



# Ensuring Adequate Laboratory Biosafety

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# GLI Strategic Priorities

- Establish GLI partnership projects
- Develop templates for country-specific roadmaps for laboratory strengthening
- Develop human resource strategies
- **Develop appropriate laboratory biosafety standards**
- Develop a TB lab accreditation system
- Move new diagnostics into countries

# Why is Biosafety Needed in the Tuberculosis Laboratory?

- Risk of infection with *Mtb* is higher for TB lab workers than for other lab workers
  - 1.4-fold higher for TB microscopists
  - 21.5-fold higher for DST technicians
- Infection often results from unrecognized production of infectious aerosols
- Infection can also occur from needle sticks, through broken skin, etc.

# **Biosafety**

**The application of a combination of administrative controls, containment principles, laboratory practices and procedures, safety equipment, and laboratory facilities to enable laboratorians to work safely with potentially infectious microorganisms.**

# **Administrative Controls**

- **Supervision by an experienced scientist**
- **All personnel are well trained, proficient, aware of hazards, follow rules**
- **Routine medical surveillance**
- **Biosafety and operations manuals**
- **Emergency plans for spills, accidents, etc.**
- **Appropriate facilities and safety equipment**

# **Good Laboratory Practices**

- **Restrict or limit access when working**
- **Biohazard warning signs**
- **Prohibit eating, drinking and smoking**
- **Prohibit mouth pipetting**
- **Minimize splashes and aerosols**
- **Decontaminate work surfaces daily**
- **Decontaminate wastes**

# Containment

- **Primary Containment: protect worker and immediate laboratory environment**
  - good microbiologic techniques
  - safety equipment
  - facility design
- **Secondary Containment: protect the environment outside the laboratory**
  - facility design
  - waste management

# Biosafety Level (BSL)

- **Conditions under which an infectious agent can ordinarily be safely handled.**
- **Conditions are a combination of:**
  - laboratory practices and techniques
  - safety equipment
  - laboratory facilities
- **Usually agent and procedure specific**
  - generic BSLs are available for many infectious agents
  - procedure-specific BSLs often missing



# GLI Biosafety Projects

- **Biosafety guidance for TB lab procedures**
  - Technical consultation in Sept. 2008
  - Expert meeting in April 2009
  - WHO and CDC were the lead agencies
- **Specifications for a ventilated work station suitable for direct AFB-smear microscopy**
  - Expert consultation in Sept. 2009
  - CDC and APHL were the lead agencies

# Biosafety Guidance

- **Consensus recommendations for minimum biosafety requirements for**
  - AFB-smear microscopy
  - Culture
  - Drug-susceptibility testing
  - Molecular testing
- **Based on a risk assessment for each TB diagnostic procedure**
  - generation of infectious aerosols
  - concentration of bacilli

# Direct AFB-Smear Microscopy

Limited risk of generating infectious aerosols

- **Work can be done on an open bench**
  - separate bench for smear-preparation
- **Facility: adequately ventilated enhanced BSL1 or basic BSL2 laboratory**
  - natural or mechanical ventilation; 6–12 ACH
  - directional airflow
- **Proper disposal of infectious material**

# Processing Sputum Specimens for Smear, Culture, Molecular Tests

**Risk of generating infectious aerosols during centrifugation and specimen manipulation**

- **Work with specimens should be done in a biosafety cabinet (BSC)**
  - BSC class I or II may be used
- **Facility: adequately ventilated BSL2 lab**
  - directional airflow; 6–12 ACH
- **Use aerosol-containing rotors or buckets**
- **Proper disposal of infectious material**

# Processing Cultures for Smear, ID, Subculture, DST, Molecular Tests

High risk of generating infectious aerosols during manipulation of liquid suspensions

- **Work with cultures should be done in a BSC**
  - class I or II BSC may be used
  - certified at least annually
- **Facility: adequately ventilated BSL3 or enhanced BSL2 laboratory**
  - directional airflow; not recirculated
- **Use aerosol-containing rotors or buckets**
- **Proper disposal of infectious material**

# **BSL3 – Secondary Containment**

**BSL2 secondary containment plus:**

- Controlled access to a separate area**
- Double door entry**
- Single-pass air; 6-12 air changes/hour**
- Enclosures for aerosol generating equipment**
- Room penetrations sealed**
- Walls, floors and ceilings are water resistant for easy cleaning**

If a facility does not have all required BSL3 features (e.g. sealed penetrations, solid ceiling), an acceptable level of safety for conducting routine procedures, including culture, may be achieved in a BSL2 facility providing:

- Directional inward airflow is maintained and exhaust air is discharged to the outside
- Access to the laboratory is restricted when work is being performed
- The recommendations for BSL3 practices, procedures, and safety equipment are rigorously followed

