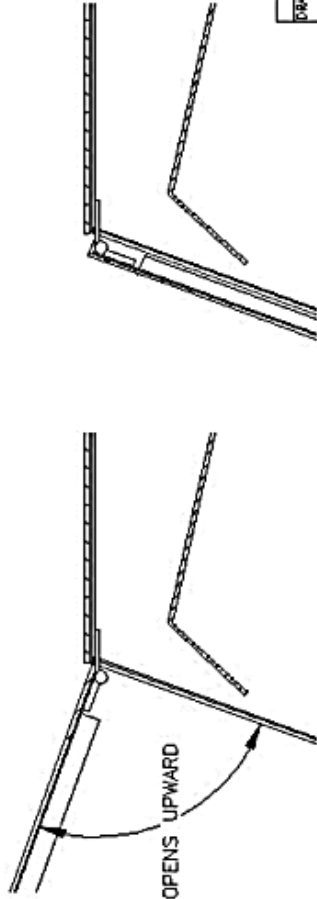
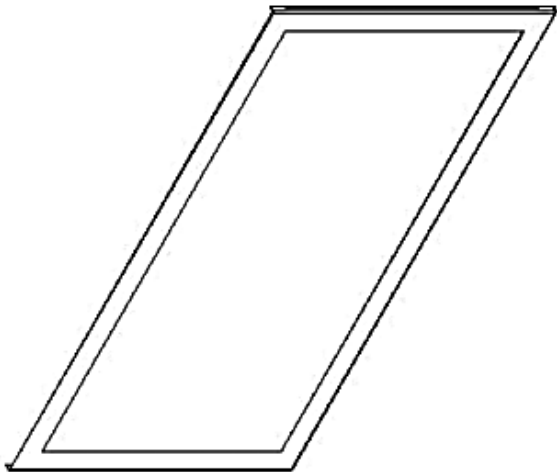
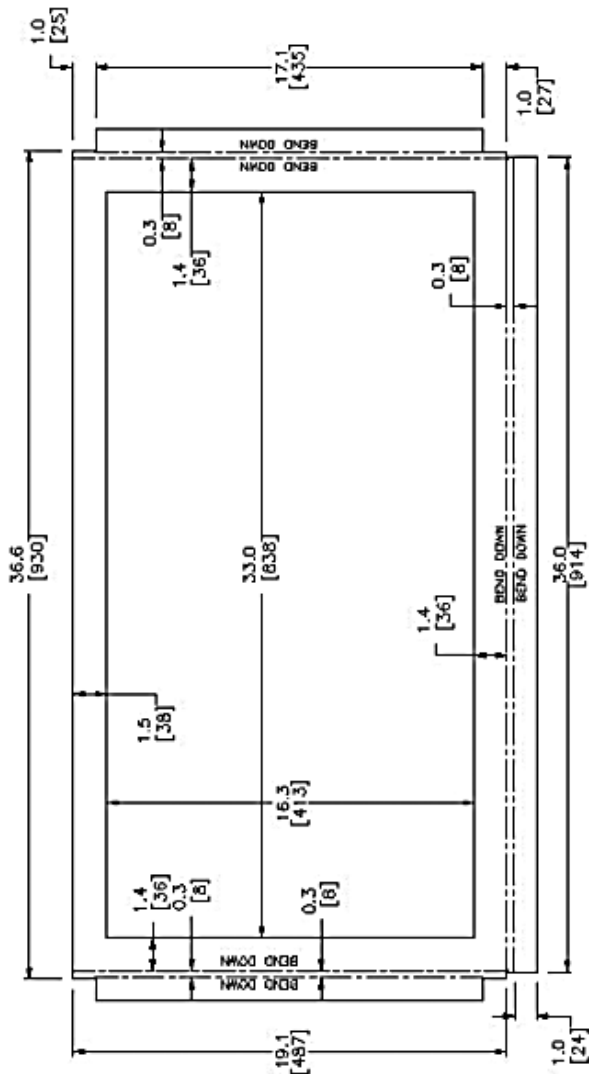
TOP PANEL

REV A	GERMFREE INC	
SCALE NTS	FILE NO.	SHEET 6 OF 10



NOTES:

- 1. THE WINDOW NEEDS TO BE HINGED AT THE TOP TO ALLOW IT TO OPEN. SEE DETAIL BELOW
- 2. 1/4" WINDOW WILL SLIDE INTO PLACE AND HINGE WILL BE PLACED AFTER WINDOW INSTALLED.

