Current Clinical Laboratory Biosafety Practices

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State Hygienic Laboratory, Director

Presentation objectives

- Understand the needs of clinical laboratories
- Review the clinical laboratory biosafety survey regarding biosafety practices
- Describe the activities of the APHL Biosafety and Biosecurity Committee on behalf of both clinical and public health laboratories

Evolving Biosafety by the Decades

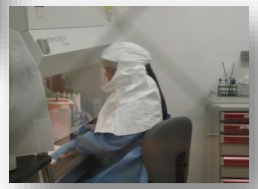
1880's

1920's

1950's

1980's

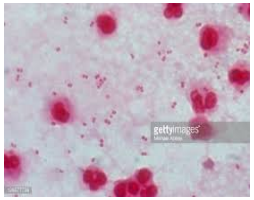
2000's



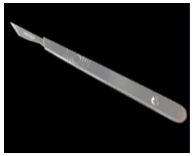
Despite improvements in laboratory safety, including specialized training, advances in laboratory design, and the use of personal protective equipment, laboratory-acquired infections still occur.

Biosafety practices evolved mostly driven by regulatory requirements

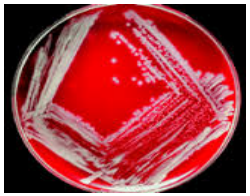
Recent Lab Acquired Infections



Maryland researcher acquired *Burkholderia mallei* in the lab diagnosed with glanders



California, 17 clinical lab scientists exposed to *Burkholderia pseudomallei,* all received antibiotics, no illnesses

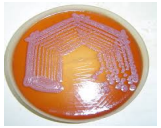


New Agent:
Pennsylvania, Lab acquired zika virus through needle stick

1988 | **2000** | **2002** | **2003** | **2006** | **2016**

California, clinical lab scientist dies after lab exposure to Neisseria meningitidis MMWR 1991

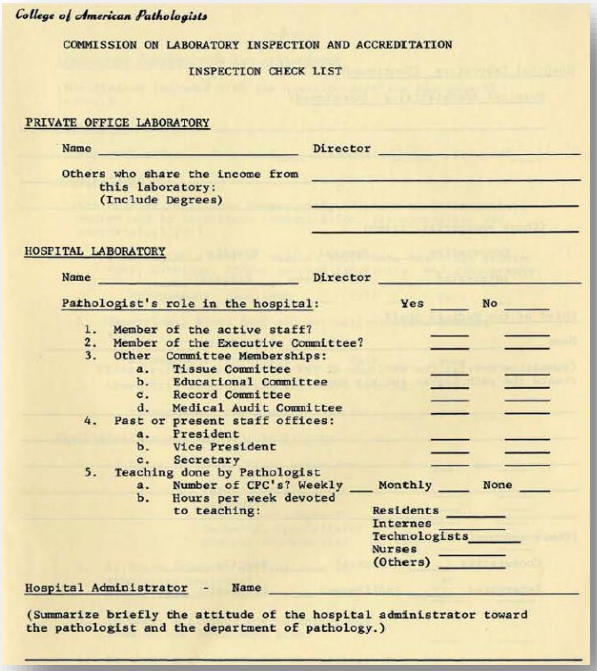
New Agent: Iowa, PHL microbiologist acquired West Nile virus through a scalpel wound when handling a dead crow



Indiana and Minnesota, clinical lab scientists acquired Brucellosis after lab exposures, unrelated strains

Historically:
Safety has been a concern

Example: First College of American Pathologists checklist in 1965



College of American Pathologists

COMMISSION ON LABORATORY INSPECTION AND ACCREDITATION

INSPECTION CHECK LIST

PRIVATE OFFICE LABORATORY

Name _____ Director _____

Others who share the income from this laboratory: (Include Degrees) _____

HOSPITAL LABORATORY

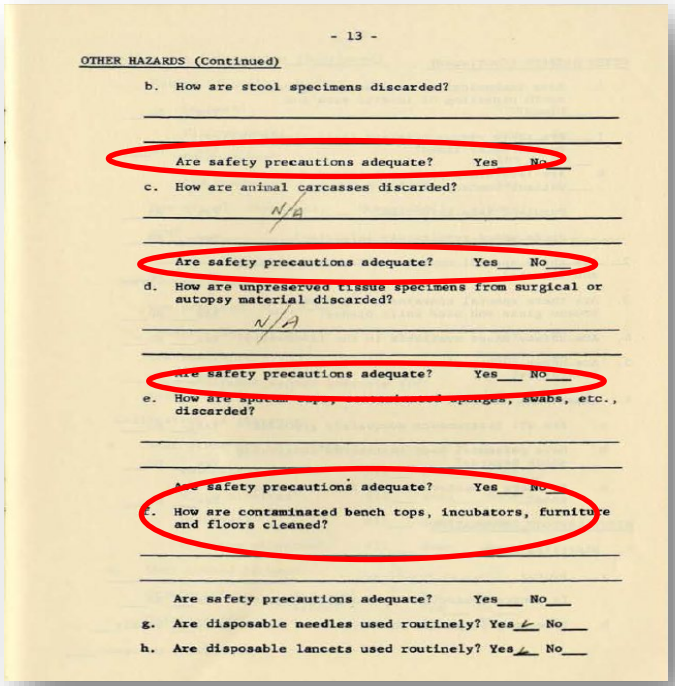
Name _____ Director _____

Pathologist's role in the hospital: Yes ____ No ____

1. Member of the active staff? ____ ____
2. Member of the Executive Committee? ____ ____
3. Other Committee Memberships: ____ ____
   a. Tissue Committee ____ ____
   b. Educational Committee ____ ____
   c. Record Committee ____ ____
   d. Medical Audit Committee ____ ____
4. Past or present staff offices: ____ ____
   a. President ____ ____
   b. Vice President ____ ____
   c. Secretary ____ ____
5. Teaching done by Pathologist
   a. Number of CPC's? Weekly ___ Monthly ___ None ___
   b. Hours per week devoted to teaching: Residents _____ Interns _____ Technologists _____ Nurses _____ (Others) _____

Hospital Administrator - Name _____

(Summarize briefly the attitude of the hospital administrator toward the pathologist and the department of pathology.)



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OTHER HAZARDS (Continued)

b. How are stool specimens discarded?

Are safety precautions adequate? Yes No

c. How are animal carcasses discarded? N/A

Are safety precautions adequate? Yes No

d. How are unpreserved tissue specimens from surgical or autopsy material discarded? N/A

Are safety precautions adequate? Yes No

e. How are sputum cups, contaminated sponges, swabs, etc., discarded?

Are safety precautions adequate? Yes No

f. How are contaminated bench tops, incubators, furniture and floors cleaned?

Are safety precautions adequate? Yes No

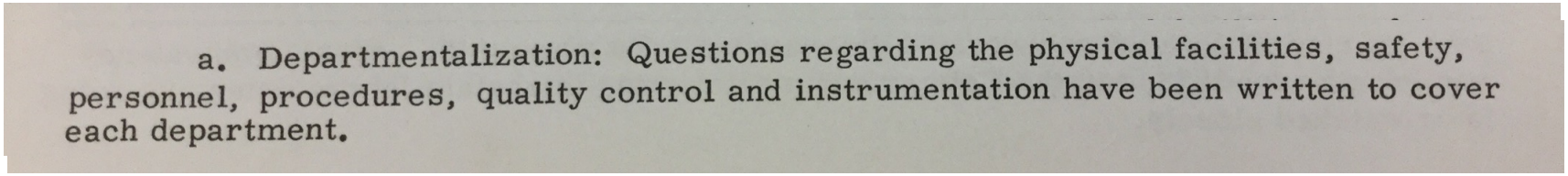
g. Are disposable needles used routinely? Yes ✓ No

h. Are disposable lancets used routinely? Yes ✓ No

Slides courtesy of Denise Driscoll, College of American Pathologists

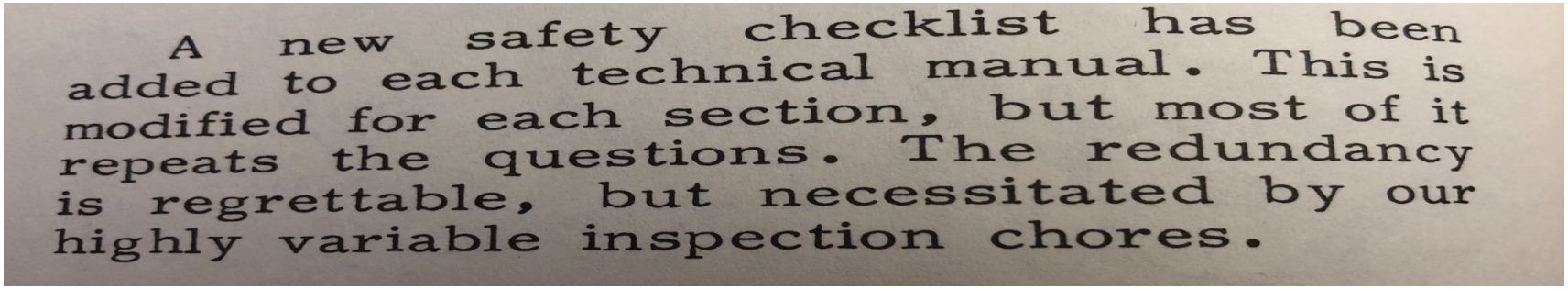
Past College of American Pathologist Inspection and Accreditation Newsletters

March 1973



a. Departmentalization: Questions regarding the physical facilities, safety, personnel, procedures, quality control and instrumentation have been written to cover each department.

