DLS ECHO Biosafety Session: August 27, 2024

Operations: Planning and Maintaining

Esmeralda Meyer, MD, JM, RBP (ABSA), CBSP (ABSA), BRM (IFBA), CPIA (PRIMR)
Director, Institutional Animal Care and Use Committee
Office of Research Compliance and Regulatory Affairs, Emory University
Atlanta, GA

June Session Recap:
"Support: Communication and Documented Information"

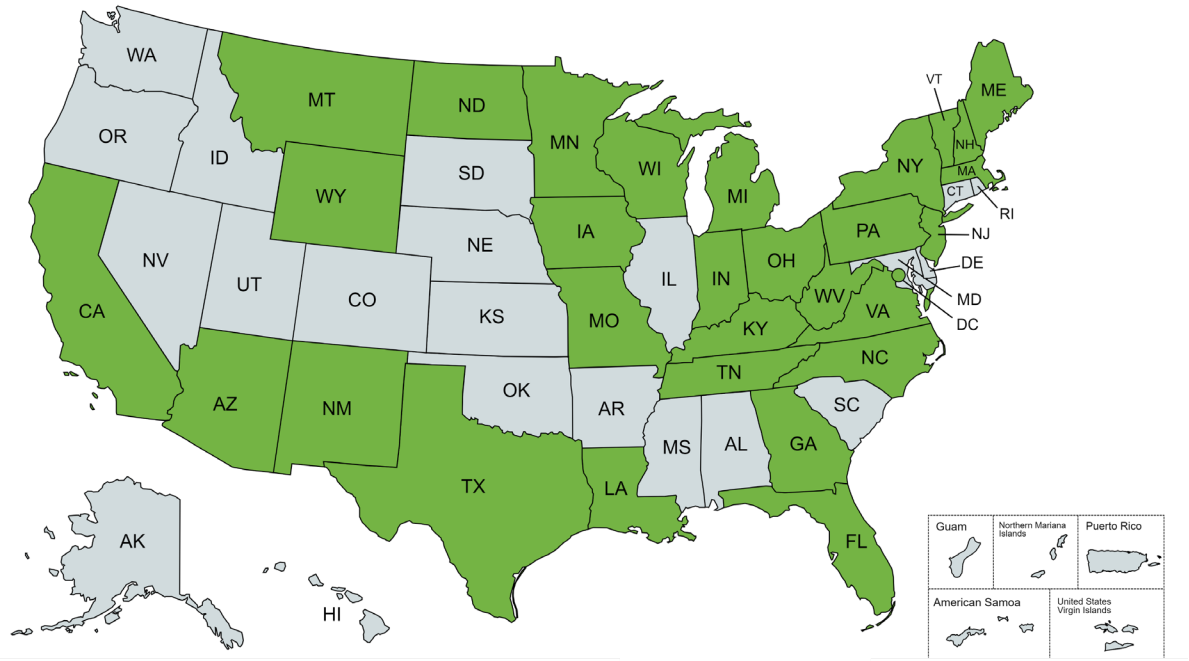
94 participants attended the session

60 organizations were represented

How does your institution ensure the root causes of biosafety incidents are communicated with all laboratory staff?

- Annual Training (57%)
- Annual Bloodborne Pathogen Training (45%)
- Computer Notice/Blog (25%)
- Newsletter/Poster (16%)
- Other (23%)

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 Canada and El Salvador were also present at the session. Eight 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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DLS ECHO Biosafety Session: August 27, 2024

Operations: Planning and Maintaining considering the ISO 35001 framework (Biorisk Management for Laboratories)

Esmeralda Meyer
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Research Compliance and Regulatory Affairs
Emory University
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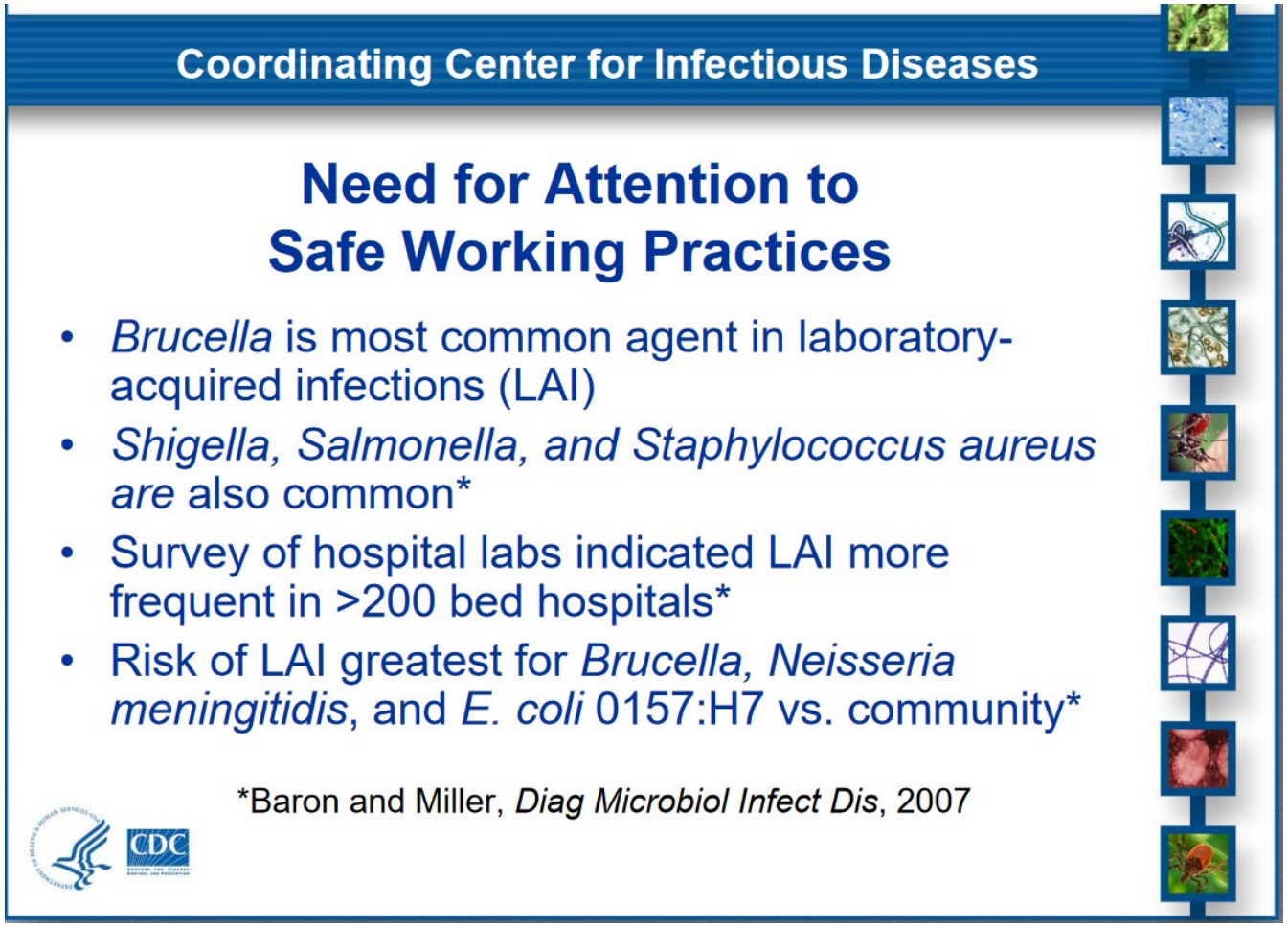
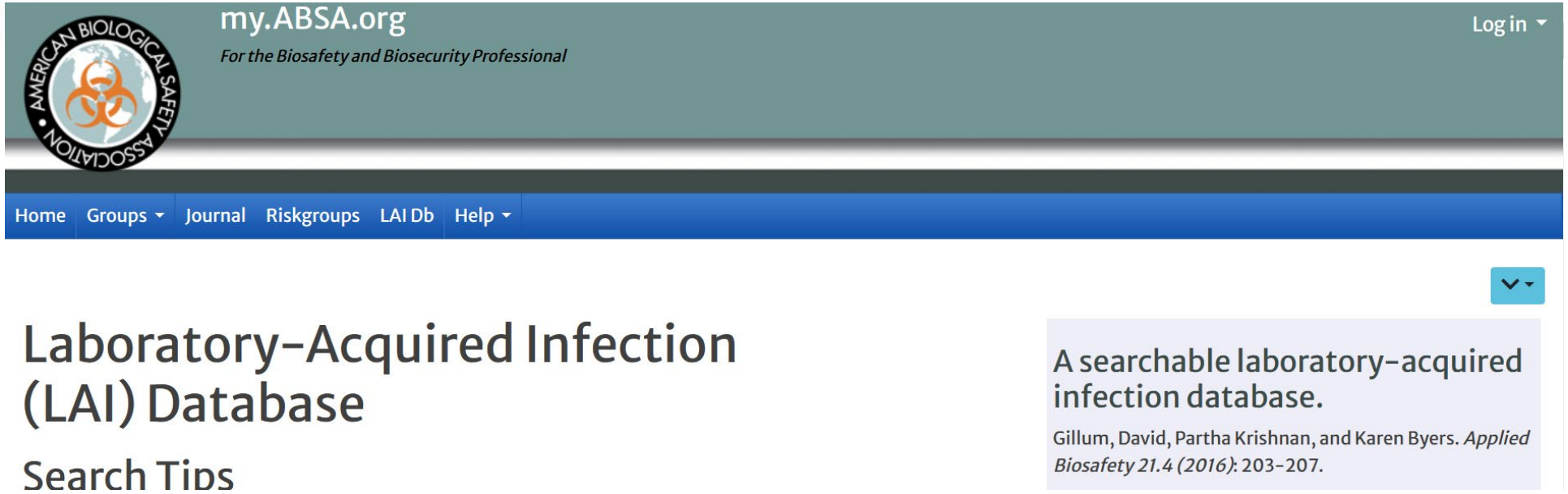
Background – The WHY



