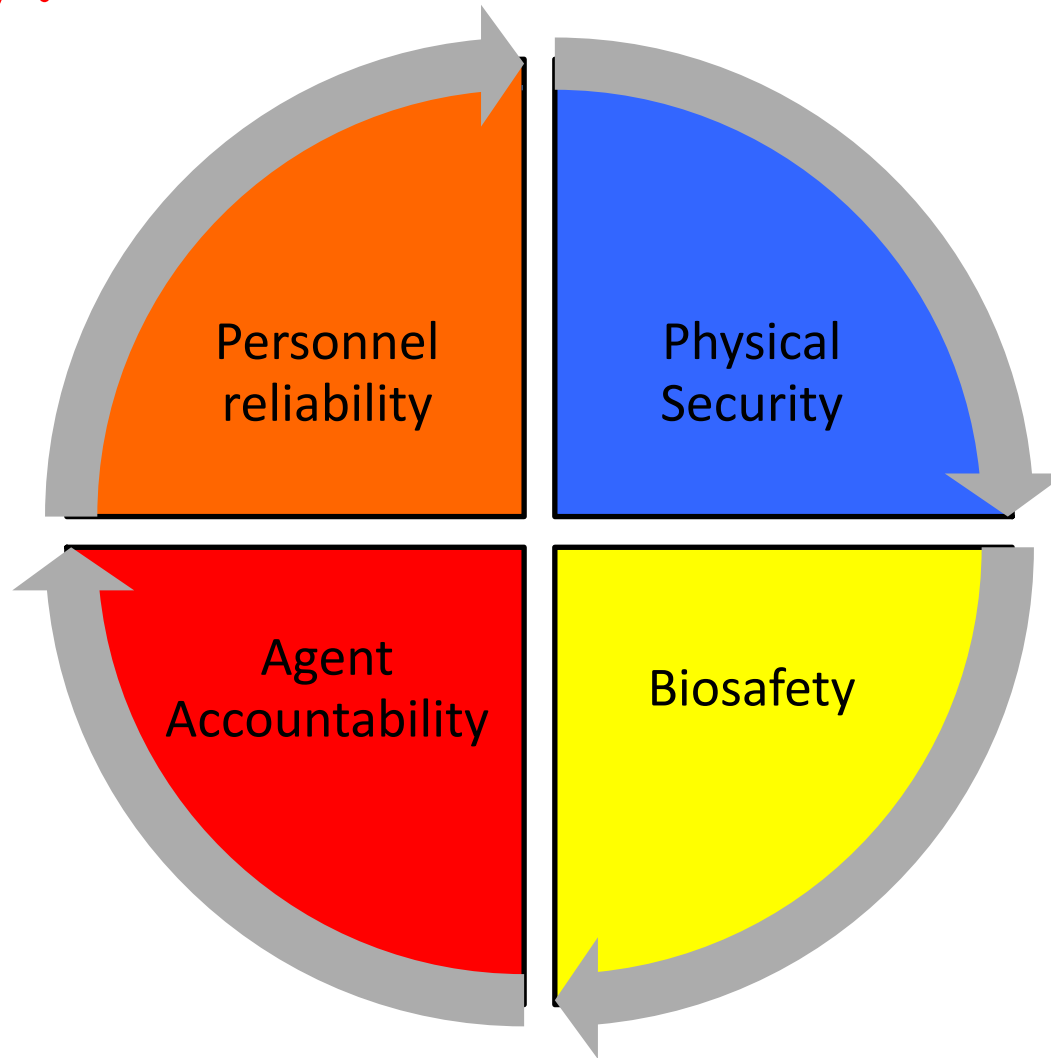




Key Components in Developing a Biosurety Program for Biosafety Level 3 Laboratories

Jessica McCormick, Ph.D., RBP

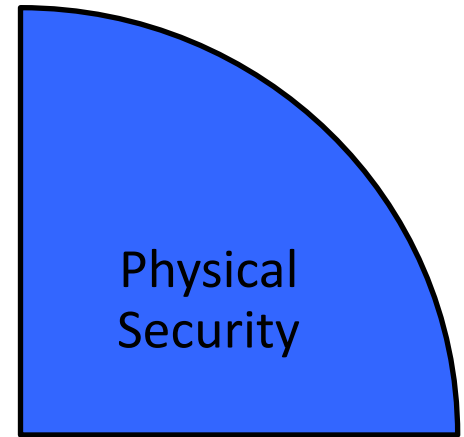
What is Biosurety?



What is Biosurety?

