

Laboratory Biosafety Competency Development for the BSL 2, 3, and 4

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Need for Development

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

Biosafety Practices in the Lab

What do *you*
think?

Much is left
to opinion
since there is
little research
in this area.

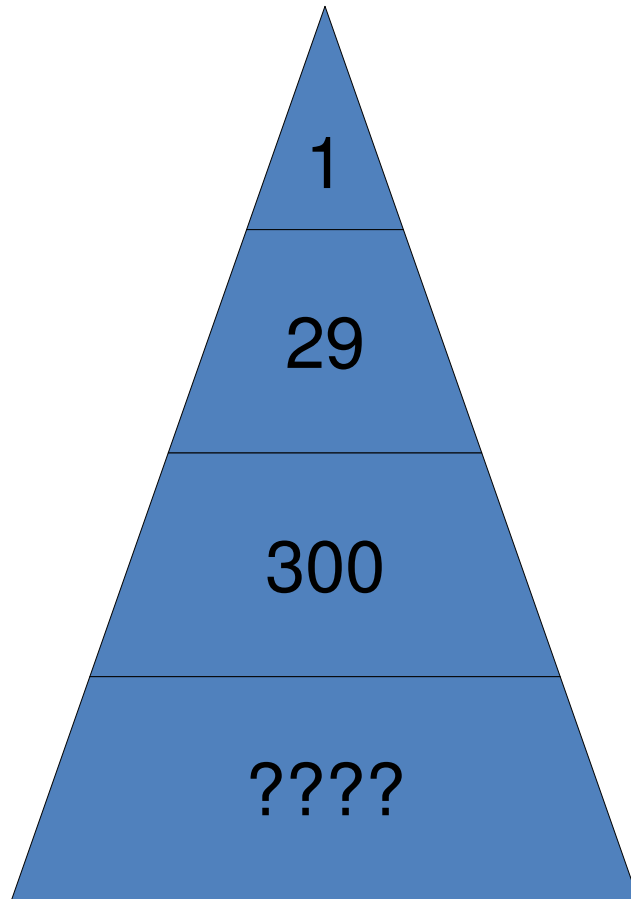


Safety Follow-up

- The second case of worker acquired HIV was in a laboratorian
- Researcher acquired SARS in Singapore
- No requirements for reporting

Common Sense and Training

The Heinrich Pyramid (1931)



