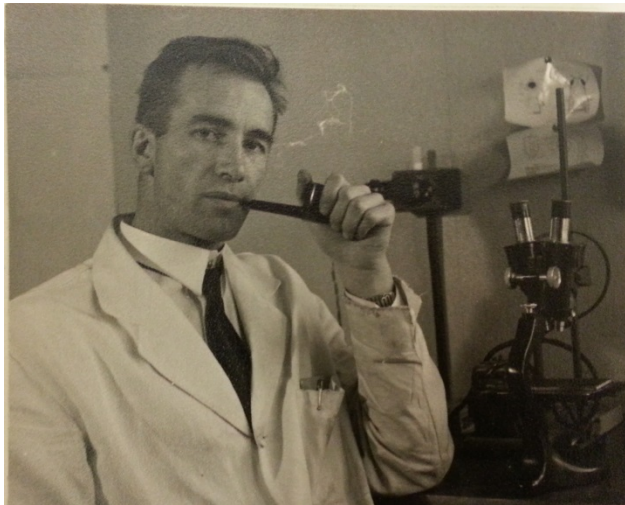




# Biosafety in the Mycobacteria Laboratory



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# Question #1

Does your laboratory

- a) Process primary AFB specimens for AFB smear and culture on site?
- b) Refer primary AFB specimens from satellite labs to your central microbiology lab for AFB smear and culture?
- c) Refer primary AFB specimens to a reference lab?
- d) Other?



## Question #2

For labs that process primary AFB specimens on site

- a) Is your biosafety level BSL1
- b) Is your biosafety level BSL2
- c) Is your biosafety level BSL2+BSL3 practices
- d) Is your biosafety level BSL3
- e) Not sure



## Question #3

The biological safety cabinet (BSC) used for AFB work is located

- a) In a separate room with closed doors and negative air pressure designed for processing AFB and possibly other similar risk level work
- b) In our microbiology lab which has closed doors and negative air pressure to other lab depts
- c) In our general lab space which includes microbiology



# Question #4

- a) Our BSC is purposely placed in a low traffic area
- b) Our BSC is placed in space available, but traffic may not be controlled at times
- c) Our BSC is placed in space available which includes more frequent traffic
- d) Our BSC is pictured below





# Question #5

Smears for AFB staining are

- a) Prepared in a BSC, dried, and fixed with heat or phenol before removal from the BSC
- b) Prepared in a BSC, dried, and then removed from the BSC to flame fix and stain
- c) Prepared in a BSC, dried, and then removed from the BSC to fix on a heat block or phenol fix
- d) Other?



# Question #6

Which best describes your experience with risk assessment?

- a) I don't have a clue what a risk assessment is.
- b) I've heard of risk assessment and know what it is, but have never participated in a lab risk assessment.
- c) I've heard of risk assessment and have participated as part of a group in performing a risk assessment.
- d) I understand risk assessment very well, have performed several risk assessments and incorporate RA's into SOP's and my daily work.



Anthrax shipments with viable organisms

Ebola virus exposures

Other





# Assess Plan Mitigate Reassess





## **Why Biosafety? To keep our workforce safe. Biological risks and laboratory acquired infections are a reality that cannot be ignored**

Increased attention has been focused on laboratory biosafety and biosecurity since 2001 but has been largely limited to precautions required for agents of bioterrorism.

Current biosafety guidelines published in Biosafety in Microbiological and Biomedical Laboratories (BMBL) by CDC/NIH have not been designed to address day to day operations of diagnostic labs.

In 2008 the CDC convened a Blue Ribbon Panel of lab representatives from a variety of agencies, organizations, and facilities to review lab biosafety in diagnostic laboratories. More detailed guidelines from the Blue Ribbon Panel were published in MMWR Jan 6<sup>th</sup> 2012 to promote a culture of safety and include recommendations that supplement the BMBL, last edition published in 2009, and address the unique needs of the diagnostic laboratory.



In October of 2014 through January of 2015, teams from CDC visited and evaluated 55 hospitals for their capacity and preparedness to receive, identify, and treat patients with suspected or confirmed Ebola virus disease. They found assumptions about laboratory safety and operations were being made but were not necessarily true. Gaps found included ...