https://www.cdc.gov/cliac/docs/addenda/cliac0908/Addendum-E.pdf

Background – The WHY



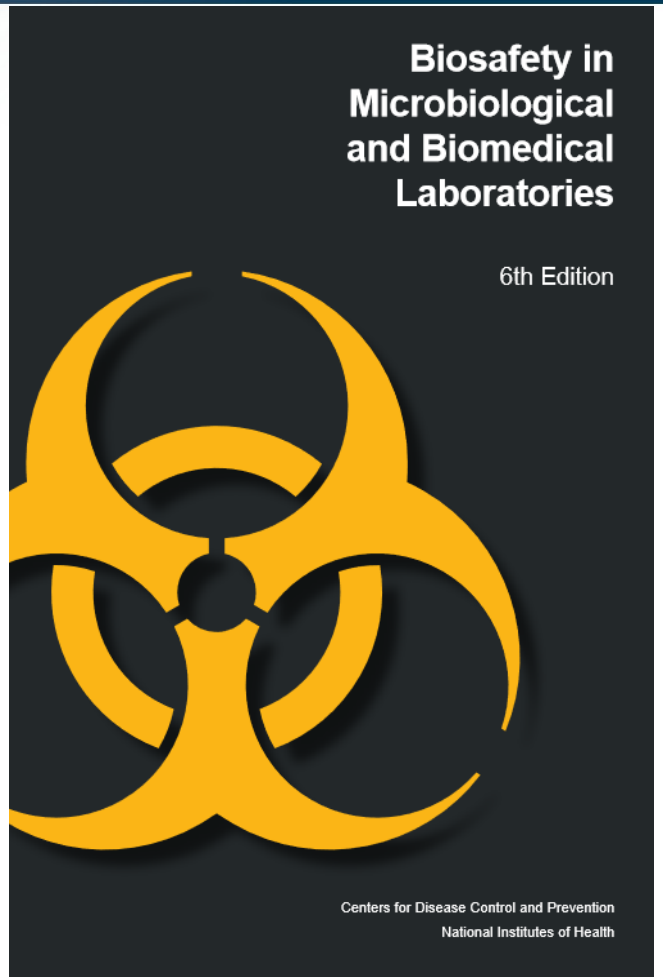
https://my.absa.org/LAI

Poll #1

How do you do biorisk assessments?
(select all that apply)

a. On the fly
b. I have a set of questions that I always ask
c. I use a software to calculate risks and outcomes
d. I use a spreadsheet (i.e BioRAM)
e. I prepare a risk assessment matrix tailored to the risk at hand
f. Other (please share in the chat)

Have a Process



Section II—Biological Risk Assessment

The ongoing practice of biological risk assessment is the foundation of safe laboratory operations. Risk assessment requires careful judgment and is an important responsibility for directors and principal investigators (PI) of microbiological and biomedical laboratories. Institutional leadership and oversight resources, such as Institutional Biosafety Committees (IBCs) or equivalent resources, animal care and use committees, biological safety professionals, occupational health staff, and laboratory animal veterinarians also share in this responsibility. When assessing risk, it is essential to broadly engage stakeholders, including laboratory and facility staff and subject matter experts, in committee reviews of work and discussions of past studies of Laboratory-associated infections (LAIs) and other published research. The biological risk assessment process is used to identify the hazardous characteristics of an infectious or potentially infectious agent or material, if known; the activities that can result in a person's exposure to an agent; the likelihood that such exposure will cause an LAI; and the probable consequences of such an infection. The information identified by risk assessment will provide a guide for the selection of appropriate mitigations, including the application of Biosafety Levels and good microbiological practices, safety equipment, and facility safeguards that can help prevent LAIs.

Promoting a positive culture of safety by integrating a risk management process into daily laboratory operations results in the ongoing identification of hazards and prioritization of risks and the establishment of risk mitigation protocols tailored to specific situations. To be successful, this process must be collaborative and inclusive of all stakeholders. Further, it must recognize a hierarchy of controls, beginning with the elimination or reduction of hazards, then progress to implementing the appropriate engineering and/or administrative controls to address residual risks, and, if necessary, identifying personal protective equipment (PPE) to protect the worker.[1]

For the purposes of this section, hazards are defined as substances or situations capable of causing adverse effects to health or safety.[2] Risks occur when people interact with hazards and are a function of both the probability of adverse events and expected consequences of a potential incident.[2] The product of probability and consequence estimates provide a relative value that can be used to prioritize risks. Since it is impossible to eliminate all risk, unless the associated hazard is eliminated, the risk assessment evaluates recognized risks associated with a particular hazard and reduces risk to an institutionally acceptable level through a documented process. For the biological laboratory, this process is usually qualitative with classifications from high- to low-risk. This section provides guidance on conducting a risk assessment, implementing a risk mitigation program, communicating during and after the assessment, and developing practices to support ongoing application of the risk assessment process.

https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf

Have a Process

ANNEX 6. COMPLETED LONG TEMPLATE: ANTIMICROBIAL SUSCEPTIBILITY TESTING

Institution/Facility name	United Microbiology Laboratories
Laboratory name	Gastrointestinal Diseases/Bacterial Unit
Laboratory manager/Supervisor	Dr Jill Smith, Laboratory Manager
Location	City on the seaside
Project titles/Relevant standard operating procedures (SOPs)	Antimicrobial susceptibility testing
Date	6 May 2020

If using this template, complete all sections following the instructions in the grey boxes. The instructions and bullet points in the grey boxes can be copied into the text boxes beneath the instructions and used as prompts to gather and record the necessary site-specific information. The grey instruction boxes can then be deleted, and the text remaining will form a risk assessment draft. This draft must be carefully reviewed, edited as necessary and approved by the risk assessment team members.

STEP 1. Gather information (hazard identification)

1.1 Provide a brief overview of the laboratory work

Instructions: Summarize the laboratory activities to be conducted that are included in the scope of this risk assessment. If the laboratory conducts other similar work on a regular basis (for example, well-defined, routine diagnostic testing), consider using one assessment to cover all laboratory activities. However, large and more complex laboratories that carry out a variety of laboratory activities, such as diagnostic testing, confirmatory testing, characterization of biological agents and research, may want to conduct separate risk assessments.

The bacterial unit will begin testing bacterial isolates sent from local laboratories and hospitals in the state for antimicrobial susceptibility. Isolates will be identified to the genus and, if possible, species before submission to the bacterial unit. All isolates will be received on either Luria broth, or MacConkey or tryplicase soy agar. Antimicrobial susceptibility testing will be by broth microdilution using minimum inhibitory concentrations established by the Clinical Laboratory and Standards Institute. Cultures received will be limited to Proteobacteria including pathogenic biological agents from Enterobacteriaceae (*Escherichia coli*, *Shigella* spp. *Salmonella* spp.) – except for *Klebsiella* (work on this bacterium is done in a separate laboratory) – *Campylobacter* spp. and *Vibrio* spp. Our laboratory has experience working with all these bacteria but has not done antimicrobial susceptibility testing using broth microdilution on this scale before. This testing is usually done on request and most often done using test strips on agar. We expect to receive between 30 and 100 isolates a month and think that this number may grow over time.

https://iris.who.int/bitstream/handle/10665/337966/9789240011458-eng.pdf?sequence=1

Have a Process

SANDIA REPORT
SAND2010-6487
Unlimited Release
Printed October 2010

Biosafety Risk Assessment Methodology

Susan Caskey*, Jennifer Gaudioso*, Reynolds Salerno*, Stefan Wagener+, Mika Shigematsu++, George Risi+++, Joseph Kozlovac#, Vibeke Halkjær-Knudsen##, Esmeralda Prat**

Prepared by
Sandia National Laboratories
Albuquerque, New Mexico 87185 and Livermore, California 94550

