OneLab™

A Unified Response to Training Needs

BMBL 6th Edition Updates: Clinical Laboratory Biosafety Recommendations

August 27th, 2025

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- BMBL 6th Edition Updates: Clinical Laboratory Biosafety Recommendations
- Q&A
- Upcoming Events

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Please keep the following in mind when using the chat feature:

- **Connect with others!** React to what you're hearing, share experiences, and ask questions of your fellow participants!
- **Have a question for the presenter?** Use the Q&A function, *not* the chat.
- **Show Respect and Professionalism**. Inappropriate language, improper conduct, or any form of discrimination may result in removal from the webinar.
- **Remain on Topic**. Ensure your comments are relevant to the topic.
- **Comply with Moderators' Guidance**. If a moderator gives direction regarding chat behavior, please comply accordingly.
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Featured Resource

Favorites

CE:
1.0 Contact Hour(s)
P.A.C.E.®

Duration:
1.0 Hour

Launch Course

Disclaimers

Introduction to Laboratory Risk Management (LRM)

Description

Introduction to Laboratory Risk Management (LRM) is the first in a series of courses focused on developing risk management strategies for laboratory settings. This basic level eLearning course provides details on applying risk management principles and briefly describes related practices to emphasize the importance of risk management in laboratory settings. Topics covered include risk management goals, terminology, processes, and associated activities.

Audience

This online course is designed for new or existing public health and clinical laboratory professionals who handle potentially hazardous materials.

Accessibility

Course content is closed captioned, where applicable, and optimized for a screen reader.

Objectives

Disclaimer

Subject matter experts and presenters wish to disclose they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Today's Presenter

Nancy E. Cornish, M.D.

Medical Officer,
Division of Laboratory Systems
Centers for Disease Control and Prevention (CDC)

Clinical Laboratory Biosafety Recommendations: Why Follow Standard Precautions?

Nancy E. Cornish
Medical Officer and Senior Advisor for Quality and Safety
Office of Laboratory Systems and Response, Division of Laboratory Systems
August 27, 2025, OneLab Reach

Objectives

1. Present hospitalization history of recent patient with unsuspected Lassa fever and how it affected the clinical laboratories handling the specimens for testing
2. Review BMBL Appendix N which addresses the needs of clinical laboratory biosafety and understand how they differ from research laboratories
3. Apply lessons learned from the Lassa fever case to all areas of the clinical laboratory.

Viral Hemorrhagic Fever (VHF) Case, 2024

- Patient with an unsuspected VHF seen at 3 institutions and specimens for testing was sent to 3 additional institutions for testing before diagnosis was suspected and confirmed.
- Lassa fever is a VHF endemic to western Africa. Before 2024, eight travel-associated cases had been identified in the United States.
- Investigation identified 180 contacts. Lassa fever virus testing was performed for five symptomatic contacts; all laboratory results were negative.

Notes from the Field: Response to a Case of Travel-Associated Lassa Fever — Iowa, October–November 2024 | MMWR

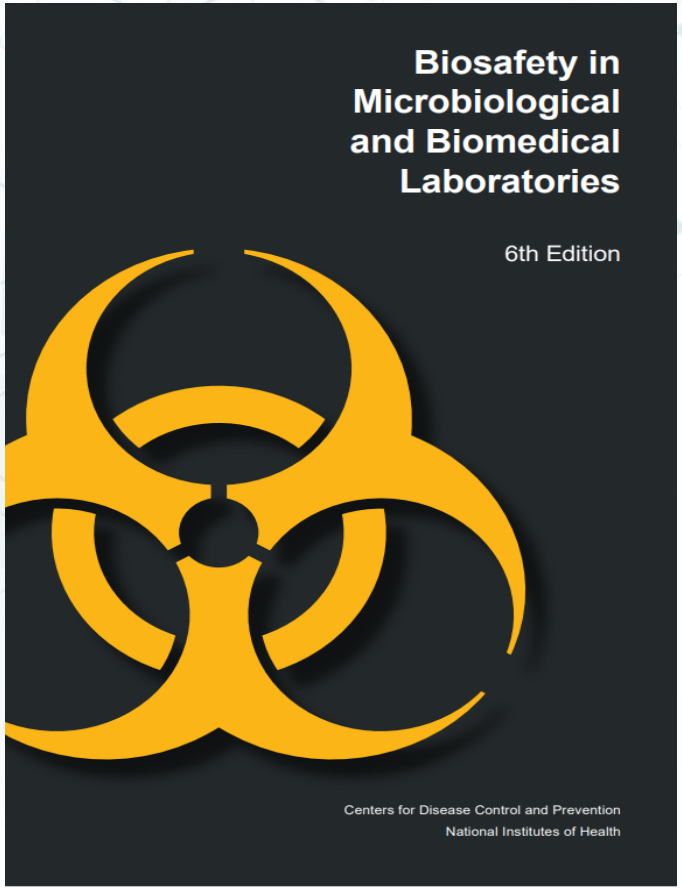
Viral Hemorrhagic Fever (VHF) Case, 2024 (continued)