Goal: Securing the laboratory area to allow entry only to authorized persons

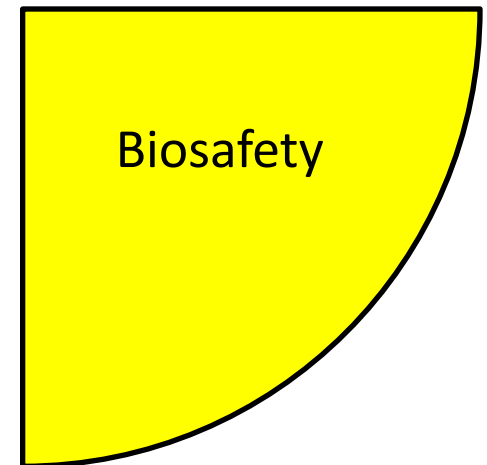
- Card readers
- Pin numbers
- Cameras
- Padlocks
- Passwords
- Security Guards
- Fences



What is Biosurety?

Goal: Conducting research safely and preventing laboratory exposure to biological agents

- Engineering Controls
- Work Practice Controls
- Administrative Controls
- Personal Protective Equipment



What is Biosurety?

Goal: Develop a method to ensure all agents are accounted for, and ensure no theft or loss of agent had occurred

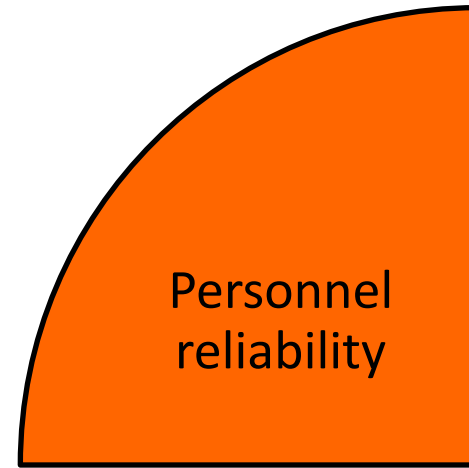
- Inventory log
- Regular inventories
- Carcass inventory
- Routine Audits



What is Biosurety?

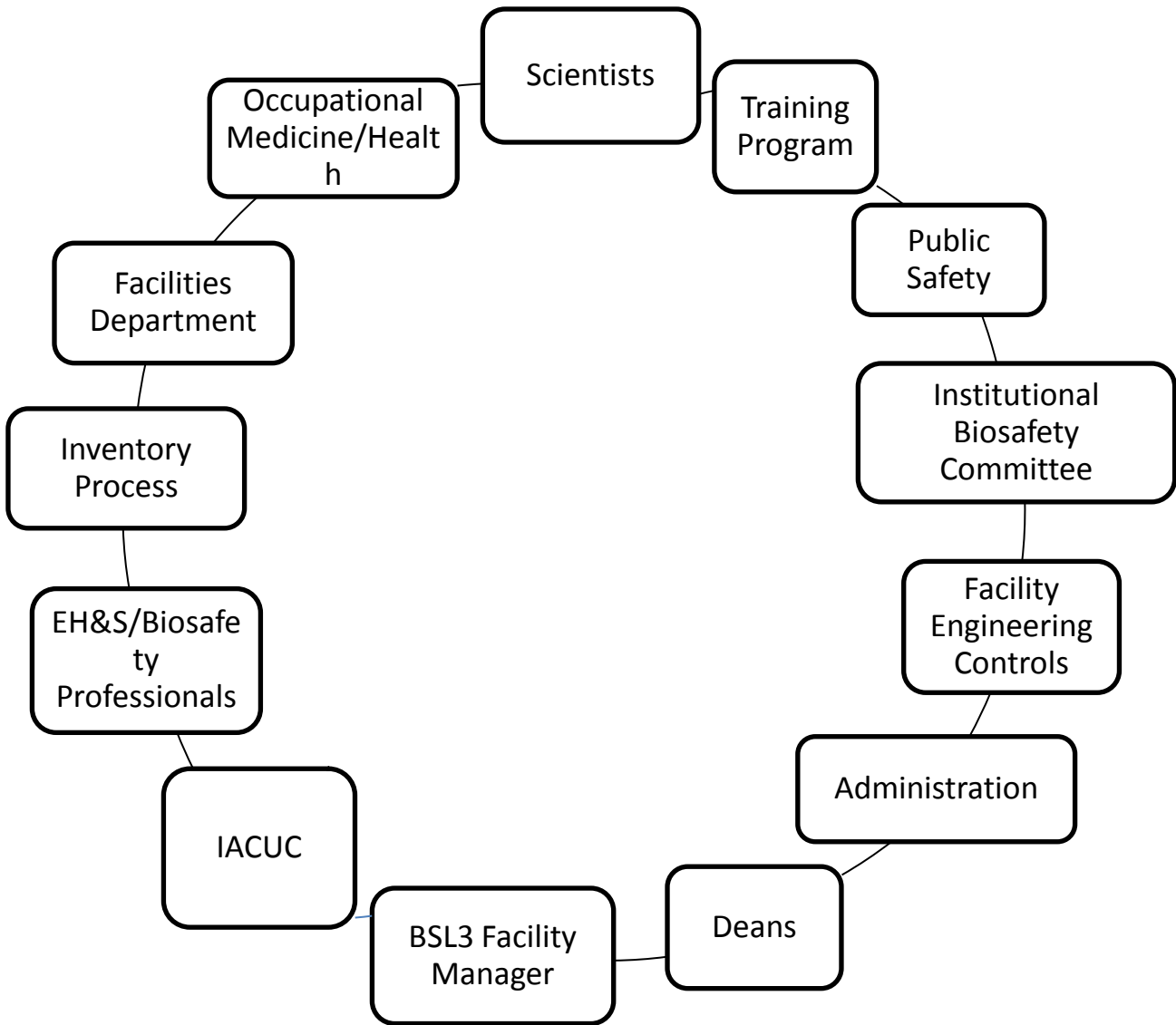
Goal: Ensuring all persons with access to agents are trustworthy, stable

