DLS ECHO Biosafety Session: October 31, 2023

Quality in Biosafety

Jill J. Power, MS, M(ASCP), CMQ/OE(ASQ)
Former Deputy Laboratory Director
New Hampshire Public Health Laboratories
Concord, NH

Agenda

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

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POLL QUESTION

To the best of your knowledge, what accrediting or licensing bodies does your laboratory follow? Select all that apply.

- CLIA (Clinical Laboratory Improvement Amendments)
- ISO 17025
- ISO 9000/9001
- ISO 15189
- Federal Select Agent Rule
- CAP (College of American Pathologists)
- TNI (The NELAC Institute)
- Other
- None

Quality in Biosafety

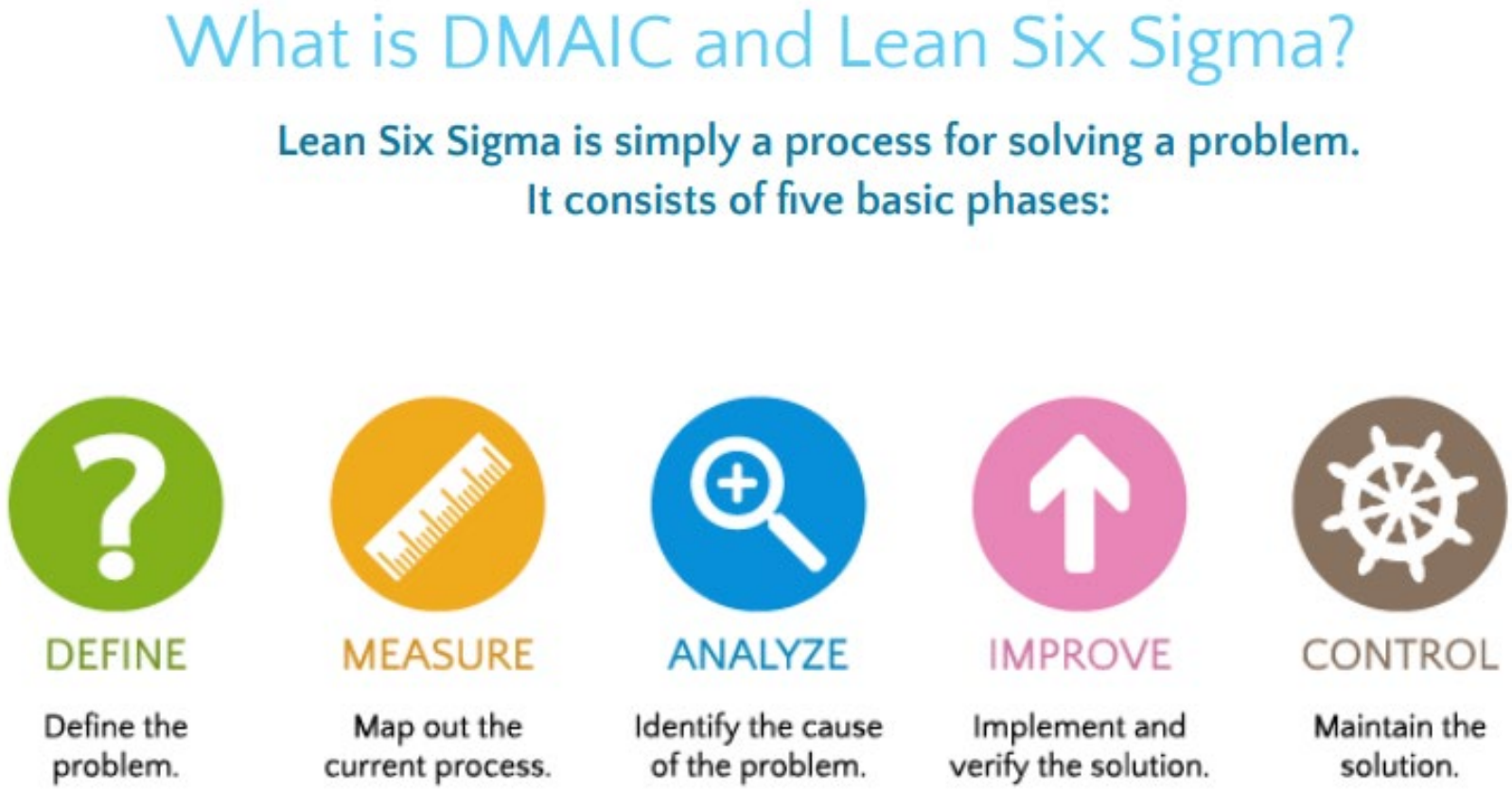
What is it?