- Lab staff not always conducting risk assessments, following OSHA blood borne pathogens standards, or implementing safe work practices
- Lab instruments were not necessarily safe for operators
- Lack of communication between lab and clinical care providers
- Insufficient training in safe work practices and use of PPE

<https://www.cdc.gov/biosafety/publications/bmbl5/>

<http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm>



CDC realized that these safety gaps presented an opportunity to improve safety and operations. To assure that clinical laboratories are prepared for biological threats and emerging infectious diseases, it was decided that additional training and education of laboratory professionals was required to increase their knowledge, skills, and abilities necessary to ensure a safe working environment. These skills include but are not limited to:

- Performing risk assessments
- Proper use of PPE
- Safe work practices including the use of BSC's



In 2015 CDC provided grants for all 50 states to recruit biosafety officials (BSO) at the public health lab level (PHL) to ensure a safe working environment. In addition, PHL's are charged to reach out to all sentinel clinical labs in their respective states to facilitate a higher overall knowledge and level of biosafety. As part of this funding, the WSLH developed a clinical microbiology risk assessment which was sent to all Wisconsin sentinel labs in November of 2015, and will be repeated in 2017 to evaluate improvements in identifying and mitigating biosafety risks.

Erin Bowles and Richard Dern are co-biosafety officials for WSLH and you'll be hearing more about biosafety as part of this national directive funded through CDC.



# Biological Safety

The World Health Organization defines biosafety as “containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release”.

More specifically, the Culture of Biosafety is based on risk assessment and includes but is not limited to ...

- 1) Concept of thinking first and then working safely
- 2) Proper use of PPE
- 3) Proper use of containment equipment, e.g. BSC's
- 4) Proper design of facilities, e.g. directional air flow less clean to more clean
- 5) Continuous ongoing validation of SOP's and safety outcomes



# Biological Risk Mitigation

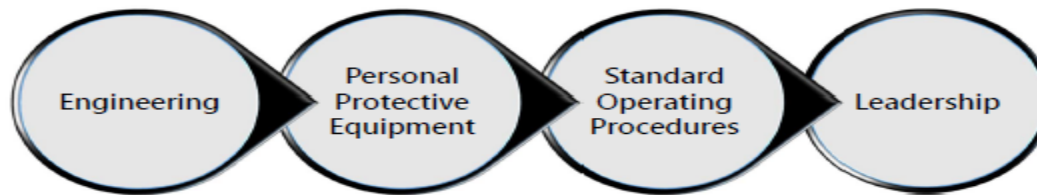


We must identify all risks, assess risks through sciences and perceptions, manage the risks with strategic plans, and ensure all staff know about the risks and can mitigate them effectively.



# Biological risk can be reduced and controlled

## Four Primary Controls of Biosafety



## Examples of the Four Primary Controls of Biosafety

<b>FOUR PRIMARY CONTROLS OF BIOSAFETY</b>			
Engineering	Personal Protective Equipment (PPE)	Standard Operating Procedures (SOPs)	Leadership
Locks on doors	Gloves	Emergency Evacuation	Training
Directional Airflow	Eye Protection	Waste Disposal	Vaccinations
Interlocked Doors	Laboratory Coat	Spill Cleanup	SOP Compliance
Biosafety Cabinets	N95	Needle stick	Surveillance (M/I)
Autoclaves	Booties	Lab Decon	SOP Evaluation/Validation
HEPA Filters	PAPR	Medical Emergencies	Background Checks





# Where to begin: Risk assessment is the foundation of biosafety

- 1) Identify hazardous agents, e.g. MTB
- 2) Identify laboratory procedure hazards, e.g. aerosols, droplets, transfer by contact, etc
- 3) Determine the biosafety level required for containment and other resources needed to work with the agent(s), e.g. BSL 2 or 3
- 4) Evaluate staff (training and competency) and equipment
- 5) Review assessments with staff that perform the work, with leadership, and IBC/other institutional oversight committees
- 6) Develop a plan to mitigate and manage the risks
- 7) Develop/update SOPs based on the risk assessment and mitigation plan to control the risks



# Importance of up to date SOP's?

- Safety requires consistent behavior, meaning we do not get to chose how we behave.
- People have different and diverse backgrounds, levels of experience, and education.
- Different people have different attitudes and perceptions of risk
- Developing SOP's based on risk assessments and mitigation plans, and compliance with these SOP's are important to standardize our behavior to ensure more predictable safety outcomes to protect our workforce and the environment.





