

Improving Biosafety in Our Nation's Laboratories

APHL POSITION STATEMENT



Statement of Position

APHL urges laboratories in the United States to enhance their biosafety practices by implementing routine risk assessments, identifying best practices and standardized training, developing consensus standards and guidelines, and improving reporting of exposure events.

Recommended by: **APHL Biosafety and Biosecurity Committee**

Approved by Board of Directors: **May 2022**

Approved by Membership: **June 2022**

Sunset Date: **June 2027**

Contact: **Peter Kyriacopoulos**, Chief Policy Officer
(240.485.2766 or peter.kyriacopoulos@aphl.org)

Background

Major strides in improving laboratory biosafety have occurred in recent years¹, but ongoing reports of exposures to biological agents^{2, 3} make it clear that there are still laboratories in the US with inadequate biosafety practices in place and gaps in funding. For example, funding from the US Centers for Disease Control and Prevention (CDC) has allowed collaborations with state and local public health agencies to strengthen healthcare infection control practices and enhance laboratory biosafety and biosecurity practices; however, more needs to be done. APHL strongly supports the expansion of efforts to improve and enhance biosafety practices in all US laboratories such as private clinical and diagnostic, public health including agricultural and food testing labs, research and academic laboratories through education, training, guidelines and incorporation of quality management practices.

Assessing the Burden of Risk in Laboratories

A critical step towards enhancing biosafety practices is an accurate measurement of laboratory exposures and laboratory-acquired infections. The lack of reporting requirements and mechanisms likely has led to an underestimation of incidents, so the actual number of exposures and laboratory-acquired infections is unknown.

While the Federal Select Agent Program requires reporting of exposure events, there is no way to ensure compliance for non-select agents. In addition, this mechanism does not capture exposures or laboratory-acquired infections in laboratories that do not work with or encounter select agents. Alternatively, a national publicly accessible, non-punitive mechanism to report exposure events and laboratory-acquired infections would allow a more accurate number of incidents to be documented and analyzed.

Development of Standard and Practices

Current biosafety standards of practice followed by laboratory professionals^{4, 5, 6} are subject to interpretation, as they do not define mechanical, physical and operational standards, and lack mechanisms to objectively and consistently apply the standards. Many of the guidelines and recommendations are not data driven science-based conclusions. Consequently, while laboratories in the US adhere to biosafety guidelines, there is extreme variability in the physical and mechanical plans and the operational procedures that support them. Laboratory staff and laboratory leadership compliance with plans and procedures is also inconsistent, and turnover requires additional diligence to maintain these competencies. To ensure greater consistency and compliance, it is essential to develop overarching consensus standards for the construction, commissioning, maintenance, and operational processes and procedures for handling infectious and potentially infectious agents and implement strategies to enforce these standards.

Implementation of Routine Risk Assessments and Training Programs

Due to the diversity of laboratory activities—which range from routine clinical testing to unique research—it is critical for laboratories to conduct site- and procedure-specific risk assessments. [Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories](#)⁷ describes the knowledge and skills needed to avoid exposure when working with microorganisms. This document outlines how to develop biosafety training resources and includes templates for laboratorians handling infectious agents. Using these guidelines as a resource while conducting risk assessments and developing training programs is highly encouraged in any laboratory.

Data on laboratory-acquired infections and best practices research is decades old, and many current biosafety recommendations are based on opinion and/or perceived risk based on a limited number of documented infections

instead of concrete data. Additional data collection and applied research are needed to guide the development and implementation of biosafety guidelines and best practices. When emerging biological threats are discovered, it takes time to generate data on the safety risks of working with them in the laboratory. As new data on biosafety practices become available, procedures should be updated and new risk assessments performed.

APHL's Recommendations

Clinical Laboratories

- Engage laboratory directors and other laboratory leadership to support a culture of safety.
- Continue to conduct written risk assessments and utilize written standard operating procedures for laboratory testing.
- Utilize public health laboratories as a biosafety subject matter expert/resource.
- Leadership must provide resources for biosafety programs and support for biosafety management, and furthermore must serve as a model for compliance with biosafety policies, procedures, and best practices.

CDC

- Increase funding opportunities (e.g., Epidemiology and Laboratory Capacity for Prevention and Control of Emerging Infectious Diseases (ELC), Public Health Emergency Preparedness (PHEP)) for public health laboratories to sustain biosafety programs.
- Support the development of standardized tools and training for laboratories to help implement biosafety guidelines, such as biosafety checklists and risk assessment templates.
- Provide expertise based on data driven science and to those working to improve laboratory biosafety practices.
- Collaborate with national stakeholders to assist in the review and implementation of best biosafety practices.
- Encourage the implementation and use of biosafety competencies and assess laboratory awareness and understanding of the biosafety competencies.
- Develop a national reporting system for exposure events and laboratory-acquired infections to support best biosafety practices.

