OneLab™

A Unified Response to Training Needs

ISO 35001:2019 Biorisk Management for Laboratories

August 5, 2024

Agenda

- Introduction
  - *New and relevant OneLab™ Resources*
  - *Today's Presenters*
- ISO 35001:2019 Biorisk Management for Laboratories
- Q&A
- Upcoming Events

Participant Rules of Engagement for the Webinar Chat

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.
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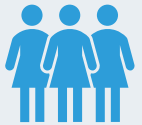
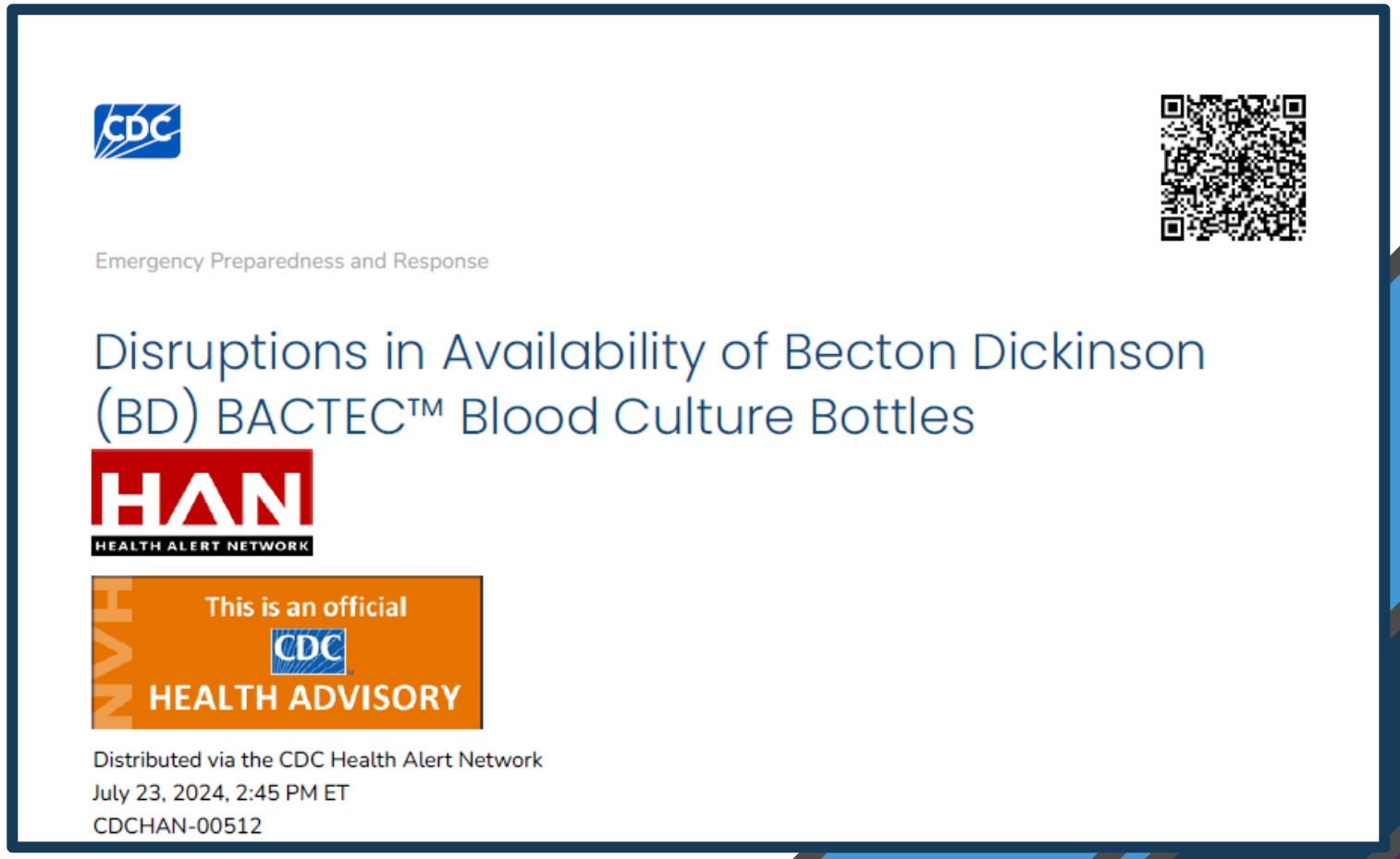
- **Comply with Moderators' Guidance.** If a moderator gives direction regarding chat behavior, please comply accordingly.
- **Report Issues.** Notify moderators if you experience technical difficulties or observe any disruptive behavior.



Health Alert Network (HAN)

Health Advisory



Emergency Preparedness and Response

Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles

HAN
HEALTH ALERT NETWORK

This is an official CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
July 23, 2024, 2:45 PM ET
CDCHAN-00512

OneLab **REACH™**

New Resource!

Mini Lesson

Disclaimer

CDC, our planners, and our 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

Folasade Kembi, PhD, MPH

Health Scientist
Quality & Safety Systems Branch (QSSB) Division of Laboratory Systems (DLS)
Centers for Disease Control and Prevention (CDC)

Today's Presenter

Mary Casey-Moore, PhD

Health Scientist, Safety Team
Quality & Safety Systems Branch (QSSB) Division of Laboratory Systems (DLS)
Centers for Disease Control and Prevention (CDC)

ISO 35001:2019

Biorisk Management for Laboratories

Folasade Kembi, PhD
Mary Casey-Moore, PhD
Quality and Safety Systems Branch
Division of Laboratory Systems

Objectives:

ISO 35001: Biorisk Management for Laboratories

- Summarize the standard
- Describe the Biorisk Management Model

Implementing a Biorisk Management System

- Discuss the initial steps to implementation
- Describe how to develop biorisk management objectives

Collaborative Pilot Project -with APHL

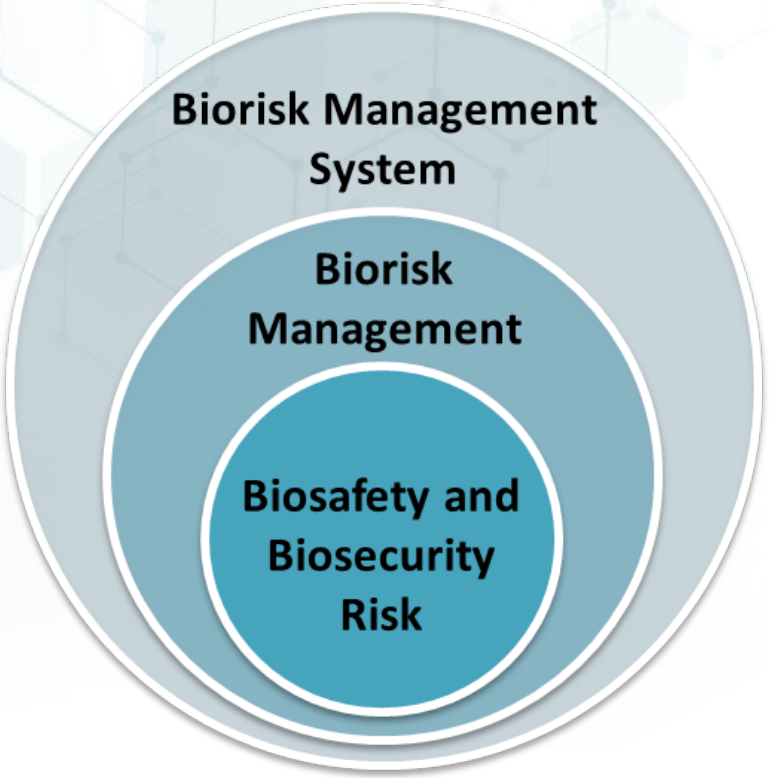
- Summarize outcomes and resources provided

What is ISO 35001?

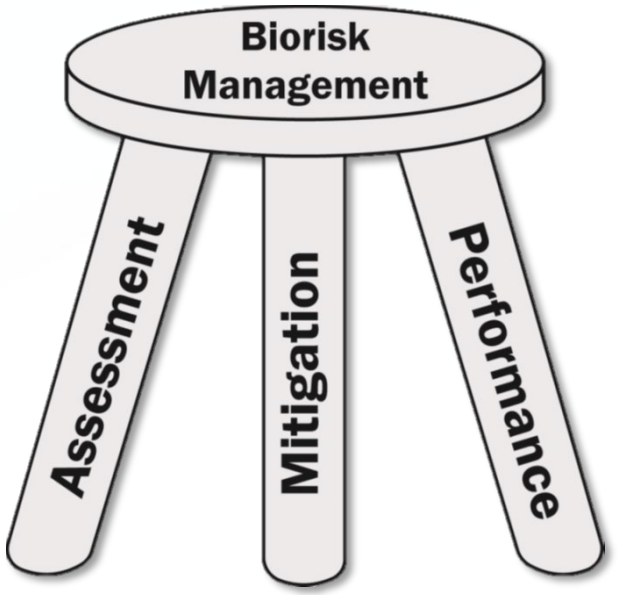
- **ISO**: **I**nternational **O**rganization for **S**tandardization
  - Global federation of national standards bodies
  - Develops voluntary, consensus-based international standards across nearly all industry sectors.

- **ISO 35001**
  - *Biorisk management for laboratories and other related organizations*
  - Published in November 2019 – 26 pages
  - Adopted from the CEN Workshop Agreement 15793:2011
  - The first international standard that **defines the requirements of the biorisk management system** for laboratories.

Biorisk Management

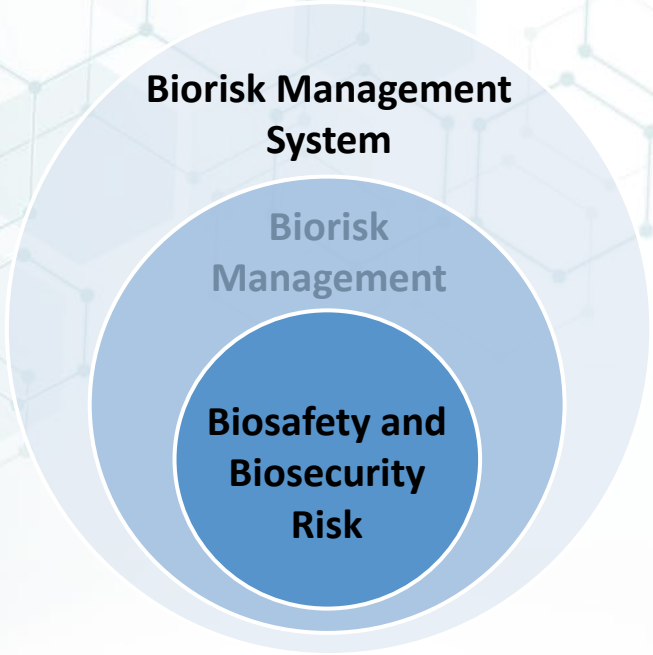


Coordinated activities to direct and control biosafety and biosecurity risks



Biorisk Management System

A systematic approach to identify, assess, control, and monitor biosafety and biosecurity risks associated with hazardous biological materials.



ISO 35001 defines the essential components for integrating biorisk management into an organization's overall governance, strategy, planning, management systems, reporting processes, policies, and culture.

The standard is structured around a management system approach

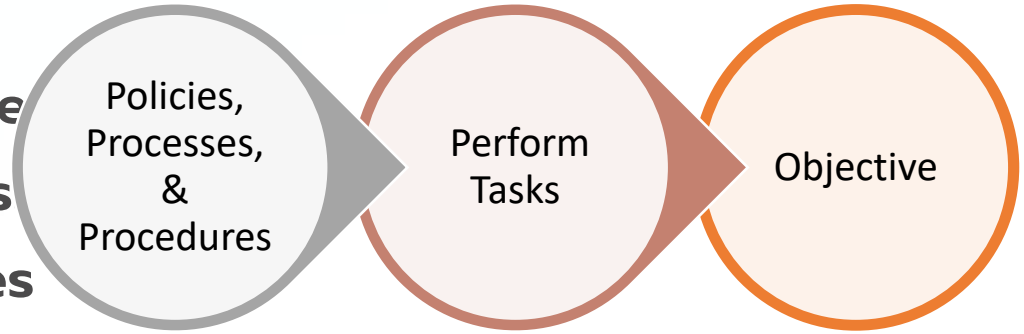
Promotes continual improvement through the Plan-Do-Check-Act (PDCA) cycle

Management System Approach

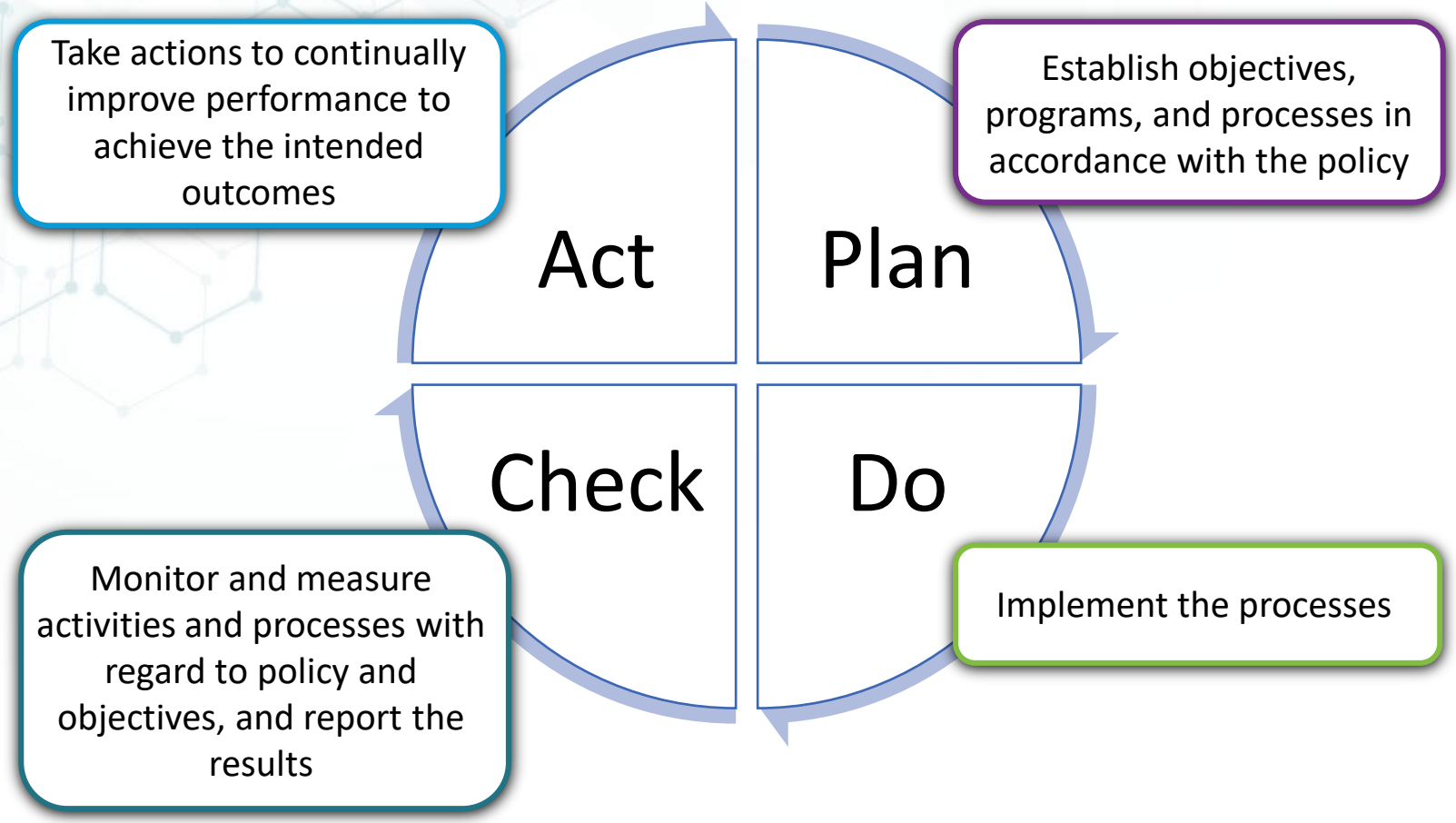
Integrated Best Practices and Procedures = Achieve Organizational Objectives

Benefits of a Management System Approach:

1. System Definition and Process Developme
2. Structured for Efficiency and Effectivenes
3. Understanding Process Interdependencies
4. Resource Awareness and Allocation
5. Continuous Improvement (PDCA Cycle)



Plan-Do-Check-ACT (PDCA)



ISO 35001 Components

Scope:

Applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials

Appropriate to the nature and scale of any organization

Not intended for:

- Risks of microorganisms and/or toxins in food or feedstuffs
- Risks from the use of genetically modified crops in agriculture

Biorisk Management System Requirements

4. Context of the Organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

Biorisk Management System Model

- 4. Context of the Organization
- 5. Leadership
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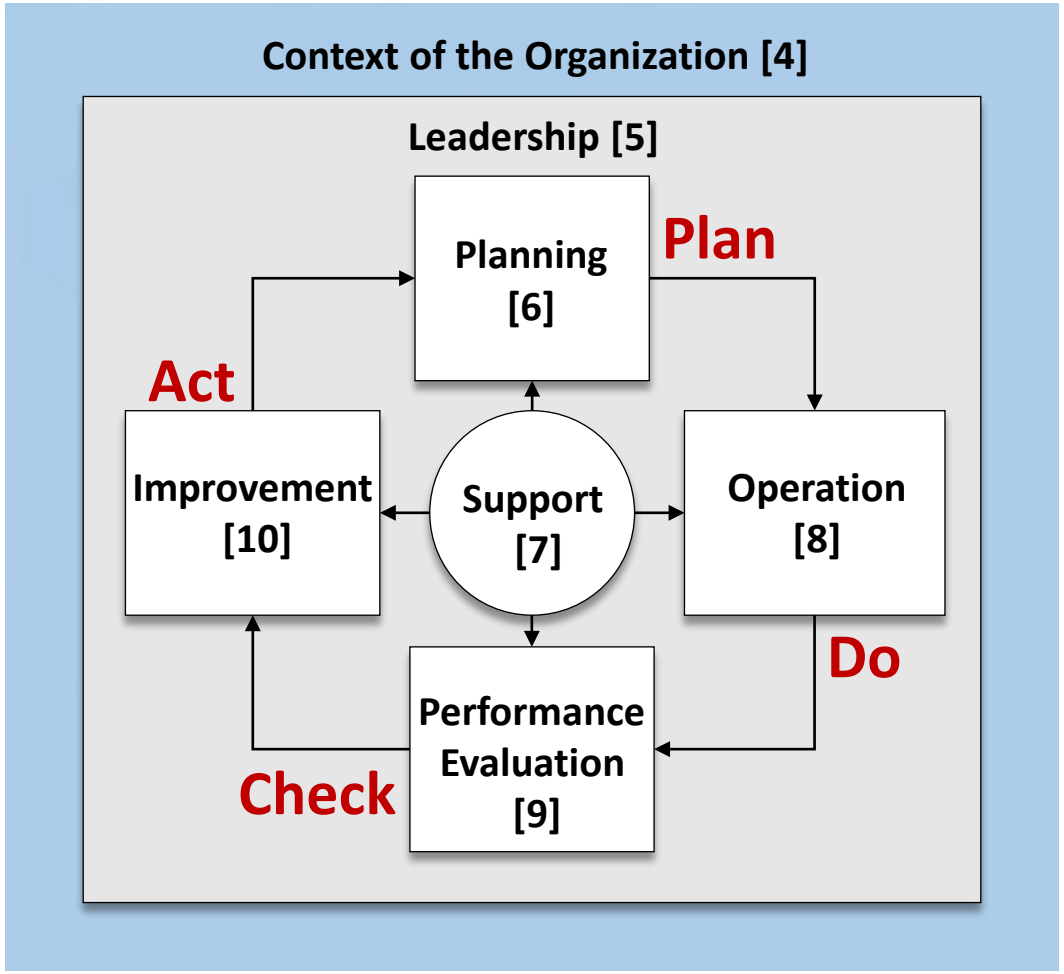

Biorisk Management System Model

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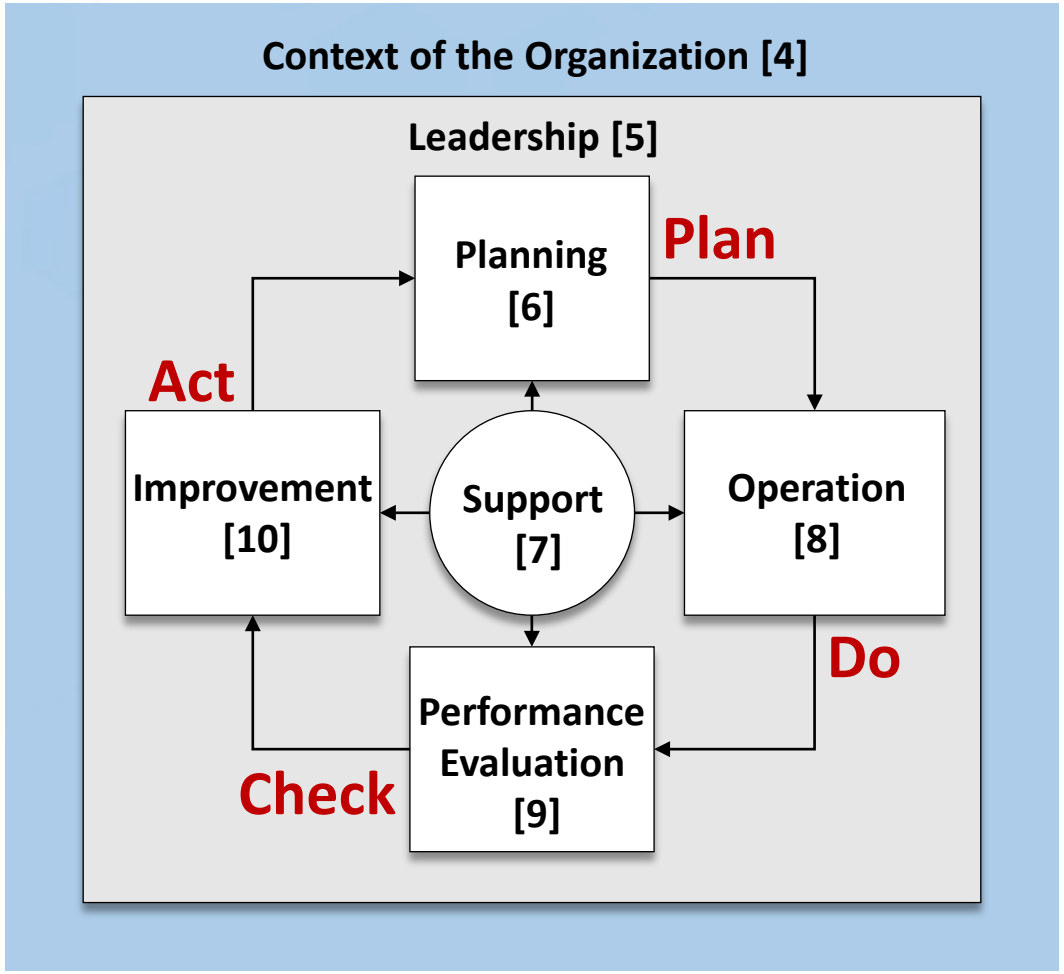


Implementing ISO 35001

Important Elements to ISO 35001 Implementation

Top Management Commitment

Planning

Documentation and Document Control

Training and Staff Awareness

Teamwork and Communication

Process to Implement ISO 35001

Step 1:
- Develop a tool to perform systematic gap assessment of the laboratory biosafety and biosecurity processes.

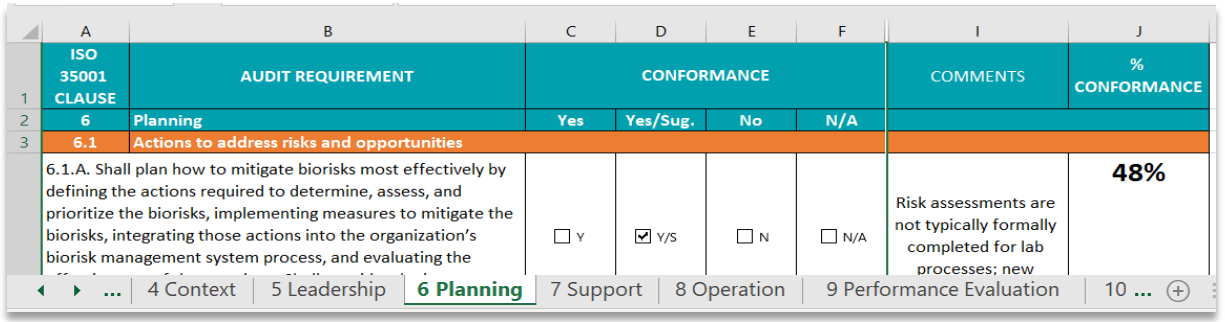
Step 2:
- Perform a gap assessment by analyzing the existing processes.

Step 3:
- Based on the results obtained from the gap assessment, define a process for the implementation of ISO 35001.

