

Introduction to Syracuse University's Microbiological Safety Program



Glossary of Terms

- **BSL-** Biosafety Level. Combination of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed.
- **BSO-**Biosafety Officer. Administers the Microbiological Safety Program.
- **HHS-** Department of Health and Human Services. Provides recommendations on safe handling of biological material.
- **NIH-** National Institutes of Health. Publishes guidelines for research involving recombinant DNA.



Glossary of Terms

- **OSHA-** Occupational Health and Safety Administration. Sets and enforces standards related to occupational health.
- **PPE-** Personal Protective Equipment (gloves, goggles, respirator, etc.)
- **RMW-** Regulated Medical Waste. Waste contaminated with infectious material.
- **Select Agents and Toxins-** Biological agents that pose a severe risk to public health.
- **Sharps-** Objects capable of puncturing the skin (needles, syringes, scalpels, etc.)
- **USDA-** U.S. Department of Agriculture.



Background

- **1976** NIH “Guidelines for Recombinant DNA Research” - specified laboratory practices for constructing and handling recombinant DNA (rDNA) molecules and organisms containing them.
- **1979** NIH “Lab Safety Monograph” – Describes specific practices, equipment, and facilities appropriate for the safe conduct of rDNA research.
- **1983** HHS “Biosafety in Microbiological and Biomedical Laboratories” (BMBL) – established risk classifications for certain organisms.
- **1990** OSHA Bloodborne Pathogen Standard – Employer must provide reasonable protection to employee against BBP found in body fluids.



Background

- **1995** Larry Wayne Harris – Arrested for the possession of *Yersinia pestis*, convicted of mail fraud.
- **1996** Anti-Terrorist Death Penalty Act – HHS shall maintain a list of biological agents that pose a severe risk to public health (“Select Agents”).
- **1998** 42 CFR 72 “Additional Requirements for Facility Transfer or Receiving Select Agents.” – Track the acquisition and transfer of certain biological agents.
- **2001** 9/11 and US Patriot Act – New Criminal Law for the inappropriate use and possession of biological agents.
- **2002** Anthrax Attacks
- **2002** Public Health Security and Bioterrorism Preparedness Response Act – 42 CFR 73 “Possession and Use of Select Agents”



Background

- **2002** Revised “NIH Guidelines for Research Involving rDNA Molecules” – Research that is conducted at an Institution that receive support form NIH, must comply with the “Guidelines”.
- **2003** Dr. Thomas Butler arrested – Texas Tech Professor investigated after 30 vials of Yersina pestis are reported missing.
- **2004** Syracuse University Approves a Microbiological Safety Program.
- **Recently** – DR. Peter Rice resigns as Head of Infectious Disease at BMC after 3 BU researchers become infected with Tularemia.



Program Introduction

- Syracuse University has developed requirements for the possession and use of biological materials. The Microbiological Safety Program was created to ensure that regulatory compliance is achieved and that adequate health and safety measures are continued or implemented to protect individuals potentially at risk from these materials.

