

Program Management

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www.biosecurity.sandia.gov

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
- Medical surveillance
- Conduct training
- Ensure regulatory compliance
- Reviews and audits



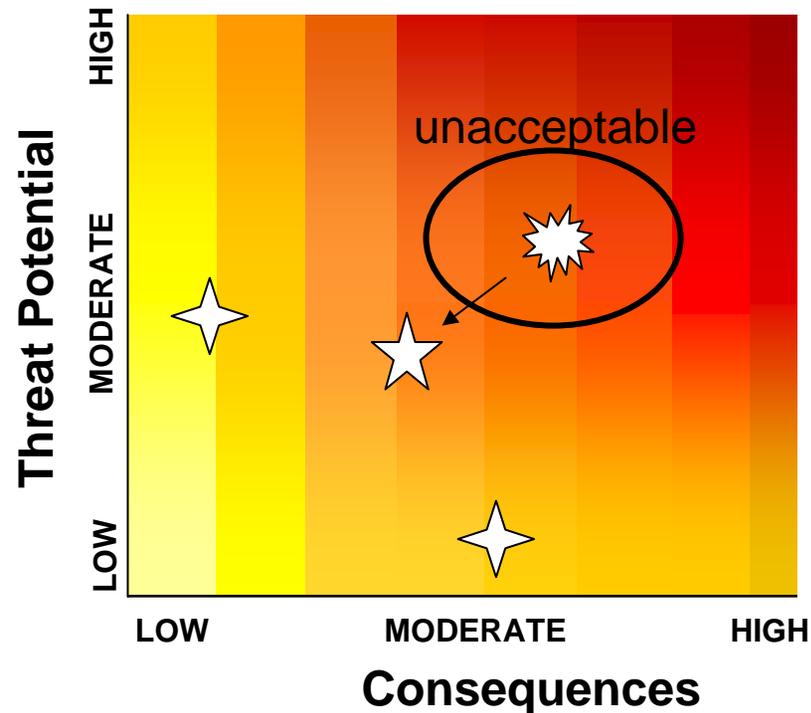
Stakeholders

- **Identify stakeholders**
 - Investigator, laboratory personnel, facilities personnel, administration, committees, 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



Establish Program Objectives

- **Biosecurity**
 - Scenarios to protect against – the “unacceptable” risks
 - Scenarios to be prepared to respond to – the “acceptable” risks
 - Ensure that protection for an agent, and the cost, is proportional



Establish Program Objectives

- **Biosafety**
 - Risk-based management of laboratory hazards to minimize likelihood of
 - Infecting of employees and public
 - Contaminating environment
 - Community confidence in your laboratory operations



Biosecurity and Biosafety Manuals

- **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 Plan

- **Develop laboratory biosecurity plan:**
 - **Facility mission and description**
 - **Risk definition(s)**
 - **Physical security**
 - **Personnel management**
 - **Material control and accountability**
 - **Material transfer security**
 - **Information security**
 - **Biosecurity program management**
 - **Incident response plans and reporting**



Laboratory Biosafety Plan

- **Develop laboratory biosafety plan:**
 - **Specific to each individual lab or lab suite**
 - **Outlines risks**
 - **Personnel requirements**
 - **Material control and accountability**
 - **Standard Operating Procedures**
 - **Laboratory practices**
 - **Containment equipment**
 - **Special laboratory design**
 - **Animal care and use**
 - **Biosafety program management**
 - **Biosafety Officer roles and responsibilities**
 - **Medical monitoring**
 - **Incident response plans and reporting**



Emergency Response

- **Types of Emergencies**
 - Security incidents
 - Spills and releases
 - Employee exposure
 - Other emergencies, such as
 - Natural disasters
 - Fire
 - Loss of electrical power
- **Preparations**
 - Each building and lab must have a plan and practice it
 - Coordinate with emergency response crews
 - Memorandums of Understanding
 - Train employees
 - Plan for external communications

