DLS ECHO Biosafety Session: November 19, 2024

Biorisk Management Performance Evaluation

Michael Pentella, PhD, D(ABMM)

Director, Iowa State Hygienic Laboratory at the University of Iowa

Clinical Professor, University of Iowa

Iowa City, IA

October Session Recap:
"The Importance of Biosecurity in Biorisk Program Management"

139 participants attended the session

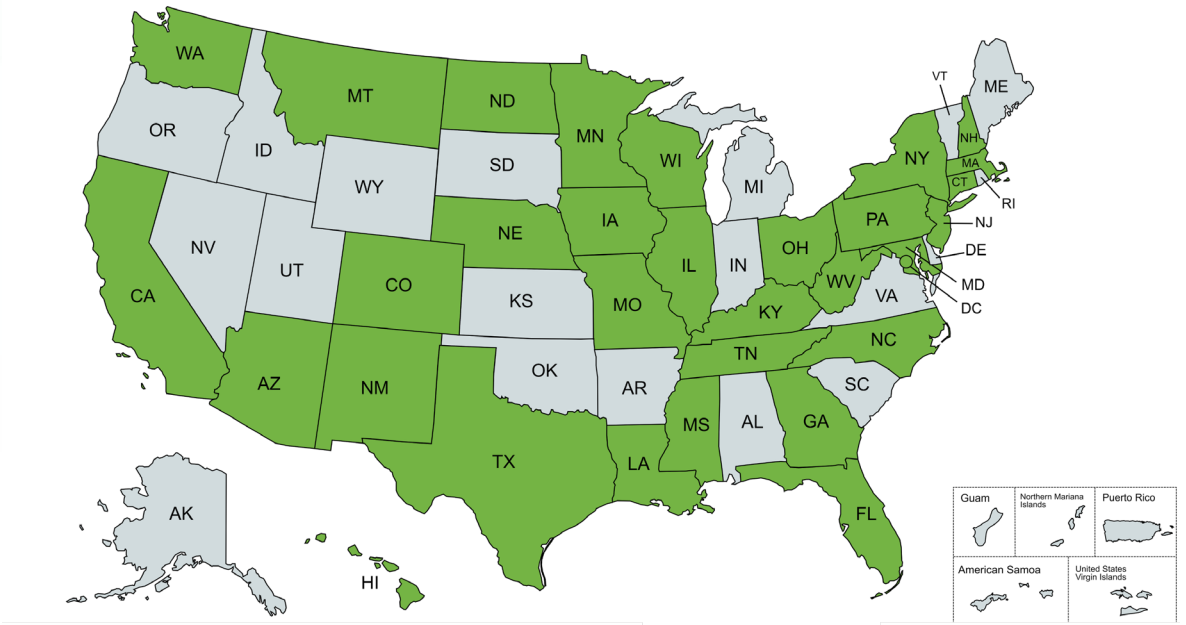
82 organizations were represented

"There has to be a **culture of security and safety** at an entity that is **supported at all leadership levels and made important**."

"It is all about **making it hard to beat the system**, not making it foolproof."

-Session Participants

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, Canada, and Indonesia were also present at the session. Thirteen national organizations also attended this session.

Agenda

- Speaker Introduction
- Didactic 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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Biorisk Management Performance Evaluation

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Clinical Professor, University of Iowa, College of Public Health

Director, State Hygienic Laboratory

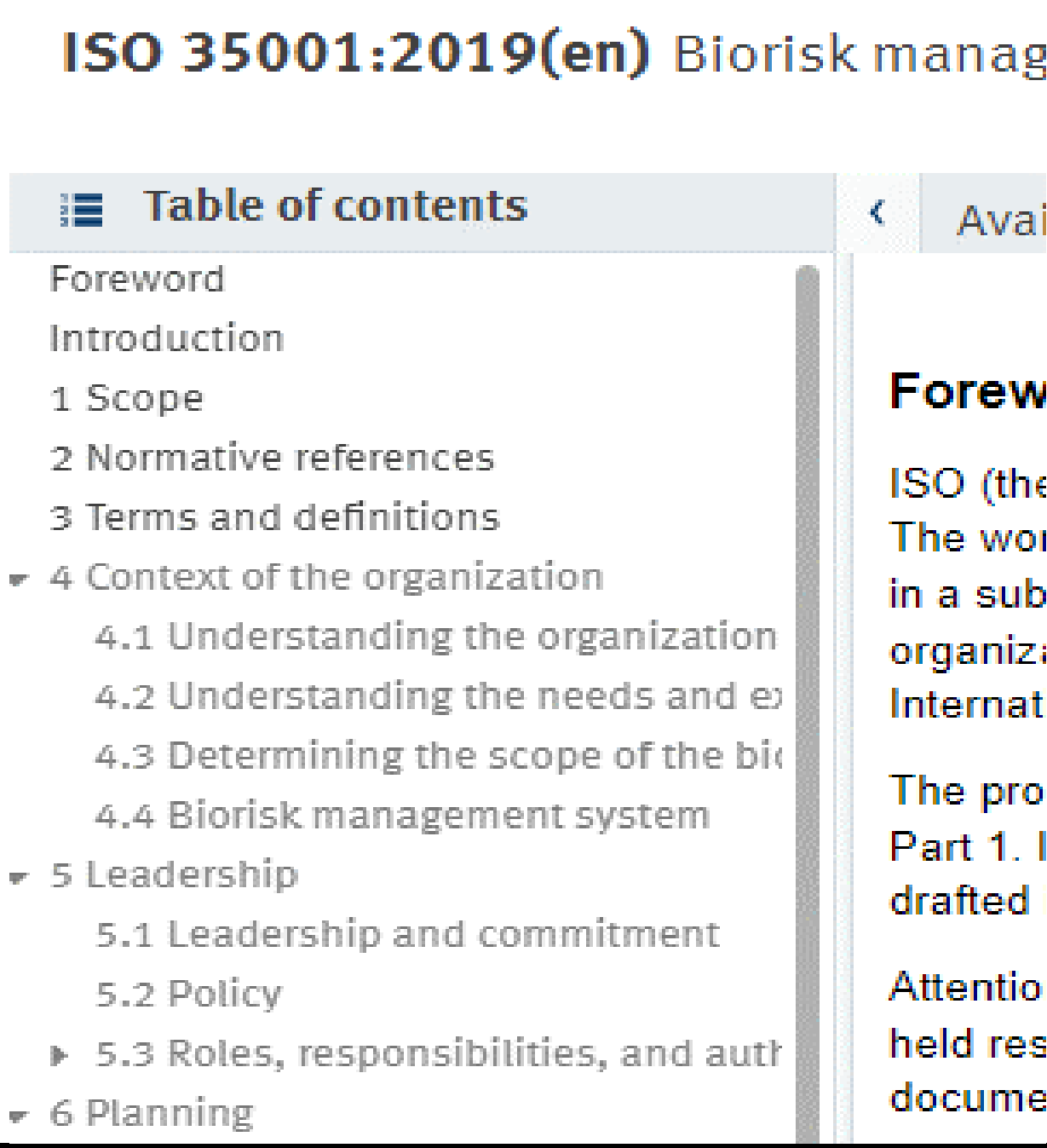
Objectives

1. Review the APHL/CDC ISO 35001 Pilot Program
2. Understand the planning and audit process
3. Consider the value of performing an audit of your biosafety program

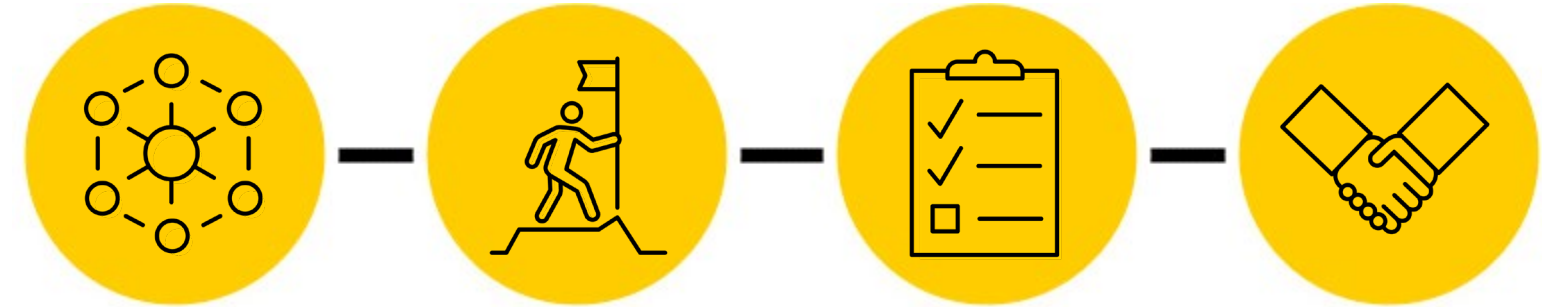
APHL/CDC ISO 35001 Pilot Program Introduction and SHL Background