- 180 contacts, 172 (96%) were health care–associated
  - Level of risk was determined using personal protective equipment (PPE)
- Laboratorians were evaluated based on activities performed and the use of appropriate PPE;
  - 34 contacts were identified across six laboratories; 23 (68%) of these were classified as high-risk and were excluded from work for 21 days, based on published recommendations for biosafety in microbiological and biomedical laboratories (BMBL-Appendix N)
  - The exposures mainly occurred in the *core laboratories,* but molecular and other areas of the laboratory had gaps as well.

Viral Hemorrhagic Fever (VHF) Case, 2024 (continued)

- 105 high-risk contacts without contraindications were offered oral ribavirin postexposure prophylaxis
- 5 contacts began prophylaxis, 4 stopped because of adverse reactions (e.g., nausea), and 1 completed the 10-day course
- 158 contacts were monitored for illness, and 5 had signs and symptoms potentially consistent with Lassa fever and were transported to a hospital under VHF precautions for evaluation and testing, all test results were negative
  - Lassa Fever
  - Viral Hemorrhagic Fevers

Clinical Laboratories and Biosafety



Appendix N—Clinical Laboratories

—Developed to address the clinical laboratories needs as critical responders and one of the first lines of public health defense

—Safe and effective operation of clinical laboratories is critical for patients, laboratory professionals, community and environment

Biosafety in Microbiological and Biomedical Laboratories—6th Edition

A Few More Cautionary Tales

Risk beyond clinical microbiology lab…

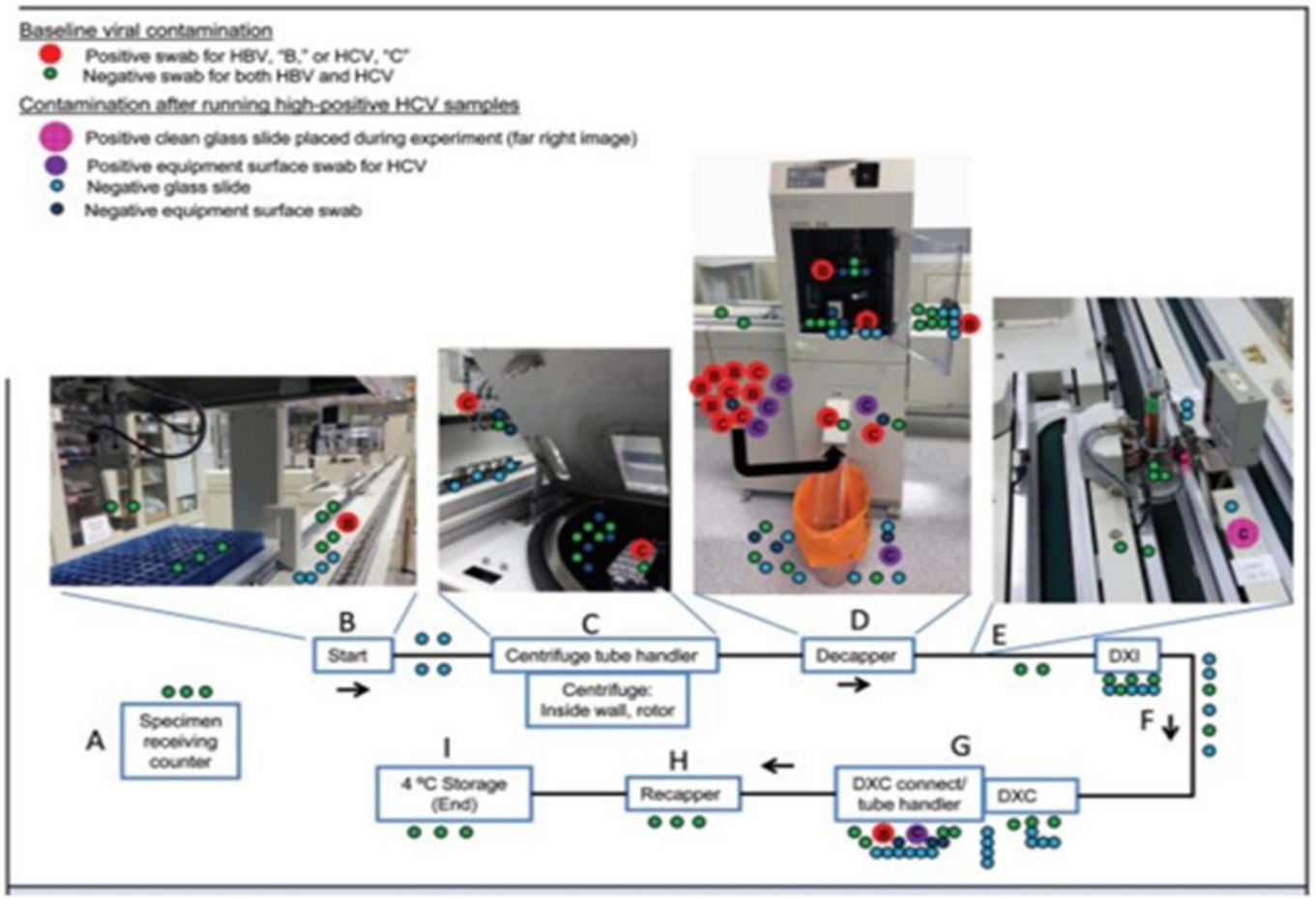
Clinical Chemistry 62:7
973-981 (2016)

