Implementing an Effective Biosafety Program

A step by step guide to creating a culture of safety in the laboratory.

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Director, Massachusetts Bureau of Laboratory Sciences
Biosafety Topics Are In the Forefront

Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1
Centers for Disease Control and Prevention

8/15/2014

CDC: Smallpox found in NIH storage room is alive

For Release upon Delivery
Expected at 10:00 a.m.
July 14, 2014
<table>
<thead>
<tr>
<th>Year</th>
<th>Pathogens</th>
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<tbody>
<tr>
<td>1970</td>
<td>Legionella pneumophila</td>
</tr>
<tr>
<td></td>
<td>Norwalk virus</td>
</tr>
<tr>
<td></td>
<td>MRSA</td>
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<tr>
<td>1980</td>
<td>Helicobacter pylori</td>
</tr>
<tr>
<td></td>
<td>E. Coli O157</td>
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<tr>
<td></td>
<td>Prions</td>
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<tr>
<td></td>
<td>VRE</td>
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<tr>
<td></td>
<td>Cryptosporidium</td>
</tr>
<tr>
<td>1990</td>
<td>Chikungunya</td>
</tr>
<tr>
<td></td>
<td>MERS</td>
</tr>
<tr>
<td></td>
<td>D68</td>
</tr>
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<td>Ebola</td>
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<td>2000</td>
<td>HIV</td>
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<td>Campylobacter</td>
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<tr>
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<td>Toxic Shock Syndrome</td>
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<tr>
<td>2010</td>
<td>Ehrlichia</td>
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<tr>
<td></td>
<td>West Nile virus</td>
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<tr>
<td></td>
<td>SARS</td>
</tr>
<tr>
<td></td>
<td>Nipah virus</td>
</tr>
<tr>
<td></td>
<td>Novel H1N1</td>
</tr>
</tbody>
</table>
Steps to implementing a biosafety program

1. Perform risk assessments
2. Select safety practices based on risk assessment
3. Link to biosafety competencies
4. Provide safety orientation and ongoing training
5. Establish a safety committee, perform regular audits and monitor compliance
6. Connect with Occupational Health Program
7. Create a culture of safety
Step 1: Perform Risk Assessments

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 Assessment Goals:
Balancing risk and work performance

Practices implemented to mitigate risk

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

- **Pre-analytical activities** from the time the specimen is collected, transported, unpackaged, centrifuged, aliquoted, and moves through the lab
- **Analytical activities**
- **Post-analytical activities** – clean up of the lab and destruction of the specimen and lab generated materials
Steps to complete RA

1.a. Identify agent hazards and perform an initial risk assessment, place the findings in writing

1.b. Identify lab procedure hazards, place the findings in writing

1.c. Review assessment with staff and management
Step 1

Risk Assessment Information: Review Protocols

- Agent Concentration in specimens
- Suspension Volume
- Generation of Aerosols, Droplets or Droplet Nuclei
- Protocol Complexity
- Use of Sharps
- Use of Animals
## 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 2: Selection of Mitigation Tools

- Biosafety level
- Engineering Controls
- PPE
- Lab Practices
- Medical Waste

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Selection of Mitigation Tools

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- Medical Waste
Lab Safety Practices

• Personal Protective Equipment
• Disinfectant
  – Daily Disinfectant BSC, Counters and Centrifuge
• Capped Centrifuge tubes
• Splash Proof Containers
• Use Of UV lights
• Use disposable loops
• Allow slides to dry in BSC
• Spill Clean-up procedure

Document annual competency
Tasks to select safety practices

• Review the risk assessment
• Determine the appropriate control for the identified risk
• Write the control into the procedure manual
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
Intent of the Guidelines

• Define essential competencies needed by laboratory personnel to work safely with biologic materials and other hazards commonly found in biologic laboratory
• Reduce the risk of exposures at all levels
• Provide essential base-line information for a format to develop facility specific competencies
• Target audience is the laboratorian
Step 3

Tasks to Link to Biosafety Competencies

- Review the competencies
- Select the competencies from each domain that are applicable to the lab based on the risk assessment
<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>PPE 1</td>
<td>List PPE required for general laboratory entry</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>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>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>PPE 4b</td>
<td>Describe the limitations of PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decon 3e</td>
<td>Describe routine surface decontamination procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decon 1</td>
<td>Describe waste segregation procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>Occ Health 4</td>
<td>Describe signs and symptoms following exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk Mgmt 3</td>
<td>Describe the risk assessment process</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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>
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<td></td>
</tr>
</tbody>
</table>

**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

## Laboratory Biosafety Competency Assessment Form – Midlevel

<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>Demonstrate correct use of PPE for handling bio materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 1</td>
<td>Monitor availability of PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 2</td>
<td>Demonstrate use of specific PPE required 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>Implement routine surface decontamination procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 1</td>
<td>Implement waste segregation procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 2a</td>
<td>Demonstrate proper disposal of different types of bio waste</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III Occ 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>Conduct a risk assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Emer Resp 2</td>
<td>Implement plans and policies for reporting emergencies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV D-3c</td>
<td>Describe proper use of autoclave</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Drills</td>
<td>Implement drills and exercises</td>
<td></td>
<td></td>
<td></td>
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<th>Importance</th>
<th>Frequency</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Bio 3a</td>
<td>Evaluate PPE for handling bio materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 1</td>
<td>Determine PPE required for general lab entry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 2</td>
<td>Determine procedures for use of specific PPE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 4a</td>
<td>Develop procedures for personnel to comply with sequence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II PPE 4b</td>
<td>Ensure personnel’s knowledge of limitations of PPE</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>II Decon 3e</td>
<td>Develop routine surface decontamination procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 1</td>
<td>Establish waste segregation procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>II Decon 2a</td>
<td>Develop protocols for biological waste disposal</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III Occ Health 4</td>
<td>Ensure personnel’s knowledge of signs and symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III Risk Mgmt 3</td>
<td>Ensure risk assessment is performed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Emer Resp 2</td>
<td>Develop plans and policies for reporting emergencies</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>II.D-3c</td>
<td>Describe proper use of autoclave</td>
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Reviewed by: __________________________ Date: ____________

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Slide Courtesy of John Ridderhof, CDC/OPHSS/CSELS
Workforce: Public Health Laboratory* Competencies

- Laboratory workforce shortage is multifactorial

- Competencies are integral to any workforce development program, supporting job descriptions, performance objectives and evaluations, training and education programs, recruiting and orienting new staff, etc.

- In 2012, APHL and CDC formed a competencies partnership
  - CSELS led
  - Involvement across CDC’s scientific CIOs—governance, SME input
  - Overall, >160 people worked to develop the competencies: CDC, APHL, state/local PHLs, state environmental lab, federal and state agriculture labs, clinical laboratories, academia

* Broadly defined to include governmental public health, environmental, and agriculture labs

Slide Courtesy of John Ridderhof, CDC/OPHSS/CSELS
Teams of subject matter experts developed general, cross-cutting technical, and specialized competencies, with a quality management system as the foundation of every activity.
Step 4: Perform Safety Education & Training

• Based on RA and competencies design the training that is needed.
• 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
Accomplish education and training

- 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 and testing
Step 5: Following up on the biosafety plans

- **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
Safety Audits

UNSAFE PRACTICES

OBVIOUS: Food in work area

LESS OBVIOUS: Boxes blocking air flow in BSC
Use a biosafety checklist

<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>
APHL Biosafety Checklist

• Checklist consists of 6 sections:
  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
Examples of Checklist Questions

1. Has the person performing the risk assessment received training and are they experienced in risk assessments?

2. Is there a written procedure for appropriate donning and doffing PPE including laboratory coats, gloves, protective eyewear, face shields, N95 and/or PAPRs?

3. Are the Biosafety Laboratory Competencies used for annual staff reviews?
Examples of Checklist Questions

4. Do all new personnel receive safety training before they begin working in their assigned laboratory?

5. Are internal safety audits performed at least annually and after significant safety breaches?

6. Are biohazard signs posted by the entrance of laboratories where infectious agents are processed and tested and in other areas where indicated?
Step #6: Occupational Health Program

- Post Exposure Management Plan
- Partner with Occupational Health clinician
Tasks to link with Occupational Health Program

- Meet with occupational health services to review the risk assessment
- Review the procedure for staff access to occupational health services
- Review reports from occupational health
- Train staff on when to connect with occupational health
Step #7: Address concerns from labs not impacted

• Hold a special meeting about safety and the emerging pathogen
• Take every safety question/concern seriously
• Communicate about the testing so that everything is transparent.
Building a culture of safety?

- Need a commitment from administration and lab leadership
- Have regular communication about safety issues