

Principles and Practices of Biosafety



Definition

Biosafety:

• The application of combinations of laboratory practice and procedures, laboratory facilities, and safety equipment when working with potentially biohazardous agents

Introduction

- The management of biological hazards through the proper application of engineered containment and administrative controls is referred to as biosafety or biohazard control.
- Biosafety or biohazard control is a team effort involving the Principal Investigator (PI), research lab personnel, Institutional Biosafety Committee (IBC), Institutional Review Board (IRB), Institutional Animal Care and Use Committee (IACUC), and Environmental Health and Safety

Why Biosafety Practices?

- To provide protection for:
 - Workers
 - Co-workers
 - Lab support personnel
 - General Public
 - Environment
 - "products"
- To comply with federal and local regulatory standards

Regulatory Requirements and Guidelines

- UNE Environmental Health & Safety Office suggest these links to the following:
 - NIH Guidelines for Research Involving Recombinant DNA

Molecules (December, 2009)

 CDC/NIH - Biosafety in Microbiological and Biomedical , 5th Edition

Laboratories (Feb, 2007)

- OSHA-Bloodborne Pathogen Standard
- DOT-Transportation of Hazardous Materials
- UNE IBC Policies

Training Requirements

- Individuals who work with or have access to biohazardous agents are required to undergo this training.
- Training needs to occur on an annual basis and be documented by the PI and the IBC.

Principal Investigator Responsibilities

- Develop standard operating procedures (SOPs) to ensure the safe use of biohazardous agents
- Submit a recombinant DNA (rDNA) and/or Infectious Agent Registration form for IBC review
- Obtain approval from the IBC prior to commencement of work
- Comply with specific biosafety protocols, practices, and procedures described in the IBC policies
- Ensure all laboratory staff are appropriately trained in biosafety
- Report incidents

Examples of problems and Reporting procedures

- Report any significant problems, violations of policies, practices and procedures, or any significant research related accidents and/or laboratory acquired infection to Environmental Health and Safety at # 2488
- Call Safety & Security at # 366 for assistance with the following types of emergencies:
- Medical Assistance is needed for injuries
- Fires
- Explosions
- Chemical spills

Laboratory Staff Responsibilities

- Comply with the specific practices and procedures described in the IBC policies
- Report all problems, spills, or violations of procedure to the PI or Lab Manager immediately

Sources of Biosafety Information

Knowledgeable supervisor

- Knowledgeable personnel
 - Awareness of potential hazards
 - Proficient in practices & techniques
- Lab specific biosafety manual which includes SOPs
- Biosafety in Microbiological and Biomedical Laboratories (BMBL)- 5th Edition

Definition of a Biohazard

Biohazard

• An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e. microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals.

Examples of Biohazardous Agents

- Infectious microorganisms (bacteria, viruses, fungi, parasites, prions, rickettsiae, etc.) affecting humans
- Diagnostic (clinical)
 specimens
- Recombinant DNA (viral vectors, gene therapy, cloning)
- Genetically modified microorganisms
- Transgenic plants and animals

- Human and non-human primate cells, cell culture (primary and immortalized), tissues, blood (whole blood or any components) and body fluids
- Animal or plant cells, cell cultures, fluids, tissues or derived wastes which may contain pathogens
- Animals known to be reservoirs of zoonotic disease.

Biosafety Considerations

- Biosafety Levels (BSLs)
- Laboratory Practices and Techniques
 - -BMBL
 - Standard Practices
 - Special Practices
- Safety Equipment (Primary Barriers)
- Facility Design and Construction (Secondary Barriers)

Biosafety Considerations- continued

- Biosafety cabinets (BSCs) for BSL 2
- Personal protective clothing
 - Gloves
 - -Gowns/lab coats
 - Eye and face protection
- Pipetting devices
- Safety centrifuge cups and rotors

Biosafety Levels (BSL)

- BSL 1: agents not known to cause disease
- BSL 2: agents associated with human disease
- BSL 3: indigenous/exotic agents associated with human disease and with potential for aerosol transmission
- BSL 4: dangerous/exotic agents of life threatening nature.