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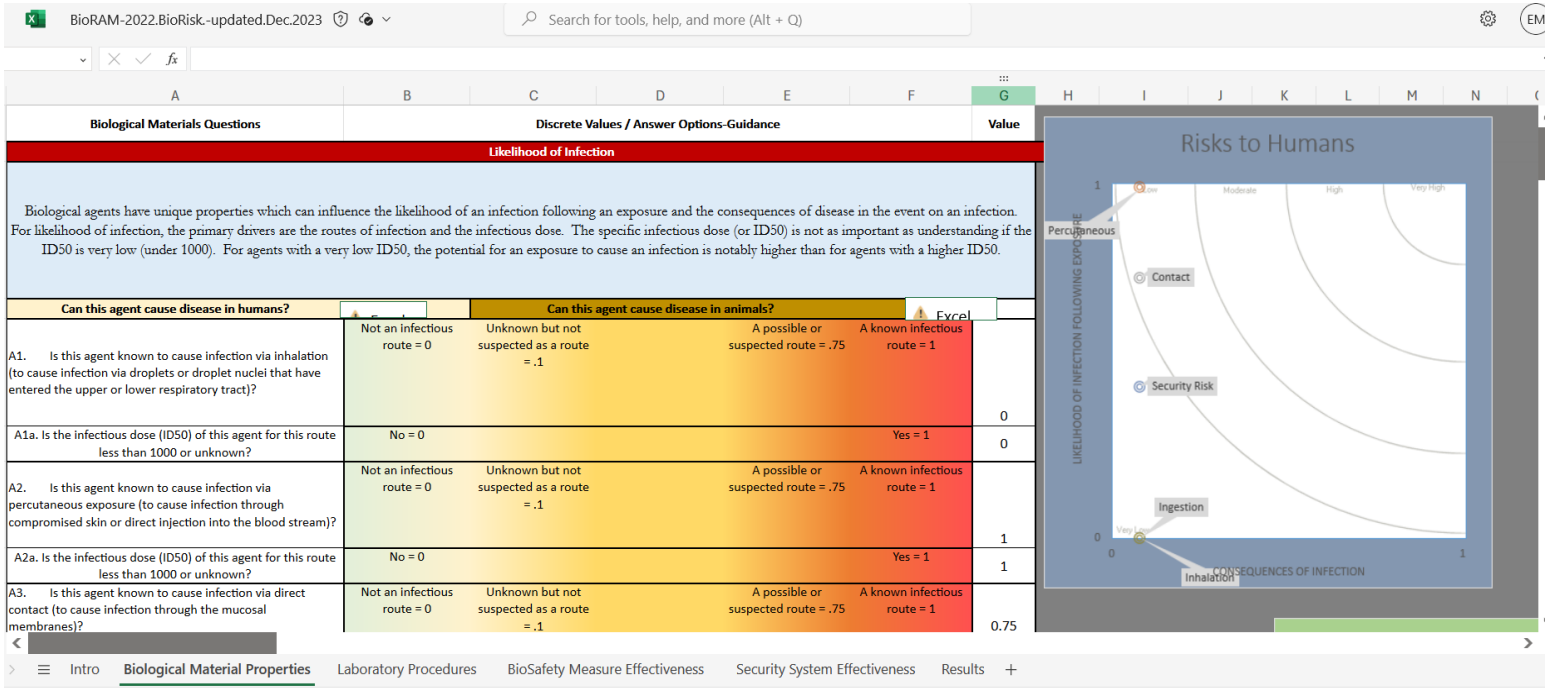
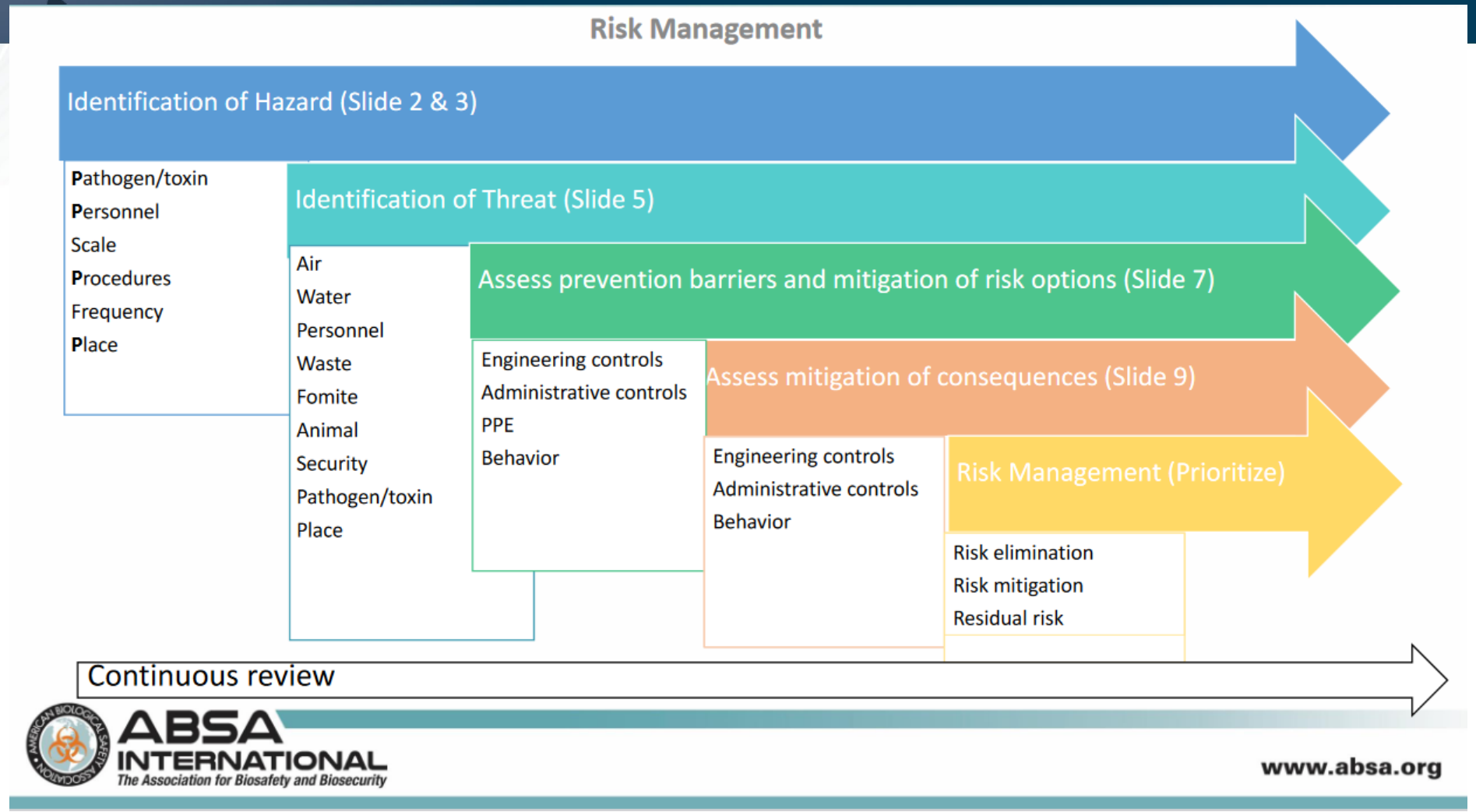


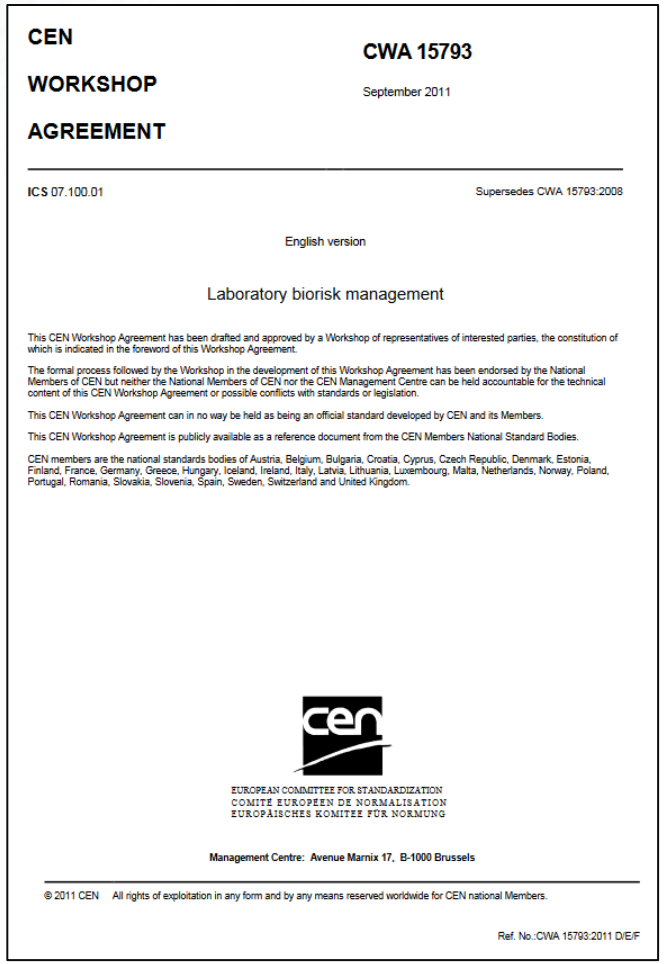
https://biosecuritycentral.org/static/f25db321edd166d353ac2a770fb45a1a/Sandia_BioRAMs_Biosafety%20Risk%20Assessment%20Methodology..pdf

Have a Process



https://absa.org/wp-content/uploads/2023/05/BioRiskEvaluation-Tool_Fungi.pdf

Background



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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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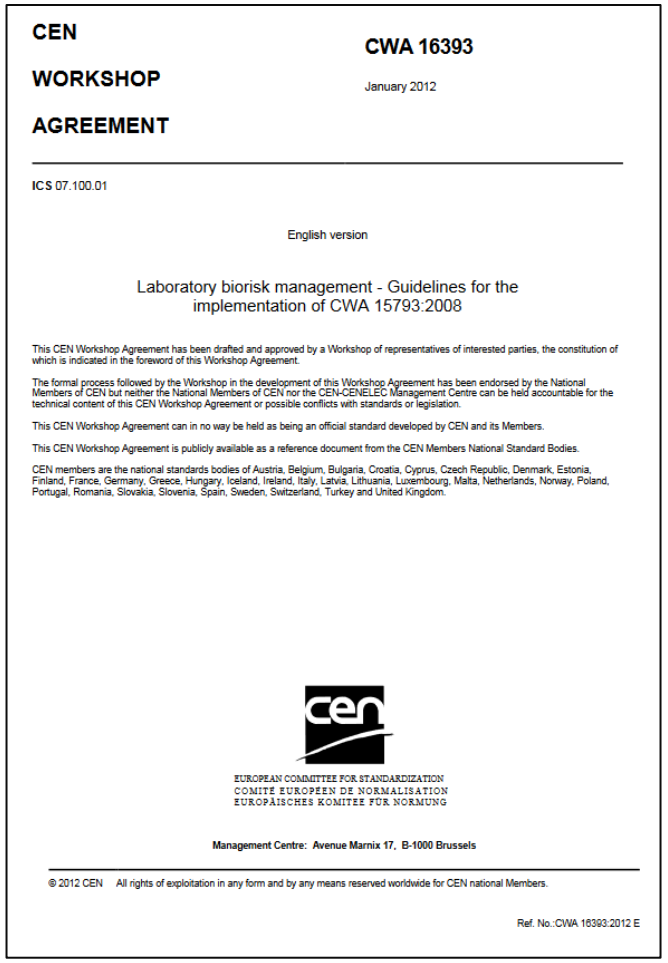
Ref. No.:CWA 15793:2011 D/E/F

https://biosecuritycentral.org/static/d440d0bbecfb340fe2b2b5d0b87be97a/CWA15793..pdf



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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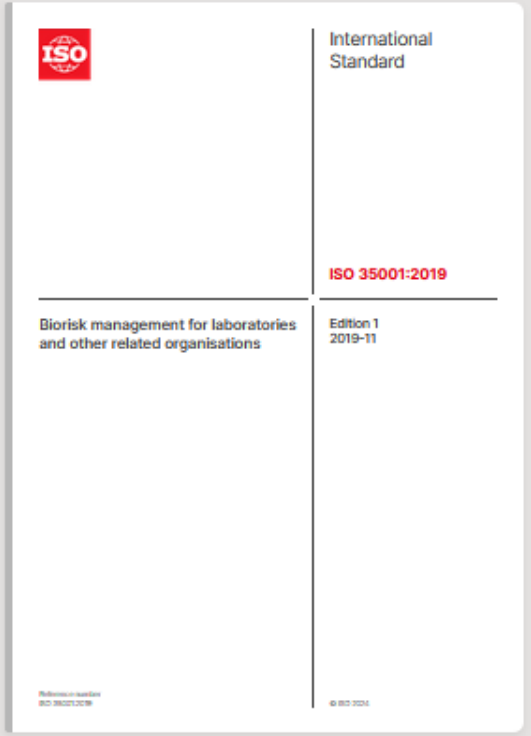
Ref. No.:CWA 16393:2012 E

https://biosecuritycentral.org/static/9f67bf2c781d3f4cde30584a73afab26/CWA%2016393..pdf

