Competencies: the building blocks of the safety culture

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Evolution of lab safety practices

As our knowledge increases safety practices improve.
Labs have become more complex.
Culture of Safety Vision

• Each lab creates a culture of safety which is open, non-punitive, encourage questions, and is willing to be self-critical or introspective.
• Everyone must be committed to safety, aware of risks, act to enhance safety and be adaptable.
• No regulation or guideline can ensure safe practices, it is the individuals and organizational attitudes that determine safe practices.
Competencies defined

• Competencies: Action-oriented statements that delineate the essential knowledge, skills, and abilities required for the performance of work responsibilities.
Competencies are important building blocks…

• Let’s staff know what is expected
• They are viewed as non-punitive
• Competencies can be used for:
  – Assessing current skills
  – Creating career development plans
  – Planning specific training to meet educational needs
Competency vs. Training

**Competency**
- Occurs after training is completed
- Ongoing assessments at least annually
- Direct observation or examination
- Demonstration of skill
- Non punitive
- Part of QI
- Builds critical thinking skills

**Training**
- Occurs before testing is performed
- Usually once unless there is a problem that requires retraining
Competencies are not new to the clinical lab

- CLIA Competency Assessment
  1. Direct observations of test performance;
  2. Monitoring the recording and reporting of test results;
  3. Review of intermediate test results
  4. Direct observations of performance of instrument maintenance and function checks;
  5. Assessment of test performance through testing;
  6. Assessment of problem solving skills.
Identification of the needs for biosafety competencies

- 2006 Pandemic All Hazards Preparedness Act
- 2009 Trans Federal Task Force on Optimizing Biosafety and Biocontainment Oversight recommended Core training and competency standards
- 2011 CDC and APHL publish “Guidelines for Biosafety Competencies”
- 2015 CDC and APHL publish “Competency Guidelines for Public Health Laboratory Professionals”
Vision: ALL labs adopt biosafety competencies as part of their annual competency program

<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>Pathologist, Laboratory manager, chief technologist, or hospital or clinic director</td>
</tr>
</tbody>
</table>
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
Guiding principles for the competency development

1. Culture of Safety must be created by each lab
2. Scope of the document is not intended to be all inclusive
3. Biological science is broad reaching
4. Competency is a measurable, documentable factor that involves skills and judgement
5. There is a continuum of competencies that should be viewed as a matrix of varying levels of responsibilities
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
## Personal Protective Equipment (Primary Barrier)

<table>
<thead>
<tr>
<th>ENTRY LEVEL</th>
<th>MID LEVEL</th>
<th>SENIOR LEVEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. List PPE required for general laboratory entry</td>
<td>1. Monitor availability of PPE for general laboratory entry</td>
<td>1. Determine PPE required for general laboratory entry</td>
</tr>
<tr>
<td>2. Describe specific PPE for each laboratory procedure</td>
<td>2. Demonstrate specific PPE required for each laboratory procedure</td>
<td>2. Determine specific PPE required for each laboratory procedure</td>
</tr>
<tr>
<td>3. Practice proper use of PPE</td>
<td>3. Implement proper use of PPE</td>
<td>3. Ensure personnel’s compliance with proper use of PPE</td>
</tr>
<tr>
<td>3a. Demonstrate donning and doffing sequence</td>
<td></td>
<td>3a. Develop procedures for personnel to follow proper donning and doffing</td>
</tr>
<tr>
<td>3b. Describe limitations of the PPE</td>
<td></td>
<td>3b. Ensure personnel’s knowledge of limitations of the PPE</td>
</tr>
<tr>
<td>3c. Demonstrate cleaning/disinfection/disposal/procedure</td>
<td></td>
<td>3c. Develop cleaning/disinfection/disposal procedures</td>
</tr>
<tr>
<td>4. Assess integrity and functionality of PPE</td>
<td>4. Implement assessment procedures for integrity and functionality of all</td>
<td>4. Establish assessment procedures for the proper integrity and functionality of PPE.</td>
</tr>
<tr>
<td>4a. Describe pre/post-use inspection protocol</td>
<td>PPE in use.</td>
<td>4a. Establish pre/post-use inspection protocol</td>
</tr>
</tbody>
</table>

1. Monitor availability of PPE for general laboratory entry
2. Demonstrate specific PPE required for each laboratory procedure
3. Implement proper use of PPE
   3a. Same as Entry Level
   3b. Same as Entry Level
3c. Implement cleaning/disinfection/disposal procedures
4. Implement assessment procedures for integrity and functionality of all PPE in use.
   4a. Implement pre/post-use inspection protocols

1. Determine PPE required for general laboratory entry
2. Determine specific PPE required for each laboratory procedure
3. Ensure personnel’s compliance with proper use of PPE
   3a. Develop procedures for personnel to follow proper donning and doffing sequence
   3b. Ensure personnel’s knowledge of limitations of the PPE
   3c. Develop cleaning/disinfection/disposal procedures
4. Establish assessment procedures for the proper integrity and functionality of PPE.
   4a. Establish pre/post-use inspection protocol
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
Workforce: Public Health Laboratory* Competencies