Infectious Disease

Bloodborne Viral Pathogen Contamination in the Era of Laboratory Automation

Andrew Bryan,[1*] Linda Cook,[1] Ederlyn E. Atienza,[1] Jane Kuypers,[1] Anne Cent,[1] Geoffrey S. Baird,[1] Robert W. Coombs,[1,2] Keith R. Jerome,[1,3] Mark H. Wener,[1,2] and Susan M. Butler-Wu[4]

- Chemistry and hematology use complex analyzers with multiples sampling stations, aliquoting events and waste pathways
  - Perform open-tube sampling
  - Require frequent maintenance
  - Multiple interaction points with both sample and users



Risk Assessment?

Cryostats: Frozen Sections

Fresh tissues may contain:

- HIV, Hep B &C
- Tuberculosis
- Prion Diseases
- Mycobacterial Diseases
- Systemic Fungal Diseases
- Viral Hemorrhagic Fevers

Safety Precautions:

- *Verify the potential of infectious diseases before handl*
- *Freezing sprays (can aerosolize small particles of tissue*

* From one package insert- this may not possible or timely

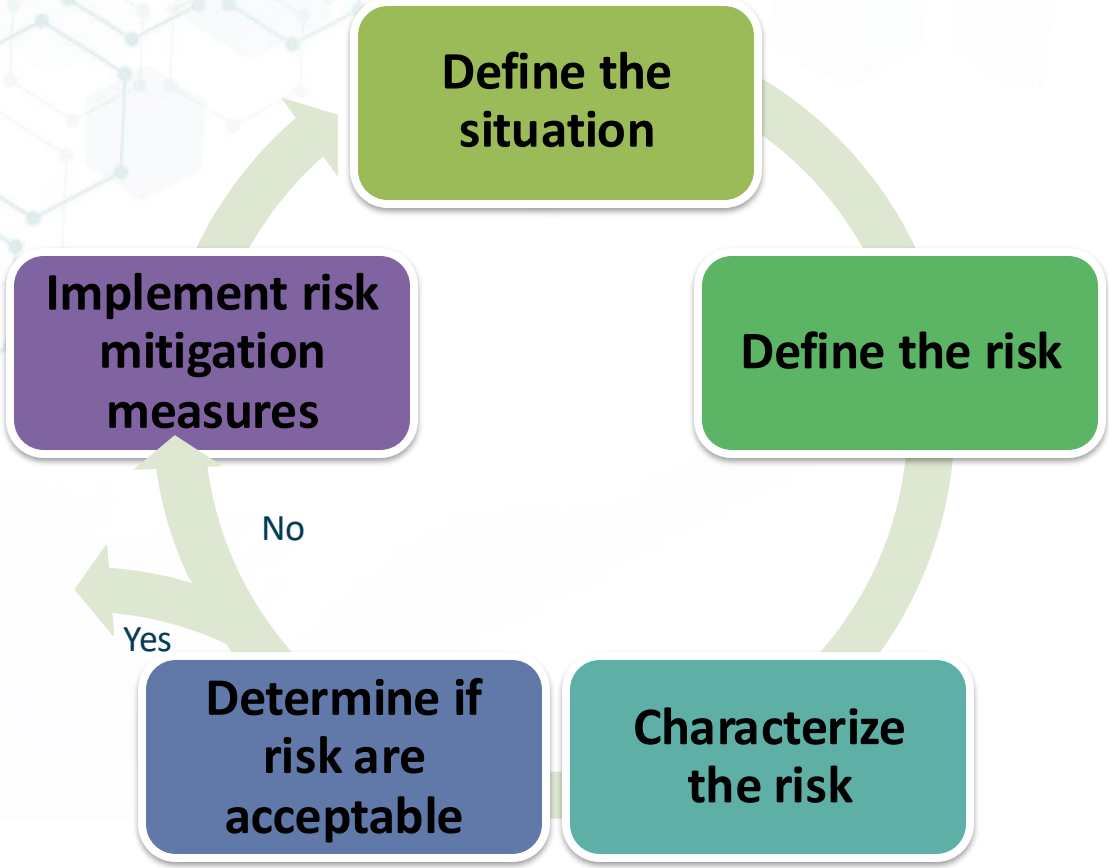
Surgical Pathology Grossing Stations

- Exhaust duct to connect to the building ventilation system to remove formalin fumes
- Faucet for water to rinse cutting boards
- Foot-operated controls for hot and cold water
- Spray hose attachment
- Light fixtures so you can see what you are doing
- Instrument holder, magnetic (may be available or not)

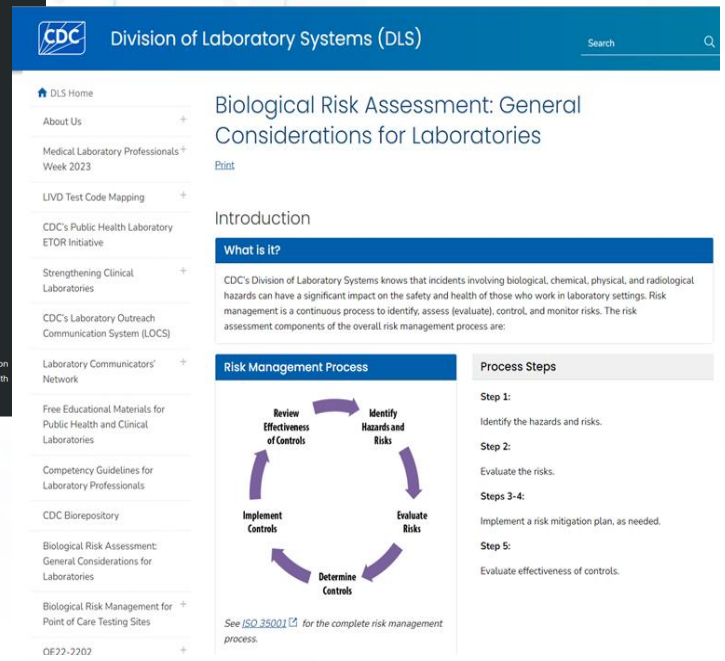
Conducting Risk Assessments - Key in Clinical Laboratories

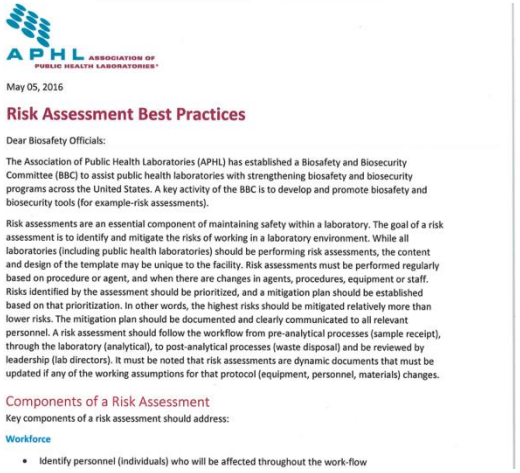
- Foundation of Bio-Risk Management (BMR)
  - Biological Risk Assessment | Safe Labs Portal | CDC
  - APHL Risk Assessment Best Practices and Examples.pdf
  - APHL-Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing.pdf
  - Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition | CDC Laboratories
    - Section II -Biological Risk Assessment (page 9)
  - Risk Assessment for Clinical Laboratories | Safe Labs Portal | CDC ECHO Session

