

DLS ECHO Biosafety Session: January 30, 2024

Laboratory Biorisk Management: What It Is and How to Improve It



Kalpana Rengarajan, PhD, MPH, JM, RBP (ABSA)
Director of Research Safety and Biosafety Officer,
Emory University
Atlanta, GA



ECHO Model

A

Amplification - Use *Technology* to leverage scarce resources



B

Share **Best Practices** to reduce disparity



C

Case Based Learning to master complexity



D

Web-based **Database** to *Monitor Outcomes*



<https://projectecho.unm.edu/model/>

Agenda

- ECHO Model
- 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.



DLS ECHO Biosafety Session: January 30, 2024

Laboratory Biorisk Management: What It Is and How to Improve It



Kalpana Rengarajan, PhD, MPH, JM, RBP (ABSA)
Director of Research Safety and Biosafety Officer,
Emory University
Atlanta, GA



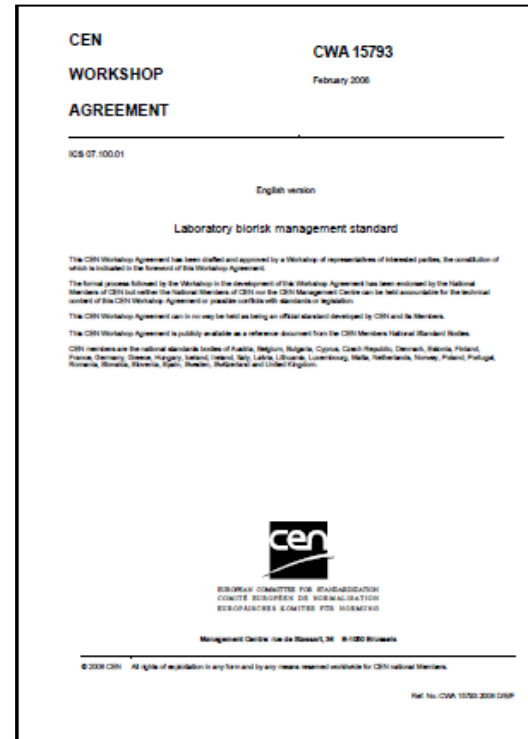
Laboratory Biorisk Management System (What it is and how to improve it)

Kalpana Rengarajan, PhD, MPH, JM, RBP (ABSA International)
Director Research Safety, Biosafety Officer
Emory University, Atlanta GA 30322

krengar@emory.edu

Laboratory Biorisk Management

- ☣ System or process to control **safety** and **security** risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.



Management System

What is a “management system”? And why is it important?

- ▶ Develop a definition for a management system and write it down.
- ▶ Can a couple of you your thoughts what is management system as you see it?

What is the ISO35001?

The first international standard that **defines the requirements of the biorisk management system** for laboratories or any other organization that works with biological agents.

Purpose:

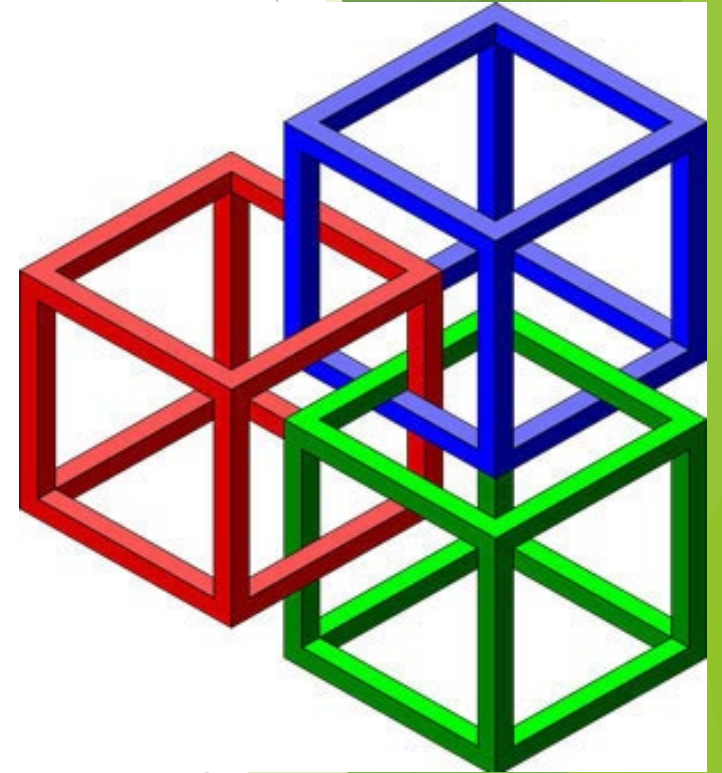
Defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials.



