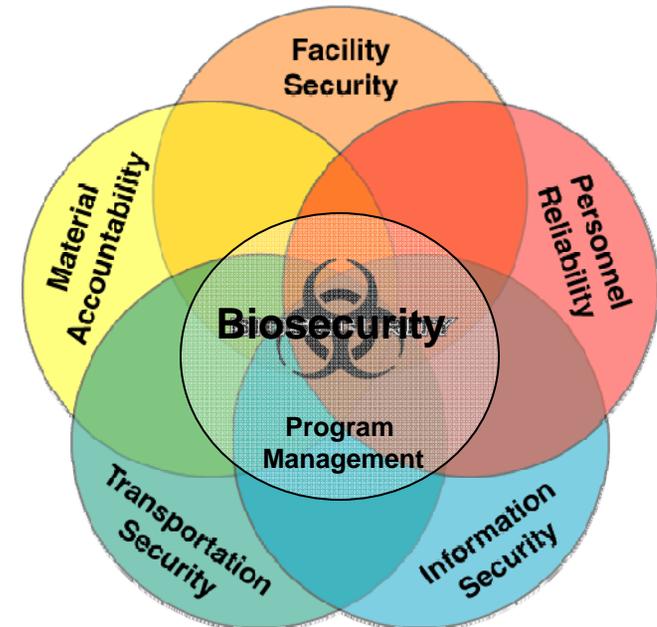

Putting It All Together: Program Management

**International Biological Threat Reduction Department
Sandia National Laboratories
October 7, 2007**

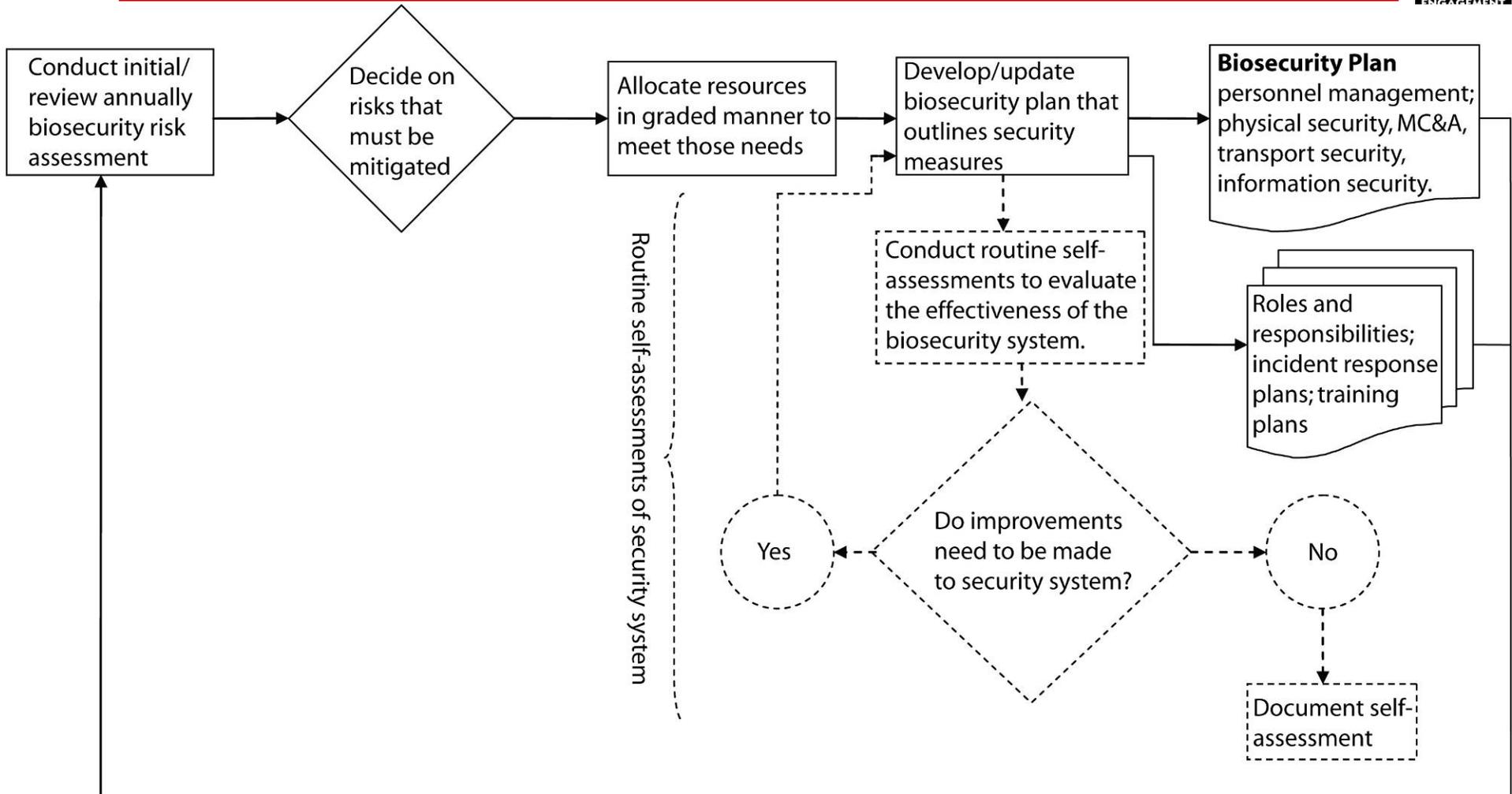
**Managing a Laboratory Biosecurity Program
ABSA Pre-Conference Course**