How to Conduct a Risk Assessment



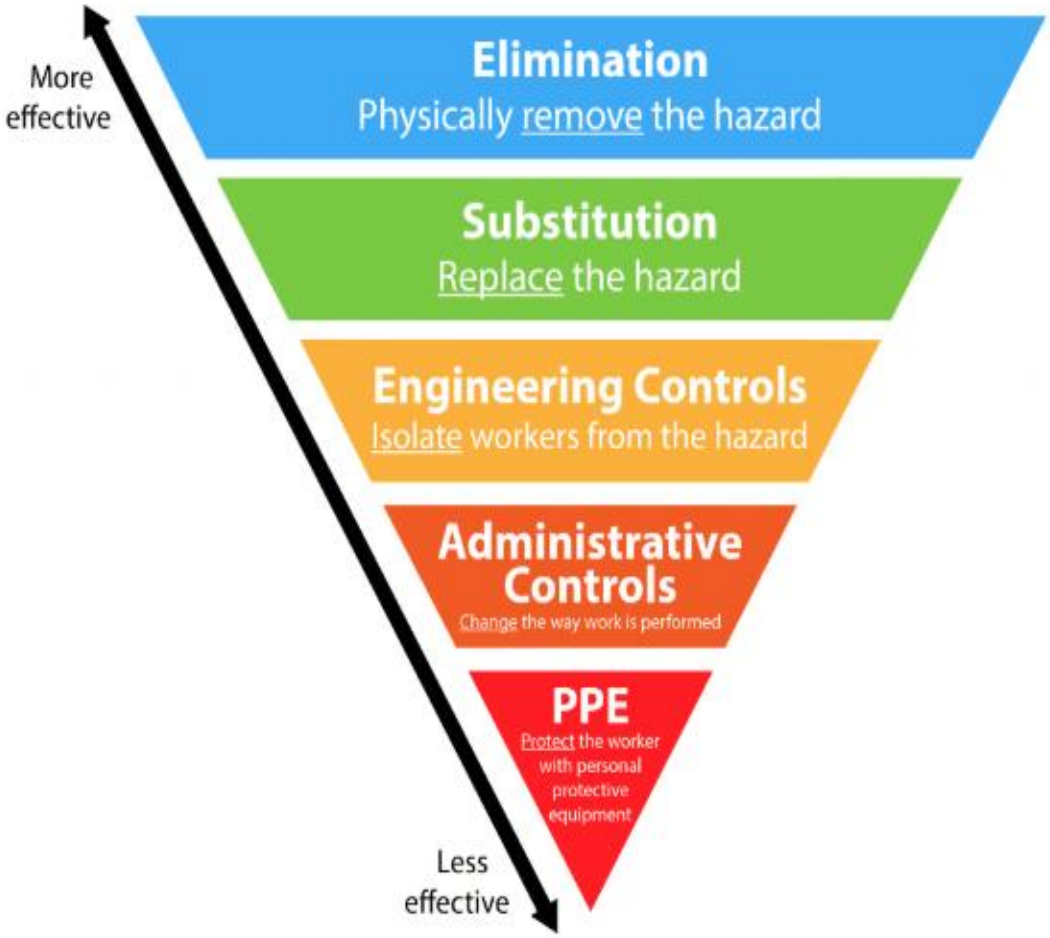
Risk Assessments Resources





[DLS Safe Labs | Safe Labs Portal | CDC]

Biosafety Considerations



Source: NIOSH

Engineering Controls	• Reduce hazards and provide barriers • Biosafety cabinets, sharp containers, shields
Administrative Controls	• Changes to work practices • Written Standard Operating Procedures
Personal Protective Equipment	• PPE is equipment worn to minimize exposure to hazards • Gloves, safety glasses, face shields, masks, respirators
Waste Management	• All clinical specimens may contain potentially infectious agents or organisms

Mitigation Resources: BMBL Appendix-N

- Engineering Controls:
  - Engineering Controls can reduce hazardous conditions or place a barrier between professional and hazard
  - Barriers commonly used are Class II BSCs
    - sharps containers, centrifuge safety cups, removable rotors, *splash shields,* directional inward airflow into the laboratory, closed automation systems
  - When engineering controls are not possible, include alternative containment devices such as:
    - Enclosed workstation in combination with additional work practices and/or enhanced PPE

