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# - 4 components of a biosafety program - Administrative controls - Work practices - Personal Protective Equipment (PPE) - Engineering Controls

# - Terms - Biocontainment Levels - BSL vs. ABSL - Facilities and Equipment - Biocontainment Program Management - References, Guidelines, and Regulations - Board Relevance - Extras (time permitting)

# - Biocontainment - Biosafety - development of protective policies and procedures to ensure a safe environment when working with these organisms - Biosecurity - Precautions taken to minimize the risk of introducing an infectious disease into an animal population. - Biosurety - Encompasses or combines security, safety and inventory management (appears to be a DoD term) - “Agent” - infectious organism

# **(Bio-)Containment** Safe methods for managing infectious materials and animals in the laboratory environment where they are being handled or maintained and to reduce or eliminate exposure to hazardous agents.

## PRINCIPLES

- **The 4 Elements of Containment**
  - **Work practices:** Laboratory practice and technique
  - **Safety equipment & Facility design and construction**
  - **Personal Protective Equipment**
  - **Administrative controls**
    - Access controls
    - Security clearance
    - etc



## BIOCONTAINMENT LEVELS

- BSL 1
- BSL 2
- BSL 3 and BSL 3 Ag
- BSL 4



## BIOSAFETY LEVEL DIFFERENCES

Containment Level	Description of Agent	Facilities
BSL-1	Microorganisms not known to cause disease in healthy adult humans ( <i>Bacillus subtilis</i> , infectious canine hepatitis)	Basic
BSL-2	Indigenous, moderate-risk agents associated with human disease of varying severity (Hepatitis B virus, <i>Salmonella</i> Spp.)	Basic

## BIOSAFETY LEVEL DIFFERENCES (CONTINUED)

Containment Level	Description of Agent	Facilities
BSL-3	Indigenous or exotic agents where potential for infection by aerosol exists and disease. May have serious-to-lethal consequences ( <i>Brucella</i> sp., Venezuelan equine encephalitis).	Containment
BSL-4	Dangerous and exotic agents that pose high risk of life-threatening disease (Lassa fever virus, Ebola virus, Marburg virus)	Maximum Containment

## ANIMAL BIOSAFETY LEVELS

- **ABSL1** – Animals infected with agents not known to cause disease.
- **ABSL2** - Animals infected with agents associated with human disease via percutaneous, mucous membrane, oral.
- **ABSL3** - Animals infected with indigenous/exotic agents associated with human disease and with potential for aerosol transmission.
- **ABSL4** - Animals infected with dangerous/exotic agents of life threatening nature.



## BSL VS. ABSL

- Used interchangeably / incorrectly
- Comparable but animals themselves pose additional risks / hazards
- BSL 1-4 work can be done in most ABSL 1-4 facilities but not necessarily vice versa, based on agent, lab design, animal species, etc.
- **BSL-3 Ag** is a high-containment agricultural ABSL where room itself is the primary containment

## BIOSAFETY LEVEL 1 BSL 1

- Basic Level of Containment relies on Standard microbiological practices
- No special primary or secondary barriers recommended other than sink- hand washing



## ABSL-1

- Standard animal care & management practices
- Standard animal facility:
  - No recirculation of exhaust air
  - Directional air flow "recommended"
  - Handwashing sink available

## BIOSAFETY LEVEL 2 BSL 2

Primary hazards to personnel working with these agents relate to:

- Mucous membrane exposure
- Percutaneous exposure
- Ingestion



## BIOSAFETY LEVEL 2 BSL 2

Examples:

- Measles virus
- *Salmonella* spp.
- *Toxoplasma* spp.
- *Mycobacterium fortuitum*
- Bloodborne pathogens
- Human body fluids/particularly when visibly contaminated with blood
- *Listeria*
- Working with Nonhuman Primates

## BIOSAFETY LEVEL 2

Must identify:

- Agent(s)
- Name of PI and Lab Manager
- Emergency phone numbers
- Special Entry Requirements



## BIOSAFETY LEVEL 2 *SAFETY EQUIPMENT (PRIMARY BARRIERS)*

In addition to BSL-1:

- Use biosafety cabinets (class II) for work with infectious agents involving:
  - Aerosols and splashes
  - Large volumes
  - High concentrations

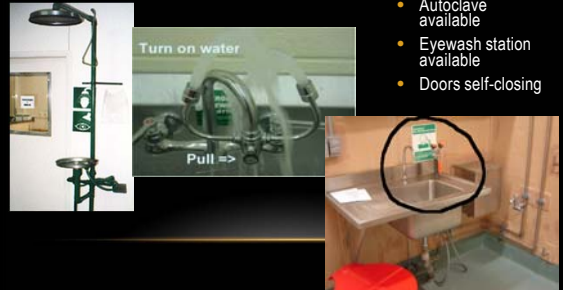
## BIOSAFETY LEVEL 2 *SAFETY EQUIPMENT (PRIMARY BARRIERS)*

- Class II Biosafety Cabinet - Technique



## BIOSAFETY LEVEL 2 *LABORATORY FACILITIES (SECONDARY BARRIERS)*

- BSL-1 Facilities PLUS:



- Autoclave available
- Eyewash station available
- Doors self-closing



### ABSL-2

- ABSL-1 plus:
  - Limited access
  - Biohazard warning signs & biosafety manual
  - Precautions for sharps
  - Decontamination of all infectious wastes and animal cages prior to washing
- PPE: Lab coats, gloves, face & respiratory protection as needed

### ABSL-2 CONT'D

- Containment equipment appropriate for the species
- Negative (inward) directional airflow
- Secondary barriers similar to ABSL-1 plus:
  - Autoclave available
  - Mechanical cagewasher "recommended"



## BIOSAFETY LEVEL 3 BSL 3



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

## BIOSAFETY LEVEL 3 BSL 3

- Exposure potential to pathogens spread by aerosol (autoinoculation and ingestion as well)
- Infection serious, possibly lethal
- More emphasis on primary barriers (BSC, for ex.) and secondary barriers (controlled lab access, ventilation requirements)
- Examples:
  - *Mycobacterium tuberculosis*, *M. bovis*
  - *Burkholderia* spp.
  - *Francisella tularensis*
  - Highly pathogenic avian influenza



### BIOSAFETY LEVEL 3

#### *SAFETY EQUIPMENT (PRIMARY BARRIERS)*

- BSL-1 and 2 Safety Equipment PLUS
  - Respiratory protection
  - Tyvek or equivalent
  - 2 pairs of gloves, one taped
  - ...and more



### BIOSAFETY LEVEL 3

#### *LABORATORY FACILITIES (SECONDARY BARRIERS)*

- BSL-1 and 2 Facilities PLUS:
  - Separate building or isolated zone
  - Double door entry
  - Directional inward airflow
  - Visual monitoring device to indicate/confirm air flow direction



### BIOSAFETY LEVEL 3

#### *LABORATORY FACILITIES (SECONDARY BARRIERS)*

- BSL-1 and 2 Facilities PLUS (cont.):
  - Enclosures for aerosol generating equipment (BSC)
  - Room penetrations sealed (but not necessarily airtight)
  - Walls, floors and ceilings are water resistant for easy cleaning

### BIOSAFETY LEVEL 3

- Limited Access
  - (Double-doored change room)
- Exhaust Air Interlocked with Supply Air (if/when exhaust shuts off, supply shuts off)
- HEPA-Filtered Room Exhaust Air optional (based on risk assessment)
- Directional Airflow
- Protective Laboratory Clothing



### BSL 2 WITH BSL 3 PRACTICES

- Reserved for routine procedures (primarily diagnostic) when BSL 3 facilities are not available
  - Exhaust air discharged to outdoors
  - Ventilation balanced for inward air flow
  - Restricted access when work in progress
  - Recommended practices for BSL 3 are rigorously followed
  - Requires authorization by lab director

### ABSL-3: REQUIRES ABSL-2 PLUS:

- Medical surveillance
- Personnel clearance and training
- Respiratory protection, PPE
  - Powered Air-Purifying Respirator
  - Full or half-face respirator
- Autoclave available in the lab/facility
- Primary containment measures such as Biosafety cabinets (I, II, III) to contain potential aerosols
- Well-established biosafety procedures, SOPs



### ABSL-3: REQUIRES ABSL-2 PLUS:

- Practices include:
  - Controlled access to facility
    - Keypunch codes
    - Biometric readers (such as fingerprint readers)
  - Decontamination of clothing before laundering (typically autoclaving)
  - Cages decontaminated (typically autoclaved) before bedding removed
  - Disinfectant foot bath, as needed

### ABSL-3: REQUIRES ABSL-2 PLUS:

- Facilities require
  - Physical separation from access corridors
  - Self-closing double-door access
  - Sealed penetrations
  - Sealed windows
  - Autoclave available in facility

### SHOWER IN OR SHOWER OUT?



### BIOSAFETY LEVEL 4

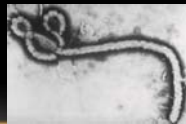


Suitable for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease (& no vaccine or therapy available)

### BIOSAFETY LEVEL 4



- Exposure potential to pathogens spread by aerosol or with unknown risk of transmission
- Infection possibly lethal
- Examples:
  - Ebola viruses
  - Marburg virus
  - Hendra virus
  - Lassa virus



*Ebola virus*

### Biosafety Level 4

A TYPICAL BSL-4 LAB. THE **YELLOW HOSES** PROVIDE FILTERED AIR TO SUITED WORKERS. ENTRY/EXIT DOUBLE-DOOR AIRLOCKS AVAILABLE; SOLID & LIQUID WASTE DECON BY HEAT, GAS, OR LIQUID DISINFECTANTS PER ENVIRONMENTAL STANDARDS.



## Biosafety Level 4



### RESEARCHERS WORKING IN A BSL-4 LABORATORY

AIRTIGHT PRESSURIZED SUITS WITH LIFE-SUPPORT, AIR COMPRESSORS, ALARMS, HEPA FILTRATION

## Biosafety Level 4



Decontaminating Shower

### ABSL-4: REQUIRES ABSL-3 PLUS:

- Practices
  - Entrance through change room where clothing is removed and lab clothing donned
  - Exit shower required
  - Wastes (*all wastes*) decontaminated before removal from facility
- Equipment: Maximum containment
  - Class III BSC or....
  - Full-body positive-pressure personnel suits used for all procedures & activities

### ABSL-4: REQUIRES ABSL-3 PLUS:

- Facility requires:
  - Separate building or isolated zone
  - Dedicated supply & exhaust
  - Decontamination systems validated & documented
  - Rooms and contaminated corridors must validate airtight "negative pressure decay test"
  - Includes sub-type doors with inflatable gaskets
  - Single HEPA supply, Double HEPA exhaust
  - Effluent Decontamination System (EDS)
  - Pass-through autoclave

### REQUIREMENTS FOR BSL3-AG

- BMBL 5<sup>th</sup> ed. Appendix D
- Unique to agriculture – to protect the environment from an economic, high-risk pathogen where studies are conducted with large animals or situations in which the **facility barriers serve as the primary containment.**
- Requires enhancements *beyond* BSL-3/ABSL-3
- Requires USDA-APHIS permit

### REQUIREMENTS FOR BSL3-AG

- Standard ABSL-3 facility is "starting point"
- Designed to protect the environment
  - **Includes almost all of the features ordinarily used for BSL-4/ABSL-4**
  - Must be designed, constructed, & certified as primary containment barriers
  - Airtight (negative pressure-decay-tested)
  - Exit shower required







**WHAT BIOSAFETY LEVEL IS REQUIRED FOR STUDIES UTILIZING RODENTS EXPERIMENTALLY INFECTED WITH *BACILLUS ANTHRACIS*?**

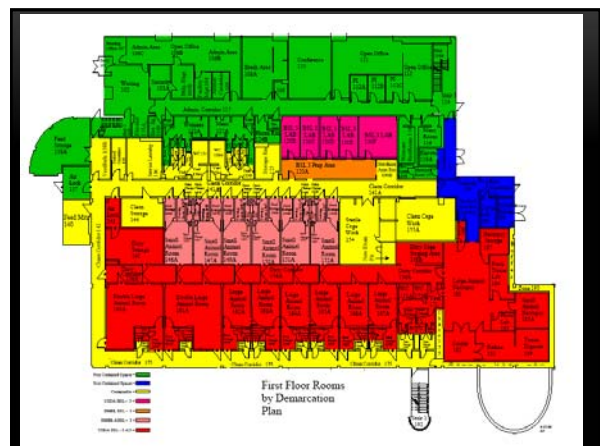
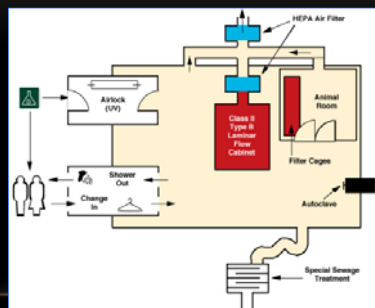
**WHAT BIOSAFETY LEVEL IS REQUIRED FOR STUDIES UTILIZING RODENTS EXPERIMENTALLY INFECTED WITH *BACILLUS ANTHRACIS*?**

- ABSL-2
- BMBL 5<sup>th</sup> ed. Section VIII-A

**FACILITIES AND EQUIPMENT**



**TYPICAL BSL 3 LABORATORY**





## HOUSEKEEPING



## HOUSEKEEPING



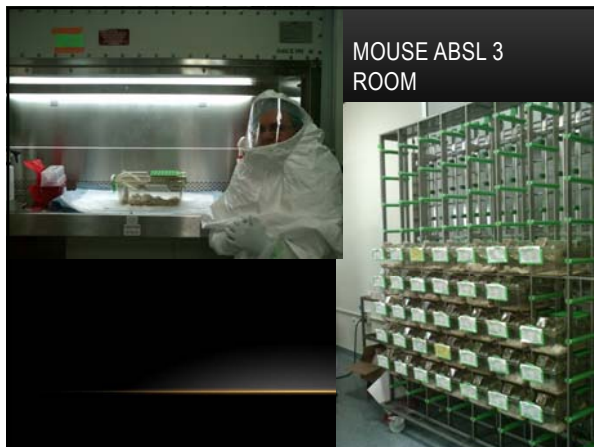
Don't underestimate the impact of waste and laundry!

## SAFETY EQUIPMENT (PRIMARY BARRIERS)

- Biosafety cabinets (BSCs)
- Enclosed containers
- PPE



## MOUSE ABSL 3 ROOM



## MOUSE ABSL 3 ROOM

## ABSL-3 ROOM ("ENHANCED")



j1      move?  
jsheets, 12/6/2005

## THE MOST COMMONLY REPORTED LABORATORY-ASSOCIATED BACTERIAL INFECTION IS...?

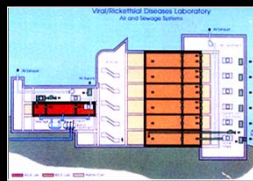
## THE MOST COMMONLY REPORTED LABORATORY-ASSOCIATED BACTERIAL INFECTION IS...?

- Brucellosis

- [http://www.cdc.gov/ncidod/dbmd/diseaseinfo/Brucellosis\\_g.htm](http://www.cdc.gov/ncidod/dbmd/diseaseinfo/Brucellosis_g.htm)
- 7 DEC 2007

## FACILITY DESIGN AND CONSTRUCTION (SECONDARY BARRIERS)

- Protects lab workers
- Protects personnel outside the labs
- Protects community
- Vary by the level of risk (Biosafety level-directed)



## Pass-through AIRLOCK

CONTROLLED CEILING EXHAUST VENT

EPOXY OR ELASTOMERIC-COATED  
WALLS

SUBMARINE-TYPE DOORS (GASKETED)

NEGATIVE DIRECTIONAL AIRFLOW  
WITH DOOR CONTROLS

*(NOT FOR ROUTINE TRAFFIC)*



## PASS-THROUGH AIRLOCK CHAMBER



## MAGNEHELIC GAUGES



- LEFT: Entry into a contained space from a corridor, to provide a **VISUAL INDICATOR** of directional airflow/differential pressure **BEFORE** you enter the room. Green = "good"
- RIGHT: Gauges on double HEPAs: When readings double, change the filters

## Slide 57

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j2

move?

jsheets, 12/6/2005

## PASS THROUGH / DUNK TANK



All work involving inoculation of hantavirus-containing samples into rodent species permissive for chronic infection should be conducted at what ABSL?

All work involving inoculation of hantavirus-containing samples into rodent species permissive for chronic infection should be conducted at what ABSL?

- ABSL-4
- BMBL 5<sup>th</sup> Ed. Section VIII-E

- Hendra Virus and Nipah Virus are members of a newly recognized genus called \_\_\_\_\_, within the family \_\_\_\_\_.
- Work with any infected animals should be conducted at what ABSL?

- Hendra Virus and Nipah Virus are members of a newly recognized genus called **HENIPAVIRUS**, within the family **PARAMYXOVIRIDAE**.
- Work with any infected animals should be conducted at what ABSL? **4**
- BMBL 5<sup>th</sup> Ed. Section VIII-E

## BIOLOGICAL SAFETY CABINETS

### PURPOSE

- Product protection
- Personal protection
- Environmental protection

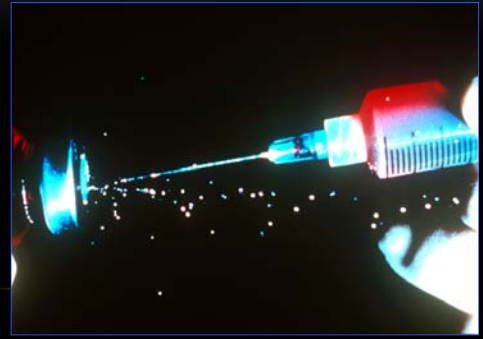
BMBL 5<sup>th</sup> Ed. Appx. A



## VORTEX



## AEROSOL GENERATION NEEDLE-CONTAINER



## BIOLOGICAL SAFETY CABINETS

### TYPES

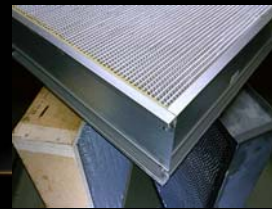
- A. Class I
  - inward airflow protects worker
  - exhaust to outside (w/wo HEPA filter)
- B. Class II
  - worker, product, environmental protection
  - "sterile" work area
  - use for work with aerosol-transmissible micro-organisms
  - use also for tissue culture/ virology
- C. Class III
  - totally enclosed, ventilated, air-tight
  - suitable for work with BSL3/4 agents

## BIOLOGICAL SAFETY CABINETS

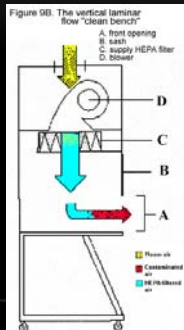
### COMPONENT

### HEPA Filter

- "High efficiency particulate air" filter
- Traps particulates only chemicals, fumes, vapors pass through
- Traps particulates 0.3  $\mu\text{m}$  99.97% efficiency

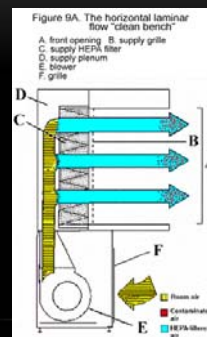


## LAMINAR FLOW VERTICAL



**Not a Biosafety Cabinet**  
Product Protection Only

## LAMINAR FLOW - HORIZONTAL



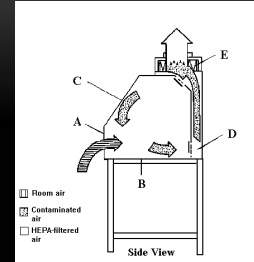
**Not a Biosafety Cabinet**  
Product Protection Only



## CABINET SELECTION VIA RISK ASSESSMENT

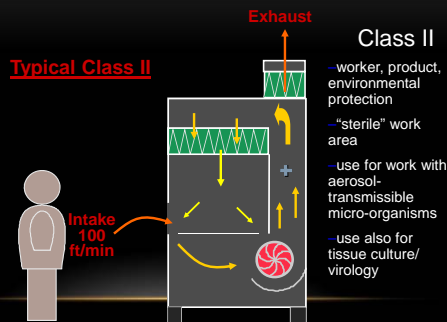
Biological Risk Assessed	Protection Provided			BSC Class
	Personnel	Product	Environmental	
BSL 1-3	YES	NO	YES	I
BSL 1-3	YES	YES	YES	II (A, B1, B2)
BSL 4	YES	YES	YES	III B1, B2

## CLASS I



- Personnel and Environmental Protection
- **No Product Protection**
- Used to enclose equipment (centrifuges).
- Hard ducted to outside.

## BIOLOGICAL SAFETY CABINETS AIRFLOW

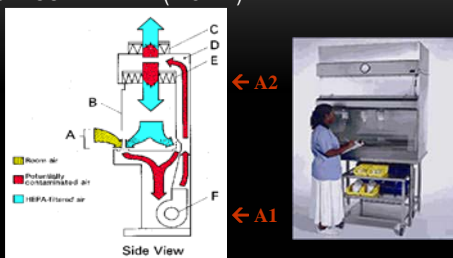


## CLASS II

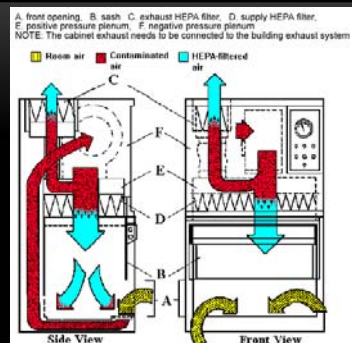


- All Class II are designed for working with BSL 1-3.
- National Sanitation Foundation (NSF) Standard 49 for Certification of Class II Biosafety Cabinets.

## CLASS II TYPE A (1 OR 2)



- Unducted- No volatile or toxic chemicals  
70 % HEPA recirculated air
- Ducted – Use a Thimble (canopy hood)
- Direct ducting to ventilation system is **not recommended**



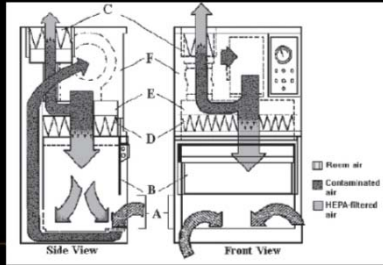
## CLASS II A2



- Can be thimble-connected to building exhaust
- Leakage in a contaminated plenum will be contained.
- Negatively-pressurized contaminated exhaust plenum.

## CLASS II A 2

Figure 7. The tabletop model of a Class II, Type A2 BSC. A. front opening, B. sash, C. exhaust HEPA filter, D. supply HEPA filter, E. positive pressure common plenum, F. negative pressure plenum. The Class II Type A2 BSC is not equivalent to what was formerly called a Class II Type B3 unless it is connected to the building exhaust system. Note: The A2 BSC should be canopy connected to the exhaust system.



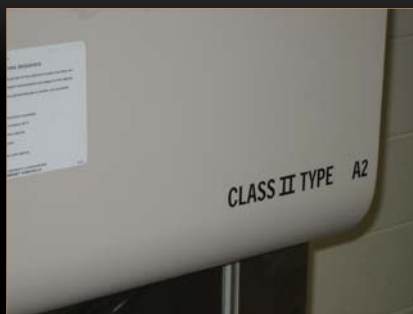
BMBL 5<sup>th</sup> Edition, Appendix A

## CLASS II A1 VS CLASS II A2

- Class II A1
  - Has a plenum that is positively pressurized (air is pushed)
  - If a leak occurs, contaminated air could escape
- Class II A2
  - Has a plenum that is negatively pressurized (air is pulled)
  - If a leak occurs, contaminated air will not escape

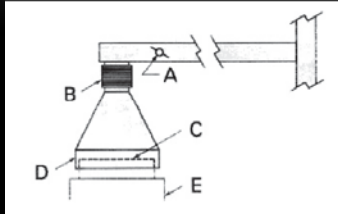


## SEE A PROBLEM?



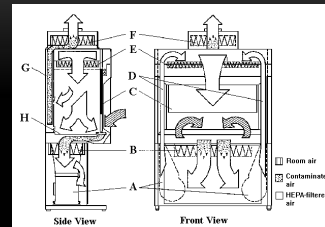
This is what you don't do to a Class II A2 BSC.

## CANOPY (THIMBLE) UNIT FOR DUCTING A CLASS II A BIOSAFETY CABINET [BMBL 5<sup>TH</sup> ED. APPX A]



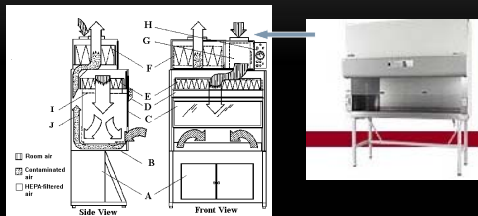
**Figure 4.** Canopy (thimble) unit for ducting a Class II, Type A BSC. A, balancing damper, B, flexible connector to exhaust system, C, cabinet exhaust HEPA filter housing, D, canopy unit, E, BSC. Note: There is a 1" gap between the canopy unit (D) and the exhaust filter housing (C), through which room air is exhausted.

## CLASS II TYPE B1



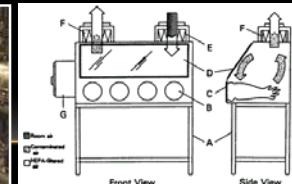
- Initially designed for work with hazardous chemicals with *in vitro* biological systems.
- 30 % HEPA recirculated.
- Must be Hard Ducted - preferably to their own exhaust system (the building's exhaust).

## CLASS II TYPE B2



- Total exhaust cabinet, *no recirculated air*.
- Provides biological and chemical containment
- Still requires building's exhaust system

## CLASS III



## CERTIFICATION OF BIOSAFETY CABINETS

- National Sanitation Foundation Standard 49
  - Certification done yearly on Class II
    - After installation
    - Change HEPA filters
    - Relocation of Biosafety cabinet
    - Cabinet has been repaired
  - Cabinet on wheels – may not require recertification (other than annual) if moved gently within a facility. Extensive movement will require cabinet to be recertified

BSC Class	Face Velocity	Airflow Pattern	Nonvolatile Toxic Chemicals and Radionuclides	Volatile Toxic Chemicals and Radionuclides
I	75	In at front, rear and top through Hepa filter	Yes	Yes, when exhausted outdoors
II A 1	75	70 % Recirculated through HEPA; 30% exhaust through HEPA or out thru canopy	Yes (minute amounts)	No
II B1	100	30% recirculated through HEPA, 70% exhaust. Exhaust via HEPA; hard ducted	Yes	Yes, minute amounts
II B2	100	No recirculation, total exhaust via HEPA, hard ducted	Yes	Yes, Small Amounts
III A II A2	100	Same as IIA. Plenums are negative to room, exhaust is ducted	Yes	Yes, Small Amounts (formerly "B3")
III (glove box)	100	Hard ducted, through 2 HEPA	Yes	Yes, Small Amounts

WHAT TYPE OF BIOSAFETY CABINET HAS A FACE VELOCITY OF 100 LFPM, NO RECIRCULATION OF AIR, AND IS DUCTED TO THE FACILITY EXHAUST SYSTEM?

WHAT TYPE OF BIOSAFETY CABINET HAS A FACE VELOCITY OF 100 LFPM, NO RECIRCULATION OF AIR, AND IS DUCTED TO THE FACILITY EXHAUST SYSTEM?

- Class II Type B2
- BMBL 5<sup>th</sup> Ed. Appendix A
- "This cabinet exhausts as much as 1200 cubic feet per minute of conditioned room air, making this cabinet expensive to operate."
  - Requires heavier gauge ductwork & higher capacity exhaust fan
  - Use of this cabinet should be justified by the research to be conducted

## PERSONAL PROTECTIVE EQUIPMENT



## KNOW HOW TO OPERATE AND MAINTAIN THE EQUIPMENT!



## STANDARD PPE



## PERSONAL PROTECTIVE EQUIPMENT BSL / ABSL3



PAPRs  
Tyvek suit  
Gloves – 2 pairs latex  
                    1 pair nylar - NHPs  
Kevlar sleeves- rabbits  
Shoe covers



### BSL 3



### BSL 4

- Personnel (Personal) Protective Equipment
  - BSL4
    - Positive-pressure suit (Blue Suit)
    - Double gloves
    - Nylar gloves with NHPs
    - Boots



RESEARCH STUDIES AND PROTOCOLS INVOLVING ANIMAL INOCULATION FOR CHARACTERIZATION OF PUTATIVE **SARS CORONAVIRUS AGENTS** MUST BE PERFORMED IN WHAT ABSL FACILITIES USING WHAT WORK PRACTICES?

RESEARCH STUDIES AND PROTOCOLS INVOLVING ANIMAL INOCULATION FOR CHARACTERIZATION OF PUTATIVE **SARS CORONAVIRUS AGENTS** MUST BE PERFORMED IN WHAT ABSL FACILITIES USING WHAT WORK PRACTICES?

- ABSL-3 (for both)
- BMBL 5<sup>th</sup> ed. Section VIII-E

### BIOCONTAINMENT PROGRAM MANAGEMENT





## LABORATORY PRACTICE AND TECHNIQUE

- Most important elements of containment:
- Training, education, risk assessment

## THE TWO BIGGEST CHALLENGES

- **Regulatory Compliance**
  - AWA regulations/policies
  - Guide
  - PHS Policy
  - DEA requirements
  - BMBL
  - 42 CFR Part 73 (for CDC/DHHS)
  - 7 & 9 CFR (for USDA)
  - Etc.
- **Occupational Health and Safety**

## MANAGEMENT CHALLENGES

- **Administrative controls**
  - Must pass security risk assessment *for select agents*
  - Pre-employment issues:
    - Vaccinations, security clearance
- **Cage cleaning and sanitation**
  - Transporting dirty caging out of containment
  - Laboratory sanitary sewer system
    - Liquid waste from larger species (esp agricultural animals, BSL3Ag)
    - Effluent decontamination may be at bench or at building level depending on situation
  - Highly absorbent, low particulate bedding preferred

## MANAGEMENT CHALLENGES

- **Inspections**
  - Qualified individuals
  - Oversight difficult
  - Annual facility performance inspections and/or verifications for containment and equipment
    - Any mechanical containment system should be annually validated, at ABSL-2 and above
- **Controlled substances**
- **Daily monitoring**
- **Emergency response plan**

## AGENT RELATED OCCUPATIONAL ILLNESSES

Years	Number of Infections	Infection rate
1989-2002 (14 yr)	5	0.36 per yr
1943-1969 (27 yr)	456	17 per yr



## OCCUPATIONAL HEALTH AND SAFETY

- Thorough medical evaluation
- Respiratory protection program
  - N95/N99/N100/half-face/full-face
    - Fit testing required
  - Powered-air purifying respirators (PAPR)- must include battery cycling procedures (don't drop them, either)
  - Positive-pressure suit
  - Respiratory clearance required for all of the above



## OCCUPATIONAL HEALTH AND SAFETY

- Vaccination requirements
- Risk assessment approach
  - For vaccine administration
  - For vaccine refusal or medical condition that precludes vaccination
  - Investigational vaccines vs. fully licensed

## Accident and Illness Reporting

- Accident reporting process (for any vivarium, regardless of agent or absence thereof)
- Reporting illness without a known exposure is based on agent-specific protocols

## OCCUPATIONAL HEALTH AND SAFETY

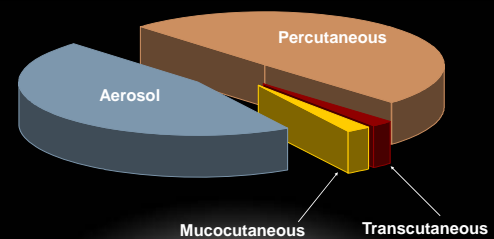
- **MUST HAVE A PLAN FOR Handling of potential exposures!**
  - Establish categories of exposure risk
  - Apply to percutaneous and aerosol exposures



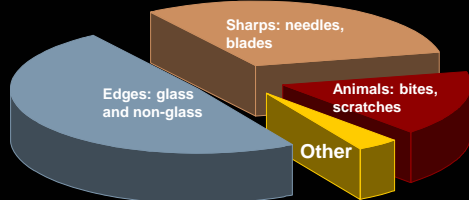
## CATEGORIES OF EXPOSURE RISK

<b>High</b>	Exposure to infectious agent (EIA) <b>highly likely</b>
<b>Moderate</b>	EIA <b>likely</b>
<b>Minimal</b>	EIA <b>unlikely</b> or exposure to material that could contain infectious agent but <b>unlikely</b>
<b>Negligible</b>	EIA <b>highly unlikely</b> or exposure to material that is <b>highly unlikely</b> to contain infectious agent but cannot absolutely rule out.
<b>No risk</b>	No greater than daily risk; confirmed no exposure

## OCCUPATIONAL HEALTH AND SAFETY ROUTES OF EXPOSURE (HISTORICAL)



## OCCUPATIONAL HEALTH AND SAFETY PERCUTANEOUS EXPOSURES (HISTORICAL)



## OCCUPATIONAL HEALTH AND SAFETY PERCUTANEOUS EXPOSURE RISK ASSESSMENT

- Moderate or high risk
  - "Puncture" from needle with prior contact to infectious agent or to ill, infected animal
  - Animal bite or scratch on cage of ill, infected animal
  - "Cut" on autoclave, flask, or other surface that may be contaminated with agent
- Minimal risk
  - "Puncture" from needle with prior contact to recently infected animal and animal not ill
  - "Cut" on object unlikely to be contaminated with agent
- Negligible risk
  - "Puncture" from sterile needle, or "cut" on object highly unlikely to be contaminated (i.e. corner of desk in hall)
  - No discernible direct contact with infected agent/animal

## OCCUPATIONAL HEALTH AND SAFETY AEROSOL EXPOSURE RISK ASSESSMENT

- Moderate or high risk
  - Splash viable agent outside BSC or break centrifuge
  - BSL-4: Breach in personal protective equipment (PPE) in environment with
    - 1) viable agent or infected animal and agent likely to be aerosolized and
    - 2) an inadequate suit pressure
- Minimal risk
  - Exposure to viable agent unlikely to aerosolize (i.e., drop of culture plate with loss of lid)
  - Splash of agent unlikely to be viable outside BSC
  - BSL-4: Breach in PPE in environment but
    - 1) adequate suit pressure maintained (aerosolized agent) or
    - 2) agent unlikely to be aerosolized (i.e., within BSC or animals unlikely to be shedding agent)
- Negligible risk
  - Breach in PPE but area highly unlikely to have infectious agent or infected animals

## OCCUPATIONAL HEALTH AND SAFETY ADDITIONAL SAFETY ISSUES

- Eliminate use of glass
- Needle use
  - Avoid if possible
  - Self-retracting needle systems
  - Use luer lock
  - No recapping
  - Puncture-proof sharps container
- Disposable/retractable scalpel with fixed handle
- Blunt-tipped scissors and forceps



## WHAT'S WRONG WITH THIS PICTURE?



## OTHER OCCUPATIONALLY RELATED ISSUES IN BIOCONTAINMENT

- Frequent showers: eczema, develop sensitivities to soaps/shampoos, athlete's foot
- When wearing PAPRs for ABSL-3 or "blue suit" for ABSL-4:
  - What do you do when you have to sneeze?
  - How about that intolerable itch?
  - Too much coffee before going in?
- Some potential personnel reactions:
  - Claustrophobia: both in the containment facility (ABSL-3 and 4) and the chemical shower (ABSL-4)
  - Fear: from both potential exposure to infectious agents and the fear of no air flow
  - Anxiety or nervousness, difficulty in focusing
  - Decreased sensory capabilities such as hearing, touch, smell, and sight
- Veterinary or animal care/resources support personnel have greater exposure than anyone else at an institution

## MANDATORY MINIMUM TRAINING

- BSL-1, 2, 3, 3-Ag, 4, laboratory operations (consistent with institution's mission)
- Respiratory protection training
- Blood-borne pathogens training
- Chemical hygiene training
- PPE training
  - PAPR/N95/N99/N100 & Tyvek suit training (typical for ABSL-3)
  - BSL-4 positive-pressure suit training (where relevant)
- Containment area orientation & mentoring program/training course

## HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)

- Horses present novel challenges in biocontainment
  - Size
  - Behavior
  - Potential medical problems
  - Euthanasia
- Facility designed to house multiple agricultural animal species may not be optimal for horses
- PPE can be an impediment to safe husbandry practices around these animals

## HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)

Gating in large animal rooms at UGA's Animal Health Research Center



## HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL): PPE REQUIRED



- Scrubs
- Tyvek suit with feet
- 2 pairs of booties
- 1 pair of plastic disposable boots
- 3 pairs of gloves, middle taped to Tyvek sleeves
- N-95 respirator
- Powered Air Purifying Respirator, full bibbed hood
- Rubber boots
- Outer impervious gown

## HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)



## HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)



- PAPR impairs movement, vision, tactile senses, and hearing



### HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)



- **Problem:** Floor is of a hard concrete surface. Cannot place straw hay on floor for bedding; will clog the Effluent Decontamination System (EDS)
- Inadequate funding to surface the floor with a more forgiving surface
- **First solution:** Cover entire stall surface with foam mats (rejected as mats were too difficult to clean)
- **Second solution:** Put soft boots on the horses

### HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)



- Horse boots as a solution for lack of bedding – final judgment still not certain
- Boots are expensive (nearly \$300/pair)
- Cannot autoclave boots
- Need to evaluate condition of hooves regularly by removing boots (additional hazard)
- Will soaking in Virkon, followed by Vaporized Hydrogen Peroxide, be sufficient? Needs to be evaluated.

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### HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)



- **Problem:** Horses fed a regular ration of hay will produce manure that will not run into the drain towards the Effluent Decontamination System
- Manure will clump and form a sludge inside cook tanks of the EDS. Grinders in the EDS system are not adequate for the job.

### HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL)

- **Solution:**
  - Feed horses a pelleted diet with hay cubes
  - Pick stalls with a shovel, place manure in barrels for alkaline hydrolysis digestion
  - Remaining feces washes easily down drains
- **Issue still remaining:** Will this diet increase chances of colic in horses?



### HORSES IN BIOCONTAINMENT (MOCK ABSL-3 DRILL – EVACUATING INJURED PERSONNEL)





## REFERENCES, GUIDELINES, AND REGULATIONS



## WHERE TO START

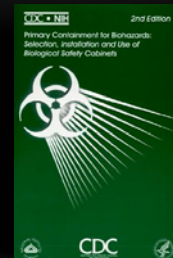
- Experts
- Publications
- Online resources
- Local committees
- Training/workshops



## CDC PUBLICATIONS



**Note: 5<sup>th</sup> Edition of BMBL!!**



## ABSA PUBLICATIONS



## TRAINING/WORKSHOPS

- ABSA Annual Conferences
- CDC-Eagleson International Symposia on Biosafety (every two years)



EAGLESON INSTITUTE



## TRAINING/WORKSHOPS

- NBBTP
- Emory University – Rollins School of Public Health



## LEGAL/REGULATORY GUIDANCE

### HEADACHE



## LEGAL/REGULATORY GUIDANCE

- Antiterrorism and Effective Death Penalty Act of 1996 (P.L. 104-132)
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PL 107-188)
- USA Patriot Act - 2001 (PL 107-56)
- 42 CFR Part 73 (Based on PL 107-188)
  - Possession, Use, and Transfer of Select Agents and Toxins
  - CDC regs
- CDC and USDA (APHIS) have been designated by HHS as the agencies responsible for providing guidance.

## LEGAL/REGULATORY GUIDANCE

- USDA/APHIS
  - 9 CFR Part 121 – Animals
  - 7 CFR Part 331 – Plants
- "Possession, Use, and Transfer of Biological Agents and Toxins" (previously just "Possession")

<http://www.cdc.gov/od/sap/docs/salist.pdf>

## SUGGESTION

- Rely on your institutional biosafety professionals
- Subject matter experts



## COMPONENTS OF SELECT AGENT REG

- New list of select agents/overlap agents CDC/USDA
- Registration of people, places (institutions and locations within), and things (agents themselves)
- Transfer and disposal requirements
- Programmatic and Facility Inspections
- Research and clinical exemptions
- Penalties – *can be severe*

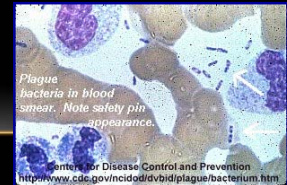


## CDC/APHIS SELECT AGENT PROGRAMS

- CDC/APHIS Select Agent Programs
  - Requires registration of facilities people, places (institutions and locations within), and things (agents themselves)
- Identification of Responsible Official (RO)
  - Develop and implement safety, security, and emergency response plan
  - Provide appropriate training or ensure that training occurs
  - Approve transfer of select agents
  - Provide timely notice of any theft, loss, or release of select agents
  - Maintain detail records and accounting
  - Report the identification of a select agent as a result of diagnosis verification or proficiency testing

## CDC SELECT AGENT PROGRAM

- Select Agent List
  - Combined CDC & USDA-APHIS list
    - HHS non-overlap select agents and toxins
      - *Rickettsia rickettsii*
    - High-consequence pathogens and toxins that also affect livestock (overlap agents)
      - *Bacillus anthracis* (Anthrax)
      - *Burkholderia* spp.
  - USDA high-consequence livestock pathogens and toxins (non-overlap agents and toxins)
    - Foot and mouth disease
  - Listed plant pathogens



## CDC SELECT AGENT PROGRAM

- Personnel Security
  - Personnel with access to select agents are those who have unescorted access.
  - Security risk assessment conducted by Criminal Justice Information Services Division of FBI.
    - <http://www.cdc.gov/sap/securisk.htm>
  - CDC/USDA grants approval for access to specified select agents as described in the laboratory's application for registration. Security risk assessment (SRA) is good for 3 years.

## WHICH GUIDELINES/REGS APPLY?

- CDC & APHIS both regulate select agents
  - Both are "reporting agencies" which issue permits
  - The regulating (reporting) agency depends on the agent. Also depends on the institution.
  - CDC regulates some pathogens
  - APHIS regulates some pathogens (agricultural pathogens)
  - CDC and APHIS may BOTH regulate some pathogens (so-called "overlap" agents)
    - Confused yet?

## TWO GREAT REFERENCES

1. Rusnak, *et al.*, 2004. Management Guidelines for Laboratory Exposures to Agents of Bioterrorism. *J Occup Environ Med.* 46:791-800
2. Rusnak, *et al.*, 2004. Experience in the Medical Management of Potential Laboratory Exposures to Agents of Bioterrorism on the Basis of Risk Assessment at the USAMRIID. *J Occup Environ. Med.* 46:801-811

## ACLAM BOARDS



- BMBL 5<sup>th</sup> edition (#1 reference)
  - Characteristics of different BSLs/ABSLs
  - Biosafety Cabinet classifications and characteristics
  - Select Agent BSLs for different kinds of work
- Biosafety Equipment / PPE
- Blue Book Chapter 24

