



# Development of a Biosafety Plan

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# Objectives

- **Participants will be able to:**
  - ◆ Recognize the importance of a biosafety plan
  - ◆ Identify the key elements of a biosafety plan
  - ◆ Determine if their existing biosafety plan is appropriate for the work being conducted in their laboratory



## 42 C.F.R. 73

- **§ 73.12 Biosafety**

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is **commensurate with the risk of the agent or toxin, given its intended use**. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures.



# Purpose of Biosafety Plans

- Protect employees, visitors and the surrounding community
- Meet applicable state, federal and institutional guidelines or requirements
- Define responsibilities for laboratory safety
- Provide laboratory-specific standard operating procedures
- Provide information about safe work practices, safety equipment and personal protective equipment
- Serve as a resource for laboratory staff



# Responsibility for Laboratory Safety



- Upper Level Administrator Responsibilities
- Safety Oversight Staff Responsibilities
- Laboratory Director/Principal Investigator
- Employee



# Upper Level Administrator



- **Responsibilities include:**
  - ◆ Promote the importance of safety in all activities
  - ◆ Identify safety oversight staff
  - ◆ Provide support to an effective, broad-based laboratory and chemical hygiene program
  - ◆ Establish an institutional biosafety committee



# Safety Oversight Staff



- **Responsibilities include:**
  - ◆ Training of staff
  - ◆ Monitor maintenance of laboratory records
  - ◆ Ensure compliance with state, federal and institutional requirements
  - ◆ Ensure compliance through regular inspection of laboratories



# Laboratory Director/ Principal Investigator



## ■ Responsibilities include:

- ◆ Ensure that potential hazards have been identified and addressed before work begins
- ◆ Ensure that there are written protocols or SOPs in place to mitigate hazards of the procedures based upon completion of a risk assessment
- ◆ Adequately train laboratory employees
- ◆ Report laboratory incidents to appropriate officials
- ◆ Enforce institutional safety policies and safe practices



# Employee

- **Responsibilities include:**
  - ◆ Completion of all required training
  - ◆ Follow safety procedures when working
  - ◆ Be knowledgeable about SOPs
  - ◆ Report incidents to Principal Investigator and/or other personnel according to institutional guidelines



## Visitor/Guest

- **The Principal Investigator/Lab Director should ensure that visitors/guests:**
  - ◆ Are informed of potential hazards in the laboratory
  - ◆ Adhere to any safety requirements in the laboratory
  - ◆ Follow instructions of laboratory personnel to minimize risk of exposure



# Identification/Handling of Laboratory Biohazards

- Determine what infectious agents or toxins are in use in the laboratory
- Description of symptoms of disease for agent in use
- Risk assessment determines appropriate biosafety level and required safety practices for work in the laboratory
- Laboratory biosecurity requirements
- Laboratory waste disposal



# Entry Requirements

- Immunizations
- Medical surveillance requirements
- Personal protective equipment required to enter the laboratory
- Personnel entry restrictions



# General Laboratory Safety Practices

- Specific to the laboratory and work being conducted
- Reference *Biosafety in Microbiological and Biomedical Laboratories* and other nationally accepted safety publications
- Define access restrictions while work in progress



# Engineering Controls

- Specific engineering controls required depend on risk assessment of work being done in the laboratory and biosafety level. Examples of engineering controls:
  - ◆ Control of airflow in laboratory areas
  - ◆ HEPA exhaust



# Safety Equipment

Can include:

- Personal protective equipment
- Biosafety cabinet and other aerosol-containment devices
- Safety centrifuge cup



# Administrative Controls

Can include:

- Entry/exit procedures
- Safety signage
- Safe work practices



# Safe Handling of Sharps

In laboratories where needles and other sharp objects are used:

- Use only when there is no alternative
- available
- Use of rigid puncture-resistant disposable
- container with a lid
- Use mechanical means to remove broken glass



# Waste Processing

- Decontamination procedures should be appropriate to the biosafety level
- Procedures for appropriate packaging and transport of waste should be included
- Procedures for off-site disposal may be applicable



# Disinfection and Spill Response

- Identification of effective disinfectant for agent in use
  - ◆ Procedures for decontamination should be appropriate to biosafety level and agent in use
  - ◆ Decontamination of equipment prior to removal from lab
  - ◆ Special consideration needed for spills in laboratories using radioactive materials
  - ◆ Spill response procedures appropriate to size of spill, location, biosafety level and agent in use



# Training

- Training appropriate to the potential hazards associated with the work involved
- Any training requirements or recommendations outside of the laboratory
- Training is updated regularly
- Training records for each employee are maintained
- Documentation that employee understands training



# Pest Control Management

- Define housekeeping practices
- Procedures for laboratory workers to report pest problems or appropriate actions to be taken



# Transport of Infectious Materials

- Procedures for safe handling or movement of agents within the facility
- Handling/receiving of infectious materials
  - ◆ Packaging for shipment
  - ◆ Entities regulated by 42 CFR 73 are required to file APHIS/CDC Form 2 Request to Transfer Select Agents and Toxins with either APHIS or CDC and obtain approval prior to transfer of a select agent or toxin.
  - ◆ Procedures for receiving package
    - ★ i.e. open in BSC



# Key Elements of a Biosafety Plan

- Responsibilities
- Identification of biohazards
- Entry requirements
- General laboratory safety practices
- Identification of operations that require Engineering controls and safety equipment
- Administrative controls
- Safe handling of sharps (if applicable)
- Waste processing
- Disinfection/spill response
- Emergency procedures
- Training requirements
- Pest control management
- Transport of infectious materials



# Summary

A laboratory specific biosafety plan protects laboratory employees, visitors and the surrounding community from the health hazards in the laboratory.

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**For More Information**

**APHIS/CDC Select Agent Program website:  
<http://www.selectagents.gov>**

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