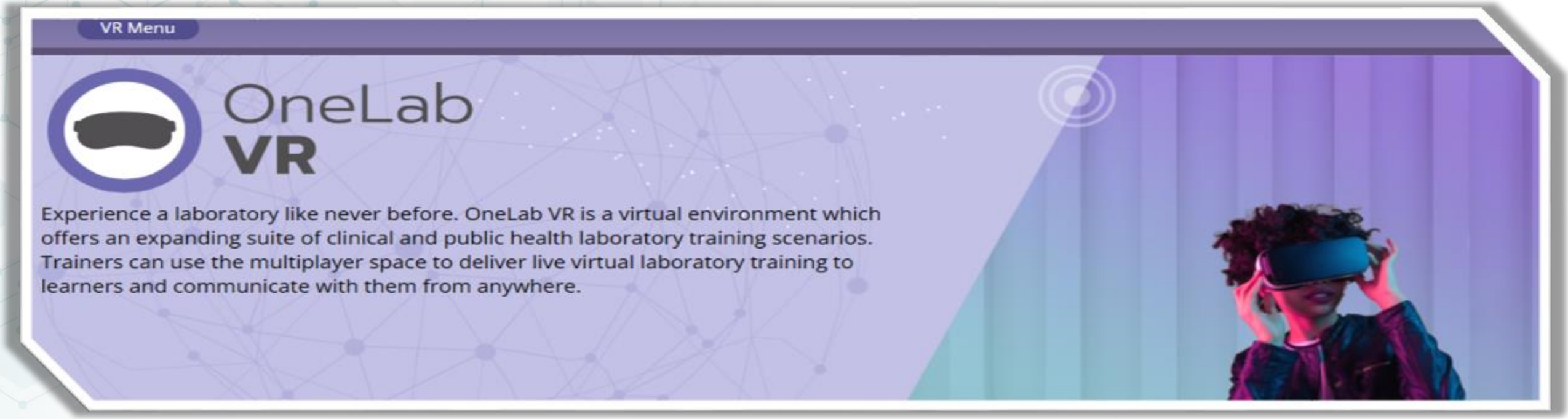
Biosafety Cabinets Resources

- Fundamentals of Working Safely in a Biological Safety Cabinet (BSC) | OneLab REACH
- LabTrainingVR: Biological Safety Cabinet Edition | OneLab REACH
- OneLab VR: Tutorial Scenario | OneLab REACH

Mitigation Resources: BMBL Appendix-N (continued)

- Administrative Controls, examples
  - Active medical surveillance program
  - Occupational health program
  - Immunizations (e.g., Hep B and N. meningitis)
  - Written Standard Operating Procedures
- Work Practice Controls, examples
  - Frequent handwashing
  - Safer sharps (e.g., self-sheathing needles and needless systems)
  - Routinely decontaminating work surfaces
  - Using biosafety cabinets appropriately
  - Using PPE routinely to protect eyes, nose, and mouth when working with blood and body fluids (Standard Precautions)

OneLab Reach Virtual Reality Resources



- 50,000 square foot virtual Laboratory created for clinical and public health laboratory training
- 100+ pieces of laboratory equipment
- 10-to-15-minute training scenarios

[OneLab VR | OneLab REACH]

Personal Protective Equipment

- Trainings- Donning and Doffing
  - Donning and Doffing PPE in Clinical Laboratories: Basic PPE for Routine Laboratory Procedures
- Other Trainings
  - Fundamentals of Personal Protective Equipment (PPE) in Clinical Laboratories | OneLab REACH
  - Fundamentals of Bloodborne Pathogens | OneLab REACH
  - Fundamentals of Laboratory Safety | OneLab REACH
  - Biosafety Trainings | Safe Labs Portal | CDC

Waste Management

- Trainings:
  - Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know | OneLab REACH
  - OneLab VR: Packing and Shipping Dangerous Goods | OneLab REACH
- ECHO session
  - Medical Waste Management | Safe Labs Portal | CDC

Laboratory Acquired Infections (LAIs)

- **Mycobacterium tuberculosis** lab personnel three to nine times more likely than the general population to get infected

  Reid DD. Incidence of tuberculosis among workers in laboratories. Br Med J 1957;2:10–14.

- **Hepatitis B** most frequent laboratory-acquired viral infection, with rate of 3.5–4.6 cases per 1000 workers, two to four times that of the general population. **Any Laboratorian who collects or handles tubes of blood is vulnerable.**

  Sewell, DL, Clinical Microbiology Reviews, July 1995, p. 389–405

- ***Neisseria meningitidis*** attack rate 30–59 yrs was 0.3 per 100,000; attack rate for microbiologists (30–59 yrs) was 20/100,000; lab personnel were 20 times more likely to get the disease than the general population

  Baron, EJ et al, Bacterial and Fungal Infections among diagnostic laboratory workers: evaluating the risks, Vol. 60, 3, March 2008, Pages 241-246

Clinical Laboratory Acquired Infections

- No distinguishable exposure events were identified
  - In approximately 80% of LAIs reported before 1978
  - In a 2005 study, 50% of LAIs had no apparent source
- In many cases, the only association was that the infected person worked with a microbiological agent or was in the vicinity of a person handling a microbiological agent.
  - Data suggest that **unsuspected infectious aerosols** can play a large role in LAIs

Pike RM. Laboratory-associated infections: incidence, fatalities, causes, and prevention. Annu Rev Microbiol 1979;33:41–66

