

Analysis. Answers. Action.

# **Building Biosafety and Biosecurity across Public Health Laboratories**

Michael Marsico, MS Senior Specialist, Biosafety and Biosecurity Association of Public Health Laboratories November 6<sup>th</sup>, 2019

## **Objectives**

- APHL Overview and our role in Biosafety and Biosecurity
- APHL Biosafety Community of Practice
- Unmet Biosafety and Biosecurity Needs identified
- Ideas/Concerns for the future

Analysis. Answers. Action.

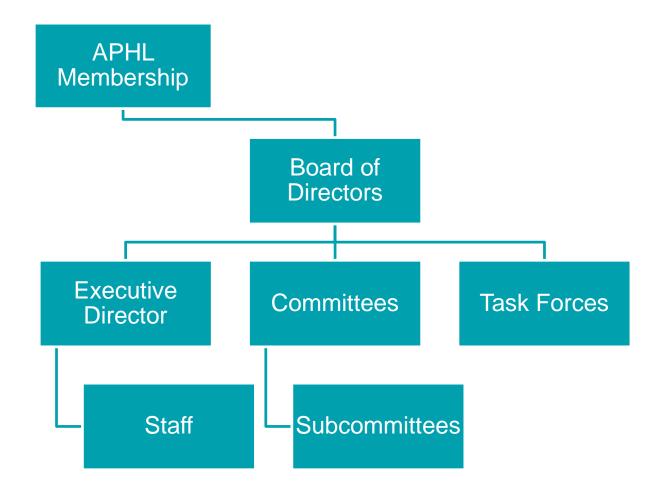


### **About APHL**

- A non-profit, non-governmental US based organization
- Over 900 members from state and local public health laboratories, state environmental and agricultural labs and others federal agencies and academic institutions.
- Advocates at the national level to shape public health policy and to secure increased support and resources for member labs
- Provides training, model practices, technical assistance domestically and internationally



## **APHL Organizational Structure**





## **Committees (many have subcommittees)**

- Public Health Preparedness and Response
- Environmental Health
- Environmental Lab Science
- Finance
- Food Safety
- Global Health
- Infectious Diseases
- Informatics
- Newborn Screening and Genetics in Public Health

- Knowledge Management
- Laboratory
   Systems and
   Standards
- Local Laboratory Committee
- Workforce
   Development
- National Legislative Review Work Group
- Biosafety and Biosecurity



## **Biosafety 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)\*
- 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.

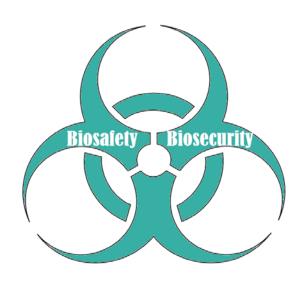
\*One Year Extension to 2019



## **Biosafety 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 Comr



BSO Peer Network

Bi

7 Webin:

pp eri PHLs with 37

Practice

250+)

s Paired)



**CULTURE OF BIOSAFETY CHANGE** 

Hire Biosafety Officers

**Provide Training and Tools for BSOs (Risk** 

Assessments, Workshops and Biosafety

**Checklists**)

- Build a Community of Practice

ide training and resources for Clinical Labs

**Intinue assisting PHL and Clinical Labs** 

Bio

Sur

onsulta

psafety and or curity Pa ners Fo

Awareness at the Nation Level

ical Labora y Biosafety

Biosafety Practices and Ne

 Biosafety Forums: Public H Laboratory Engagement ar

Biorisk Management Works



Il Laboratories Survey ory Outreach, Clinical

nittee







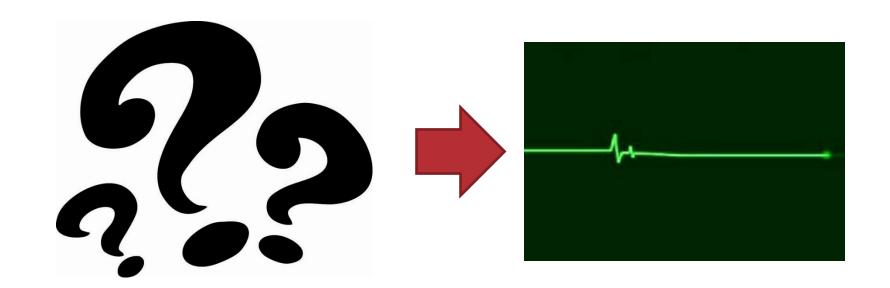
## **Biosafety and Biosecurity ColLABorate Communities**