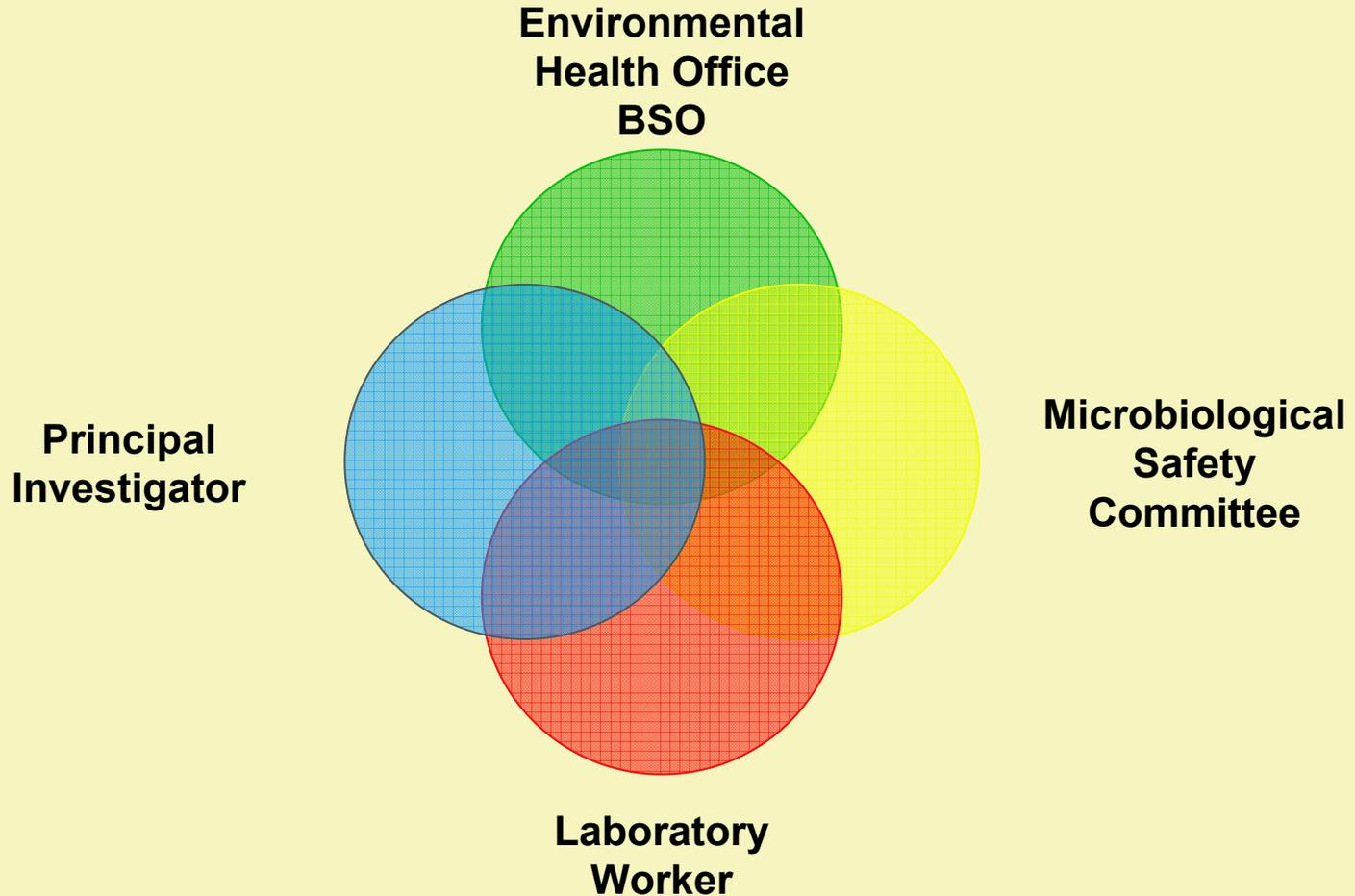


Program Overview

- Program Organization
- Registration/Application of Biological Material
- Biological Inventories
- Biosafety Levels
- Laboratory Practices
- Laboratory Equipment
- Designated Areas
- Disposal of Biological Waste
- Emergency Procedures
- Biosafety Assessments
- Laboratory Decommissioning
- Transfer of Biological Material
- Select Agents



Program Organization



Microbiological Safety Committee

- Comprised of Faculty, and Representatives from Health Services, RIPS, and EHO.
- Developed the Microbiological Safety Program.
- Ensure research involving biological materials (including Select Agents and rDNA) is conducted in accordance with Federal, State, and Local requirements.
- Review applications and authorize research involving human pathogens, including Select Agents.
- Periodically assess compliance of PI's who maintain human pathogens with the requirements of the MSP.
- Recommend and require remedial action to correct any violations of Program requirements.



Biosafety Officer

- Employed by Environmental Health Office
- Administers Microbiological Safety Program.
- Communicate the requirements of the MSP to PI's and laboratory workers.
- Conducts initial review of Applications to conduct research with human pathogens.
- Maintains a database of the location and name of all microorganisms stored at Syracuse University.
- Assess microbiological safety practices, equipment, and containment in laboratories using human pathogens.
- Investigate laboratory accidents involving infectious material.



