DLS ECHO Biosafety Session: April 30, 2024

Planning: Developing and Achieving Biorisk Management Objectives

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Concord, NH

March Session Recap:
"Leadership – Roles, Responsibilities and Authorities"

123 participants attended the session

80 organizations were represented

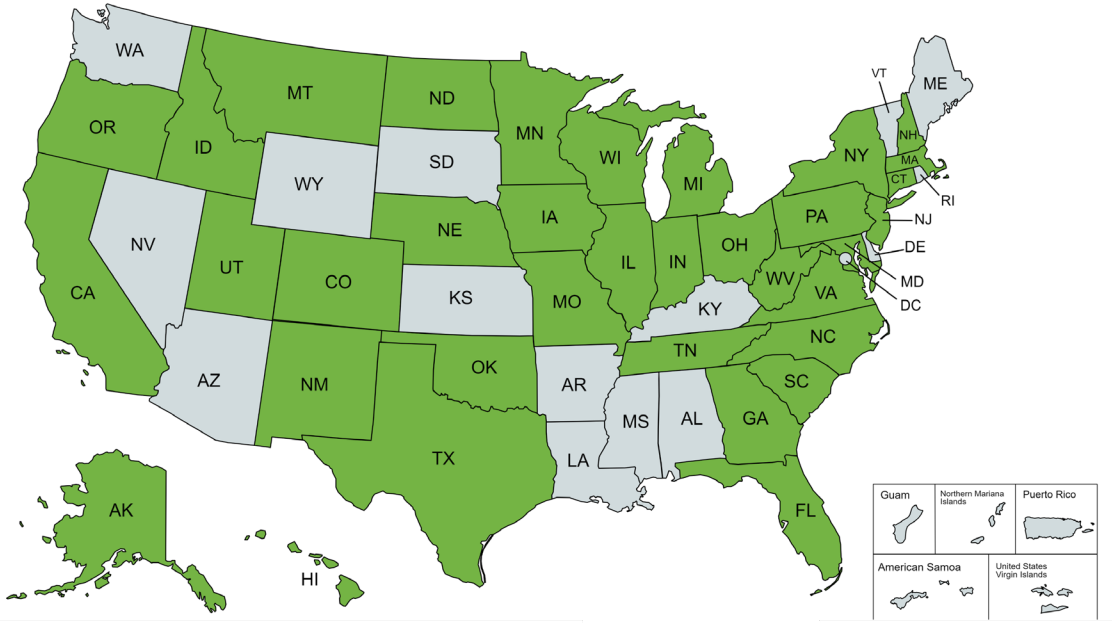
"We promote the idea that

good ideas can come from anyone…

I also have **employees help with finding solutions to get buy-in"**

- Session Participant

Organization Affiliation by State



Note: States shaded in green had at least one organization located in that state in attendance at this session. Attendees from at least one organization located in Belize and El Salvador were also present at the session but are not represented on the map. Six national organizations also attended this session.

Agenda

- Speaker Introduction
- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

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Planning: Developing and Achieving Biorisk Management Objectives

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PLANNING: DEVELOPING AND ACHIEVING BIORISK MANAGEMENT OBJECTIVES

MICHAEL STEVENSON, PHD
DEPUTY LAB DIRECTOR, NH PUBLIC HEALTH LABORATORIES
APRIL 30, 2024

OBJECTIVES:

- ISO 35001: Biorisk Management System and Biorisk Management Objectives
- APHL/CDC ISO 35001 Pilot Program
- ISO 35001 Outcomes for New Hampshire Public Health Laboratories (NH PHL)
- Biorisk Management Objective Examples

  Note: NH PHL has applied the principles of ISO 35001 towards lab safety in general, including chemical safety and radiation safety.
- Polls and Group Discussions throughout this presentation

POLL: Does your facility have the following full-time designated positions (select all that apply):

- BIOSAFETY OFFICER
- CHEMICAL HYGIENE OFFICER
- RADIATION SAFETY OFFICER
- GENERAL LAB SAFETY OFFICER
- OTHER
- NONE

DISCUSSION: What gaps do you think you have for an effective lab safety program without having a dedicated safety officer?

ISO 35001 – WHAT IS IT?

- ISO (International Organization for Standardization, www.iso.org) is a worldwide federation of national standards bodies. ISO has published over 25,000 international standards covering almost all aspects of technology and manufacturing.
- ISO 35001 is the standard entitled, "Biorisk management for laboratories and other related organisations."
- The standard was published in November 2019 – 26 pages.
- Currently there is no accrediting body to provide lab accreditation.