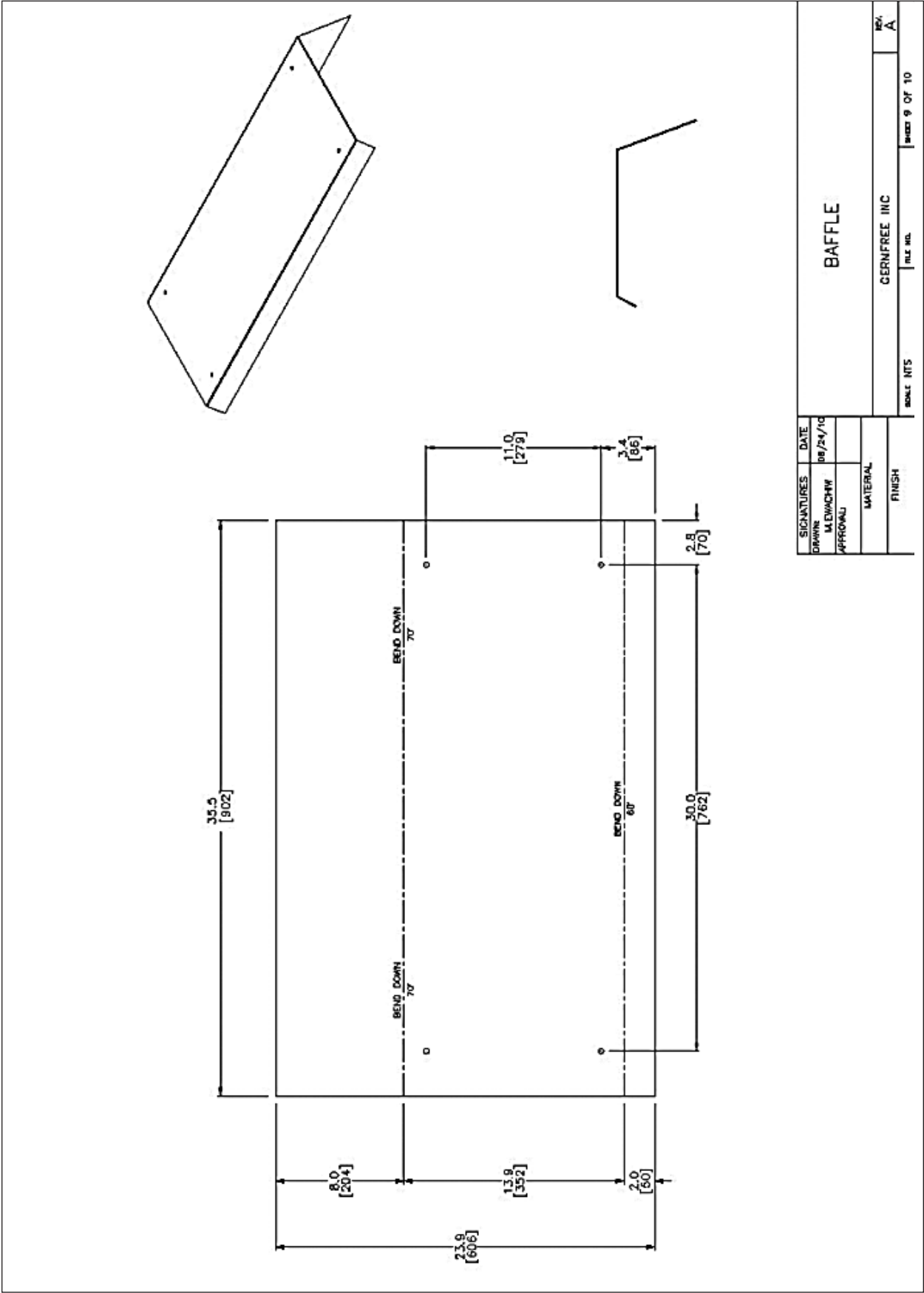


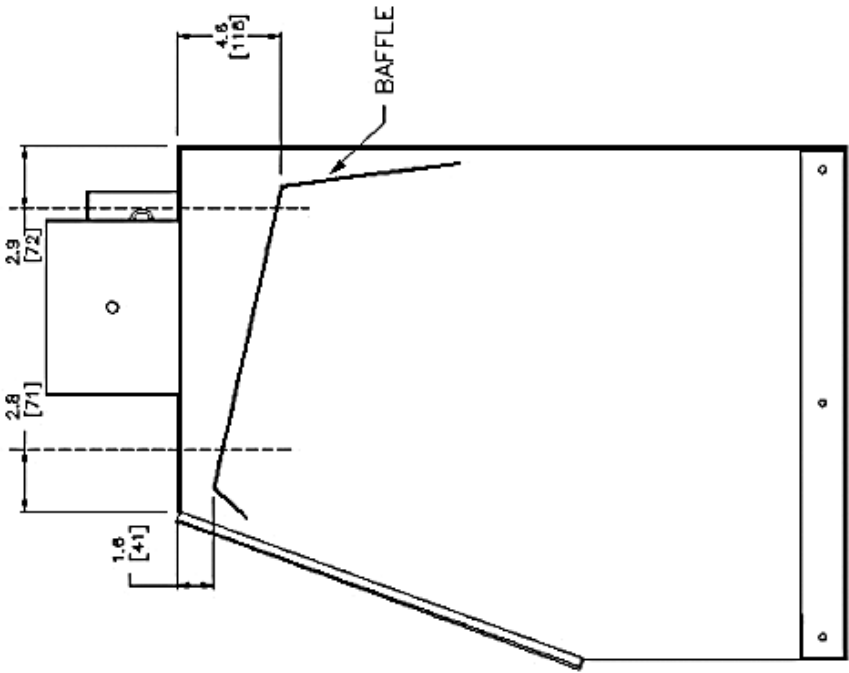
HINGE DETAIL

SIGNATURES	DATE
DRAWING	08/24/10
APPROVAL	
MATERIAL	
FINISH	

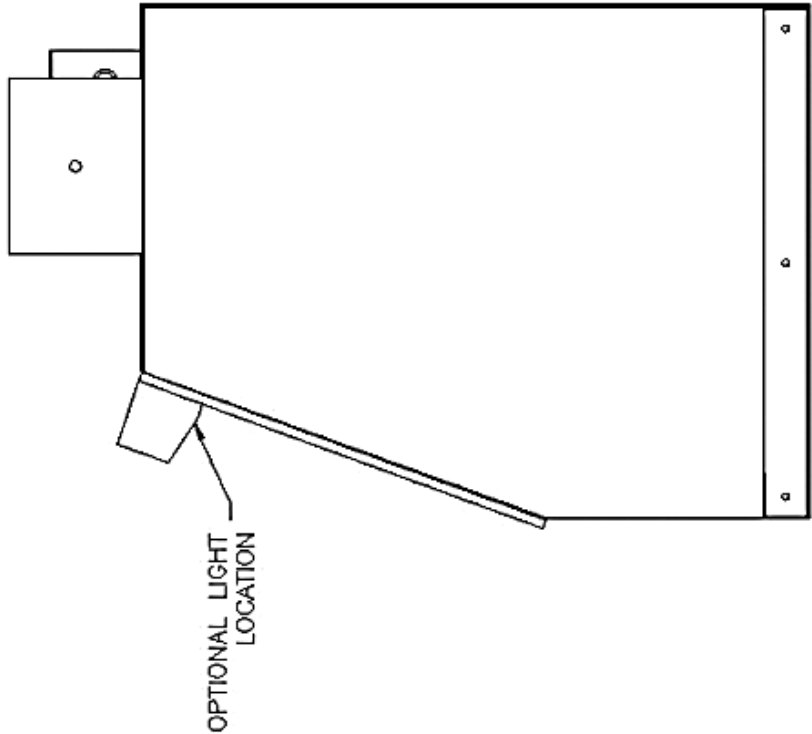
WINDOW FRAME

SCALE NTS	GERMFREE INC	FILE NO.	SHEET 8 OF 10	REV
				A





BAFFLE LOCATION



LIGHT LOCATION

SIGNATURES	DATE
DESIGN: M. LEWIS	08/24/10
APPROVAL:	
MATERIAL:	
FINISH:	

BAFFLE/LIGHT LOCATION			
SCALE: NTS	FILE NO.	GERM FREE INC	REV. A
