



Center for Surveillance, Epidemiology, and Laboratory Services

Laboratory Safety Updates

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U.S. Department of
Health and Human Services
Centers for Disease
Control and Prevention

Four DLS Goal Areas

Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care



Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories



Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance



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Safe and Prepared Laboratories



Background: CLIAC Recommendations

CLIAC has issued five recommendations that address safety:

February 2001

Wild poliovirus
containment

April 2015

Emerging
infections

April 2016

Biosafety in
clinical
laboratories:
an unmet
national need

November 2016

Laboratory-
associated
incident
reporting
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November 2019

Laboratory
workforce:
safety included

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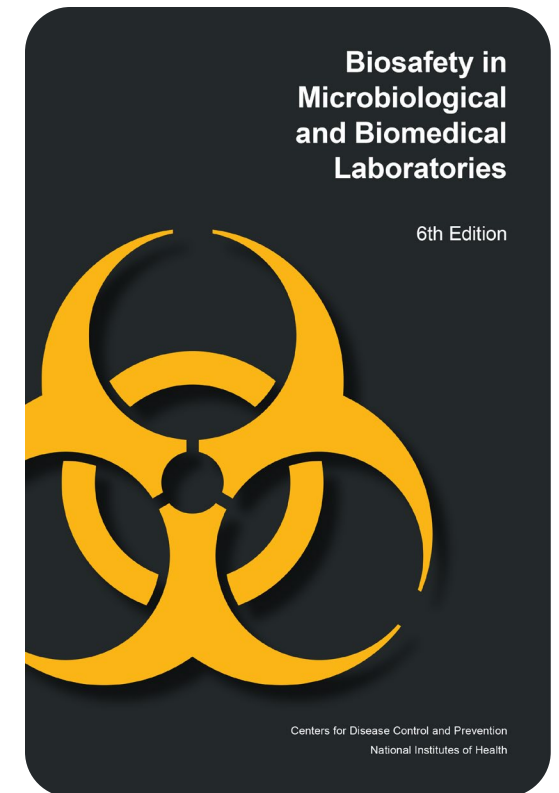
Laboratory
workforce:
safety included

CLIAC Recommendation: April 2016

CLIAC RECOMMENDATION	STATUS
<p>CLIAC considers the matter of biosafety in clinical laboratories as an urgent, unmet, national need. We, therefore, recommend that CDC convene a multidisciplinary task force to develop a biosafety strategy for clinical laboratories that:</p> <ul style="list-style-type: none">• Includes stakeholders from all areas of clinical laboratories (including professional societies), diagnostic instrumentation industry, other relevant Federal agencies, and patient/clinician representatives.• Recommends areas requiring further research in clinical laboratory safety.• Develops tools, templates, and guidelines for risk assessment in all areas of the clinical laboratories, both for routine operations and emerging infectious diseases.• Publishes interim materials and progress reports broadly, and specifically to CLIAC, to inform and to solicit input from the clinical laboratory and broader medical communities.• Describes cultural, regulatory, measurement, and evaluation strategies for goal achievement in biosafety.• Develops a framework for the implementation of good clinical practices that also addresses transparent evaluation and monitoring of biosafety practices.	<div data-bbox="1946 522 2142 711" data-label="Image"></div> <p>CDC updated CLIAC during the November 1-2, 2019 meeting.</p> <p>An update to progress from November 2016 until September 2019 can be found at: https://www.cdc.gov/cliac/docs/fall-2019/CLIAC-April-13-2016-Biosafety-Update_09232019.pdf.</p>

