Putting It All Together: Program Management

International Biological Threat Reduction Department
Sandia National Laboratories
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Managing a Laboratory Biosecurity Program
ABSA pre-conference course

www.biosecurity.sandia.gov

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Laboratory Management Responsibilities

- Establish program objectives
- Communication
- Institutional support
- Allocate resources
- System design
- Determine standards
- Develop manuals and standard operating procedures (SOPs)
- Emergency response planning
- Conduct exercises
- Maintenance
- Conduct training
- Ensure regulatory compliance
- Reviews and audits

Stakeholders

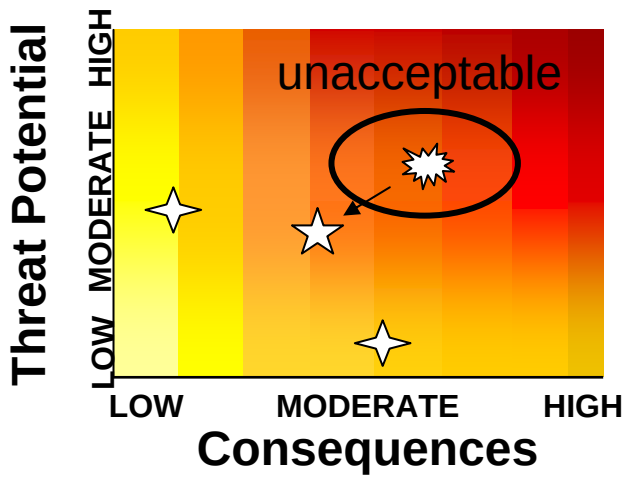
- **Identify stakeholders**
  - **Investigator, laboratory personnel, facilities personnel, administrators, relevant committees (e.g. safety committee), legal counsel, emergency responders, security personnel, local public health officials, contractors, community**
- **Communicate**
  - **Risk (Why we are concerned and why you should be concerned too.)**
  - **Standard (What we want you to do to minimize concern.)**
  - **Consensus (Get agreement on what is to be done)**
  - **Written and / or direct**
    - **Fact sheets, memos, manuals, SOPs**
    - **Training, walk through, meetings**

Risk Decision

- **Director or other individual authorized to make decisions on behalf of the institution needs to determine what is the desired protection strategy**
  - **Deny:**
    - **Prevent the adversary from gaining access to, or use of, a particular space, structure, or asset**
  - **Contain:**
    - **Prevent an adversary from leaving the jurisdiction of the facility while in possession of an illicitly acquired asset or following the destruction of an asset.**
  - **Deter:**
    - **Discourage an adversary from attempting an assault by making a successful assault appear very difficult or impossible**

Establish Program Objectives

- Establish a protection strategy AND, if the strategy fails, what to do about it
- Determine which scenarios to protect against – the "unacceptable" risks (risk decision)
  - E.g. Intends to detect and deter unauthorized access to dangerous pathogens and toxins
- Determine which scenarios to be prepared to respond to – the "acceptable" risks (risk decision)
  - Identify which possible but unlikely scenarios the security system should not be required to protect against
- Ensure that protection for an agent, and the cost, is proportional

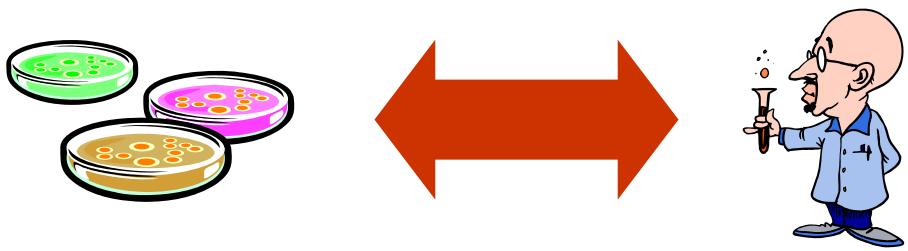


Roles and Responsibilities of a Biosecurity Officer

- Conduct risk assessments
  - Determine assets
  - Coordinate team to evaluate site
  - Coordinate threat and consequence assessments
  - Ensure appropriate management is responsible for risk decision
- Design and implement system
  - Resolving potential conflicts between safety and security
  - Coordinate with biosafety officer (if different person)
  - Coordinate with local security
    - On-site guard force and/or
    - Local law enforcement
      - MOU
  - Write facility biosecurity plan
- Testing of security system
  - Initial acceptance test after installation
  - Periodic testing
- Provide biosecurity training

MC&A Procedures and the Biosecurity Officer

- Ensure access to dangerous pathogens and toxins is appropriately controlled
  - Specify where they can be used and where they can be stored
- Specify accountability requirements
  - What materials?
  - What forms?
    - Repository stocks, working samples, infected animals?
  - When does accountability begin and end?
  - What information is captured in the inventory?
  - How often are the physical inventories and book inventories reconciled?



Transport Procedures and the Biosecurity Officer

- Establish procedures for transport
  - Security for packages
    - Shipping and receiving areas
  - Documentation
  - Who is able to authorize, transport, and receive dangerous pathogens and toxins
  - Internal transport
    - SOPs?
    - Pre-approvals?
    - Chain of custody requirements/
  - External transport
    - Material Transfer Agreements?
    - Knowledge/pre-approval of recipient?
    - Regulatory requirements
    - Which carriers are used?