SHEET 10 OF 10			

5.4 PROTOTYPE VWS TEST REPORT

This section provides the details of validation studies that were conducted on VWS to ensure that VWS will continuously provide the safe work environment when preparing smears or performing other PCR based methods (e.g., GeneXpert MTB/RIF Assay from Cepheid) on sputum specimens. This validation was conducted according to NSF 49 to define the safe airflow limits for working in VWS by using *Bacillus subtilis* spores concentration modified to 5.0×10^6 spores/ml.

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

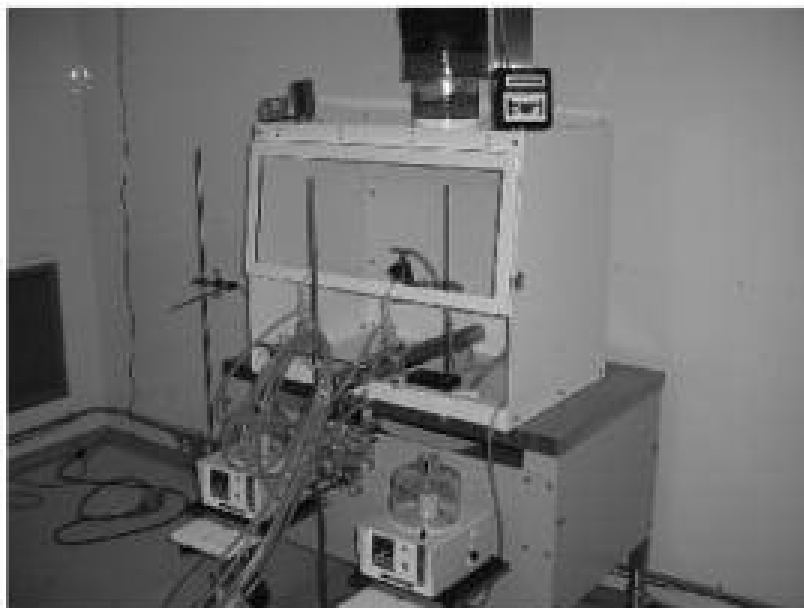
Document Number: BAKT153 Rev D

August 17, 2010

Revised February 1, 2011

Martin Rogers

Microbiological Testing Laboratory Manager



Purpose:

To report the results of microbiological testing of a Ventilated Workstation, 254 mm (10 in) sash opening, manufactured by Germfree.