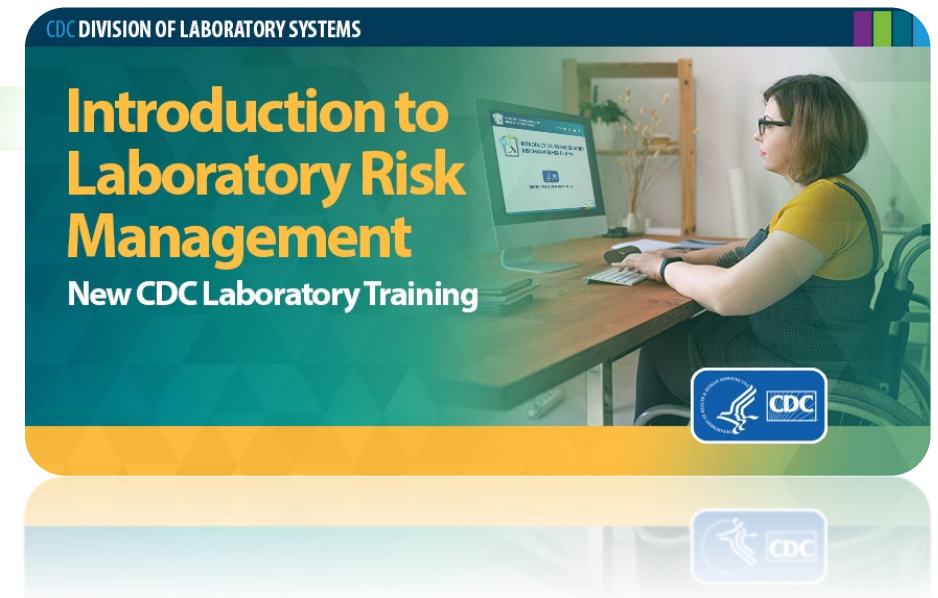
CLIAC Safety Recommendations: Accomplishments

- CDC updated the CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition ”
 - Provides guidance on risk assessment and safe work practices
 - 6th Edition of the BMBL includes new sections written by DLS staff
 - Section III – Principles of Biosafety
 - Appendix N – Clinical Laboratories
 - Addresses the risks unique to clinical laboratories, including how to assess and mitigate risks when the infectious agent is unknown
- Developed and presented live courses for the American Biological Safety Association International Annual Biosafety and Biosecurity Conference
 - Risk Management for Clinical Laboratories
 - Biological Risk Assessment



CLIAC Safety Recommendations: Accomplishments

- DLS staff served as subject matter experts for the development of e-Learning courses for clinical and public health laboratories
 - Including Risk Assessment for Clinical Laboratories
 - Introduction to Laboratory Risk Management eLearning course
 - LabTrainingVR: Personal Protective Equipment Edition
- Other CDC trainings disseminated for external audiences
 - Use of methylene chloride
 - Safe handling of gas cylinders



CLIAC Safety Recommendations: Accomplishments

- DLS reactivated the Laboratory Outreach Communication System (LOCS) to distribute information to clinical laboratory organizations, public health laboratories, and private reference laboratories
- **LOCS facilitates information** exchange between CDC and the laboratory community
 - Over 104,000 subscribers
 - 23% average open rate (MMWR: 29% open rate)
- DLS proposed the development of a new Clinical and Laboratory Standards Institute (CLSI) guideline document on **Decontamination of Laboratory Equipment and Instrumentation** (QMS27)



Biosafety Gaps Manuscript

- Manuscript in Clinical Microbiology Reviews, published collaboratively with external partners
- Describes the biosafety gaps identified during an infectious disease outbreak and the need for future efforts



Cornish NE, et al. Clinical Laboratory Biosafety Gaps: Lessons Learned from Past Outbreaks Reveal a Path to a Safer Future. Clinical Microbiology Reviews. 2021 Jun 9;34(3):e00126-18.

Biosafety Gaps Manuscript: Next Steps

DLS and FDA will collaborate on efforts to improve instrument biosafety

Cornish et al.'s publication identified many gaps, including related to instrument biosafety

In response, CDC and FDA intend to collaborate on efforts to identify opportunities to address improvements

COVID-19 Response Highlights

Accomplishments:

Provided timely laboratory biosafety expertise to support the CDC Laboratory and Testing Task Force

Drafted guidance documents, web pages, and FAQs

Answered biosafety related questions submitted by public health and clinical laboratory partners



- 3 COVID-19 biosafety guidance web pages created



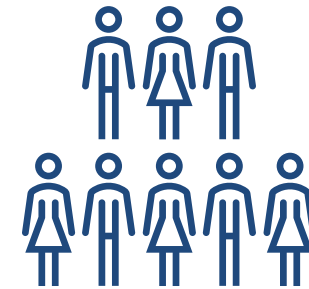
- Over 250 biosafety inquiries addressed