1 serious accident
is preceded by

29 minor incidents
which are preceded by

300 near misses
which are preceded by

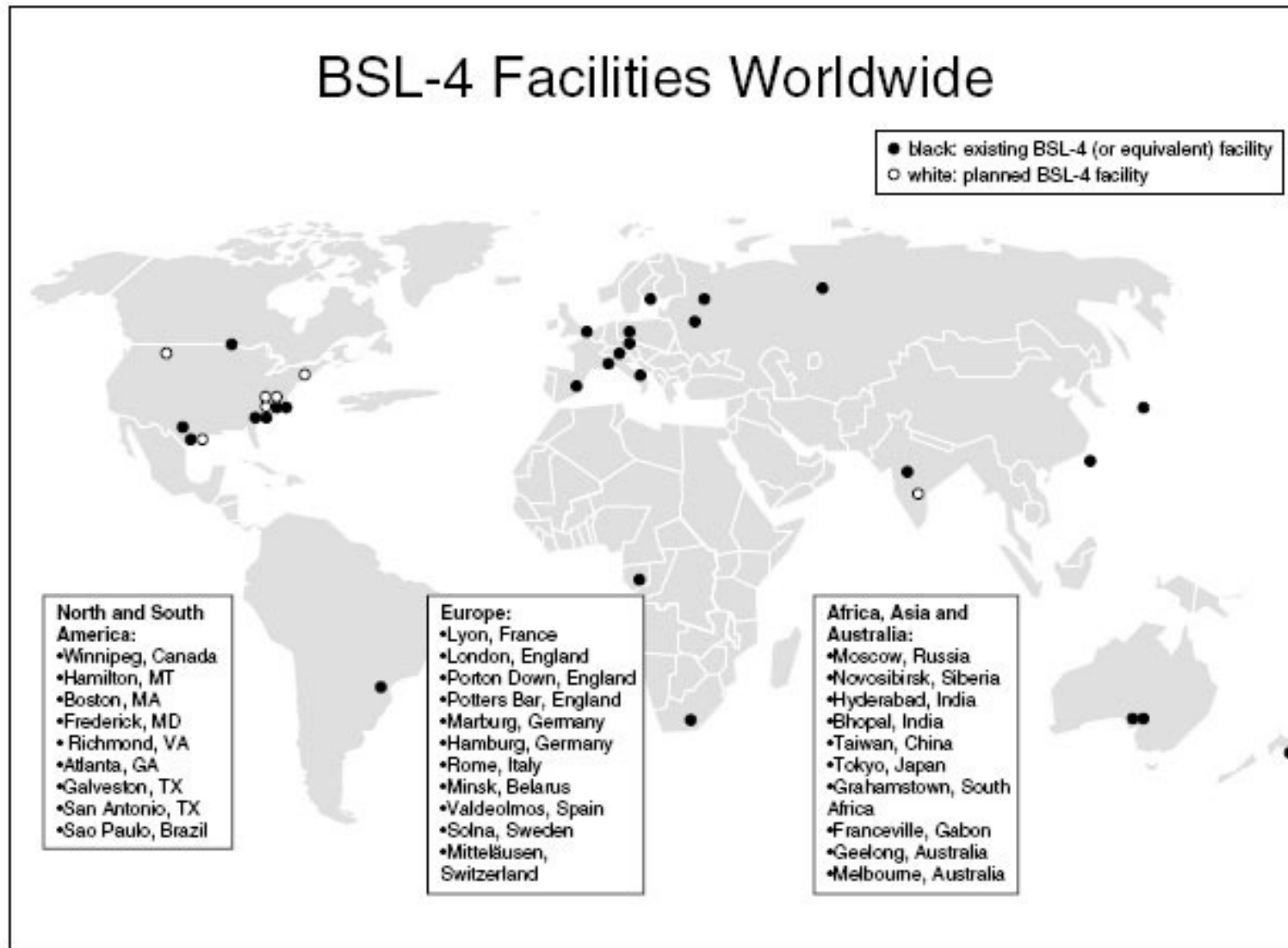
??? unsafe practices or
unsafe conditions.

Biosafety Issues Grow

Example - **Laboratory - Acquired *Clostridium difficile* Polymerase Chain Reaction Ribotype 027: A New Risk for Laboratory Workers?**

Emilio Bouza, Adoración Martin, Renata J. Van den Berg, and Ed J. Kuijper. [Clinical Infectious Diseases](#). Volume 47, Issue 11, Page 1493–1494, Dec 2008.

As of 2006



<http://www.upmc-biosecurity.org/bin/p/a/2007-04-04-highcontainmentb.jpg>

Competency Definition

- Competencies: Action-oriented statements that delineate the essential knowledge, skills, and abilities required for the performance of work responsibilities

Uses for Competencies

- **Practitioners**

- Assessing current skills
- Creating career development plans
- Planning specific training to meet educational needs

Uses for Competencies

- **Employers**

- Creating career ladders for employees
- Developing position descriptions and job qualifications
- Developing training plans for employees
- Assessing the workforce capacity of an organization