ISO 35001

- International Organization for Standardization (ISO)
- Goal: to identify, assess, control and monitor the risks associated with hazardous biological materials in a laboratory setting.
- Seven different principles



Seven Different Principles of ISO 35001



Context of the Organization

Leadership

Planning

Support

Operations

Performance Evaluation

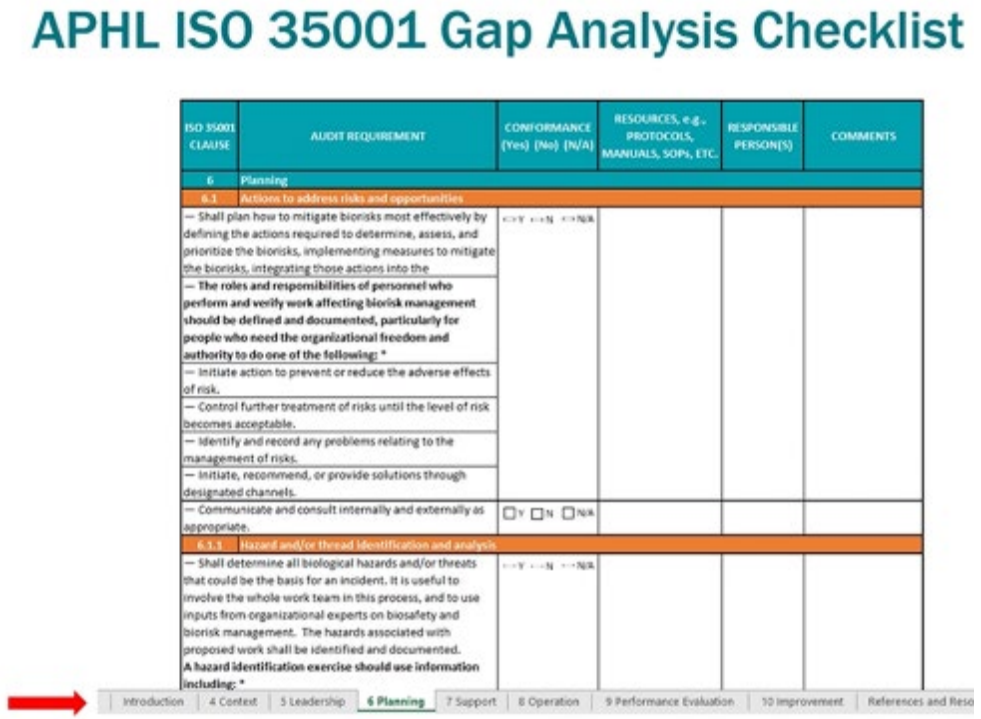
Improvement

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

ISO 35001 Gap Analysis

- The CDC/APHL ISO 35001:2019-Biorisk Management Gap Analysis Checklist



Knowledge Check

- What other ISO accreditation do clinical and public health laboratories typically aspire to?
- A. ISO 17025
- B. ISO 15189
- C. Both 17025 and 15189

ISO standards are internationally agreed by experts

Think of them as a formula that describes the best way of doing something.

It could be about making a product, managing a process, delivering a service or supplying materials – standards cover a huge range of activities.

Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade

Facts about the State Hygienic Laboratory at the University of Iowa

110+

Clinical and environmental scientists

15

Fellows and interns in FY2024

170+

Specialized instruments and techniques

3 Locations: Coralville, Ankeny and Mildford, Iowa

University System

- 1 of 2 across the nation.
- Environmental Health and Safety Office (EHS)
- Office of the Vice President for Research

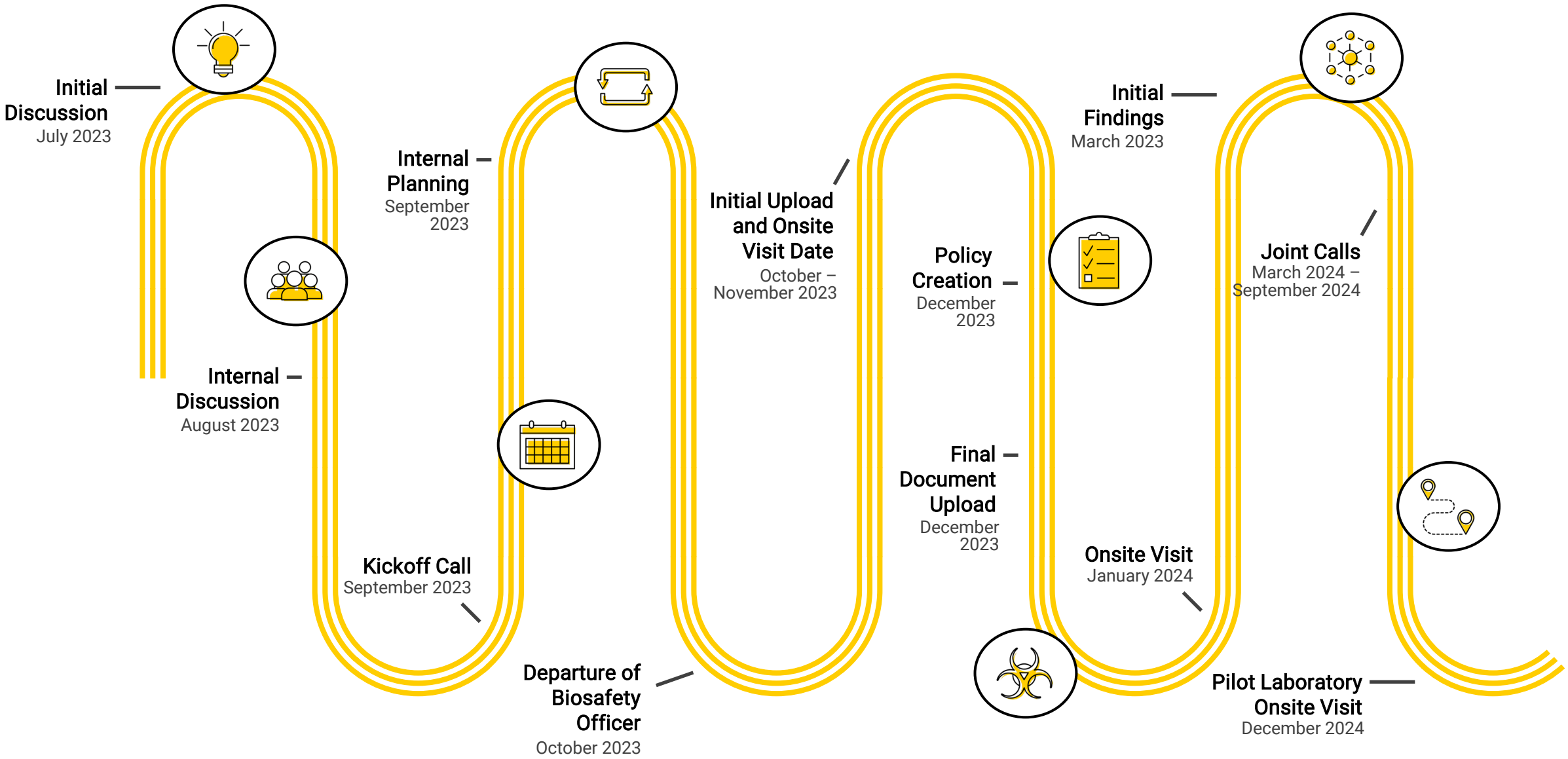
Mission Statement

The Environmental Health & Safety Office (EHS) provides services intended to pr
compliance, and environmental management. We offer a variety of services in th
Occupational, and Radiation safety as well as select Environmental programs. Sc
include chemical and radiation exposure monitoring, worksite hazard evaluations
equipment recommendations, safety program reviews, safety training, and dispo
and infectious waste. Consultative services include regulatory compliance assist
and CDC/USDA-related responsibilities within health care, research, academic, f

