Biosafety Competencies: Embraced or abandoned?

Michael Pentella, PhD, D(ABMM)
Representing APHL
Michael.pentella@state.ma.us
It has been over two and a half years that the “Guidelines for Biosafety Laboratory Competency” were published in Morbidity and Mortality Weekly Report on April 15, 2011 (60:1-6).

http://www.cdc.gov/mmwr/preview/mmwrhtml/su6002a1.htm?s_cid=su6002a1_w
Need for Biosafety Competencies

• Pandemic All Hazards Preparedness Act (PAHPA)
• Transfederal Task Force
• CDC Steering Committee
• Industry standard - training linked to competencies
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
Development Process

- CDC and the Association of Public Health Laboratories (APHL) partnered on project
- June 2009, panel of 30 experts convened
  - From federal and state public health, government-funded research, military, private clinical and reference, and academic laboratories.
  - Organizations represented included APHL, ASM, UTMB, DOD/USAMRID, CDC, FDA, NIH, OSHA, ABSA, AALAS, ACLA, Eagleson Institute, Emory University, Frontline Foundation, Georgia State University, and Grady Hospital (Atlanta)
Guiding Principles

• Each facility must develop a “Culture of Safety” to continually reduce the risk
• The document is limited in scope and only serves as a starting point for the facility
• Competencies must have broad application
• Safety is a collaborative effort
Competency Definition

• “Competency is a measurable, documentable factor that involves not only skills that can be taught and developed but also the judgment and ability to recognize the limitations of the work environment and one’s own skills and the skills of others in the laboratory”
Competency Domains

- Skill Domain I: Potential hazards
- Skill Domain II: Hazard controls
- Skill Domain III: Administrative controls
- Skill Domain IV: Emergency preparedness and response
Skill Domain I: Potential hazards

• Focused on competencies involved with understanding the hazards.
• Recognition is the first step in prevention
• Subdomains:
  – Biologic Materials
  – Research animals
  – Chemical materials
  – Radiologic materials
Skill Domain II: Hazard controls

• Focuses on use of primary and secondary barriers to prevent exposure
• Competencies for decontamination and management of hazardous waste
• Subdomains:
  – Personal protective equipment
  – Engineering controls-equipment (primary barriers)
  – Engineering controls- facility (secondary barriers)
  – Decontamination and waste control management
Skill Domain III: Administrative Controls

• Focuses on administrative controls to reduce the duration, frequency and severity of exposure to hazardous materials or situations

• Subdomains:
  – Hazard communication and signage
  – Guidelines and regulatory compliance
  – Safety program management
  – Occupational health – medical surveillance
  – Risk Management
Skill Domain IV: Emergency preparedness and response

• Focuses on management of emergencies
• Subdomains:
  – Emergencies and incident response
  – Exposure prevention and hazard mitigation
  – Emergency response – exercises and drills
## Competencies are Tiered to Three Professional Levels of Practitioners

<table>
<thead>
<tr>
<th>Field</th>
<th>Entry Level</th>
<th>Midlevel</th>
<th>Senior level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academia or research</td>
<td>Technician, research associate, or specialist</td>
<td>Principal investigator, laboratory manager, postdoctoral student, or senior or staff scientist</td>
<td>Principal investigator or branch or division manager</td>
</tr>
<tr>
<td>Clinical setting</td>
<td>Laboratory scientist or medical technologist</td>
<td>Chief/head scientist or medical technologist, laboratory specialist, or laboratory manager</td>
<td>Laboratory manager, chief technologist, or hospital or clinic director</td>
</tr>
</tbody>
</table>
Definition of Terms

• Appendix A: Terms Used in these guidelines
  – 62 specialized terms used in the document
  – Designed to standardize the interpretation of the meaning of the document
Kirkpatrick Learning Model 1994

- **Reaction of student** - what they thought and felt about the training
- **Learning** - the resulting increase in knowledge or capability
- **Behavior** - extent of behavior and capability improvement and implementation/application
- **Results** - the effects on the business or environment resulting from the trainee's performance
Survey Monkey Questions

1. Are you aware of the “Guidelines for Biosafety Laboratory Competency” published in Morbidity and Mortality Weekly Report on April 15, 2011 (60:1-6) http://www.cdc.gov/mmwr/preview/mmwrhtml/su6002a1.htm?s_cid=su6002a1_w? Yes  No

2. Have you reviewed the competencies? Yes  No

3. How would you rate the competencies? Do NOT meet expectations; Meet expectations; or Exceed expectations

4. Have you used the competencies for any of the following? (check all that apply.)
   a. for staff training and development?
   b. for staff assessment?
   c. for training new employees?
   d. for teaching students?
   e. for other reasons?
Survey Monkey Questions