The Gap Assessment Tool

- Excel-based tool with tabs for each of the seven major ISO 35001 sections
  - Guidelines from the standard copied into respective sections
  - 184-line items created across all sections
- Quantitative Assessment and Scoring:
  - Scoring system: Yes/No for each line item
  - Calculated average percentage conformance for each section
  - Set goals for desired compliance increase over time

Section	Number of Questions
Context of the Organization	7
Leadership	29
Planning	21
Support	49
Operation	38
Performance Evaluation	20
Improvement	20



	A	B	C	D	E	F	I	J
1	ISO 35001 CLAUSE	AUDIT REQUIREMENT	CONFORMANCE				COMMENTS	% CONFORMANCE
2	6	Planning	Yes	Yes/Sug.	No	N/A		
3	6.1	Actions to address risks and opportunities						
	6.1.A. Shall plan how to mitigate biorisks most effectively by defining the actions required to determine, assess, and prioritize the biorisks, implementing measures to mitigate the biorisks, integrating those actions into the organization's biorisk management system process, and evaluating the		☐ Y	☑ Y/S	☐ N	☐ N/A	Risk assessments are not typically formally completed for lab processes; new	48%

... | 4 Context | 5 Leadership | 6 Planning | 7 Support | 8 Operation | 9 Performance Evaluation | 10 ...

After Assessment: Setting Goals and Objectives

Organizations establish biorisk management objectives at relevant functions and levels.

What is a goal and an objective?

Goal (an observable and measurable result)

We want to aim our resources and efforts towards this outcome.

Objectives

These are the steps we need to take, in a more or less fixed timeframe, to move towards and achieve the outcome.

Setting Goals and Objectives

ISO 35001 Requirement: Biological materials inventory

Use ISO 35001 requirement as a goal statement:

The organization shall maintain an accurate, verifiable inventory of biological materials specifying biological agents and toxins based on the biorisk assessment.

What questions does the goal statement present?

- What constitutes an "accurate" inventory?
- How is the inventory verified for accuracy?
- What details must be included in the inventory?
- How frequently must the inventory be updated/reviewed?
- Who is responsible for maintaining the inventory?

Setting Goals and Objectives

Specific
Measurable
Achievable
Relevant
Time-based

Create SMART objectives to meet the goal:

Conduct a comprehensive biorisk assessment of all laboratory activities and materials by the end of Q3 2024 to identify biological agents requiring inventory control.

Develop and implement standard operating procedures (SOPs) for inventory management, verification, documentation, and reporting by Q4 2024, ensuring compliance with ISO 35001 requirements.

Train 100% of laboratory staff handling controlled materials on proper inventory management procedures, including the new SOPs, by Q1 2025.

Implementing and Continuously Improving Biorisk Objectives

Determine roles and responsibilities for each objective

- Assign clear ownership and accountability
- Ensure necessary resources and support

Establish performance indicators and measures

- Define observable metrics to track progress
- Monitor advancement towards objectives and overall goal
- Identify areas for improvement or adjustment

Conduct regular gap assessments

- Evaluate the effectiveness of biorisk management processes
- Identify non-conformities against ISO 35001 requirements
- Implement corrective and preventive actions

Review and update objectives periodically

- Align objectives with changing organizational needs
- Incorporate lessons learned and best practices
- Maintain relevance and drive continuous improvement

Short term

Long term

Pilot Project to Implement ISO 35001

CDC/ APHL ISO 35001 Pilot Project Process

Step 1

- Identify Public Health Laboratories as Pilot Sites.
- Phase 1 = Labs 1 & 2
- Phase 2 = Labs 3 & 4

Step 2

- Initial site visits using the Gap Analysis Checklist to review existing process to support the adoption of ISO 35001.

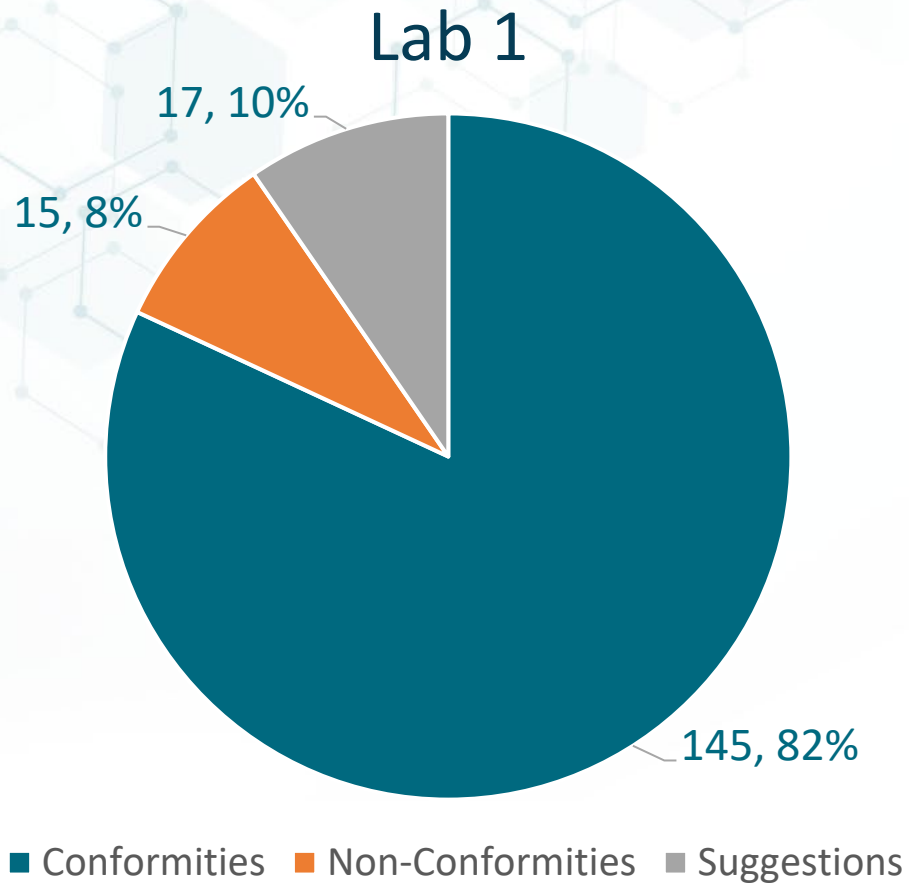
Step 3

- Utilize findings from the site visit and the checklist to define elements for ISO 35001 implementation via virtual meetings.

Step 4

- Second site visits reviewing processes to support the adoption of ISO 35001 and project closeout.

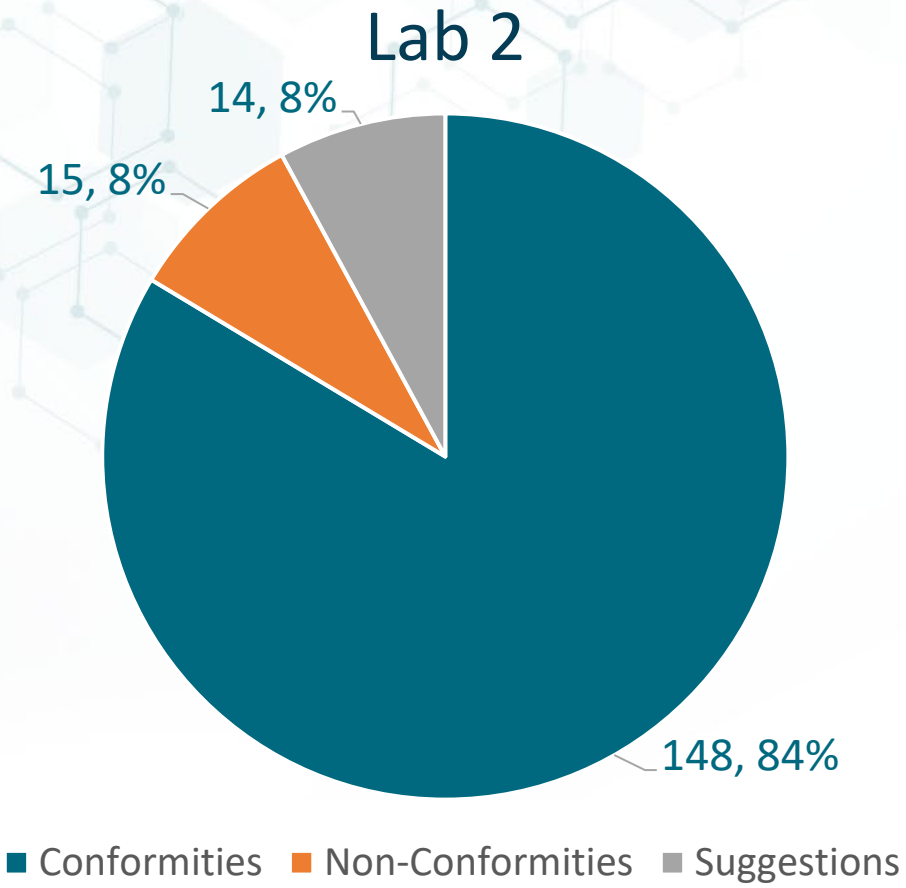
Pilot Laboratories Assessment Results - Phase 1



Non-Conformities:

- Biorisk management objectives
- Biological materials inventory
- Emergency plan training
- Internal audit- expand to BRM

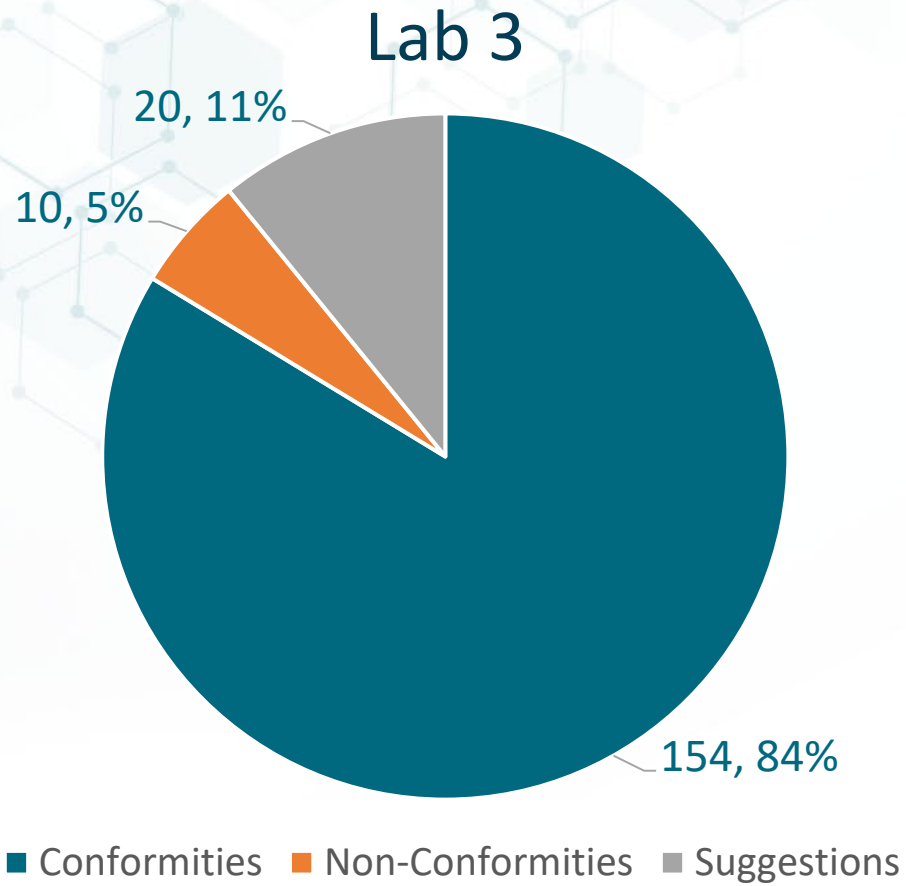
Pilot Laboratories Assessment Results - Phase 1



Non-Conformities:

- Roles, responsibilities, and authorities
- Senior management- prioritization of BRM
- Biorisk management advisor- stretched thin
- Biorisk management objectives
- Management review- biorisk management system and objectives review

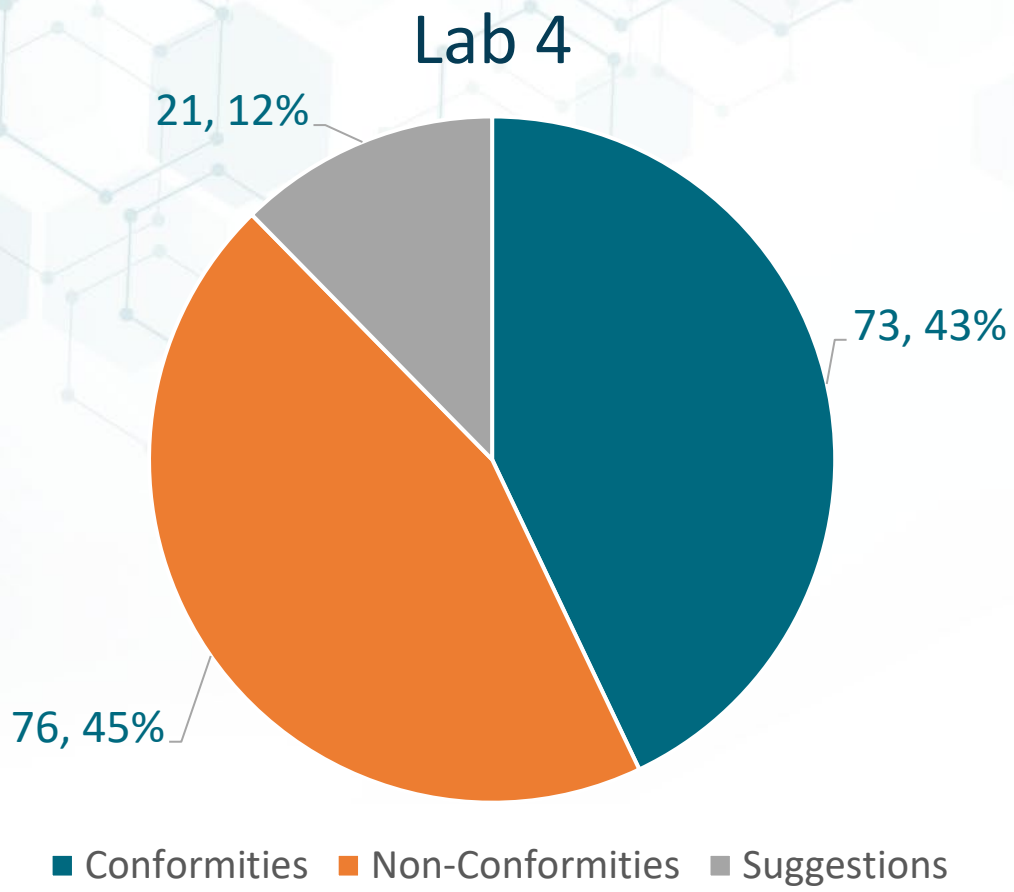
Pilot Laboratories Assessment Results - Phase 2



Non-Conformities:

- Biorisk management objectives
- Audit policy
- Emergency Exercises

Pilot Laboratories Assessment Results - Phase 2



Non-Conformities:

- Leadership and management
- Biorisk management objectives
- Roles, responsibilities, and authorities
- Continual Improvement Process
- Internal audit
- Communication

Suggestions for the Pilot Laboratories

- Establish biorisk management committee oversight
- Develop biorisk management objectives
- Conduct risk assessments: how-to training, form completion, process
- Establish escort responsibilities for supervising non-employees
- Provide insider threat training
- Shared CDC and APHL resources

International Organization for Standardization (ISO) 35001:2019 Biorisk Management

CDC's Division of Laboratory Systems (DLS) is offering free access to the **ISO 35001:2019 - Biorisk management for laboratories and related organizations** for clinical and public health laboratories

Process Overview:

- Select a point of contact responsible for biorisk management (e.g., Laboratory Director, Biosafety Officer).
- Point of contact email DLSBiosafety@cdc.gov
  - Name and physical address of the institution
  - Name and work e-mail address
  - Role in the organization
- DLS notifies the approved point of contact with details on how to access the standard.

DLS supports the enhancement of biorisk management in laboratories and encourages your institution to participate.

For questions, contact DLSBiosafety@cdc.gov.

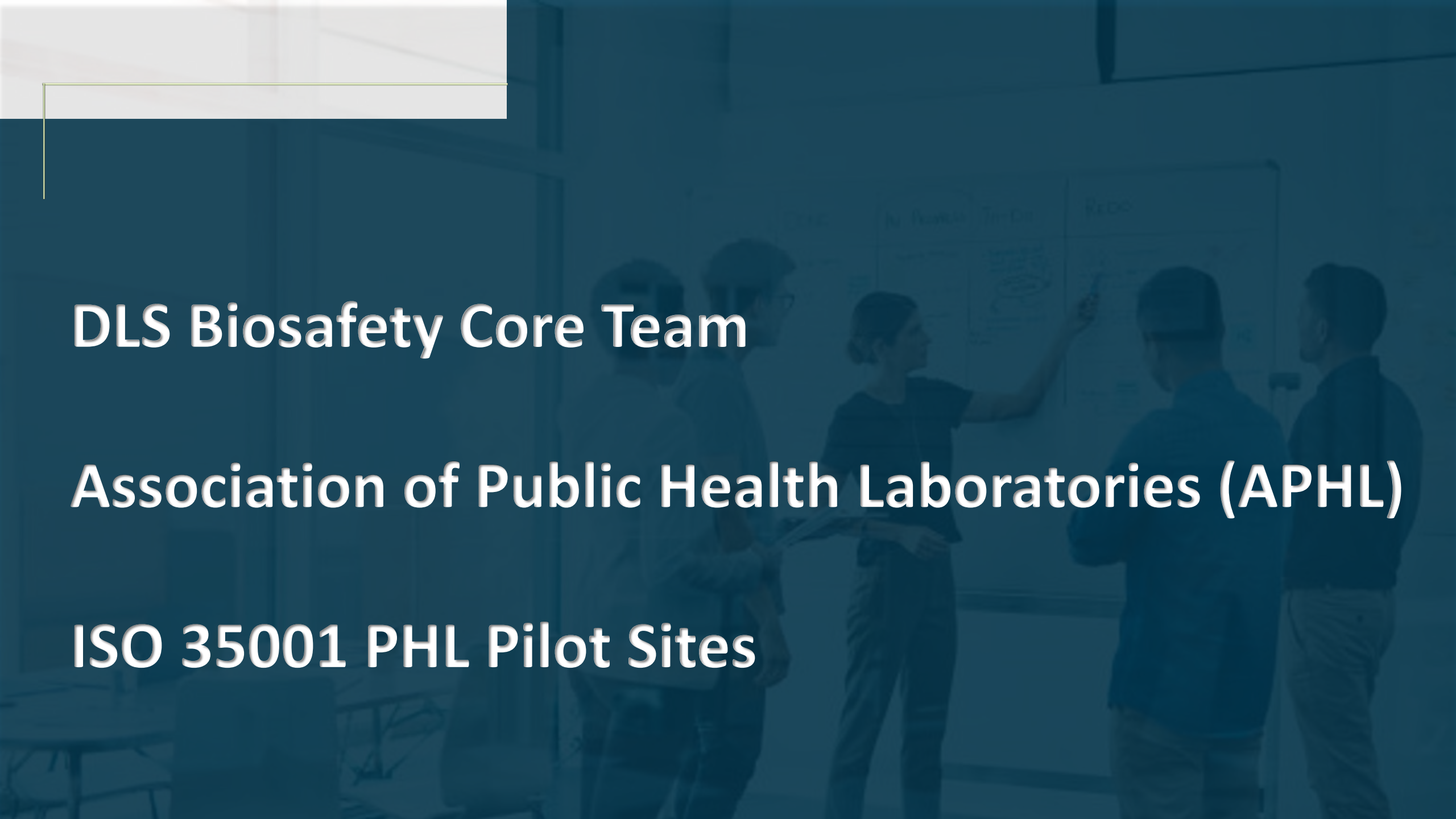
Summary

Covered the sections of ISO 35001, highlighting how they collectively create a robust biorisk management system.