Program Management

- **Overarching component of laboratory biosecurity and biosafety programs**
- **Guides and provides oversight to both biosecurity and biosafety**
- **Delineated in a Biosecurity Plan**
 - **Comprehensive guidance on biosecurity**
 - Implementation
 - Outlines roles and responsibilities
 - Outlines security measures
 - Policies and procedures
 - **Incident Response Plan**
- **Biosecurity manuals specific for each laboratory**
 - **Base on laboratory-specific risk assessment**
 - **Standard operating procedures (SOPs)**

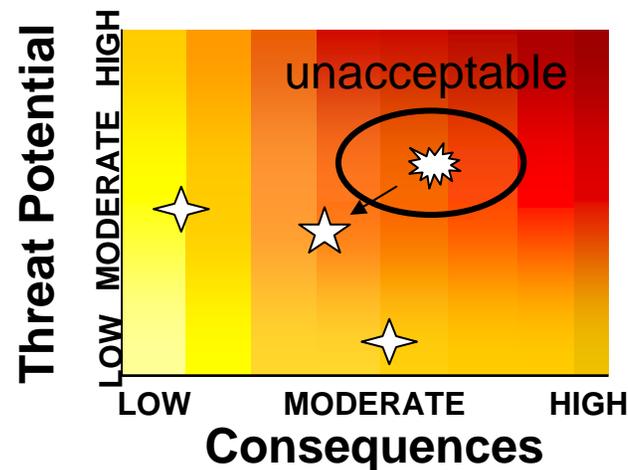


Program Management Flow Chart



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



Biosecurity Plan



- Central document of the **facility** biosecurity program
- Address federal regulations regarding pathogen security
- Summarize the risks and threats
- Outline security measures
- Provides comprehensive guidance on implementation
- Delineates roles and responsibilities
- Addresses policies and procedures
- Addresses training
- Includes Incident Response