ISO 35001 – WHAT IS IT?

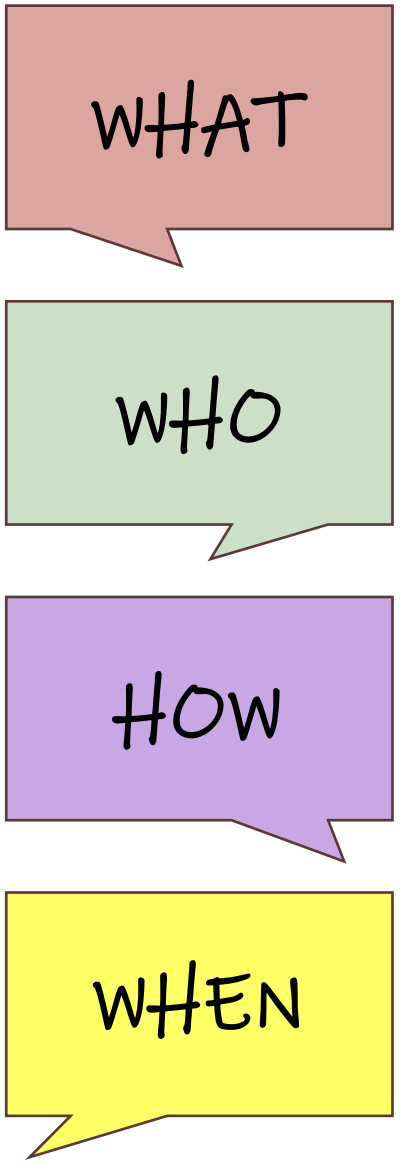
The standard defines a Biorisk Management System (BMS) to:

- Establish principles that enable laboratories to achieve their biosafety and biosecurity objectives
- Define essential components of a BMS framework to integrate into a laboratory or other related organization's overall governance, strategy and planning, management, reporting processes, policies, values, and culture
- Develop and implement Biorisk Management Objectives to continuously improve the BMS

ISO 35001 – WHAT IS IT?

Biorisk Management Objectives shall be:

- Measurable
- Monitored
- Communicated
- Updated as appropriate



POLL: Has your facility implemented any part of ISO 35001?

- YES
- NO
- NO, BUT I WOULD LIKE TO

DISCUSSION: For those who have implemented ISO 35001, what successes have you had? What challenges?

APHL/CDC ISO 35001 PILOT PROGRAM

- July 2021 – Association of Public Health Laboratories (APHL) and Centers for Disease Control and Prevention (CDC) established a cooperative agreement on ISO 35001 implementation in the PHL setting.
- March 2022 – NH PHL was identified as a pilot site.
- June 2022 – Two-day site visit occurred at NH PHL.
- September 2022 – Gap analysis results
- April 2023 – Second APHL/CDC site visit to NH PHL
- Throughout a great collaborative platform to exchange ideas and identify and implement best practices

ISO 35001 GAPS FOR NH PHL

ISO 35001 REQUIREMENTS	PILOT PROGRAM GAP ANALYSIS
Biorisk management objectives and planning to achieve them	Develop measurable Biorisk Management Objectives
Actions to address risk and opportunities	Evaluate, monitor, and communicate performance of biorisk management control measures
Biological materials inventory	Develop and standardize biological materials inventory
Decontamination and waste management	Validate autoclave biowaste sterilization cycles
Performance: monitoring, measurement, analysis, and evaluation	Ensure incident investigations, corrective actions, etc. are monitored and checked for continual quality improvement

ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Actions to address risk and opportunities	Evaluate, monitor, and communicate performance of biorisk management control measures

DISCUSSION: How do you evaluate, monitor, and communicate performance of biorisk management or other safety control measures?

- Risk assessments?
- Internal audits?
- Safety Officer role?
- Quality Manager role?
- Other?

NH PHL BIORISK MANAGEMENT OBJECTIVE

Implement standardized safety risk assessment process

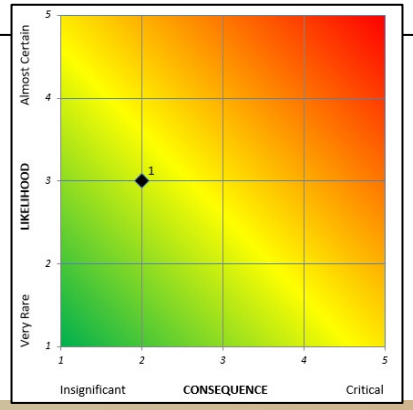
NH PHL Safety Risk Assessment Tool

Test/Platform: _____
Program/Unit Name: _____
Initial SRA completed by: _____
Initial SRA date completed: _____

Suggested risks to consider that could impact safety and/or operations:
- sample receipt • sample accessioning • sample transport • sample preparation in the lab
- sample loading/unloading on instrument • sample storage • sample disposal
- biowaste disposal • handling chemicals • chemical waste disposal • other staff present in lab
- housekeeping activities

RISK								
Risk #	**Risk Title**	**Describe the identified risk.**	**How will you mitigate the risk, if possible?**	**Comments/Concerns**	**Consequence of risk happening**	**Likelihood of risk happening**	**Consequence Rating**	**Likelihood Rating**
1	Sample receipt	Samply may leak in bag or requisition form may be in same pouch as sample.	Open and handle sample in a biosafety cabinet.	None	Minor	Possible	2	3

- Excel file, generates heat map ----------→
- Approved in Ideagen Quality Management (Qualtrax) document control system
- Annually reviewed or if method changed



ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Biological materials inventory	Develop and standardize biological materials inventory

DISCUSSION:

How do you maintain inventory of biological materials? Of chemicals?

How frequently do you perform biological and chemical inventory?

Do you have an inventory management system in place that also encompasses supplies and equipment?

ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Biological materials inventory	Develop and standardize biological materials inventory

POLL: How do you maintain your chemical safety data sheets?

- PAPER COPIES
- ELECTRONIC COPIES
- BOTH
- OTHER

NH PHL BIORISK MANAGEMENT OBJECTIVE

Create inventory template for biologicals and chemicals, and perform lab-wide inventory

- Example: Chemical Inventory
- Excel file

									Required	*Optional*						
					NFPA 704 Hazard Diamond											
Chemical name	**Program/Unit**	**Room #**	**Maximum quantity stored (e.g., 100 g, 2 x 4 L)**	**Unit of measure**	**Health hazard**	**Fire hazard**	**Reactivity hazard**	**Specific hazard**	**Location in room**	**Received Date**	**Expiration Date**	**CAS #**	**Manufacturer**	**Product/Catalog Number**	**Lot #**	**Comments**
Methanol	CHEMISTRY-LRN-C	109	200	mL	1	3	1	Poisonous			N/A	67-56-1	Fisher	A4564		
Acetonitrile	CHEMISTRY-LRN-C	109	200	mL	2	3	0	Toxic, irritation			N/A	75-05-8	Fisher	A955-4		

REQUIRED	OPTIONAL
Chemical name	Location in room
Program/Unit	Received date
Room #	Expiration date
Maximum quantity stored	CAS #
Unit of measure	Manufacturer
NFPA 704 Hazard Diamond rating	Product Number / Lot #

ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Decontamination and waste management	Validate autoclave biowaste sterilization cycles

POLL: (multiple choice) Do you regularly evaluate the effectiveness of your autoclave biowaste sterilization cycles?

- YES
- NO
- NO, BUT I WANT TO
- I have access to onsite incineration
- OTHER

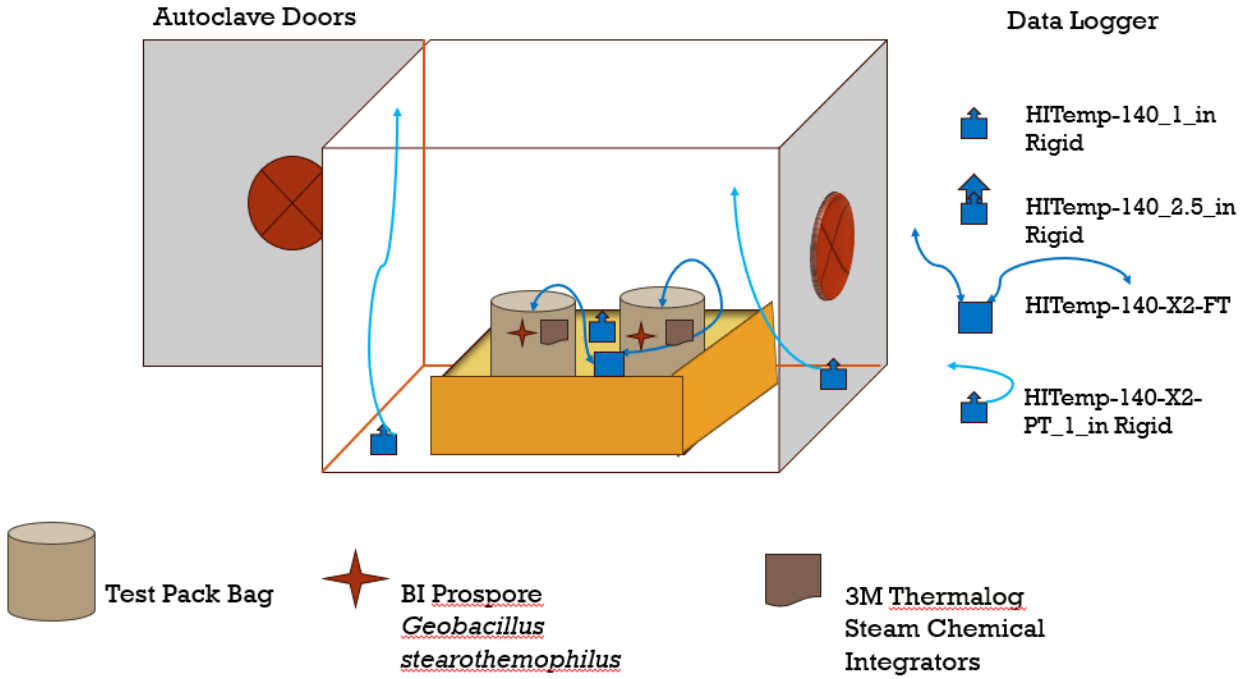
ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Decontamination and waste management	Validate autoclave biowaste sterilization cycles

DISCUSSION: How do you validate your sterilization cycle? How frequently? If you don't validate, what are you doing instead to ensure effective sterilization has occurred?

NH PHL BIORISK MANAGEMENT OBJECTIVE

Develop and implement validation of biowaste autoclave sterilization

- Annual validation
- Representative biowaste autoclave test
- 2 bags tested in a sterilization cycle
- Data loggers for temperature and pres
- Biological indicators
- Chemical indicators



ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Performance: monitoring, measurement, analysis, and evaluation	Ensure incident investigations, corrective actions, etc. are monitored and checked for continual quality improvement

DISCUSSION: How do you ensure incident investigations, root cause analysis, corrective actions, etc. are monitored and checked for continual improvement?

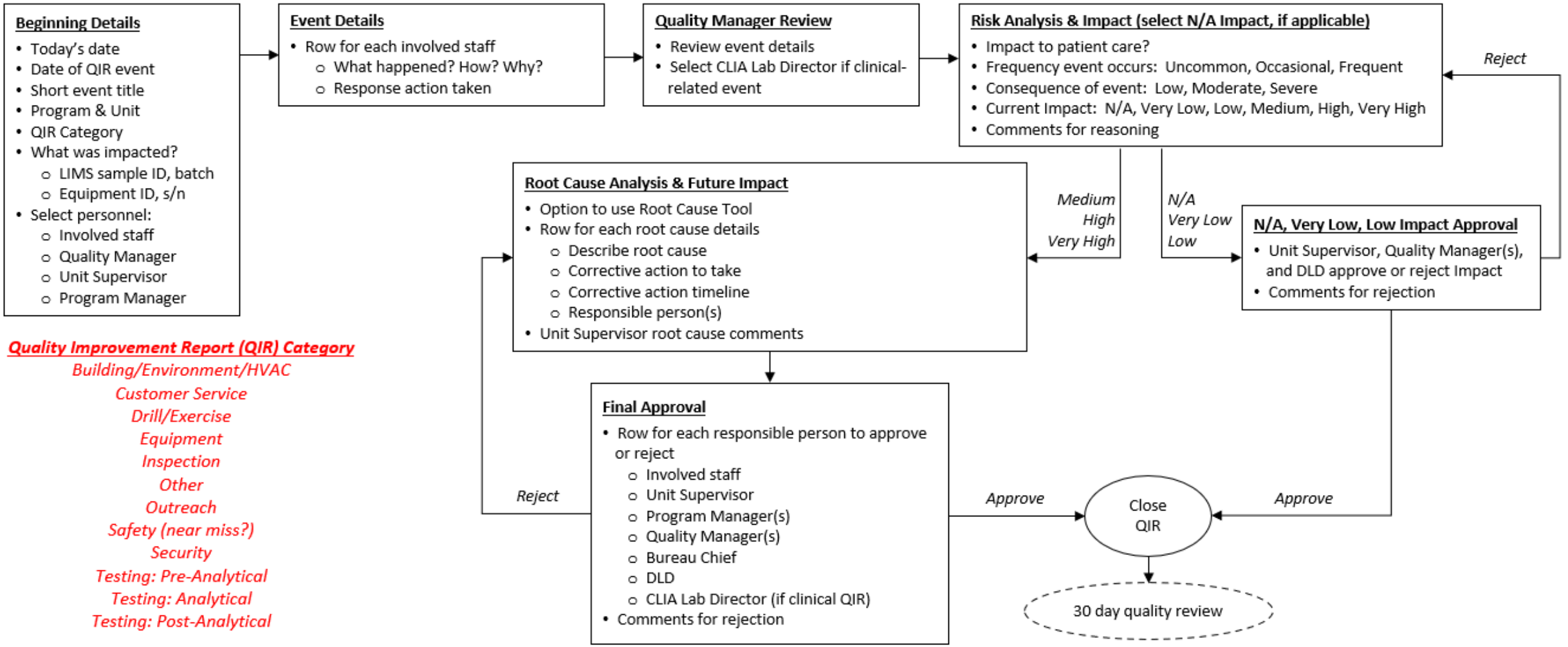
ISO 35001 REQUIREMENT	PILOT PROGRAM GAP ANALYSIS
Performance: monitoring, measurement, analysis, and evaluation	Ensure incident investigations, corrective actions, etc. are monitored and checked for continual quality improvement

POLL: (multiple choice) What electronic document control system(s) do you use?

- Ideagen Quality Management (Qualtrax)
- iPassport
- MasterControl
- MediaLab
- SharePoint
- Other
- None

NH PHL BIORISK MANAGEMENT OBJECTIVE

Create electronic workflow to document and monitor quality events



Quality Improvement Report (QIR) Category

Building/Environment/HVAC
Customer Service
Drill/Exercise
Equipment
Inspection
Other
Outreach
Safety (near miss?)
Security
Testing: Pre-Analytical
Testing: Analytical
Testing: Post-Analytical

DISCUSSION: What Biorisk Management Objectives would you want to implement at your facility?

NH PHL BIORISK MANAGEMENT OBJECTIVES

2024
Ensure completeness of chemical safety data sheets for all chemicals in the lab
Implement updates identified in 2023 lab safety inspections
Carryover establish autoclave sterilization validation procedure – APHL Fellow project
Update biological and chemical spill kits & perform spill drills

RESOURCES

- ISO 35001:2019 "Biorisk management for laboratories and other related organisations" https://www.iso.org/standard/71293.html
- Association of Public Health Laboratories (APHL) Position Statement, "Improving Biosafety in Our Nation's Laboratories" – June 2022 https://www.aphl.org/programs/preparedness/Documents/APHL%20Position%20Statement%20Improving%20Biosafety%20in%20Our%20Nations%20Laboratories.pdf
- APHL Lab Matters Winter 2023 Issue 4, page 32, "Piloting the ISO 35001:2019 Standard" https://viewer.joomag.com/lab-matters-winter-2023/0448207001701443860/p32
- APHL "Nonconforming Events" document, October 2021 https://www.aphl.org/aboutAPHL/publications/Documents/QSA-2021-PHL-Model-Practices-QMS11-A.pdf
- "Validation Testing Protocol for Wadsworth Center RMW Treatment Autoclaves" – courtesy from New York State Department of Health Wadsworth Center

DLS ECHO Biosafety Session: May 30, 2024

Support: Resources, Competence, and Awareness

William Pinard, MS, BRM/BSEC (IFBA)
Project Lead, Principal Engineering Team
Global Chemical and Biological Security
Sandia National Laboratories
Albuquerque, NM

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

ISO 35001:

- ISO 35001 defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials.
- The standard applies to laboratories or organizations that work with, store, transport, and/or dispose of hazardous biological materials.
- The offer is currently limited to interested laboratories and organizations within the United States.

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

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.