- Debated topic
- Many potential methods
 - FESAP report
 - SA regulations
- Traditionally DOD
 - recommended by NSABB
 - Required for DSAT labs with Tier 1 agents



How do you develop an effective biosurety program?

The Players



Risk Management

Risk = f (threat, consequence, vulnerability)

Risk assessments performed on all aspects of day to day bio-containment lab function:

- Experimental
- Security
- Emergency response

Risk Management

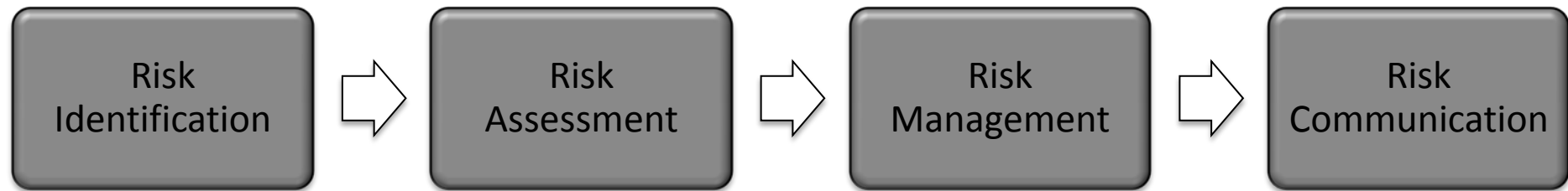
Risk = f (threat, consequence, vulnerability)

Threat (or Hazard) – consider probability of bad things occurring

Consequence – people, operations, infrastructure, environment, reputation

Vulnerability – susceptibility to threats/hazards causing consequences

Risk Mitigation



Risk Communication

It is important to be able to explain the risks/benefits regarding your biocontainment laboratories.

- Is there buy in from all parties?
- Do you know the right people to talk to?
- Do you have the necessary tools to implement new policies?
- What about other safety professionals at your institution?

Policy Development

Institutional Wide Policies

- Incorporate into performance standards
- Leverage for implementation

Departmental Policies

- Methods for day to day implementation

Standard Operating Procedures

- Backbone of the biosafety program
- More detailed, procedures for facilities

Policy Development

Other Areas for Consideration:

- Is there buy in from all parties?
- Do you know the right people to talk to?
- Do you have the necessary tools to implement new policies?

Policy Development

Elements of an effective SOPs?

- **User input**
- Purpose/ Objective
- Equipment needed for procedure
- Description of procedure (safety focus)
- Extra precautions
- Annual review

Policy Development

Who reviews/ approves SOPs?

- Users- day to day basis
- Committee- annually, as needed
 - Users
 - Facility Managers
 - Principle Investigators
 - Veterinarians
 - Biosafety Professionals

Training Programs

The best training program combines didactic learning, hands on learning and refresher training specific to the laboratory facility.

Mentorship is crucial to a successful training program.