Procedure:

Gatehouse Rd., Sanford, Maine 04073 USA · (207) 324-8773 · 1-800-992-2537 · FAX

(207) 324-2632

Internet address: [http:// www.bakerco.com](http://www.bakerco.com)

"Creating Immaculate Atmospheres"

Page 1 of 7

All tests are performed to the procedures of NSF standard 49, 2009. The NSF challenge was modified to use a lower spore concentration for the Personnel Protection tests of 5.0×10^5 spores per mL (compare to the standard NSF Personnel Protection test of 5.0×10^6 spores per mL).

Personnel Protection tests:

Challenged with a bacterial aerosol spore concentration 5.0×10^5 spores per mL.

Personnel Protection Microbiological test



Test 1 – 3 replicates

Personnel Protection Test:

5.0×10^5 spores/mL. 5-minute impinger sampling time, 6.5 minute nebulizer challenge, 30-minute slit sampler total testing time

Airflow measurements:

Inflow Velocity: 0.60 m/s (118 fpm); DIM: $0.1392 \text{ m}^3/\text{s}$ (295 cfm); 203 mm (8 in) duct static pressure -177 Pa (-0.71 in w.g.)

Test apparatus location:

Nebulizer Location: Inside workstation, center of view screen, 355.6 mm (14 in) above work surface

Impingers and slit samplers: As in the NSF standard 49, 2009

Test 1 (Continued)**Passing criteria:**

Total cfu allowed passing (filtered from impingers): 10 maximum

Total cfu allowed passing (from two slit sampler plates): 5 maximum

Results:

Replicate #1: Control plate: positive; 0 total cfu; slit samplers 0, impingers filtered 0

Replicate #2: Control plate: positive; 0 total cfu; slit samplers 0, impingers filtered 0

Replicate #3: Control plate: positive; 0 total cfu; slit samplers 0, impingers filtered 0

Pass ☒ Fail ☐

Test 2 – 3 replicates**Personnel Protection Test:**

5.0×10^5 spores/mL. 5-minute impinger sampling time, 6.5 minute nebulizer challenge, 30-minute slit sampler total testing time

Airflow measurements:

Inflow Velocity: 0.50 m/s (98 fpm); DIM: $0.1156 \text{ m}^3/\text{s}$ (245 cfm); 203 mm (8 in) duct static pressure -120 Pa (-0.48 in w.g.); 101.6 mm (4 inch) velocity measurements: 1.8 m/sec (355 fpm) average of 9 readings

Test apparatus location:

Nebulizer Location: Inside workstation, center of view screen, 355.6 mm (14 in) above work surface

Impingers and slit samplers: As in the NSF standard 49, 2009

Passing criteria:

Total cfu allowed passing (filtered from impingers): 10 maximum

Total cfu allowed passing (from two slit sampler plates): 5 maximum

Results:

Replicate #1: Control plate; positive; 0 total cfu; slit samplers 0, impingers filtered 0

Replicate #2: Control plate; positive; 0 total cfu; slit samplers 0, impingers filtered 0

Replicate #3: Control plate; positive; 0 total cfu; slit samplers 0, impingers filtered 0

Pass ☒ Fail ☐

Test 3 – 3 replicates**Personnel Protection Test:**

5.0 x 10⁶ spores/mL. 5-minute impinger sampling time, 6.5 minute nebulizer challenge, 30-minute slit sampler total testing time

Airflow measurements:

Inflow Velocity: 0.40 m/s (79 fpm); DIM: 0.0906 m³/s (192 cfm); 203 mm (8 in) duct static pressure -82 Pa (-0.33 in w.g.); 101.6 (4 inch) velocity measurements: 1.57 m/sec (308 fpm) average of 9 readings

Test apparatus location:

Nebulizer Location: Inside workstation, center of view screen, 355.6 mm (14 in) above work surface

Impingers and slit samplers: As in the NSF standard 49, 2009

Passing criteria:

Total cfu allowed passing (filtered from impingers): 10 maximum

Total cfu allowed passing (from two slit sampler plates): 5 maximum

Results:

Replicate #1: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Replicate #2: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Replicate #3: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Pass ☒ Fail ☐