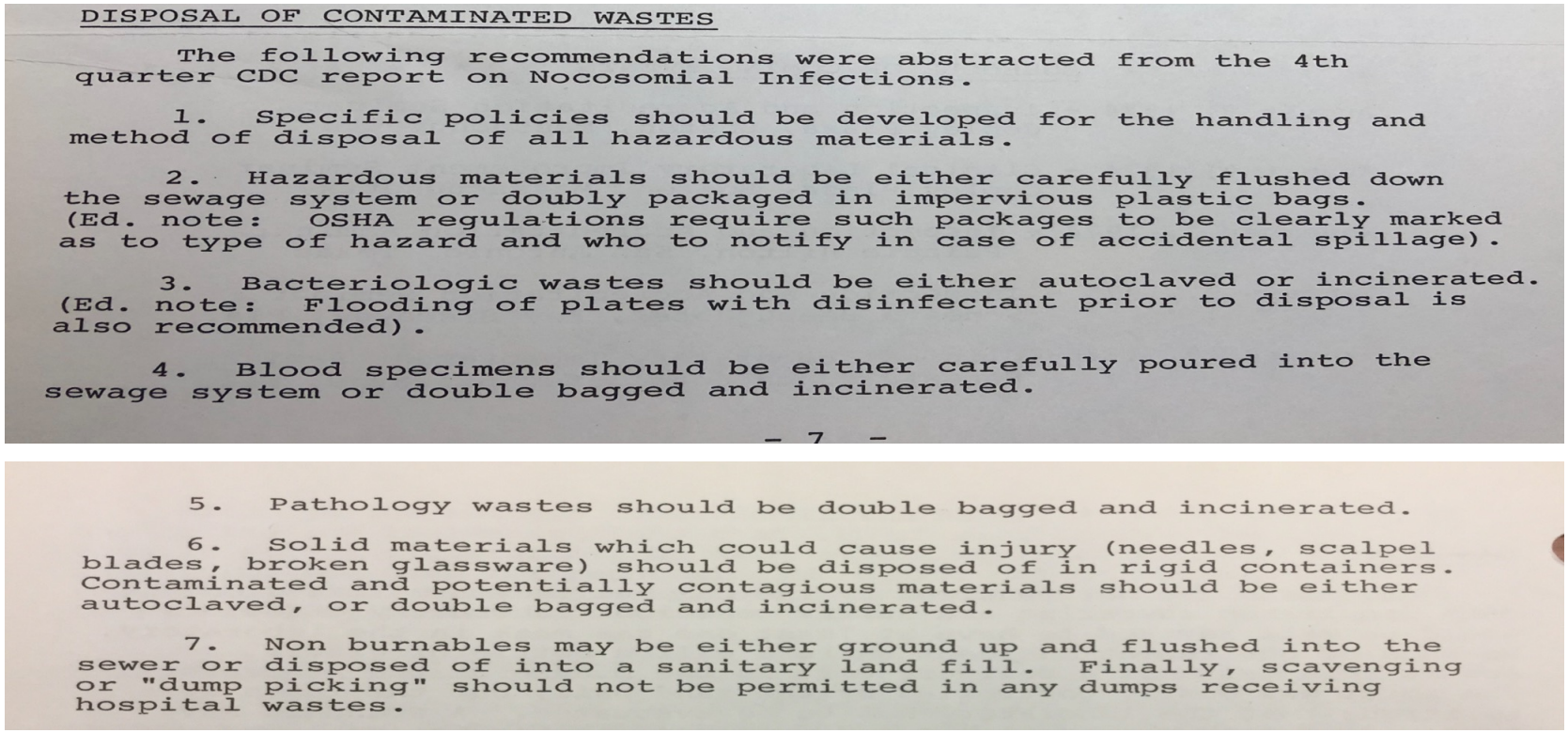
Winter 1981



A new safety checklist has been added to each technical manual. This is modified for each section, but most of it repeats the questions. The redundancy is regrettable, but necessitated by our highly variable inspection chores.

Slides courtesy of Denise Driscoll, College of American Pathologists

Then – Summer 1974
Note – no “dump picking”



DISPOSAL OF CONTAMINATED WASTES

The following recommendations were abstracted from the 4th quarter CDC report on Nocosomial Infections.

1. Specific policies should be developed for the handling and method of disposal of all hazardous materials.

2. Hazardous materials should be either carefully flushed down the sewage system or doubly packaged in impervious plastic bags. (Ed. note: OSHA regulations require such packages to be clearly marked as to type of hazard and who to notify in case of accidental spillage).

3. Bacteriologic wastes should be either autoclaved or incinerated. (Ed. note: Flooding of plates with disinfectant prior to disposal is also recommended).

4. Blood specimens should be either carefully poured into the sewage system or double bagged and incinerated.

- 7 -

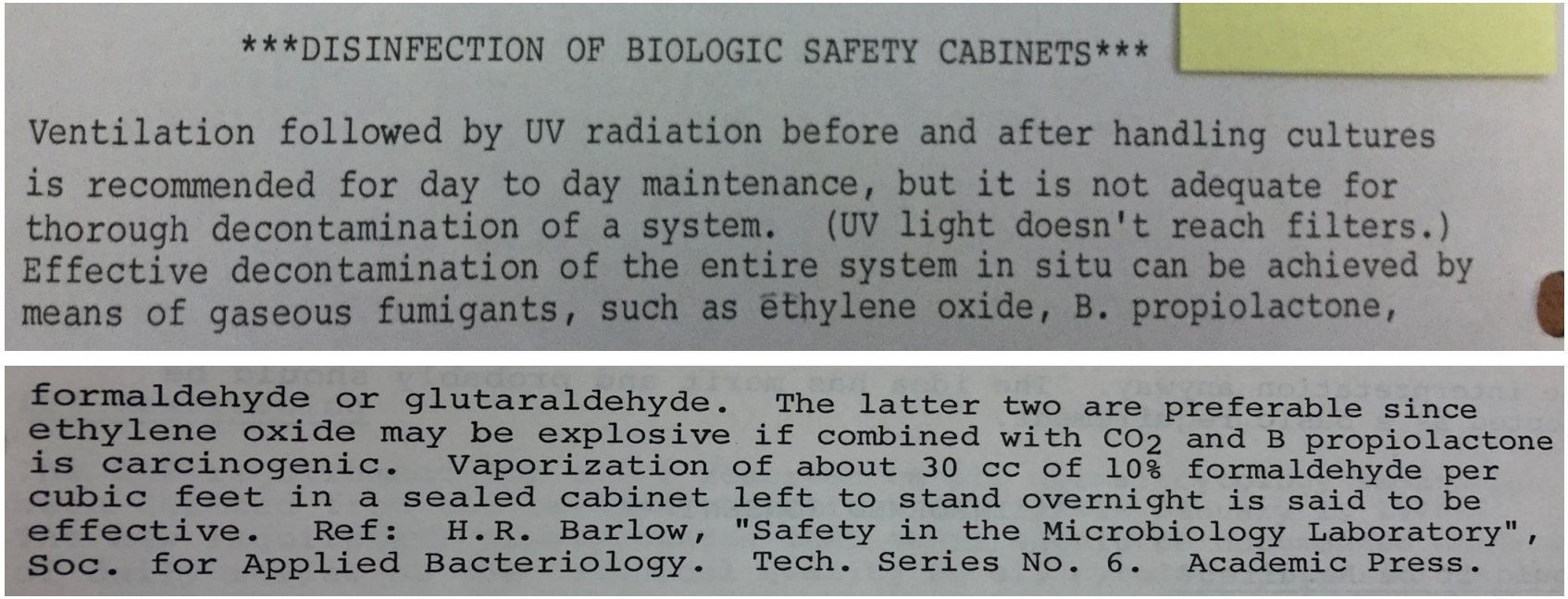
5. Pathology wastes should be double bagged and incinerated.

6. Solid materials which could cause injury (needles, scalpel blades, broken glassware) should be disposed of in rigid containers. Contaminated and potentially contagious materials should be either autoclaved, or double bagged and incinerated.

7. Non burnables may be either ground up and flushed into the sewer or disposed of into a sanitary land fill. Finally, scavenging or "dump picking" should not be permitted in any dumps receiving hospital wastes.