Uses of Competencies

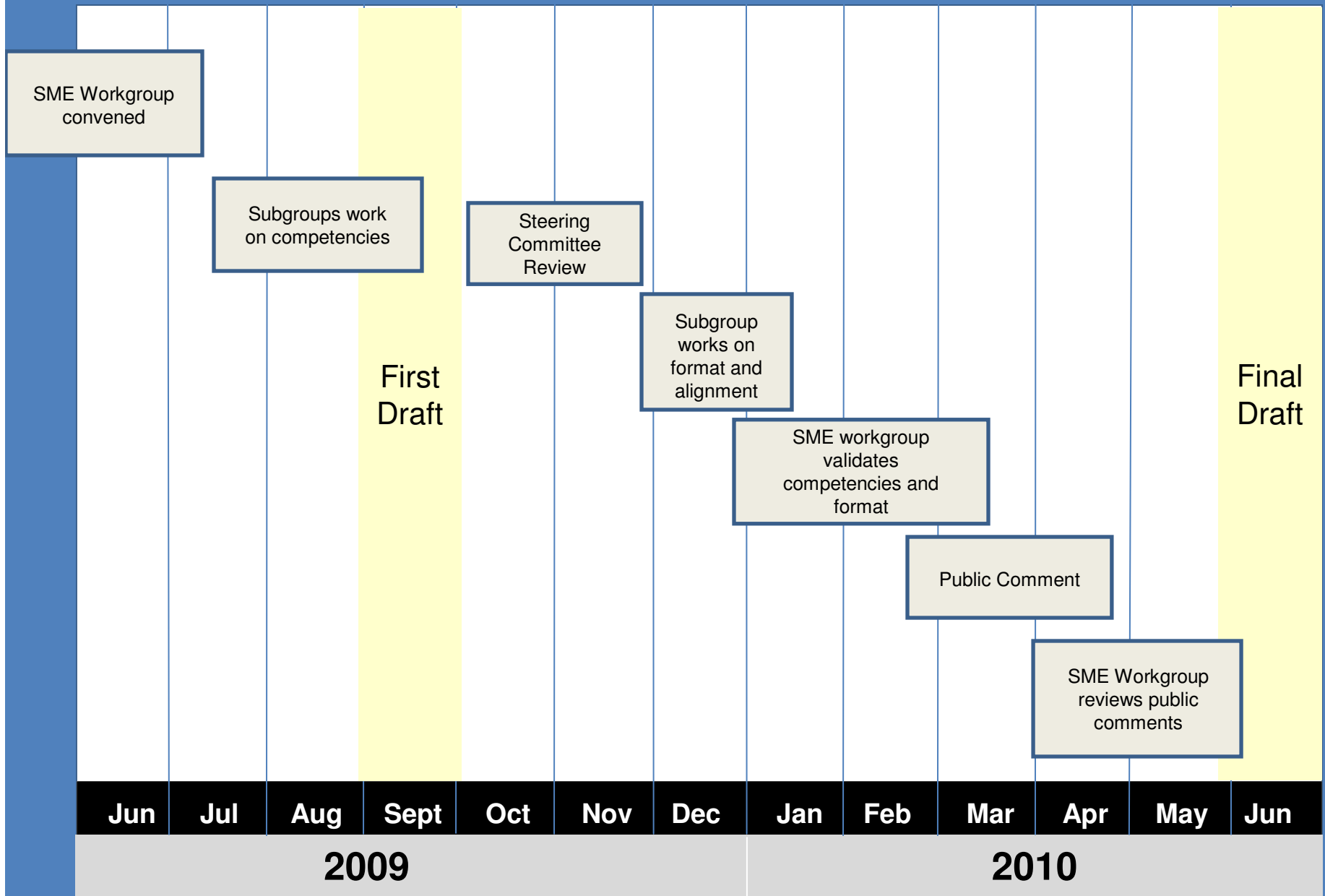
- **Educators**

- Designing education programs that meet needs of public health agencies
- Incorporating critical elements of laboratory biosafety practice into existing coursework

Process

- CDC Steering Committee
- Partner with Association of Public Health Laboratories
- Panel of SMEs representing federal and private sectors
- In-person meetings, workgroup and subgroup meetings and teleconferences

Laboratory BioSafety Competency Development Timeline



SME Workgroup

- APHL
- ASM
- UTMB
- DOD/USAMRID
- CDC
- FDA
- NIH
- OSHA
- ABSA
- AALAS
- Eagleson
- ACLA
- Emory
- Frontline
- GA State University
- Grady Hospital

Format

- PH Practice Domains of the ASPH/PHF Council of Linkages
- Documents for BSL-2, BSL-3, BSL-4 labs which built on preceding level
- Three levels of practice within these biosafety levels: entry, mid-level, senior

Council on Linkages

- Assessment and Analysis
- Basic Public Health Science
- Communication
- Community Dimensions
- Cultural Competency
- Financial and Operational Management
- Leadership and Systems Thinking
- Policy Development

