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.

• **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.

• **Report Issues.** Notify moderators if you experience technical difficulties or observe any disruptive behavior.
Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles

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

PUBLIC HEALTH LABORATORIES
DIVISION OF LABORATORY SYSTEMS
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

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Centers for Disease Control and Prevention (CDC)
Today’s Presenter

Mary Casey-Moore, PhD

Health Scientist, Safety Team
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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**: International Organization for Standardization
  - 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 Development
2. Structured for Efficiency and Effectiveness
3. Understanding Process Interdependencies
4. Resource Awareness and Allocation
5. Continuous Improvement (PDCA Cycle)
Plan-Do-Check-ACT (PDCA)

**Plan**
- Establish objectives, programs, and processes in accordance with the policy

**Do**
- Implement the processes

**Check**
- Monitor and measure activities and processes with regard to policy and objectives, and report the results

**Act**
- Take actions to continually improve performance to achieve the intended outcomes
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
6. Planning
7. Support
8. Operation
9. Performance Evaluation
10. Improvement

Diagram:

- **Context of the Organization** [4]
- **Leadership** [5]
- **Planning** [6]
- **Support** [7]
- **Operation** [8]
- **Performance Evaluation** [9]
- **Improvement** [10]

Flow:
Biorisk Management System Model

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

Create **SMART** objectives to meet the goal:

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

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

- **Achievable**: 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

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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

Lab 1

145, 82%
17, 10%
15, 8%

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

Lab 3

154, 84%

20, 11%

10, 5%

Non-Conformities:
- Biorisk management objectives
- Audit policy
- Emergency Exercises

Conformities | Non-Conformities | Suggestions
Pilot Laboratories Assessment Results - Phase 2

Lab 4

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

Conformities: 76, 45%
Non-Conformities: 73, 43%
Suggestions: 21, 12%
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
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
  o Name and physical address of the institution
  o Name and work e-mail address
  o 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)


• 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)

Questions?

Contact: DLSinquiries@cdc.gov
Questions?
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!

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
Share your feedback and laboratory training needs with us!

Email OneLab@CDC.gov