

# Components of a 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 Bureau of Laboratory  
Sciences  
June 9, 2015

# Biosafety Is Getting Attention



## Review of CDC Anthrax Lab Incident

Thomas R. Frieden, M.D., M.P.H.  
Director

Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services



For Release upon Delivery  
Expected at 10:00 a.m.  
July 16, 2014

**UNDER EMBARGO** until NOON, August 15, 2014

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

A screenshot of a CNN Health website article. The article title is 'CDC: Smallpox found in NIH storage room is alive' by Jen Christensen, dated July 11, 2014. The article includes a large image of a scanning electron micrograph showing smallpox virus particles. To the right of the image is a sidebar with social media sharing options and a CVS Health advertisement. The top of the page shows the CNN Health navigation bar with various menu items like Home, TV &amp; Video, U.S., World, Politics, etc.

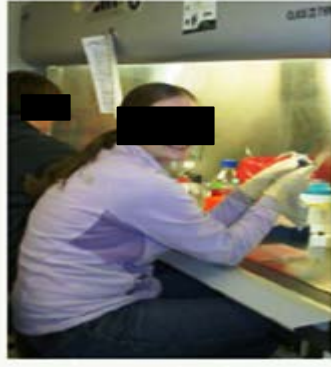
# What has been missing?

- Must be a Culture of Biosafety in the Laboratory
- Biosafety is Part of the Systemic Approach to
- Quality
- For Biosafety, Laboratories are Somewhat Self-
- Monitoring (Safety not a major component of CLIA or CAP)
- Laboratories Will Never be Risk Free
  - USA Today Report (August 2014), 240 Incidents/Year Between 2009-2012

# How would you rate the culture of safety in your lab? Biosafety Perception?



No labcoats



Two in a BSC

Bare arms, no gloves, hand touching mouth



Staff should be trained in safe practices and their adherence to these practices should be monitored.

1. *Great - no problems*
2. *Very good - few problems*
3. *Needs some work*
4. *Biosafety practices are weak*

# ***Risk Identification***

Studies and  
data are old

**LAI are  
under  
reported**

Facilities are  
reluctant to report

Hospital labs

Research labs

Veterinary labs

Government labs



TABLE 1. Most frequently reported laboratory-acquired infections in the United States and Great Britain

Infection	Total no. (%) of cases reported for:			
	U.S. <sup>a</sup>	U.S. and world <sup>b</sup>	Great Britain <sup>c,d</sup>	NADC <sup>e</sup>
Brucellosis	274 (9.4)	423 (10.8)	2 (2.1)	18 (52.9)
Q fever	184 (6.3)	278 (7.1)	0	
Typhoid fever	292 (10.0)	256 (6.5)	3 (3.2)	
Hepatitis	126 (4.3)	234 (6.0)	19 (20.0)	
Tularemia	129 (4.4)	225 (5.7)	0	
Tuberculosis	174 (6.0)	176 (4.5)	24 (25.3)	4 (11.8)
Dermatomycosis	84 (2.9)	161 (4.1)	0	2 (5.9)
Venezuelan equine encephalitis	118 (4.1)	141 (3.6)	0	
Typhus	82 (2.8)	124 (3.2)	0	
Psittacosis	70 (2.4)	116 (3.0)	0	4 (11.8)
Coccidioidomycosis	108 (3.7)	93 (2.4)	0	
Streptococcal infections	67 (2.3)	78 (2.0)	3 (3.2)	
Histoplasmosis	81 (2.8)	71 (1.8)	0	
Leptospirosis	43 (1.5)	87 (2.2)	0	3 (8.8)
Salmonellosis	54 (1.9)	48 (1.2)	11 (11.6)	1 (2.9)
Shigellosis	54 (1.9)	58 (1.5)	26 (27.4)	
All reported infections	2,912	3,921	95	34

<sup>a</sup> 1969 data adapted from reference 151.

<sup>b</sup> 1976 data adapted from reference 110.

<sup>c</sup> 1980 to 1989 data adapted from references 51 through 55.

<sup>d</sup> Includes possibly attributable and attributable cases.

<sup>e</sup> NADC, National Animal Disease Center; 1975 to 1985 data adapted from reference 93.

