DLS ECHO Biosafety Session: October 22, 2024

The Importance of Biosecurity in Biorisk Program Management

Cristine C. Lawson, PhD, RBP, CBSP

Deputy Director for Biosecurity

Biological Select Agent and Toxin (BSAT) Biorisk Program Office

U.S. Department of Defense

Frederick, MD

September Session Recap: "Operations: Emergency Response and Contingency Plans"

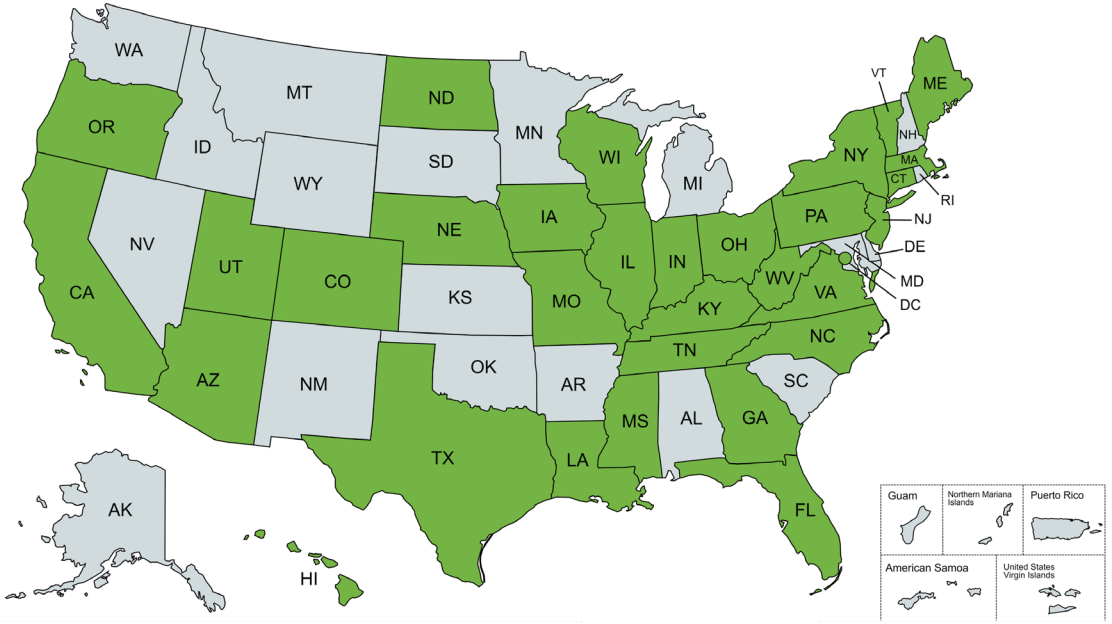
119 participants attended the session

67 organizations were represented

"We just had a **hotwash** this morning for last week's **man-down drill for our BSL-3 bioterrorism lab**. We have this drill every 2-3 years **with the Fire/Hazmat team**… We **involve all stakeholders** in the drill and **follow-up plan changes and competency training**."

-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 were also present at the session. Seven 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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THE IMPORTANCE OF BIOSECURITY IN BIORISK PROGRAM MANAGEMENT

CDC ECHO Biosafety Sessions
22 October 2024

Cristine C. Lawson, Ph.D., RBP (ABSA), CBSP (ABSA)
DoD BSAT Biorisk Program Office (BBPO)

DISCLAIMER

This presentation is based on publicly available information. The views expressed in this presentation are those of the author and do not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.

OVERVIEW

- Defining Biosecurity
- Building an Integrated Biorisk Program
- Why is Biosecurity Important?
- Redefining Biosecurity
- Closing Remarks

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DEFINITIONS

- “Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release.” ***-WHO Biosafety Manual, 4th Edition, 2020***

- “Practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials.” ***-ISO/DIS 35001, 2019***

- ***“***Laboratory biosecurity: The measures designed to prevent loss, theft, or deliberate misuse of biological material, technology, or research-related information from laboratories or laboratory-associated facilities.” ***–BMBL, 6th Edition, 2019***

- “Agricultural biosecurity: The scientifically-based policies, measures, and regulatory frameworks that are applied to protect, manage, and respond to risks associated with food, agriculture, health, and the environment.” ***–BMBL, 6th Edition, 2019***

DEFINITIONS

- “Biosecurity is a series of management practices designed to prevent the introduction, delivery, and spread of disease pathogens that can harm or adversely affect livestock, crops, environments, and people. These practices may also help eliminate or control diseases already existing on the premises.” ***–USDA/APHIS Biosecurity for Sheep and Goat Producers, 2020***
- “Biosecurity refers to everything people do to keep diseases – and the viruses, bacteria, funguses, parasites, and other microorganisms that cause disease – away from birds, property, and people. It includes: Structural biosecurity: measures used in the physical construction and maintenance of coops, pens, poultry houses, family farms, commercial farms, and other facilities. Operational biosecurity: practices, procedures, policies that are consistently followed by people.” ***–USDA/APHIS Defend the Flock – Biosecurity 101, 2021***
- “Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of regulated materials, and other related assets (e.g., personnel, equipment, non-infectious material, animals, sensitive information).