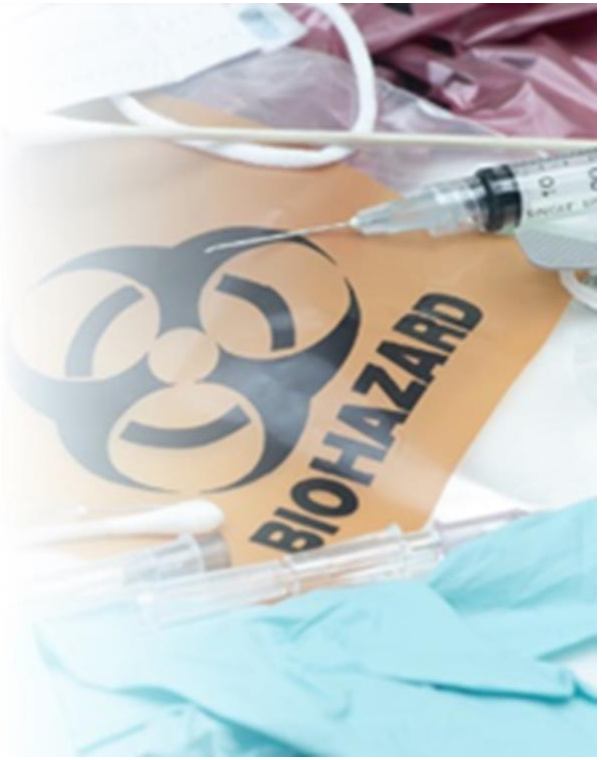
CDC Division of Regulatory Science and Compliance

- **The Federal Select Agent Program (FSAP)**
  - Monitors occupational exposures to 68 select agents (e.g., *Brucella*, *Francisella*, *Yersinia pestis*, others)
  - Submitted reports from ***clinical laboratories*** in 2021
    - 103 reports
    - 102 reports associated with work outside primary containment
    - 551 exposures resulted
  - Root causes included not following training on existing policy and a lack of cross communication with providers

Automated Devices & Reports of Select Agent Release

Chemistry Laboratory Injuries

- Needle puncture (103 cases)
- Glass cuts (44 cases)
- Splash in eye (19 cases
- Bruises and cuts (45 cases)
- Same issues in specimen processing areas



Miller et al. Centers for Disease Control and Prevention (CDC) Guidelines for safe work practices in human and animal medical diagnostic laboratories. Recommendations of a CDC-convened, Biosafety Blue-Ribbon Panel. 2012 MMWR Suppl 61:1–102.

Hematology Laboratory Injuries

- Exposure to blood and body fluids
- Needle sticks
- Aerosols from centrifuges, removal of tube stoppers
- Tube breakage
- Contaminated gloves

Miller et al. Centers for Disease Control and Prevention (CDC) Guidelines for safe work practices in human and animal medical diagnostic laboratories. Recommendations of a CDC-convened, Biosafety Blue-Ribbon Panel. 2012 MMWR Suppl 61:1–102.

Other Areas of the Laboratory

- Specimen processing
- Blood bank
- Immunology testing
- Microbiology
  - Handles culture plates
  - Positive blood culture bottles, loaded with organisms
  - Often working on open benches

Miller et al. Centers for Disease Control and Prevention (CDC) Guidelines for safe work practices in human and animal medical diagnostic laboratories. Recommendations of a CDC-convened, Biosafety Blue-Ribbon Panel. 2012 MMWR Suppl 61:1–102.

Work with Instrument Manufacturers

- Instrument Pre-purchase Risk Assessment APHL *NEW!*
- Recommended by CLIAC Biosafety workgroup Clinical Laboratory Improvement Advisory Committee (CLIAC) November 6-7, 2024 Meeting Summary
- Bloodborne Pathogen Contamination on Laboratory Automation Systems | Clinical Chemistry | Oxford Academic comment from J. Zakowski from Beckman Coulter, Inc. and CLSI
- Can't Touch This! Contamination of Laboratory Equipment with Bloodborne Pathogens | Clinical Chemistry | Oxford Academic

Risk Factors for Laboratory Personnel

- **Who is at risk?**
  - Anyone who handles blood and body fluids
- **Where is the risk?**
  - Aerosols/Droplets can be generated from most routine laboratory procedures often are undetectable
    - Aspirating and transferring body fluids
    - Expelling the last drop from a pipette (all types of pipettes)
    - Centrifugation
    - Withdrawing needles from stoppers, removing stoppers from tubes
    - Pouring, splitting, or decanting liquid specimens
    - Preparing smears, performing heat fixing, and staining slides

National Safety Standards

- **Containment:**
  - Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices be used whenever procedures with a potential for creating infectious aerosols or splashes are conducted, in accordance with nationally recognized safety standards [BMBL: (BSL-2) B4.a, B4.c].