D. L. Sewell.  
1995.  
Clinical  
Microbiology  
Reviews. 8:  
389-405.

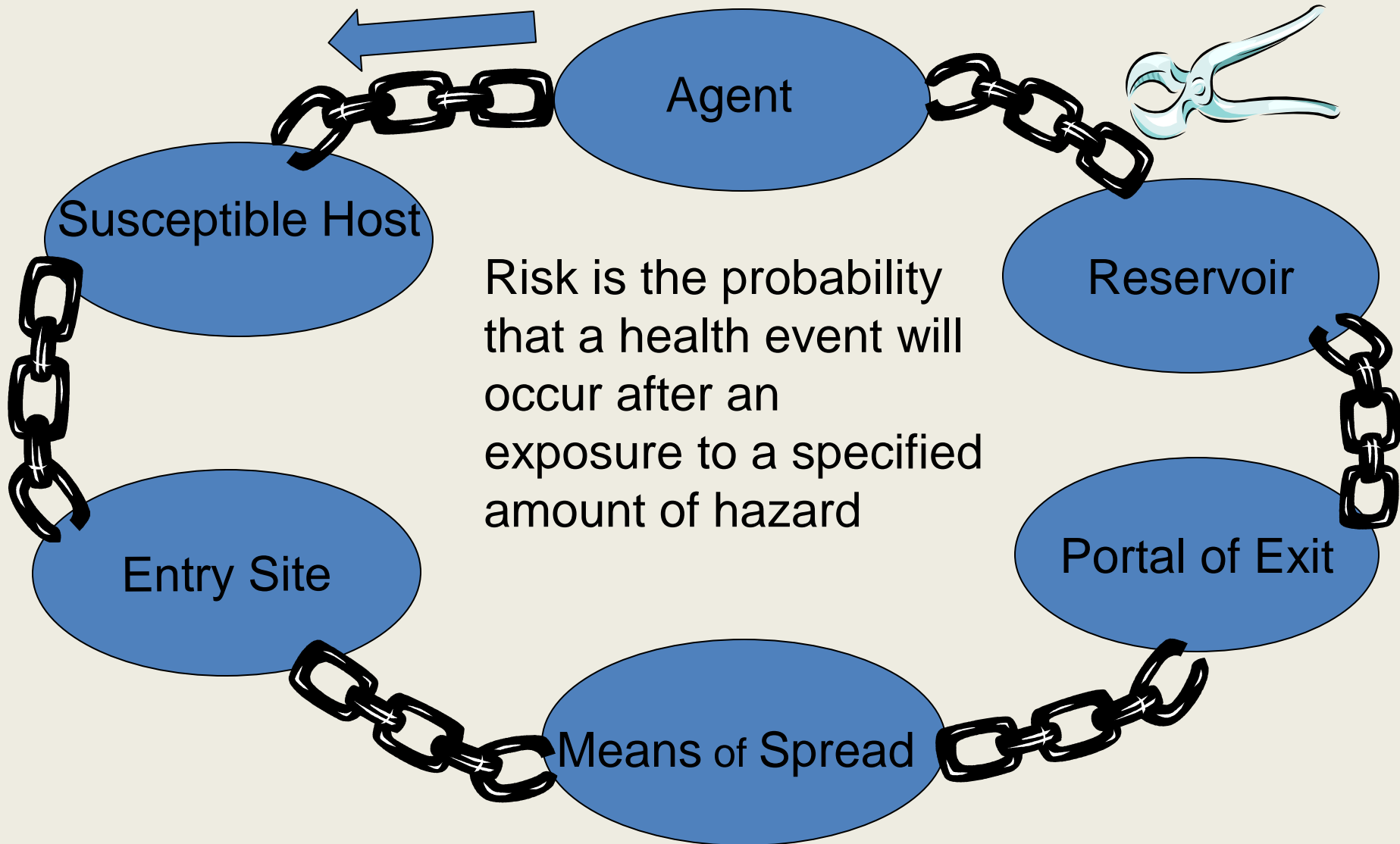
---

Morbidity and Mortality Weekly Report

## Fatal Meningococcal Disease in a Laboratory Worker — California, 2012

Channing D. Sheets, MEd<sup>1</sup>, Kathleen Harriman, PhD<sup>1</sup>, Jennifer Zipprich, PhD<sup>1</sup>, Janice K. Louie, MD<sup>1</sup>, William S. Probert, PhD<sup>1</sup>, Michael Horowitz, MS<sup>2</sup>, Janice C. Prudhomme, DO<sup>2</sup>, Deborah Gold, MPH<sup>2</sup>, Leonard Mayer, PhD<sup>3</sup> (Author affiliations at end of text)

# Potential Hazards: Chain of Infection



# ***Definition of Biosafety (USA):***

The development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biohazardous agents to workers, other persons, and the environment.