Principal Investigator

- Notify the Committee in writing of all rDNA research conducted under their supervision.
- Submit an Application to the MSC for the possession and use of human pathogens for approval before initiating research.
- Contact the MSC or BSO before taking possession of a Select Agent or Biosafety Level 3 organism.
- Provide the Biosafety Officer with a list of all microbiological organisms in their possession.
- Develop and implement Standard Operating Procedures that address specific safety procedures for handling human pathogens.
- Train staff in the practice and techniques required to ensure the safe handling of human pathogens.



Laboratory Personnel

- Follow the provisions of any laboratory specific Standard Operating Procedure and the MSP.
- Report accidents, possible exposures or unsafe conditions to their supervisor and BSO.
- Use personal protective equipment and engineering controls when recommended and provided.



Biological Inventory

- PI's must notify the BSO of all biological materials in their possession by completing a Biological Inventory Form. <http://bfasweb.syr.edu/eho/bi/microprogram/Forms/BioInventory.htm>
- Full name (ie. Genus and species)
- In use or storage
- Building and room #
- Update as organisms are added or destroyed and at least annually.



Possession and Use Application

- PI's conducting work with human pathogens (Biosafety Level 2) must complete and submit an Application to the Committee prior to the initiation of the experiment. Appendix K or, <http://bfasweb.syr.edu/eho/bi/microprogram/Attachments/Attachment%20K%20Bio%20Notification.doc>
- List of individuals who will be working under applicant
- Applicants CV and related work experience
- Detailed procedures for proposed operations
- Description of equipment available to minimize hazard
- PPE to be used
- Emergency procedures



rDNA Notification

- PI's are required to notify the MSC of all rDNA experiment. Appendix M or, <http://bfasweb.syr.edu/eho/bi/microprogram/Forms/rDNARegistration.htm>
- General description of research
- Categorize research according to the definitions provided by the NIH.
- Source DNA (genus, species)
- Cloning Vector (specific phage, plasmid or virus)
- Propagation Host (genus, species)
- Target Recipient (species or cell lines used)



Biological Safety Levels

- The CDC and NIH have published guidelines that describe combinations of microbiological practices, safety equipment, and facilities recommended for working with biological organisms.
- Biosafety Level 1 – Not known to cause disease
- Biosafety Level 2 – Associated with human disease
- Biosafety Level 3 – Potential for aerosol transmission
- Biosafety Level 4 – Life Threatening
- The risk associated with the organism will determine the appropriate Biosafety Level.



Selecting Biological Safety Levels

The framework for selecting the appropriate biosafety level or risk group is based on, but not limited to,

- pathogenicity,
- route of transmission,
- agent stability,
- infectious dose,
- concentration,
- origin,
- availability of data from human studies,
- availability of an effective prophylaxis,
- and medical surveillance.



Selecting Biological Safety Levels

- [Appendix A](#)
- The National Institute of Health
- Center for Disease Control
- Canadian Laboratory for Disease Control
- Commission of the European Communities
- This is not a complete list and those agents not listed in biosafety level 2, 3 and 4 are not automatically or implicitly classified as biosafety level 1.
- A risk assessment must be conducted based on the known and potential properties of the agent listed and their relationship to agents that are listed.



BSL 1

Facilities

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



BSL 1

Lab Practices

- Prohibit eating, drinking and smoking
- Prohibit mouth pipetting
- Minimize splashes and aerosols
- Decontaminate work surfaces daily
- Dispose of contaminated wastes in RMW container
- Wash hands
- Provide **Biological Inventory** as items are added or deleted and at least annually.



BSL 2

Facilities (same as BSL1 Plus)

- Laboratories have locking doors
- Biological safety cabinets installed as needed
- Eyewash readily available
- Autoclave available



BSL 2

Lab Practices (Same as BSL1 Plus)

- Restrict Access when work is in progress
- **Decontaminate** stock cultures (chemical or autoclave) prior to disposal as RMW
- Complete **Possession and Use Application** and Receive Committee approval prior to the initiation of experiment
- Report **spills and accidents** to BSO
- Use leak-proof containers when **transporting material**
- Develop policies and procedures for entry and exit of lab and require use of appropriate hand and eye protection.



BSL 2

Lab Practices Continued

- Provide lab personnel with **Standard Operating Procedures** for experiment
- Provide Documented training to lab personnel on specific hazards associated with organism
- **Label Designated Areas** (equipment, storage and work areas) in which organism will be used.
- Post **Biohazard Sign** at entrance to lab
- Use **Biosafety Cabinets** (class II) for work with infectious agents involving:
 - Aerosols and splashes
 - Large volumes
 - High concentrations



BSL 3

BSL 3 Materials not allowed at SU

SU is limited by facilities

- Separate building or isolated zone
- Double door entry
- Directional inward airflow
- Single-pass air; 10-12 air changes/hour
- Enclosures for aerosol generating equipment
- Room penetrations sealed
- Walls, floors and ceilings are water resistant for easy cleaning



Select Agent Possession

- Syracuse University is currently restricted by the Federal Government form possessing [Select Agents](#) in non-exempt quantities.
- Notify Committee
- Registration with CDC/USDA
- DOJ Background Checks
- Internal Security Risk Assessments
- Receipt of Transfers
- Recordkeeping
- CDC/USDA Inspections
- Agency Notifications prior to possession



Select Agents-Exempt Quantities

Toxin Maximum allowable per PI for exemption

- Abrin 100 mg
- Botulinum neurotoxins 0.5 mg
- Clostridium perfringens epsilon toxin 100 mg
- Conotoxins 100 mg
- Diacetoxyscirpenol 1000 mg
- Ricin 100 mg
- Saxitoxin 100 mg
- Shigatoxin and Shiga-like ribosome inactivating proteins 100 mg
- Staphylococcal enterotoxins 5 mg
- Tetrodotoxin 100 mg
- T-2 toxin 1000 mg



Select Agents-Exempt Quantities

- Application to Committee prior to possession
- Create Standard Operating Procedure
- Documented Training for personnel
- Proper PPE
- Disinfection
- Fume Hood instead of Biosafety Cabinet
- Stored in locked areas
- List of PI Approved Users
- Daily Use Inventory Log – all quantities must be accurately tracked
- Cannot be transferred without approval

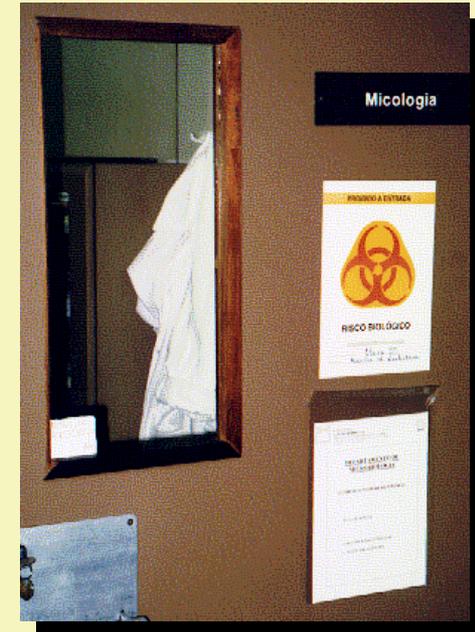


Standard Operating Procedures

- Identify Hazards – [Biological MSDS](#)
- Specific policy and procedures to minimize risk
 - Containment
 - PPE
 - Spill management
 - Safety Equipment
 - Decontamination
 - Waste Disposal
- Template located at:
<http://bfasweb.syr.edu/eho/bi/microprogram/Attachments/Attachment%20N%20SOP.doc>



Designated Areas

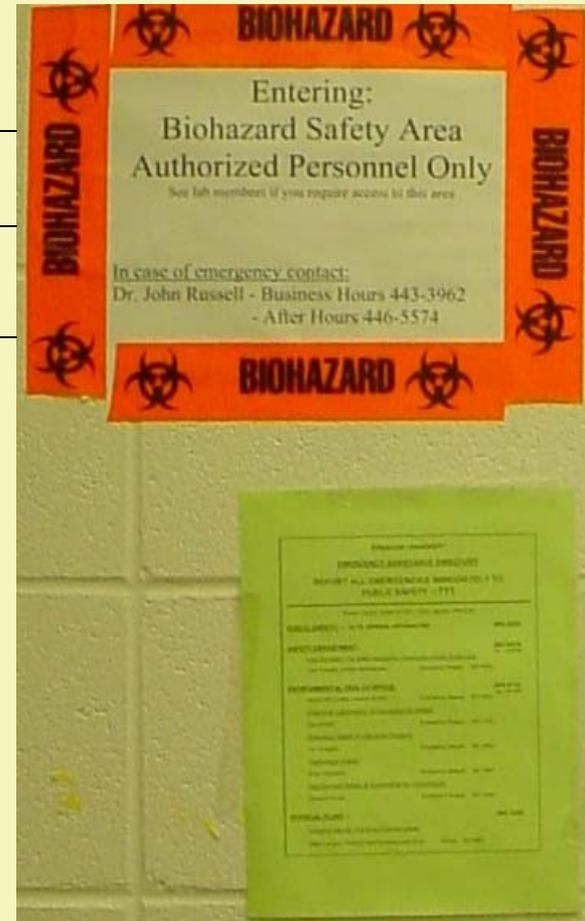
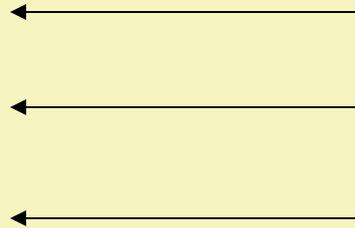


Access to Designated Areas

Name of the material

Entrance Requirements

Contact Number



PPE

- Lab Coat
- Appropriate Gloves
- Appropriate Eye Protection
- Respirator



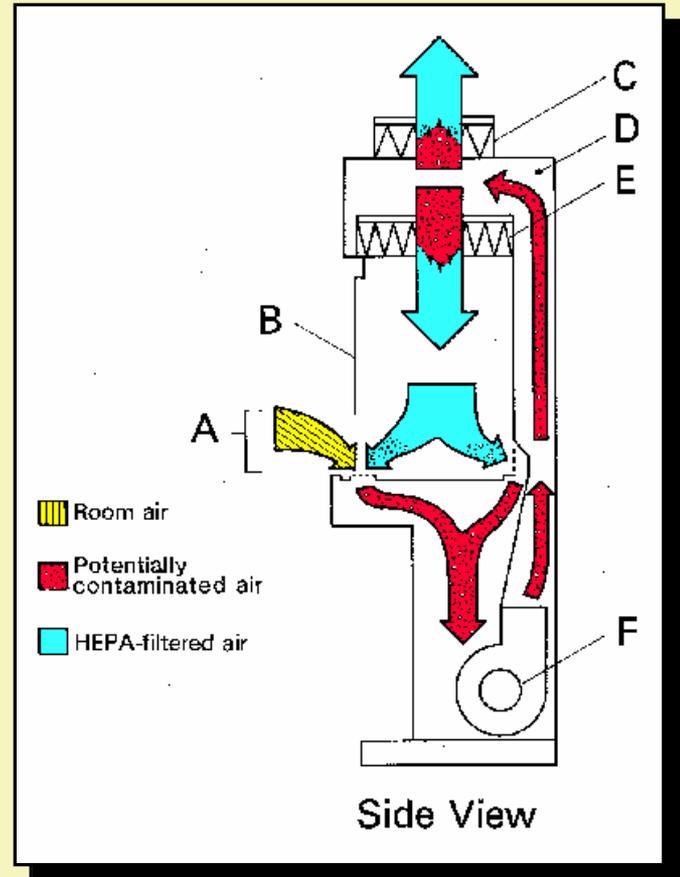
Safety/Containment Equipment

- Biological Safety Cabinet
- Sealed Rotors/Safety Buckets
- Mechanical Pipette
- Plastic-backed disposable paper



Biosafety Cabinets

- Required if experiment will produce aerosolization of infectious material.
- Connection to building exhaust required.
- Must be installed by an approved contractor
- Must be tested and certified:
 - After installation
 - Any time the cabinet is moved
 - At least annually



