

Biosafety Basics and “What’s New” in Biosafety

Presented by

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Agenda

- Introduction
- Hazard identification
- Risk (Hazard) assessment
- Hazard controls/ Biosafety levels
- Conclusion/ What's New

Introduction

Biosafety Program Goals

- Prevent occupational exposure.
- Prevent environmental contamination.
- Compliance with applicable regulations and guidelines.

Introduction

Key Guidance Documents

- “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) 5th Edition
- “NIH Guidelines for Research Involving Recombinant DNA Molecules” 2009
- Others



Introduction

Key Regulations

- Bloodborne Pathogens Standard
- Select Agent and Toxin Regulations
- Others

Hazard ID

- Viruses, bacteria, fungi, parasites, rickettsiae
- Toxins of biological origin
- Prions
- Recombinant DNA
- Synthetic DNA
 - Reverse genetics
- Materials likely to contain biohazards



Risk Assessment

Laboratory-Acquired Infections

- Risky procedures
- Routes of exposure
 - 80 % of laboratory-acquired infections (LAIs) from aerosols
- Aerosol generating procedures
- Percutaneous inoculation
 - Second most common route of infection
- Other routes of exposure

Risk Assessment

Risky Procedures

Ingestion

Mouth pipetting, Splashes of material into mouth; Contaminated articles or fingers placed in mouth; Consumption of food or drink in workplace

Inoculation (Percutaneous)

Needle sticks, cuts from sharps; animal or insect bites or scratches

Contamination of skin or mucous membranes

Spills or splashes into eyes, mouth, nose; Spills or splashes on skin; Contaminated surfaces, equipment, articles

Inhalation

Aerosol generation procedures

Risk Assessment

Aerosol Generating Procedures

Inoculating-loop manipulation	Subculturing and streaking cultures; Flaming a loop; Cooling a loop in culture media
Pipetting	Mixing microbial suspensions; Pipette spills on hard surfaces
Needle and syringe manipulation	Expelling air; Withdrawing needle from stopper; Injecting animals; Spray created when needle separates from syringe
Others	Centrifuging; Using blenders, shakers, sonicators, mixing instruments; Pouring or decanting fluids; Opening culture containers; Spillage of material; Lyophilization, filtration, or aspiration under vacuum; Egg inoculation and harvesting, necropsy

Risk Assessment

Summary of Hazardous Procedures

Aerosol exposure	80%
Other exposure routes	20%

Types of lab accidents associated with infection other than aerosol route:

- Splashes and sprays 26.7%
- Sharps 54.6%
 - Needlesticks, sharps objects, animal or ectoparasite bite/scratch
- Mouth pipetting 13.1%
- Unknown or not indicated 5.5%

Risk Assessment

The Process

The risk assessment process involves 3 main steps:

1. Identify hazards. **Initial Risk Assessment**
2. Assess risk based on **Comprehensive Risk Assessment** procedures and processes.
3. Identify safety controls **Final Biosafety and other controls** needed to allow work to be performed safely.

Risk Assessment

Initial – Risk Groups (RG)

Agents not associated with disease in healthy adults.

1

Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

2

Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual , low community risk).

3

Agents likely to cause serious or lethal human disease for which preventive or therapeutic intervention are not usually available. (high individual, high community risk).

4

Risk Assessment

Risk Groups

- Convenient descriptive system to assist in Risk Assessment
- Risk Groups range from 1 through 4
 - Country-specific variations
 - RG1 organisms can still be highly regulated
 - Animal or plant pathogens
 - Lack of RG designation \neq RG1 or no hazard
 - Correlation between an agent's RG and BSL

Risk Assessment

Comprehensive

- Pathogenicity
- Route(s) of transmission
- Agent stability
- Infectious dose
- Working concentration
- Gene product effects

Risk Assessment

Comprehensive

- Origin of material
- Animal studies
- Prevention or treatment
- Medical surveillance
- Experience and skill level
- Procedures conducted

Risk Assessment

Final

When does BSL *not* equal RG?

- BSL is higher than RG for agents that are:
 - Intentionally aerosolized
 - Large volume or high concentration
- BSL is lower than RG for:
 - Certain operations with clinical samples
 - Attenuated strains

Controls

Biosafety Levels (BSLs)

- Convenient descriptive system to assist in determining containment controls
- Range from BSL1 through BSL4
- Intermediate levels — BSL2+

Controls

Biosafety Levels

- Purpose:
 - Confine biohazardous materials and agents.
 - Reduce or eliminate exposure.
- Achieved through:
 - Laboratory practices
 - Containment equipment
 - Special laboratory design

Controls

Biosafety Levels

Biosafety Levels consist of:

- **Laboratory practices**

- Standard microbiological practices
- Special practices

Practices +
Administrative Controls

- **Primary barriers**

- Safety equipment
- Personal protective equipment

Engineering Controls
PPE

- **Secondary barriers**

- Laboratory and facility design

Engineering Controls

Controls

Examples of Practices

- Hand washing
- No eating/drinking
- Mouth pipetting prohibited
- Sharps handling
- Minimizing aerosols
- Signs and labels
- Proper equipment and PPE use
- Proper laundry handling

Controls

Examples of Administrative Controls:

- Access
- Training
- Occupational health
- Emergency management
- Accident reporting/investigation
- Decontamination plans
- Biosafety manual

Controls

Examples of Engineering Controls – Primary Barriers:

- Biological safety cabinet
- Sharps disposal container
- Engineered sharps protective devices
- Centrifuge safety cups
- Sealed centrifuge rotors

Controls

Examples of PPE:

- Laboratory coat
- Tyvek jump suit
- Booties
- Hair bonnet
- Gloves
- Eye and face protection
- Masks and respirators

Controls

Examples of Engineering Controls – Secondary Barriers:

- Hand washing sink
- Lab surfaces that are easy to clean
- Non-cloth chairs/furniture
- Eyewash
- Location of biosafety cabinet/ equipment
- Directional air flow
- Filtration of exhaust air
- Collection and decontamination of liquid effluent
- Access control devices

Conclusion

What's New?

- CA Airborne Transmissible Diseases Std.
- Dual use review at institutions
- Revision of BMBL/NIH Guidelines
- Lab Accreditation for BSL3 and higher labs
- Training initiatives/ task based training
- Synthetic biology techniques
- National reporting of LAIs and near misses