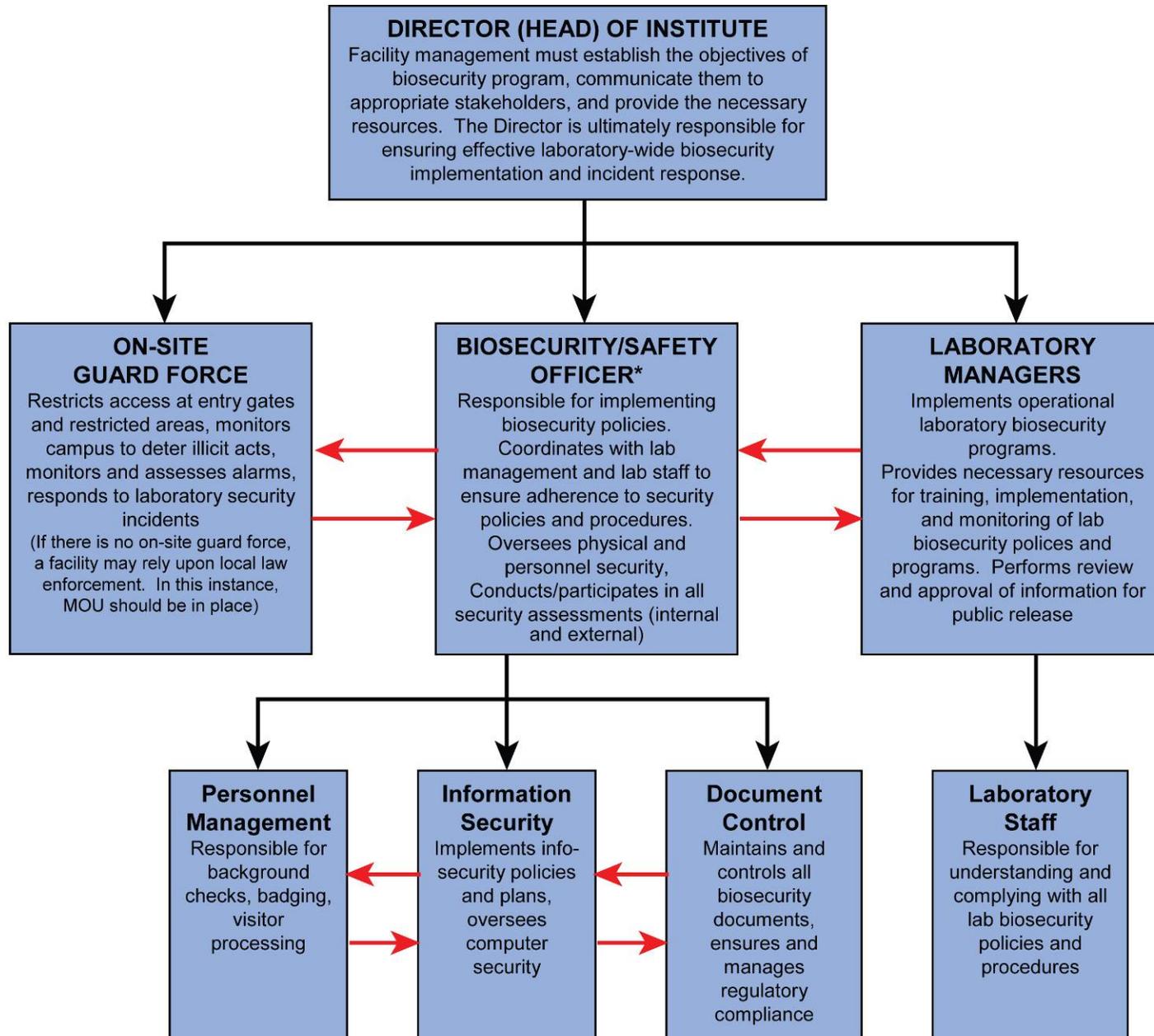


Biosecurity Program Documentation

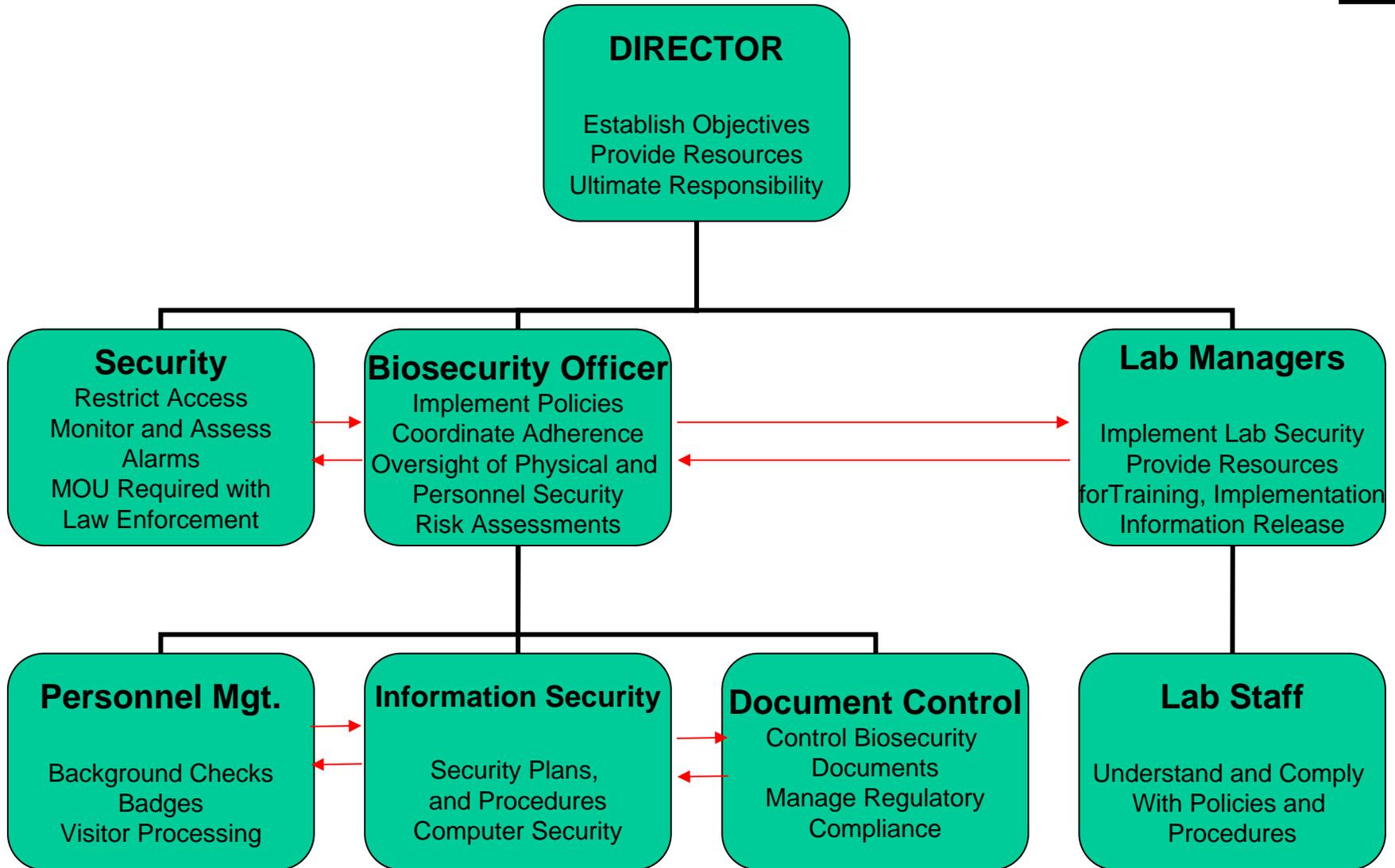


- **Goals:**
 - Demonstrate institutional support
 - Document chain of command and responsibilities
 - Ensure institutional memory
- **Types:**
 - **Policy statements**
 - Guide for staff
 - Where is institutional oversight? IBC?
 - **Manuals**
 - Big picture documents that are the foundation of your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

Roles and Responsibilities



Roles and Responsibilities



Roles and Responsibilities: Management



- **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)
 - Provide resources and institutional support
 - Written and / or direct
 - Fact sheets, memos, manuals, SOPs
 - Training, walk through, meetings
- **Conduct routine assessments and update accordingly**
- **May need to designate Biosecurity Officer**



Risk Decision: Director

- **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
- **Ultimately responsible**
 - Laboratory-wide implementation of biosecurity
 - Incident response

Roles and Responsibilities: Security Force



- Onsite vs. Off site
- Restrict access
- Monitor and assess alarms
- Respond to alarms
- Monitor the area to deter illicit acts

- This may be the responsibility of local law enforcement
 - MOU should be developed
 - Training to know how to respond appropriately
 - Alarm response
 - Patrol