# Biosafety Cabinet---OMG



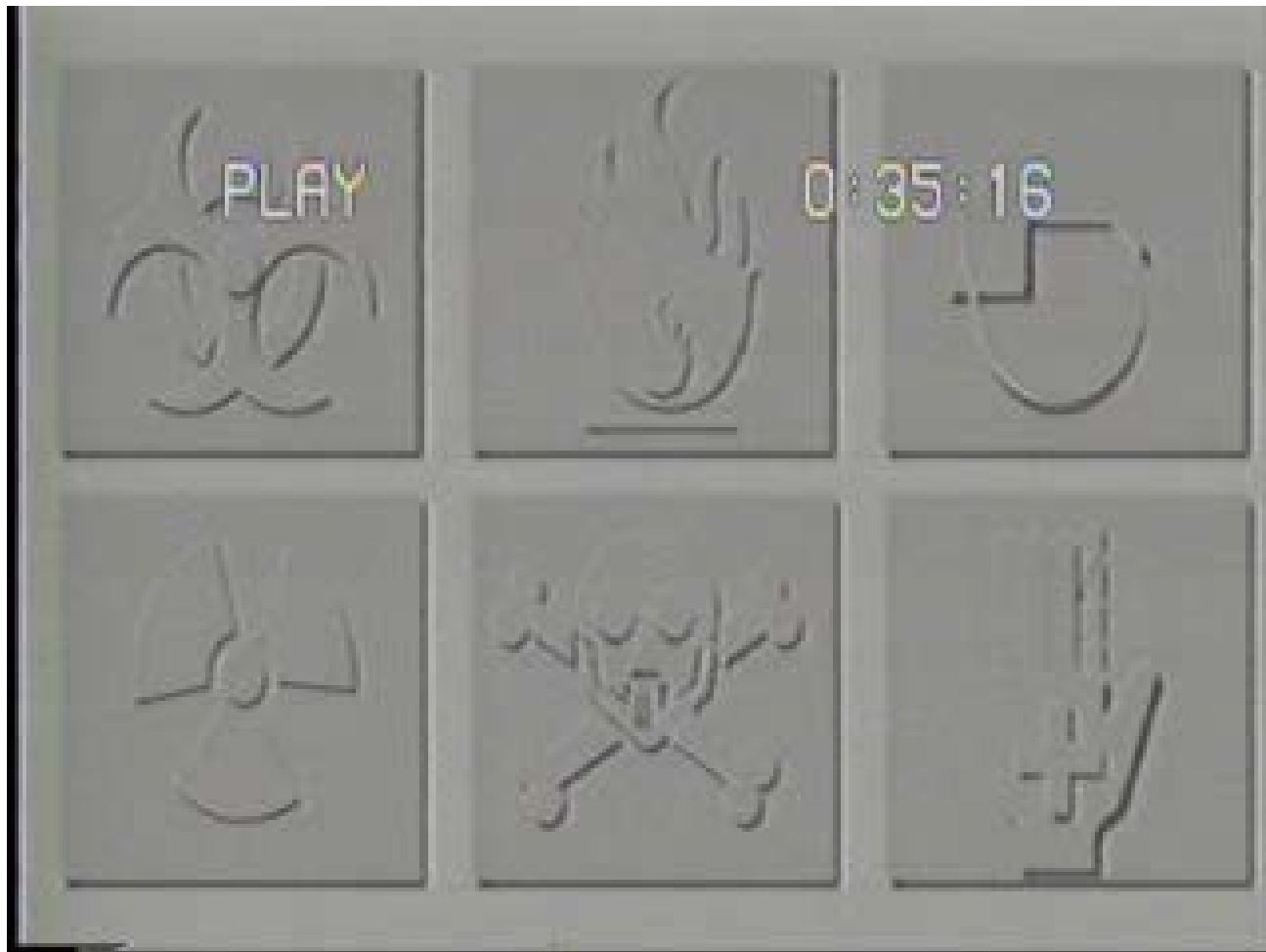


# Biosafety Cabinet





# Biosafety Cabinet





# The Right Way





# Biosafety Levels

- **Biosafety Levels 1-4**
- Increasing levels of personnel and environmental protection
  - BMBL 5<sup>th</sup> Edition
    - Guidelines for working safely in microbiological and biomedical laboratories





# BMBL 5<sup>th</sup> Ed

- Guidelines which describe combinations of:
  - Laboratory Practices and Techniques
    - Standard Microbiological Practices
    - Special Microbiological Practices
  - Safety Equipment (Primary Barriers and PPE)
  - Laboratory Facilities (Secondary Barriers)



# Personnel

- Knowledgeable supervisor
- Personnel
  - Aware of potential hazards
  - Proficient in practices/techniques
- Biosafety manual specific to lab



# Safety Equipment

(Primary Barriers)

- Biosafety cabinets (BSCs) [BSL-2/3]
- Personal protective clothing
  - Gloves
  - Gowns
- Pipetting Devices
- Safety centrifuge cups and rotors
- Eye and face protection
- Respiratory protection [BSL-3]



# Facility Design

(Secondary Barriers) - Introduction



- Easily cleaned and decontaminated



# Reality





# Biosafety Level 1

- Suitable for work involving well-characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.



# Biosafety Level 1

## Introduction

### Examples:

- *Bacillus subtilis*
- *S. epidermidis*
- *E. coli*
- *Lactobacillus sp.*
- *Bacillus subtilis*



# Biosafety Level 1

## Standard Microbiological Practices

- Use mechanical pipetting devices
- Wash hands
- Restrict or limit access when working
- Prohibit eating, drinking and smoking
- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Decontaminate wastes
- Maintain insect & rodent control program





# Biosafety Level 1

## Standard Microbiological Practices (cont.)

- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Decontaminate wastes
- Maintain insect & rodent control program



# Biosafety Level 1

## Safety Equipment (Primary Barriers)

- Protective clothing
  - Lab coat recommended
  - Gloves
  - Protective eyewear
  - Face protection





# Biosafety Level 1

## Laboratory Facilities (Secondary Barriers)

- Sink for handwashing
- Work surfaces easily cleaned
- Bench tops impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals
- Sturdy furniture
- Windows fitted with fly screens



# Biosafety Level 1

## Special Practices

NONE



# Biosafety Level 2

- Suitable for work involving agents of moderate potential hazard to personnel and the environment.
- Immunization or antibiotic treatment is available



# Biosafety Level 2

Examples:

- *Streptococcus pneumoniae*
- Salmonella and other enterics
- *Toxoplasma* spp.
- Hepatitis B virus
- Influenza viruses
- *Staphylococcus aureus*



# Biosafety Level 2

## Standard Microbiological Practices

- **As in BSL-1**

With emphasis on :

- ☐ Gloves

- ☐ Mechanical pipetting

- ☐ Attention to sharps

- ☐ Eye protection



# Biosafety Level 2

## Safety Equipment (Primary Barriers)

- **BSL-1 guidelines PLUS:**

Use biosafety cabinets (class II) for work with infectious agents involving:

- Aerosols and splashes
- Large volumes
- High concentrations





# Biosafety Level 2

Laboratory Facilities (Secondary Barriers)



- Method for decontaminating all laboratory wastes
- Eyewash station available



# Biosafety Level 2

## Special Practices

### Needles & Sharps Precautions

- **DON'T**
  - Break, bend, resheath or reuse syringes or needles
  
- **DO**
  - Use sharps containers



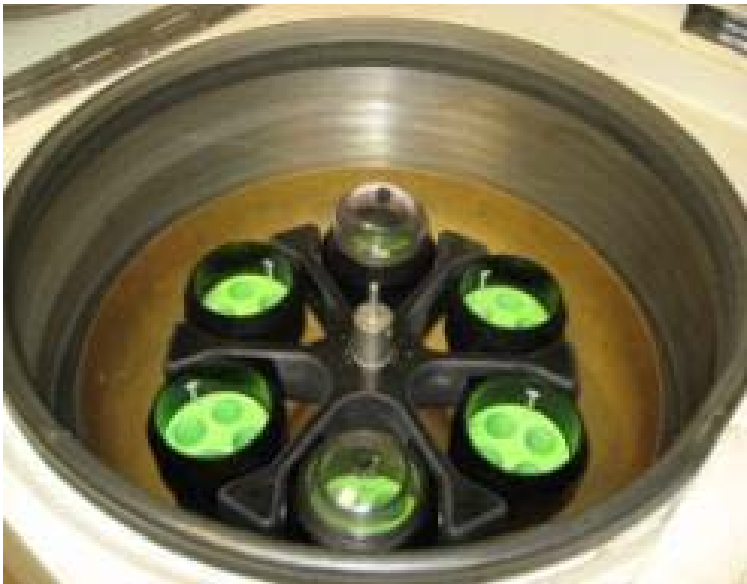


# Biosafety Level 2

## Special Practices

### CENTRIFUGE

- Tubes sealed tightly
- Sealed carriers
- After centrifugation, open sealed carriers inside BSC





# Biosafety Level 2

Special Practices (cont.)

## Needles & Sharps Precautions

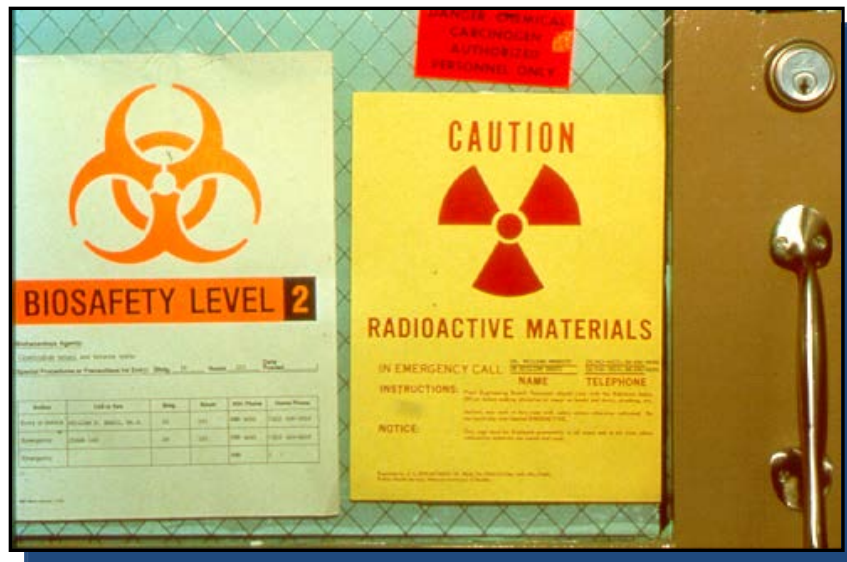
- **DON'T**
- Touch broken glass with hands





# Biosafety Level 2

Special Practices (cont.)



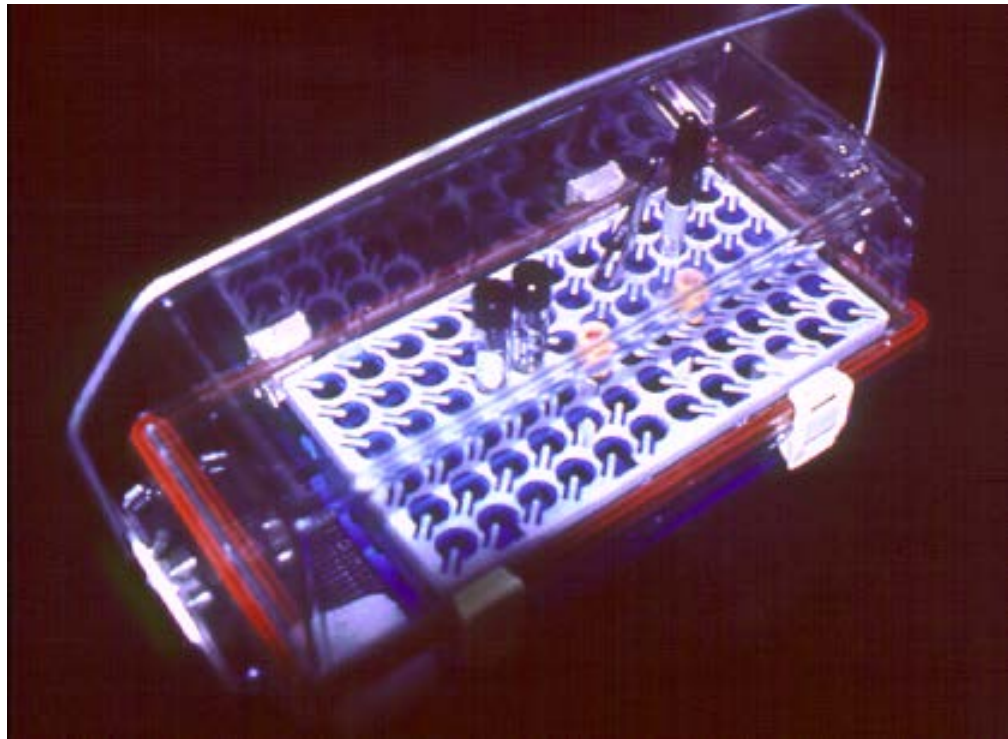
- Policies and procedures for entry
- Biohazard warning signs
- Biosafety manual specific to lab
- Training with annual updates (Documented)



# Biosafety Level 2

Special Practices (cont.)

☐ Use leak-proof transport containers





# Biosafety Level 2

Special Practices (cont.)

- Immunizations
- Baseline serum samples from at-risk personnel





# Biosafety Level 3

- Suitable for work with infectious agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.





# Biosafety Level 3

- Exposure potential to pathogens spread by aerosol
- Infection serious, possibly lethal
- Examples:
  - *M. tuberculosis*
  - Eastern equine encephalitis virus
  - *Coxiella burnetii*
  - *Francisella tularensis*
  - *Clinical specimens from suspected Ebola virus patients*



# Biosafety Level 3

**Standard Microbiological Practices**

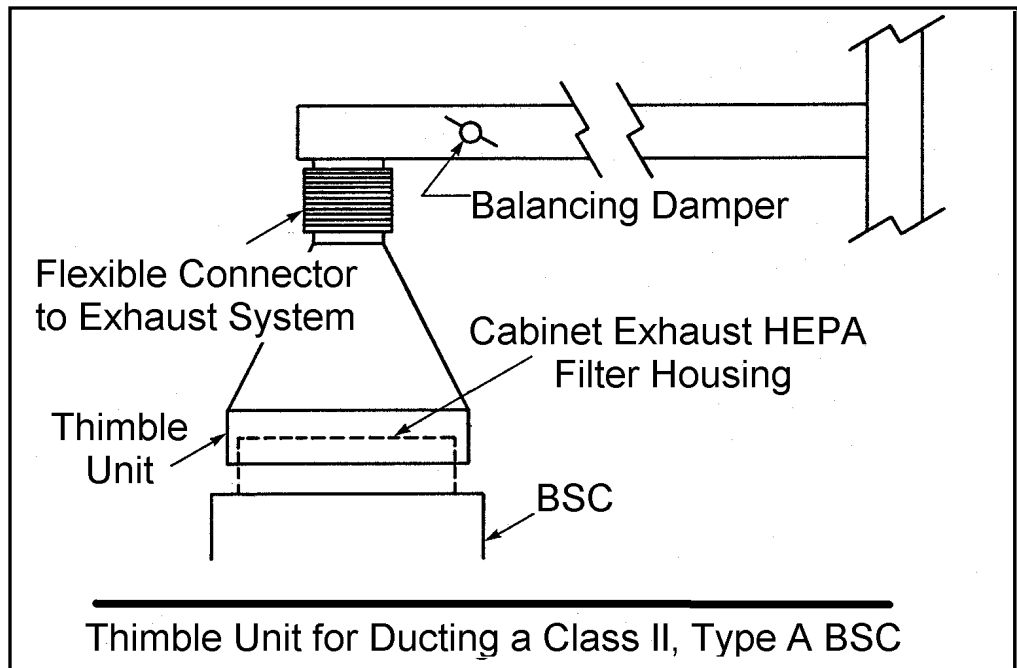
**As in BSL-1 and -2**



# Biosafety Level 3

## Safety Equipment (Primary Barriers)

- **BSL-1 and 2 Safety Equipment PLUS:**
  - BSC class II or III to manipulate infectious material





# Biosafety Level 3

## Safety Equipment (Primary Barriers)

### ■ BSL-1 and 2 Safety Equipment PLUS:

- Respiratory protection may be indicated
  - N-95
  - PAPR
- Solid-front gowns with snug cuffs





# Biosafety Level 3

Laboratory Facilities (Secondary Barriers)

- **BSL-1 and 2 Facilities PLUS:**
  - Separate building or isolated zone
  - Double door entry
  - Directional inward airflow
  - Single-pass air



# Biosafety Level 3

Laboratory Facilities (Secondary Barriers)

- **BSL-1 and 2 Facilities PLUS** (cont.):
  - Enclosures for aerosol generating equipment
  - Room penetrations sealed
  - Walls, floors and ceilings are water resistant for easy cleaning