The screenshot shows the ISO website interface. At the top left is the ISO logo, which consists of a red square with a white globe icon and the letters 'ISO' in white. To the right of the logo is a dark navigation bar containing a search icon, a shopping cart icon, the text 'EN' with a dropdown arrow, and a hamburger menu icon. Below the navigation bar, the text 'TC > ISO/TC 212' is displayed in white on a red background. The main title of the page is 'ISO 35001:2019 Biorisk management for laboratories and other related organisations', written in large, bold, black font.

Biorisk Management Approach in ISO35001

- ❖ Comprehensive process
- ❖ Establishes principles
- ❖ Essential components of framework
- ❖ Guidance on the implementation where appropriate.



Management Approach in ISO35001

Application of the management systems approach principle leads to:

- a) defining the system by identifying or developing the processes that affect a given objective
- b) structuring the system to achieve the objective in the most effective manner
- c) understanding the interdependencies among the processes of the system
- d) continually improving the system through measurement and evaluation
- e) establishing resource constraints prior to action.

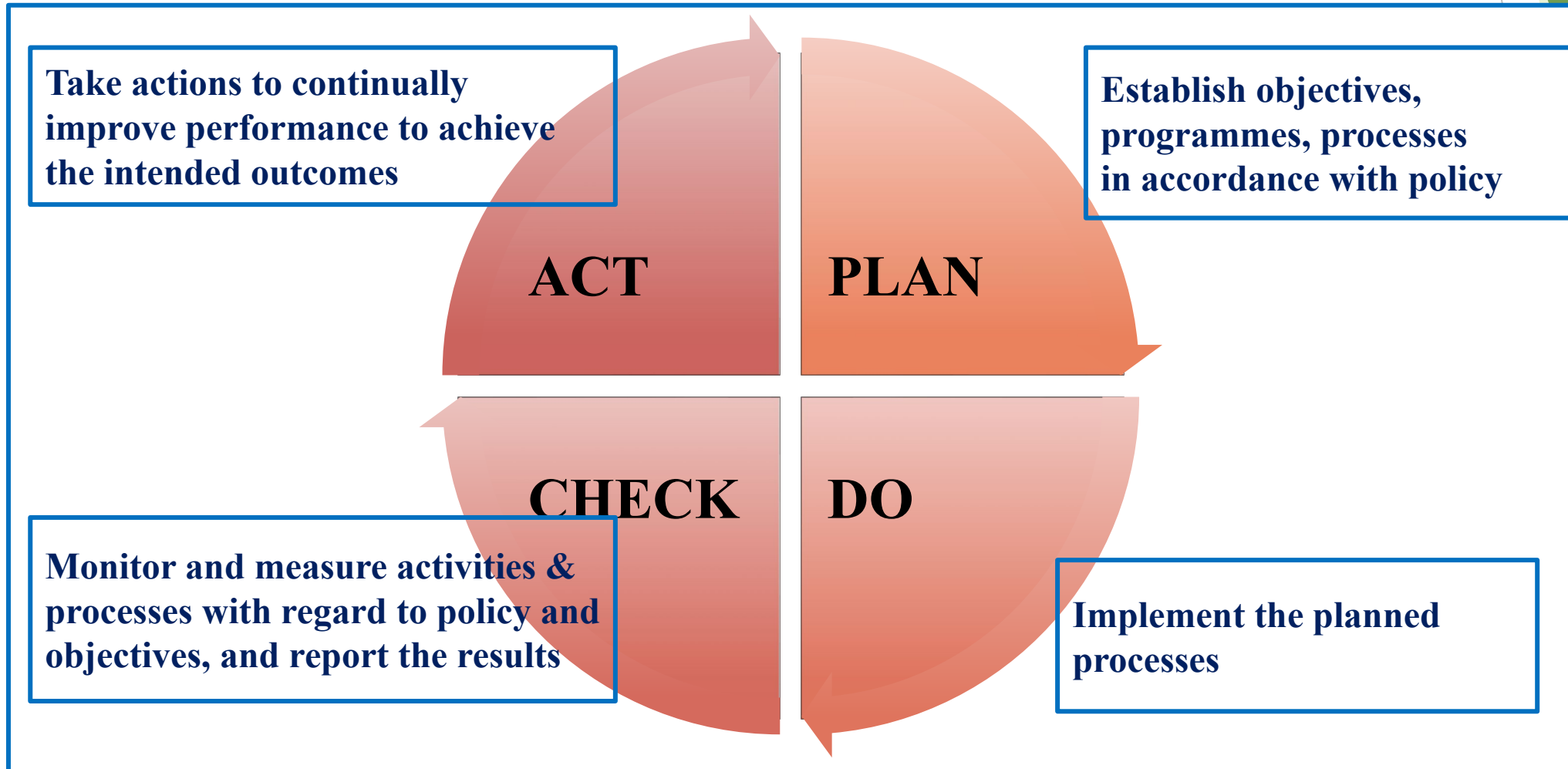
ISO35001 – Performance Oriented

- ▶ Describes **what** needs to be achieved.
- ▶ Allows **organizations** to determine how best to achieve objectives.
- ▶ **Not** a technical document.
- ▶ Use PDCA cycle.



PDCA

- ▶ Built on the concept of continual improvement.



Individual Reflection

- ▶ How could you improve biorisk management at your own lab, short-term and long-term?
- ▶ What would be the benefits of implementing a more comprehensive standardized biorisk management system?
- ▶ Write your answers on a piece of paper; please share with the audience.



Individual Reflection

Consider your own institution. If you could make three changes to the management system at your facility today, what are your top three priorities?

Write your three priorities down.

We will ask for a few volunteers to share with the group.



Group Exercise

▶ Now list the following:

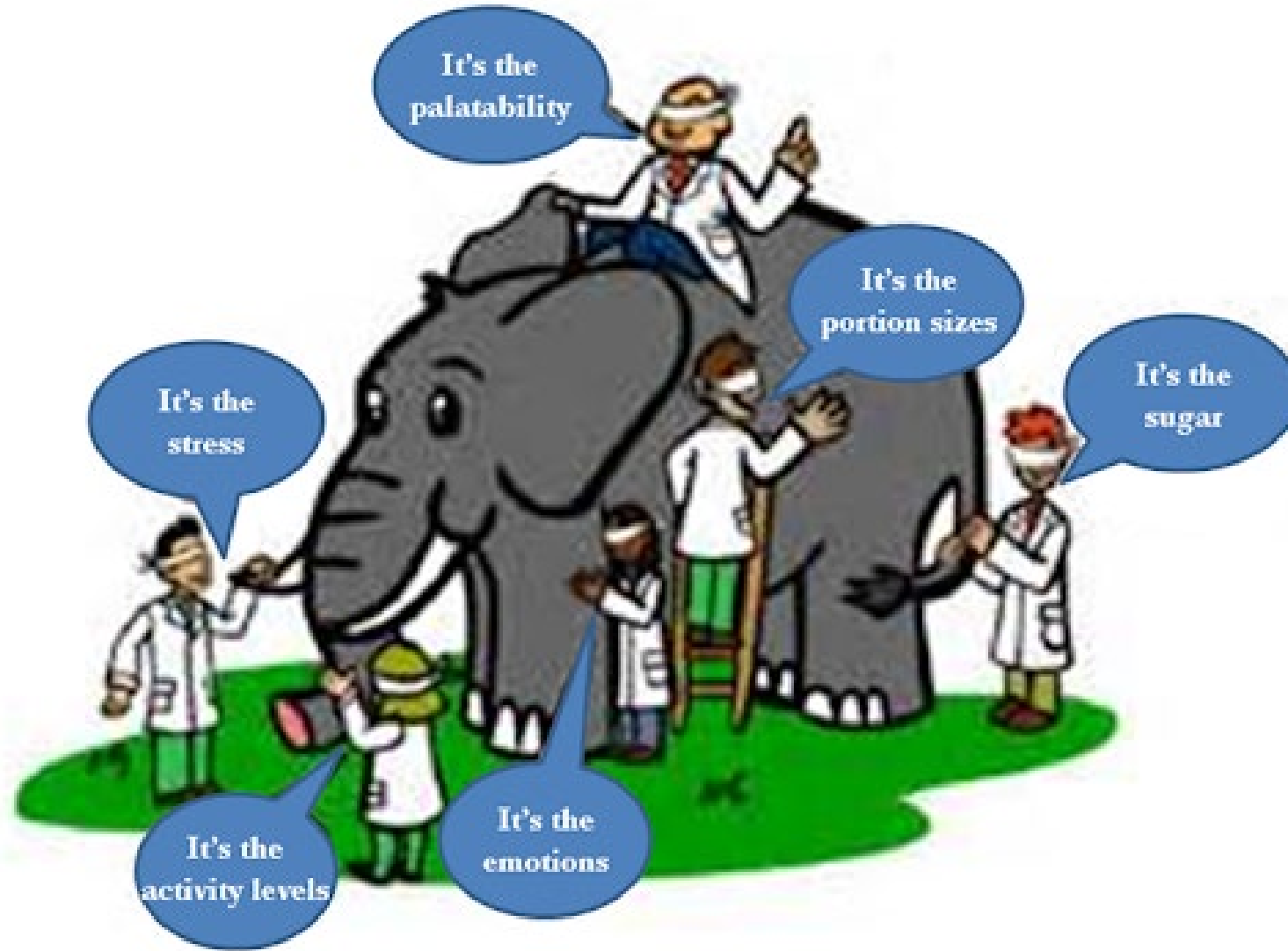
- ❖ *What are the key challenges or factors to consider in establishing and implementing a biorisk management system?*
- ❖ Write down at least 3 - 5 factors



Discussion

What are the expected challenges of implementation?





WHERE

DO

START?



Gap Analysis

An examination and assessment of your current performance for the purpose of identifying differences between your current state of business and where you'd like to be.

Answers questions like:

"Where are we now?"

"Where would we like to be?"

"How do we get there?"



ClearPoint Strategy

Initiation of ABSL3 Influenza work based on the Biorisk Management System (CWA 15793:2008)

Objectives of this Study...

- ▶ In order to effectively implement the CWA, a gap analysis was conducted to compare and analyze the existing processes and systems
- ▶ The gap analysis allowed us to:
 - ▶ Determine which requirements are in place and to what degree they are implemented
 - ▶ Develop an implementation strategy for future use
 - ▶ Provide a framework that may be used as the basis for training and raising awareness of biosafety and biosecurity guidelines and best practices

Predicted Outcomes

- ▶ Identifying gaps in the existing program
- ▶ Developing an action plan for implementation of the CWA and continuous improvement of the program
- ▶ Improvements will address following issues:
 - ▶ Effectiveness of process reviews
 - ▶ Effectiveness of follow-up activities
 - ▶ Documented procedures and instructions
 - ▶ Training and awareness programs
 - ▶ Risk assessment and management
 - ▶ Preventive actions
 - ▶ Conformity and compliance



Stakeholders Involved in this Gap Analysis

Biosafety
Officer /
Environmental
Health & Safety
Office

Principal
Investigator /
Researchers

Division of
Animal
Resources Staff

IBC Members

Campus
Services (HVAC
and associated
items)

Occupational
Health



Internal Scoring System

Section	Line	Summary Description of Requirement	Applicable (Y/N)	Written Program Required (Y/N)	GAP Score 1=Audit Ready 2=In Process 3=Nothing/Don't Know	Implementation Action Required	Responsible Party
---------	------	------------------------------------	------------------	--------------------------------	--	--------------------------------	-------------------

Results

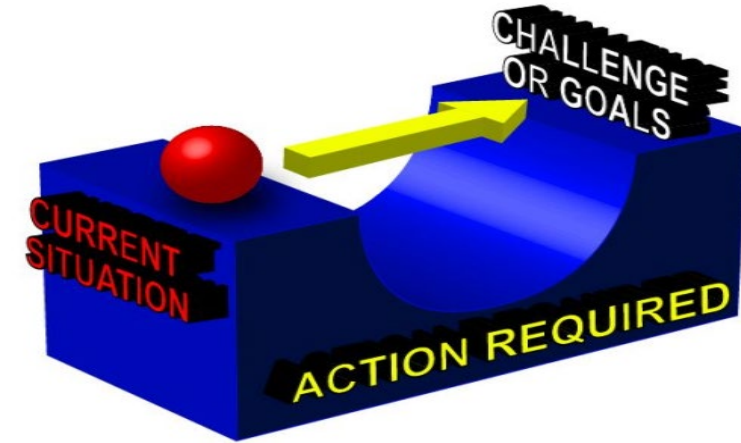
Section	Average Score
4.1: General Requirements	1.4
4.2: Policy	1.3
4.3: Planning for Hazard Identification, Risk & Risk Control	1.0
4.4: Implementation and Operation	1.5
4.5: Checking & Corrective Action	1.5
4.6: Review	1.8
Overall Score	1.4

Study Findings

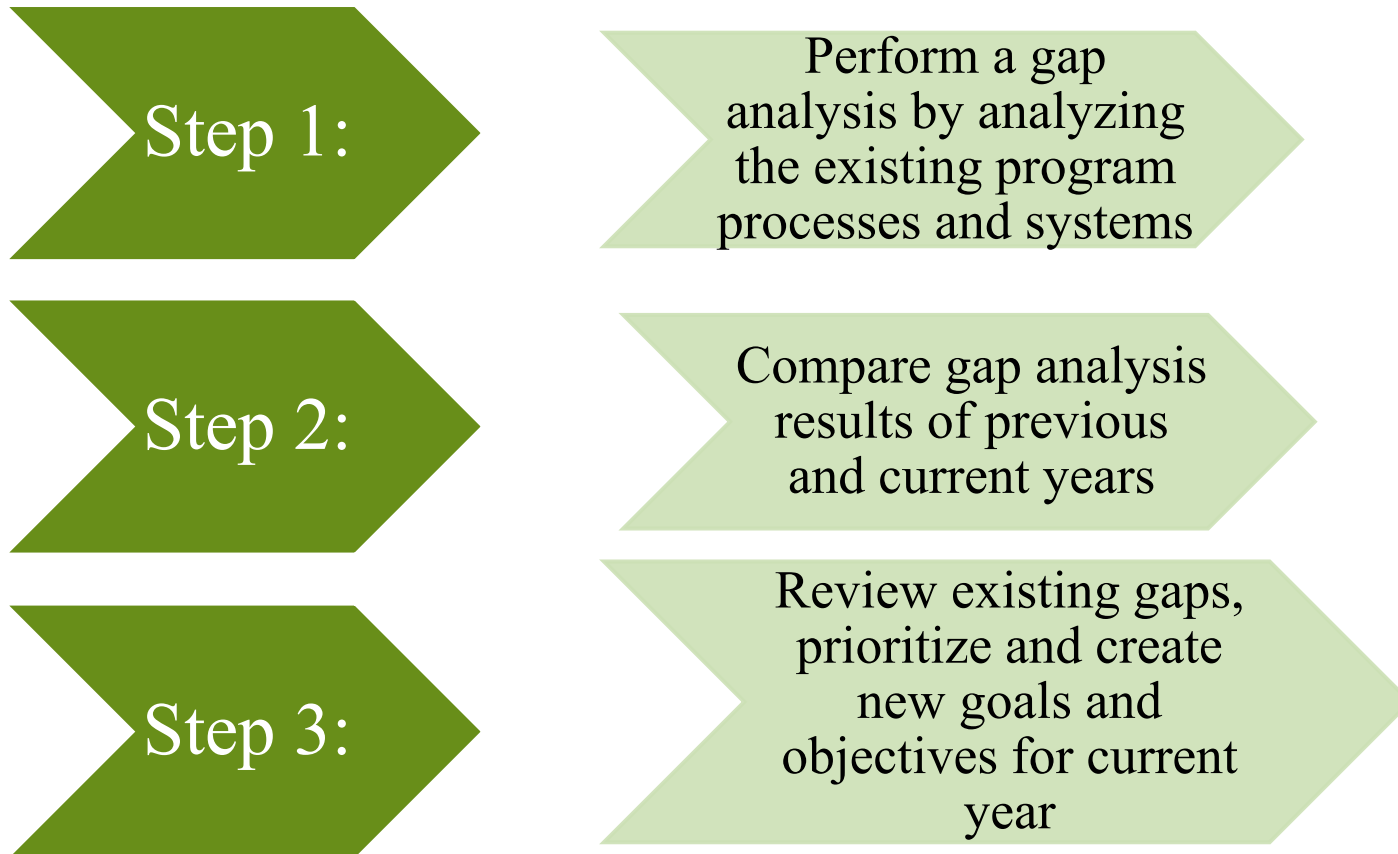
- ▶ We have a strong biosafety program but some written policies/procedures need to be further developed to come in line with the CWA requirements
- ▶ An institution-wide approach would have been an overwhelming undertaking
- ▶ However, by going through this Gap Analysis exercise on a smaller scale we were able to get a snapshot of how the overall biosafety program stands up to the CWA

Taking it Further

- ▶ The gap analysis is intended as a living and evolving document
- ▶ Thus, it is a good way to determine what the current situation is, where action is critically needed, and gain support from upper management to close discovered gaps
- ▶ We **continued** to:
 - ✓ List out the corrective actions needed to fill the gaps
 - ✓ Prioritize action items based on program needs and available resources
 - ✓ Assign corrective actions to appropriate responsible individuals
 - ✓ Document procedures used and time spent to close the gaps



Methods to Implement a successful Program



Results – Scores by Section

Section	Average Score First Year	Average Score Second Year
4.1: General Requirements	1.38	1.00
4.2: Policy	1.27	1.00
4.3: Planning for Hazard Identification, Risk & Risk Control	1.05	1.02
4.4: Implementation and Operation	1.45	1.34
4.5: Checking & Corrective Action	1.32	1.21
4.6: Review	1.75	1.17
Overall Score	1.38	1.26

Group Exercise

- ▶ List one program that you would like to Improve
- ▶ *What are the key challenges or factors to consider in establishing and implementing a biorisk management system for the program you are considering?*
- ▶ Write down at least 3 - 5 factors that you would like to consider starting to address the gaps for the program you are thinking about



**Baby steps count,
too, as long as
you're moving
forward.**

Chris Gardner



THANK YOU

Any Questions?

Do you have any questions or comments for me before we conclude?

DLS ECHO Biosafety Session: February 27, 2024

A Stepwise Process to Improve Biorisk Management Systems

Eric Cook, MPH, CBSP

Biosafety Officer

Global Chem/Bio Security Program, Sandia National Laboratories

Albuquerque, NM