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



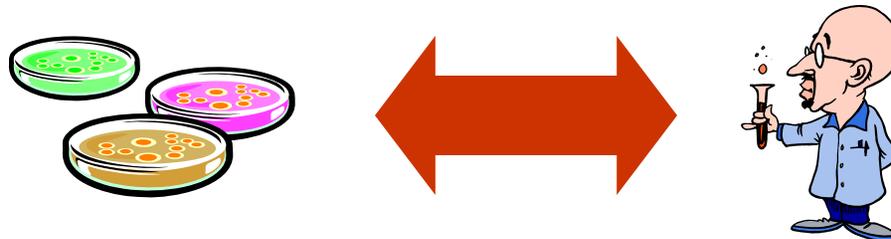
Roles and Responsibilities: Biosecurity Officer

- **Conduct risk assessments with laboratory managers**
 - Determine assets
 - Coordinate team to evaluate site
 - Coordinate threat and consequence assessments
 - Ensure appropriate management is responsible for risk decision
- **Develop and implement the biosecurity plan**
 - Resolve 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
 - Maintain and update the plan routinely
 - Ensure adherence to policies and procedures
- **Test the 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?
 - Tracking requirements
 - **External transport**
 - Material Transfer Agreements?
 - Knowledge/pre-approval of recipient?
 - Regulatory requirements
 - Which carriers are used?
 - Tracking requirements



Roles and Responsibilities: Laboratory Managers



- Provide oversight to the risk assessment process
- Implement operational biosecurity
- Monitor the laboratory biosecurity program
- Provide training resources and verify successful completion of training
- Verify staff termination efforts
 - Key return/password termination
 - Notebooks turned in
 - Access terminated
- Review the biosecurity program
- Review all information prior to release
 - Publications
 - Media releases
- Provide oversight to staff members
- Ultimately responsible for laboratory biosecurity



Roles and Responsibilities: Laboratory Staff



- Understand and comply with all biosecurity policies and procedures
- Keep up to date on training
- Assist with laboratory security
 - Maintain current inventories
 - Limit access as necessary
- Participate with laboratory biosecurity plan development
- **Be vigilant to unusual behavior**
 - **Late hours for no apparent reason**
 - **Experiments that are not necessary**
 - **Unusual requests**
- Maintain all necessary documentation

Laboratory Biosecurity Manual



- Describe how the **laboratory** meets any local or federal regulations pertaining to securing dangerous pathogens and toxins
- Be based on a **laboratory**-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
- Policies and procedures for security



Laboratory Biosecurity Manual (continued):

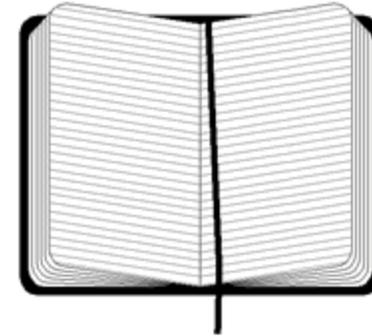


- Describe, justify, and document the graded protection provided to dangerous pathogens and toxins
- Indicate how the system will achieve the desired strategy (e.g. detect, deter, respond to, and contain unauthorized access to these agents)
- Include additional requirements as a result of local threats
- 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

Training



- **Annual training tailored to different audiences**
 - New and current employees
 - Managers
 - Laboratory staff
 - 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: Law Enforcement or Security



- **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
 - Personal protective equipment
 - **Regulatory requirements**
 - E.g. Overview of US Select Agent Regulations
 - **Facility's biosecurity plan**
 - Emphasize how law enforcement responsibilities fit into bigger picture
- **Training exercises**
 - Facility-specific training
 - Local law enforcement participation
 - Reports of training exercises summarizing results provided to management for review

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 security 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**
- **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**

Summary



- **Program management is an overarching component of both biosafety and biosecurity programs**

- **Ensures success of the programs by:**
 - **Planning**
 - **Staffing**
 - **Funding**
 - **Training**

- **Should address every element of the biosafety and biosecurity program**