• 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
  • Overall, >160 people worked to develop the competencies: CDC, APHL, state/local PHLs, state environmental lab, federal and state agriculture labs, clinical laboratories, academia

• Companion documents – 2015 based on the 2011 Guidelines, content revised and restructured. Expands levels of responsibility. Critical task-level details not included.
Teams of subject matter experts developed general, cross-cutting technical, and specialized competencies, with a quality management system as the foundation of every activity.
Safety Competency Domains

I. Potential Hazard Recognition Sub-Domain

1. Physical environment
2. Biological materials
3. Research animals
4. Chemical materials
5. Radiological materials

<table>
<thead>
<tr>
<th>Sub-competency</th>
<th>Beginner</th>
<th>Competent</th>
<th>Proficient</th>
<th>Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical hazards in the lab facility</td>
<td>Describes the physical hazards</td>
<td>Recognizes new physical hazards</td>
<td>Assesses staff knowledge of the physical hazards</td>
<td>Evaluates the lab facility for physical hazards</td>
</tr>
</tbody>
</table>
II. Hazard Controls Sub-Domain

1. Engineering controls
2. Safe work practices
3. Personal Protective Equipment
4. Systems to track hazards
5. Preventive maintenance
6. Decontamination

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</tr>
</thead>
<tbody>
<tr>
<td>Engineering controls</td>
<td>Describes engineering controls</td>
<td>Employs engineering controls to eliminate or reduce targeted hazards</td>
<td>Develops SOP’s and work instruction that incorporate engineering controls</td>
<td>Ensures the implementation of policies, processes, and procedures related to design</td>
</tr>
</tbody>
</table>
III. Admin Controls Sub-Domain

1. Safety program management
2. Guideline and regulation compliance
3. Risk management
4. Occupational health and medical surveillance

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<th>Proficient</th>
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</thead>
<tbody>
<tr>
<td>Program audits</td>
<td>Participates in audits of the safety program</td>
<td>Conducts audits of the safety program</td>
<td>Designs safety program audits</td>
<td>Evaluates the safety program audit results to identify problem areas</td>
</tr>
</tbody>
</table>
IV. Communication and Training

Sub-Domain

1. Hazard communication
2. Safety training

<table>
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<th>Competent</th>
<th>Proficient</th>
<th>Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety training</td>
<td>Describes requirements for documenting safety training</td>
<td>Adheres to procedures for recording training</td>
<td>Implements procedures for documenting staff training</td>
<td>Develops policies, process, and procedures for documentation and verification</td>
</tr>
</tbody>
</table>
## V. Documents and Records Sub-Domain

1. Documents and record keeping

<table>
<thead>
<tr>
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<th>Beginner</th>
<th>Competent</th>
<th>Proficient</th>
<th>Expert</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety documentation management</td>
<td>Describes procedures for safety document management</td>
<td>Adheres to procedures</td>
<td>Manages safety document management process</td>
<td>Designs the safety document management system</td>
</tr>
</tbody>
</table>
Competencies for Biosafety Officer
Job Description

• Safety
• Security
• Workforce Training
• Microbiology
• Communication
• Emergency Management and Response
• Quality Management System
• General Laboratory Practice
Competencies for Biosafety Officer

• Safety
  – Works safely with biological materials in the lab
  – Implements intervention strategies to control hazards
  – Designs work practices to minimize exposure risk
  – Employees the selection, use and care of PPE
  – Establishes a system to detect and control the underlying causes of exposures
  – Provides guidance on medical waste management
  – Ensures staff compliance with guidelines and regs
  – Manages risks
  – Effectively hazard communication
  – Ensures safety training needs are identified and provided
Competencies for Biosafety Officer

• Security
  – Ensures risk mitigation plan meets goals, requirements and established standards
  – Ensure security plan meets organizational goals, regulatory requirements and standards
  – Implements a transportation of hazardous material security plan
Competencies for Biosafety Officer

• Workforce Training
  – Gathers training content
  – Designs training
  – Manages logistics of training delivery
  – Applies principles of learning to training delivery
  – Evaluates learner knowledge and skill development
  – Markets training opportunities
Ideas for competency assessment

• Generate ideas from near misses, observations, expressed concerns
  – Proper and Safe Handling Practices
  – Use of the BSC
  – Biohazardous waste handling
  – Use of autoclave
  – Disease symptoms
  – Post exposure management
  – Reporting exposures and illnesses
## Laboratory Biosafety Competency Assessment Form – Senior Level

<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>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>
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<tr>
<td>II PPE 2</td>
<td>Determine procedures for use of specific PPE</td>
<td></td>
<td></td>
<td></td>
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</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>
<td></td>
<td></td>
<td></td>
</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>
<td></td>
</tr>
<tr>
<td>II ID-3c</td>
<td>Describe proper use of autoclave</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Drills</td>
<td>Develop drills and exercises</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reviewed by: __________________ Date: ______

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**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