

# Implementing an Effective Biosafety Program

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

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# Biosafety Topics Are In the Forefront



## Review of CDC Anthrax Lab Incident

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U.S. Department of Health and Human Services



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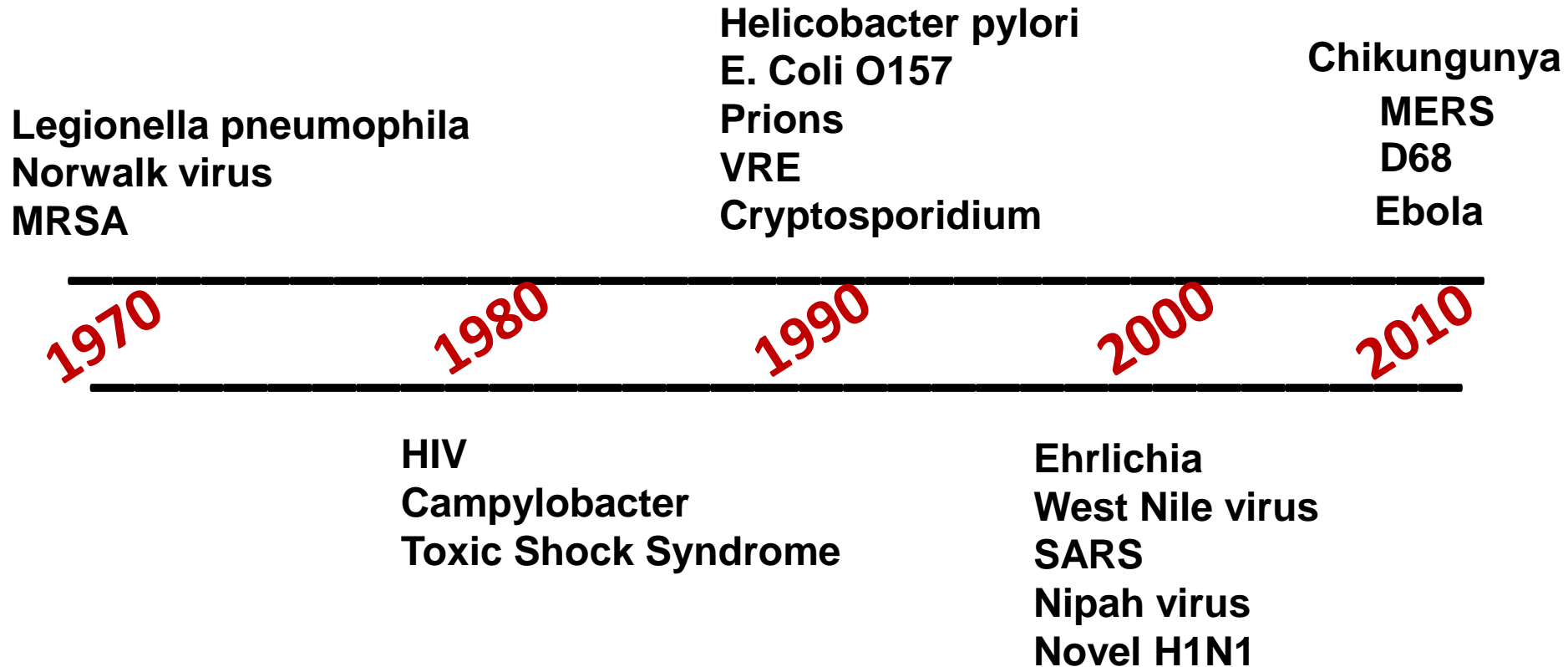
**UNDER EMBARGO** until NOON, August 15, 2014

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, CNN, updated 3:07 PM EDT, Fri July 11, 2014. The article features a large image of a microscopic view of smallpox virus particles. To the right of the image is a CVS Health advertisement with the text 'CVS/minuteclinic™ helps keep America working. Health is everything. Learn More'. The CNN Health navigation bar is visible at the top, and the footer includes 'More from CNN:' and 'Internet | Protected Mode: On'.

# Emerging Pathogens by Decade



# 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**



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



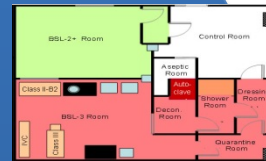
# Risk Assessment Information: Review Protocols

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

# Risk Assessment: Predict, Identify, & Mitigate Risk

Procedure	Potential Hazards	Control	Comment
<p><b>Preparation of Specimens for Testing</b></p>	<p>Aerosolization/ Splash/ Splatter</p>	<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

# 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

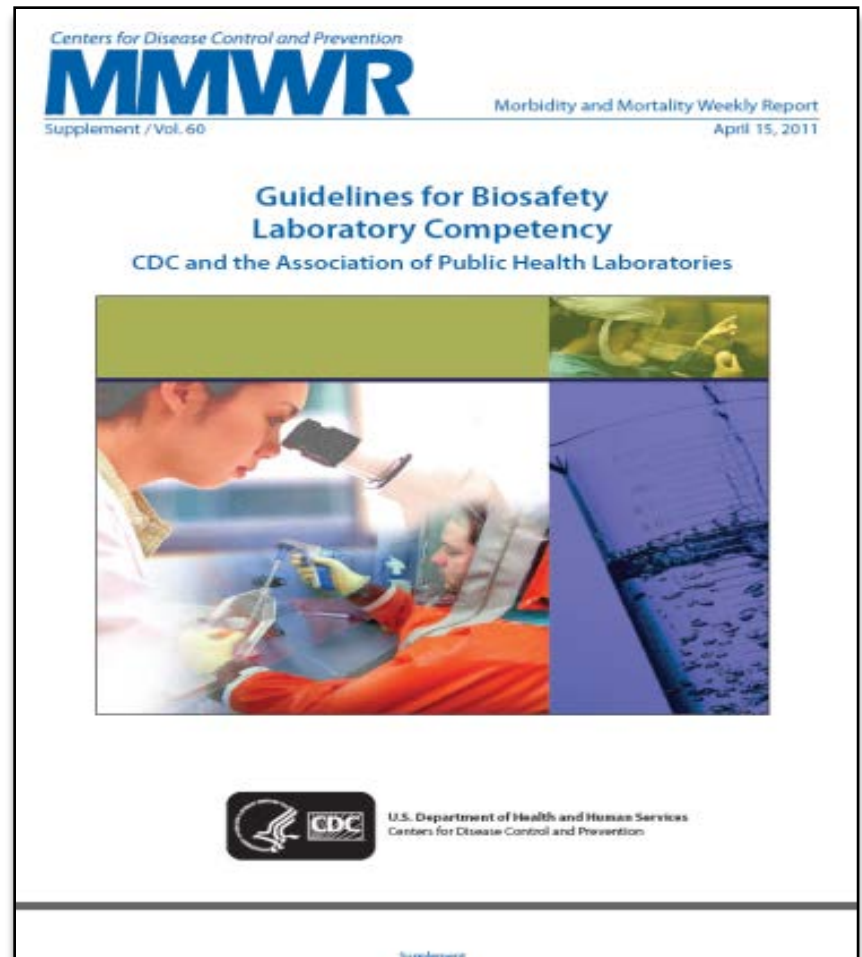
# Tasks to select safety practices

- 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

# 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 PPE 2	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:

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- 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

[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

# Schematic of Competency Domains for PHL Professionals



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



## 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



## 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

## Step 5

# 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