Slides courtesy of Denise Driscoll, College of American Pathologists

Then – BSC
Fall 1975 – I&A newsletter

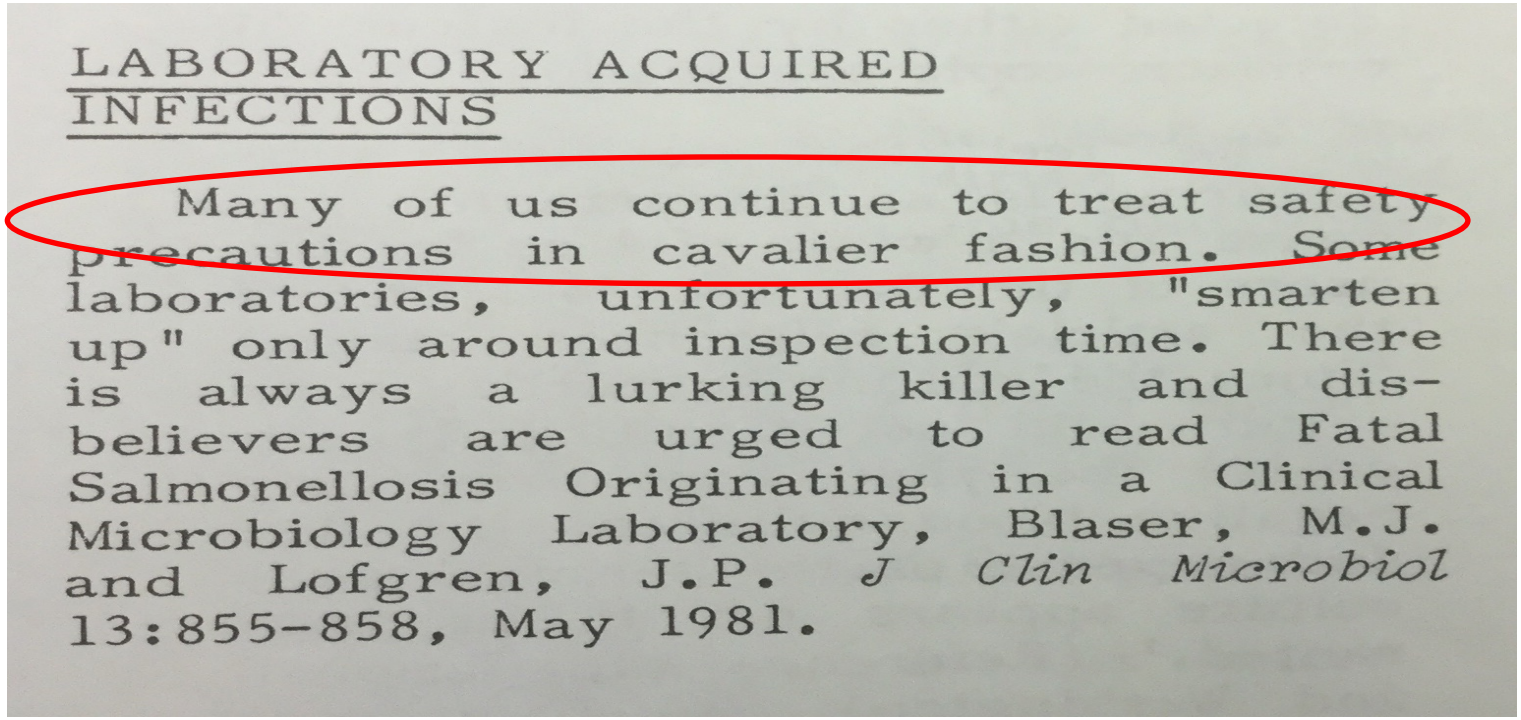


DISINFECTION OF BIOLOGIC SAFETY CABINETS

Ventilation followed by UV radiation before and after handling cultures is recommended for day to day maintenance, but it is not adequate for thorough decontamination of a system. (UV light doesn't reach filters.) Effective decontamination of the entire system in situ can be achieved by means of gaseous fumigants, such as ethylene oxide, B. propiolactone, formaldehyde or glutaraldehyde. The latter two are preferable since ethylene oxide may be explosive if combined with CO_2 and B propiolactone is carcinogenic. Vaporization of about 30 cc of 10% formaldehyde per cubic feet in a sealed cabinet left to stand overnight is said to be effective. Ref: H.R. Barlow, "Safety in the Microbiology Laboratory", Soc. for Applied Bacteriology. Tech. Series No. 6. Academic Press.

Slides courtesy of Denise Driscoll, College of American Pathologists

Then – Exposure
Fall – 1981 CAP I&A newsletter



LABORATORY ACQUIRED INFECTIONS

Many of us continue to treat safety precautions in cavalier fashion. Some laboratories, unfortunately, "smarten up" only around inspection time. There is always a lurking killer and disbelievers are urged to read Fatal Salmonellosis Originating in a Clinical Microbiology Laboratory, Blaser, M.J. and Lofgren, J.P. *J Clin Microbiol* 13:855-858, May 1981.

Slides courtesy of Denise Driscoll, College of American Pathologists

2019: Safety – Major Laboratory Concern

CAP Addresses Safety

LABORATORY GENERAL INDEX:
Safety policies, procedures and records
Bloodborne Pathogens
Other Infectious Hazards
Fire Prevention and Protection
Electrical Safety
Chemical Safety
Compressed Gases
Radiation Safety
Environmental Safety
Other Hazards
Waste Disposal

MICROBIOLOGY CHECKLIST:
Biosafety
Laboratory Safety

CLIA Addresses Safety:

§493.1101, §493.1254 (a)(1)(2), §493.1407 (e)(2, 10, 11 & 12), §493.1445 (e) (11, 12, & 13)
Safety procedures must be established
Facilities – space, ventilation, and utilities meet the testing needs.
Director – ensure that the testing environment is safe

Biosafety GEN.74000, 74100, and 74200

- Infection Control policies must comply with OSHA Bloodborne Pathogens Standard
- Engineering and Work Practice Controls to reduce or eliminate exposure to bloodborne pathogens

Slides courtesy of Denise Driscoll, College of American Pathologists

- Specific PPE requirements, with exception of glove use, is determined by facility and based on “reasonably anticipated exposure”
- Records of training/instructions for use of PPE
- If tasks are identified and required PPE stipulated, practice must match policy

GEN.74250

- Hand cleaning
  - Personnel remove gloves, use an effective antimicrobial method
    - After manipulating biological samples
    - After each patient contact

Slides courtesy of Denise Driscoll, College of American Pathologists

GEN.74700, 74800, 74900

- Employer must educate staff on risk of BBP and offer Hepatitis B Vaccinations
- Exposure Control Plan – Viral (HIV, HBV, HCV)
  - Testing of the source patient, with consent
  - Records of the evaluation of the healthcare worker
  - Appropriate prophylaxis and follow-up
  - Reporting, as required by law
- TB Exposure Plan
  - Written plan
  - Include exposure determination at defined intervals; can use risk-based approach
  - Includes the use of NIOSH-approved, fit-tested, filter respirators
  - Defined engineering and work practice controls

Slides courtesy of Denise Driscoll, College of American Pathologists

GEN.75000

Sterilizing Device Monitoring

- Frequency must be defined
- Biologic or chemical indicator
- Test performed under conditions that simulate actual use

GEN.77900

Biohazard Disposal Containers

- All infectious wastes are discarded in labeled containers
- Container must be leak proof with solid tight-fitting covers
- Compliant with local regulations

Slides courtesy of Denise Driscoll, College of American Pathologists

MIC.19035, 19010

- MIC.19035 Safe Specimen Processing
  - Written policies and procedures
  - Tight sealing containers
  - Spills
  - PPE
- Benchtop Decontamination
  - Daily, with records

MIC.18968, 18976

- Agents of Bioterrorism
  - policies and procedures for recognition of microorganisms likely to be used as biological weapons
  - safe handling of potential agents – use of BSC, not using automated instruments for identification
- Bioterrorism Response Plan
  - must define the laboratory's role and responsibilities

Slides courtesy of Denise Driscoll, College of American Pathologists

MIC.19840, 20520

- Biological Safety Cabinet
  - available per biosafety level
  - maintained
  - certified annually, with records
  - meets minimum requirements for testing performed

MIC.19060, 19160

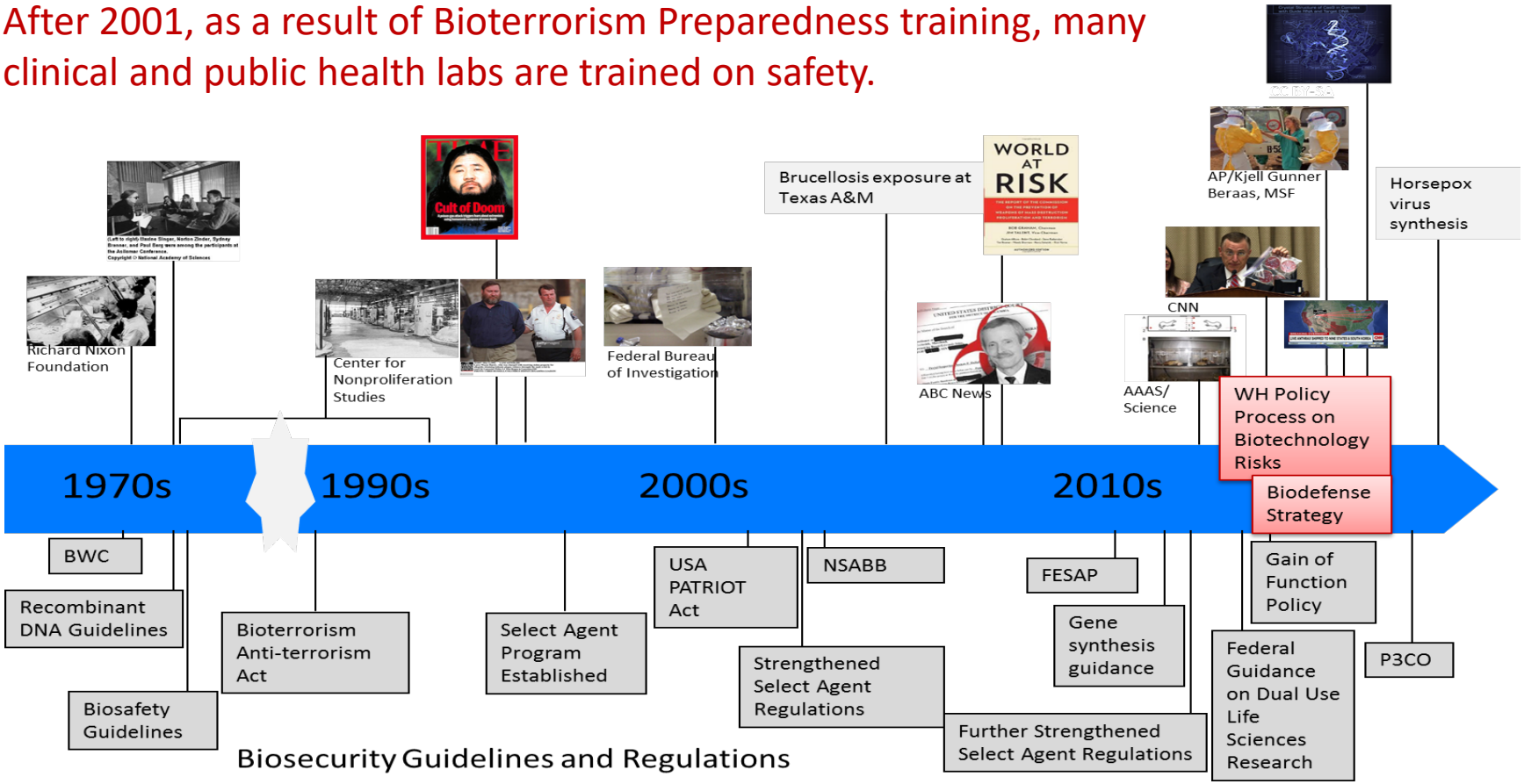
- Biosafety Levels
  - In accordance with current recommendations for working with different organisms
    - Engineering
      - Equipment
      - Containment
    - Work practices