Background



ISO 35001:2019

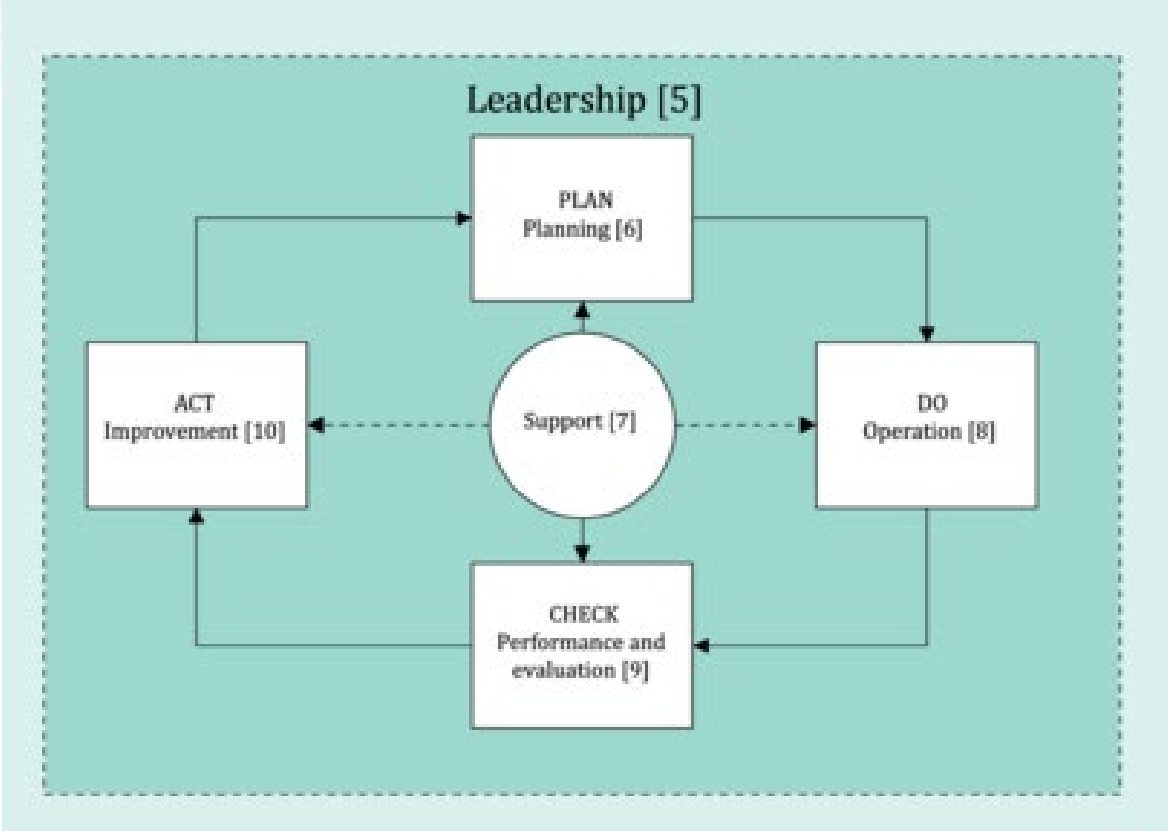
Biorisk management for laboratories and other related organisations

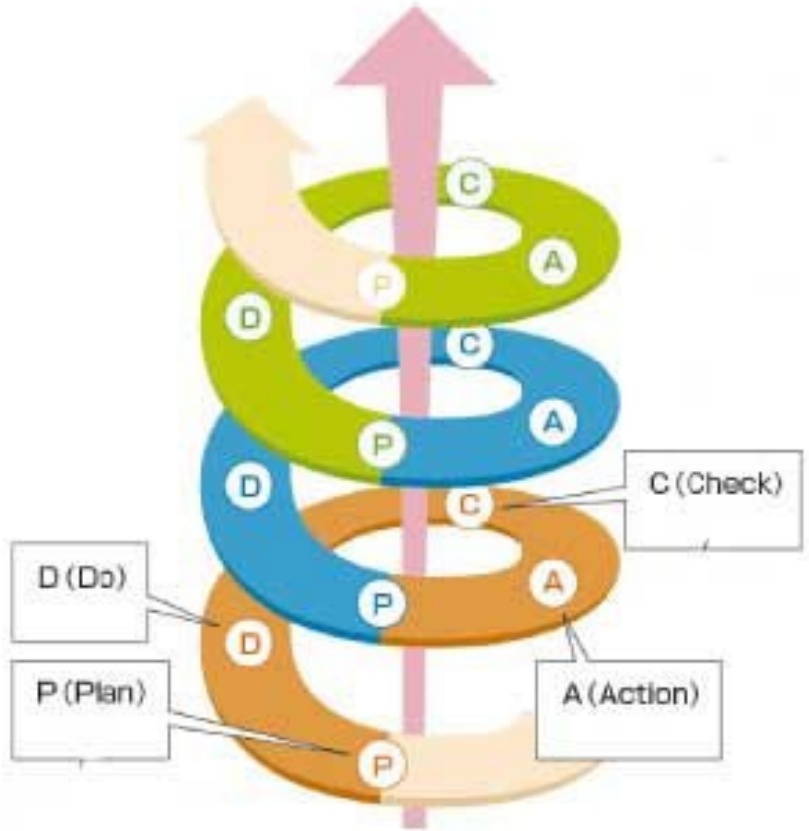
Published (Edition 1, 2019)

↳ This standard has 1 amendment.

https://www.iso.org/obp/ui/en/#iso:std:iso:35001:ed-1:v1:en

Fundamental Principle for Biorisk Management to Work





https://www.iso.org/obp/ui/en/#iso:std:iso:35001:ed-1:v1:en

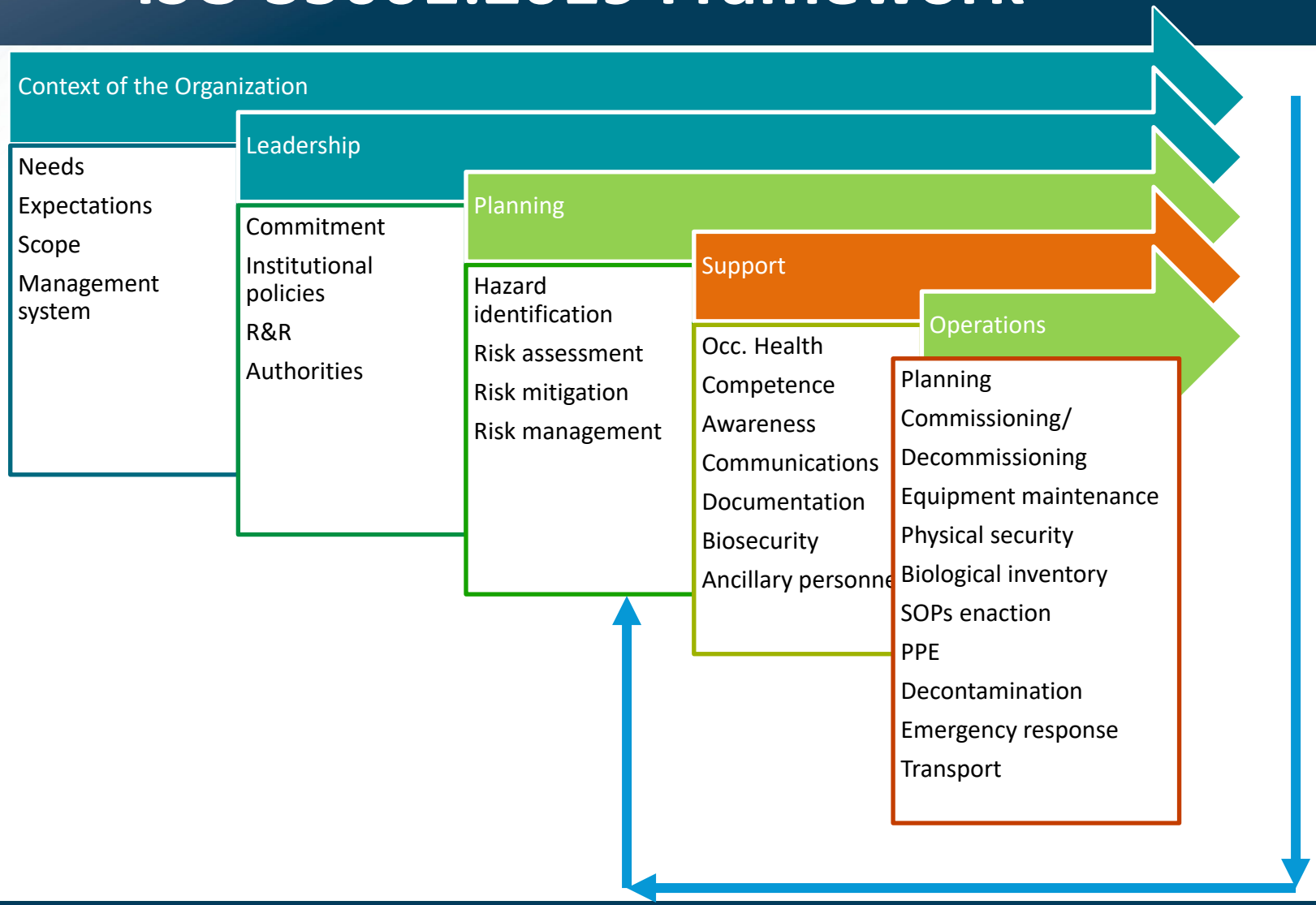
Poll #2

Tell us where you are in the implementation of a biorisk management at your institution

(select your best answer)

a. Getting buy-in from the leadership
b. Assessing risks
c. Drafting SOPs
d. Operationalizing SOPs
e. Evaluating operational controls
f. Other (please enter in the chat)