- Biosafety and Biosecurity Community
  - Currently includes PHLs BSOs (~140), Biosafety Outreach Officers, and other pertinent Biosafety personnel
- Laboratory Biosafety and Biosecurity Community
  - Currently includes PHLs BSOs (~190), Biosafety Outreach Officers along with clinical laboratory staff
    - Public Health Lab 65
    - o Private Clinical Lab 115
    - National Organization 10
    - Federal Agency 1





# Public Health Laboratory Biosafety Officer (BSO) Technical Knowledge in 2015





## Workshop Series

- Technical Workshop Series (2016 2017)
  - Recognizing the needs of the newly hired BSOs, APHL convened regional workshops to provide training on biosafety and biosecurity fundamentals
  - Two day technical workshops were held at 4 state and local PHLs: MA, HI, FL and Los Angeles County
  - > 51 BSOs from 47 PHLS
  - Core Curriculum: Risk Assessments, Biosafety Competencies, Biosecurity, Donning and Doffing, Components of a Biosafety Plan, Decontamination, Engineering Controls, Outreach to Sentinel Clinical Labs, Buying into Biosafety, Ethical Issues, Leadership in Biosafety







## **Workshop Series**

- Leadership Workshop Series (2017 2018)
  - Due to an ever changing and increasingly complex environment, PHLS need biosafety leaders who embrace change, manage people and processes efficiently and anticipate future needs.
  - > 37 BSOs from 34 PHLs
  - Goal: Shape BSOs into future leaders within the laboratory system.
  - 4 day leadership workshops were held at 3 state PHL: HI, FL and AZ











## **DEMOGRAPHICS**







## Leadership Workshop Participants' Takeaways

"I plan to use RACI charts in project management areas in the workplace. This will help with defined roles and responsibilities."

"Helped focus the biggest challenges facing BSOs and provided opportunities to network and build relationships with peers."

"The SOCO training was very effective in identifying communication strengths and weaknesses."

"The past few days rejuvenated the passion for the safety of our employees and community that lay dormant for the past few years."

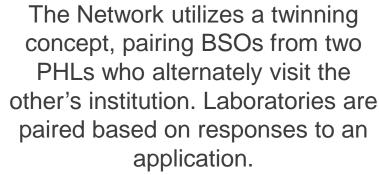


**BSO Peer Network Program** 

Northern Mariana Islands

ion.

Deliverables: Peer
Network Posters,
PowerPoints, Trip
Reports and Lab Culture
Podcast



Thank You

Biocontainmen

**Unit Team** 



## **Community of Practice Takeaways**

- 1. Highly successful workforce development tool
- 2. Provided BSOs exceptional training and tools where they can perform their duties effectively
- 3. Network of biosafety professionals in both PHLs and clinical laboratories where they can interact daily, monthly and in person
- 4. Created a highly engaged community of biosafety professionals
- 5. Plan to continue to evolve and build this community





#### **Practical Disinfection Guidance** for the Clinical Laboratory

March 28, 2018

Dial-In Number: 866,740,1260 Access Code: 4852701

#### BIOSAFETY CHECKLIST

A Biosafety Checklist:

**Developing A Culture of Biosafety** 



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 bloading lapses highlight the need to enhance the culture of bloading scross the laboratory commanity in the unitied States. The isosciation of Public Health Laboratories (PPAI) had developed all Bloading Public Receipts (Laboratory & Cluster of Bloading to bene as a starting port for bloadratories to be provided to the public scross of the public scross to assess the biosefety measures that they have in place.

#### Intended Use

A Blosafety Checklist: Developing A Culture of Blosafety 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.

- Selection of Safety Practices
   Biosafety Level
   Engineering Controls
- Personal Protective Equipment (PPE)
   Laboratory Practices
- Safety Orientation and Training Audits, Monitoring and Safety Co 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 blosecurity 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 for mist your shoratory is needs as necessary and information gained from this tool can be used to help alsocatories identify areas for improvement in their biopatety practices.



Knowledge Retention **Toolkit** 





\$5ex 05, 2016

#### **Risk Assessment Best Practices**

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 89C is to develop and promote biosafety and siosecurity tools (for example-risk assessments).

