Responsibilities of the Biosafety Professional and Institution

Debra L. Hunt, DrPH, CBSP
Director, Biological Safety; Responsible Official (Select Agents)
Assistant Professor
Duke University / Duke Medicine
Durham, NC
One day Alice came to a fork in the road and saw a Cheshire cat in a tree. "Which road do I take?" she asked. "Where do you want to go?" was his response. "I don't know," Alice answered. "Then," said the cat, "it doesn't matter."
Where Do You Want to Go?

• What responsibility does the Institution play in Biosafety?
• What is your role as a Biological Safety Professional?
  • Definitions of Biological Safety Professionals
• Where do you NEED to go?
• How do you get there?
• Where can you find HELP?
Goals of a Biosafety Program

- *To protect employees and their families* from acquiring work-associated infectious diseases or harm from biological agents/toxins

- *To prevent contamination of the environment* and promote environmental quality

- *To comply with all National, International and Local guidelines and regulations* for the use of potentially hazardous and/or regulated biological materials
Institutional Responsibility

Develop a “Culture of Safety”

Safety is a shared responsibility (shared accountability) among the institution and the workers, and is built upon an atmosphere of trust.
References provide a starting point to develop Institutional performance-oriented and risk-based systems.
NIH Guidelines – Section IV

- Roles and Responsibilities
  - Institution
  - Institutional Biosafety Committee (IBC)
  - Biological Safety Officer (BSO)
  - Principal Investigator (PI)
  - NIH
International Standards

- International Laboratory Biorisk Management Standard: CWA 15793
CEN Workshop Agreement: Biosafety Program (Biorisk Management System)

- Institutional oversight & acceptance
  - President, CEO, CFO
- Biosafety Committee (e.g., IBC)
  - peer review, adopt/establish policies
- Biosafety Office / Biosafety Professional
  - inform, administer program, assist
- Faculty, staff, students & visitors
  - merge biosafety into work
Institutional Responsibility: CEN Workshop Agreement

4.2.1 Biorisk management policy

The organization’s top management shall develop, authorize, and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity).

The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities.
Where Would You Expect a Biological Safety Program?

- Research Laboratories:
  - Universities
  - Pharmaceuticals
  - Government Agencies
- Health Care (Infection Control):
  - Hospitals
  - Clinics
  - Clinical Laboratories
- Manufacturing
- Other
Understanding the Scope of Your Institution

- How Big is Your Plate????
  - Type of Work:
    - Basic / Biomedical Research
    - Animal (lab/ag)
    - Plant (lab/greenhouse/field)
    - Medical / Patient Care
    - Industrial / Manufacturing
  - Small vs Large:
    - Multi-system
    - Local / National / International scope?
  - Security Needs:
    - Select Agents
    - High containment
Seek Relevant US Federal Standards for Biological Research/Issues in Your Institution

- DOT/IATA Infectious Agents (Import/Export Regulations)
- USDA (Animal & Plant Pathogens)
- NIH rDNA Guidelines
- FDA (vaccines, treatments)
- CDC Guidelines for M. tuberculosis
- Bloodborne Pathogens (OSHA Regulations)
- Local and International Guidelines and Regulations!!!

Require Institutional Oversight
Biorisk Management Systems: Institutional Inter-relationships

- Facility Support
- Animal Handlers
- Occupational Health
- Security
- Administration
- Computer Support
- Biosafety Committee
- Researchers
- Procurement
- Greenhouse Managers
- Risk Management
- Biological Safety
Institutional Research Oversight Committees

Federal Oversight

- NIH RAC / CDC SA
- IRB (humans)
- RSC (Radiation)
- IACUC (animals)
- IBC (rDNA &/or biological)
What is your role as a Biosafety Professional?
What is a Biosafety Professional?

A biosafety professional *develops and participates* in programs to *promote* safe microbiological practices, procedures, and proper use of containment equipment and facilities; *stimulates* responsible activities among workers; and *provides advice* on laboratory design.
“Biological Safety Officer” Duties
NIH rDNA Guidelines

- Periodic inspections to ensure that laboratory standards are rigorously followed;
- **Report** to the IBC and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses;
- **Develop** emergency plans for handling accidental spills/personnel contamination and for investigating lab accidents involving rDNA research;
- **Provide advice** on laboratory security;
- **Provide technical advice** to PIs and the IBC on research safety procedures.
Biorisk Management (CEN Agreement): Responsibilities of the BSP

- Biological Safety Professional (“Biorisk Management Advisor”, “Biosafety Officer”):
  - Advise on biorisk management issues within the organization; have delegated authority to intervene, if necessary
  - Verify that biorisks have been addressed
  - Review and advise on investigations of accidents/incidents/exposures
  - Communicate current biorisk issues with scientists and other personnel as needed
  - Develop biosafety training activities
  - Ensure compliance with all biological regulations/guidelines relevant to the institution
Examination Content

National Registry of Certified Microbiologists
SM: Biological Safety Microbiology

A list of the tasks tested on the exam is provided below. Questions are classified first by domain and then by task. The examination will have at least one question from each task. The number of questions from each domain is listed below the domain name in the task list.

**Disinfection, Decontamination, Sterilization** (18 questions)
- Understand the differences between sterilization, decontamination, and disinfection and the applicability and means of monitoring each.
- Demonstrate knowledge of use, applicability, and potential hazards (e.g., pyrogenic, flammable, corrosive, carcinogenic) and incompatibility with various disinfectants and sterilants.
- Understand how to use chemicals, steam, dry heat, irradiation, filtration, ultraviolet (UV) sources, gases, or other agents to kill or inactivate microorganisms.

**Work Practices and Procedures** (28 questions)
- Understand the application of sterile (aseptic) techniques.
- Develop, evaluate, and document exposure control procedures for hazardous agents and materials.
- Develop procedures and practices to prevent release of infectious aerosols from equipment.
- Perform biosafety level of work practices and procedures associated with large-scale operations.
- Understand and apply monitoring techniques and equipment to determine effectiveness of exposure control measures and to investigate environmental problems.
- Understand use and disposal of waste.
- Select and understand use of personal protective equipment.
- Select and understand use of respiratory equipment.
- Develop and implement procedures for managing hazardous spills or releases.
- Assess documentation of worker exposure to hazardous materials and preparation of an incident report.
- Develop comprehensive emergency response plan for hazardous areas.

**Risk Assessment and Hazard Identification** — Infectious Agents and Recombinant DNA (33 questions)
- Demonstrate knowledge of personal risk factors associated with microbial exposure.
- Assess the risk of occupational exposure and infection associated with handling infectious agents.
- Demonstrate familiarity with routes of exposure, modes of transmission, and other criteria that determine the hazard category of a recombinant.
- Assess the risk to the community from various work environments where infectious agents or recombinant materials may be present.
- Demonstrate understanding of microbial toxins and their potential to cause work-related illness.
- Demonstrate the ability to recognize the characteristics of bacteria, viruses, fungi, and parasites.
- Understand the hazard of exposure of personnel to biological materials.
- Understand factors that may affect susceptibility, resistance, or consequences of infection.
- Understand the difference between risk of infection and consequences of infection.
- Understand the risk associated with point source release of biological aerosols in the workplace, such as from homogenizers, cell culture, centrifuges, fermenters, and laboratories.
- Understand the risk associated with recombinant DNA technology.
- Demonstrate knowledge of unique biosafety conditions associated with naturally or experimentally infected animals, including nonhuman primates.
SM: Biological Safety Microbiology
“Domains”
Certification Exam for CBSP

- Disinfection, Decontamination, Sterilization
- Risk Assessment and Hazard Identification- Infectious Agents and Recombinant DNA
- Work Practices and Procedures
- Regulatory Aspects, Standards, and Guidelines
- Program Management and Development
- Equipment Operation and Certification
- Facility Design
SM: Biological Safety Microbiology

“Tasks”
Certification Exam for CBSP

DISINFECTION, DECONTAMINATION, STERILIZATION
(10 questions)

1. Understand the difference between sterilization, decontamination, and disinfection and the applicability and means of monitoring each.

2. Demonstrate knowledge of use, applicability, and potential hazards (explosive, flammable, corrosive, carcinogenic, and irritating) associated with various disinfectants and sterilants.

3. Understand how to use chemicals, steam, dry heat, irradiation, filtration, ultraviolet (UV) sources, gases, or other agents to kill or inactivate microorganisms.
How do you DO this?
Planning for Biorisk Management

“PLAN”

- Identify the Scope of the Institution
- Identify those Responsible for the Plan
- Identify methods to conduct Risk Assessments (RAs)

Conduct Risk Assessments
  - Use previous RA results
  - Analyze risk of new hazards
    - MSDSs for infectious agents (Canadian website)
    - Lab-acquired or health-care infections published
    - Current guidelines/regulations
    - Procedures involved with agents
    - Facility appropriateness
  - Identify Security vulnerabilities
Implementing Biorisk Management

“DO”

- Develop Risk Controls based on the RAs
- Develop an Institutional Biosafety Plan (i.e., Manual, Standard Operating Procedures)
- Train all relevant personnel based on SOPs, institutional policies
- Develop expedient communication methods
- Develop and implement Emergency Procedures
Evaluation/Monitoring of Biorisk Management

“CHECK”

- Conduct audits based on a defined schedule, i.e., annually
- Use monitoring tools to collect safety-related data
  - Training records, accident reports, audit results, etc.
- Develop an Internal Auditing Process of Safety Programs (Office of Compliance, Risk Management, etc.)
Updating and Improving Biorisk Management

“ACT”

- Review Monitoring Data and implement changes for improvement
- Develop Performance Improvement Projects
- Support Personnel Development (education) and External Networking
- Provide Methods for Institutional Employee Feedback
  - Those in the workforce are able to communicate problems and/or offer improvement suggestions
Sustainability of a Biorisk Management System

**Safety Culture**

**PLAN:**
- Policy Development

**DO:**
- Implementation

**CHECK:**
- Evaluation & Monitoring

**ACT:**
- Update and Improve

IBC, BSP, & Lab Contributions

Lab & BSP Contribution

IBC, BSP & Lab Contribution
Seek Relevant US Federal Standards for Biological Research/Issues in Your Institution

- Infectious Agents (BMBL)
- USDA (Animal & Plant Pathogens)
- DOT/IATA (Import/Export Regulations)
- Select Agents (CDC/APHIS Regulations)
- NIH rDNA Guidelines
- FDA (vaccines, treatments)
- CAP / TJC (Hospital or Clinic Accreditation)
- Bloodborne Pathogens (OSHA Regulations)
- CDC Guidelines for M. tuberculosis
- EPA (microbial pesticides, ex.)
- AALAS (Animal Welfare)
- AALAS (Animal Welfare)
- Local and International Guidelines and Regulations!!!
- Require Institutional Oversight
- Future Regulations?
There is help!!

Conferences
Affiliates
Workshops
Listserves (Biosafety, Occup. Env Med)
Networking
Webinars
www.absa.org
trust yourself. you know more than you think you do.

(dr. spock)