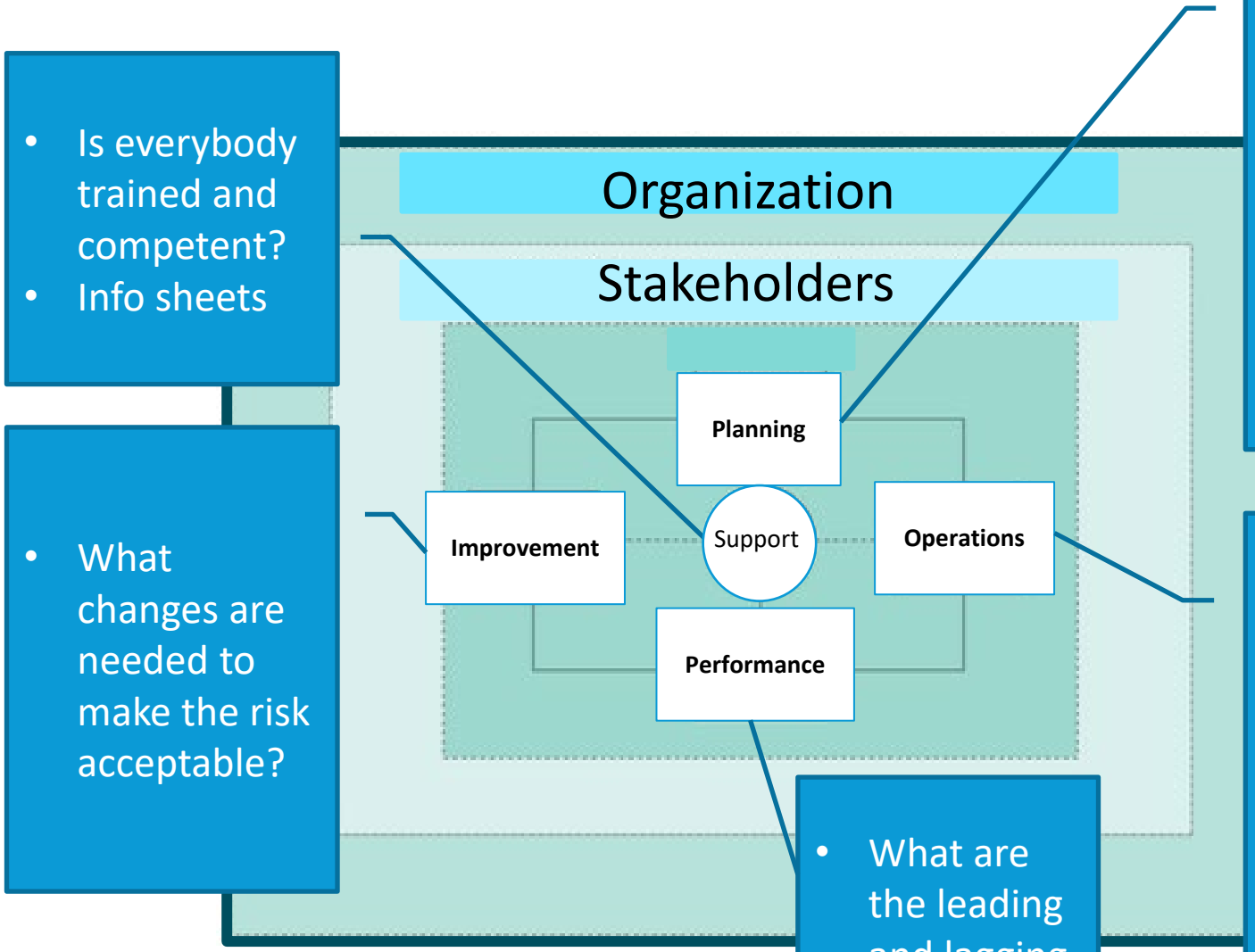
Biorisk Management Following the ISO 35001:2019 Framework



ISO 35001 – Processes

- Is everybody trained and competent?
- Info sheets

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



- What changes are needed to make the risk acceptable?

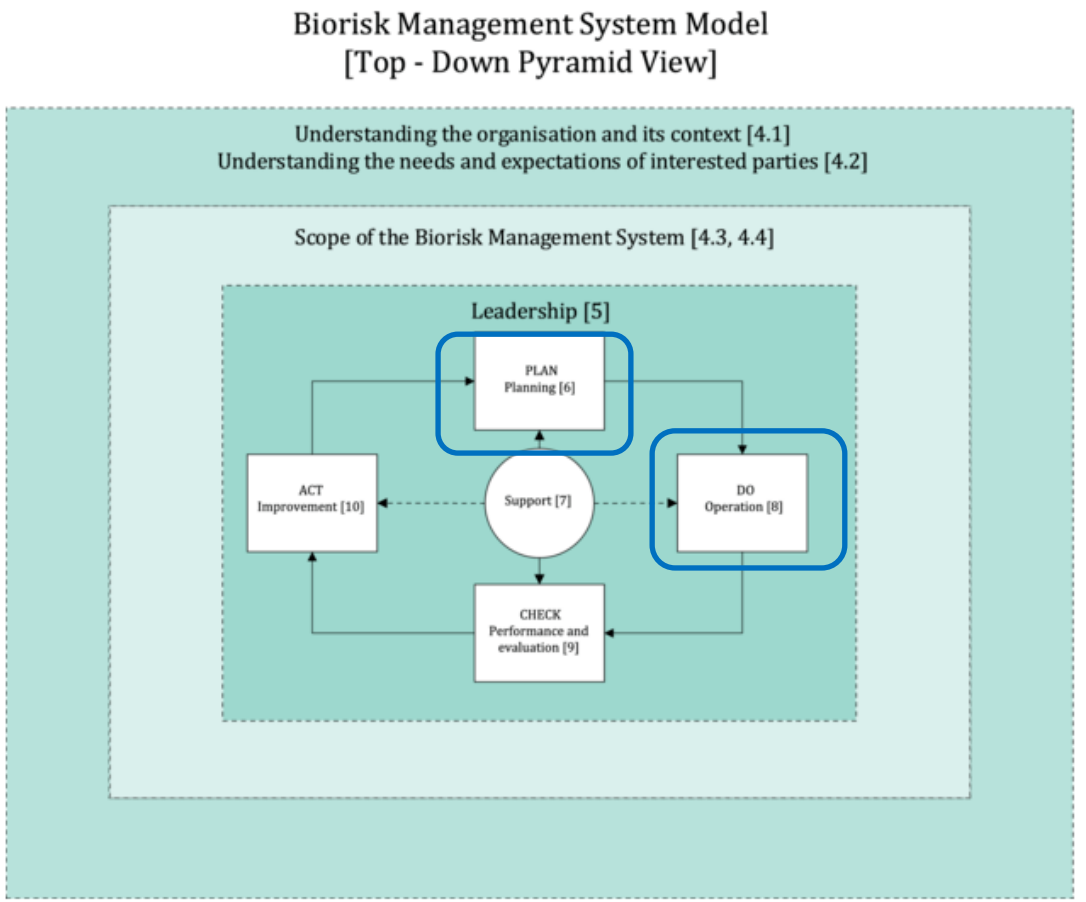
- Are the controls working?
- Are the SOPs being followed?
- Who is doing the work?

- What are the leading and lagging indicators?

Doing Also Involves Planning

NOTE Figure 1 is adapted from ISO 45001 *Occupational health and safety management system — Requirements with guidance for use.*

Figure 1 — Top down pyramid view of a biorisk management system model



Poll #3

Match the activity to the BRM Planning phase or to the Operational planning

Planning phase	Operational Planning

ACTIVITY

Standard Operating Procedures for the activities identified in the RA

Strategies to mitigate risks

Understand context of organization

Engineering controls include the use of the biosafety cabinet

Activities include culture, genetic modifications

Risk assessment

Poll #3

Match the activity to the BRM Planning phase or to the Operational planning

Planning phase	Operational Planning
Risk assessment	Activities include culture, genetic modifications
Understand context of organization	Engineering controls include the use of the biosafety cabinet
Strategies to mitigate risks	Standard Operating Procedures for the activities identified in the RA