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) changer

#### Components of a Risk Assessment

Key components of a risk assessment should address:

- Montify personnel (individuals) who will be affected throughout the work-flow
- . Assess the competency and experience of laboratory personnel
- · Consider staff enrollment in occupational health programs

- · 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



## aphl.org/biosafety



#### Biorisk Management for Clinical and Public Health Laboratories

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 se 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.

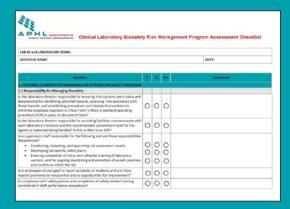
Key terms used in this document are defined as follows:

- 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
- · Biosofety: 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
- . Blosecurity: 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

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:
- 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.







#### 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 oplicable other sources, state and local public health laboratories will recruit Biosafety Officers with th ultimate goal of improving safety across the jurisdiction. While the term Biosafety is frequently used in the position description, APHI, 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 (PO) Template are from the Safety, Workforce Training, Security and Communications domains found in the Competency Guideline: Public Health Laboratory Professionals. <sup>1</sup> To complete the expected duties and responsibilities of this inique 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 ompetency 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 ompetency 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 Competence Guidelines for Bublic Health Laboratory Professionals. Users of the APHI Blossfety 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; ecommended 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 Worksroup 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





#### **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

eadership 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

## **Building Biosafety Awareness**

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



#### 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.

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

in their jurisdictions that are osafety practices and guidelines. public health laboratories ublic about the principles of



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





## **Building Biosafety Awareness**

Biosafety Month

#### **WEBINAR**

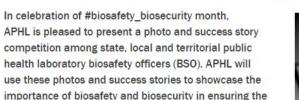
#### **Biosafety: Out of the Box!**

Thursday, October 31, 2019 | 2:00 - 3:00 pm ET



APHL Celebrates Biosafety and Biosecurity Month

#### **Photo and Success Story Contest**



Win 2 coach airline tickets on Delta to anywhere in the continental US!



#### Biosafety Officer Spotlight Series

#### Peter Davis

Responsible Official/BT Coordinator/Biosafety Officer
Colorado Department of Public Health and Environment

#### When you were a kid, what did you want to be when you grew up?

Well the first thing I ever remember wanting to be was a stegosaurus. But realistically (or unrealistically) a professional athlete.

#### How did you come to work in a public health lab and in the field of biosafety and biosecurity?

I was shadowing physicians before going to medical school and generally, they didn't seem happy with their careers. Several of them directly recommended not following in their footsteps. I then took a job in toxicology at the Colorado Department of Public Health and Environment, I then was promoted into a safety position, then the ELC grant provided funding and I was awarded the position of biosafety officer for our laboratory.

#### What do you like most about being a Biosafety Officer?

Supporting the staff. Doing what I can to provide them the tools to help themselves, but assist them when a need develops.

#### What is a challenge you face as a Biosafety Officer?

A lack of authority makes implementation and behavior correction difficult for laboratory workers and research scientists.







safety of laboratorians and the public.

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.

#### 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
--	--------------------------------	---	--------------	---------------------------------------	----------------------------------



### Focus:

- 1. Describe Laboratory biosafety successes and unmet needs.
- 2. Define outreach and characteristics of a model outreach program.
- 3. Participate in an affinity exercise and perform a root cause analysis to capture and prioritize laboratory biosafety needs