EHS has over 100 safety-related educational programs that are intended to infor
workplace. By utilizing the information presented, individuals will be capable of i
developing safe work practices and protocols in order to protect not only thems

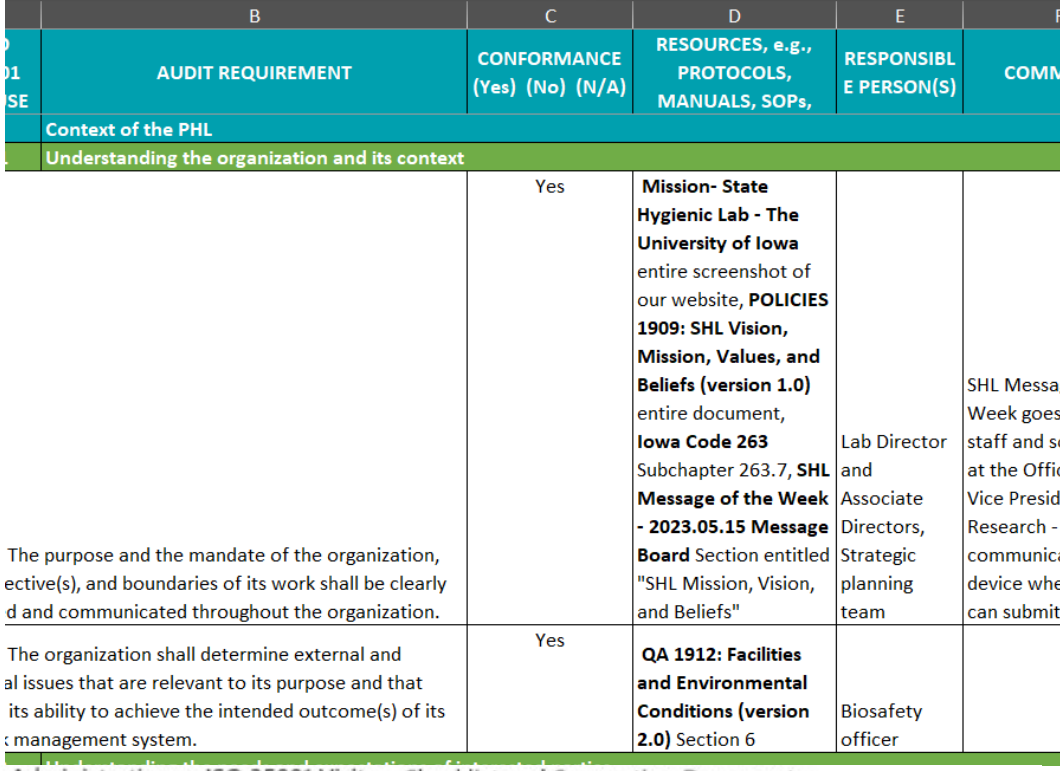
Evaluation Planning and Process

Timeline


Initial Discussion
July 2023
Internal Discussion
August 2023
Kickoff Call
September 2023
Internal Planning
September 2023
Departure of Biosafety Officer
October 2023
Initial Upload and Onsite Visit Date
October – November 2023
Policy Creation
December 2023
Final Document Upload
December 2023
Onsite Visit
January 2024
Initial Findings
March 2023
Joint Calls
March 2024 – September 2024
Pilot Laboratory Onsite Visit
December 2024

Organization

- Microsoft Teams location
- Organized by seven principles
- Other folders
  - Meeting notes
  - Archive
  - Onsite visit materials



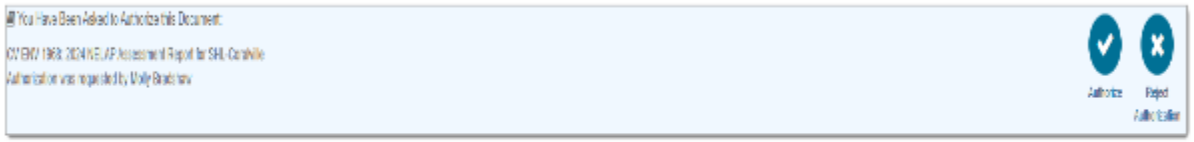
	B	C	D	E	F
01 SE	AUDIT REQUIREMENT	CONFORMANCE (Yes) (No) (N/A)	RESOURCES, e.g., PROTOCOLS, MANUALS, SOPs,	RESPONSIBLE PERSON(S)	COMM
	Context of the PHL				
	Understanding the organization and its context				
	The purpose and the mandate of the organization, ective(s), and boundaries of its work shall be clearly d and communicated throughout the organization.	Yes	**Mission- State Hygienic Lab - The University of Iowa** entire screenshot of our website, **POLICIES 1909: SHL Vision, Mission, Values, and Beliefs (version 1.0)** entire document, **Iowa Code 263** Subchapter 263.7, **SHL Message of the Week - 2023.05.15 Message Board** Section entitled "SHL Mission, Vision, and Beliefs"	Lab Director and Associate Directors, Strategic planning team	SHL Messa Week goes staff and s at the Offi Vice Presid Research - communica device whe can submit
	The organization shall determine external and al issues that are relevant to its purpose and that its ability to achieve the intended outcome(s) of its management system.	Yes	**QA 1912: Facilities and Environmental Conditions (version 2.0)** Section 6	Biosafety officer	

Biosafety and Biosecurity Policy Centralize

THE UNIVERSITY OF IOWA

STATE HYGIENIC LABORAT
Iowa's Environmental and Public Health Laboratory
www.shl.uiowa.edu

Passport



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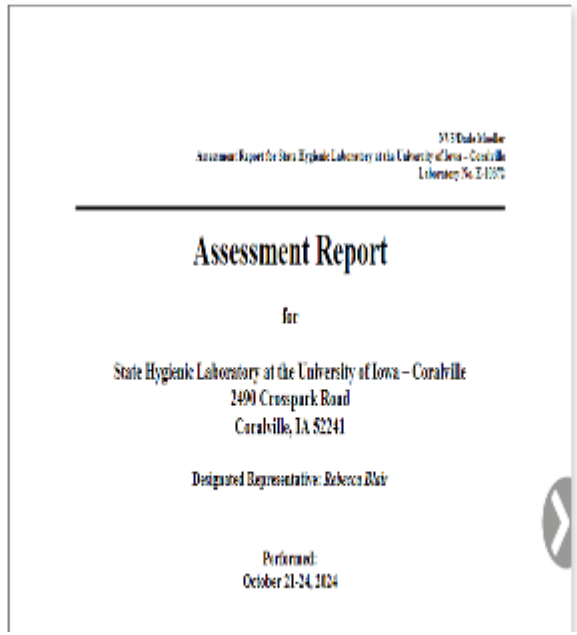


Assessment Report

for

State Hygienic Laboratory at the University of Iowa – Coralville
2490 Crosspark Road
Coralville, IA 52241

Designated Representative: Rebecca Blair

Performed:
October 21-24, 2024

SHL Biosafety and Biosecurity

Version:	1.0
Subject:	
Authors:	Michael Pentella
Code:	POLICIES 1911
Document Status:	Authorized
Release Date:	19-Dec-2023
Document Category:	Policy
Document Type:	Policy
Authorized By:	Michael Pentella, Molly Bradshaw, and Rebecca Blair
Authorized on:	19-Dec-2023
Ou Name:	SHL POLICY
Section:	SHL Policies
Review by Date:	18-Dec-2025
Location Of Copy:	unknown
Last Update:	19-Dec-2023 07:52
Date Time Printed:	PREVIEW ONLY - UNCONTROLLED
Number Of Copies:	N/A
Print History:	No recorded print history

IOWA


In-person
Evaluation

Discussion Insert #1

What do you see as the positives and negatives of participating in an ISO35001 audit?