Why do we care?

Integrating Quality and Biosafety

- Administrative Tools Linking Quality & Safety
  - Organizational Structure
  - Position Descriptions
  - Key Job Duties
  - Evaluation Mechanism
- Quality & Safety Interactions

Quality Improvement Tools



www.goleansixsigma.com

LEAN

- Lean training teaches you how to reduce waste and increase efficiency for your organization

RACI Chart

Process Name / Description:	*Safety Committee - responsible for assuring all staff are equipped with safety training, proper PPE, and the lab is considered a safe place to work.*
Created On:	*Jan-12* Revision: *4/1/2012*
Created by:	*Biosafety Officer*

	Biosafety Officer	Chemical Safety Officer	Deputy Lab Director	Committee Members	Quality Manager
Safety Welcome for new employees	A	A	C	R	I
Safety Training	R	R	I	C	C
Review SOPs and update	R	R	C	I	C
Safety Inspections/Audits	A	A	I	R	C
Safety Incident Investigations	R	R	C	I	I
Risk Assessments	R	R	I	C	C
BSL-3 Training	R	I	I	I	I

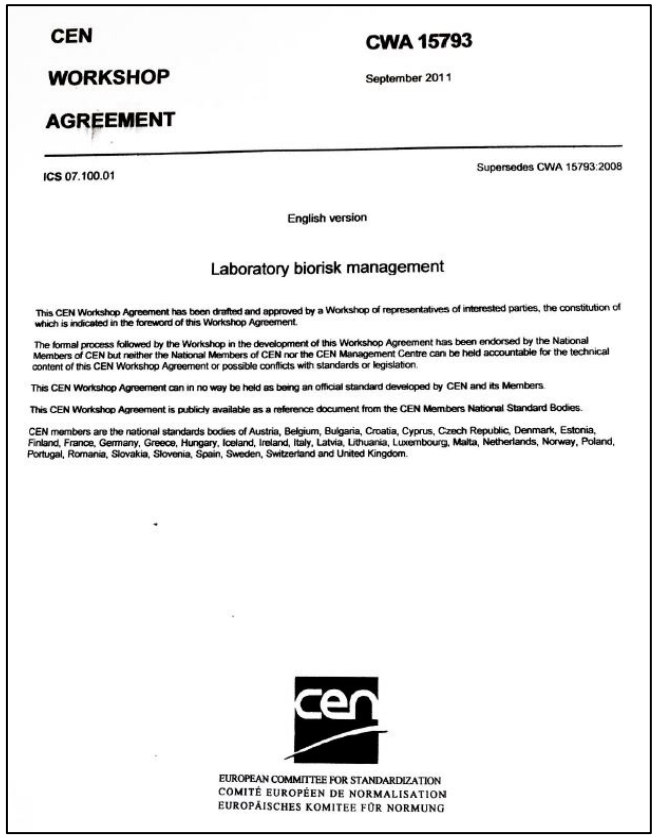
R = Responsible, A = Accountable, C = Consulted, I = Informed

- **R** -The **Responsible** person is the person who carries out the process or task and is responsible to get the job done.
- **A** -The **Accountable** person is the one ultimately accountable for the process or task being completed appropriately. Responsible persons are accountable to this person.
- **C** - **Consulted** is for the people not directly involved with carrying out the tasks but are consulted to achieve the goal and may be someone vested in the process or task or is a subject matter expert.
- **I** - The **Informed** are those who receive output from the process or task or who have a need to stay informed.

Overview of ISO 35001

Biorisk management for laboratories and other related organisations

ISO 35001 Foundation



CEN

WORKSHOP

AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN/TC (internationalbiosafety.org)

CEN

WORKSHOP

AGREEMENT

CWA 16393

January 2012

ICS 07.100.01

English version

Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

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EUROPÄISCHES KOMITEE FÜR NORMUNG

/TC (internationalbiosafety.org)

ISO 35001: Biorisk management for laboratories and other related organisations

- Process to identify, assess, control, and evaluate biosafety and biosecurity concerns
- Globally applicable to any laboratory that works with, stores, transports, and/or disposes of hazardous biological materials
- Complements existing international standards for laboratories
- Plan, Do, Check, Act (PDCA) principle
- Currently there is no accrediting body to provide lab accreditation.

ISO 35001: Biorisk Management System

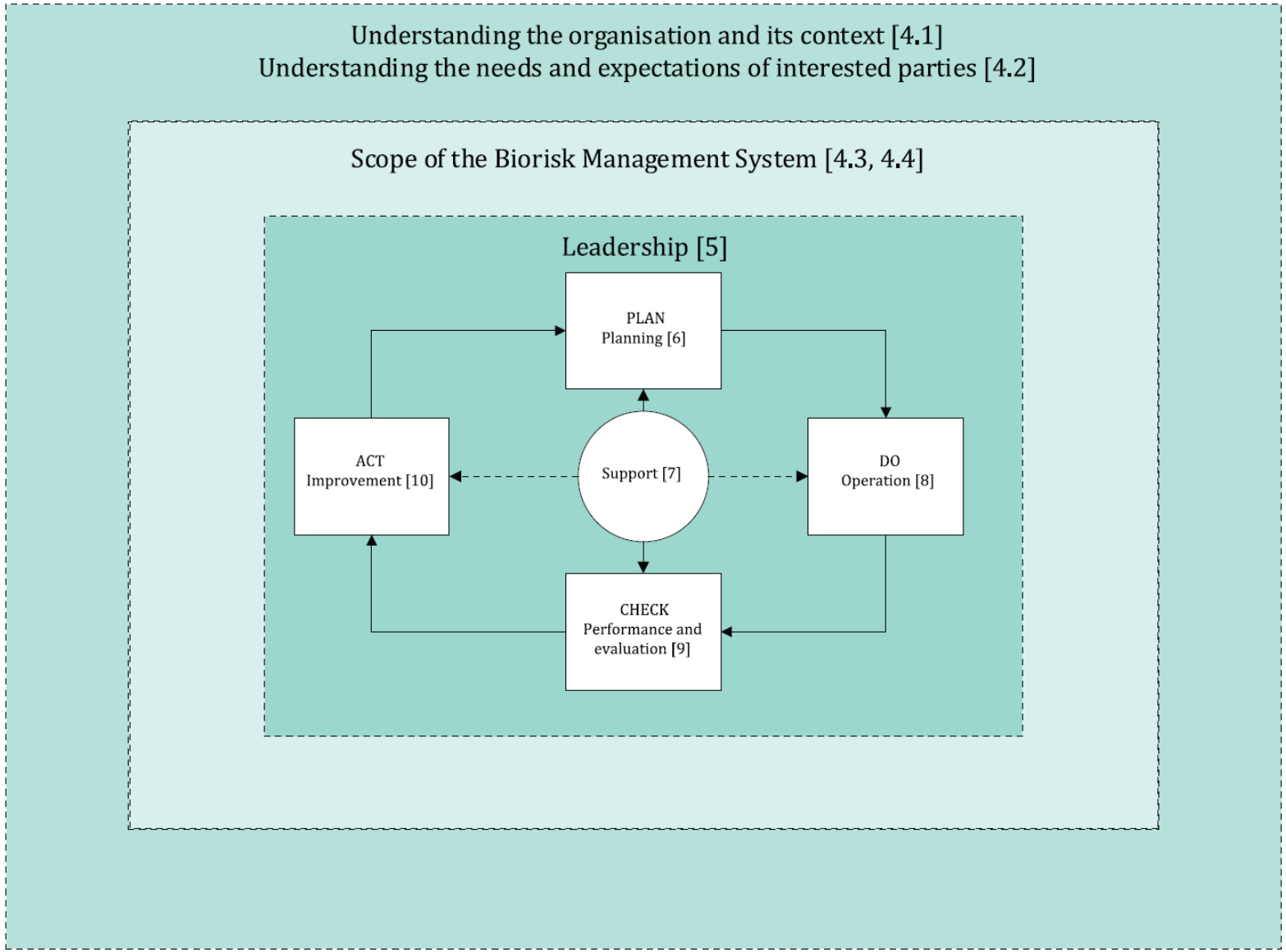
The standard defines a Biorisk Management System (BMS) to:

- Establish the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives
- Define the essential components of a BMS framework to be integrated into a laboratory or other related organization's overall governance, strategy and planning, management, reporting processes, policies, values, and culture
- Describe a comprehensive biorisk management process that mitigates biorisk (biosafety and biosecurity risks)
- Provide guidance on the implementation and use of the standard, where appropriate

ISO 35001: Overview of Clauses in the Standard

1. **Scope**: defines a process working with risks associated with hazardous biological materials
2. **Normative references**: none (no outside or precursor references)
3. **Terms and definitions**: 46 of them! (e.g., worker, objective, facility, audit, performance)
4. **Context of the organization**: establish BMS
5. **Leadership**: commitment, policy, roles/responsibilities/authorities
    - top management > senior management > biorisk management committee > biorisk management advisor > scientific management
6. **Planning** (*Plan* of PDCA): hazard ID, risk assessment, mitigation, evaluation
7. **Support**: occupational health program, competency, training, communication
8. **Operation** (*Do* of PDCA): operations, security, inventory, PPE, emergency response
9. **Performance evaluation** (*Check* of PDCA): audits, management reviews
10. **Improvement** (*Act* of PDCA): incidents, corrective actions, non-conformances

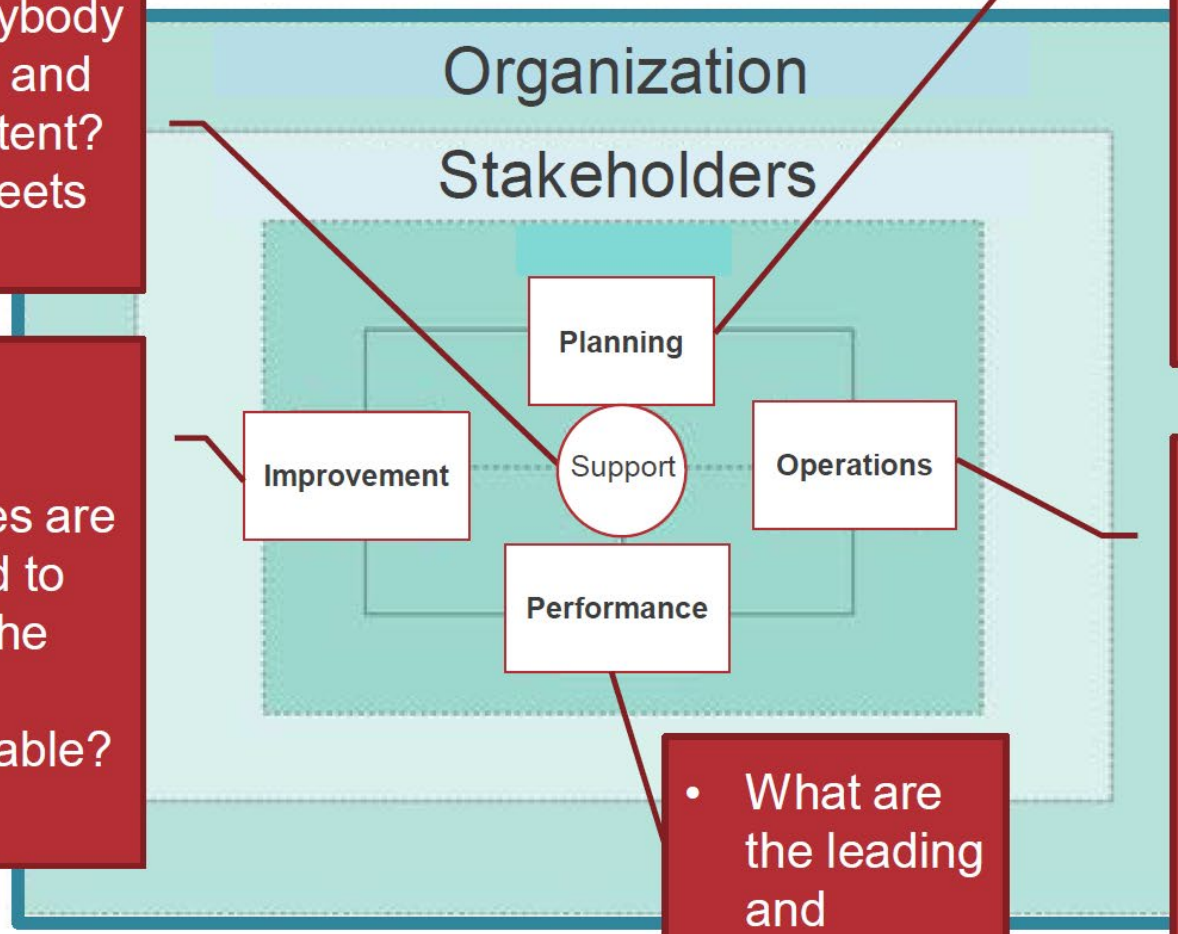
Biorisk Management System Model



ISO 35001 – Processes

- Is everybody trained and competent?
- Info sheets

- What changes are needed to make the risk acceptable?



- What will be done?
- What can go wrong?
- What is the likelihood of occurring?
- What are the consequences?
- What controls are in place?

- Are the controls working?
- Are the SOPs being followed?
- Who is doing the work?

- What are the leading and lagging indicators?

ISO 35001: Biorisk Management System

- **BMS is built on the concept of continual improvement, following the Plan-Do-Check-Act Cycle**

PLAN – establishes objectives, programs, and processes necessary to deliver results in accordance with the Lab's biorisk management policy

DO – implement the processes as planned

CHECK - monitor and measure activities and processes with regard to the biorisk management policy and objectives and report the results

ACT – take actions to continually improve the biorisk management performance to achieve the intended outcomes

Using Plan/Do/Check/Act (the PDCA cycle) for safety initiatives
A Successful Integration!

- **Plan**

  Safety committee reviews audit data and target activity for highest impact.

- **Do**

  Hands-on spill clean-up training was planned and completed.

- **Check**

  Immediate feedback was good! Only 1 subsequent spill incident.

  Request made for a pre-measured container for 10% bleach.

- **Act**

  Provided mop & bucket with water and bleach levels marked.

  Additional hands-on safety training sessions performed.

Value and Benefits of ISO 35001 Biorisk Management Implementation

- Achieve the highest quality laboratory science while ensuring laboratory safety
- Promotes a culture of scientific safety and continual quality improvement
- Improves validity, transparency and reliability of test results
- Ensures a reliable process to prevent, detect and remedy laboratory mistakes
- Provides a systematic framework for effective program management
- Cost Effective! Benefits from investments towards assessment and prevention outweigh the costs of failures

APHL/CDC ISO 35001 Implementation Project

APHL/CDC ISO 35001 Implementation Project

- Develop a strategy, provide guidance, and support the implementation and use of a biorisk management system in accordance with ISO 35001 in public health laboratories.
- **Goal:** Improve internal processes to reduce incidents, accidents, infections and illnesses that may result from laboratory operations
- **Collaboration!**

Real life ISO 35001 non-conformance, NH PHL

6.2 Biorisk management objectives and planning to achieve them

The organization shall establish biorisk management objectives at relevant functions and levels.

The biorisk management objectives shall:

a) be consistent with the biorisk management policy;

b) be measurable (if practicable);

c) take into account applicable requirements;

d) be monitored;

e) be communicated;

f) be updated as appropriate.

SMART Objectives

https://www.teamqi2.com/smart-performance-metrics/

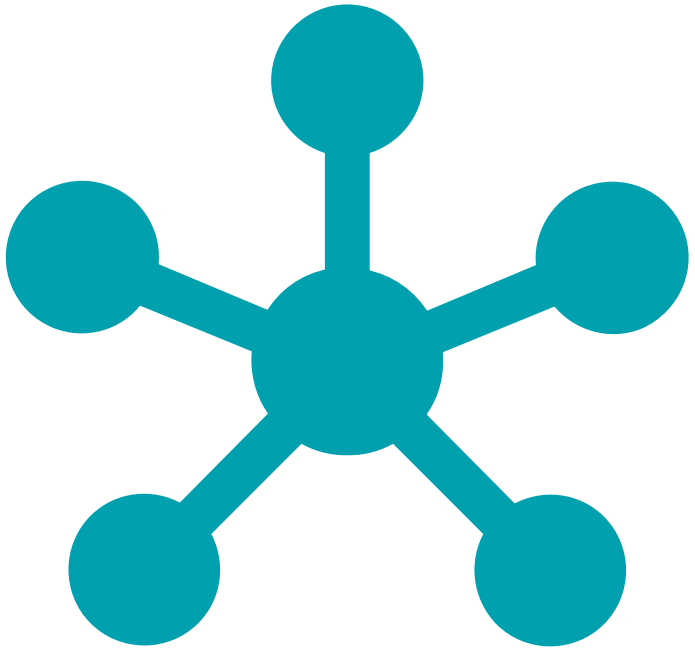
Real life ISO 35001 non-conformances, NH PHL

- No reporting system for drills/exercises/incidents
- No standardized biological and chemical inventory system
- No autoclave sterilization validation procedure found

Real life ISO 35001 non-conformance

NH PHL 2023 ISO 35001 Biorisk Management Objectives:

- The Quality Manager will create an electronic reporting system for drills/exercises/incidents/ non-conforming events by 2/28/23.
  - Measurable: Document 100% drills/exercises/incidents/non-conforming events in the calendar year 2023.
- The Safety Committee will create a standardized PHL biological and chemical inventory system by 5/31/23.
  - Measurable: 100% of individual laboratories will begin a biological/chemical inventory by 12/31/23.
- The Safety Committee will establish an autoclave sterilization validation procedure by 8/31/23.
  - The Safety Committee will perform an autoclave sterilization validation on 100% of PHL autoclaves by 12/31/23.



Challenges around Integration

Challenges around Integration

- Safety & Quality are not foremost in the minds of laboratorians. (*fluff, extra work, not the important stuff*)
- New staff are not confident in standard laboratory practices.
- Not enough time available to devote to staff training.
- Inadequate representation from staff on the Safety Committee. (*primarily managers*)
- Lack of understanding of what helps build a culture of safety and quality. (‘*check the box’ mentality*)

Suggested Tips & Tricks

- Control safety documentation.
- Make safety a Quality Indicator and track it!
- Involve your Safety Officer in quality management meetings.
- Hire personnel that focus on customer service internally and externally, safety and quality improvement.
- Teach, train, mentor!

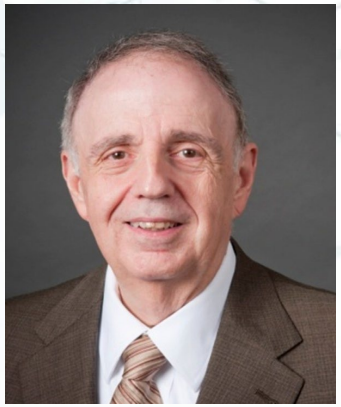
Thank you!
Questions?

October Evaluation Survey

- Link is in the chat
- Survey should take no more than 2 minutes to complete
- Participation is voluntary
- Responses will be anonymous, and no unique information will be sought or kept
- Feedback will be summarized in aggregate only and used to improve future sessions

DLS ECHO Biosafety Session: November 28, 2023

Laboratory Professional Vaccine Compliance and Effect on Safety



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