Public Health Laboratories

- Engage laboratory directors and other laboratory leadership to support a culture of safety.
- Develop and maintain subject matter expertise and resources to improve biosafety policies and procedures.
- Leadership must provide resources for biosafety programs and support for biosafety management, and furthermore must set a precedent for complying with biosafety policies, procedures, and best practices.
- Provide outreach and training to other laboratories within their jurisdictions that would benefit from implementing biosafety practices and guidelines.
- Collaborate with CDC to educate the public about the principles of biosafety practices used in laboratories to protect laboratory workers, the public and the environment.
- Communicate the need for biosafety practices and funding to key federal, state, local and other policy makers.

US Centers for Medicare and Medicaid Services (CMS)

- Establish Clinical Laboratory Improvement Amendments (CLIA) standards that address biosafety practices and competencies.

US Food and Drug Administration (FDA)

- Support collaboration between manufacturers and federal agencies to improve product design of instrumentation and testing processes, including decontamination procedures to enhance safety in the laboratory.

Occupational Safety and Health Administration (OSHA)

- Update the current Bloodborne Pathogens Standard to include other infectious agents or implement an Infectious Diseases Standard.
- Clarify risk hazard sections in OSHA standards to include biohazardous agents.

References

1. Health Security (2019, October). Building Biosafety Capacity in Our Nation's Laboratories. Retrieved July 9, 2021 from: <https://www.liebertpub.com/doi/pdf/10.1089/hs.2019.0056>
2. Journal of Clinical Microbiology (2020, February). Brucella Exposure Risk Events in 10 Clinical Laboratories, New York City, USA, 2015 to 2017. Retrieved February 1, 2021 from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6989065/pdf/JCM.01096-19.pdf>
3. Emerging Infectious Diseases (2020, July). Laboratory-Acquired Dengue Virus Infection, United States, 2018. Retrieved March 1, 2021 from: https://wwwnc.cdc.gov/eid/article/26/7/19-1598_article
4. US Centers for Disease Control and Prevention (2012, January). Guidelines for Safe Work Practice in Human and Animal Medical Diagnostic Laboratories: Recommendations of a CDC-convened Biosafety Blue Ribbon Panel. Retrieved November 10, 2014, from: <https://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
5. US Department of Health and Human Services (Washington, D.C., 2020) Biosafety in Microbiological and Biomedical Laboratories, 6th ed. Retrieved February 1, 2021 from: https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf
6. US Department of Health and Human Services (Washington, D.C., 2019) NIH Guidelines for Research Involving Recombinant DNA Molecules. Retrieved February 1, 2021 from: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
7. US Centers for Disease Control and Prevention (2014, May). Competency Guidelines for Public Health Laboratory Professionals: CDC and the Association of Public Health Laboratories. Retrieved July 16, 2015 from <https://www.cdc.gov/mmwr/preview/mmwrhtml/su6401a1.htm>

Additional Resources

1. Sewell D. (1995, July). Laboratory-Associated Infections and Biosafety. Clinical Microbiology Reviews. 8:389-405. Retrieved December 12, 2014 from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC174631/>
2. US Government Accountability Office (2017, October). High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens. (Publication No. GAO-18-145). Retrieved March 1, 2021, from GAO Reports: Main Page via GPO Access: <https://www.gao.gov/assets/690/687868.pdf>
3. Centers for Disease Control and Prevention (2021, September). 2020 Annual Report of the Federal Select Agent Program. Retrieved November 1, 2021 from https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf
4. US Government Accountability Office (2016, March). High Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety. (Publication No. Gao-16-305). Retrieved March 1, 2021 from: <https://www.gao.gov/assets/680/675925.pdf>
5. The White House. (2014, September). Enhancing Biosafety and Biosecurity in the United States. Retrieved December 8, 2014 from <https://obamawhitehouse.archives.gov/blog/2014/12/16/enhancing-biosafety-and-biosecurity-united-states>
6. Food and Drug Administration (2017, March). Biosafety and Biosecurity Framework. Retrieved March 1, 2021 from <https://www.fda.gov/media/116875/download>
7. International Organization for Standardization (2019, November). ISO 35001:2019 Biorisk management for laboratories and other related organisations. Retrieved November 1, 2021 from <https://www.iso.org/standard/71293.html>

8. Association of Public Health Laboratories (2019, February). Biosafety Practices and Needs in Clinical Laboratories Survey Summary Data Report. Retrieved February 20, 2019 from <https://www.aphl.org/programs/preparedness/Documents/Clinical-Lab-Biosafety-Practices-Survey-Data-Report.pdf>
9. Occupational Safety and Health Administration (2019, May). Occupational Safety and Health Standards. Retrieved November 1, 2021 from <https://www.osha.gov/laboratories/standards>
10. The Conversation (2021, October). Reporting all biosafety errors could improve labs worldwide – and increase public trust in biological research. Retrieved November 1, 2021 from <https://theconversation.com/reporting-all-biosafety-errors-could-improve-labs-worldwide-and-increase-public-trust-in-biological-research-168552>
11. Occupational Safety and Health Administration (2011, June). Respiratory Protection. Retrieved December 1, 2021 from <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134>