Critique from Steering Committee

- Alignment
- Duplications
- Build-up of competencies from BSL-2-3 to 4
- Not user friendly
- Need to redefine scope

2010 Laboratory Biosafety Competencies Status

- New domains
- Alignment – use of N/A or duplicate statement as warranted
- Separate, stand-alone documents
- Identify gaps (animal labs)
- Build lexicon
- Definitions of domains, words or phrases as needed

Intended Users

- Entry Level Laboratorian:
- Mid Level Laboratorian:
- Senior Level Laboratorian:

Entry Level Laboratorian

- Education with no hands-on experience at a given BSL level
- Works under direct observation until proficient then works under direct supervision
- Not working independently—limited discretion to make decisions
- Understanding of life sciences

Mid Level Laboratorian

- Mastered the competencies of introductory level
- Has some hands-on experience at given BSL level
- Performs work tasks independently
- Works under supervision
- Provides inputs and possible solutions to make decisions
- Ability to trouble shoot problems and report to supervisor
- Escort support staff into lab
- May train, mentor or oversee the work of introductory-level staff in the lab

Senior Level Laboratorian

- Mastered the competencies of mid-level knowledge
- Has extensive experience at given BSL level
- Works under minimal supervision
- Will train, mentor and oversee the work of introductory and mid-level staff in the lab
- Discretion to make decisions
- Provide input for risk assessment
- May serve as the PI, would then be responsible for PI tasks
- Manages directly staff
- Coordinate with facility personnel
- Responsible for maintaining regulatory compliance
- Input into selection of outside contractors
- Should have understanding of the facility operations

Defining Terms

2. Lexicon

Definitions of terms used in the Skill Domains

General: The institution/facility has an established culture of safety (top to bottom commitment), supervisory personnel utilize good management practices, etc.

Skill Domain: Identifying Sources of Potential Hazards

1. **Biological Materials**—any microorganism (including but not limited to bacteria, viruses, fungi, helminths, protozoa); material derived from a living source (including but not limited to cell lines [human or animal, natural or cultured]; genomic materials; clinical material (tissues/organs; body fluids) biological toxins, or allergens; or any naturally occurring, bio-engineered or synthesized component of any such microorganism/material as mentioned above. May or may not be infectious (e.g. prions, recombinant DNA, etc.).
2. **Chemical Materials**—solids, liquids, mists, vapors, gases need a better definition here
3. **Radiological Materials**—includes radioisotopes, radioactive waste products, and chemical/biological materials that have been modified to include isotope labels
4. **Physical Hazards**—includes by not limited to ergonomic issues; exposure to hot and cold; electrical, compressed gas cylinders, equipment and sharps
5. **Research Animals**—includes not only the risks associated with handling animals (bites, scratches and allergens), but also risks with handling their bedding and other associated waste products

http://www.aphl.org/profdev/el/Documents/EL_2010April21_SurveyBSLCompetencyPrintable.pdf

Domains

- Identification of Potential Hazards
- Hazard Controls
- Administrative Controls
- Emergency Preparedness and Response

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Skill Domain: Potential Hazards

- Biological Agents and Materials
- Research Animals
- Chemical Hazards
- Physical Hazards
- Radiological Materials

Biological agents

ENTRY LEVEL	MID LEVEL	SENIOR LEVEL
<p>1. Describe concept of biohazardous materials</p> <p>1a. List biohazardous materials present in the laboratory</p> <p>2. Recognize potential hazards associated with biohazardous materials handled in the laboratory</p> <p>2a. Describe relationship of infectious agents and toxins to disease</p> <p>2b. Describe the virulence and pathogenicity of the organisms</p> <p>2c. Describe the principle routes of laboratory-acquired infections</p> <p>2d. Recognize potential hazards of unknown/non routine samples</p>	<p>1. Distinguish biohazardous from nonhazardous materials</p> <p>1a. Same as Entry</p> <p>2. Same as Entry</p> <p>2a. Same as Entry</p> <p>2b. Same as Entry</p> <p>2c. Same as Entry</p> <p>2d. Mitigate hazards of unknown/non routine samples</p>	<p>1. Ensure personnel's knowledge of biohazardous materials</p> <p>1a. Ensure personnel have knowledge of biohazardous materials handled in the laboratory</p> <p>2. Manage biohazardous materials</p> <p>2a. Assess personnel's knowledge of infectious agents and toxin risk group classifications</p> <p>2b. Assess personnel's knowledge of the virulence and pathogenicity of the organisms handled in the laboratory</p> <p>2c. Assess personnel's knowledge of the principle routes of laboratory-acquired infections</p> <p>2d. Manage mitigation of hazards of unknown/non routine samples</p>

Skill Domain: Hazard Controls

- Personal Protective Equipment (Primary Barrier)
- Engineering Controls (Facilities – Secondary Barriers)
- Laboratory Waste Management

Personal Protective Equipment (Primary Barrier)

ENTRY LEVEL	MID LEVEL	SENIOR LEVEL
<ol style="list-style-type: none"> 1. List PPE required for general laboratory entry 2. Describe specific PPE for each laboratory procedure 3. Practice proper use of PPE <ol style="list-style-type: none"> 3a. Demonstrate donning and doffing sequence 3b. Describe limitations of the PPE 3c. Demonstrate cleaning/disinfection disposal/procedure 4. Assess integrity and functionality of PPE <ol style="list-style-type: none"> 4a. Describe pre/post-use inspection protocol 	<ol style="list-style-type: none"> 1. Monitor availability of PPE for general laboratory entry 2. Demonstrate specific PPE required for each laboratory procedure 3. Implement proper use of PPE <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 4a. Implement pre/post-use inspection protocols 	<ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> 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. <ol style="list-style-type: none"> 4a. Establish pre/post-use inspection protocol

Skill Domain: Administrative Controls

- Hazard Signage and Communication Program
- Guidelines and Regulatory Compliance
- Safety Program Management
- Medical Surveillance
- Risk Assessment
- Risk Associated with Lab procedures

Hazard communication and signage

ENTRY LEVEL	MID LEVEL	SENIOR LEVEL
<p>1. Explain safety signs, labels, and posted information</p> <p>1a. Adhere to safety signs, labels and posted information</p> <p>1b. N/A</p> <p>2. Describe labeling of samples, containers, and cultures according to appropriate regulatory requirements</p> <p>3. Describe process to communicate sample-specific hazard information according to SOP</p> <p>3a. N/A</p> <p>3b. Describe procedures to identify hazardous infectious agents in the</p>	<p>1. Implement safety signs, labels and posted information</p> <p>1a. Monitor adherence to safety signs, labels and posted information</p> <p>1b. N/A</p> <p>2. Implement labeling of samples, containers, and cultures according to appropriate regulatory requirements</p> <p>3. Implement process to communicate sample-specific hazard information according to SOP</p> <p>3a. Convey information regarding potential infectious agents in non-routine specimens brought into the laboratory</p> <p>3b. Apply procedures to identify hazardous infectious agents in the</p>	<p>1. Determine required safety signs, labels and posted information</p> <p>1a. Ensure adherence to safety signs, labels and posted information</p> <p>1b. Evaluate effectiveness of safety signs, labels and posted information</p> <p>2. Ensure the implementation of labeling of samples, containers, and cultures is compliant with appropriate regulatory requirements</p> <p>3. Develop procedures to communicate sample-specific hazard information according to SOP</p> <p>3a. Advise laboratory staff regarding potential infectious agents in non-routine specimens brought into the laboratory</p> <p>3b. Ensure personnel's knowledge</p> <p>4. Ensure personnel's knowledge communication processes for applicable</p>

Skill Domain: Emergency Preparedness and Response

- Emergencies and Incident Response
- Exposure Prevention and Hazard Mitigation
- Exercises and Drills

Emergency response exercises and drills

ENTRY LEVEL	MID LEVEL	SENIOR LEVEL
<p>1. Comply with personnel emergency response training requirements</p> <p>1a. Participate in entry level personnel training</p> <p>1b. N/A</p> <p>1c. N/A</p> <p>2. Participate in drills and exercises for laboratory personnel</p> <p>2a. N/A</p> <p>2b. N/A</p>	<p>1. Conduct required emergency response training of laboratory personnel</p> <p>1a. Demonstrate ability to train entry level staff</p> <p>1b. N/A</p> <p>1c. N/A</p> <p>2. Conduct drills and exercises for laboratory personnel</p> <p>2a. N/A</p> <p>2b. N/A</p>	<p>1. Develop required emergency response training</p> <p>1a. Evaluate ability of mid level staff to train all laboratory personnel</p> <p>1b. Ensure adherence to laboratory's emergency response training requirements</p> <p>1c. Evaluate effectiveness of the laboratory's emergency response training</p> <p>2. Advise on development of drills and exercises for laboratory personnel</p> <p>2a. Assess effectiveness of drills & exercises</p> <p>2b. Incorporate lessons learned into training program</p>

Competencies can be found at...

- http://www.aphl.org/profdev/el/Documents/EL_2010April21_SurveyBSLCompetencyPrintable.pdf
- Survey can be found at:
<http://www.surveymonkey.com/s/bslcompetencies>

12. HAZARD CONTROLS: Personal Protective Equipment (Primary Barrier)

HAZARD CONTROLS: Personal Protective Equipment (Primary Barrier)

* Do you agree with *all* of the competencies below?

- Yes—please proceed to next page
- No—please indicate which ones you disagree with and comment below

Entry level

	Disagree
1. List PPE required for general laboratory entry	<input type="checkbox"/>
2. Describe specific PPE for each laboratory procedure	<input type="checkbox"/>
3. Practice proper use of PPE	<input type="checkbox"/>
3a. Demonstrate donning and doffing sequence	<input type="checkbox"/>
3b. Describe limitations of the PPE	<input type="checkbox"/>
3c. Demonstrate cleaning/disinfection disposal/procedure	<input type="checkbox"/>
4. Assess integrity and functionality of PPE	<input type="checkbox"/>
4a. Describe pre/post-use inspection protocol	<input type="checkbox"/>
4b. Identify compromised PPE	<input type="checkbox"/>
5. Describe response to compromised PPE	<input type="checkbox"/>
5a. N/A	<input type="checkbox"/>

Mid level

Disagree

1. Monitor availability of PPE for general laboratory entry	<input type="checkbox"/>
2. Demonstrate specific PPE required for each laboratory procedure	<input type="checkbox"/>
3. Implement proper use of PPE	<input type="checkbox"/>
3a. Same as Entry Level	<input type="checkbox"/>
3b. Same as Entry Level	<input type="checkbox"/>
3c. Implement cleaning/disinfection/disposal procedures	<input type="checkbox"/>
4. Implement assessment procedures for integrity and functionality of all PPE in use.	<input type="checkbox"/>
4a. Implement pre/post-use inspection protocols	<input type="checkbox"/>
4b. Monitor personnel's ability to identify compromised PPE	<input type="checkbox"/>
5. Implement appropriate response procedures to compromised PPE	<input type="checkbox"/>
5a. N/A	<input type="checkbox"/>

Senior level

Disagree

1. Determine PPE required for general laboratory entry	<input type="checkbox"/>
2. Determine specific PPE required for each laboratory procedure	<input type="checkbox"/>
3. Ensure personnel's compliance with proper use of PPE	<input type="checkbox"/>
3a. Develop procedures for personnel to follow proper donning and doffing sequence	<input type="checkbox"/>
3b. Ensure personnel's knowledge of limitations of the PPE	<input type="checkbox"/>
3c. Develop cleaning/disinfection/disposal procedures	<input type="checkbox"/>
4. Establish assessment procedures for the proper integrity and functionality of PPE.	<input type="checkbox"/>
4a. Establish pre/post-use inspection protocol	<input type="checkbox"/>
4b. Ensure personnel can identify compromised PPE	<input type="checkbox"/>
5. Develop procedures for appropriate response to compromised PPE	<input type="checkbox"/>
5a. Ensure personnel's knowledge of procedures for appropriate response to compromised PPE	<input type="checkbox"/>

Next Steps

- National Feedback
 - APHL Website for feedback and comment
 - Information disseminated through professional society networks and work environments
- Review and decision about comments
 - SME workgroup
- Final Draft review by Steering Committee
- Dissemination and publication