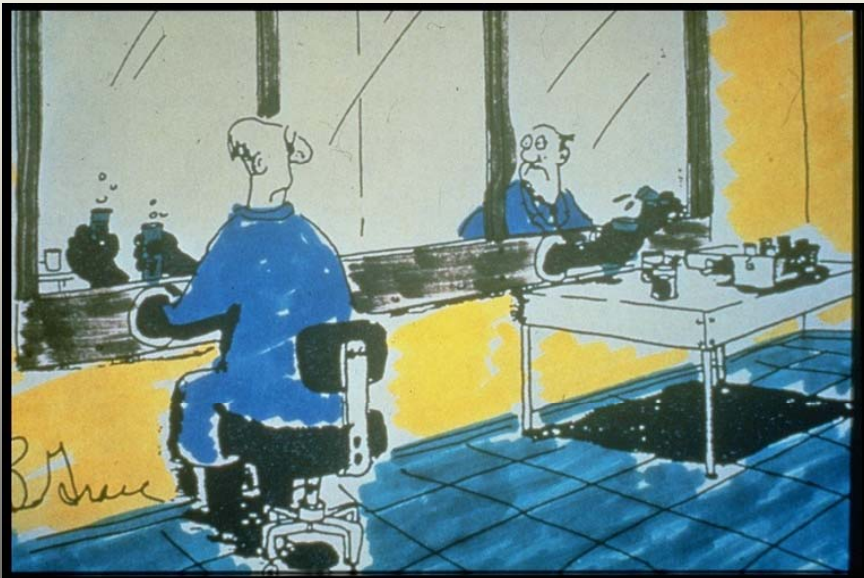


Controlling Laboratory Bio-risk Operations Manuals

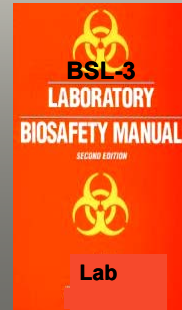


Dr. Robert Heckert DVM, PhD, CBSP
Robert Heckert Consulting, LLC
www.safevet.com



How do you work this thing to minimize risk?

- Operations manuals
- Basic ones:
 - Biosafety manual
 - Biosecurity manual
 - Incidence/emergency response manual
 - Facilities operation/maintenance (s)
- Components, separate or together (bio-risk)



Who Should Have These Programs

- Any institute or facility working with biological materials that could cause harm to humans, animals, plants, or the environment.
- Any institute that has biological materials or information that has value (is an asset) or is considered to be proprietary
- More important at the higher biocontainment levels



Developing the Plans

- Why are the plans important?
 - The plans are developed to
 - Provide biosafety/security/incidence response and operations of the laboratory
 - Improve preparedness
 - Protect the product and business 'liability'
 - Protect public health and agricultural assets from the agents under study.

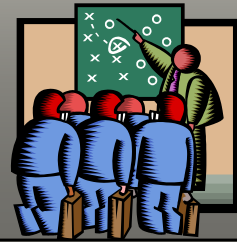


Developing the Plans

- How are they created?
 - A risk assessment and mitigation approach is developed in a graded manner to protect important assets
 - Systematic approach where assets, threats & vulnerabilities are identified.
 - Compiling existing equipment and system manuals into an integrated comprehensive one

Developing the Plans

- Who creates the plans?
 - The research and writing of the plans is a team approach and should include individuals from: science, safety, security, emergency response, local law enforcement, scientists, engineering, management, industrial hygiene, animal care and use, etc ...



Developing the Plans

- How are the plans implemented?
 - The institution is ultimately responsible for implementation by ensuring:
 - Management commitment
 - Resources and manpower
 - Delegation of program oversight
 - Follow up and oversight



Components of a Biosafety Plan

- Responsibilities – director, BSO, PIs, etc
- Administrative – forms, registrations,
- Entry/Exit procedures
- Laboratory-specific procedures
- Waste disposal – liquid, solid, tissue
- Medical surveillance plan

Components of a Biosafety Plan

- Animal use and procedures
- Equipment use and procedures
 - centrifuge, biosafety cabinet
- Detailed spill procedures
- Transport, decontamination, storage
 - samples, equipment, materials



Biosafety manual

- Living document – change as needed
- Everyone trained – as needed and refreshed annually
- No one size fits all – must be site-specific
- Forms the corner stone of safe operation along with a chemical hygiene plan



Defining Biosecurity

- Prevent loss, theft or misuse of microorganisms, biological materials, and research-related information.
 - Protect pathogens from dangerous people
 - Limit access to areas that contain certain biological agents or assets



Why You Need A Biosecurity Program

- Prevent loss, theft or misuse of microorganisms, biological materials, and research-related information.
 - Deter criminals, activists and bioterrorists from acquiring materials to harm humans, agricultural assets (animals/plants), or inflict economic damage
- Protect employees and coworkers – insider threat



Why You Need A Biosecurity Program

- Protect proprietary materials and information.
- Protect the reputation and mission of the institute.
- Ethically, we are responsible for safeguarding biological materials that may pose harm to others.



Components of a Biosecurity Plan

- Program management
- Physical security- access control and monitoring
- Personnel management
- Inventory and accountability
- Information security



Components of a Biosecurity Plan

- Transport of biological materials
- Accident, injury and incident response plans
- Reporting and communication
- Training and practice drills
- Security updates and re-evaluations

Challenges to the Concept of Biosecurity

- Most agents exist in nature, environment, and clinical specimens.
- Many have been globally shared between labs, institutes, collection repositories and clinical facilities.
- Securing/inventorying minute amounts (they can replicate into large amounts)

Challenges to the Concept of Biosecurity

- Ensuring requirements do not hinder biomedical and biotechnical R&D, collaboration, and medical or veterinary responses
- Lack of a global consensus or norms on 'how to' implement biosecurity
- Genomic and synthetic biology...



Biosecurity in Relation to Biosafety

- Biosecurity and biosafety are integrated – bio-risk – one enhances the other
- Biosecurity and biosafety are components of Good Laboratory Practices
- Laboratories with good biosafety programs have already integrated basic elements of biosecurity



Programmatic Overlaps in Biosecurity and Biosafety

- Management oversight
 - Biosafety and biosecurity become a code of practice in responsible research
- Risk Assessment, management, mitigation and communication
 - Determines the principles, practices and technology needed to work safely and securely



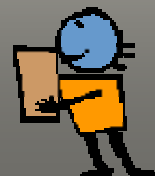
Programmatic Overlaps in Biosecurity and Biosafety



- Training
 - Staff and management understand responsibilities, processes and best practices endorsed/required by the institute
- Personnel Accountability
 - Staff are trained and qualified to work safely
 - Access to materials is limited to approved staff

Programmatic Overlaps in Biosecurity and Biosafety

- Material Accountability
 - Inventory and records of stocks, materials and other 'assets'
 - What, where, how much?
- Shipping and Transportation
 - Safe packaging, containers & transport
 - Processes to ensure transfer is tracked, documented and arrives securely

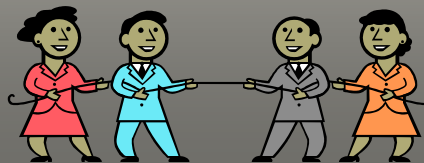


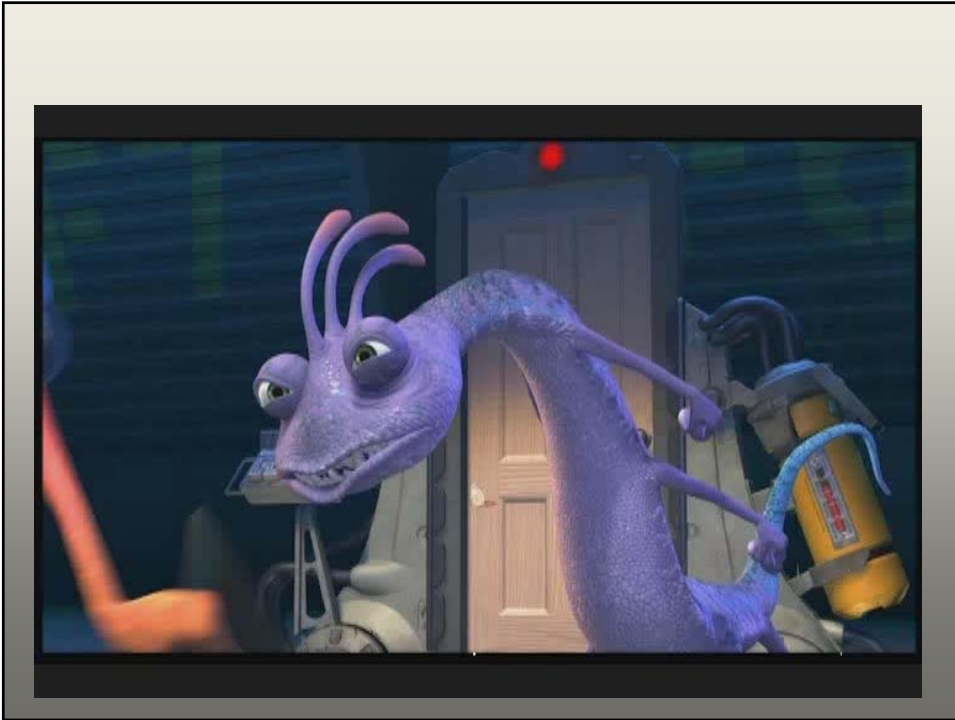
Programmatic Overlaps in Biosecurity and Biosafety

- Physical elements
 - Access control and communications technologies
 - Facility design and containment
- Emergency plans
 - Specific for the institute, hazards, threats, etc
 - Safety, security and natural disasters
 - Relationship, MOA, MOU with first responders

Avoiding Conflicts Between Biosecurity and Biosafety

- Access Control
 - Responders must be able to access controlled areas during emergencies
 - During building evacuation all doors must open...at what point do they 'relock'
- Hazard Communication
 - Modify signs on doors so presence of agents is disclosed within the lab, not on the outside of the door
 - Judicious disclosure of facility systems information





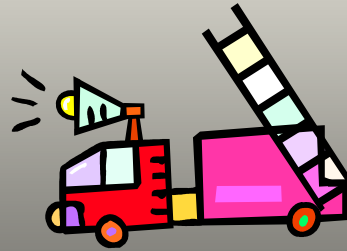
Emergency/Incident Response

Being Aware ...
Being Prepared



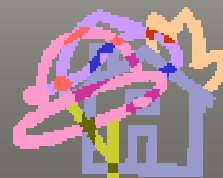
Potential Emergencies

- **External events**
 - Hurricanes, tornados, earthquakes
 - Power outages
 - Terrorism
- **Internal events**
 - Medical
 - Fires, explosions
 - Spills, splashes
 - Environmental releases



Lessons Learned from Emergencies

- **Often insufficient planning**
- **An Integrated Emergency Management Plan (IEMP)**
 - Integrates multiple planning requirements
 - Incorporates regulations/guidelines
 - Describes emergency management structure
 - Provides guidance to personnel



A Comprehensive Structure

- **Executive Management Team (EMT)**
 - Provides high-level strategic guidance to all top managers
- **Emergency Support Team (EST)**
 - Provides support/guidance to ERT
- **Emergency Response Team (ERT)**
 - Coordinates response actions on-scene

Emergency Response

Procedures

- **Written procedures**
- **On-site preparation**
 - Spills, decontamination, first-aid supplies equipment
- **Training**
 - Spill cleanup
 - First-aid
- **Develop relationship w/ emergency responders**

Emergency Response

Procedures

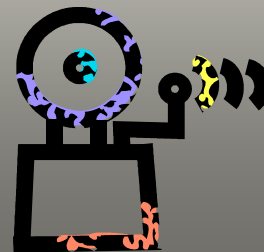
- Identification of key personnel
 - Emergency contacts
 - Local coordinators
- Procedures developed to include special safety needs (bio, rad, etc)
- Training and practice sessions
 - Alarm testing and evacuation drills
 - Basic First Aid, CPR



Emergency Response

Procedures

- Evacuations
- Location specific plans
 - Escape paths
 - Alarm systems
 - Safety equipment & use
- Handicap assistance
- Assembly areas
- Accountability



Personal Contamination

- Basic response for chemical, radiation, biological contamination
- Don't panic
- Send for help
 - If you feel you cannot handle
 - If you need a respirator
- Assist any injured or contaminated personnel
 - Injured persons are priority
 - Obtain medical attention
- Notify supervisor

Environmental Exposure

- Notify personnel
- Evacuate if necessary or unsure
- Control entry until spill cleaned up
- Call emergency response if necessary
- Call security to keep area clear & direct emergency response



Emergency Response

Environmental Exposure

Biologics

- Use absorbents with disinfectants

Solvents

- Use solvent absorbents

Acids

- Use acid neutralizers

Caustics

- Use caustic neutralizers

Mercury

- Use *Hg Absorb* sponges & powder

Strong Oxidizers

- Use inert absorbents

Emergency Response

Medical

- Check the scene and victim:

Is the scene safe, what happened, how many victims, is there any help?

- Call for medical help if victim is:

Unconscious, has trouble breathing, has chest pain/pressure, bleeding severely, has possible broken bones, has persistent pressure/pain in abdomen, is vomiting/passing blood, has seizures, headache or slurred speech

- Care for victim:

Only if you are trained, do not move unless you have training, provide CPR and first aid if trained, comfort victim until help arrives



Bio-Risk

- CEN Workshop Agreement (CWA 15793) Feb 2008
- Laboratory biorisk management standard
- Describes a management standard that integrates biosafety, biosecurity and incident response
- Download from the ABSA web site

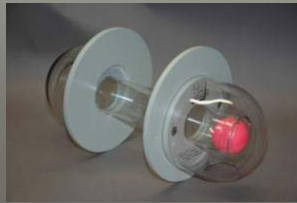
Facilities

- Facilities are our secondary and tertiary containment
- We rely upon technology to keep us safe
- How do we know it is working to keep us safe?
- How do we know when it is broken?
- How do we keep it working?



Facilities Operations Manual

- Management – need to know costs
- Lab manager – understand basic operations, need to know when something is wrong, report failures
- PI/scientist/technician - need to know when something is wrong (reversal of air, reading tell tails, etc)



Facilities Operations Manual

- Must have for facilities maintenance personnel
- Must be trained on all the infrastructure and equipment that maintains the biosafety and biosecurity and incident response for the building
- Facilities must be maintained



Facilities Operations Manual

- Often a collection of facilities SOPs describing how the system work (independently and together)
- System SOPs provided by equipment manufacture
- Should also describe some type of inspection and maintenance frequency and

Maintenance Strategies / Approaches

- Corrective Maintenance (CM)
 - Reactive (failure-based); fix it when it breaks
- Preventive Maintenance (PM)
 - Scheduled (time-based); usually off-line
- Predictive Maintenance (PdM)
 - Condition monitoring utilizing advanced diagnostics
- Proactive Maintenance (PAM)
 - Root-cause based; failure elimination
- Condition Based Maintenance (CBM)
 - Based upon real-time data, utilizes an optimal mix of Preventive, Predictive, and Proactive maintenance strategies

A Condition Based Maintenance strategy is designed to

- Improve Reliability- reduce downtime
- Increase Operational Efficiency
- Reduce Energy Consumption
- Optimize Maintenance
- Reduce Lifecycle Costs
 - O&M Costs
 - Capital Costs
 - Extended Equipment Life



It is possible!





Thank you to all the biosafety
colleagues, SNL and Smith Carter
that provided slides