Test 4 – 3 replicates**Personnel Protection Test:**

5.0 x 10⁶ spores/mL. 5-minute impinger sampling time, 6.5-minute nebulizer challenge, 30-minute slit sampler total testing time

Airflow measurements:

Inflow Velocity: 0.30 m/s (59 fpm); DIM: 0.0684 m³/s (145 cfm); 203 mm (8 in) duct static pressure -50 Pa (-0.20 in w.g.); 101.6 mm (4 in) velocity measurements: 1.2 m/sec (237 fpm) average of 9 readings

Test apparatus location:

Nebulizer Location: Inside workstation, center of view screen, 355.6 mm (14 in) above work surface

Impingers and slit samplers: As in the NSF standard 49, 2009

Test 4 (Continued)**Passing criteria:**

Total cfu allowed passing (filtered from impingers): 10 maximum

Total cfu allowed passing (from two slit sampler plates): 5 maximum

Results:

Replicate #1: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Replicate #2: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Replicate #3: Control plate; positive; 0 cfu total; 0 slit samplers, 0 filtered

Pass ☒ Fail ☐

Test 5, 6 and 7 – Failure Points**Personnel Protection Test:**

5.0×10^6 spores/mL, 5-minute impinger sampling time, 6.5-minute nebulizer challenge, 30-minute slit sampler total testing time

Airflow measurements:**Inflow Velocity:**

Test 5: 0.15 m/s (29.5 fpm) DIM 0.0331 m³/s (70 cfm); 203 mm (8 in) duct static pressure -5.0 Pa (-0.02 in w.g.);

Test 6: 0.10 m/s (19.7 fpm) DIM 0.0189 m³/s (40 cfm); 203 mm (8 in) duct static pressure -2.5 Pa (-0.010 in w.g.);

Test 7: 0.00 m/s (0 fpm) DIM 0 m³/s (0 cfm)

Test apparatus location:

Nebulizer Location: Inside cabinet, center of view screen, 355.6 mm (14 in) above work surface

Impingers and slit samplers: As in the NSF standard 49, 2009

Passing criteria:

Total cfu allowed passing (filtered from impingers): 10 maximum

Total cfu allowed passing (from two slit sampler plates): 5 maximum

Results:

Test #5: Control plate; positive; 52 cfu total; 17 slit samplers, 35 filtered

Test #6: Control plate; positive; tntc cfu total; tntc slit samplers, tntc filtered

Test #7: Control plate; positive; tntc cfu total; tntc slit samplers, tntc filtered

Note: tntc = too numerous to count

Pass ☐ Fail ☒

Conclusion:

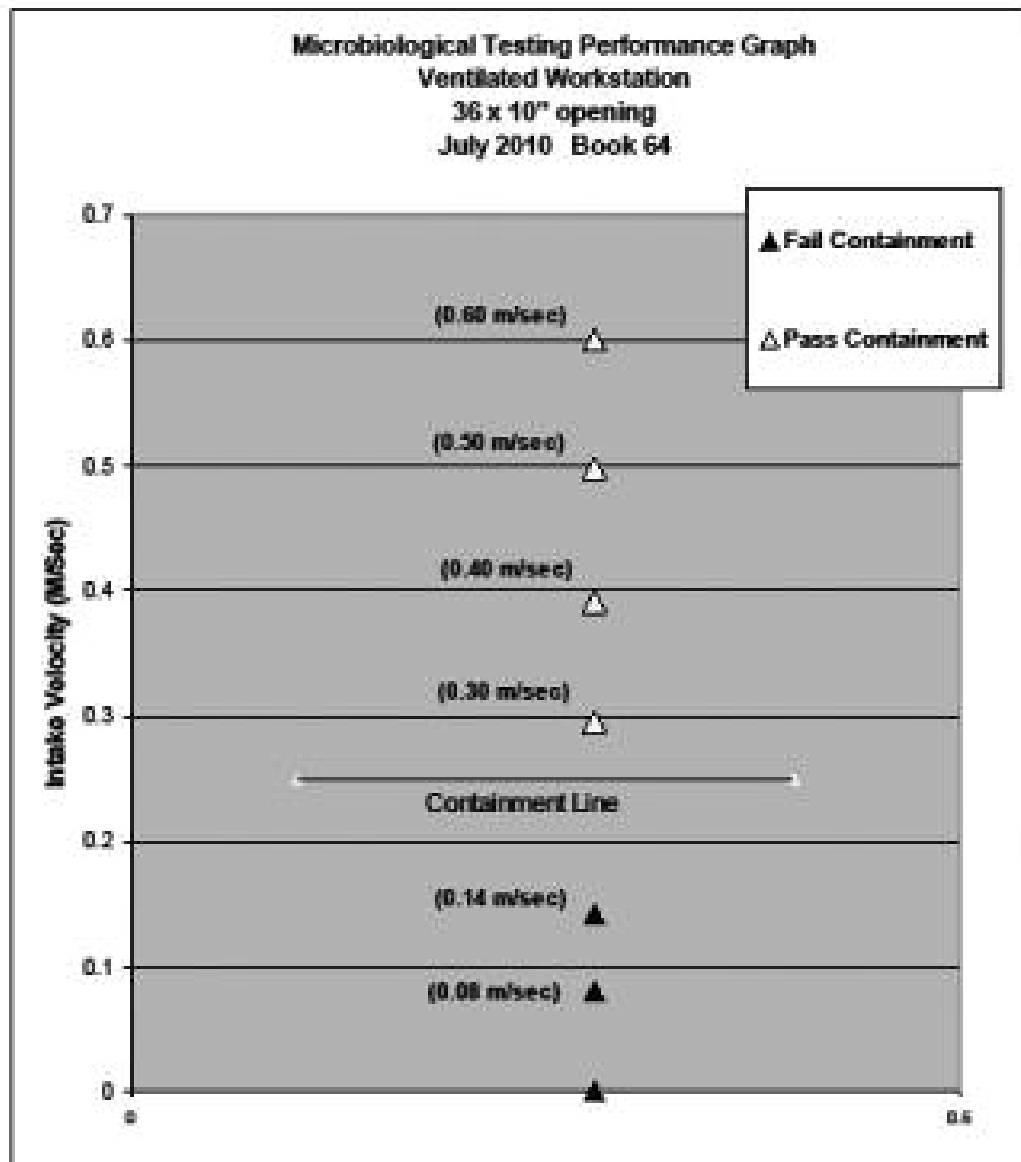
The Ventilated workstation passed the test for Personnel Protection (adapted from NSF Standard 49) at several inflow velocities. The passing inflow velocity values are 0.6 m/s (118 fpm); 0.5 m/s (98 fpm); 0.4 m/s (79 fpm), and 0.3 m/s (59 fpm). The Ventilated workstation failed the test for Personnel Protection at inflow velocities lower than 0.30 m/s (59 fpm), including 0.15 m/s (29.5 fpm), and 0.10 m/s (19.7 fpm). (See results graph, last page of this report)