5. Which domain have you found most useful?
   a. Potential Hazards
   b. Hazard Controls
   c. Administrative Controls
   d. Emergency Preparedness and Response

6. Did the appendix with definitions help you to understand the meaning of the competency?

7. Your work environment is? Clinical Lab; State, County or City Public Health Lab; Research Lab; or Other

8. Types of labs in your facility? BSL-1, BSL-2, BSL-3, or BSL-4
How to get the word out?

• DivC list serv
• ClinMicroNet list serv
• ABSA list serv
• Others
  – Iowa clinical labs
  – Minnesota clinical labs

N = 98
Are you aware of the “Guidelines for Biosafety Laboratory Competency” published in Morbidity and Mortality Weekly Report on April 15, 2011(60:1-6)? N = 98

- Yes: 72.45%
- No: 27.55%
Have you reviewed the competencies?  N = 96

68.75%  
n = 66

31.25%  
n = 30
How would you rate the competencies? N = 71
Have you used the competencies for any of the following? N = 58 (88% of those who reviewed)
Comments on using competencies n = 16

• “I've used the guidelines to assess if our current DOH policies are adequate in addressing all the skill domains and topics - which they do not. Our policies fall short in the area of Biosafety competency in our BSL-3. Without the opportunity to bring in experts for a formal lab assessment, this document has been useful in pointing out our deficiencies. We have yet to incorporate all the competencies into trainings as we struggle with the expertise to create and administer training.”
Comments on using competencies n = 16

• “The competency list is very high-level with little detail provided on how/what to specifically implement; our facility already had programs in place for these areas and the document didn't add to that program.”
Which domain have you found most useful? N = 64

- Potential Hazards: 35.94%, n = 23
- Hazard Controls: 20.31%, n = 13
- Administrative Controls: 9.38%, n = 6
- Emergency Preparedness & Response: 34.38%, n = 22
Did the appendix with definitions help you to understand the meaning of the competency? N = 70

- Yes: 91.43% (n = 64)
- No: 8.57% (n = 6)
Your work environment is? N = 95

- Clinical Lab: 78.95% (n = 75)
- Public Health Lab: 12.63% (n = 12)
- Research: 5.26% (n = 5)
- Other: 3.16% (n = 3)
Other work environment. N = 3

- Academic Medical Center
- Research and Educational lab
- Educational lab
Types of labs in your facility? N = 90

- BSL-1: 31.11% (n = 28)
- BSL-2: 86.67% (n = 78)
- BSL-3: 26.67% (n = 24)
Where have the competencies been mentioned?

• ASM Microbe Magazine (August 2011)
• OSHA Healthcare Connection newsletter (April 2011)
• APHL web page
Articles that have referenced the competencies:

Articles that have referenced the competencies:

Web links
How to measure return on investment (ROI)?

- Assess change, determine relevance of change, and sustainability of change
- Worker compensation claims?
- Have exposures been reduced?
Next Steps?

• Reach out to other lab communities, ex. Veterinary Diagnostic Labs.
• Informing those new to the field or new to their position.
• A road map of how to incorporate the competencies into the biosafety program.
• Work with CLIA, CAP and JCAHO for incorporation of biosafety into inspection process?
Joint Project of CDC, NIH, and FDA

Report laboratory-acquired infections here!

Report-LAI is a website dedicated to the anonymous reporting of laboratory incidents that may result in a laboratory-acquired infection. As a joint project of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), this website’s goal is to provide an easy and secure means of collecting data that can be analyzed to help you make your workplace safer.

In addition to being able to enter data about incidents in biological laboratories, site visitors will have access to standardized reports generated from all data entered here.

Report-LAI is a simple, voluntary and anonymous reporting system. At no point will you be tracked by any other means that will identify you.

Our Mission

Laboratory biosafety is in everyone’s best interest. The more we know about accidents, exposures to potentially infectious agents, any resulting laboratory-acquired infections, and patient outcomes, the better prepared we will be to respond to situations appropriately.

Click here to read more.

About the Joint Project

During revision of the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories (BMBL), it was necessary to make decisions about inclusion of pertinent agent summary statements in the 5th Edition.

Click here to read more.

Why You Should Participate

Report-LAI-participating individuals or institutions cannot be identified, whether they have submitted an incident report or are viewing standardized reports, alerts, and safety trend analyses.

Click here to read more.

UNDER DEVELOPMENT