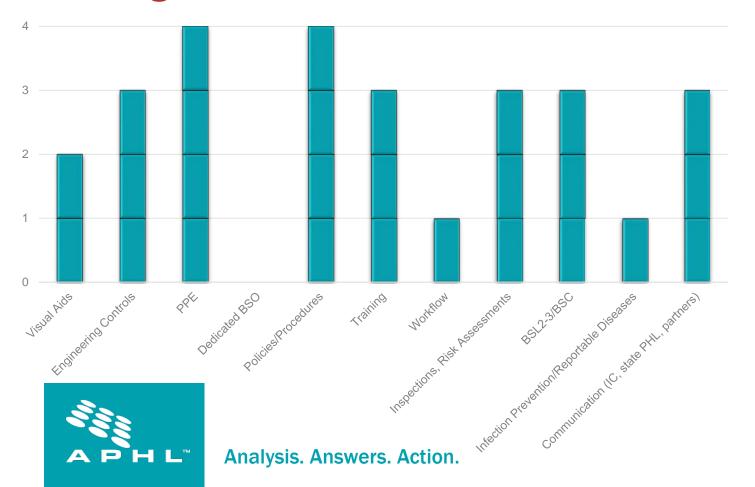


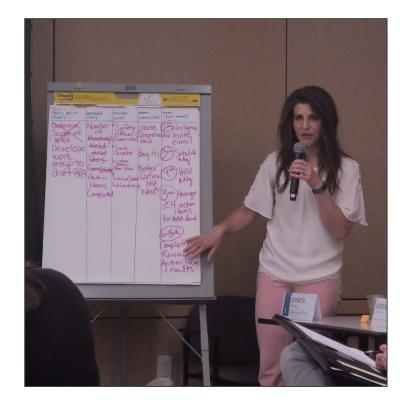






**Top Successes: Policies and Procedures, PPE Lacking Dedicated BSO** 





Characteristics of a Successful Outreach Program: Face-to-face and networking and the availability of training and access to resources







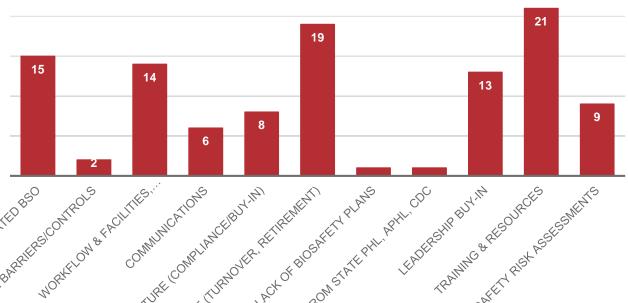
## **Biosafety Forums Continued**

Analysis. Answers. Action.

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









www.aphl.org

HALLENGES

CK OF DEDICATED BSO

STAFF TURNOVER

7 ASSESSMENTS

CULTURE IN

## **Biosafety Forums Continued**

### **Solutions**











Identified Needs	Proposed Solutions
Training & Resources	

#### Workforce (turnover & retirement)

- Participants recommended convening career days at local high schools to recruit possible laboratory staff along with **recruiting** through the state Medical Technician and Medical Laboratory Technician programs.
- Participants also recommended partnering with clinical laboratory science schools to train students on the potential hazards in the workplace and to become familiar with best practices to reduce the risk of LAIs.
- Participants recommended including biosafety discussions during monthly staff meetings to address safety as a daily priority in the laboratory workplace.
- Working with academic institutions and national organizations to build biosafety in current graduate, undergraduate and professional development curricula and to promote the value of biosafety to the emerging workforce.

#### Lack of a dedicated **BSO**

Human Resources should develop a position description for BSOs and distribute across jurisdictions to hire and fill the BSO position. APHL mentioned they have developed a competency based BSO position description that is housed on their biosafety website (www.aphl.org/biosafety) which attendees can utilize. The BSO should also report directly to the laboratory director to influence buy-in from staff.

## **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		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		373	
Emergency Management and Response		368	

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

Question		Yes	
Question	%	n	
Sharps Hazard	99.6%	487	
Bloodborne Pathogens		486	
Personal Protective Equipment (PPE)		485	
Spill Prevention, Control, and Countermeasure		477	
Chemical Hazards	95.9%	469	
Biological Safety Cabinets (BSCs) and other Engineering Controls	92.6%	453	
BSL-2 safe practices (fundamentals of biological materials safety practices, excluding bloodborne pathogen training)	91.6%	448	
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
- BSL-2&3 Practices



Analysis. Answers. Action.





## Mentorships across laboratories

- In person site assessments with four US-Affiliated Pacific Islands PHLs
  - FSM, Guam, Northern Marianas Islands, American Samoa
  - Included Virtual Leadership Exercise with Safer Behaviors
  - Utilized BBC membership
  - Provided summary reports for APHL and CDC
  - Invited staff to attend Biorisk Management Workshop







## Hands on training/Risk Assessment

- **Ceiter**learning partners
- Colter Instructional Design Series
- Biorisk Management Workshop
  - PHL and Clinical Lab Attendees





### **BSL-2&3 Practices**

- Eagleson BSL-3 Seminar Series
  - BSL3 Facilities: Design and Operation, Advanced BSL3
     Practices and Procedures
  - 18 PHL staff







### **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





## **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





### **Concerns for the Future**

- Sustainable Federal Funding
- BSOs leaving for other biosafety careers for private/academic institutions
  - Other bench role duties at PHL
  - Loosing 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		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.



## Thank you!

## Questions?