Tuesday, January 9th Agenda

8:45AM	**Arrival at the State Hygienic Laboratory**
9:00 AM – 10:00 AM	**Kickoff meeting with all participants** (State Hygienic Laboratory Staff)
10:00 AM – 12:00 PM	**Initial meeting with Biosafety/Quality Staff and obtain documents** (Eileen Moran and Michael Pentella)
12:00 PM – 1:00 PM	**Lunch**
1:00 PM – 2:30 PM	**Laboratory Tour** (Eileen Moran and Michael Pentella)
2:30 PM – 5:00 PM	**Laboratory Staff Discussions**

- UI Office of Environmental Health and Safety Discussion at 2:30 PM
  - *Haley Sinn, Director, University of Iowa Environmental Health and Safety*
  - *Nyree Mortensen, Biological Safety Officer, University of Iowa Environmental Health and Safety*
- Safety Committee Discussion at 3:00 PM
  - *Angela Goetzinger, Environmental Lab Analyst, Analytical Chemistry, Environmental (Ankeny)*
  - *Don Simmons, Environmental Lab Manager, Lab Certification, Environmental (Ankeny)*
  - *Cynthia Cass, Clinical Lab Manager, Assistant Director, Diagnostic and Clinical*
  - *Paul Beney, Environmental Lab Analyst, Air Quality, Environmental*
  - *David Trieweiler, Engineering Coordinator, Biosecurity Officer, Security and Maintenance, Director*
  - *James Luzier, Environmental Supervisor, Limnology, Environmental (Ankeny)*
  - *David Gonzalez, Graduate Fellow, Quality Management, Director*
  - *Doug Oppedal, Environmental Lab Analyst, Environmental Microbiology, Diagnostic and Clinical*
  - *Eileen Moran, Postdoctoral Research Fellow, Diagnostic and Clinical*
  - *Mike Pentella, Director*
- Biosecurity Officer Discussion at 4:00 PM
  - *David Trieweiler, Engineering Coordinator, Biosecurity Officer, Security and Maintenance, Director*
- Diagnostic and Clinical Associate Director Discussion at 4:30 PM
  - *Cynthia Cass, Clinical Lab Manager, Assistant Director, Diagnostic and Clinical*

Wednesday, January 10th Agenda

8:45AM **Arrival at the State Hygienic Laboratory**

9:00 AM – 9:30 AM **Quick debrief with Biosafety/Quality Staff** (Eileen Moran and Michael Pentella)

9:30 AM – 11:30 AM **Review documents/additional laboratory tour** (Eileen Moran and Michael Pentella)

11:30 AM – 12:00 PM **Processing/Accessioning Staff Interview**

- *Laura Clark, Program Coordinator, Accessioning/Support Services, Environmental*
- *Cameron Aarhus, Laboratory Technician II, Accessioning/Support Services, Environmental*
- *Debra Gale, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Michael Hodnett, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Tami Orr, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Jessica Antonini, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Nadjia Kecira, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Molly Standard, Laboratory Technician I, Accessioning/Support Services, Environmental*
- *Jenny Bui, Temp Professional Employee, Accessioning/Support Services, Environmental*
- *Ariel Kopel, Environmental Lab Analyst, Reference Microbiology, Diagnostic and Clinical*

1:00 PM – 5:00 PM **Review documents and Laboratory Staff Discussions**

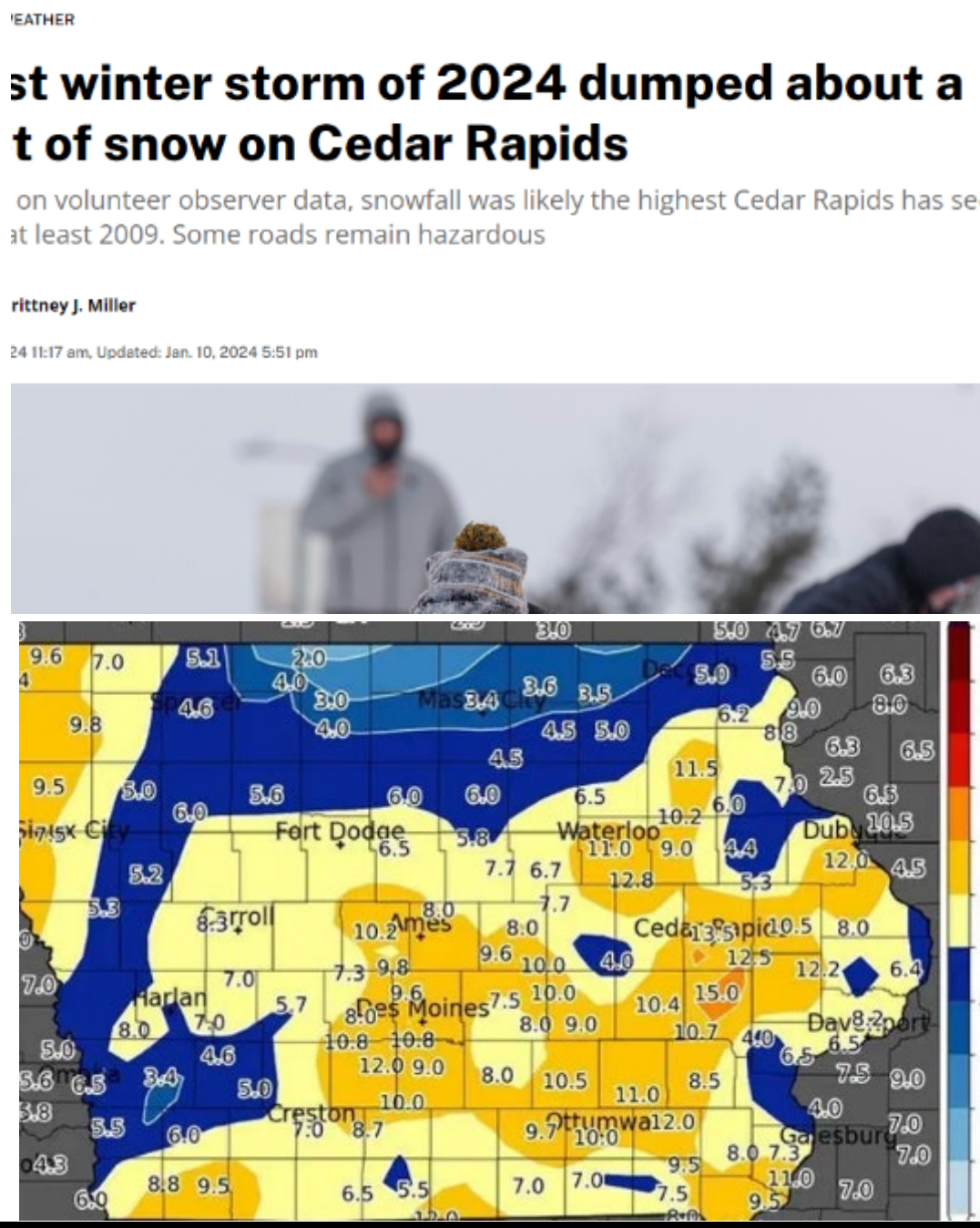
- Environmental Supervisor and Staff Discussion at 1:30 PM
  - *Dennis Heimdal, Environmental Lab Supervisor, Lakeside, Environmental (Lakeside)*
  - *Terry Cain, Environmental Lab Supervisor, Analytical Chemistry, Environmental*
  - *Jessica Elliott, Environmental Lab Manager, Analytical Chemistry, Environmental (Ankeny)*
  - *Amanda Hughes, Environmental Manager, Air Quality, Environmental*
  - *Michele Yacopucci, Environmental Lab Scientist, Analytical Chemistry and Chemical Threat, Environmental*
  - *James Luzier, Environmental Supervisor, Limnology, Environmental (Ankeny)*
  - *Don Simmons, Environmental Lab Manager, Lab Certification, Environmental (Ankeny)*
  - *Sherri Marine, Program Director, Support Services, Environmental*
  - *Dustin May, Environmental Lab Manager, Analytical Chemistry, Environmental*
  - *Brian Wels, Environmental Lab Scientist, Analytical Chemistry, Environmental (Ankeny)*
  - *Kelsey Wieland, Chemical Threat Coordinator, Chemical Threat, Environmental*
  - *Patty Rose, Clinical Lab Technical Spec, Analytical Chemistry, Environmental*
- Clinical Supervisor Discussion at 2:00 PM
  - *Kenneth Coursey, Clinical Lab Manager, Newborn Screening, Diagnostic and Clinical (Ankeny)*
  - *Jeff Benfer, Clinical Lab Supervisor, Molecular Biology, Diagnostic and Clinical*
  - *Jay Boman, Clinical Lab Supervisor, Serology, Maternal Screening, and Diagnostic Microbiology, Diagnostic and Clinical*
  - *Ryan Jepson, Environmental Lab Manager, Environmental Microbiology, Diagnostic and Clinical*
  - *Megan Nelson, Clinical Lab Supervisor, Reference Microbiology, Diagnostic and Clinical*
  - *Wes Hottel, Asst Research Scientist/Engin, Bioinformatics, Diagnostic and Clinical*
  - *Valerie Phoenix, Clinical Lab Supervisor, Newborn Screening, Diagnostic and Clinical (Ankeny)*
  - *Hang Mo Koo, Clinical Lab Technical Spec, Newborn Screening, Diagnostic and Clinical (Ankeny)*
- Quality Team Discussion at 2:30 PM
  - *Rebecca Blair, Qual & Op Improv Snr Engineer, Quality Management, Director (Ankeny)*
  - *Molly Bradshaw, Qual & Op Improv Engineer, Quality Management, Director*
  - *David Gonzalez, Graduate Fellow, Quality Management, Director*
- Training Coordinator Discussion at 3:00 PM
  - *Laina Edwards, Program Manager, Education and Training, Director*
- Lab Director/Interim Biosafety Officer Discussion at 4:00 PM
  - *Mike Pentella, Director*

Interview Discussions

- 10 discussions with 25 staff held in person and by zoom.
- Met with the Safety Committee members.

Challenges Faced

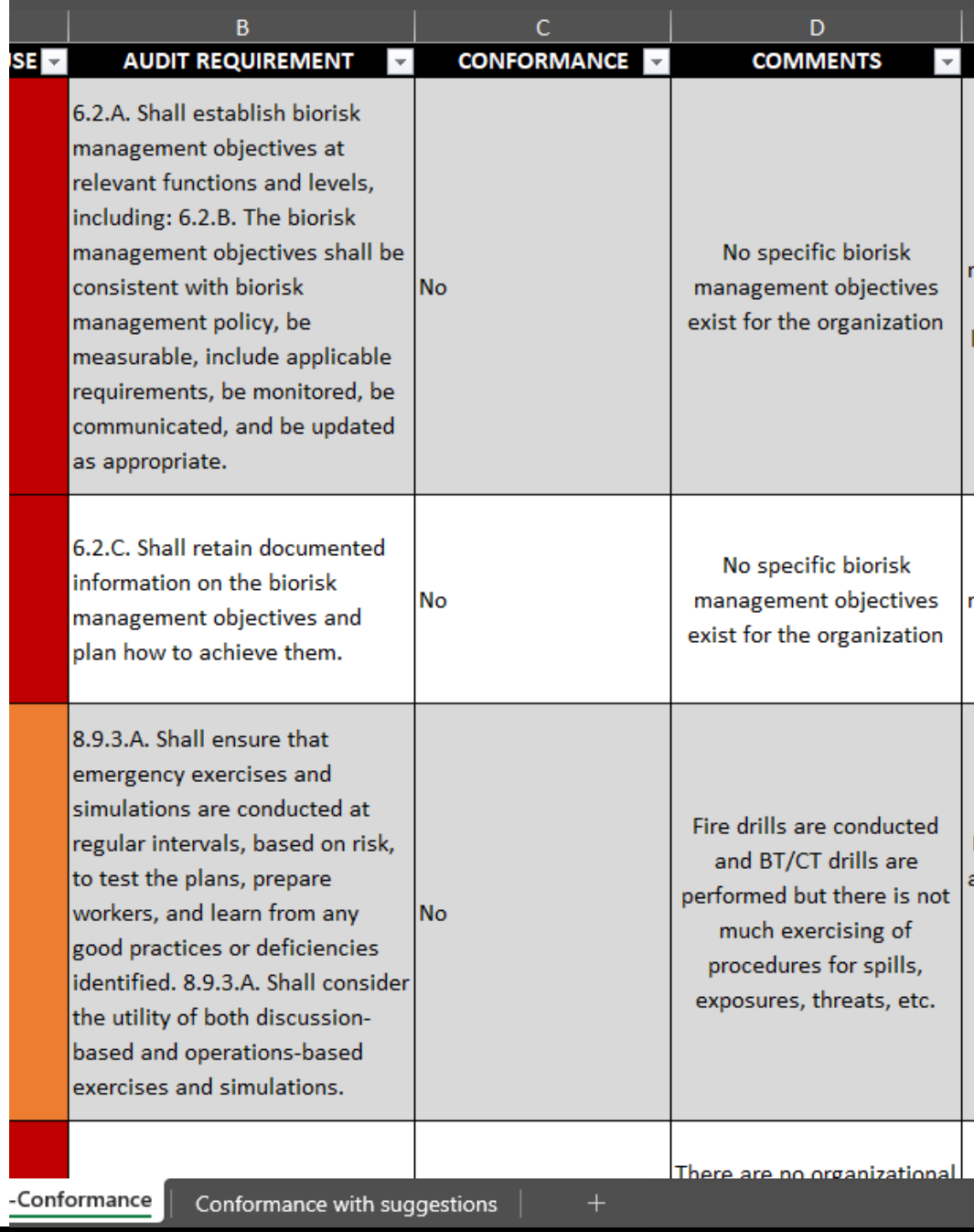
- BT coordinator's departure
- Everyday challenges
- Inclement weather 1/9/24 and 11/10.
  - In-person to Zoom
  - Catering
  - Staff participation




Post-Evaluation

Gap Analysis Checklist

- Four evaluation options
  - Yes
  - Yes - with Suggestions
  - No
  - Non-applicable
- 20 conformances with suggestions
- 9 non-conformances



	B	C	D
SE	AUDIT REQUIREMENT	CONFORMANCE	COMMENTS
	6.2.A. Shall establish biorisk management objectives at relevant functions and levels, including: 6.2.B. The biorisk management objectives shall be consistent with biorisk management policy, be measurable, include applicable requirements, be monitored, be communicated, and be updated as appropriate.	No	No specific biorisk management objectives exist for the organization
	6.2.C. Shall retain documented information on the biorisk management objectives and plan how to achieve them.	No	No specific biorisk management objectives exist for the organization
	8.9.3.A. Shall ensure that emergency exercises and simulations are conducted at regular intervals, based on risk, to test the plans, prepare workers, and learn from any good practices or deficiencies identified. 8.9.3.A. Shall consider the utility of both discussion-based and operations-based exercises and simulations.	No	Fire drills are conducted and BT/CT drills are performed but there is not much exercising of procedures for spills, exposures, threats, etc.
			There are no organizational

-Conformance | Conformance with suggestions | +

Conformances with Suggestions

Conformances with Suggestions – 5 Leadership

5.1.A. Shall demonstrate leadership and commitment with respect to the biorisk management system by: 5.1.A.1. Ensuring that the biorisk management policy and biorisk management objectives are established and are compatible with the strategic direction of the organization.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL

5.2.A.2. Provides a framework for setting biorisk management objectives.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL

Conformances with Suggestions – 7 Support

7.1.1.A. Shall ensure that risks to worker health are managed effectively, including consideration for preventive and protective measures. All workers whose health could be directly impacted by exposure to biological materials shall be included in the worker health program.

Suggested Solution: Standardize worker health/vaccination program for staff based on department and/or role to facilitate communications and assignment of medical surveillance with HR and Occ health

7.1.1.1.A. Shall establish and implement vaccination policy as part of the worker health program.
7.1.1.1.B. Shall ensure that the required and/or recommended vaccines and its information are made available to the worker(s).
7.1.1.1.C. Shall maintain immunization records in accordance with national, regional, and local requirements.

Suggested Solution: Standardize worker health/vaccination program for staff based on department and/or role to facilitate communications and assignment of medical surveillance with HR and Occ health

7.2.B. Shall ensure that these persons are competent based on appropriate education, training, or experience.

Suggested Solution: Standardize competence and training for staff based on department and/or role for all new (and transferred) staff; send list to HR for compliance tracking

Conformances with Suggestions – 7 Support

7.2.2.A. Shall implement personnel reliability measures to determine and provide assurance that workers are reliable, trustworthy, and competent, and to determine individuals who may pose a biosecurity or biosafety risk to the organization. **7.2.2.B.1-5**

Suggested Solution: Check on personnel reliability measures applied to all staff (beyond those enrolled in FSAP)

7.3.1.A. Shall ensure that requirements and procedures for biorisk management training of workers are identified, established, and maintained.

Suggested Solution: Consider utilizing training program standardization process (7.2 above) to create proactive training with learning paths specific to roles; gain buy in from supervisors and SMEs to work with training coordinator to develop materials; consider incorporating more hands-on training

7.4.B.2. Shall ensure two-way directional communication is established with, and access to up-to-date information is provided to, workers on relevant biorisks.

Suggested Solution: Consider having departmental supervisors condense/provide safety messaging to staff, relevant to their department, at their regular group meetings

IOWA

Conformances with Suggestions – 8 Operation

8.9.2. Shall ensure that all relevant workers are trained on the organization's emergency response plans.

Suggested Solution: Provide additional training on emergency response plans

8.9.4. Shall ensure that adequate contingency measures are in place to ensure the safety and security of continued operations in the event of an emergency.

Suggested Solution: Provide additional training on contingency measures (COOP) after plan has been reviewed and approved

Conformances with Suggestions – 9 Performance Evaluation

9.2.1.A.1. Shall conduct internal audits and inspections at planned intervals to provide information on whether the biorisk management system conforms to the organization's own requirements for its biorisk management system.

Suggested Solution: Add BRM/safety components to audit policies and procedures

9.2.2.A. Shall plan, establish, implement, and maintain an audit program(s), including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned and the results of previous audits.

Suggested Solution: Add BRM/safety components to audit policies and procedures

9.3.A. Shall review the organization's biorisk management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness.

Suggested Solution: Add BRM/safety components to management review process and incorporate BRM objectives

Conformances with Suggestions – 10 Improvement

10.1.A. Shall determine opportunities for improvement (see Clause 9) and implement necessary actions to achieve the intended outcomes of its biorisk management system.

Suggested Solution: Add BRM/safety components to quality management review to identify areas for improvement

10.3.A. Shall continually improve the suitability, adequacy, and effectiveness of the biorisk management system.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

10.3.A.1. Shall enhance biorisk management performance.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

10.3.A.2. Shall promote a culture of continual improvement that supports the biorisk management system.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

Conformances with Suggestions – 10 Improvement

10.3.A.3. Shall promote the participation of workers in implementing actions for the continual improvement of the biorisk management system.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

10.3.A.4. Shall communicate the relevant results of continual improvement to workers and other relevant interested parties.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

10.3.A.5. Shall maintain and retain documented information as evidence of continual improvement.

Suggested Solution: Add BRM/safety components to CQI and preventative action plans/SOPs

Non-Conformances

Non-Conformances – 6 Planning

6.2.A. Shall establish biorisk management objectives at relevant functions and levels, including: 6.2.B. The biorisk management objectives shall be consistent with biorisk management policy, be measurable, include applicable requirements, be monitored, be communicated, and be updated as appropriate.

Suggested Solution: Create SMART Biorisk Management (BRM) objectives that include metrics that can be tracked for BRM program that can lead to Continuous Quality Improvement (CQI) for State Hygienic Lab

6.2.C. Shall retain documented information on the biorisk management objectives and plan how to achieve them.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL

Knowledge Check

- What are “Smart Objectives?”
  - A. Sensitive, Mastered, Accountable, Rational, Tenured
  - B. Specific, Measurable, Achievable, Relevant, Time-bound
  - C. Short, Mindful, Accelerated, Relatable, Techniques

Does your lab currently use SMART objectives?

- A. Yes
- B. No

Discussion Insert #2

What are the barriers to using the SMART goal model in your laboratory?

Non-Conformances – 8 Operation

8.9.3.A. Shall ensure that emergency exercises and simulations are conducted at regular intervals, based on risk, to test the plans, prepare workers, and learn from any good practices or deficiencies identified. 8.9.3.A. Shall consider the utility of both discussion-based and operations-based exercises and simulations.

Suggested Solution: Provide additional training and hands-on or simulation-based drills on potential BRM topic incidents/emergencies

Non-Conformances – 9 Performance Evaluation

9.1.A. Shall continuously evaluate the performance and effectiveness of the biorisk management system, including:

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

9.1.A.1. Shall determine what needs to be monitored and measured.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

9.1.A.2. Shall determine the methods for monitoring, measurement, analysis, and evaluation, as applicable, to ensure valid results.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

Non-Conformances – 9 Performance Evaluation

9.1.A.3. Shall determine when the monitoring and measuring shall be performed.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

9.1.A.4. Shall determine when the results from monitoring and measurement shall be analyzed and evaluated.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

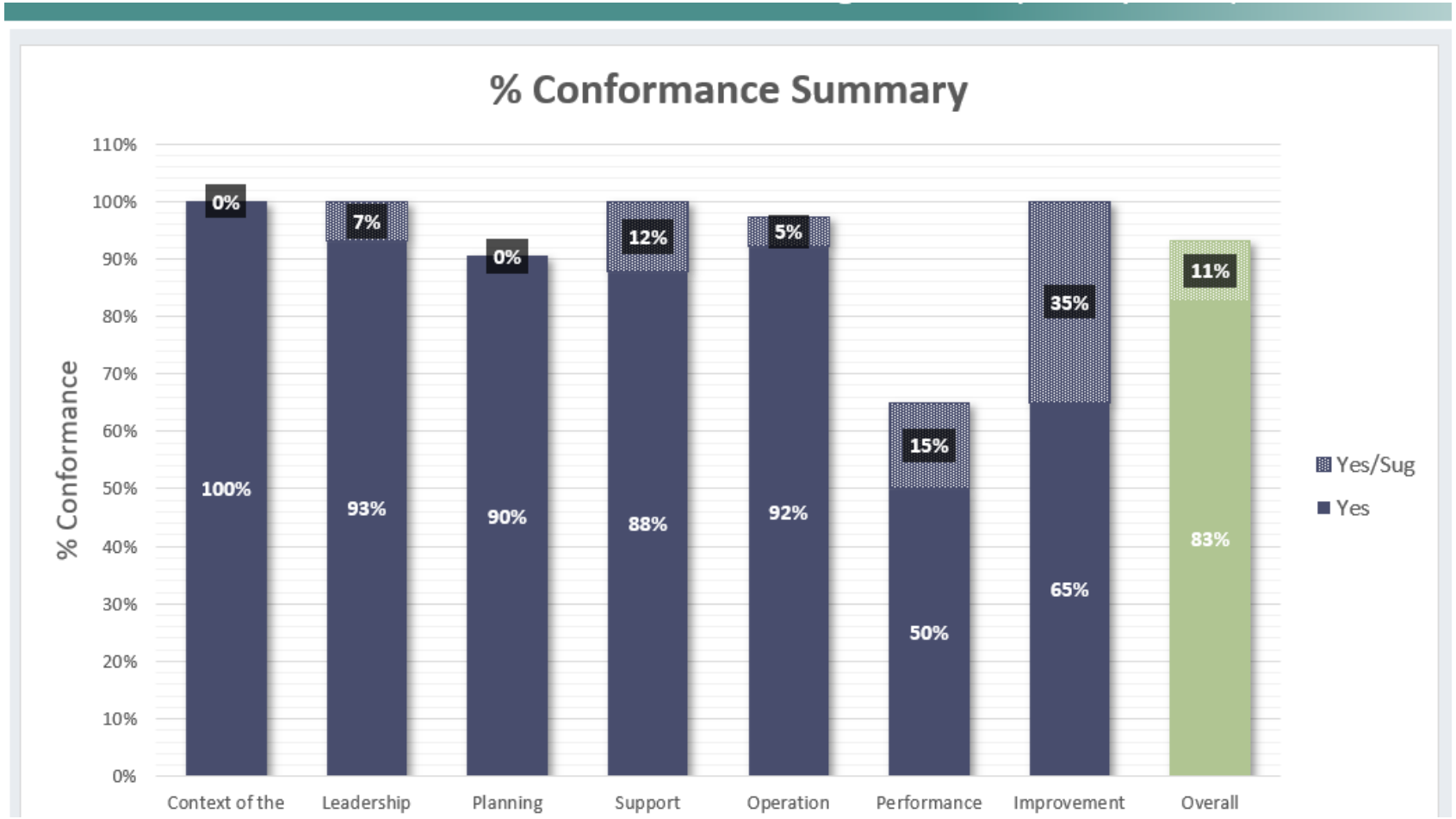
9.1.B. Shall retain appropriate documented information as evidence of the results.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly

Non-Conformances – 9 Performance Evaluation

9.3.B.A-B. Shall include consideration of the status of the organization's progress towards its biorisk management objectives as well as consideration of the status of actions from previous management reviews.

Suggested Solution: Create SMART BRM objectives that include metrics that can be tracked for BRM program that can lead to CQI for SHL; consider conducting additional internal SHL audits regularly



Conformance by Category

Category	# Applicable Tasks	Compliant	Comp/Suggestion	Noncompliant	Priority
Context of the PHL	7	7	0	0	
Leadership	29	27	2	0	
Planning	21	19	0	2	
Support	49	43	6	0	
Operation	38	35	2	1	
Performance Evaluation	20	10	3	7	
Improvement	20	13	7	0	

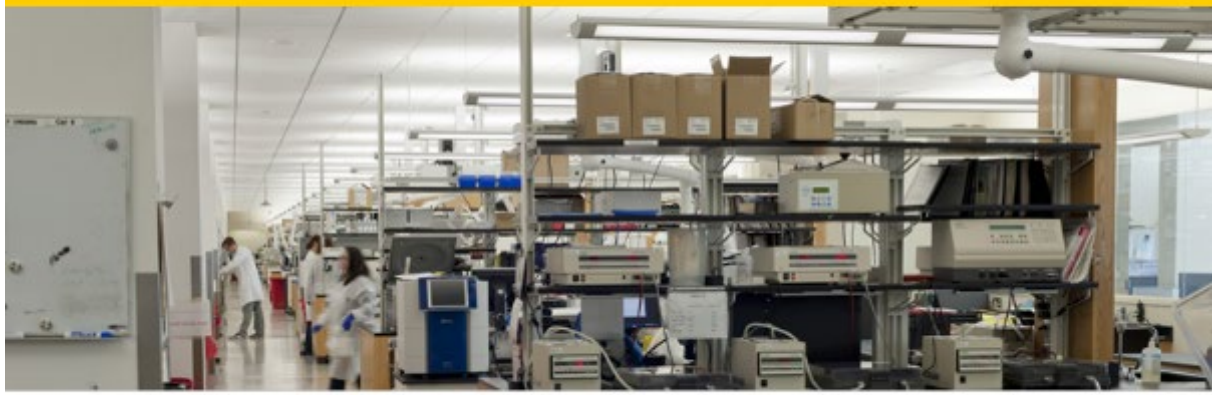
Discussion Insert #3

How is relevant information on biosafety communicated with your staff?

Communication

- All Staff meetings
- SHL Message of the Week
- Bulletin board
- Emergency Preparedness Committee
- Safety Committee

IOWA State Hygienic Laboratory



SHL Message - Week of January 2, 2024

APHL/CDC ISO 35001 Lab Visit

APHL and CDC are collaboratively working with the State Hygienic Laboratory to develop a strategy, provide guidance, and support implementation and use of a bio-risk management system in accordance with ISO 35001. As a partner, SHL will host APHL and CDC for an in-person visit from **Tuesday, January 9 to Thursday, January 11 next week**. This visit will consist of a document review and interviews of SHL and UI staff that can share a bit more about what our bio-risk management system currently looks like.

All staff are invited to the kickoff meeting on Tuesday and the closing/summary meeting on Thursday. These invites have been sent to everyone's calendar. If there are any issues viewing this invite, please don't hesitate to reach out to me at lauren-kovarna@uiowa.edu.

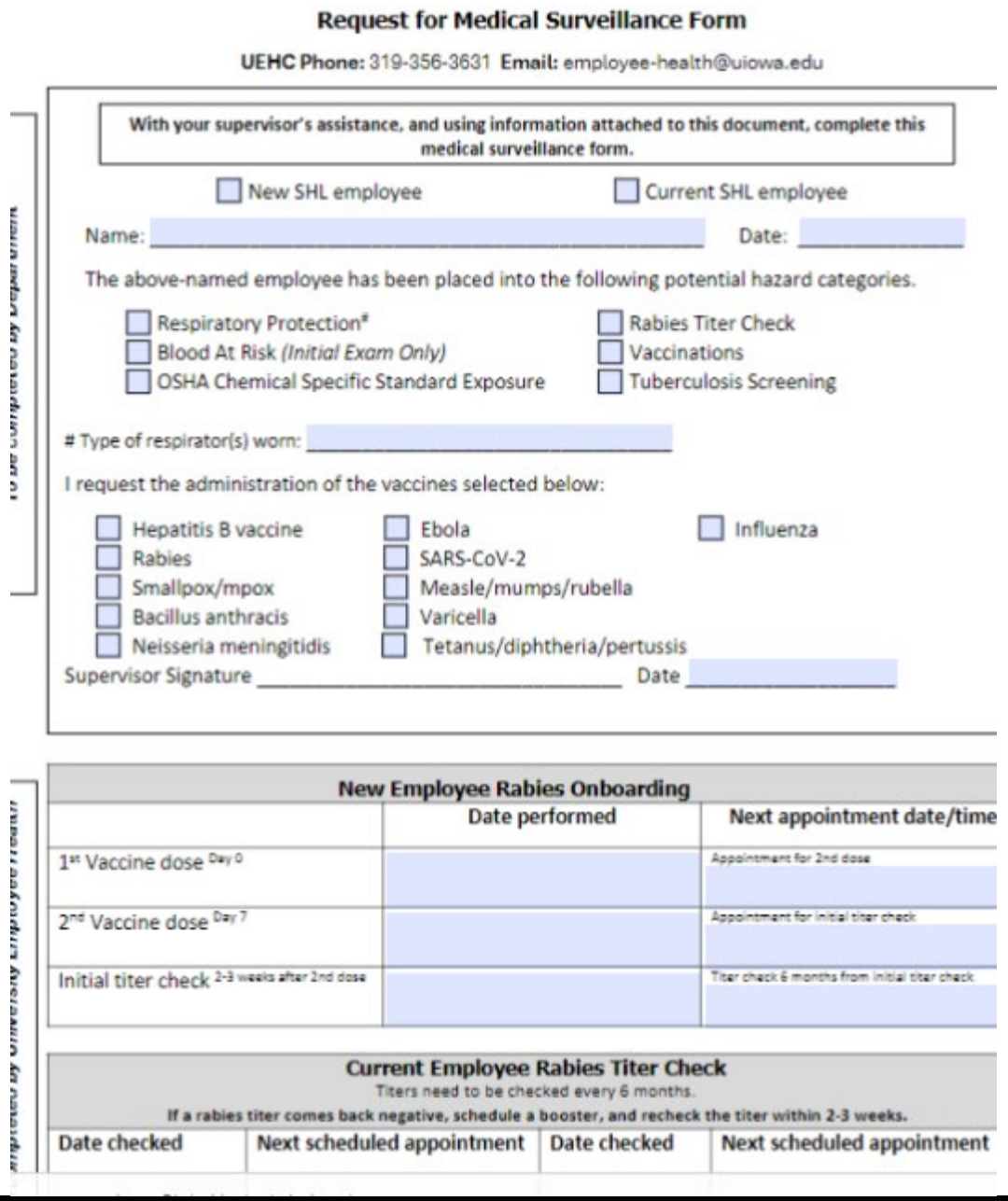
Laboratory Leadership Monthly Meeting

Lab Leadership met on **Thursday, April 9th**. The discussion included a Salesforce demo, ISO 35001 gap analysis update, a proposed employee health form, Lab Week updates, and student outreach. Find the notes here: M:\\Committees\\Lab Leadership Team\\Agendas and meeting notes\\2024 Agenda and Meeting Notes\\4-09-2024 Lab Leadership Notes.docx.

IOWA

Solutions in Action

- Medical Examination Form
  - iPassport
- Autoclave validation
- In-person FD drill
  - Spill drill and trainings in future
- Safety committee goals



Request for Medical Surveillance Form

UEHC Phone: 319-356-3631 **Email:** employee-health@uiowa.edu

With your supervisor's assistance, and using information attached to this document, complete this medical surveillance form.

☐ New SHL employee ☐ Current SHL employee

Name: _____ Date: _____

The above-named employee has been placed into the following potential hazard categories.

☐ Respiratory Protection* ☐ Rabies Titer Check
☐ Blood At Risk *(Initial Exam Only)* ☐ Vaccinations
☐ OSHA Chemical Specific Standard Exposure ☐ Tuberculosis Screening

Type of respirator(s) worn: _____

I request the administration of the vaccines selected below:

☐ Hepatitis B vaccine ☐ Ebola ☐ Influenza
☐ Rabies ☐ SARS-CoV-2
☐ Smallpox/mpox ☐ Measle/mumps/rubella
☐ Bacillus anthracis ☐ Varicella
☐ Neisseria meningitidis ☐ Tetanus/diphtheria/pertussis

Supervisor Signature _____ Date _____

New Employee Rabies Onboarding

	Date performed	Next appointment date/time
1st Vaccine dose Day 0		Appointment for 2nd dose
2nd Vaccine dose Day 7		Appointment for initial titer check
Initial titer check 2-3 weeks after 2nd dose		Titer check 6 months from initial titer check

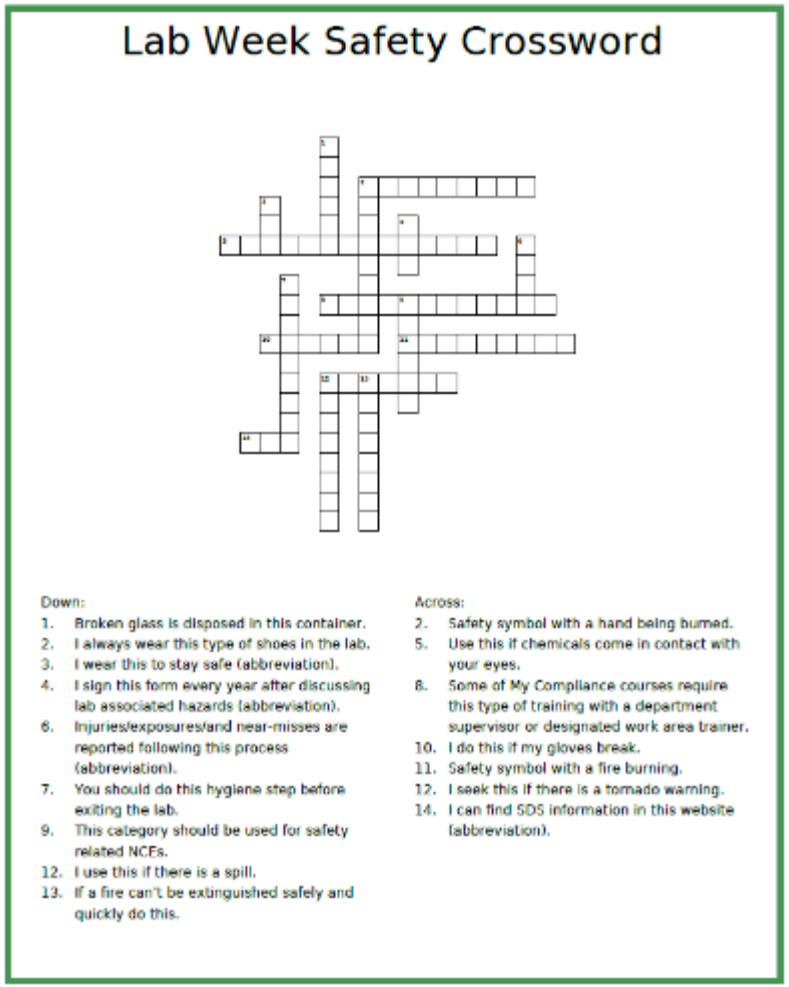
Current Employee Rabies Titer Check

Titers need to be checked every 6 months.

If a rabies titer comes back negative, schedule a booster, and recheck the titer within 2-3 weeks.

Date checked	Next scheduled appointment	Date checked	Next scheduled appointment

Safety Committee's Goals and Efforts



Lab Week Safety Crossword

Down:

1. Broken glass is disposed in this container.
2. I always wear this type of shoes in the lab.
3. I wear this to stay safe (abbreviation).
4. I sign this form every year after discussing lab associated hazards (abbreviation).
6. Injuries/exposures/and near-misses are reported following this process (abbreviation).
7. You should do this hygiene step before exiting the lab.
9. This category should be used for safety related NCEs.
12. I use this if there is a spill.
13. If a fire can't be extinguished safely and quickly do this.

Across:

2. Safety symbol with a hand being burned.
5. Use this if chemicals come in contact with your eyes.
8. Some of My Compliance courses require this type of training with a department supervisor or designated work area trainer.
10. I do this if my gloves break.
11. Safety symbol with a fire burning.
12. I seek this if there is a tornado warning.
14. I can find SDS information in this website (abbreviation).

1. Review Injury Reports and Safety Assessments and offer recommendations for corrections and corrective actions. Monitor safety incident trends and identify potential improvements to prevent future incidents from occurring.

2. Discuss safety-related concerns brought to the committee by committee membership or SHL staff. Aid in risk assessments and root cause analyses, as needed, to identify corrections and corrective actions.

3. Participate in Internal Audit Program in collaboration with Quality Management team to conduct internal laboratory safety audits.

4. Review and update policies and procedures for emergency egress (fire, evacuation, etc.) Re-train staff and conduct an exercise. Record 100% of fire/tornado/spill drills on iPassport by the end of FY25.

5. Resolve and record completion of 65% of safety non-compliances in iPassport by the end of FY25.

6. Reduce the average length of time to close a safety non-compliance by 20%, from 113 days to 90 days, by the end of FY25.

7. Record 100% of biological safety cabinet recertifications, snorkels and fume hoods in iPassport by July 1st, 2025.

8. By December 31, 2024, perform one biological and chemical spill drill with each SHL department that uses biological and chemical agents.

9. Within 3-weeks of each safety committee meeting, write and deliver meeting minutes to all department supervisors.

10. Offer CPR classes to 12 staff members from both Coralville and Ankeny facilities by July 1st, 2025.

Discussion Insert #4

Do you have an electronic quality management system such as iPassport?

Collaboration

- iPassport demo
- Tampa joint calls
  - Material sharing example

Thrills… Chills… SPILLS!

Can you clean up the spill correctly, protecting yourself and others?

Or does a SPILL make you ILL?

Choose your path(s) and proceed with caution!

It was a dark and stormy night. (Of course it was…)
There's an early hurricane headed toward Florida, and your lab is in the center of the "cone". The Everbridge notice of a Monday lab closure went out Friday after most staff had already left, so your lab director asked for volunteers to come in Saturday evening to come and help make preparations before the weather turns nasty. Since you live pretty close to the lab, and don't have plans, you volunteer to go in…

What will you do?

Do you help put plastic bags over uncovered computers? Go to 2

Do you help put sandbag "snakes" around low-lying doorways? Go to 3

A visiting VIP posing for a photo op	dropped a liter bottle of acetone	and some got in that drawer that keeps opening on its own.	**A visiting VIP posing for a photo op,dropped a liter bottle of acetone,and some got in that drawer that keeps opening on its**

Example: Autoclave Validation

Title: Performance Qualification (PQ) Validation Procedure for Liquid and Gravity Displacement Autoclave Cycles – Mixed Loads: Dry/Wrapped Waste and Liquids

Section: All sections that perform steam sterilization of biohazardous waste

Division: Diagnostic and Clinical Division
State Hygienic Laboratory at the University of Iowa

1. Objective
To validate the sterilization performance of liquid and gravity displacement autoclaves for processing dry/wrapped and liquid biohazardous waste produced during regular operations at State Hygienic Laboratory,

2. Scope
This protocol applies to all liquid and gravity displacement autoclaves used at the State Hygienic Laboratory, excluding the necropsy lab autoclave.

Discussion Insert #5

If you had the ISO35001 standards available to you, would you use them to do an audit of your biosafety program?

Discussion Insert #6

Have you heard any ideas during this session that you intend to use in your laboratory? Can you share them?

Thank you

→ **shl.uiowa.edu**

Michael Pentella, PhD, D(ABMM)
Clinical Professor, University of Iowa, College of Public Health
Director, State Hygienic Laboratory

Michael-Pentella@uiowa.edu

Post-session Survey

- Takes 2 minutes to complete and helps improve ECHO Biosafety Program and CoP
- Participation is voluntary
- Responses are anonymous and feedback will be summarized in aggregate
- Questions? Contact DLSbiosafety@cdc.gov

Scan here to take the November survey

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 (cont.)

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.

DLS ECHO Biosafety Session: December 17, 2024

Biorisk Management Improvement

Patricia Olinger, JM

Chief Relationship Officer, Y2X Life Sciences

President/CEO, BEAMS LLC