Emphasized the critical components for a successful implementation, including top management commitment.

Discussed the initial steps of implementation, including conducting gap assessments and creating SMART biorisk management objectives.

Shared experiences from collaborating with APHL to implement ISO 35001 in four public health laboratories.



DLS Biosafety Core Team

Association of Public Health Laboratories (APHL)

ISO 35001 PHL Pilot Sites

Resources

CEN WORKSHOP AGREEMENT CWA 15793 - CEN/TC (internationalbiosafety.org)

CEN Workshop Agreement 16393: Laboratory Biorisk Management Standard- Guidelines for Implementation of CWA 15793 - **CEN Workshop Agreement 16393: Laboratory Biorisk Management Standard- Guidelines for Implementation of CWA 15793 | Biosecurity Central**

- **ISO 35001 Laboratory biorisk management system for laboratories and other related organizations; external icon** note that users will have to purchase the standard to view the full document
- Biological Risk Assessment: General Considerations for Laboratories- **Biological Risk Assessment: General Considerations for Laboratories (cdc.gov)**
- **Biorisk Management for Clinical and Public Health Laboratories- APHL_Biorisk_management_program_guidance_document.pdf**

Questions?

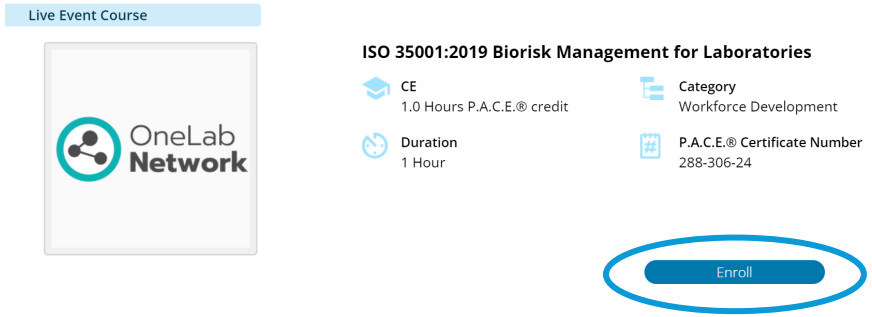
Contact:
DLSinquiries@cdc.gov

Questions?

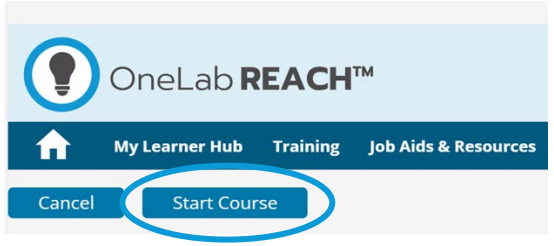
OneLab REACH™ Continuing Education

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

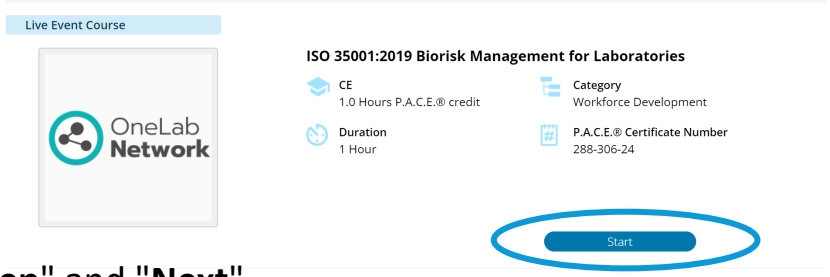
1. Log into your OneLab REACH account. **You must be logged into your REACH account to access the evaluation.**
2. Click on biorisk-management-laboratories to take you to the survey.
3. Enter passcode “**N528**"
4. Click "**Enroll**"



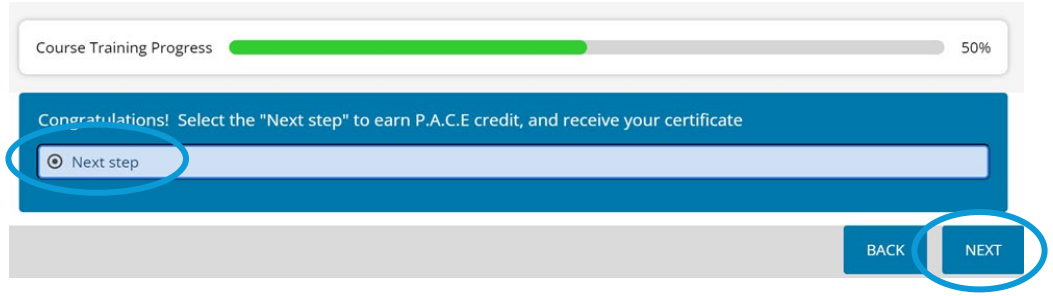
5. Select "**Start Course**".



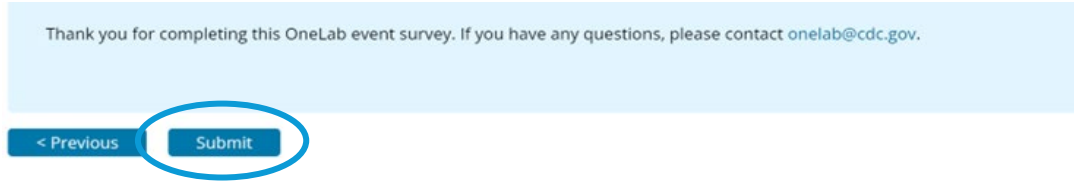
6. Select "**Start**".



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!

Register Now!

https://bit.ly/3YchRbG

OneLab TEST

REGISTER FOR THE WEBINAR

Let's Talk TESTing:
An Open Forum Event

August 13, 2024 12 PM ET

Click the link to **register** for the event

Upcoming Event!

Register Now!

https://bit.ly/4dqSgQT

OneLab TEST

REGISTER FOR THE WEBINAR

“Ready? Set? Test!”

Patient Testing is Important.
Get the Right Results. Session 1

August 28, 2024 12 PM ET

Click the link to **register** for the event

OneLab **Assessments**

Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov