Implementing an Effective Biosafety Program

What needs to be in place to achieve a culture of Biosafety?

Michael Pentella, PhD, D(ABMM)
Michael.pentella@state.ma.us
Director, Massachusetts State Public Health Laboratory
April 12, 2016
Outline

Precedent and Context
Building blocks of biosafety programs
  Risk Assessments
  Work Practices
  Engineering Controls
  Occupational Health
  Spill Cleanup
  Disinfection
  Competencies
Resources and Regulations
Biosafety Risk Assessment to break the Chain of Infection

- Reservoir of pathogen
- Portal of escape
- Transmission
- Route of entry/infectious dose
- Susceptible host
- Incubation period
- Illness

Proper Work Practices
- Personal Protective Equipment (PPE) and Engineering Controls
- Occupational Health
- Immunization
- Treatment
- Surveillance

Risk Assessment
Biosafety Risk Assessment Process

Factors to consider:
- Infectious agents
- Procedures to be performed
- Vaccines or treatments available
- Route of transmission
- Volume or conc. of agent
- Training of staff

Diagram:
1. Identify hazards (agent if known, lab procedures and worker)
2. Evaluate/prioritize risks
3. Determine necessary controls
4. Implement control measures
5. Evaluate effectiveness of controls

Options for controls:
- Engineering controls
- Administrative and work practice controls
- Personal protective equipment

(CDC logo)
Modes of Transmission:

- Aerosol
- Injection
- Absorption (mucus membrane or dermal)
- Ingestion

Counter Measures:

- **Work Practices** – Training, SOPs, hand washing, etc.
- **Engineering Controls** – Biosafety Cabinet, centrifuge safety cups, controlled access, etc.
- **PPE** – Lab coat, gloves, face shield, goggles, PAPR, etc.
- **Occupational Health** – Immunization, treatment, surveillance, etc.
- **Other** – Disinfection, waste management, emergency procedures, spill clean up, etc.
Steps to implementing a successful biosafety program

1. Perform risk assessments
2. Select mitigation tools based on risk assessment
3. Incorporate biosafety competencies
4. Provide safety orientation and ongoing training
5. Establish a safety committee, perform regular audits and monitor compliance
6. Engage Occupational Health
7. Create and nurture a culture of safety
Risk assessment is the process of gathering all available information on a hazardous substance and evaluating it to determine the possible risks associated with exposure. This is followed by determining the mitigation strategies necessary to provide protection. There is no one standard approach to the RA process.

The risk can be mitigated but never zero.

**Goal:** Predict, Identify and Mitigate Risk

**Risk** can be defined as the probability that a health effect will occur after an individual has been exposed to a specified amount of hazard.
Benefits of a Risk Assessment

• Keeping the laboratorian, their families and the community safe
• Identification of training needs
• Evaluation of procedural changes
• Ensure compliance with regulatory agencies
• Justification for space and equipment needs
• Evaluation of emergency plans
Who performs a risk assessment?

A knowledgeable assessor

- Practical experience
- Problem-solving skills

Must engage staff

Assessor needs to have knowledge of:

- The facility
- Safety principles
- Modes of transmission
- Hazards
- Local, state and federal regulations
Risk Assessment Goals: Balancing risk and work performance

Practices implemented to mitigate risk

Performance of work in an accurate and efficient manner.
What should the Risk Assessment Cover?

• **Pre-analytical activities** from collection, transported, unpackaged, centrifuged, aliquoted, and moves through the lab

• **Analytical activities**
  – Agent Concentration in specimens
  – Suspension Volume
  – Generation of Aerosols, Droplets or Droplet Nuclei
  – Protocol Complexity
  – Use of Sharps

• **Post-analytical activities** – clean up of the lab and destruction of the specimen and lab generated materials
When to perform the risk assessment?

- Before work begins
- Whenever there is a move or renovation
- New employees
- New infectious agent or reagent
- New equipment
- Repeat when changes are to made in agents, practice, employees or facilities
Four Parts to a Risk Assessment

• Hazard Identification – microbes?

• Hazard Evaluation or Dose-Response Assessment – pathogenicity?

• Exposure Assessment – LAI?

• Risk Characterization – exposures?
1) Identify agent hazards and perform an initial risk assessment

2) Identify lab procedure hazards

3) Determine appropriate biosafety level and select additional precautions

4) Evaluate staff competency and performance of safety equipment

5) Review assessment with staff and management

Engage Everyone
Start with the Pathogens seen

Common

E. coli

Staph. aureus

Less common

Francisella tularensis

Emerging

H5N1 Avian Influenza
# Risk Assessment Matrix for Agent Hazards*

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Degree of Laboratory Risk</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agent Hazards</strong></td>
<td><strong>Low to Moderate</strong></td>
<td><strong>Moderate to High</strong></td>
</tr>
<tr>
<td><strong>Pathogenicity</strong></td>
<td>Mild to moderate disease ((Salmonella typhimurium))</td>
<td>Moderate to serious disease ((Mycobacterium tuberculosis))</td>
</tr>
<tr>
<td><strong>Virulence</strong></td>
<td>Mild to moderate disease or low infectivity</td>
<td>Severe disease or moderate infectivity</td>
</tr>
<tr>
<td><strong>Infective dose</strong></td>
<td>(&gt;10^6) IU ((Vibrio cholerae))</td>
<td>(10^6 – 100) IU ((Influenza A virus))</td>
</tr>
<tr>
<td><strong>Transmission</strong></td>
<td>Indirect contact (contact with contaminated surfaces, animal bedding))</td>
<td>Direct contact (droplet, tissue, fluid, secretion contact with mucous membranes; ingestion))</td>
</tr>
</tbody>
</table>

*adapted from D.O. Fleming ,personal communication
## Step 1
### Risk Assessment Matrix for Protocol Hazards

<table>
<thead>
<tr>
<th>Protocol Hazards</th>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent Concentration</td>
<td>$&lt; 10^3$ IU/ml</td>
<td>$10^3 – 10^6$ IU/ml</td>
<td>$&gt; 10^9$ IU/ml</td>
</tr>
<tr>
<td>Suspension Volume</td>
<td>$&lt; 1$ ml</td>
<td>$1$ ml – $1$ L</td>
<td>$&gt; 1$ L</td>
</tr>
<tr>
<td>Generate droplets &amp; droplet nuclei</td>
<td>Streaking “smooth” agar</td>
<td>Pipetting</td>
<td>Flaming an inoculating loop</td>
</tr>
<tr>
<td>Protocol Complexity</td>
<td>Standard repetitive procedures</td>
<td>Periodic change in procedures</td>
<td>Frequent change and complex procedures</td>
</tr>
<tr>
<td>Use of Animals</td>
<td>Use of safe animal care practices</td>
<td>Necropsies; large animals handling</td>
<td>Aerosol challenge protocols</td>
</tr>
<tr>
<td>Use of Sharps</td>
<td>With protective devices - safety sharps</td>
<td>Without protective devices</td>
<td></td>
</tr>
</tbody>
</table>
## Risk Assessment Matrix for Susceptibility to Disease

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Degree of Laboratory Risk</th>
<th>Low to Moderate</th>
<th>Moderate to High</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susceptibility to Disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential for Exposure</td>
<td>Visitor to lab</td>
<td>Lab worker in room where agent is handled</td>
<td>Lab worker who handles agent</td>
<td></td>
</tr>
<tr>
<td>Individual Susceptibility</td>
<td>Effective immunization</td>
<td>Immunocompetent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of vaccine or other prophylaxis</td>
<td>Yes</td>
<td>Less effective prophylaxis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Availability of effective treatment</td>
<td>Yes</td>
<td>Treatment offers some value</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

### Step 1

- Risk factors: Susceptibility to Disease, Potential for Exposure, Individual Susceptibility, Availability of vaccine or other prophylaxis, Availability of effective treatment.
- Degree of Laboratory Risk: Low to Moderate, Moderate to High, High.
- Examples:
  - Visitor to lab: Low to Moderate
  - Lab worker in room where agent is handled: Moderate to High
  - Immunocompetent: High
  - Less effective prophylaxis: Low to Moderate
  - Treatment offers some value: Moderate to High
  - No: High
Neisseria meningitidis

Requires BSL 2, BSC, aerosol/droplet precautions.

11 out of 31 LAIs were fatal in lab techs preparing a suspension or doing a catalase test on the open bench.

Estimated 3,000 isolates of Nm per year. Est. attack rate= 131/100,000 lab techs vs 0.2/100,000 adults aged 30-59
## Risk Assessment Matrix for *Neisseria meningitidis*

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Degree of Laboratory Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low to Moderate</td>
</tr>
<tr>
<td><strong>Agent Hazards</strong></td>
<td></td>
</tr>
<tr>
<td>Pathogenicity</td>
<td></td>
</tr>
<tr>
<td>Virulence</td>
<td></td>
</tr>
<tr>
<td>Infective dose</td>
<td></td>
</tr>
<tr>
<td>Transmission</td>
<td></td>
</tr>
</tbody>
</table>

*adapted from D.O. Fleming, personal communication*
# Risk Assessment Matrix for *N. meningitidis*

<table>
<thead>
<tr>
<th>Protocol Hazards</th>
<th>Low Risk</th>
<th>Moderate Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agent Concentration</td>
<td></td>
<td></td>
<td>$&gt;10^9$ IU/ml</td>
</tr>
<tr>
<td>Suspension Volume</td>
<td>$&lt;1$ ml</td>
<td>$1$ ml – $1$ L</td>
<td></td>
</tr>
<tr>
<td>Generate droplets &amp; droplet nuclei</td>
<td></td>
<td></td>
<td>Making a suspension for gram stain on bench top</td>
</tr>
<tr>
<td>Protocol Complexity</td>
<td>Standard repetitive procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of Animals</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Use of Sharps</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>
Protocol Driven Risk Assessment

• The lab activity drives the level of containment
  – Ex. HIV amplification increases the risk of exposure and leads to an increase in the level of containment (BSL3 practices)
## Risk Assessment Example 1

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Potential Hazard(s)</th>
<th>Control</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subculture of Positive Blood Culture</strong></td>
<td>Aerosols Splash Splatter</td>
<td>• Work inside a certified class II Biosafety Cabinet (BSC) with the sash at the appropriate level.</td>
<td>Bring all necessary material into the BSC before starting to work. Do not enter and re-enter BSC once specimen processing begins.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PPE must be used: fluid resistant back-closing gown, double gloves, N95 respirator and goggles, or full face shield, (eyes and mucous membranes covered).</td>
<td></td>
</tr>
</tbody>
</table>
## Risk Assessment Example 2

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Potential Hazard(s)</th>
<th>Control</th>
<th>Comment</th>
</tr>
</thead>
</table>
| *M. tuberculosis* Susceptibility Test | • Aerosol generation; spill, leaks  
• Personnel exposure while manipulating solid culture tubes: moderate risk  
• Exposure to liquid culture: high risk | • PPE (double gloves, N-95 respirator, gown, and shoe covers) donned prior to entry to BSL-3 area  
• All the culture manipulation performed in BSC on vesphene soaked pads  
• Dispose inoculation loops and transfer pipettes in rigid containers containing disinfectant |
Risk Assessment is one part of LAI prevention program

- Creating a culture of safety
- Training/education
- Written competencies
- Audits by the safety committee
- Monitoring
- Engaging all stakeholders
### Risk Assessment: Predict, Identify, & Mitigate Risk

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Potential Hazards</th>
<th>Control</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preparation of Specimens for Testing</td>
<td>Aerosolization/ Splash/ Splatter</td>
<td>- Minimize the number of workers handling the specimens.</td>
<td>- No exposed skin inside the BSC.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Use PPE: fluid resistant back-closing gown, double gloves, N95 respirator and goggles, or full face shield, (eyes and mucous membranes covered).</td>
<td>- Immediately change gloves if contamination is visible or suspected.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Limit the traffic around the BSC.</td>
<td>- Bring all necessary material into the BSC before starting to work.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Do not enter and re-enter BSC once specimen processing begins.</td>
</tr>
</tbody>
</table>

**Step 1**

Have you done a written risk assessment for all of the protocols in your lab?
Step 2: Selection of Mitigation Tools

Biosafety level
Engineering Controls
PPE
Lab Practices
Medical Waste
# Laboratory Biosafety Level Criteria

## Summary of Recommended Biosafety Levels for Infectious Agents

<table>
<thead>
<tr>
<th>BSL</th>
<th>Agents</th>
<th>Practices</th>
<th>Primary Barriers and Safety Equipment</th>
<th>Facilities (Secondary Barriers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not known to consistently cause diseases in healthy adults</td>
<td>Standard Microbiological Practices</td>
<td>None required</td>
<td>Laboratory bench and sink required</td>
</tr>
</tbody>
</table>
| 2   | • Agents associated with human disease  
• Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure | BSL-1 practice plus:  
• Limited access  
• Biohazard warning signs  
• “Sharps” precautions  
• Biosafety manual defining any needed waste decontamination or medical surveillance policies | Primary barriers:  
• Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials  
• PPEs*:  
  • Laboratory coats; gloves; face protection as needed | BSL-1 plus:  
• Autoclave available |
| 3   | • Indigenous or exotic agents with potential for aerosol transmission  
• Disease may have serious or lethal consequences | BSL-2 practice plus:  
• Controlled access  
• Decontamination of all waste  
• Decontamination of laboratory clothing before laundering  
• Baseline serum | Primary barriers:  
• Class I or II BSCs or other physical containment devices used for all open manipulation of agents  
• PPEs:  
  • Protective laboratory clothing; gloves; respiratory protection as needed | BSL-2 plus:  
• Physical separation from access corridors  
• Self-closing, double-door access  
• Exhaust air not recirculated  
• Negative airflow into laboratory |

*PPEs: Personal Protective Equipment
Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
Recommendations of a CDC-convened, Biosafety Blue Ribbon Panel

http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm?s_cid=su6101a1_w
BSL-2 Practices - Why Personal Protective Equipment?

- Act as a barrier to protect skin, mucous membrane or respiratory tract from exposure
- Prevent spread of contamination
- Protect the worker from splash and splatter
- Protect product from contamination
BSL-2 PPE
Lab coat-long sleeved and buttoned
Eye and face protection
Gloves

• Are sandals and shorts appropriate? Allowed?
• Separate waste stream for used PPE?
• Is PPE being worn outside the laboratory?
• Are personnel trained?
When do you wear gloves in the general micro lab?

- “Gloves should be worn at the specimen receiving and set-up areas, and in TB/virology labs, and when hands may contact potentially infectious material, contaminated surfaces or equipment.” (CLSI M29-A3)

- “Gloves must be worn to protect hands from exposure to hazardous materials” (BMBL 5th edition).

  - Based on a lab-specific risk assessment, the Laboratory Director or supervisor determines laboratory hazards and when to wear gloves.
Personal Protective Equipment: Gloves

- Check integrity before use
- Do not wash or reuse
- Disinfectants or chemicals enhance permeation
- Change often - Integrity decreases with use
- Do not touch “clean” surfaces

*Does not eliminate the hazard!*
Biosafety Level 2: Special Practices

✓ Policies and procedures for entry
✓ Restricted access (doors closed) when work in progress
✓ Site-specific safety manual
✓ Signs on entry door

✓ Entry requirements-PPE,
✓ vaccinations
✓ BSL
✓ Emergency contact info
Biosafety Level 2: Special Practices

Use biosafety cabinets (Class II) for work with infectious agents involving:

- Aerosols
- Large volumes
- High concentrations of organisms
- Small Gram negative diplococci from spinal fluid or blood
- Small Gram negative or Gram variable rods, slow growth on BA, no growth on Mac
Biosafety Level 2: *Special Practices*

- Use leak-proof transport containers
- Report spills and accidents
- Baseline serum samples when indicated
- Appropriate medical evaluation and treatment are provided
- Written records are maintained
Biosafety Level 3

Differs from BSL-2 in that:

- Personnel have specific training to handle particular pathogens
- Supervised by scientists experienced with these agents
- All manipulations of infectious material carried out in BSCs
- Laboratory has special engineering and design features
- Supervisors evaluate effectiveness of training
What are BSL-3 practices?

• Restricted access to the laboratory
• Additional PPE (solid-front gown, gloves and eye protection as a minimum) are worn in the lab.
• Lab personnel must demonstrate proficiency prior to BSL-3 work.
• NO work in open vessels is conducted on the bench-work in BSC or other containment equipment!
What are BSL-3 practices?

• Doors are kept closed and locked
• Persons at increased risk of infection are not allowed in lab
• Use bioaerosol-containing equipment
• Load/unload centrifuge rotors in BSC
What are BSL-3 practices?

All cultures, stocks and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving…….

Preferably within the Laboratory
Biosafety Level 3: Special Practices

- Additional Personal Protective Equipment based on risk assessment (not always necessary)
  - Coveralls
  - Booties, head covers
  - Double gloves
  - Disposable sleeves
  - Scrubs
  - Respirators
Biosafety Level 3 Respirators

- Personnel must have medical clearance, be fit tested and trained annually (OSHA 29 CFR 1910.134)
- Respirators must be maintained
- Facial hair interferes with N95 seal
- REDUCE exposure, do NOT eliminate exposure-risk is never zero
- Surgical masks are NOT respirators!
Biosafety Level 3 Respirators

• N95 Mask
• PAPR

Have you ever been fit tested?
When do you use BSL-3 practices in a BSL-2 lab?

- When working with agents that are normally handled under BSL-3 conditions, and a BSL-3 laboratory is not available
- When determined by the laboratory director based on their risk assessment
- When specific high-risk pathogenic organisms are suspected (such as *Brucella* spp., *Coccidioides*, *Blastomyces dermatitidis*, *Franciscella tularensis*, *Histoplasma capsulatum*, Mtb, etc)
Step 3: Connect to Biosafety Competencies

• Connect competencies to required skills
  – Skill Domain I: Potential hazards
  – Skill Domain II: Hazard controls
  – Skill Domain III: Administrative controls
  – Skill Domain IV: Emergency preparedness and response
Step 3

New Safety Competency Guidelines

- Potential Hazards
- Hazard Control
- Administrative Controls
- Communication and Training
- Documents and Records

http://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm?s_cid=su6401a1_e
<table>
<thead>
<tr>
<th>Skill Domain</th>
<th>Biosafety Competency – abbreviated from the Guidelines for Biosafety Laboratory Competency</th>
<th>Competency Level Ranking</th>
<th>Importance</th>
<th>Frequency</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Bio 3a</td>
<td>Describe PPE used when handling biologic materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 1</td>
<td>List PPE required for general laboratory entry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 2</td>
<td>Describe specific PPE to be used for each procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 4a</td>
<td>Demonstrate proper donning and doffing of gloves and gown</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 4b</td>
<td>Describe the limitations of PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 3e</td>
<td>Describe routine surface decontamination procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 1</td>
<td>Describe waste segregation procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 2a</td>
<td>Describe proper disposal of different types of biological waste</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III Qcc Health 4</td>
<td>Describe signs and symptoms following exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III Risk Mgmt 3</td>
<td>Describe the risk assessment process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Emer Resp 2</td>
<td>Describe reporting requirements for emergencies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Drills</td>
<td>Participate in drills and exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewed by: ___________________ Date: ________

Legend:

**Competency Level**: Entry Level: Laboratory Scientist or Medical Technologist; Midlevel: Chief/Lead Scientist or Medical Technologist, Laboratory Specialist or Laboratory Manager; Senior Level: Laboratory Manager, Chief Technologist, or Hospital or Clinical Director.

**Competency Level Ranking**:
1 = Awareness: You have no training or experience.
2 = Basic: You have received basic training.
3 = Intermediate: You have repeated successful experiences.
4 = Advanced: You can perform the actions associated with this skill without assistance.
5 = Expert: You can train others in this competency

**Importance to the Position**:
1 = An important competency for position
2 = Neutral

**Frequency Competency Performed**:
D = Daily
W = Weekly
M = Monthly
R = Rarely
A = As Needed

Step 4:
Design Safety Education & Training

- Based on regulatory requirements, RA and competencies determine training needs.
- Determine what outside training is available and what site specific training is needed.
- Consider the best format for the training
- Write materials and exams for in house training
Conduct Training

- Train new staff and existing staff (annual)
- Educate staff about the hazards identified in the risk assessment
- Train staff on use of safety practices: Engineering controls, PPE, lab practices
- Require staff to review changes to the procedures
- Determine staff level of knowledge by observation, exams, drills and exercises
Step 5: Exercises, Audits and Drills

• **Exercise** the procedures
• **Audit** the program by self audits, internal audits, external audits
• **Monitor** staff and equipment performance
• **Mandate Reporting and Follow up** on accidents, incidents, and near misses
• **Revise** the plans accordingly
• **Discuss** biosafety at regular meetings
Exercise and drill: small space decontamination

- Disinfect with Liquid Disinfectant
- Routine surface disinfection of production equipment and rooms by wiping
- Spill Clean Up
Exercise and drill: large space decontamination

- Plan for decontamination during design phase
- Reduce human exposure to disinfecting agents
- Schedule/coordinate for decontamination process. Determine impact of decontamination time
- Select appropriate disinfecting agent
- Determine location of equipment
- Prepare the site
- Monitor concentration of disinfectant
- Post decontamination clean up and testing
Auditing Your Biosafety Program - Why?

