Introduction to Biosafety and the BMBL

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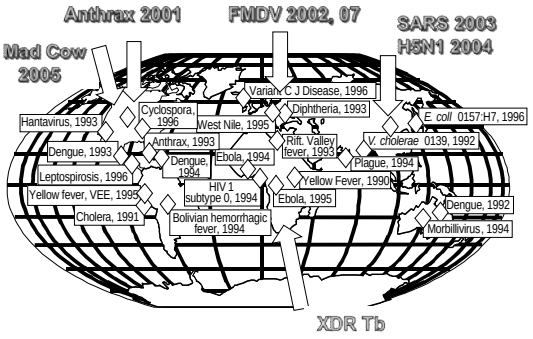
Recent Global Microbial Threats



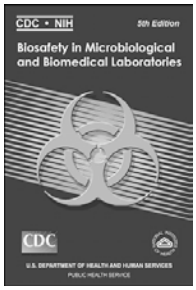
Proliferation of Containment

- **BSL-2**
- **BSL-2+**
- **BSL-3**
- **BSL-3+**
- **BSL-4 Suit**
- **BSL-4 Cabinet**
- **ABSL-3**
- **ABSL-3 Ag**
- **ABSL-4 Suit**
- **ABSL-4 Cabinet**

Proliferation of Containment

BMBL Outlines:

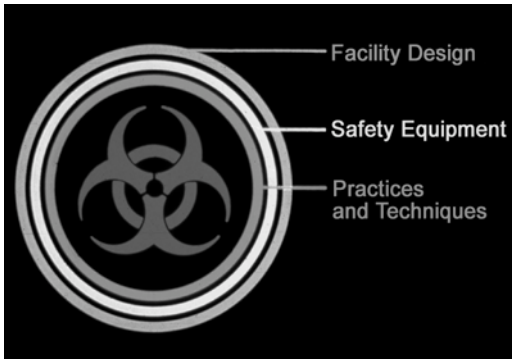
- **Standard Microbiological Practices**
- **Special Microbiological Practices**
- **Safety Equipment**
- **Facilities**



Biosafety in Microbiological and Biomedical Laboratories*

- **Outcome-oriented, not prescriptive**
- **Responsible scientist assesses risks and sets the biosafety level**
- **Participatory strategy works**
  - **involve workers, safety professionals**
  - **develop training initiatives**
  - **vigilant review for effectiveness**

*** BMBL, CDC/NIH**



BMBL 5th edition

- Expanded sections
  - Risk assessment
  - Security
  - Agent summary statements
- New sections
  - Working with tissue cultures, toxins
  - USDA 's ABSL-3 requirements
  - Occupational Health

"Biosafety Culture"

Key Concepts

- Risk: "the probability of harm, injury or disease"
- Hazard: "a recognized risk"
- Safe: "free from risk"

Biosafety

- Fundamental objective:
  - Containment of potentially harmful biological agents
- Purpose of containment:
  - Reduce or eliminate exposure of lab workers, other persons, and outside environment

Biosafety Principles

- Good microbiological techniques
- Knowledgeable supervisor
- Knowledgeable laboratorians
  - Aware of potential hazards
  - Proficient in practices and procedures
  - Lab specific biosafety manual used

Lab Specific Biosafety Manual

- Identifies known and potential hazards
- Specifies practices and procedures to eliminate such hazards
- Based on risk assessment
- Followed by all lab-associated personnel
- Best if developed by all concerned

Biosafety Levels (BSLs)

- Combinations of lab practices and techniques, safety equipment, and laboratory facilities
- Appropriate level determined by risk assessment.
- Specifically appropriate for:
  - Operations performed
  - Known or suspected routes of infection
  - Lab function or activity

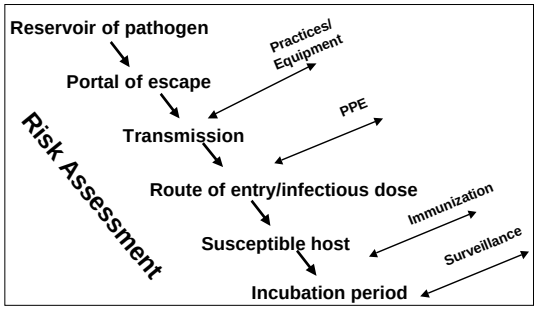
Determining BSLs

- Conditions under which the agent ordinarily can be handled *in the laboratory*
- Based on risk assessment
- Established by responsible scientist
- Resources include:
  - Published data
  - Biological safety officer (BSO)
  - Institutional Biosafety Committee (IBC)

Risk Assessment

- Consideration for:
  - Manipulations to be done
  - Volumes handled
  - Virulence
  - Pathogenicity
  - Antibiotic resistance patterns
  - Vaccine and treatment availability
  - Other factors

Chain of Infection



Assessing Risk ...

- Helps to assign the biosafety level that reduces to an absolute minimum the worker's exposure to agents, their risk of LAI, and potential impact on the environment.
- Will also assist in QA/QC and product protection.

