Pathogen Control

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Don’t be caught off guard!

Biosafety vs. Biosecurity – Two separate but related subjects

Biosafety- Development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agent to workers, other persons or the environment.

Biosecurity- Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.

With Regard to Biosafety… How is Risk Assessed?

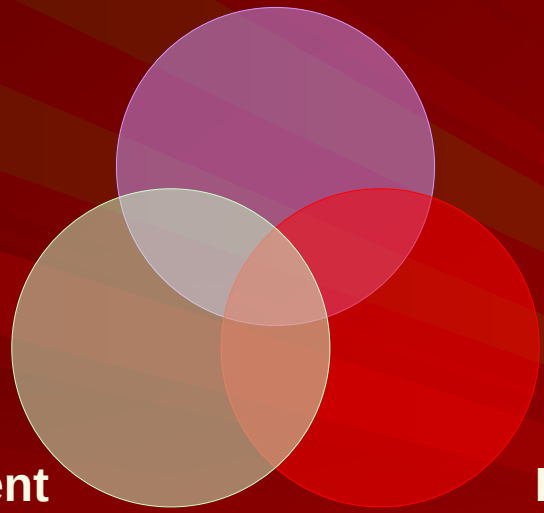
- **Organisms**
  - **Indigenous v. Exotic**
  - **Route of Transmission**
  - **Severity of Disease**
  - **Stability of Agent**
- **Procedures**
  - **Concentration**
  - **Quantity**
  - **Aerosols or Splashes**
  - **Animal Use**

CDC's Biosafety Level (BSL) Classifications

BSL	Agent	Example
1	Not known to cause disease in healthy adult humans	Bacillus subtillis, Baker's yeast
2	Associated with human disease, moderate diseases and low aerosol risk	Salmonella, Staph, Strep, Giardia, HBV
3	Associated with serious human disease with potentially lethal consequences, high aerosol transmission risk	Yersinia pestis, Brucella spp., Yellow Fever
4	Associated with life threatening diseases, high risk of aerosol transmission, no known treatment	Ebola, Smallpox

Risk Management Components

Practices and Techniques



Safety Equipment

Facility Design

Resources

- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
- OSHA Bloodborne Pathogens Standard
- NIH Guidelines for Research Involving Recombinant DNA Molecules

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002

- 2 regulatory agencies, DHHS (CDC) and USDA (APHIS)
- 72 agents and toxins currently listed effecting humans, animals and plants
- Updated regulations now cover possession, use and transfer of listed agents
- Several deadlines associated with registration scheduled for 2003

Meeting the Regulatory Mandate

- Facilities must address:
  - Risk/Threat Assessment
    - Facility specific
    - Agent specific
  - Physical Security
    - Access control (Facility, Building and Laboratories)
    - Data control
  - Personnel Security
    - Worker screening
    - Identification
  - Inventory Accountability
    - Up-to-Date
    - What? Where? How?
  - Agent Transfer
    - Shipping
    - Receiving
  - Emergencies

USDA National Pathogen Inventory

The inventory of biological agents accounted for by each individual Unit should prove an invaluable tool for assessing the risk associated with such agents and determining the commensurate biosafety and biosecurity levels and protocols needed at each Unit.

USDA National Pathogen Inventory

- More than 5,000 agent entrees 2,365 individual biological agents
- Reports Biological Inventories for
  - All ARS Laboratory Locations
  - All AMS Laboratory Locations
  - All FSIS Laboratory Locations
  - All APHIS Agents Co-Located within ARS Facilities

Summary

- Study of infectious disease is an important and often profitable field of research
- Regulations governing the safety and security in this field are getting more stringent
- Failure to comply with the regulatory mandates may have disastrous consequences
- Striking a balance between accessibility and biosafety/biosecurity precautions is necessary for a successful program

Questions