OSHA Laboratory Safety Guidance 2011

- **General Duty Clause**, employers "shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm to his employees."
- **Bloodborne Pathogens standard (29 CFR 1910.1030**), including the Needlestick Safety and Prevention Act of 2001, requires employers to protect workers from infection with human bloodborne pathogens in the workplace.
- **Personal Protective Equipment (PPE) standard (29 CFR 1910.132)** requires that employers provide and pay for PPE and ensure that it is used.
- **Respiratory Protection standard (29 CFR 1910.134)** requires that a respirator be provided to each worker when such equipment is necessary to protect the health of such individual.
- **Hand Protection standard (29 CFR 1910.138)** requires employers to select and ensure that workers use appropriate hand protection when their hands are exposed to hazards.

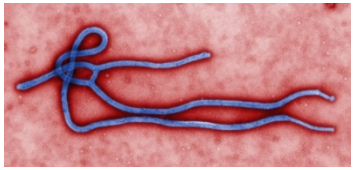
Historical Events Triggering Regulations

After 2001, as a result of Bioterrorism Preparedness training, many clinical and public health labs are trained on safety.



2014 Clinical Lab Response to Ebola

- Labs reluctant to test specimens from suspect patients
- Unfamiliar with risk assessment process and had not adopted biosafety competencies
- Only considered risk of emerging infectious agent to the clinical microbiology lab section, not chemistry, hematology, anatomic path
- Some instrument manufacturers refuse to service instruments used to test patient's with ebola specimens

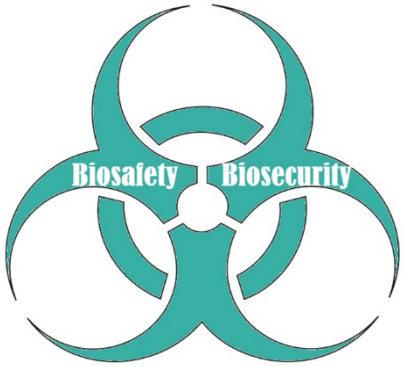


Cooperative Agreement Overview

- May 2015: APHL was awarded a $2.2 million CoAg by the Centers for Disease Control and Prevention (CDC) for Domestic Laboratory Biosafety for Ebola and other Highly Infectious Diseases.
- Funded for three years (May 2015 - May 2018)
  - Received a one year extension to 2019
- Linked to the $21 million funding opportunity awarded to 62 PHLs via the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Ebola Supplemental project B-Enhanced Laboratory Biosafety and Biosecurity Capacity.

Biosafety and Biosecurity Committee Charge

- Serve as Subject Matter Expert (SME), providing guidance and support for public health labs (PHLs)
- Coordinate national efforts to improve biosafety in PHLs and support outreach to clinical laboratories



APHL Major Biosafety and Biosecurity Accomplishments

- **Biosafety Community of Practice**
  - Two ColLABorate Platforms (250+)
  - BSO Peer Network (50+ PHLs Paired)
  - Biosafe360 Program (200+)
  - Technical Skills Building Workshops/ Webinars (750+)
  - Leadership Development Workshop Series (34 PHLs with 37 BSOs)
- **Biosafety and Biosecurity Committee**
  - Subject Matter Expertise
  - Consultations with PHLs
- **Biosafety and Biosecurity Partners Forum**
  - Awareness at the National Level
- **Clinical Laboratory Biosafety**
  - Biosafety Practices and Needs in Clinical Laboratories Survey
  - Biosafety Forums: Public Health Laboratory Outreach, Clinical Laboratory Engagement and Needs

<u>CULTURE OF BIOSAFETY CHANGE</u>

- Hire Biosafety Officers
- Provide Training and Tools for BSOs (Risk Assessments, Workshops and Biosafety Checklists)
- Build a Community of Practice
- Provide training and resources for Clinical Labs
- Continue assisting PHL and Clinical Labs

Analysis. Answers. Action. www.aphl.org

Practical Disinfection Guidance for the Clinical Laboratory
March 28, 2018

Dial-In Number: 866.740.1260
Access Code: 4852701

May 05, 2016

Risk Assessment Best Practices

Dear Biosafety Officials:

The Association of Public Health Laboratories (APHL) has established a Biosafety and Biosecurity Committee (BBC) to assist public health laboratories with strengthening biosafety and biosecurity programs across the United States. A key activity of the BBC is to develop and promote biosafety and biosecurity tools (for example-risk assessments).

Risk assessments are an essential component of maintaining safety within a laboratory. The goal of a risk assessment is to identify and mitigate the risks of working in a laboratory environment. While all laboratories (including public health laboratories) should be performing risk assessments, the content and design of the template may be unique to the facility. Risk assessments must be performed regularly based on procedure or agent, and when there are changes in agents, procedures, equipment or staff. Risks identified by the assessment should be prioritized, and a mitigation plan should be established based on that prioritization. In other words, the highest risks should be mitigated relatively more than lower risks. The mitigation plan should be documented and clearly communicated to all relevant personnel. A risk assessment should follow the workflow from pre-analytical processes (sample receipt), through the laboratory (analytical), to post-analytical processes (waste disposal) and be reviewed by leadership (lab directors). It must be noted that risk assessments are dynamic documents that must be updated if any of the working assumptions for that protocol (equipment, personnel, materials) changes.

Components of a Risk Assessment

Key components of a risk assessment should address:

Workforce

- Identify personnel (individuals) who will be affected throughout the work-flow
- Assess the competency and experience of laboratory personnel
- Identify which trainings to offer staff
- Consider staff enrollment in occupational health programs

Risk Characterization

- Identify hazards
- Consider risk group of the agent
- Classify the potential for exposure (modes of transmission, potential for spill or inhalation, organism concentrations, virulence, etc.)
- Identify activities which may increase risk of exposure
  - Classify which instruments will be used to process each sample and identify potential for exposure

Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing

Important Note: This template is designed to assist laboratories in the development of their risk assessment for Ebola Virus Disease (EVD). It may not be an all-encompassing plan as each facility will have their laboratory specific risk assessment procedures.

Standard precautions have been highly effective in preventing transmission of bloodborne infection in the course of handling blood and other potentially infectious material in the clinical laboratory. Standard precautions should be effective in preventing the transmission of Ebola virus and other viral hemorrhagic fever agents in the clinical laboratory. However, Ebola virus is a high consequence pathogen, and there has been limited experience handling specimens potentially contaminated with such a high consequence pathogen in a clinical laboratory using current specimen handling procedures and automated instrumentation. **Therefore, this risk assessment is provided for enhanced precautions and personal protective equipment (PPE) in handling specimens from patients who may be at risk of having Ebola virus infection.**

Laboratory Unit/Section	
Date of Assessment	
Name of Assessor	
Name of Organism/Agent	Ebola Zaire Virus (Ebola Virus)

Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

LAB ID and LABORATORY NAME:
ASSESSOR NAME: DATE:

Question	Y	N	NA	Comments
1. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
1.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?	○	○	○	
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?	○	○	○	
Are supervisory staff responsible for the following and are these responsibilities documented?				
• Conducting, reviewing, and approving risk assessment results.	○	○	○	
• Developing lab-specific safety plans;	○	○	○	
• Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab.	○	○	○	
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?	○	○	○	
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?	○	○	○	

BIOSAFETY CHECKLIST APRIL 2015

A Biosafety Checklist: Developing A Culture of Biosafety

Background

There is an inherent risk in a laboratory handling any infectious agents. Biosafety practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Recent incidents involving biosafety lapses highlight the need to enhance the culture of biosafety across the laboratory community in the United States. The Association of Public Health Laboratories (APHL) has developed *A Biosafety Checklist: Developing A Culture of Biosafety* to serve as a starting point for laboratories to assess the biosafety measures that they have in place.

Intended Use

A Biosafety Checklist: Developing A Culture of Biosafety is intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents in the United States. It is designed to provide laboratories with the broad recommendations for components that should be considered for inclusion in any laboratory's biosafety policy. The checklist consists of six sections:

1. Risk Assessment
2. Selection of Safety Practices
   - Biosafety Level
   - Engineering Controls
   - Personal Protective Equipment (PPE)
   - Laboratory Practices
3. Biosafety Competencies
4. Safety Orientation and Training
5. Audits, Monitoring and Safety Committee
6. Administrative Controls

This checklist is for your laboratory's internal use only. The questions in this checklist are included to guide biosafety discussion within your laboratory and do not address biosecurity practices. Some questions may not be applicable to every laboratory and some laboratories may want to add additional questions to perform their risk assessments. This tool can be modified to meet your laboratory's needs as necessary and information gained from this tool can be used to help laboratories identify areas for improvement in their biosafety practices.