ACTIVITY

Standard Operating Procedures for the activities identified in the RA

Strategies to mitigate risks

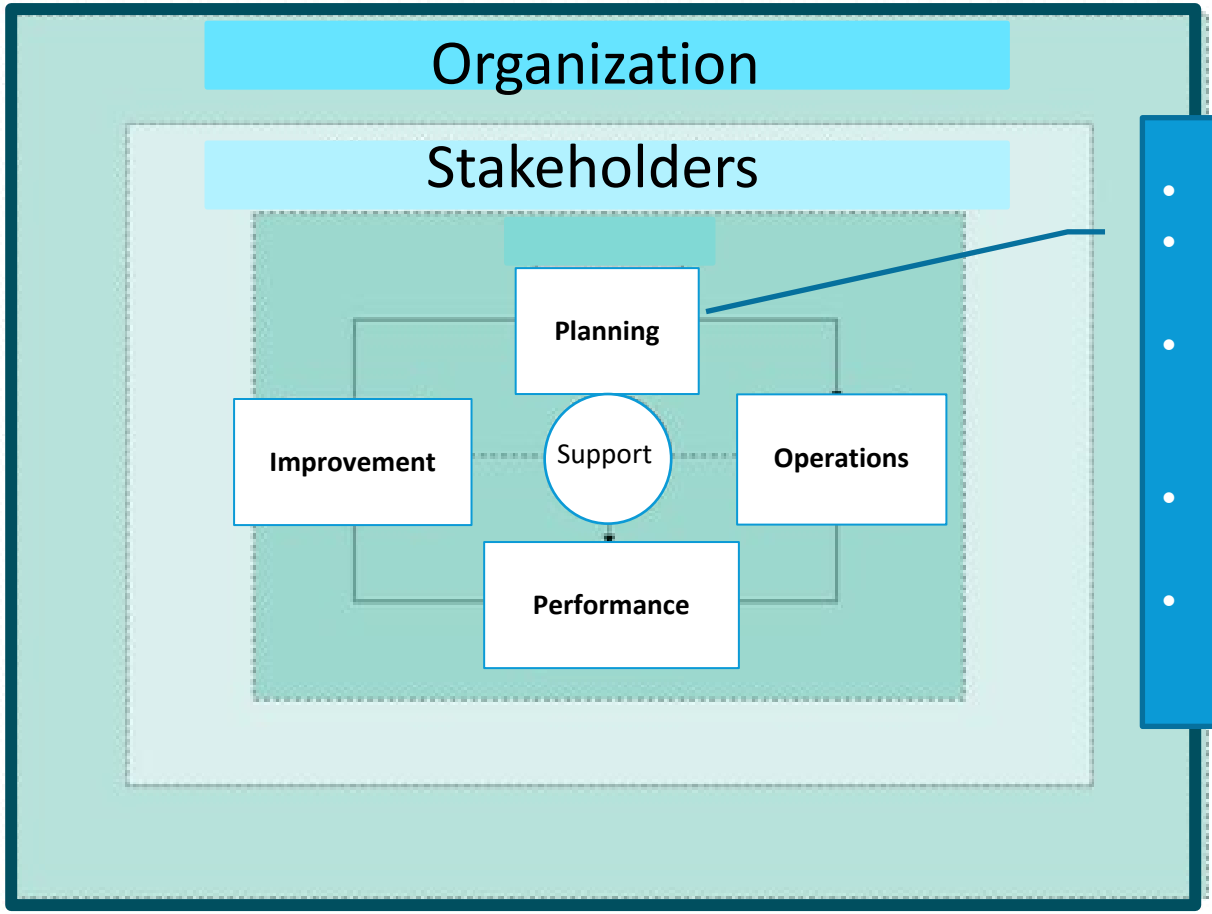
Understand context of organization

Engineering controls include the use of the biosafety cabinet

Activities include culture, genetic modifications

Risk assessment

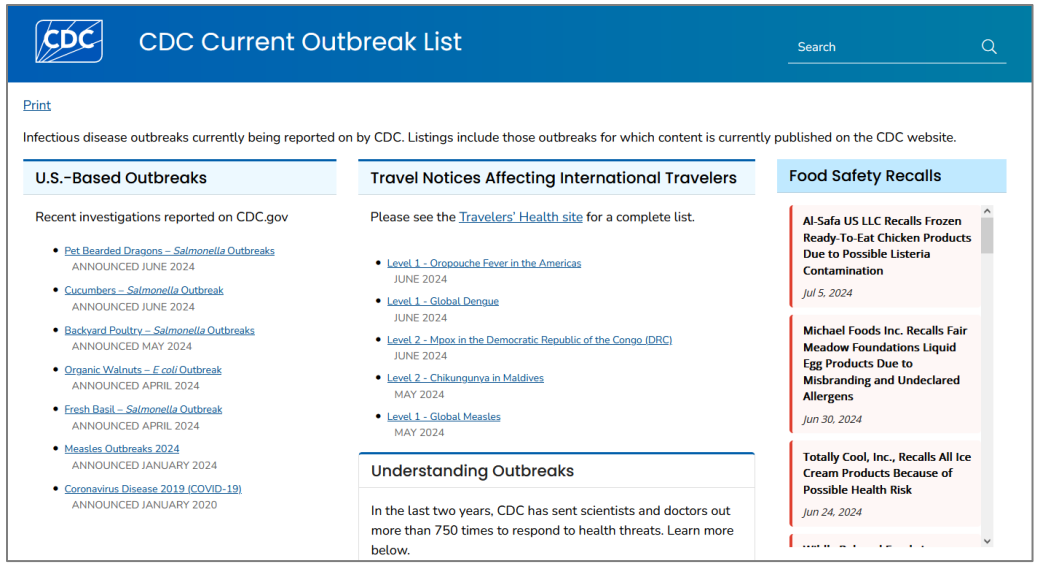
ISO 35001 - Planning



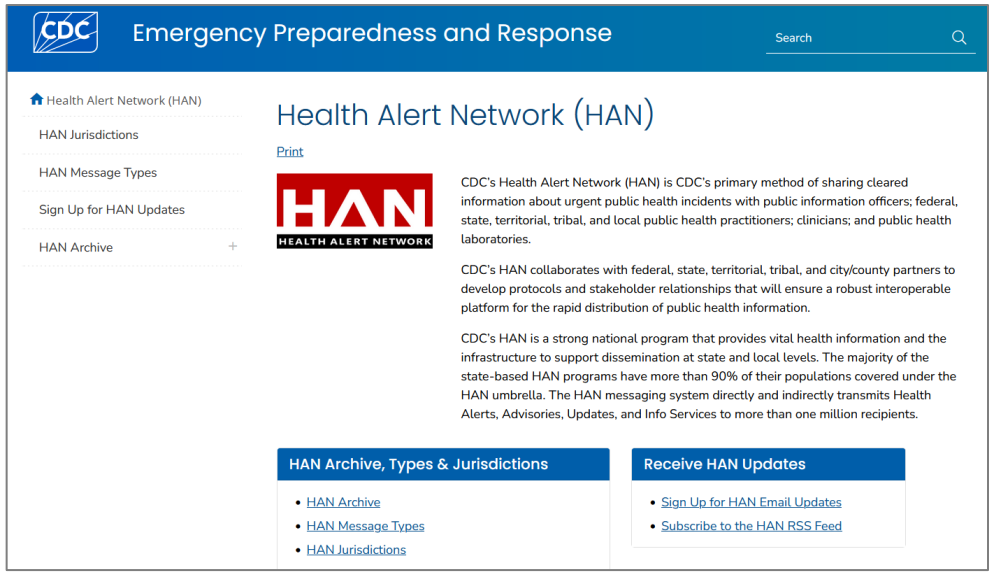
- What will be done?
- What can go wrong?
- What is the likelihood of occurring?
- What are the consequences?
- What controls are in place?

Take home message: ***Ask questions***

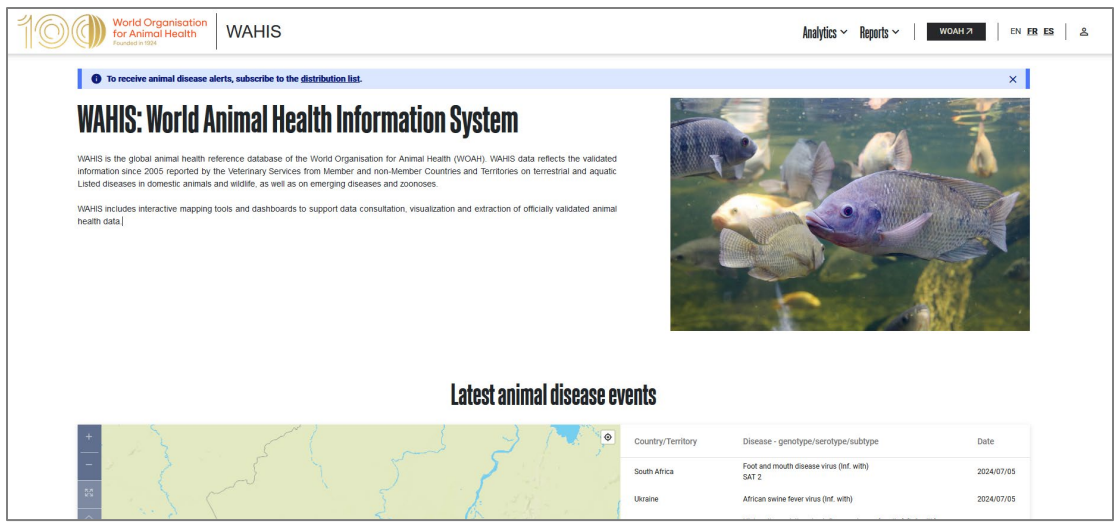
Be Aware of Conditions



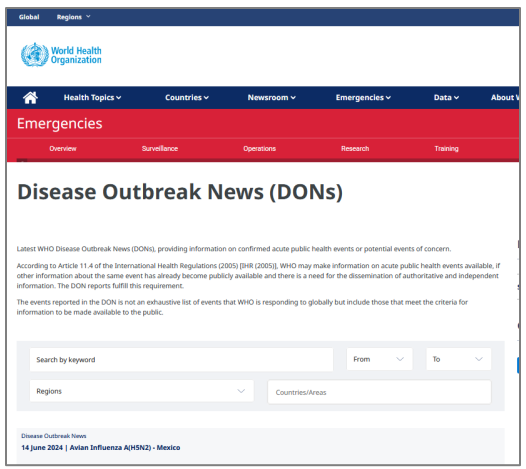
https://www.cdc.gov/outbreaks/index.html



https://emergency.cdc.gov/han/

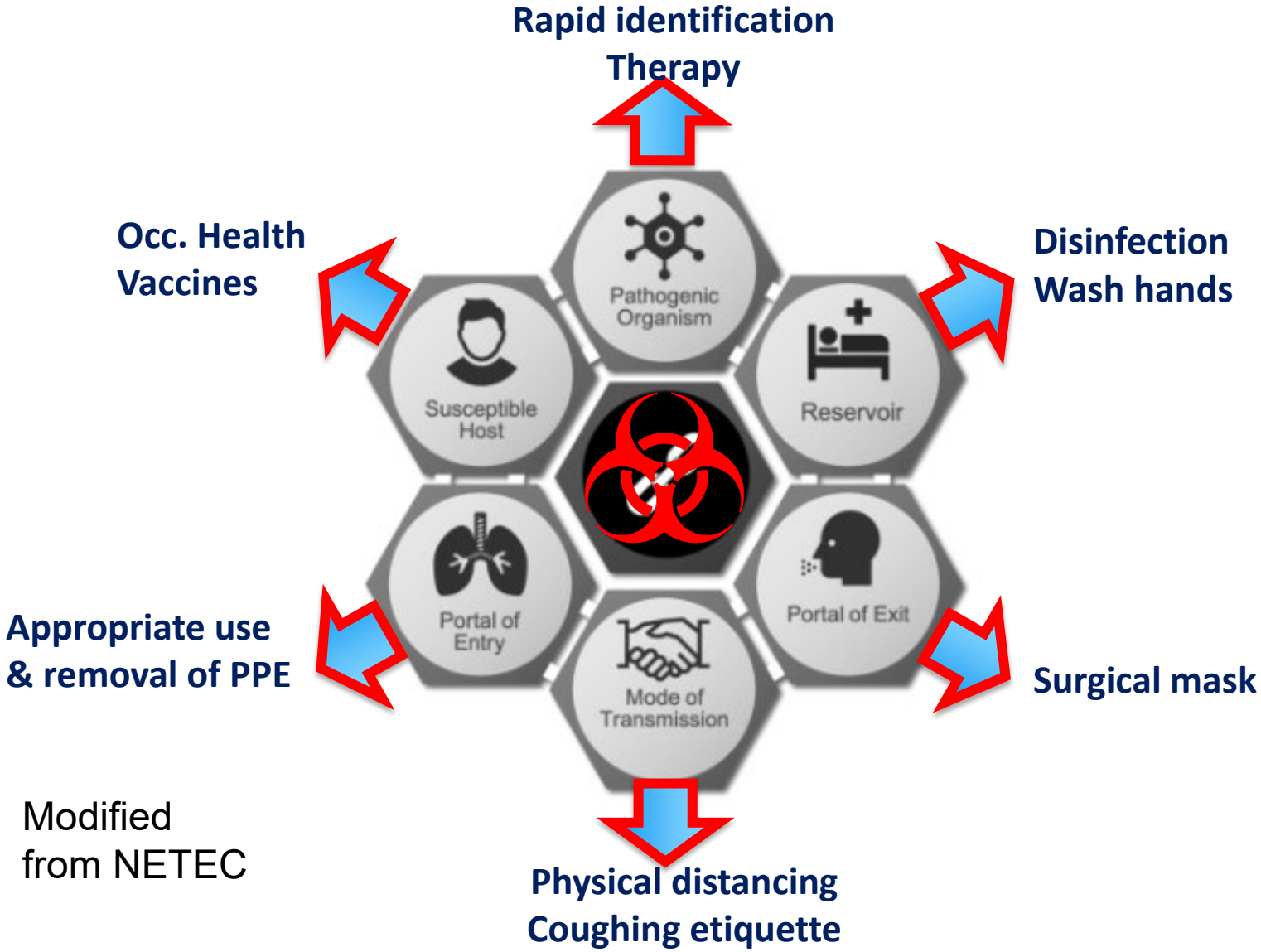


https://wahis.woah.org/#/home



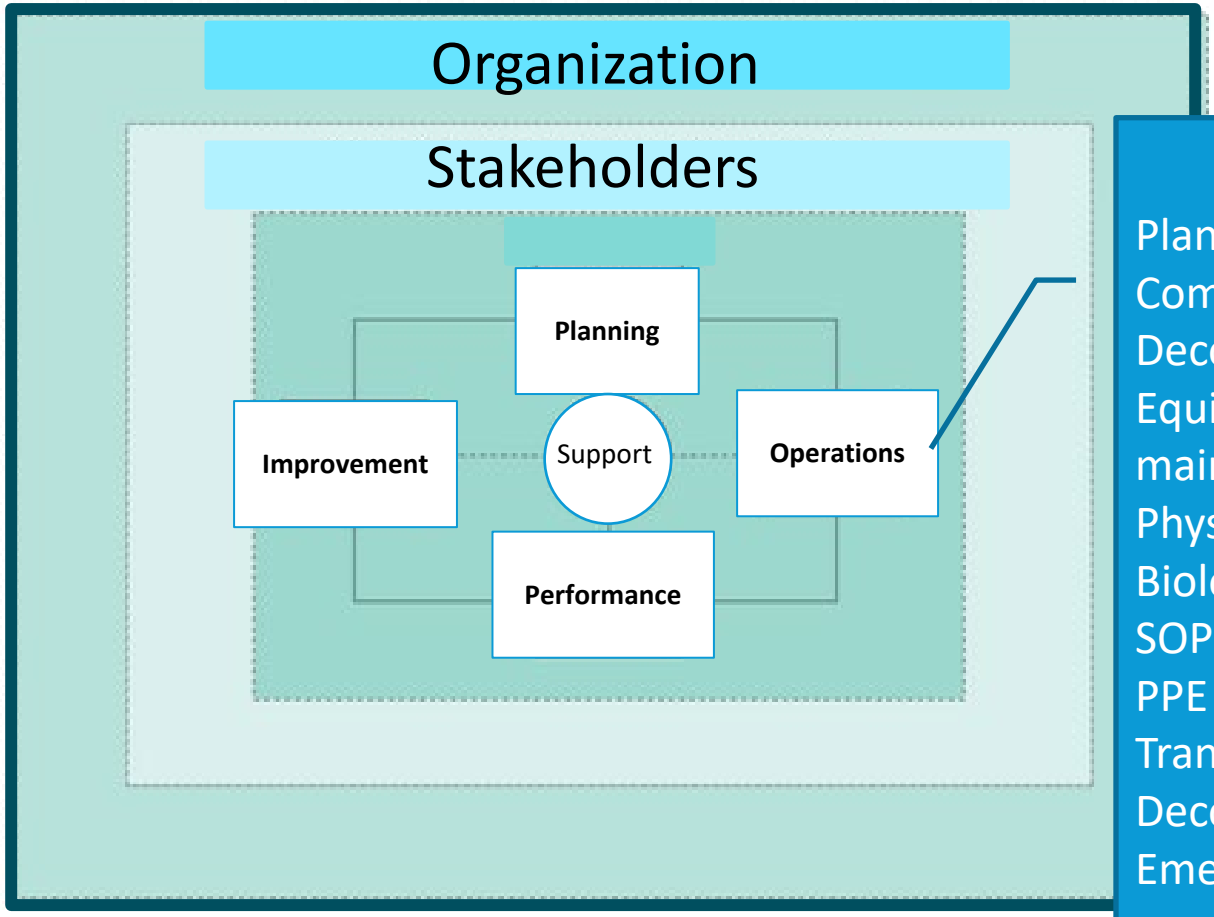
https://www.who.int/emergencies/disease-outbreak-news

The Goal of the Risk Assessment: To Break the Chain of Infection



- Modified from NETEC

ISO 35001 - Operations



Planning
Commissioning/ Decommissioning
Equipment maintenance
Physical security
Biological inventory
SOPs enaction
PPE
Transport
Decontamination
Emergency response

Applying ISO 35001

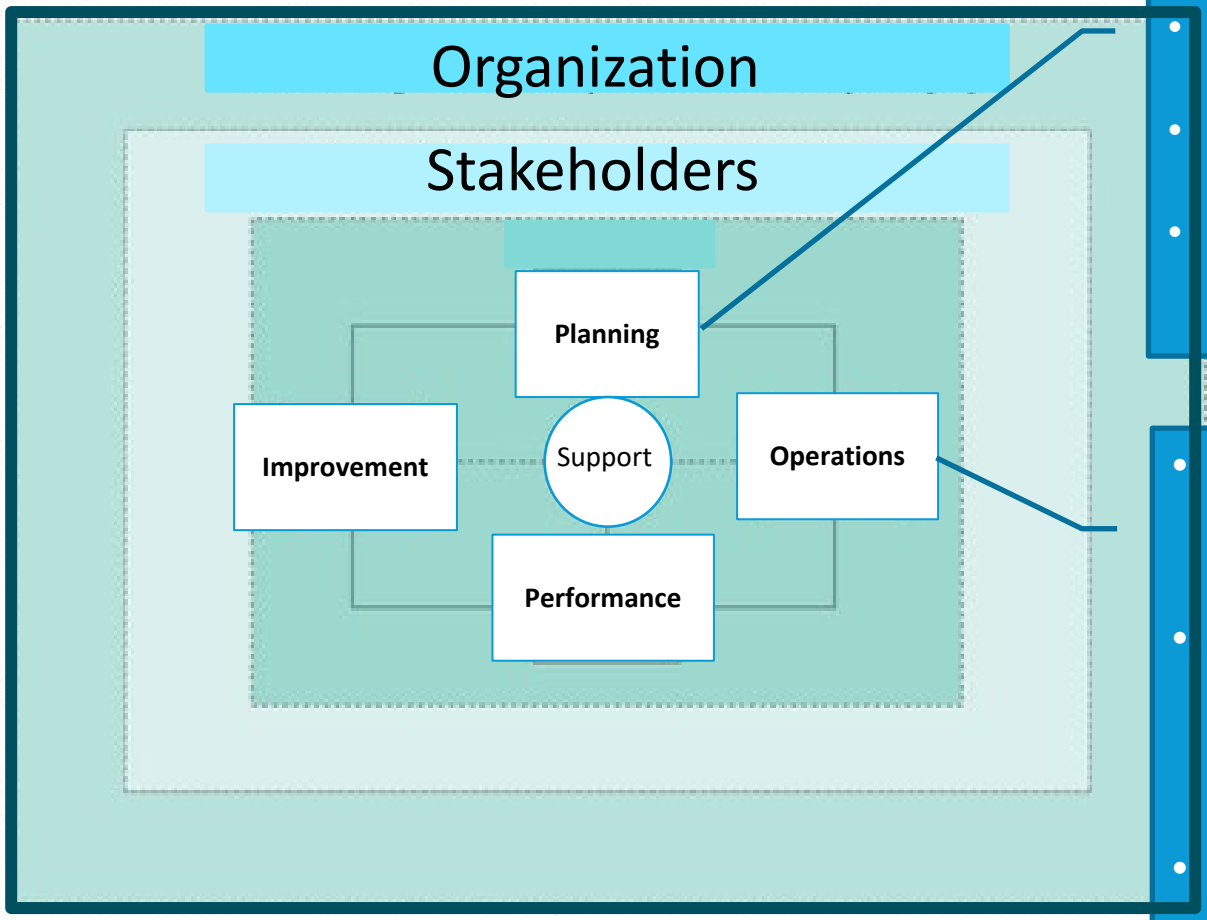
Donald R. Callihan, Marian Downing, Esmeralda Meyer, Luis Alberto Ochoa, Brian Petuch, Paul Tranchell, and David White. Applied Biosafety. ahead of print January 2021. http://doi.org/10.1089/apb.20.0068

Table 1. How can the ISO 35001 standard be applied to laboratories handling coronavirus disease 2019-related materials? (Table view)

ISO 35001 components	*Considerations for COVID-19 laboratories*	*Examples of mitigation measures*
Operations	Standard operating procedures for specimen processing, inactivating, transferring, shipping, and donning and doffing of PPE Facility engineering controls (i.e., airflow check, biosafety cabinet certification, and eyewash station) Centrifuge with aerosol containment Inventory management systems to control access and movement of VBMs and other laboratory reagents based on the biosecurity assessment (i.e., log of samples transferred from high containment) Inventory of inactivated samples Validation of inactivation methods Emergency alert card Quality of reagents used	Purchase additional engineering control equipment, such as centrifuge safety cups and workspace dividers Coordinate for the certification of biosafety cabinets Provide portable handwash stations and eyewash bottles in surge or mobile laboratories Purchase commercially available or develop an in-house inventory system to track VBMs, inactivated samples, and other valuable laboratory reagents Recruit BSL-3 principle investigators to assist in inactivation studies, if necessary Generate a handbook of acceptable inactivation methods, based on in-house studies Work with engineers to evaluate the ventilation system and, if possible, increase the air exchange per hour

Donald R. Callihan, Marian Downing, Esmeralda Meyer, Luis Alberto Ochoa, Brian Petuch, Paul Tranchell, and David White. Applied Biosafety. ahead of print January 2021. http://doi.org/10.1089/apb.20.0068

ISO 35001 – Application to COVID-19



- SKAs to perform RA
- Training for surge staff
- Compliance with standards

- Additional engineering controls
- Coordinate relocation and certification of BSCs
- Inactivation methods

Is the Laboratorian Competent?

Knowledge + Skills + Attributes + Experience

APHL Association of Public Health Laboratories	**Laboratory Biosafety Competency Assessment Form** https://www.aphl.org/programs/preparedness/Documents/APHL%20Approved%20Conversation-Based%20Biosafety%20Competency%20Assessment%20Form.pdf
ISO	**ISO/TS 5441:2024(en)** **Competence requirements for biorisk management advisors** https://www.iso.org/obp/ui#iso:std:iso:ts:5441:ed-1:v1:en
Centers for Disease Control and Prevention MMWR Supplement / Vol. 60	**Guidelines for Biosafety Laboratory Competency** CDC and the Association of Public Health Laboratories Supplement / Vol. 60 April 15, 2011 https://www.cdc.gov/mmwr/pdf/other/su6002.pdf
ABSA International The Association for Biosafety and Biosecurity alliance An OSHA Cooperative Program	**Biological Safety Officer (BSO) Competency** https://absa.org/wp-content/uploads/2018/05/OSHABSOcompetencyFactSheet.pdf

Poll #4

What <u>OTHER</u> information do you include in your biorisk assessments? (select all that apply)

a. General lab safety (i.e., slip & fall)
b. Fire safety
c. Electrical safety
d. Compressed gases
e. Chemical safety
f. Other (please enter in the chat)

Other Elements of Operations

General Safety

- Chemical safety
- Compressed gases
- Fire safety

Work with animal subjects
Housekeeping

Materials Inventory

- Paper and pen
- Electronic

Who is responsible?
Is it current?

Facilities & Equipment

- HVAC
- Biosafety cabinets/fume hoods

Centrifuges
Pipettes

Decontamination/Inactivation/Waste Management

- Validation procedures
- Transfer from high containment

Other Elements of Operations

Transport

- Intra-institution
- Domestic shipping
- International shipping

Occupational Health

- Who is included in the evaluation
- Risk-based vaccination

Biosecurity

- Personnel reliability
- Physical plant

Ancillary Personnel

- Environmental Services
- Contractors
- Animal care personnel

Poll #5

How often are SOPs reviewed at your institution?
(select your best answer)

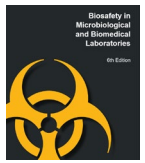
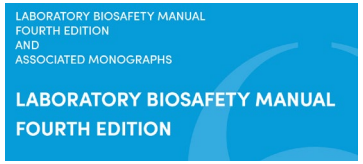
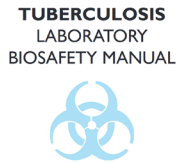
a. As often as necessary
b. Annually
c. Periodically

Poll #6

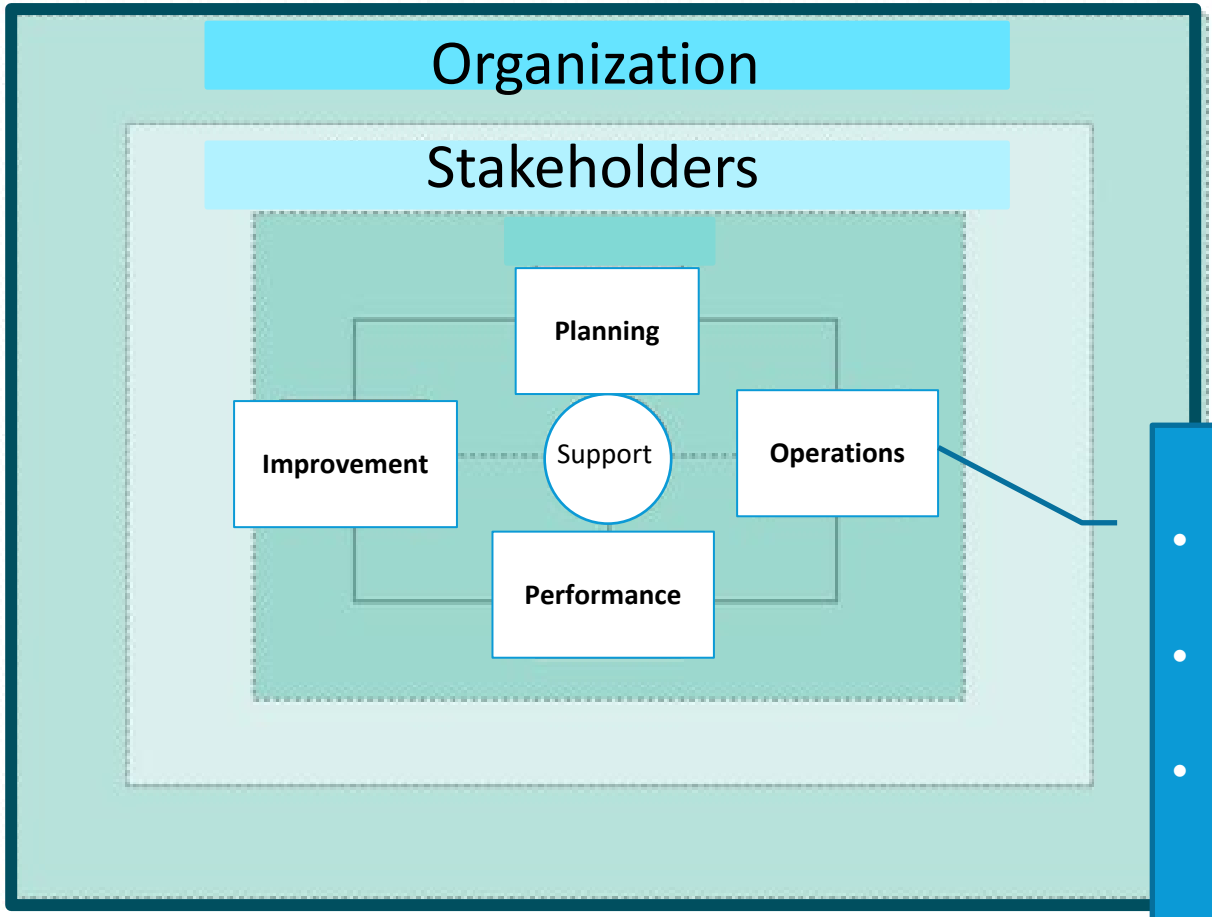
How are changes to SOPs communicated?
(select all that apply)

a. Via e-Newsletter
b. During inspections
c. During lab meetings
d. Other (please enter in chat)

Have Standard Operating Procedures

Centers for Disease Control and Prevention MMWR Morbidity and Mortality Weekly Report Supplement / Vol. 61 January 6, 2012	**Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories** https://www.cdc.gov/mmwr/pdf/other/su6101.pdf
	**Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition** https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf
	**Sandia National Laboratories - Core Biorisk Management Document Templates** https://gcbs.sandia.gov/core-documents/
	**WHO Laboratory Safety Manual 4th Edition** https://iris.who.int/bitstream/handle/10665/337956/9789240011311-eng.pdf?sequence=1
	**WHO Tuberculosis Laboratory Safety Manual** https://iris.who.int/bitstream/handle/10665/77949/9789241504638_eng.pdf?sequence=1

ISO 35001 - Operations

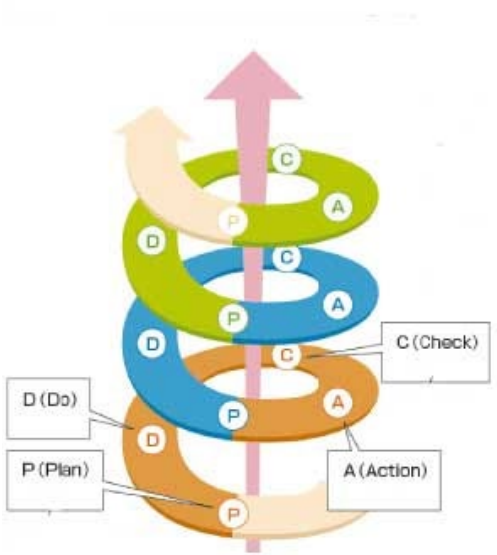


- Are the controls working?
- Are the SOPs being followed?
- Who is doing the work?

Laboratory safety is everyone's responsibility

Communication is critical

Ongoing process review and improvement (PDCA^n)



Courtesy Kaizen Lean

ISO 35001

- **Process to identify, assess, control, and monitor the risks** associated with hazardous biological materials
- **Globally applicable** to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials
- **Complements** existing international standards for laboratories
- **Concept of continual improvement**
  Plan, Do, Check, Act (PDCA) principle

Summary of Discussion

CDR Folasade Kembi, PhD
CDC Division of Laboratory Systems
Quality and Safety Systems Branch

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 August survey

DLS ECHO Biosafety Session: September 24, 2024

Operations: Emergency Response and Contingency Plans

Benjamin Fontes, MPH, CBSP
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