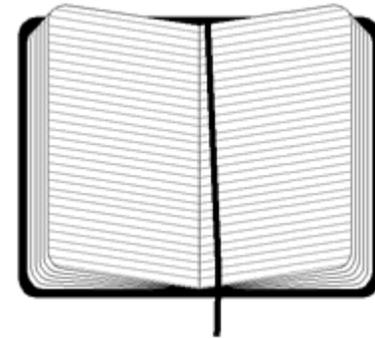
Response Force Training

- **Should develop and maintain the competencies needed by the on-site response force**
 - **Bioresearch-facility specific training**
 - **Standard response force training**
- **Training exercises**
 - **Facility-specific training**
 - **Local law enforcement participation**
 - **Reports of training exercises summarizing results provided to management for review**



Training

- **Annual training tailored to different audiences**
 - New and current employees
 - Managers
 - Emergency responders
 - Guard force
- **Topics**
 - Applicable manuals, SOPs
 - Statutory requirements
 - Operations and procedures
 - PPE
 - Access control procedures
 - Physical security, personnel security, information security
 - Equipment
 - Spills, general emergency response
 - Appropriate containment
 - Incident reporting
 - Disciplinary actions
 - Media and public requests



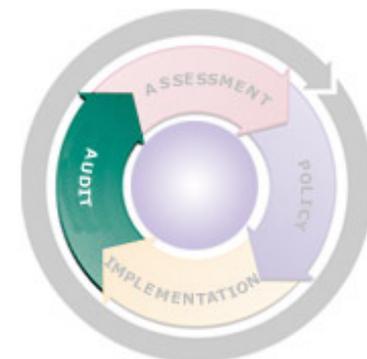
Training

- **Task-specific training**
 - **Critical for biosafety in BSL2 or higher laboratories**
 - **For example, using biosafety cabinets**

- **Evaluate effectiveness of training**
 - **Written evaluations**
 - **Quizzes and tests**
 - **Skills evaluations**
 - **Observations**
 - **Performance tests with noninfectious substitutes (e.g. water or saline)**

Program Evaluations

- **Internal and third party**
 - **Self assessments ensure compliance with standards and evaluate effectiveness of the biosecurity and biosafety programs**
 - Regular self-inspections by designated employees (daily/weekly)
 - Supervisor inspections to reinforce employee inspections (weekly/monthly)
 - **Management reviews institute corrective and preventive actions, and allocate required resources**
 - Inspections by a site team of employees, supervisors, and site management
 - **Periodic third party reviews provide an independent assessment**



Responding to Inspection / Audit Findings

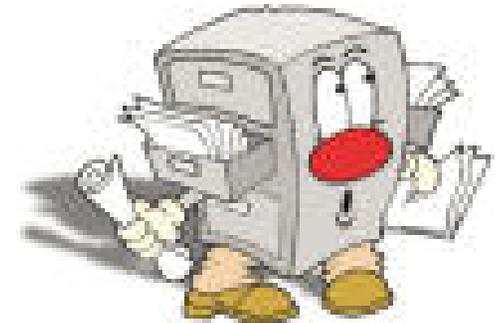
- **Ensure corrective actions are taken to eliminate identified deficiencies**
- **Assign responsibilities**
 - **Ensure that a responsible individual is assigned for the identified deficiency or action item**
- **Implementation schedule**
 - **Create an implementation schedule with set milestones and follow through to completion**
 - **Identify a completion date and provide periodic updates against that completion date**
- **Document completion**
 - **Document all actions and sign-off when corrective actions are completed**

Documentation

- **Protocol approvals, registration**
 - Signed by investigator, department director, biosafety officer (biosafety coordinator), responsible official (biosecurity coordinator)
- **Medical & vaccination records**
 - Confidentiality requirements must be addressed
- **Policies, Manuals, SOPs**
- **Training records**
 - Document initial training, supervisor training, refresher training
 - Include dates, trainer qualifications, course syllabus, method of evaluation
- **Auditing records**
 - Include follow up actions

Documentation Systems

- **Establish a records management system**
 - **Designate a responsible document control coordinator**
 - **Define appropriate document retention time**
 - **Establish procedures for handling sensitive information**



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**