Class II Type B1



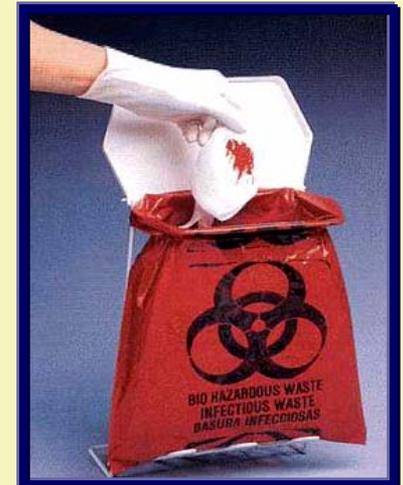
Disinfection

- What is the target organism?
- What disinfectants inactivate the target organism?
- What degree of inactivation is required?
- What is the highest concentration of organisms anticipated to be encountered?
- Can the disinfectant be expected to contact the organism and can effective duration of contact be maintained?
- What restrictions apply with respect to compatibility of materials?
- What is the stability of the disinfectant in use concentrations?



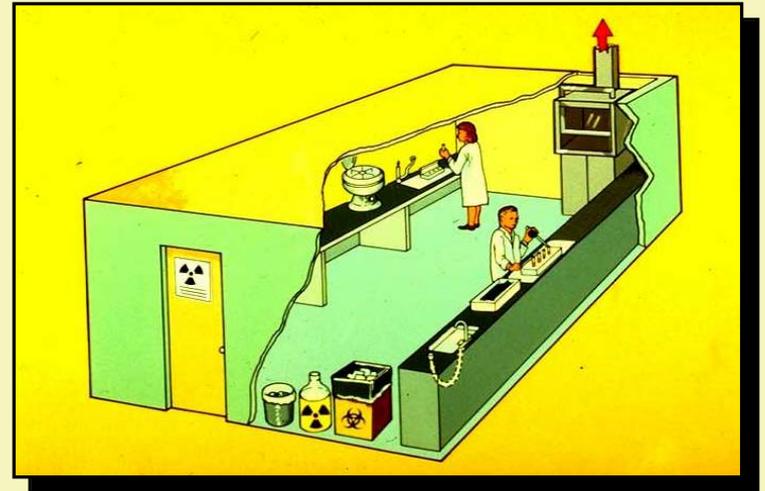
Waste Disposal

- All waste material contaminated with human pathogens are considered Regulated Medical Waste
- All cultures and stocks must be biologically deactivated before removal by EHO
- All sharp objects contaminated with human pathogens must be place in a Sharps Container



Biosafety Assessments

- Are labs meeting compliance?
- Laboratory equipment
- Work practices
- Administrative Controls
- BSO will conduct using a [Biosafety Assessment Form](#)



Laboratory Decommissioning

- Inform the BSO 30 days prior to the anticipated move date.
- Inventory the biological materials and determine which materials will be transferred to your new laboratory, to another Investigator, or destroyed.
- All transfers of biological materials must comply with Section 3.14, Biological Material Transfers.
- All biological safety cabinets require decontamination, even if they are not moved.
- Decontaminant all surfaces and equipment labeled as biohazard and remove label



On-Site Material Transfer

- Complete [Biological Material Record of Transfer Form](#)
- During the move, all biological materials to be relocated must be transported using secondary containment.
- Wear appropriate personal protective equipment for the materials being handled (safety glasses or goggles, lab coat, gloves, closed-toe shoes, etc.).
- You may not transport biological materials in private vehicles.



On-Site Material Transfer

- Do not leave biological materials or other items in the corridors during moving.
- Materials that will be moved on public roads must be shipped using a qualified vendor and in compliance with the Off-site Transfer Requirements.
- Ensure that you have immediate access to adequate and proper materials for cleanup of a spill at any point during the move.
- Leave the material with a known responsible individual in the receiving lab. Do not leave the material unattended or with an unknown individual



Off-Site Material Transfer

- Advance arrangements must be made with the recipient and carrier when shipping infectious materials.
- Biological materials must be properly identified and packaged for shipping.
 - Identification
 - Classification
 - Packaging
 - Labeling
 - Marking
 - Documentation
- The International Air Transport Association (IATA)
- US Department of Transportation (DOT)
- United States Public Health Service (PHS).
- United States Postal Service (USPS)



Entire Program Located at:
EHO Website on Biosafety Page
or

<http://bfasweb.syr.edu/eho/bi/microprogram/microprogram.htm>