Documentation for a Biosecurity Program

- **Goals:**
  - **Demonstrate institutional support**
  - **Document chain of command and responsibilities**
  - **Ensure institutional memory**
- **Types:**
  - **Policy statements**
    - **Guide for staff**
    - **Where is institutional oversight? IBC?**
  - **Manuals**
    - **Big picture documents that are the foundation of your program**
    - **Ex: Biosafety, *Biosecurity*, Animal care, Waste disposal**
  - **Standard Operating Procedures (SOPs)**
    - **Detailed – an experienced person can read SOP and carry out the operations**
    - **Ex: Equipment maintenance, Spill clean up, transport procedures**

Laboratory Biosecurity Manual should:

- Describe how the facility meets any local or federal regulations pertaining to securing dangerous pathogens and toxins
- Be based on a facility-specific risk assessment
  - Include a threat definition
- Address the facility-specific biosecurity program including
  - Biosecurity program management,
  - Physical security
  - Personnel security
  - Information security
  - Material control and accountability
  - Transport security

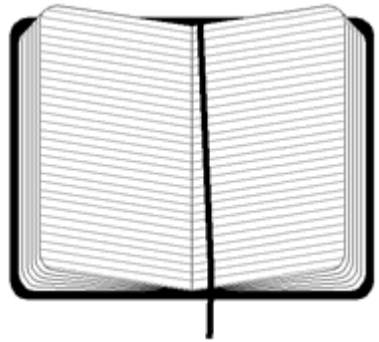
Laboratory Biosecurity Manual should also:

- Describe, justify, and document the graded protection provided to dangerous pathogens and toxins
- Indicate how the system will achieve the desired strategy (e.g. detect, deter, respond to, and contain unauthorized access to these agents)
- Include additional requirements as a result of local threats
- Contain guidance for oral and written reports to provide notification upon discovery of the theft, loss, or release of HCPTs
- Contain an explanation of the biosecurity training to be received by all personnel and contractors
- Contain provisions for routine cleaning, maintenance, and repairs of restricted areas
- Contain escorting procedures
- Contain procedures that the facility will follow to prepare for and comply with biosecurity program audits

Laboratory Biosecurity Plan Should Address Incident Response

- Be coordinated with the Emergency Response Program, and the Biosafety Plan
- Include responses to the following types of incidents:
  - Biocontainment breaches, biosecurity breaches, inventory violations, material transport violations, IT security breaches, and non-biological security incidents (e.g., violence in the workplace, severe weather, power outages, natural disasters)
- Address those "acceptable" security risks that the physical protection system is not designed to protect against
- Instruct facility personnel, including its guard forces, local law enforcement, and emergency responders, on the exact procedures to follow in the event of an incident
- Indicate, when appropriate, what Memoranda of Understanding are in place with local law enforcement and emergency response agencies and officials
- Develop a public relations strategy to communicate the realities of the situation and its consequences to the public
- Develop a chain-of-command for incident reporting at the facility level
- Include actions required to protect forensic evidence of a theft or attempted theft
- Include actions to be taken when the national threat conditions change

Training



- Annual training tailored to different audiences
  - New and current employees
  - Managers
  - Emergency responders
  - Guard force
- Topics
  - Applicable manuals, SOPs
  - Statutory requirements
    - All employees should be informed of their responsibilities for meeting the legal requirements
  - Operations and procedures
    - PPE
    - Restricted access areas
    - Access control procedures
    - Physical security, personnel security, information security
    - Equipment
    - Spills, general emergency response
    - Appropriate containment
  - Incident reporting
  - Disciplinary actions
  - Media and public requests

Biosecurity Training Example: Managers

- Educate managers on detecting personnel issues that may result in security problems and options available to employees
- Encourage managers to report any information that raises doubts about an employee's continued access to restricted areas and/or materials
- Ensure managers are aware of the need to obtain agency-owned property from terminating or transferring personnel

Biosecurity Training Example: Guard Forces

- **Should develop and maintain the competencies needed by the on-site response force**
  - **Bioresearch-facility specific training**
    - **Rationale for biosecurity**
    - **A brief history of BW and bioterrorism**
    - **Overview of biology**
    - **General biosafety and biosecurity**
  - **Regulatory requirements**
    - **E.g. Overview of US Select Agent Regulations**
  - **Facility's biosecurity plan**
    - **Emphasizing how guard force responsibilities fit into bigger picture**
  - **Standard response force training**

- **Training exercises**
  - **Facility-specific training**
  - **Local law enforcement participation**
  - **Reports of training exercises summarizing results provided to management for review**

Memorandum of Understanding with Local Law Enforcement

- **Purpose:**
  - **Provide a clear basis for contingency response planning, coordination and cooperation between LLE and the Institution**
  - **Facilitate effective communication and exchange of relevant information**
  - **Assure timely, reliable, effective decision-making and response actions**
- **Specify response guidelines:**
  - **Notification of LLE by Institution**
  - **Command and Control structure**
  - **LLE response**
    - **Roles and responsibilities**
- **Specify terms of MOU**
  - **Effective date**
  - **Procedure for termination of agreement**
  - **Frequency (annual?) of exercises to ensure MOU is effective**

Summary

- **Program management is an overarching component of both biosafety and biosecurity programs**
- **Ensures success of the programs by:**
  - **Planning**
  - **Staffing**
  - **Funding**
  - **Training**
- **Addresses every element of the biosafety and biosecurity program**