# Next Steps for Work Group

- **Finalize guidelines**
- **Distribute guidelines**



# GLI Biosafety Projects

- **Biosafety guidance for TB lab procedures**
  - Technical consultation in Sept. 2008
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- **Specifications for a ventilated work station suitable for direct AFB-smear microscopy**
  - Expert consultation in Sept. 2009
  - CDC and APHL were the lead agencies

# Why is a Ventilated Work Station Needed for Direct Microscopy?

- Risk of *Mtb* infection with is 1.4-fold higher for TB microscopists than non-TB workers
- Potential need for increasing BSL
  - Increased vulnerability of HIV-infected staff
  - Decreased treatment efficacy (M/XDR TB)
  - Increased exposure (unreliable airflow)
- Class I and II BSCs are expensive and require annual maintenance

# What is Done in The Work Station

- Open sputum cup
- Smear (disposal sticks/loops, re-usable loops w/ flame/micro-incinerator)
- Air dry
- Close sputum cup
- Disposal of sticks
- heat fix?
- Stain?

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

by

R. W. Smithwick and G. P. Kubica

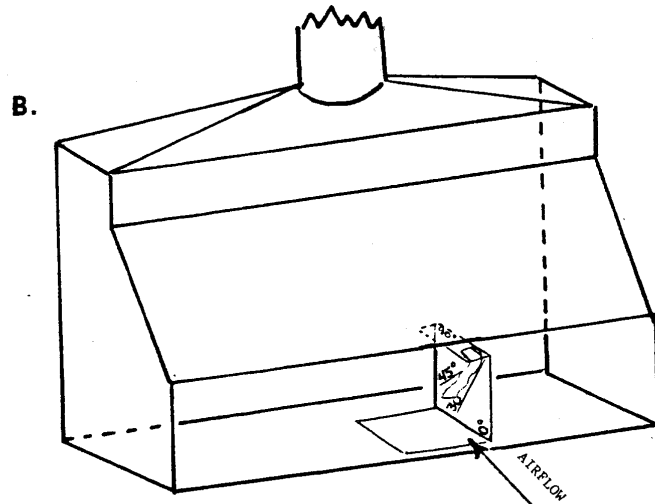
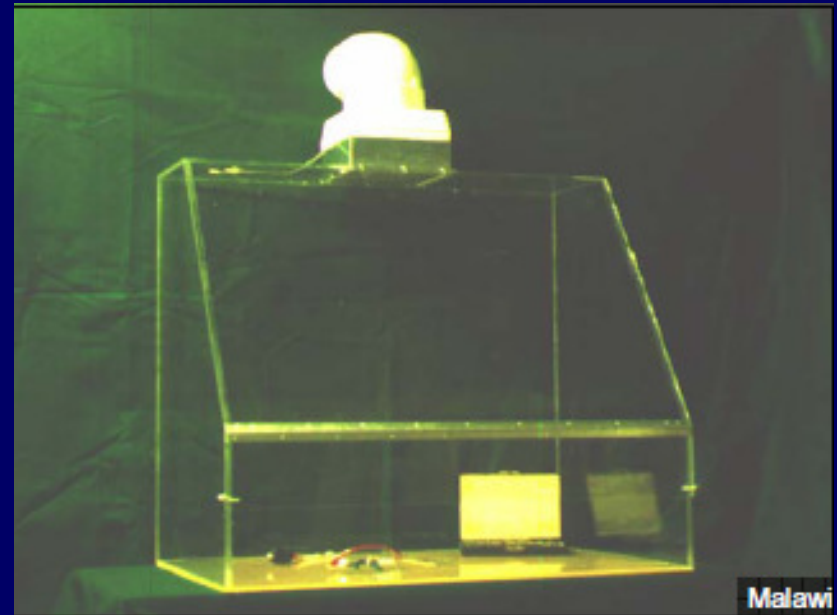


Figure 3. A simple airflow gauge: A. Close-up drawing of construction;  
B. Placement in BSC for airflow check (see text for details).



# Objectives of Expert Consultation

- To assess the need for ventilated work stations in resource-limited settings
- To provide guidelines for design, materials, and construction of work stations
- To provide guidance on validating the recommendations to ensure the safety, reliability, and integrity of the work stations

# Issues Addressed

- **General requirements to reduce risk of infection with AFB smear microscopy**
- **Balance need for safety with unintended messages about AFB smear microscopy**
- **Appropriate vs. non-appropriate use**
  - not intended for TB culture, TB DST
- **A guideline is not a standard and certification will not be available**

# Recommendations made for Minimum Requirements

- **Materials**
- **Ergonomics**
- **Electric Components**
- **Design**
- **Validation**
- **SOP Checklist**

# Next Steps for Work Group

- Prepare report of expert consultation
- Prepare guidelines in simple language suitable for an international audience detailing instructions how to construct a work station
- Prepare specifications for materials, ergonomics, electric components, design, validation, and SOPs



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