Quantitative Risk Assessment

- Biological agents -- many variables
  - host range & individual susceptibility
  - infective dose
  - route of transmission
  - potential for amplification
  - Strain / type variants
- Prescribed algorithms undependable

Qualitative Risk Assessment

- Identify all applicable risk factors
- Review guidelines, regulations, publications
- Assess EPI and field data
- Consult subject matter experts
- Recognize animal data

Biosafety Practices

Protection of:

- laboratorians
- "products"
- co-workers
- lab support personnel
- environment (community)

Definition

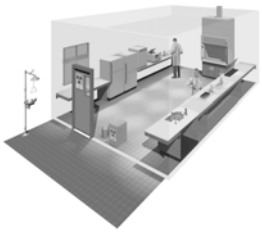
- Biohazard

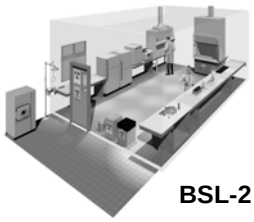
  An agent of biological origin that has the capacity to produce deleterious effects on humans

  …generally a microorganism, or toxins and allergens derived from those organisms

Biosafety Levels 1 & 2

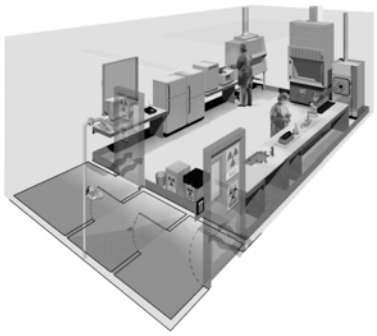
BSL-1





BSL-2

BSL-3



Access

- International biohazard sign posted on doors of BL-2, -3, and -4 labs
- Only authorized personnel may enter laboratories.
- Lab doors are kept closed.
- Children should not be allowed in lab working areas.

All Biosafety Levels

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

All Biosafety Levels

Personal protection

- Eating, drinking, applying cosmetics or handling contact lenses not permitted in laboratory working areas

All Biosafety Levels

Procedures

- Pipetting by mouth is strictly forbidden.
- Materials must not be placed in mouth.

Biosafety Level 1 & 2

Essential biosafety equipment

Use pipetting aids

All Biosafety Levels

Personal protection

- Wear proper lab clothing at all times for work in lab.
- Wear gloves appropriate for the work .

All Biosafety Levels

Personal protection

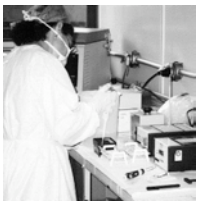
Personnel wash hands after handling:

- infectious materials
- animals, and
- before leaving lab

All Biosafety Levels

Personal protection

- **Protective devices for eyes and face**



All Biosafety Levels

Personal protection

- **Human foods and drinks not stored in lab**
- **Open-toed foot wear not worn in lab**
- **Protective clothing & devices not worn outside lab**
- **Proper clothing storage available**

All Biosafety Levels

Procedures

- **Report all spills, accidents and overt exposures to infectious materials.**

- **A written spill clean-up plan must be developed and followed.**

Biosafety Levels 2 & 3

Essential biosafety equipment

Autoclaves or other means for decontamination

All Biosafety Levels

Waste handling

- **Waste segregation (chem., bio., rad., sharps)**
- **Effective decontamination**
  - **Autoclaving, chemical disinfection**

All Biosafety Levels

- **Packaging to remove for incineration**
- **Protection of personnel handling waste**

All Biosafety Levels

Procedures

- **Contaminated liquids are decontaminated before discharge.**
- **Protect written documents from contamination that are expected to leave lab.**

All Biosafety Levels

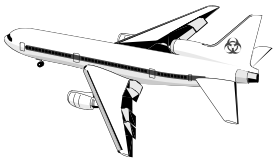
Laboratory Working Areas

Laboratory is neat, clean and free of materials not pertinent to work

All Biosafety Levels

Laboratory Working Areas

Packaging and transport of diagnostic specimens and infectious materials must follow all international regulations.



All Biosafety Levels

Laboratory Working Areas

Move infectious materials safely around or between labs.

All Biosafety Levels

Biosafety Management

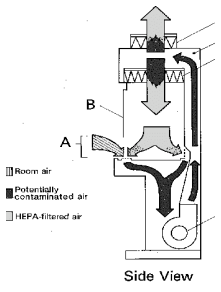
- **Have a rodent and arthropod control program.**
- **Provide appropriate medical evaluation, surveillance and treatment.**
- **Maintain adequate medical records.**
- **Certify biological safety cabinets annually.**

All Biosafety Levels

Essential biosafety equipment

BSCs used whenever:

- **infectious materials are handled**
- **increased risk of airborne infection**
- **procedures create aerosols**



All Biosafety Levels

Health and medical surveillance

- **Pre-employment medical history is recorded**
- **Targeted occupational health assessment performed**
- **Illnesses and laboratory accidents are reported**
- **Women of child-bearing age counselled regarding occupational risks to fetus**

All Biosafety Levels

Wash hands after:

- **Handling infectious materials**
- **Removing gloves, and**
- **Before leaving the lab**

Risk Management Responsibilities

- **Top management**
  - **overall safety policy**
  - **resource allocation**
- **Supervisor**
  - **implements policies, access**
  - **training, practices & procedures**
- **Workers**
  - **strict & rigorous attention to details of practices and procedures**
  - **report incidents and exposures**