ASSOCIATION OF PUBLIC HEALTH LABORATORIES 1 A Biosafety Checklist: Developing A Culture of Biosafety

Introductory Memorandum: Recruiting Biosafety Officers

The Association of Public Health Laboratories (APHL) developed the enclosed **competency-based Biosafety Officer Position Description (PD) Template** to assist state and local public laboratories with their recruitment efforts. Utilizing funds from the Centers for Disease Control and Prevention (CDC) Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement and if applicable other sources, state and local public health laboratories will recruit Biosafety Officers with the ultimate goal of improving safety across the jurisdiction. While the term Biosafety is frequently used in the position description, APHL envisions that the Biosafety Officer will work in concert with other personnel to address safety across the public health laboratory and in sentinel clinical laboratories.

The majority of the competency statements used in the Biosafety Officer (PD) Template are from the Safety, Workforce Training, Security and Communications domains found in the *Competency Guidelines for Public Health Laboratory Professionals*.[1] To complete the expected duties and responsibilities of this unique position, additional competencies from the Microbiology, Emergency Management and Response, Quality Management Systems and General Laboratory Practice domains were also included. The competency tier levels selected from these eight domains are marked at the end of each competency statement (i.e., C = Competent, P = Proficient, E = Expert). Users may interchange tier levels to better fit the position responsibilities in their respective agencies. **APHL recommends reviewing the competency guidelines referenced above for additional tier levels and/or other competencies important to the specific position.**

Please note that in most instances, the competencies listed here are verbatim from the *Competency Guidelines for Public Health Laboratory Professionals*. **Users of the APHL Biosafety Officer PD Template may want to condense and/or combine competencies to meet their requirements and needs.**

The following may vary with the agency electing to use the Biosafety Officer PD Template: position title; recommended education and experience; agency organizational structure and reporting requirements; and weights (%) for each domain/topic area.

APHL thanks the Workforce Development Public Health Laboratory Competency Implementation Workgroup for developing the PD Template and appreciates the feedback provided by the Biosafety and Biosecurity Committee. In the coming months, APHL will work closely with CDC and other partners to create a Community of Practice for Biosafety Officers. For questions pertaining to APHL's biosafety activities, please contact biosafety@aphl.org.

Knowledge Retention Toolkit

Biorisk Management for Clinical and Public Health Laboratories

Purpose
The Association of Public Health Laboratories, Centers for Disease Control and Prevention, and (Your Public Health Lab) are enhancing support to clinical and local health department laboratories to reduce risk in the areas of laboratory biosafety and biosecurity. As such, new programmatic support has been developed and conversations around biorisk management will be incorporated into ongoing outreach programs. This document provides an overview of a comprehensive, systematic approach to laboratory biorisk management. It includes a list of essential elements laboratories can use to assess their operations and better integrate and enhance programs for biosafety and biosecurity.

Definitions
Key terms used in this document are defined as follows:

- *Biorisk:* combination of the probability of occurrence of harm and the severity of harm where the source of harm is a biological agent or toxin
- *Biosafety:* laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to the biological agents and toxins, or their accidental release
- *Biosecurity:* laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release

Introduction
Clinical and public health laboratories should develop and maintain biorisk management systems that address laboratory biosafety and biosecurity tailored to the unique operations and risks of each laboratory. There is no one-size-fits-all biorisk management system. However, each formal, written biorisk management system should:

a) establish the principles that enable the management and staff of laboratories to achieve their biosafety and biosecurity objectives;
b) define the essential components that integrate biosafety and biosecurity processes into the laboratory's overall governance, strategy and planning, management, quality management system, reporting processes, policies, values, and culture; and
c) describe a comprehensive biorisk management process that identifies biorisks (both biosafety and biosecurity risks) and reduces and/or maintains them at acceptable levels.

Enhancing Biosafety and Biosecurity in the Nation's Public Health Laboratories
A Report of the APHL 2016 Biosafety and Biosecurity Survey

APHL Position Statement
Improving Biosafety in Our Nation's Laboratories

A. Statement of Position

Biosafety practices in the nation's laboratories must be enhanced through implementing routine risk assessments and standardized training, identification of true risk and best practices, development of consensus standards and guidelines, and improved reporting of exposure events.

leadership to promote a culture of biosafety in their laboratories.

4. APHL will work with public health laboratories to provide outreach and training to other laboratories within their jurisdictions that are implementing biosafety practices and guidelines.
5. APHL will assist public health laboratories educating the public about the principles of

aphl.org/biosafety

Building Biosafety Awareness

- Advocacy: need continued federal funding
- Connection with Academia: Biosafety Curricula
  - Kirkwood Community College

BIOSAFETY & BIOSECURITY

UNMET NEEDS

- Increase funding to the US Centers for Disease Control and Prevention (CDC) for public health laboratories to sustain biosafety and biosecurity programs to protect laboratory workers and the public
- Provide resources to support public health laboratory outreach and training to clinical laboratories
- Provide resources to build and maintain a competent public health laboratory biosafety and biosecurity workforce, ensuring at least one full-time biosafety officer in each public health laboratory
- Bridge the lack of connectivity between healthcare and public health systems

Diseases (ELC) - Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments.

APHL Position Statement
Improving Biosafety in Our Nation's Laboratories

A. Statement of Position

Biosafety practices in the nation's laboratories must be enhanced through implementing routine risk assessments and standardized training.

leadership to promote a culture of biosafety in their laboratories.

4. APHL will work with public health laboratories to provide outreach and training to other

CDC/APHL
BIOSAFETY AND BIOSECURITY PROGRAM
MAKING LABS SAFER FOR SCIENTISTS AND COMMUNITIES

February 2018

During the Ebola virus outbreak in 2014, a four-year-old year old girl who had recently returned from West Africa arrived in the emergency room of a hospital in the US Northeast suffering from a high fever and severe dehydration. Out of concern that their young patient might be infected with Ebola, the hospital staff sought the advice of the state epidemiologist who informed them that the girl's illness was most likely malaria. But this information did not allay their concerns. Fearing exposure to the virus, they refused to insert an IV or perform other laboratory tests until they had test results from the state public health laboratory.

So for over 10 hours the girl waited, receiving only popsicles, while a specimen was transported to the laboratory and analyses conducted. And the result? The girl was positive for malaria. With this diagnosis, the hospital finally initiated treatment.

The girl was fortunate—she lived—but others were not so lucky; at least two others died in similar

Partners Forum:
A collaboration for culture change

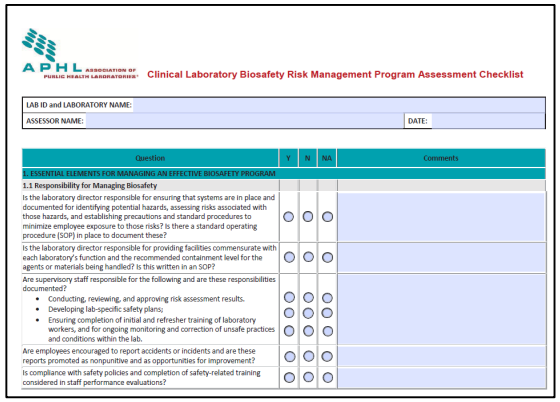
- APHL led collaboration between Federal and private sector partners connected with clinical laboratories engaged in evaluating and improving PH and clinical lab biosafety and biosecurity practices in the U.S.
- Convene an annual in person meeting (2016 and 2017) and 6 month follow up call
- Transitioning to the Clinical Laboratory Partners Forum

ABSA Was There!

Amer. Society Of Clinical Pathology
Amer. Biological Safety Assoc.
Amer. Assoc. For Clinical Chemistry
APHL
The Joint Commission
Amer. Assoc. Of Bioanalysts
Centers For Disease Control And Prevention
Centers for Medicare & Medicaid Services
CLIAC
COLA
Amer. Society For Microbiology
Food And Drug Administration
Clinical Laboratory Management Assoc.

Slide courtesy of Michael Marsico

Biosafety and Biosecurity Partners Forum



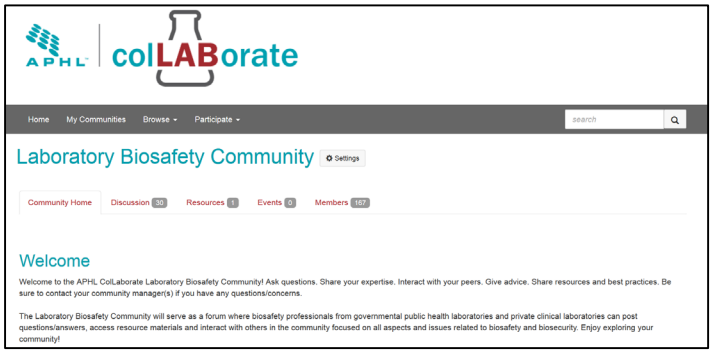
APHL Association of Public Health Laboratories — Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

LAB ID and LABORATORY NAME:

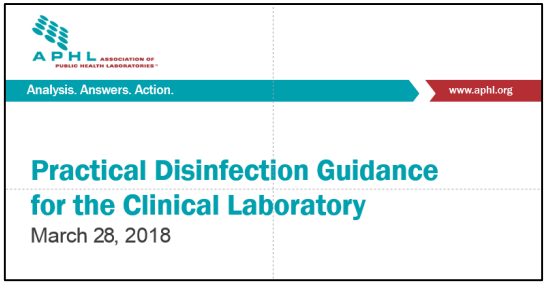
ASSESSOR NAME: DATE:

Question	Y	N	NA	Comments
I. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
1.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?	○	○	○	
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?	○	○	○	
Are supervisory staff responsible for the following and are these responsibilities documented? • Conducting, reviewing, and approving risk assessment results. • Developing lab-specific safety plans; • Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab.	○ ○ ○	○ ○ ○	○ ○ ○	
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?	○	○	○	
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?	○	○	○	

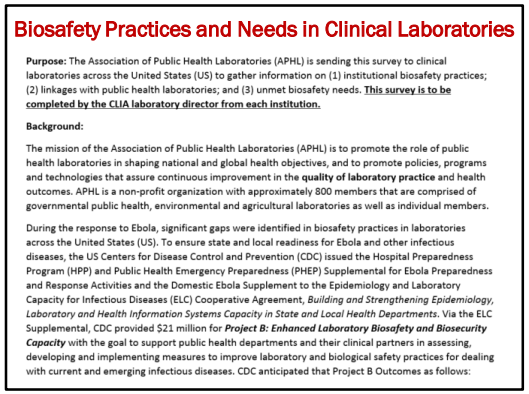
Clinical Laboratory Biosafety Risk Management Program Assessment Checklist



Laboratory Biosafety ColLABorate Community



Disinfectant Webinar



Biosafety Practices and Needs in Clinical Laboratories

Purpose: The Association of Public Health Laboratories (APHL) is sending this survey to clinical laboratories across the United States (US) to gather information on (1) institutional biosafety practices; (2) linkages with public health laboratories; and (3) unmet biosafety needs. **This survey is to be completed by the CLIA laboratory director from each institution.**

Background:

The mission of the Association of Public Health Laboratories (APHL) is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs and technologies that assure continuous improvement in the **quality of laboratory practice** and health outcomes. APHL is a non-profit organization with approximately 800 members that are comprised of governmental public health, environmental and agricultural laboratories as well as individual members.

During the response to Ebola, significant gaps were identified in biosafety practices in laboratories across the United States (US). To ensure state and local readiness for Ebola and other infectious diseases, the US Centers for Disease Control and Prevention (CDC) issued the Hospital Preparedness Program (HPP) and Public Health Emergency Preparedness (PHEP) Supplemental for Ebola Preparedness and Response Activities and the Domestic Ebola Supplement to the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement, *Building and Strengthening Epidemiology, Laboratory and Health Information Systems Capacity in State and Local Health Departments*. Via the ELC Supplemental, CDC provided $21 million for ***Project B: Enhanced Laboratory Biosafety and Biosecurity Capacity*** with the goal to support public health departments and their clinical partners in assessing, developing and implementing measures to improve laboratory and biological safety practices for dealing with current and emerging infectious diseases. CDC anticipated that Project B Outcomes as follows:

Clinical Laboratory Survey

Slide courtesy of Michael Marsico

Partners Forum Activities

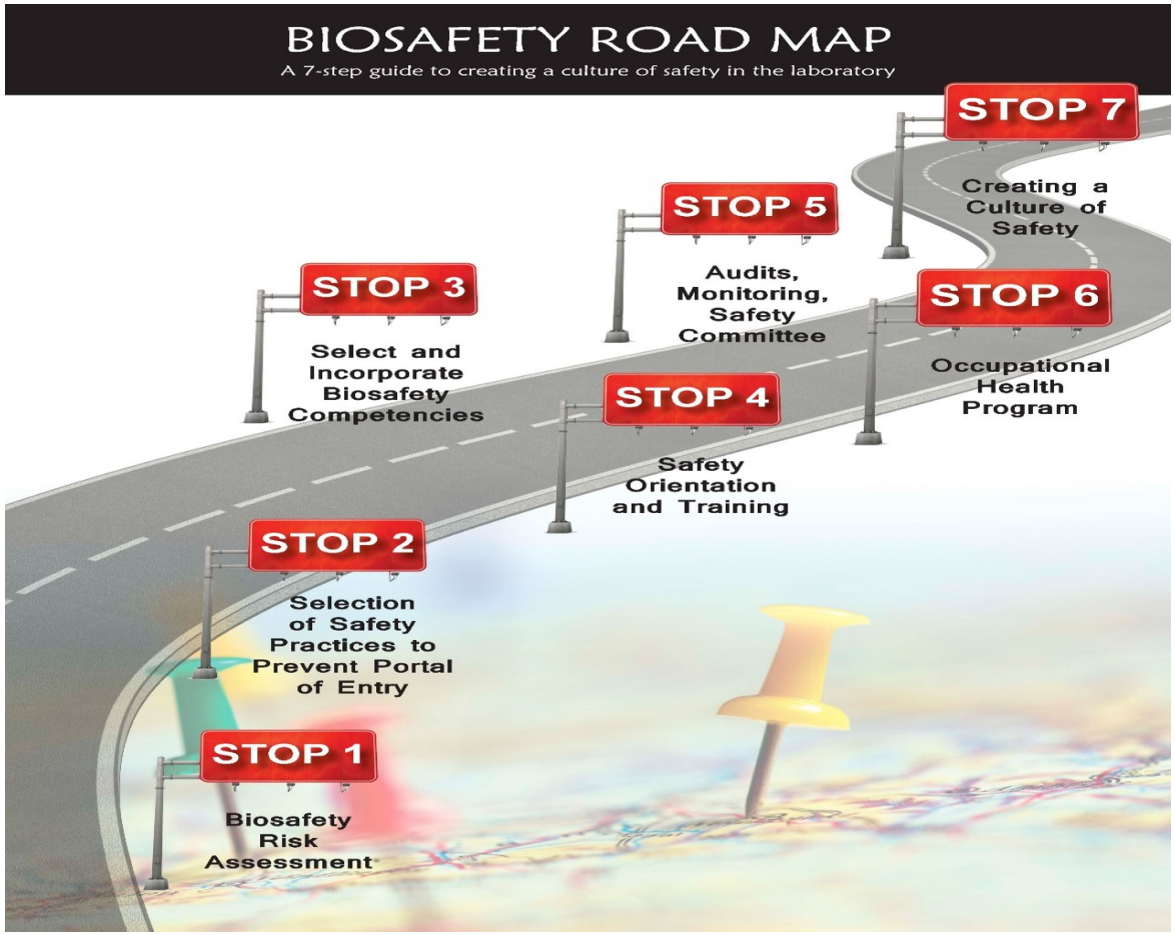
Beginning Challenges

- Reviewed state of biosafety in clinical labs
- Lack of familiarity with biosafety risk assessment process
- Unknown risk of new technology ex. MALDI-ToF

Future Activities

- Potential regulatory action by some organizations
- Adding additional biosafety items to checklists already in place
- Continue to promote biosafety awareness

Biosafety Roadmap for Clinical Labs



Biosafety Practices and Needs in Clinical Laboratories Survey

- Launched in June 2018
- Purpose: to determine needs in sentinel clinical laboratories as well as laboratories in facilities that were identified as Ebola Treatment Centers (ETCs) and Ebola Assessment Hospitals (EAHs) across the United States
- Estimated target audience of 5,000 laboratories: 489 laboratories responded
- 376 stated they were defined as a sentinel clinical laboratory
- 147 stated they identified an Ebola Assessment Hospital
- 21 stated they identified as an Ebola Treatment Center

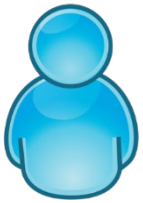
Response by State

Responses ranged from

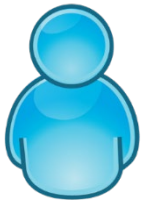
- A high 11% in Georgia and New York (54 laboratories each)
- A low of 0.2% in Alaska, Alabama, Colorado, Kentucky, Michigan, Nebraska, and New Mexico (1 laboratory each)


WASHINGTON
10
OREGON
10
IDAHO
2
MONTANA
3
WYOMING
2
NORTH DAKOTA
5
SOUTH DAKOTA
1
NEBRASKA
24
MINNESOTA
17
IOWA
9
WISCONSIN
MICHIGAN
1
9
CALIFORNIA
NEVADA
UTAH
1
COLORADO
KANSAS
3
MISSOURI
2
ILLINOIS
10
INDIANA
16
OHIO
1
KENTUCKY
5
WEST VIRGINIA
7
VIRGINIA
13
PENNSYLVANIA
9
NEW YORK
5
4
6
NEW JERSEY
2
DELAWARE
3
1
0
5
6
24
MAINE
VERMONT
RHODE ISLAND
ARIZONA
1
NEW MEXICO
OKLAHOMA
5
TEXAS
42
ARKANSAS
18
LOUISIANA
6
TENNESSEE
20
MISSISSIPPI
9
ALABAMA
1
GEORGIA
54
FLORIDA
13
SOUTH CAROLINA
10
NORTH CAROLINA
29
1
ALASKA
HAWAII
2

Does your institution have staff who are responsible for biosafety?



54.4%, **No full time staff dedicated to biosafety but responsibility is allocated to multiple staff across all institutional laboratories**



10%, **No**

34.7%, Yes, includes full time or part time

How many staff in your facility are currently certified in safe packaging/shipping of International Air Transport Association (IATA) Division 6.2 Category A Infectious Substances?

n	Total	Average	Median	Min	Max
489	2,743	6	4	0	100

1-9	76.9%	376
10-24	11.2%	55
25-49	1.8%	9
50-74	0.4%	2
75-100	0.4%	2

9.2%, n = 45

Does your institution have a biosafety plan in place?

YES = 91.4%
n = 447

NO = 8.6%
n = 42

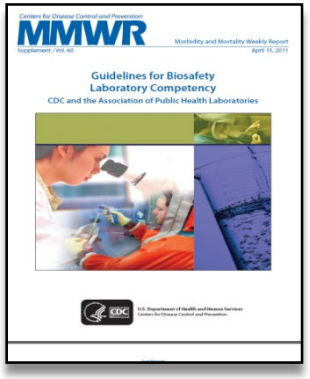
Have you developed safety-specific competencies for laboratory staff?

YES = 84.9%
n = 415

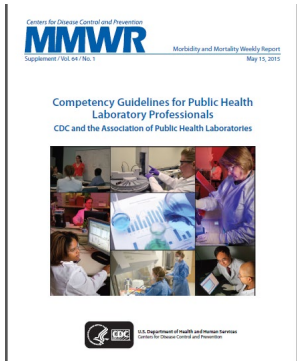
NO = 15.2%
n = 74

The majority were incorporation into their annual general competencies review. Other *responses included laboratories were unaware of safety specific competencies and not being able to develop them due to time constraints*

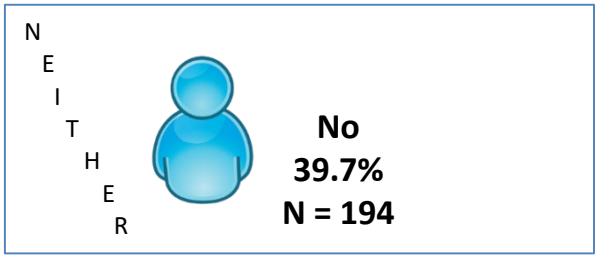
Are you aware of the following Competency Guidelines?



YES 55.2%
N = 217



YES 44.7%
N = 217



From May 2015 to May 2018, did your institution complete risk assessments?

YES = 56.4%
n = 276

NO = 32.9%
n = 161

Yes at least one = 37.4% 183

Yes - at least two = 19% (33)

Yes – other = 10.6% (52)

Annual risk assessments and general laboratory risk assessments or utilizing risk assessments and evaluating risks when conducting LPX.

Has your staff received training on the following topics: 100% - 95%

TOPIC	YES	N =	No	N =
Sharps Hazard	**99.6%**	**487**	**0.4%**	**2**
Bloodborne Pathogens	**99.4%**	**486**	**0.6%**	**3**
Personal Protective Equipment (PPE)	**99.2%**	**485**	**0.8%**	**4**
Spill Prevention, Control, and Countermeasure	**97.5%**	**477**	**2.5%**	**12**
Chemical Hazards	**95.9%**	**469**	**4.1%**	**20**

Has your staff received training on the following topics: 94%-90%

TOPIC	YES	N =	NO	N =
Biological Safety Cabinets (BSCs) and other Engineering Controls	**92.6%**	**453**	**7.4%**	**36**
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	**91.6%**	**448**	**8.4%**	**41**
Regulated Waste Management	**90.8%**	**444**	**9.2%**	**45**
Emergency Management and Response	**90.2%**	**441**	**9.8%**	**48**
Continuous Quality Improvement (review, improvement, and implementation)	**90.2%**	**441**	**9.8%**	**48**

Has your staff received training on the following topics: 89%-30%

TOPIC	YES	N =	NO	N =
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	89.4%	437	10.6%	52
Decontamination	87.5%	428	12.5%	61
Biological Risk Assessment	69.3%	339	30.7%	150
Select Agent Regulations	67.1%	328	32.9%	161
Biosecurity Plan	64.6%	316	35.4%	173
BSL-3 safety practices	44.4%	217	55.6%	272
Safe Handling and Use of Cryogenic Liquids	30.5%	149	69.5%	340

Additional training needs

TOPIC	%	n
Biosecurity Plan	**16.2%**	**79**
Select Agent Regulations	15.1%	**74**
Biological Risk Assessment	**14.9%**	**73**
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	12.9%	**63**
BSL-3 safety practices	11.7%	**57**
Continuous Quality Improvement (review, improvement, and implementation)	9.4%	**46**
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	**7.8%**	**38**

Additional training needs

TOPIC	%	n
Emergency Management and Response	7.4%	36
Decontamination	7.2%	35
Regulated Waste Management	5.1%	25
Safe Handling and Use of Cryogenic Liquids	4.1%	20
Chemical Hazards	3.9%	19
Biological Safety Cabinets (BSCs) and other Engineering Controls	3.3%	16
Spill Prevention, Control, and Countermeasure	2.0%	10
Personal Protective Equipment (PPE)	1.0%	5
Sharps Hazard	0.6%	3
Bloodborne Pathogens	0.6%	3

Training: What training materials do you use?

Public Health Laboratory Provided Training

67.7% n = 331

Self Developed Training

63.0% n = 308

Purchased training

32.5% n = 159

Other - *CDC and CAP developed training materials and trainings offered through* hospital and health care systems.

16.6% n = 81

What training mechanism(s) do you currently use?

Answer	%	n
In-Person/Classroom	**65.6%**	**321**
Online/Archived Webinar	**58.1%**	**284**
Online/Live Webinar	**47.6%**	**233**
Virtual Course	**32.3%**	**158**
Other - responses included hands-on drills, tabletop exercises and written procedures.	**10.8%**	**53**
Telephone (no web component)	4.5%	22

How do you identify biosafety training needs?

Answer	%	n
Accreditation/Certification checklist	71.6%	350
Gap risk assessment	41.1%	201
None, do not evaluate	11.5%	56
Other - individual staff competency assessments, review of public health laboratory resources, institutional safety inspections and site visits by consultants and public health laboratory staff, and mock drills and exercises.	11.2%	55

Briefly describe biosafety training needs for your facility and your plans to address those needs.

- Responses included training in the areas of packaging and shipping, risk assessments and proper personal protective equipment usage.
- Other responses included training needs in biosafety plans, biosafety competencies and regulatory requirements.
- Responses to address these needs included online and in-person courses available through public health laboratories, CDC and consultants.

What top three conferences would you or your colleagues attend to strengthen your biosafety knowledge, skills and abilities?

- The majority of responses included
  - American Society for Microbiology (ASM) Microbe,
  - CDC International Biosafety Symposium
  - American Biological Safety Association Annual Biosafety and Biosecurity Conference.

Connections with PHL

How satisfied are you with the services and support provided by your public health laboratory biosafety officer?

Answer	%	n
Very satisfied	30.4%	91
Satisfied	50.2%	150
Somewhat satisfied	17.4%	52
Unsatisfied	1.3%	4
Very unsatisfied	0.7%	2

Briefly describe your rating of the public health laboratory biosafety officer.

- The majority rated their public health laboratory biosafety officer very highly, stating that these staff are very knowledgeable and communicate regularly, sending pertinent information on available trainings and available at all times for questions.
- Respondents saw the site visits provided by the biosafety officers as very useful.
- Some respondents stated that they have not directly interacted with their public health laboratory biosafety officer as of yet and would like more involvement and information from their biosafety officers.

What are your needs of a public health laboratory biosafety officer?

- More guidance and communication around laboratory biosafety was needed specifically relevant information and trainings.
- Some respondents stated that more in-person communications and visits across the laboratory would be helpful.

Biosafety Forum: Public Health Laboratory Outreach, Clinical Laboratory Engagement and Needs

Focus: Discuss the current and unmet biosafety needs and challenges of both public health and clinical laboratories, define a successful outreach program and discuss solutions to enhance biosafety.

Biosafety Forums: Public Health Laboratory Outreach, Clinical Laboratory Engagement and Needs

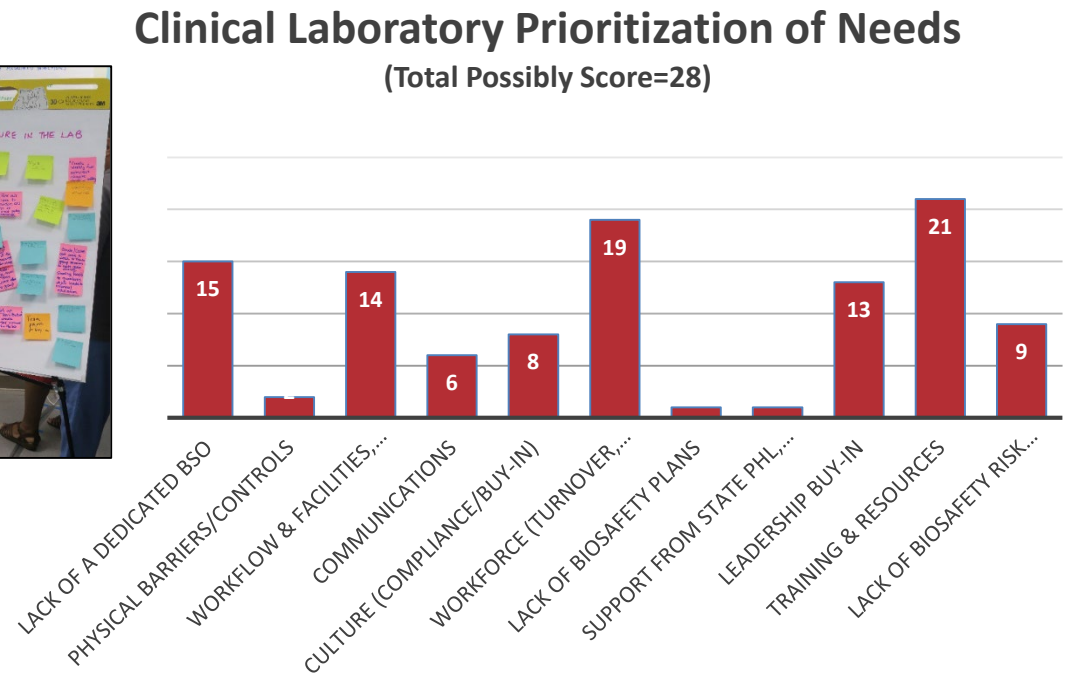
Regional one day forums inviting clinical laboratories from a jurisdiction
Discuss the effectives of biosafety outreach programs and ongoing needs from public health labs and clinical labs

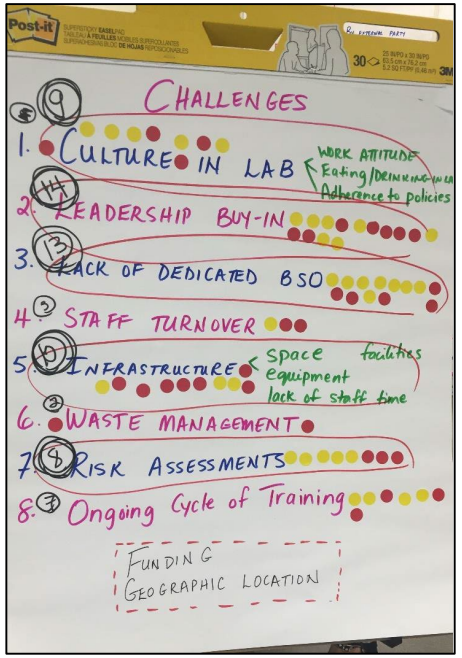
Forum locations: Minnesota Department of Health Public Health Laboratory, Hawaii State Laboratories Division, North Carolina State Laboratory of Public Health, California Department of Public Health State Public Health Laboratory

84 clinical laboratory representatives	**28 hosting PHL representatives**	**12 local PHL representatives (CA forum)**	**5 APHL staff**	**6 CDC staff (5 DLS, 1 DPEI/ELC)**	**1 Retired LabCorp Participant**

Biosafety Forums Continued

Challenges and Needs: Training and Resources, Workforce, and Lack of a Dedicated BSO followed by Leadership Buy-In and Improvement in Workflow, Facilities, and their Infrastructure





Training and Resources Needs Identified

- Risk Assessments
- Packaging and Shipping
- BSL-2&3 Practices

9a. If public health laboratory training was available to you at no cost, would you choose the following areas/ topics?

Question	Yes	
	%	n
Biological Risk Assessment	89.8%	439
Biosecurity Plan	87.1%	426
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	84.9%	415
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	80.8%	395
Continuous Quality Improvement (review, improvement, and implementation)	76.5%	374
Select Agent Regulations	76.3%	373
Emergency Management and Response	75.3%	368

9. Has your staff received training on the following topics?

Question	Yes	
	%	n
Sharps Hazard	99.6%	487
Bloodborne Pathogens	99.4%	486
Personal Protective Equipment (PPE)	99.2%	485
Spill Prevention, Control, and Countermeasure	97.5%	477
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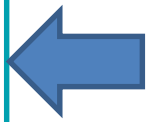
Regulated Waste Management	90.8%	444
Emergency Management and Response	90.2%	441
Continuous Quality Improvement (review, improvement, and implementation)	90.2%	441
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	89.4%	437
Decontamination	87.5%	428
Biological Risk Assessment	69.3%	339
Select Agent Regulations	67.1%	328
Biosecurity Plan	64.6%	316
BSL-3 safety practices	44.4%	217
Safe Handling and Use of Cryogenic Liquids	30.5%	149

Unmet Needs and Issues across Laboratories

- Dedicated Biosafety Officers
- Clinical laboratory biosafety practices
- Lack of biosafety buy in from leadership
- Biosafety not seen as a priority across laboratories
- Hands on training
  - Risk Assessments
- Mentorships across laboratories
- Biorisk Management Workshop - invited over 40 clinical laboratories from across the state of Florida to attend

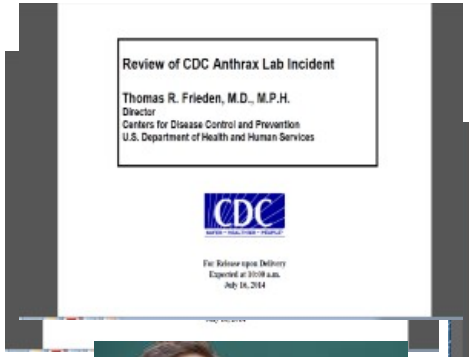
Unmet Needs and Issues across Laboratories

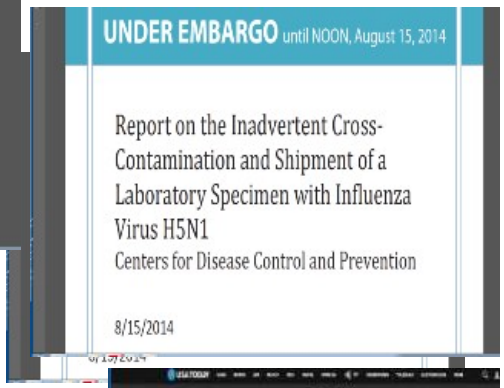
- Dedicated Biosafety Officers
- Clinical laboratory biosafety practices
- Lack of biosafety buy in from leadership
- Biosafety not seen as a priority across laboratories
- Hands on training
  - Risk Assessments
- Mentorships across laboratories

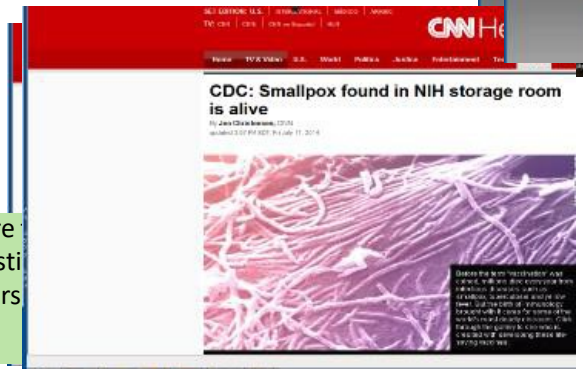


APHL
BBC
Priorities

Good News! Biosafety has gotten attention in the last several years…







sealed vials with freeze-dried smallpox virus were
in July 2014 in a storage room at the National Insti
of Health (NIH) in Bethesda MD USA that 42 years
had been turned over to the FDA

Concerns for the Future

- Sustainable Federal Funding
- BSOs leaving for other biosafety careers for private/academic institutions
  - Other bench role duties at PHL
  - Losing subject knowledge
- Relationships built across laboratories
- Are we prepared for the next Ebola?

10. Based on the training and knowledge of your laboratory staff, do you believe they are prepared to respond to an emerging threat comparable to Ebola Virus Disease?

Answer	%	n
Yes	60.5%	296
No - Please provide a brief explanation as to why staff are not prepared to respond to an emerging threat	39.5%	193

Explanations included lack of specific knowledge and training on how to respond to an emerging threat, institutions not having the proper resources including facilities, equipment and staff necessary, and lack of documented laboratory procedures. Individual responses are on file with APHL.

New Instruments another area of need

TABLE 1 Viability of BT agents following MALDI-TOF sample preparation

Organism(s)	No. of tubes with growth using indicated sample preparation method/no. tested								
	Direct colony			On-plate formic acid			Tube extraction		
	Target	Spot + Matrix	Spot	Target	Spot + Matrix	Spot	Target	Spot + Matrix	Spot
Bacillus anthracis	3/5	5/5	5/5	1/5	5/5	5/5	0/5	1/5	5/5
Burkholderia thailandensis	0/5	5/5	5/5	0/5	5/5	5/5	0/5	0/5	5/5
Clostridium botulinum/Clostridium perfringens	1/5	1/5	3/5	1/5	0/5	2/5	0/5	1/5	4/5
Francisella tularensis	1/5	2/5	4/5	1/5	2/5	5/5	0/5	1/5	5/5
Yersinia pestis	0/4	3/4	4/4	1/4	4/4	4/4	0/4	0/4	3/4
Brucella abortus	0/4	3/4	4/4	1/4	4/4	4/4	0/4	0/4	3/4
Total	5/28	19/28	25/28	5/28	20/28	25/28	0/28	3/28	25/28

Rudrik et al. JCM. Safety and Accuracy of MALDI for identification highly pathogenic organisms. October 2017

Ideas for the Future

- Identify Solutions for the Needs Addressed
  - Training Needs
  - Workforce/Biosafety Curriculum
  - Biosafety Culture/Buy-In
  - Connections with Physicians and Nurses
  - Biosecurity
- Streamlined Approach towards Biological Risk Assessment Training

Transforming biosafety into a quantitative practice

- We need evidence based data to as the basis for recommendations
- Risk assessments identify mitigation needs but there is no data on which to base the mitigation selected
  - Ex. Risk of aerosols from some lab procedures
  - Ex. What is the benefit of PPE in certain testing circumstances
- Data on the containment effectiveness of equipment and laboratories are scarce and fragmented.
- The tendency is to over protect which leads some to disregard the recommendation
- Using evidence-based data will enhance the effectiveness of biosafety measures as well as compliance with these measures

Future Vision

- Evidence based data to support decisions
- Collection of data on human reliability
- Collection of data on biosafety incidents
- Develop mathematical models to support further development of knowledge of biosafety, to detect gaps in our knowledge, and to support the development and evaluation of new biosafety measures

Biosafety in clinical labs at a crossroads

- Will the ebola experience have resulted in lasting changes in biosafety in the clinical labs?
  - Through CDC and APHL efforts many more labs recognize the importance of biosafety
  - There are limited requirements for biosafety in clinical labs.
  - Through the APHL Partners Forum, other organizations are considering changes that will keep biosafety in the forefront .

Thank you for your attention!

Questions?