



## **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.

## **B.** Scope

The scope of this position statement relates specifically to biosafety. It does not address equally important topics of chemical and radiological laboratory safety.

## **C. Implementation**

- 1. The Association of Public Health Laboratories (APHL) will seek opportunities to communicate these needs to key federal and other policy makers to improve biosafety policies, practices and laboratory safety.
- 2. APHL will continue to collaborate with the Centers for Disease Control and Prevention (CDC) to encourage and monitor the implementation and use of biosafety competencies and will routinely survey laboratories to assess their awareness and understanding of the biosafety competencies.
- 3. APHL will encourage laboratory directors and

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 biosafety in order to inform the public about safety devices and tools, protocols and practices that are used in laboratories to protect laboratory workers, the public and the environment.
- 6. APHL will pursue opportunities to provide expert opinion and advice to others working towards improving biosafety practices in the laboratory.
- 7. APHL will develop tools for state and local government laboratories to aid in the implementation of biosafety guidelines including items such as biosafety checklists and risk assessment templates.

## D. Background/Data Supporting Position

The lapse of biosafety practices reported recently in federal high containment laboratories highlight the need to enhance the culture of biosafety. <sup>1,2</sup> Through education, training, guidelines and incorporation of quality management practices, APHL strongly supports ongoing efforts and encourages the expansion of efforts to improve and enhance the practice of biosafety in all clinical, public health, research and academic laboratories throughout the nation.

#### Understanding of the True Burden of Risk

A critical step towards enhancing biosafety practices is an accurate measurement of laboratory exposures and laboratory acquired infections. The lack of reporting mechanisms and requirements to report has led to a gross underestimation of incidents, therefore, the true burden of exposures and laboratory acquired infections is unknown. While the Federal Select Agent Program requires these events be reported, there are no means to assure compliance and this mechanism does not capture laboratory exposure events or laboratory acquired infections that occur in laboratories that are not working with select agents. A non-punitive mechanism to report exposure events and laboratory-acquired infections should be developed and implemented to allow incidents to be documented and analyzed.

#### Development of Standard Guidelines and Practices

While laboratory professionals accept the Guidelines for Safe Work Practice in Human and Animal Medical Diagnostic Laboratories, Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the NIH Guidelines for Research Involving Recombinant DNA Molecules as the current standards of practice, these documents are subject to interpretation.<sup>3,4,5</sup> They also lack specifications defining mechanical, physical and operational standards and how those standards are objectively and consistently applied. Consequently, while laboratories in the U.S. adhere to biosafety guidelines, there is great variability with respect to the physical and mechanical plans that support them and the operational procedures that may be in place. Additionally, there is inconsistency with which staff comply with plans and procedures. This necessitates the development of consensus standards for the construction, commissioning,

maintenance, and the operational processes and procedures used in all laboratories handling infectious and potentially infectious agents, along with an emphasis on implementation strategies to facilitate compliance.

# Implementation of Routine Risk Assessments and Training Programs

Due to the diversity of laboratory activities ranging from routine clinical testing to unique research, it is critical that each laboratory conduct a site-specific and procedure-specific risk assessment. The "Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories",6 describes the knowledge and skills needed to work with microorganisms to prevent transmission to self and others. The document includes details to develop biosafety training resources and templates for use by laboratory staff, researchers and students working in laboratories and handling infectious agents. The use of this resource is encouraged as laboratories conduct risk assessments and develop training programs.

Additionally, because most of the current data on laboratory acquired infections and research to determine best practices is decades old, laboratories would benefit from additional research to realistically assess the risk of laboratory procedures and practices. Many biosafety recommendations today are based on opinion and a limited number of documented infections. Furthermore, most practices have not been sufficiently evaluated. As new research data on biosafety practices becomes available, procedures should be updated and new risk assessments performed.

Fundamentally, it is in the best interest of laboratories to implement and maintain the most effective biosafety procedures and compliance strategies in order to protect their staff, the public and the environment. These efforts can be maximized with support from laboratory leadership to promote a culture of safety and through education, training, consensus guidelines and adherence to accepted practices and procedures.

### **E. References**

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## **F. Additional References**

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- 15. CLSI M29-A4: Protection of Laboratory Workers From Occupationally Acquired Infections

Recommended Jointly by: The Biosafety/Biosecurity Committee, the Infectious Disease Committee and the Public Health Preparedness and Response Committee Approved by Board of Directors for Interim Use: October 2015, Approved by Membership: November 2015, Sunset Date: November 2020

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