Training Programs

Didactic training:

- Interactive training
- Scientist involvement/ input
- Embrace technology
 - Online, videos
- Unique styles
 - Games (jeopardy)



Training Programs

Four areas for competencies:

- Potential hazards
- Hazard controls
- Administrative controls
- Emergency Preparedness and response

Exercise Development

Main types of exercises:

Tabletop

Functional

Full Scale Exercise

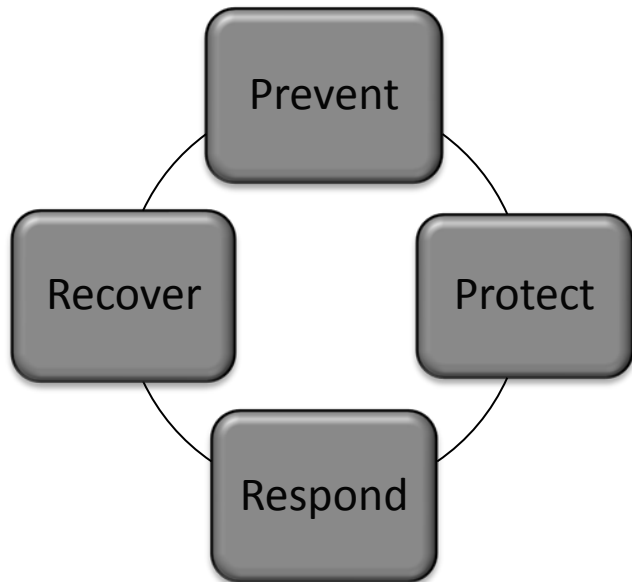


Determine if resources, support, time, facilities, funding and personnel needed are available to conduct an exercise

Exercise Development

Target Capabilities:

Derived from threat and mission analysis.



Exercise Development

Design S.M.A.R.T. objectives

Simple

Measureable

Achievable

Realistic

Task-Oriented

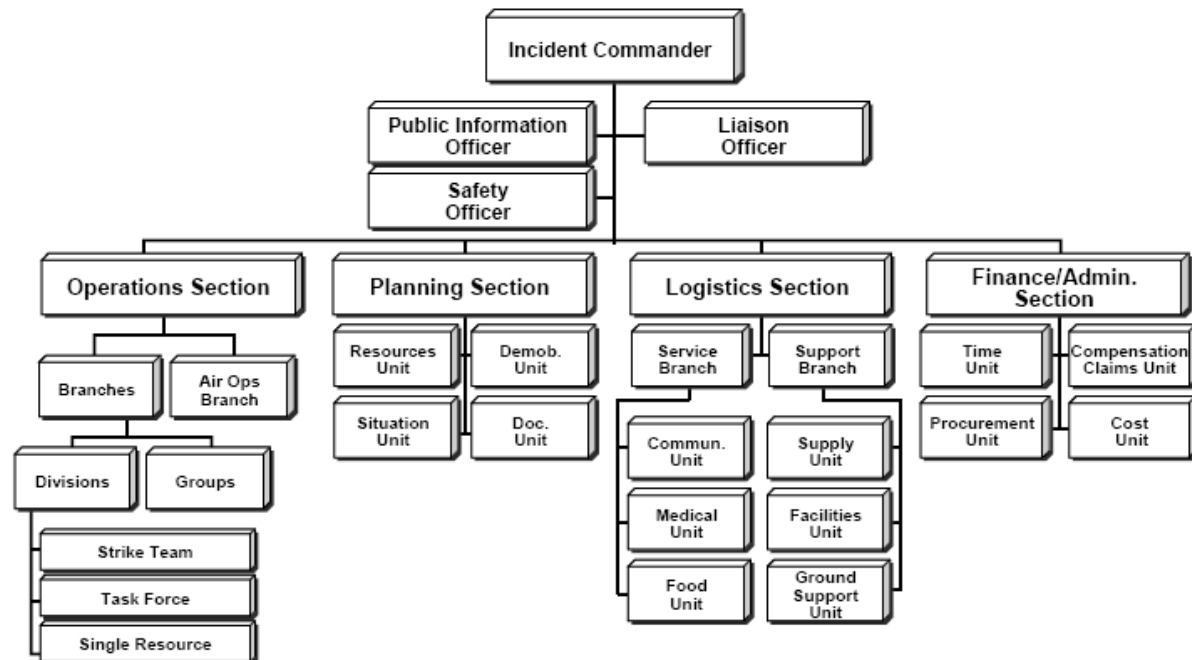
<http://training.fema.gov/is/nims.asp>

Exercise Development

Incident Command System: standardized, onscene, all hazards incident management

Recommended Training:

- ICS-100HE
- ICS 200
- ICS 300/400
- ICS 700



What is

Biosurety?

Risk Assessment/Management/Communication