- 21 Frequently asked questions developed

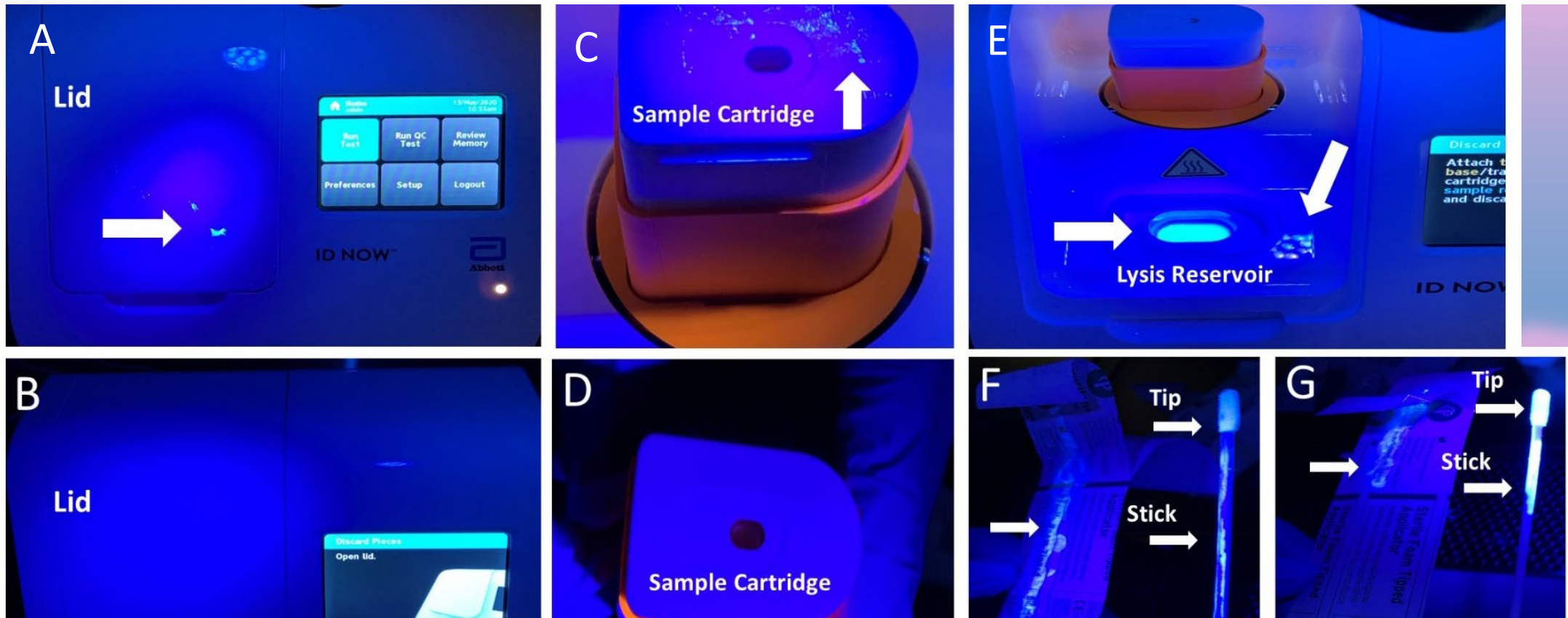
COVID-19 Response Highlights

- DLS staff contributed extensively to the COVID-19 Response
- Biosafety-related accomplishments
 - Staff field deployments to Atlanta, New York, and Texas to support:
 - HHS Office of Refugee Resettlement
 - CDC COVID-19 Laboratory and Testing Task Force
 - PROTECT Study
- Onsite consultations with testing staff resulted in improved safety practices
 - Waste handling and multi-patient testing workflows



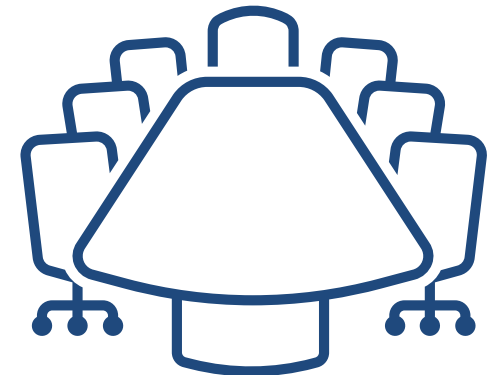
Abbott ID NOW Workflow Risk Assessment (NYC)

COVID-19 Response Highlights



APHL Collaboration

- DLS staff serve on the Association of Public Health Laboratories' Biosafety and Biosecurity Committee
 - Develop guidance, checklists, job aids, and templates to assist clinical and public health laboratories in conducting risk assessments
 - Documents can be found at
 - <https://www.cdc.gov/safelabs/resources-tools.html>
 - [Strengthening Lab Biosafety & Biosecurity \(aphl.org\)](http://aphl.org)
- New projects:
 - Biosafety Preparedness for Non-Traditional Testing Sites
 - ISO 35001 Implementation



Biosafety Preparedness for Non-Traditional Testing Sites

- DLS and APHL will develop and provide risk assessment and biosafety training and education materials for non-traditional testing sites
 - Non-traditional sites are often selected as locations to deploy Point-of-Care (POC) testing technologies since a traditional laboratory is not required to conduct POC tests
- Once developed, the training materials will be adapted and shared more broadly

Development of new training materials focused on non-traditional testing site needs will enable staff to safely perform these tests and respond rapidly to emerging threats

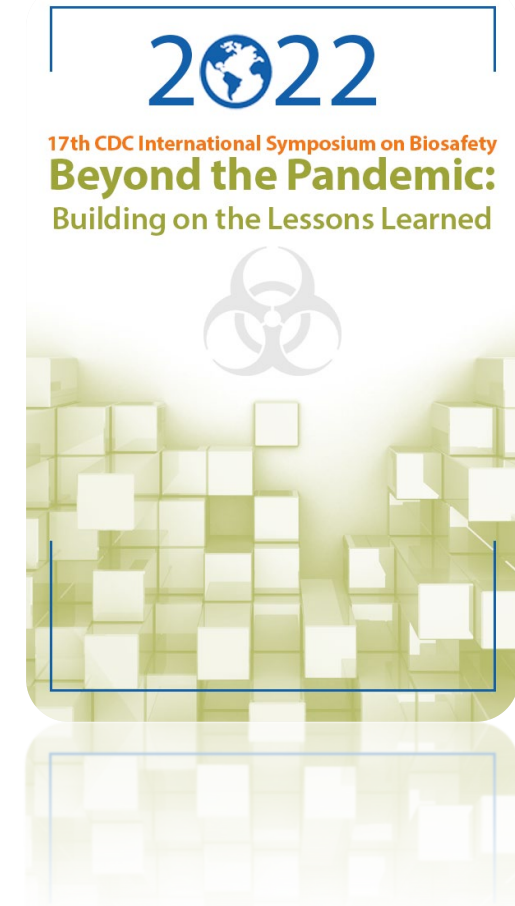
ISO 35001 Implementation in Public Health Laboratories

- **Purpose:** Develop a strategy, provide guidance, and support the implementation and use of a biorisk management system in accordance with ISO 35001:2019 *Biorisk management for laboratories and other related organizations*
- **Expected Results:** Implementation of ISO 35001 in public health laboratories helps facilities improve their internal processes to reduce incidents, accidents, infections, and illnesses that may result from laboratory operations



Biosafety Symposium

- August 27-31, 2022
 - Pre-conference course highlights
 - *Challenges of Biosafety Program Management*
 - *Interactive Decontamination Experience*
 - Program highlights
 - *Lessons from the U.S. COVID-19 Response*
 - *The Changed Workplace*
 - *Did Existing Preparedness Plans Work?*
- [CDC International Biosafety Symposium - The Eagleson Institute](#)

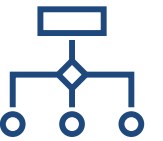


Summary



Laboratory safety is fundamental to clinical laboratories and laboratory medicine

- Strategies to improve laboratory safety rely on continuous engagement with professional organizations and other stakeholders
- CLIAC recommendations provide a guide for leveraging clinical laboratory engagement



Summary

- DLS enables and supports collaborations with federal partners and other stakeholders to exchange information about laboratory safety best practices
- DLS supports CLIAC as they address issues that have faced the national laboratory and healthcare communities for more than 20 years
- DLS is committed to develop safety guidelines and training resources for clinical and public health laboratories

Thank you!

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For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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