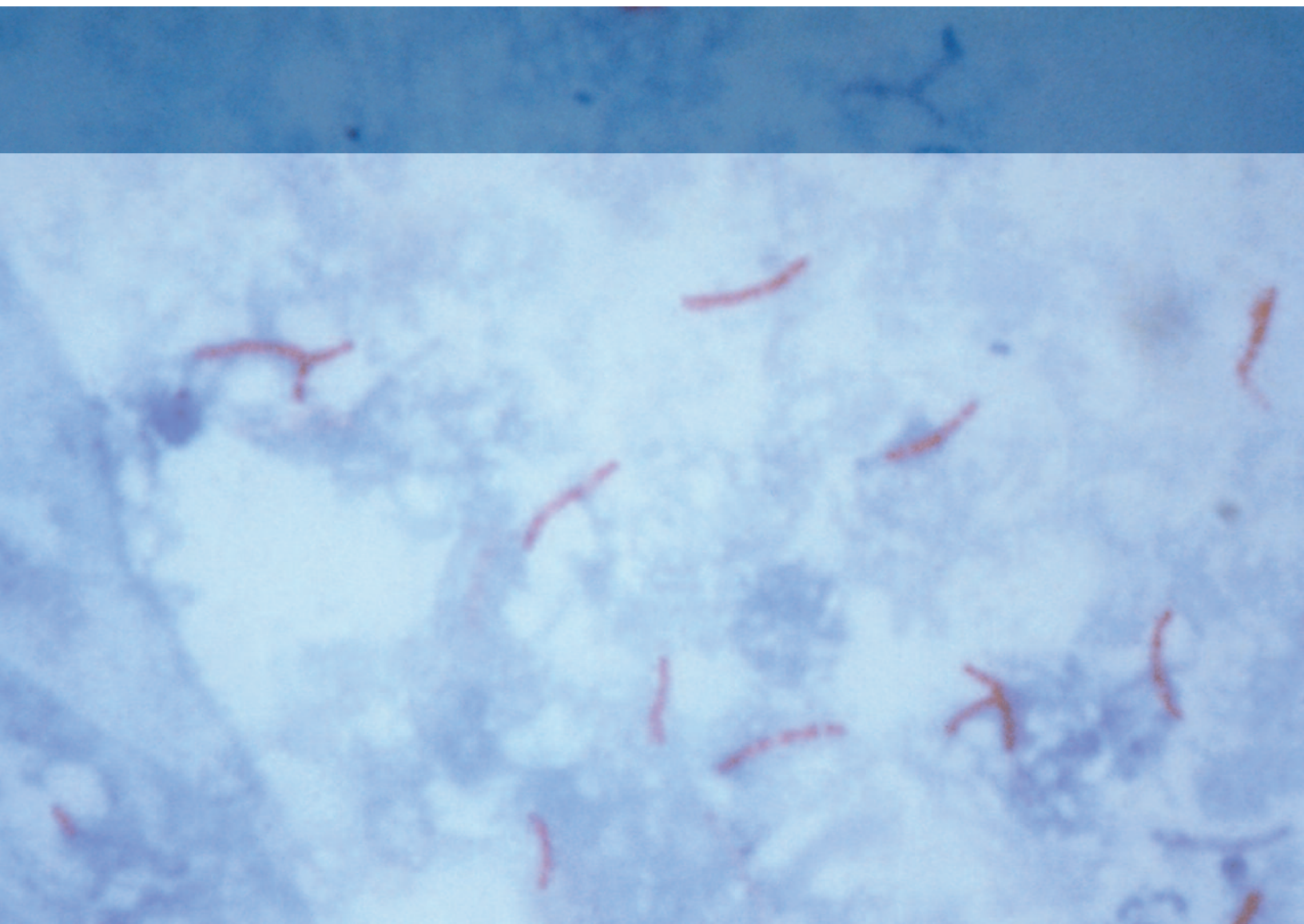
The velocities were calculated using a direct inflow measurement device (DIM) flow hood to measure the inflow, and dividing by the area of the access opening which is 0.2323 m² (2.50 ft²).

The inflow velocity (V) equals the volumetric airflow rate (Q) divided by the access open area (A); $V = Q / A$

Additional Information:**Personnel Protection Test**

The cabinet was challenged with *Bacillus Subtilis* bacterial spores at 5.0×10^6 spores/mL for each test run. Note that this challenge is two orders of magnitude less than the NSF Standard 49 Personnel Protection test (5.0×10^8 spores/mL). 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 two slit sampler impaction plates combined.





This publication was supported by cooperative agreement number U62/CCU323096 from Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC.