Examples of Human & Primate Source Material

- Blood and blood products
- Vaginal secretions
- Semen
- Amniotic fluid
- Unfixed tissues
- Cerebrospinal, synovial, pleural, pericardial, and peritoneal fluids
- Cell cultures

- Saliva
- Urine
- Tears
- Sputum
- Feces
- Vomit
- Other excretions and secretions

Second column materials are not covered in the Bloodborne Pathogen Standard, and are possibly not occupationally regulated.

Human & Primate Source Material: (continued)

- May transmit infectious agents
- Imperfect knowledge of infectious status
 - Incubation period (asymptomatic)
 - Not every pathogen has a test
- Most tissues and body fluids
 - Bloodborne Pathogens:
 - HBV, HCV, HIV, HTLV-1
 - Pathogens causing:
 - malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jacob disease and viral hemorrhagic fever

Bloodborne Pathogen Standard

- All exposure to human/primate blood and or fluids is regulated by the U.S. Department of Labor Occupational Safety & Health Administration (OSHA).
- The regulations are called the Bloodborne Pathogen Standard
- Human blood, fluids and most human/primate cultures are designated as BSL2.

Biosafety Level 2: Introduction

• Suitable for work involving agents of moderate potential hazard to personnel and the environment

Biosafety Level 2: Examples

- Measles virus
- Salmonellae
- Toxoplasma spp.
- Human body fluids particularly when contaminated with blood
- Human blood
- Hepatitis B virus
- One degree cell lines or human cell lines
- Viral vectors
- Bloodborne pathogens

*Immunization or antibiotic treatment is available

Biosafety Level 2 Facility Design

Requirements:

- Laboratories have lockable doors
- Sink for hand washing
- Work surfaces easily cleaned
- Bench tops are impervious to water
- Sturdy furniture
- Autoclave available

Biosafety Level 2: Facility Design

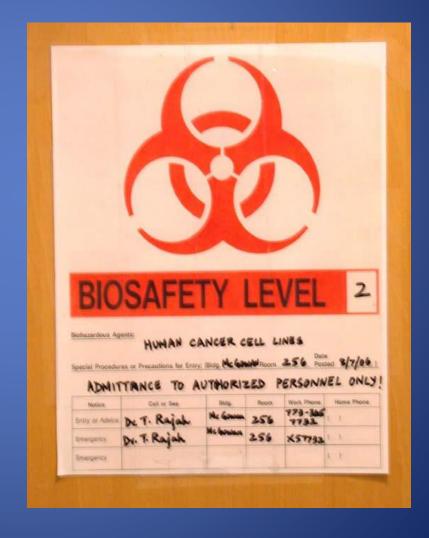
Secondary Barriers

- Requirements
 - Biological safety cabinets installed as needed
 - Adequate illumination
 - `Eyewash readily available
 - Air flows into lab without re-circulation to non-lab areas
 - Windows fitted with fly screens

Biosafety Level 2 Facility Design

Secondary Barriers

• Restricted access when with work in progress



Biosafety Level 2 Facility Construction

Secondary Barriers & Standard Microbiological Practices

- Requirements
 - Location: separate from public areas
 - Structure: normal construction
 - Ventilation: directional
 - Standard Microbiological Practices
 - Same as BSL 1

Biosafety Level 2 Safety Equipment

Primary Barriers

- In addition to BSL 1:
 - Use class II biosafety cabinets for work with infectious agents involving:
 - Aerosols and splashes
 - Large volumes
 - High concentrations
 - Purpose
 - Product protection
 - Personal protection
 - Environmental protection



Biosafety Level 2 Special Practices

Needles and Sharps Precautions





Biological Waste

- Types
 - Cultures, stocks, isolates
 - Materials containing or contaminated with blood
 - Sharps
 - Pipettes, wrappers, tips
 - All materials used in the lab and exposed to biohazards

Biological Waste

- Disposal
 - Puncture proof, leak-proof, and sealable receptacles
 - Avoid over filling
 - Dispose of properly