(CDC/NIH, 1999)



# *How do laboratorians get infected?*

Needle stick/sharps

Inhalation of aerosols

Ingestion

Ocular/Mucosal splash or contact

Lab animal/vector exposure

Persons affected in adjacent workspace

Unknown route

**TABLE 2—Distribution of Injury Types Among Public Health Laboratories and Minnesota Hospital Laboratories, 1986**

Injury Type	Public Health Laboratories		Minnesota Hospital Laboratories	
	N	%	N	%
Needlestick	17	6	300	63
Cut/scrape	152	50	101	21
Sprain	25	8	22	5
Eye injury	18	6	7	1
Burn	25	8	3	1
Inhalation, ingestion or skin injury	18	6	3	1
Other	45	15	18	4
Missing	3	1	19	4
<b>Total</b>	<b>303</b>	<b>100</b>	<b>473</b>	<b>100</b>

# Steps to a successful biosafety program



1. Perform risk assessments
2. Select mitigation tools 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**



# ***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

Step 1

# Risk Assessment Goals: Balancing risk and work performance

Practices  
implemented to  
mitigate risk



Performance  
of work in a  
safe, accurate  
and efficient  
manner.



## Step 1

# 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

# Risk Assessment Information: Review Protocols

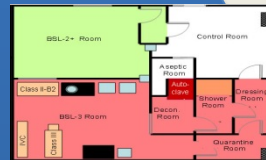
- Agent Concentration in specimens
- Suspension Volume
- Generation of Aerosols, Droplets or Droplet Nuclei
- Protocol Complexity
- Use of Sharps
- Use of Animals

## Step 1

# Risk Assessment: Predict, Identify, & Mitigate Risk

Procedure	Potential Hazards	Control	Comment
<b>Preparation of Specimens for Testing</b>	Aerosolization/ Splash/ Splatter	<ul style="list-style-type: none"><li>-Minimize the number of workers handling the specimens.</li><li>-Use PPE: fluid resistant back-closing gown, double gloves, N95 respirator and goggles, or full face shield, (eyes and mucous membranes covered).</li><li>-Limit the traffic around the BSC.</li></ul>	<ul style="list-style-type: none"><li>-No exposed skin inside the BSC.</li><li>-Immediately change gloves if contamination is visible or suspected.</li><li>-Bring all necessary material into the BSC before starting to work.</li><li>-Do not enter and re-enter BSC once specimen processing begins.</li></ul>

# Step 2: Selection of Mitigation Tools



Biosafety level



Engineering Controls



PPE

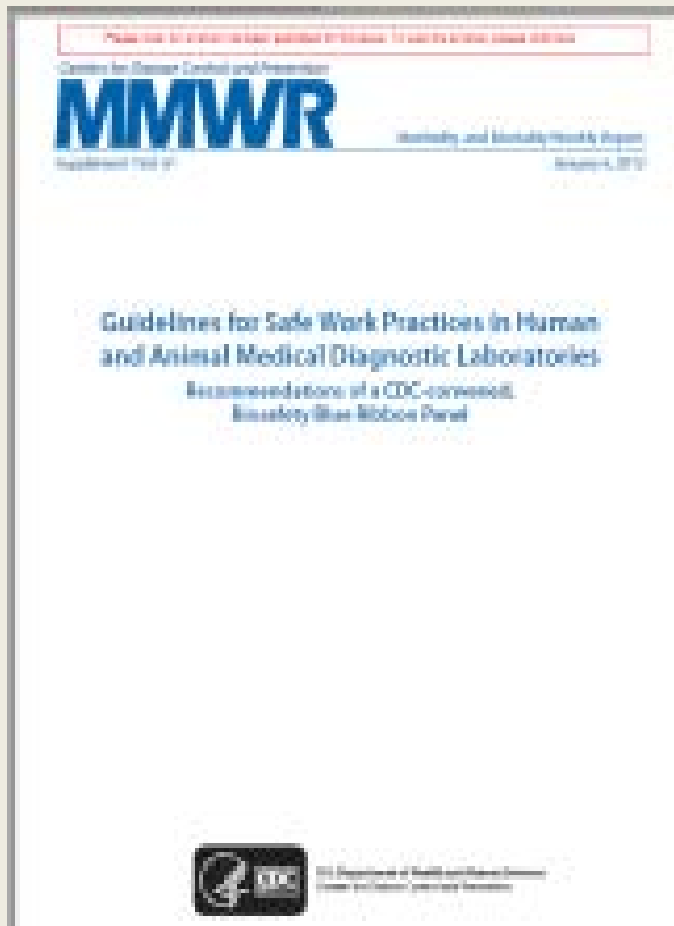


Lab Practices



Medical  
Waste

## Step 2



# 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](http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm?s_cid=su6101a1_w)

# Tasks to selecting safety practices

- Review the risk assessment
- Determine the appropriate control for the identified risk
  - Biosafety Level
  - Engineering Controls
  - PPE
  - Lab Practices
  - Medical waste
- Write the control into the procedure manual



# Select the Biosafety Level

- BSL-1 Basic Containment for organisms not known to cause disease in health adult
- BSL-2 For moderate risk agents: BSC, aerosol containment, PPE
- BSL-3 For organisms that cause serious or lethal diseases or exotic agents
- BSL-4 Dangerous and exotic agents that cause life-threatening disease

# Select Engineering Controls

- Primary Containment
  - Biosafety Cabinet
  - Sharps containers and sharps safety devices
  - Sealed rotor centrifuge
  - Pipette aid
- Secondary Containment
  - Building design
  - Sinks for handwashing
  - Self-closing doors

# Select Personal Protective Equipment (PPE)

- Types
  - Gloves
    - Latex, nitrile
  - Lab coats
    - Coats, gowns, single use
  - Eye goggles
  - Face masks
  - Suits
    - Tyvek
  - Sleeve covers
  - Respiratory Protection
    - N95, HEPA filtered
- Standards
  - ASTM
    - Coats, gloves
  - ANSI
    - Eye and face protection
  - OSHA
    - Use of PPE, hand sanitation
  - FDA
    - gloves

# Lab Safety Practices

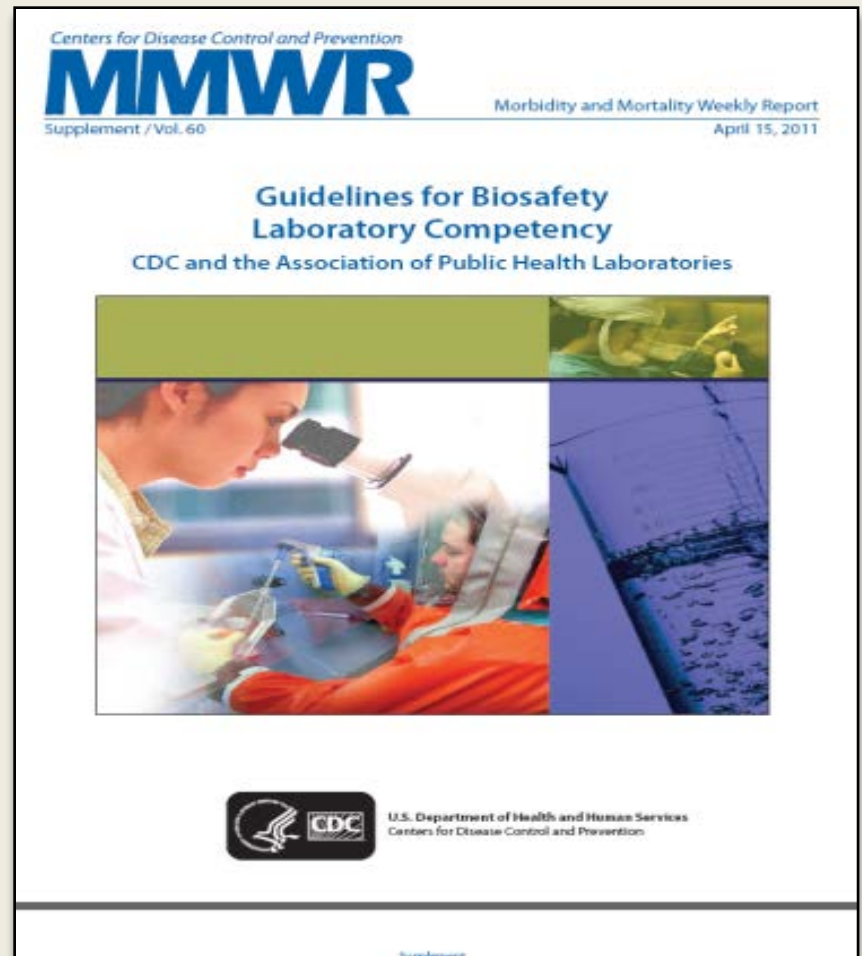
- Use of Personal Protective Equipment
- Disinfectant
  - Daily Disinfectant BSC, Counters and Centrifuge
- Capped Centrifuge tubes
- Splash Proof Containers
- Use Of UV lights
- Use disposable loops
- Allow slides to dry in BSC
- Spill Clean-up procedure



Document annual competency

# 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

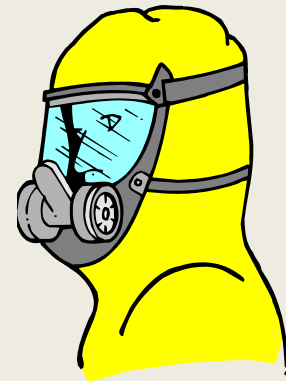
### Step 3

# Competencies are Tiered to Three Professional Levels of Practitioners

Field	Entry Level	Midlevel	Senior level
Academia or research	Technician, research associate, or specialist	Principal investigator, laboratory manager, postdoctoral student, or senior or staff scientist	Principal investigator or branch or division manager
Clinical setting	Laboratory scientist or medical technologist	Chief/head scientist or medical technologist, laboratory specialist, or laboratory manager	Laboratory manager, chief technologist, or hospital or clinic director

# 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



# Biological agents

## ENTRY LEVEL

1. Describe concept of biohazardous materials

1a. List biohazardous materials present in the laboratory

2. Recognize potential hazards associated with biohazardous materials handled in the laboratory

2a. Describe relationship of infectious agents and toxins to disease

2b. Describe the virulence and pathogenicity of the organisms

2c. Describe the principle routes of laboratory-acquired infections

2d. Recognize potential hazards of unknown/non routine samples

## MID LEVEL

1. Distinguish biohazardous from nonhazardous materials

1a. Same as Entry

2. Same as Entry

2a. Same as Entry

2b. Same as Entry

2c. Same as Entry

2d. Mitigate hazards of unknown/non routine samples

## SENIOR LEVEL

1. Ensure personnel's knowledge of biohazardous materials

1a. Ensure personnel have knowledge of biohazardous materials handled in the laboratory

2. Manage biohazardous materials

2a. Assess personnel's knowledge of infectious agents and toxin risk group classifications

2b. Assess personnel's knowledge of the virulence and pathogenicity of the organisms handled in the laboratory

2c. Assess personnel's knowledge of the principle routes of laboratory-acquired infections

2d. Manage mitigation of hazards of unknown/non routine samples

# 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)

ENTRY LEVEL	MID LEVEL	SENIOR LEVEL
<ol style="list-style-type: none"> <li>1. List PPE required for general laboratory entry</li> <li>2. Describe specific PPE for each laboratory procedure</li> <li>3. Practice proper use of PPE               <ol style="list-style-type: none"> <li>3a. Demonstrate donning and doffing sequence</li> <li>3b. Describe limitations of the PPE</li> <li>3c. Demonstrate cleaning/disinfection disposal/procedure</li> </ol> </li> <li>4. Assess integrity and functionality of PPE               <ol style="list-style-type: none"> <li>4a. Describe pre/post-use inspection protocol</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Monitor availability of PPE for general laboratory entry</li> <li>2. Demonstrate specific PPE required for each laboratory procedure</li> <li>3. Implement proper use of PPE               <ol style="list-style-type: none"> <li>3a. Same as Entry Level</li> <li>3b. Same as Entry Level</li> <li>3c. Implement cleaning/disinfection/disposal procedures</li> </ol> </li> <li>4. Implement assessment procedures for integrity and functionality of all PPE in use.               <ol style="list-style-type: none"> <li>4a. Implement pre/post-use inspection protocols</li> </ol> </li> </ol>	<ol style="list-style-type: none"> <li>1. Determine PPE required for general laboratory entry</li> <li>2. Determine specific PPE required for each laboratory procedure</li> <li>3. Ensure personnel's compliance with proper use of PPE               <ol style="list-style-type: none"> <li>3a. Develop procedures for personnel to follow proper donning and doffing sequence</li> <li>3b. Ensure personnel's knowledge of limitations of the PPE</li> <li>3c. Develop cleaning/disinfection/disposal procedures</li> </ol> </li> <li>4. Establish assessment procedures for the proper integrity and functionality of PPE.               <ol style="list-style-type: none"> <li>4a. Establish pre/post-use inspection protocol</li> </ol> </li> </ol>

## 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



# 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>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>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. Describe labeling of samples, containers, and cultures according to appropriate regulatory requirements</p>	<p>2. Implement labeling of samples, containers, and cultures according to appropriate regulatory requirements</p>	<p>2. Ensure the implementation of labeling of samples, containers, and cultures is compliant with appropriate regulatory requirements</p>
<p>3. Describe process to communicate sample-specific hazard information according to SOP</p> <p>3a. N/A</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>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. Describe procedures to identify hazardous infectious agents in the</p>	<p>3b. Apply procedures to identify hazardous infectious agents in the</p>	<p>3b. Ensure personnel's knowledge</p> <p>4. Ensure personnel's knowledge communication processes for applicable</p>

# 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



## Emergency response exercises and drills

### ENTRY LEVEL

1. Comply with personnel emergency response training requirements
  - 1a. Participate in entry level personnel training
  - 1b. N/A
  - 1c. N/A
2. Participate in drills and exercises for laboratory personnel
  - 2a. N/A
  - 2b. N/A

### MID LEVEL

1. Conduct required emergency response training of laboratory personnel
  - 1a. Demonstrate ability to train entry level staff
  - 1b. N/A
  - 1c. N/A
2. Conduct drills and exercises for laboratory personnel
  - 2a. N/A
  - 2b. N/A

### SENIOR LEVEL

1. Develop required emergency response training
  - 1a. Evaluate ability of mid level staff to train all laboratory personnel
  - 1b. Ensure adherence to laboratory's emergency response training requirements
  - 1c. Evaluate effectiveness of the laboratory's emergency response training
2. Advise on development of drills and exercises for laboratory personnel
  - 2a. Assess effectiveness of drills & exercises
  - 2b. Incorporate lessons learned into training program

# 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



# 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

## Laboratory Biosafety Competency Assessment Form – **Entry Level**

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Skill Domain	Biosafety Competency – abbreviated from the Guidelines for Biosafety Laboratory Competency	Competency Level Ranking	Importance	Frequency	Comment
I Bio 3a	Describe PPE used when handling biologic materials				
II PPE 1	List PPE required for general laboratory entry				
II PPE 2	Describe specific PPE to be used for each procedure				
II PPE 4a	Demonstrate proper donning and doffing of gloves and gown				
II PPE 4b	Describe the limitations of PPE				
II Decon 3e	Describe routine surface decontamination procedures				
II Decon 1	Describe waste segregation procedures				
II Decon 2a	Describe proper disposal of different types of biological waste				
III Occ Health 4	Describe signs and symptoms following exposure				
III Risk Mgmt 3	Describe the risk assessment process				
IV Emer Resp 2	Describe reporting requirements for emergencies				
IV Drills	Participate in drills and exercises				

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

## Laboratory Biosafety Competency Assessment Form – **Midlevel**

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Skill Domain	Biosafety Competency – abbreviated from the Guidelines for Biosafety Laboratory Competency	Competency Level Ranking	Importance	Frequency	Comment
I Bio 3a	Demonstrate correct use of PPE for handling bio materials				
II PPE 1	Monitor availability of PPE				
II PPE 2	Demonstrate use of specific PPE required for each procedure				
II PPE 4a	Demonstrate proper donning and doffing of gloves and gown				
II PPE 4b	Describe the limitations of PPE				
II Decon 3e	Implement routine surface decontamination procedures				
II Decon 1	Implement waste segregation procedures				
II Decon 2a	Demonstrate proper disposal of different types of bio waste				
III Occ Health 4	Describe signs and symptoms following exposure				
III Risk Mgmt 3	Conduct a risk assessment				
IV Emer Resp 2	Implement plans and policies for reporting emergencies				
II.D-3c	Describe proper use of autoclave				
IV Drills	Implement drills and exercises				

### 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 – Senior Level

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Skill Domain	Biosafety Competency – abbreviated from the Guidelines for Biosafety Laboratory Competency	Competency Level Ranking	Importance	Frequency	Comment
I Bio 3a	Evaluate PPE for handling bio materials				
II PPE1	Determine PPE required for general lab entry				
II PPE2	Determine procedures for use of specific PPE				
II PPE4a	Develop procedures for personnel to comply with sequence				
II PPE4b	Ensure personnel's knowledge of limitations of PPE				
II Decon 3e	Develop routine surface decontamination procedures				
II Decon 1	Establish waste segregation procedures				
II Decon 2a	Develop protocols for biological waste disposal				
III Occ Health 4	Ensure personnel's knowledge of signs and symptoms				
III Risk Mgmt 3	Ensure risk assessment is performed				
IV Emer Resp 2	Develop plans and policies for reporting emergencies				
II.D-3c	Describe proper use of autoclave				
IV Drills	Develop drills and exercises				

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 3

[http://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm?s\\_cid=su6401a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm?s_cid=su6401a1_e)

## Competency Guidelines for Public Health Laboratory Professionals CDC and the Association of Public Health Laboratories



Slide Courtesy of  
John Ridderhof,  
CDC/OPHSS/CSELS



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

# 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

## Step 3

# Schematic of Competency Domains for PHL Professionals



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 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



## Step 4

# 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

# Develop a Training Plan

- New employee training
- Training for transfers into new lab sections
- Annual training requirements
- Refresher training needs
- Exercises and drills

# Who should be trained?

- Laboratory staff working in the facility
- Maintenance and cleaning staff
- External first responders
- Security staff
- Fellows, students and other visitors
- Training should be commensurate with the roles and responsibilities and authorities of staff.

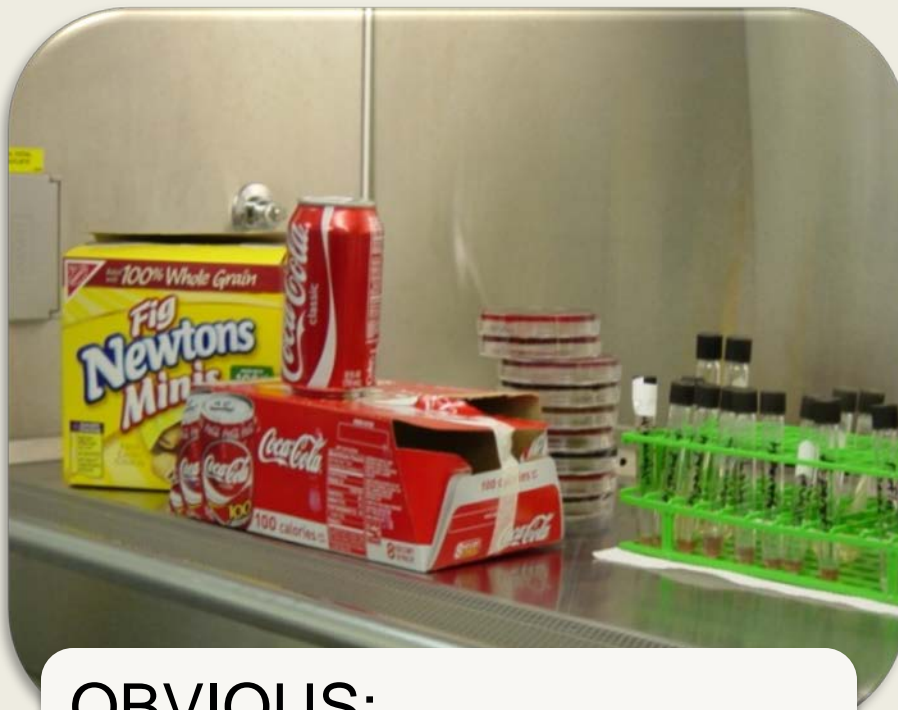
## Step 5:

# 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

YES	NO	Standard	Resources	Comments
<input type="checkbox"/>	<input type="checkbox"/>	<b>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.)</b>	<a href="http://www.cd.c.gov/HAI/prevent/ppe_train.html">http://www.cd.c.gov/HAI/prevent/ppe_train.html</a>	Any observation made during audit

# 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:

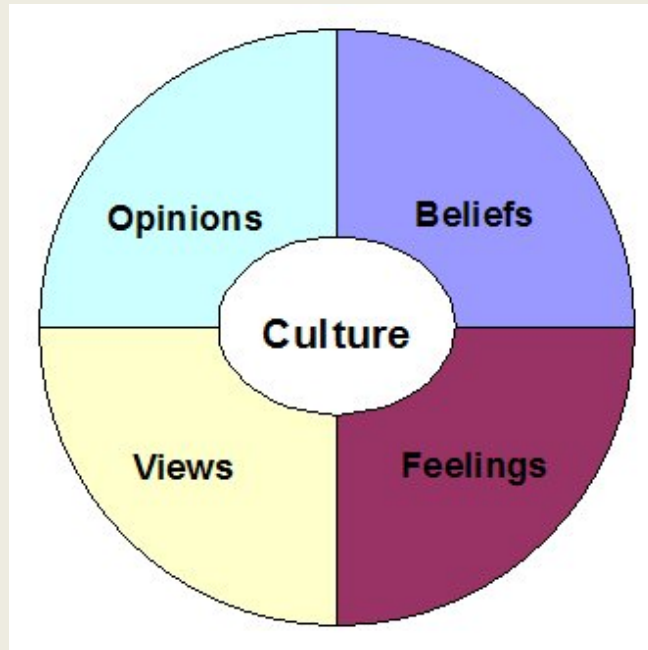
# Address concerns from labs not impacted

- 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



# APHL forms Biosafety and Biosecurity Committee 3-26-15

## **Proposed Priorities for the Committee:**

- Serve as an information resource to assist public health laboratories with implementing the activities outlined in the ELC
- Inform and assist in establishing a repository for new and existing biosafety and biosecurity tools and promoting their use
- Advise on the development of a “community of practice” for biosafety officers in member laboratories
- Collaborate with APHL staff and partners to develop and deliver biosafety and biosecurity competency based training materials, including convening workshops for biosafety officers
- Promote APHL’s position statement on biosafety and collaborate with partners to encourage a culture of biosafety and biosecurity as part of each laboratory’s quality management system

# Membership

- Dr. Michael Pentella (MA), Chair
- 2. *TBD, APHL Board Liaison*
- 3. Mr. Jack Bennett (CT), Institutional Research Committee
- 4. Dr. Christina Egan (NY State), Public Health Preparedness and Response Committee
- 5. Dr. Andrew Cannons (FL - Tampa), Member at Large
- 6. Dr. Leah Gillis (FL – Miami), Workforce Development Committee
- 7. Mr. David Hill (NY State), Biosafety Officer and Member at Large
- 8. Mr. Royden Saah (NC) – Responsible Official, Member at Large
- 9. Mrs. Charlene Thomas (AL), Laboratory Systems and Standards Committee
- 10. Dr. Dave Warshauer (WI), Infectious Diseases Committee
- 11. Mr. Bill Homovec, CBSP, American Biological Safety Association
- 12. Dr. James Snyder, American Society for Microbiology
- 13. Dr. Leslie Dauphin, Office of Infectious Diseases/CDC (temporary)
- 14. Mr. Greg Jones, CDC/Division of Preparedness and Emerging Infections, NCEZID/CDC
- 15. Mr. John Kools, CDC/Office of Public Health Preparedness and Response, CDC
- 16. Dr. Toby Merlin, Director, Division of Preparedness and Emerging Infections, NCEZID/CDC
- 17. Ms. Betsy Weirich, MS, SM(NRCM), CBSP, Center for Surveillance, Epidemiology and Laboratory Services (CSELS), CDC

# What do clinical labs need?

- National standards and guidance (checklist)
- Incentive to get this accomplished and recognition of accomplishment
- Training and education
- Simple, comprehensive tools to make this achievable
- Engagement of all lab sections
- Commitment from administration/leadership
- National resource to report accidents and exposures
- Assistance with difficult issues, ex. Medical waste management