Occupational Safety Health Administration (OSHA)

Bloodborne Pathogens - Worker protections against occupational exposure to infectious diseases | Occupational Safety and Health Administration

- Standard precautions(SP)-1996 CDC, protect healthcare workers not only from pathogens in human blood and certain body fluids, but also pathogens present in other body fluids. SP includes hand hygiene; use of certain types of PPE based on anticipated exposure; safe injection practices; and safe management of contaminated equipment and other items in the patient environment. **SP is applied to *all* patients *(specimens)* even when they are not known or suspected to be infectious.**
- **OSHA proposed rule 1218 title Infectious Disease Standard- supplement the SP with Transmission-Based Precautions (TMP)**

Anatomic Pathology

Engineering Controls and PPE

- Ventilation of rooms: negative pressure rooms with at least 12 air changes per hour, adequate lighting, and surfaces easily disinfected
- Only minimum number of staff that's needed
- Appropriate PPE
  - Scrub suits
  - Head cover or bonnet
  - Long sleeve fluid-resistant gown and an apron
  - Two pairs of gloves to cover cuffs
  - Face shield (preferably) or goggles
  - Mask or N95 or PAPR
  - Booties to cover shoes, leg covers, or tall boots

WHO-COVID-19-lPC_DBMgmt-2020.1-eng.pdf

Stay Safe and Thank you!

Questions?

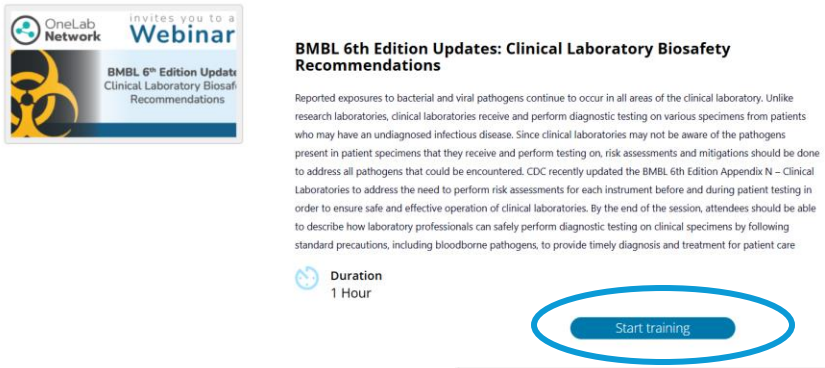
Contact:
DLSinquiries@cdc.gov

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

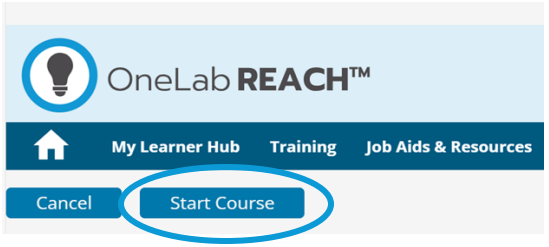
OneLab REACH™ Continuing Education

After participating in today's session, to receive continuing education credits you must:

1. Log into your OneLab REACH account. **You must be logged into your REACH account to access the evaluation.**
2. Click on this link to take you to the survey.
3. Enter passcode "**Z615**"
4. Click "**Start Training**"

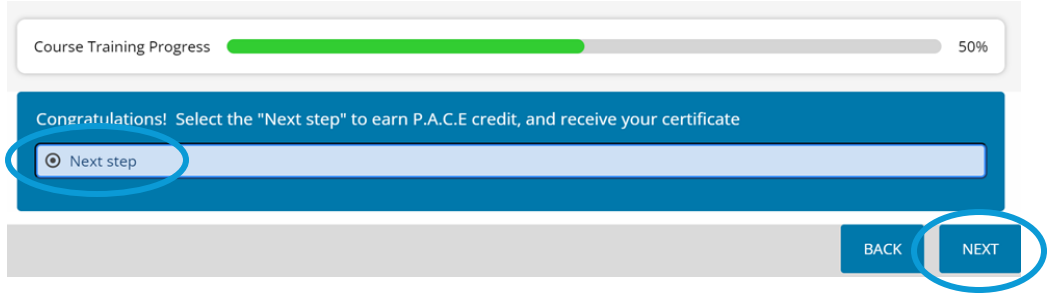


5. Select "**Start Course**".

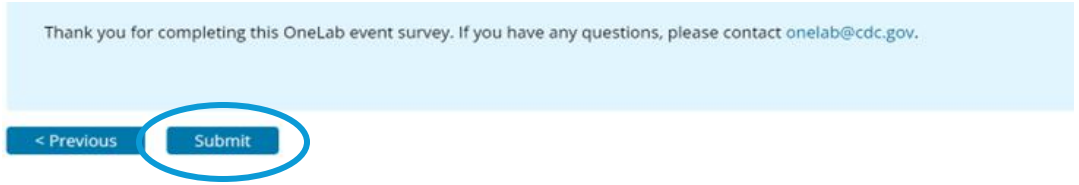


6. Select "**Start**".

7. Select "**Next step**" and "**Next**".



8. Complete the evaluation and click "**Submit**". Receive your P.A.C.E.® certificate in your MyLearnerHub.



Upcoming Event!

Introduction to Laboratory Director University (LDU)

September 24th, 2025
2:00 p.m. ET

Registration link is forthcoming

OneLab **Assessments**

Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov