

Program Management: Putting It All Together

Laboratory Biosafety and Biosecurity Workshop

**Cairo, Egypt
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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**
- **Medical surveillance**
- **Conduct training**
- **Ensure regulatory compliance**
- **Reviews and audits**



Stakeholders

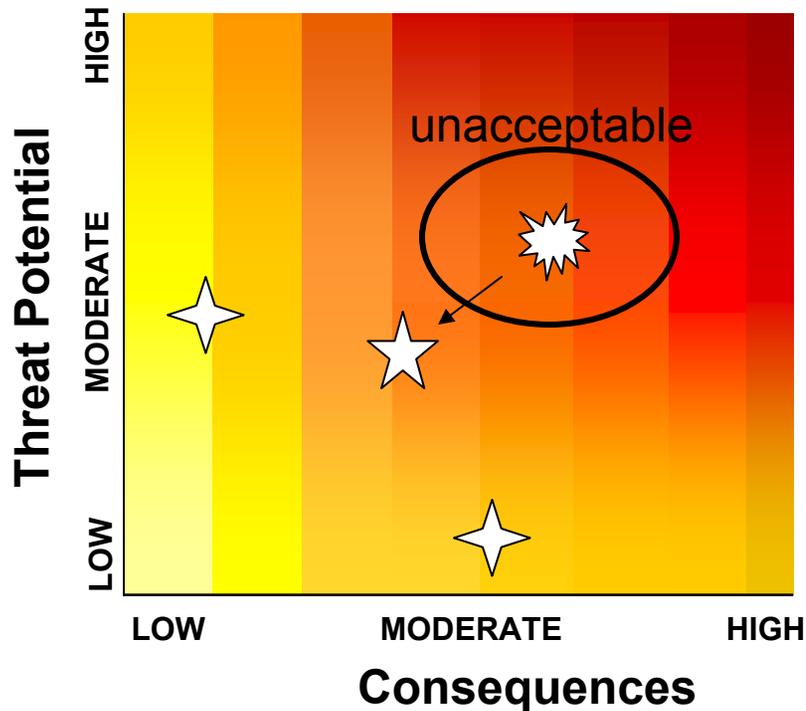
- **Identify stakeholders**
 - Investigator, laboratory personnel, facilities personnel, administration, committees, legal counsel, emergency responders, security personnel, local public health officials, contractors, community

- **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 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**
 - **Standard Operating Procedures (SOPs)**
 - **Detailed – an experienced person can read SOP and carry out the operations**
 - **Ex: Equipment maintenance, Spill clean up, transport procedures**

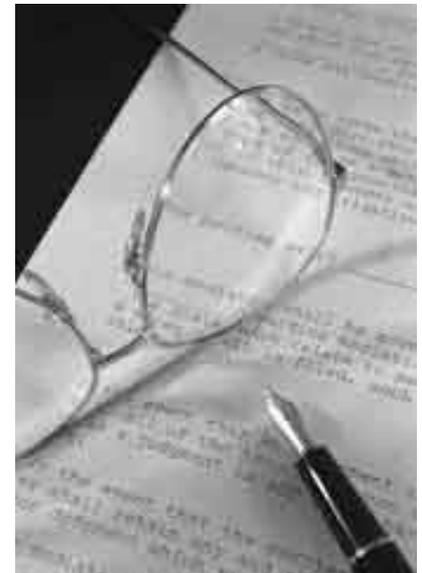
Laboratory Biosecurity Plan

- **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**



Standard Operating Procedures (SOPs)

- **Goal: someone who has experience and is familiar with a process can read it should be able to safely and securely do the work**
 - **Balance between too much detail and not enough**
 - **May be a regulatory document and can be problematic if not followed exactly**
- **Areas to address with SOPs**
 - **BSL 3 operation**
 - **Emergency response, including biological and chemical spill clean up**
 - **Equipment maintenance**
 - **Shipping and receiving infectious materials**
 - **Research-specific**
 - **Agent specific**
 - **Animal handling**

SOPs for Operating a BSL 3

- **Entry / exit**
 - Including who is qualified to enter
 - Visitor policy
 - Entry logs
- **PPE requirements for each room**
- **Exiting normally and in emergencies**
 - Fire
 - Spills
 - Ventilation failures
 - Health problems
- **Decontamination of facility and equipment**
- **Facility inspection process**



Facility Equipment SOPs

- **Biological safety cabinets**
- **Autoclaves**
- **Cage wash**
- **Centrifuge**
- **Annual mechanical system test balance**
- **Filter replacement schedules**
- **Effluent treatment systems**
- **Vacuum systems**
- **Ensuring directional airflow**
- **Access controls and alarms**



Medical Surveillance

- **“The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel.**
- **The objective of such surveillance is to monitor for occupationally acquired diseases.**
- **Appropriate activities to achieve these objectives are:**
 - **Provision of active or passive immunization where indicated**
 - **Facilitation of the early detection of laboratory-acquired infections**
 - **Exclusion of highly susceptible individuals (e.g. pregnant women or immunocompromised individuals) from highly hazardous laboratory work**
 - **Provision of effective personal protective equipment and procedures”**

WHO Laboratory Biosafety Manual, 3rd edition



Medical Surveillance for BSL 3

- **“Medical examination of all laboratory personnel who work in containment laboratories – Biosafety Level 3 is mandatory.**
- **This should include recording of a detailed medical history and an occupationally-targeted physical examination.**
- **After a satisfactory clinical assessment, the examinee may be provided with a medical contact card stating that he or she is employed in a facility with a containment laboratory – Biosafety Level 3. This card should include a picture of the card holder, be wallet-sized, and always be carried by the holder. The name(s) of the contact persons to be entered will need to be agreed locally but might include the laboratory director, medical adviser and/or biosafety officer.”**

WHO Laboratory Biosafety Manual, 3rd edition



Recommended Medical Contact Card (back)

TO THE PHYSICIAN

The holder of this card works in an area at _____
in which pathogenic viruses, rickettsia, bacteria, protozoa or helminths are
present. In the event of an unexplained febrile illness, please call the employer
for information on agents to which this employee may have been exposed.

Name of laboratory:

Address:

Tel:



Occupational Health Program

- Health history, medical clearance
- Respirator clearance
- Screening
- Immunization and testing
- Serum storage program?
- Post-exposure evaluation and response



Special Immunization Program

- Designed for at-risk laboratory workers - part of occupational health program
- Recommendations and guidelines established for immunization “requirements”

IND Vaccines

Licensed Vaccines

Inactivated

Anthrax vaccine
Hepatitis B vaccine
Japanese encephalitis vaccine
Rabies vaccine

Live, attenuated

Yellow fever vaccine
Vaccinia (VIG availability)

Inactivated

Botulinal toxoid (pentavalent)
EEE virus vaccine
Q fever vaccine
Rift Valley vaccine
TBE vaccine
WEE virus vaccine

Live, attenuated

Chickungunya virus vaccine
Junin vaccine
Hantaan vaccine
Rift Valley vaccine (MP12)
Tularemia vaccine
VEE virus vaccine

Facility Maintenance Program

- **Needs to be planned**
 - How often is needed?
 - What needs to be covered?
 - Does it need to be shut down?
 - Preventative (Routine maintenance)
 - Reactive (Emergency repairs)

- **Elements of a maintenance program**
 - **SOPs**
 - Minor routine, major routine, major failure, periodic shutdown
 - PPE, entrance requirements, decon requirements
 - **Awareness**
 - Concepts of biohazards, modes of transmission, controls, PPE
 - **Training**
 - SOPs, facility orientation, PPE use, equipment/facility-specific issues, emergency protocols
 - **Communication**
 - Facility operations, scope of work, decon QA results
 - **Implementation**
 - Follow the SOP, monitor effectiveness, Review and revise SOP

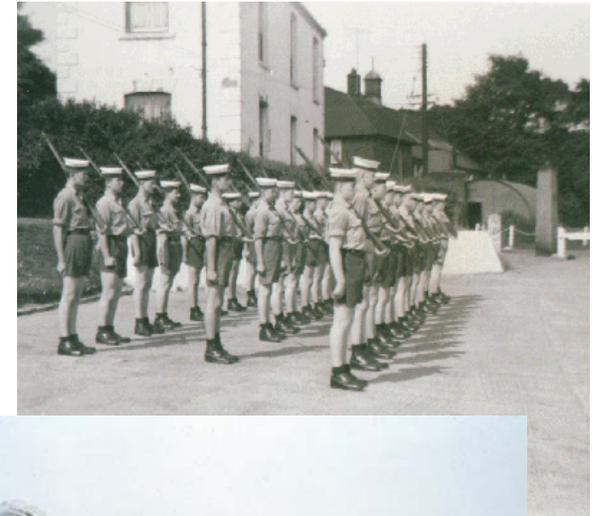


Emergency Response

- **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

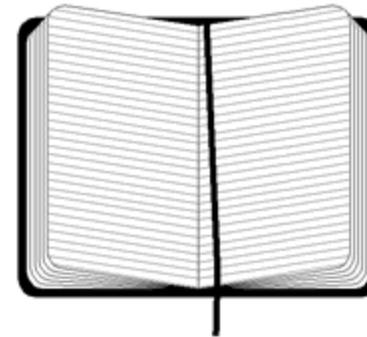
Response Force Training

- **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



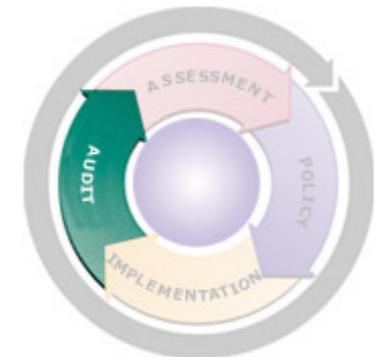
Training

- **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

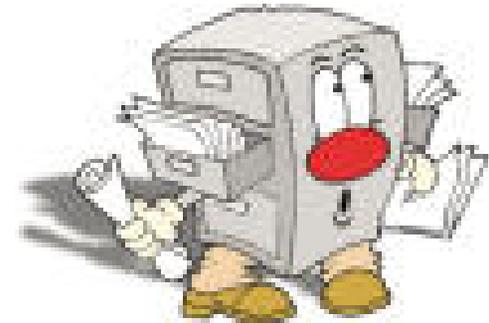
- **Ensure corrective actions are taken to eliminate identified deficiencies**
- **Assign responsibilities**
 - **Ensure that a responsible individual is assigned for the identified deficiency or action item**
- **Implementation schedule**
 - **Create an implementation schedule with set milestones and 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

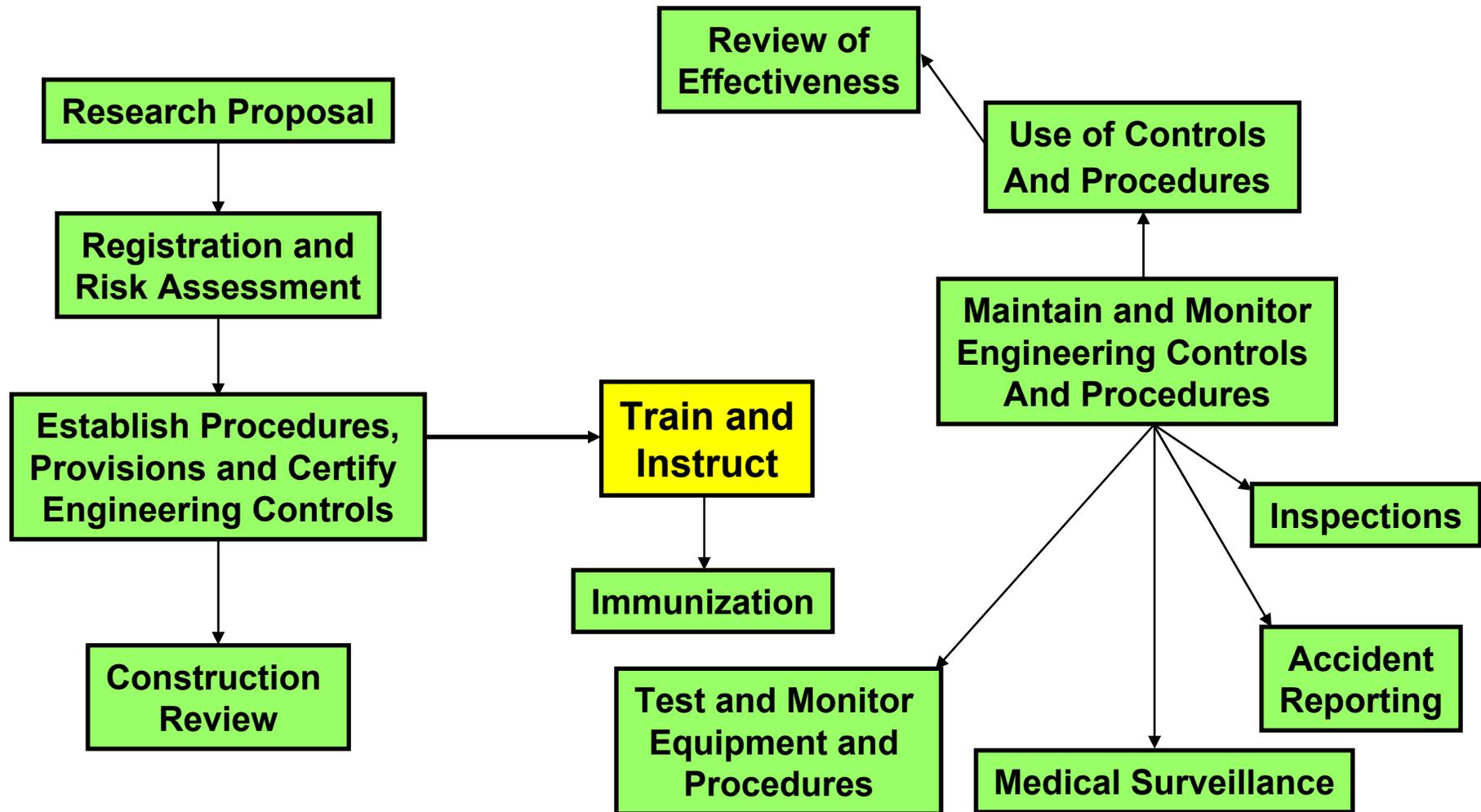
- **Protocol approvals, registration**
 - Signed by investigator, department director, biosafety officer (biosafety coordinator), responsible official (biosecurity coordinator)
- **Medical & vaccination records**
 - Confidentiality requirements must be addressed
- **Policies, Manuals, SOPs**
- **Training 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**



Program Management Office Involvement with Research



Safety and Security Responsibilities

- **Supervisors**
 - **Conduct orientation training**
 - **Conduct training in techniques and procedures unique to specific area**

- **All Personnel**
 - **Practice Good Laboratory Techniques**
 - **Ask questions if you do not understand procedures**
 - **Notify supervisor of any personal condition**
 - **Promptly report on-the-job injuries, accidents, and incidents**

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**