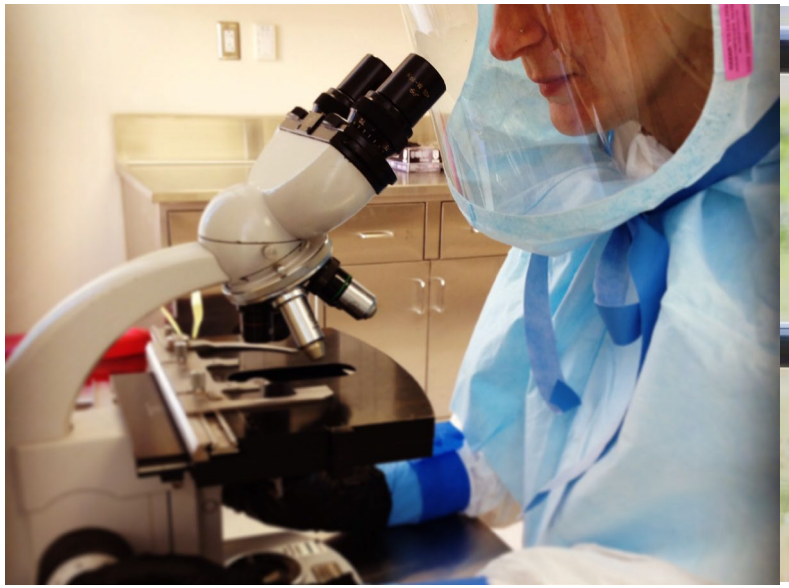
DEFINITIONS

- Several definitions
- Many languages have only one term to describe the concepts of biosafety and biosecurity.
- One word for describing how workers, the public, animal and plant health, the environment, and research must be protected.
- Keep in what needs to stay in, and keep out what needs to stay out.

Biosécurité **Biosicurezza**

Biosegurança

Bioseguridad **Biosicherheit**



BIOSECURITY
KEEP IN WHAT NEEDS TO STAY IN
KEEP OUT WHAT NEEDS TO STAY OUT

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BIORISK

- “Biorisk is the effect of uncertainty expressed by the combination of the consequence of an event (including changes in circumstances) and the associate “likelihood” (as defined in ISO guide 73) of occurrence, where biological material is the source of harm.”

- “Harm is the adverse effect on the health of people, animals, or plants, on the environment, or on property.”

- “Harm can be a consequence of unintentional exposure, accidental release, or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.”

-ISO/DIS 35001, 2019

RISK ASSESSMENT

GUIDING PRINCIPLES

- Identify hazard
- Potential consequence
- Probability of occurrence
- Develop a risk mitigation/management plan

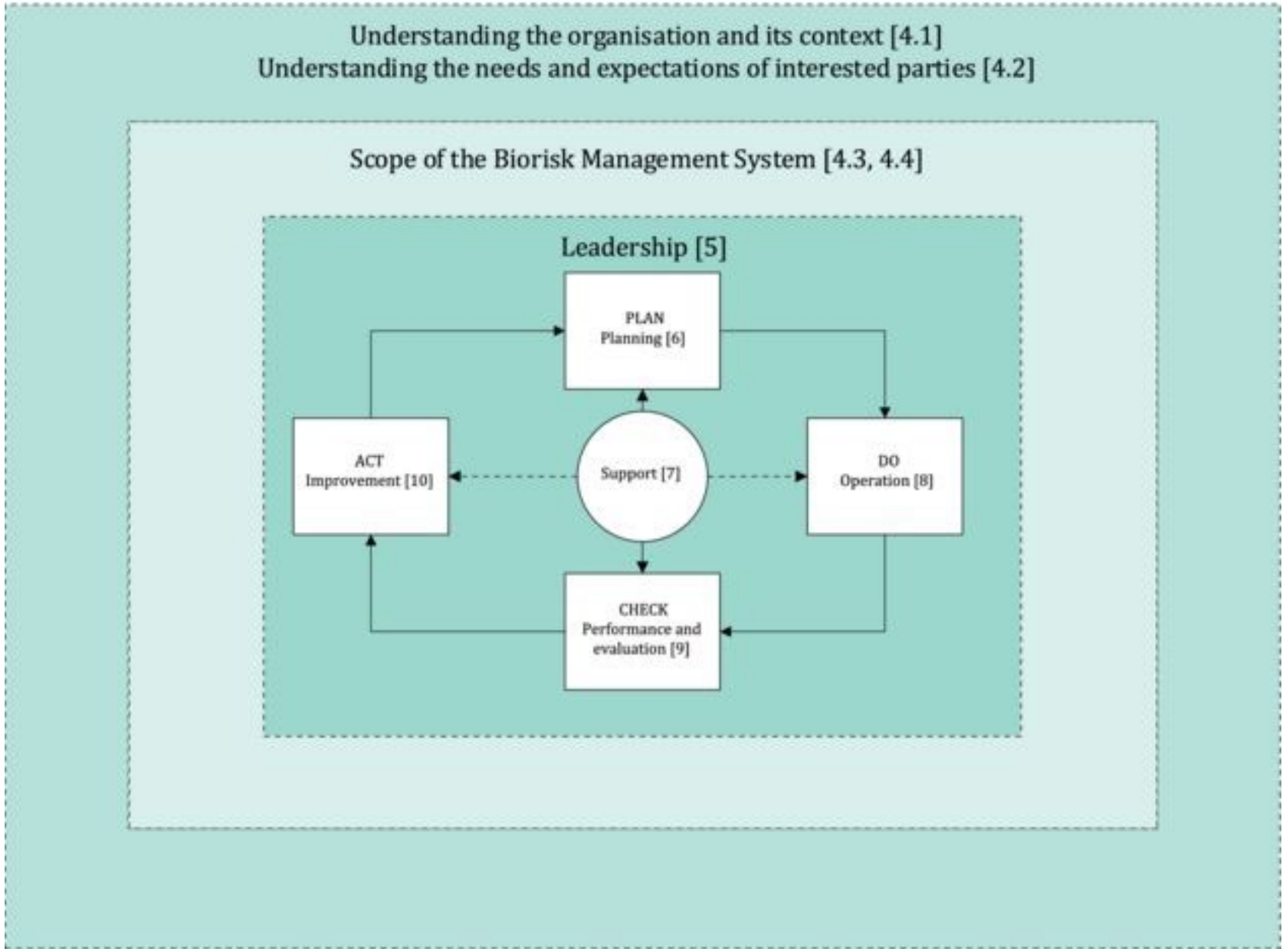
- There are many types of risk (e.g. compliance, perceived, safety, security) all requiring a robust risk assessment, and risk mitigation/management plan.
- Risk is a function of probability and consequence.
- Risk assessment must be conducted on a reoccurring basis, and requires a **team** with appropriate expertise and knowledge.
- Risk mitigation/management plans can reduce risk to an acceptable level, and must be reevaluated on a reoccurring basis.

BIORISK MANAGEMENT

- “Biorisk management [is defined as] coordinated activities to direct and control an organization with regard to biorisk”. ***-ISO/DIS 35001, 2019***

- “Biorisk management system [is] a management system or part of a management system used to establish biorisk management, policies, objectives, and processes to achieve those objectives. A biorisk management system addresses the control of biorisk(s)”. ***-ISO/DIS 35001, 2019***

Biorisk Management System Model
[Top - Down Pyramid View]



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CASE STUDIES

https://www.vulture.com/2018/04/ma-anand-sheela-wild-wild-country-falling-in-love.html

- In 1984, members of the religious cult used *Salmonella typhimurium* to contaminate restaurant salad bars in The Dalles, Oregon.
- Diane Yvonne Onang (Ma Anand Puja), a nurse practitioner, purchased bactrol disks from VWR Scientific and isolated *Salmonella typhimurium* from the bactrol disks. Disks were purchased under the state-licensed medical laboratory she worked at.
- A total of 751 people were documented to became ill from the attack.

https://wmdcenter.ndu.edu/Portals/97/Documents/Publications/Articles/Bioterrorism-and-Biocrimes.pdf

CASE STUDIES

- In 1996, Diane Thompson, a laboratory technician at St. Paul Medical Center in Texas infected co-workers with *Shigella dysenteriae* type 2.
- Diane stole beads impregnated with the agent from the laboratory and used to contaminate blueberry muffins and doughnuts.
- Twelve workers became ill.
- In 1995, she had committed similar acts against a boyfriend.

https://wmdcenter.ndu.edu/Portals/97/Documents/Publications/Articles/Bioterrorism-and-Biocrimes.pdf

CASE STUDIES

- In 2017 Merck downloaded software infected with malware. About 40,000 machines at Merck were infected causing massive disruption to sales, manufacturing, research and development. The same malware impacted many other organizations in over 65 countries.

- In 2021, hackers targeted the University of Oxford's Division of Structural Biology research laboratory, gained access to several cyberphysical systems (integrate cyber-based controls into physical structures), and demonstrated the ability to control pumps and pressure, including disabling pressure alarms. The hacked machines were used to purify proteins and prepare samples used in coronavirus research.

https://www.frontiersin.org/articles/10.3389/fbioe.2023.1240281

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REDEFINING BIOSECURITY

The application of principles, technologies, and processes to ensure **protection and accountability**, **prevent loss**, **theft**, **misuse**, **diversion**, **unauthorized access and possession**, **introduction or release** of pathogens, toxins, other biological materials, and related information and/or technology.

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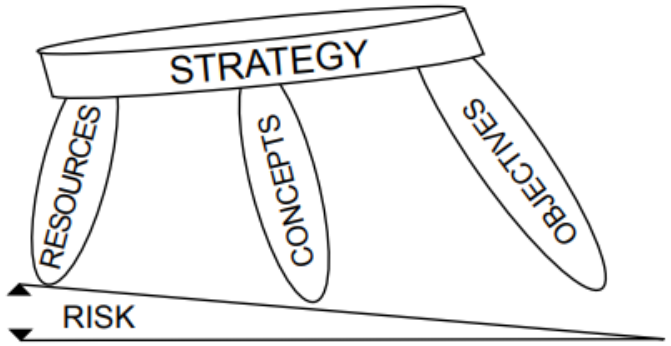
THE LYKKE MODEL
STRATEGY = ENDS + WAYS + MEANS



Ends = objective

Ways = concepts for accomplishing the objective

Means = resources for supporting the concepts

- Some risk is inherent to all strategy, and the best any strategy can offer is a favorable balance against failure.
- If not in balance, there is assumption of greater risk.
- Key questions: What is to be done? How is it to be done? What resources are required to do it in this manner?
- One might add resources, use a different concept, change the objective, or accept the risk.

https://www.jstor.org/stable/pdf/resrep12025.12.pdf

THE 5 TRAITS OF HIGH RELIABILITY ORGANIZATIONS

Preoccupation with failure

- Constantly think of ways processes might fail
- Employees encouraged to share concerns

Reluctance to Simplify

- Find real source of a problem

Sensitivity to Operations

- Constantly aware of how processes and systems affect the organization
- No assumptions

Commitment to Resilience

- Prepared to respond to failures and find new solutions
- Resilience and swift problem solving prevent catastrophes

Deference to Expertise

- Listen to people with most knowledge regardless of seniority

http://www.beckershospitalreview.com/hospital-management-administration/5-traits-of-high-reliability-organizations-how-to-hardwire-each-in-your-organization.html

Cristine C. Lawson, Ph.D., RBP (ABSA), CBSP (ABSA)
Deputy Director for Biosecurity
DoD BSAT Biorisk Program Office
cristine.c.lawson.civ@health.mil

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 October 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.

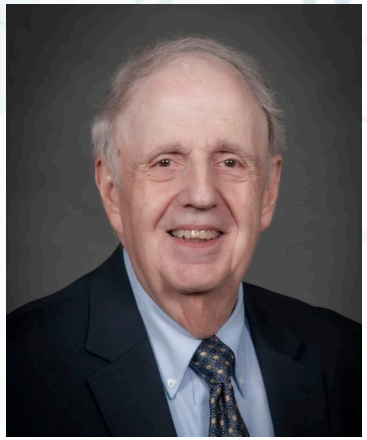
CLIAC 2024 Fall Meeting

November 6-7, Virtual Meeting

- Save the date on CDC's CLIAC website: https://www.cdc.gov/cliac/php/meetings/upcoming.html
- Contribute oral and written comments to CLIAC@cdc.gov by Tuesday, October 29, 2023
- Topics include:
  - Reports from two CLIAC workgroups, the Biosafety Workgroup, and the Next Generation Sequencing Workgroup
  - Cybersecurity requirements in the clinical laboratory
  - Determination of clinically relevant range of values for proficiency testing samples
  - Utilization of remote technology for competency assessments

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