- Need to Ensure the Program is Successful
- Need to Ensure the Program is Maintained, Improved Where Necessary
- Need to Ensure Staff Understand the Program and Show Compliance
How to Monitor - Internal Auditing

• Use Checklists
  – What To Monitor?
  – How Detailed?
• Frequency of Audits
  – Monthly, Yearly?
• How to Report
  – Major Issues
  – Minor Issues
  – Recurring Issues
• Incident Reports
  – Identify Issues Between Audits
APHL Biosafety Checklist

1. Risk Assessment
2. Selection of Safety Practices
   a. Biosafety Level
   b. Engineering Controls
   c. Personal Protective Equipment (PPE)
   d. Laboratory Practices
3. Biosafety Competencies
4. Safety Orientation and Training
5. Audits, Monitoring and Safety Committee
6. Administrative Controls

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Standard</th>
<th>Resources</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Is basic PPE provided for all personnel working in the laboratory? (basic PPE includes gloves, laboratory coats or gowns, protective eyewear or face protection, etc.)</td>
<td><a href="http://www.cdc.gov/HAI/prevent/ppe_train.html">http://www.cdc.gov/HAI/prevent/ppe_train.html</a></td>
<td>Any observation made during audit</td>
</tr>
</tbody>
</table>
How to Monitor - Internal Auditing

Incident Reports

- Documents All Incidents In BSL3 Labs
- Completed By Persons Involved/PI/RO
- Way to Identify:
  - Corrective Action
  - Recurring Issues
  - Can Supplement CDC Form 3
  - Used to Update Biosafety, Incident Response, Security Manuals
Step #6: Occupational Health Program

• Post Exposure Management Plan
• Partner with Occupational Health clinician
  – Review the risk assessment
  – Review the procedure for staff access to occupational health services
  – Review reports from occupational health services
  – Train staff on when to connect with occupational health
Reporting Incidents, Accidents, Near Misses

• All Incidents Involving Infectious Agents Should be Reported Via the Agency’s Procedures
  – Spill (minor, major)
  – LAI
• Incident Report Should be Completed
• Workman’s Compensation
• Possible Form 3 to Select Agent Program
Step #7: Address concerns from labs not impacted

- Build a culture of safety
  - Hold a special meeting about safety and the emerging pathogen
  - Take every safety question/concern seriously
  - Communicate regularly about safety issues
  - Need a commitment from administration and lab leadership
  - Have regular communication about safety issues
You’ve accomplished it all! Next consider…

• ISO 15190:2003 - Medical Laboratories Requirement for Safety
  – Specifies requirements to establish and maintain a safe working environment
  – Ensures that there is a designated person ultimately responsible and that all employees to personal responsibility for their own safety and the safety of others
  – Every task requires a risk assessment with the aim that hazards be eliminated when possible

• Where this cannot be done, the risk from each hazard is reduced to a level that is practicable, using the following order of priority:
  – a) by substitution;
  – b) by containment; or
  – c) by the use of personal protective measures and equipment
• **5.1 Management responsibilities:**
  – Laboratory management shall have responsibility for the safety of all employees and visitors to the laboratory. The ultimate responsibility shall rest with laboratory director or a named person of equivalent standing

• **5.2 Management of staff health:**
  – All personnel shall have documented evidence of training related to potential risks associated with working with any medical (clinical) laboratory facility.
Creating an Environment of Safety

• Management sets the tone for safety culture

• Report exposures and near misses
  – Promote benefits of reporting

• Use incident investigation in your training to accentuate the “opportunity this presents” not the “failure it represents”
  – Case studies of real incidents
A Culture of Safety

- Establish and Enforce a Policy of Safety
- Identify Hazards Ahead of Time to Minimize
- Consider All Personnel in the Process
- Ensure Training is in Place
  - Having a Biosafety Program is Ineffective if Staff Do Not Know it, Use it, Embrace it
- Work to Improve Biosafety Practices
- All Components of the Biosafety Program Must Be Operational
  - Processes, Equipment, Barriers