DLS ECHO Biosafety Session: December 17, 2024

Biorisk Management: Continuous Improvement

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ISO Convener for Technical Committee 212 Working Group 5

November Session Recap: "Biorisk Management Performance Evaluation"

135 participants attended the session

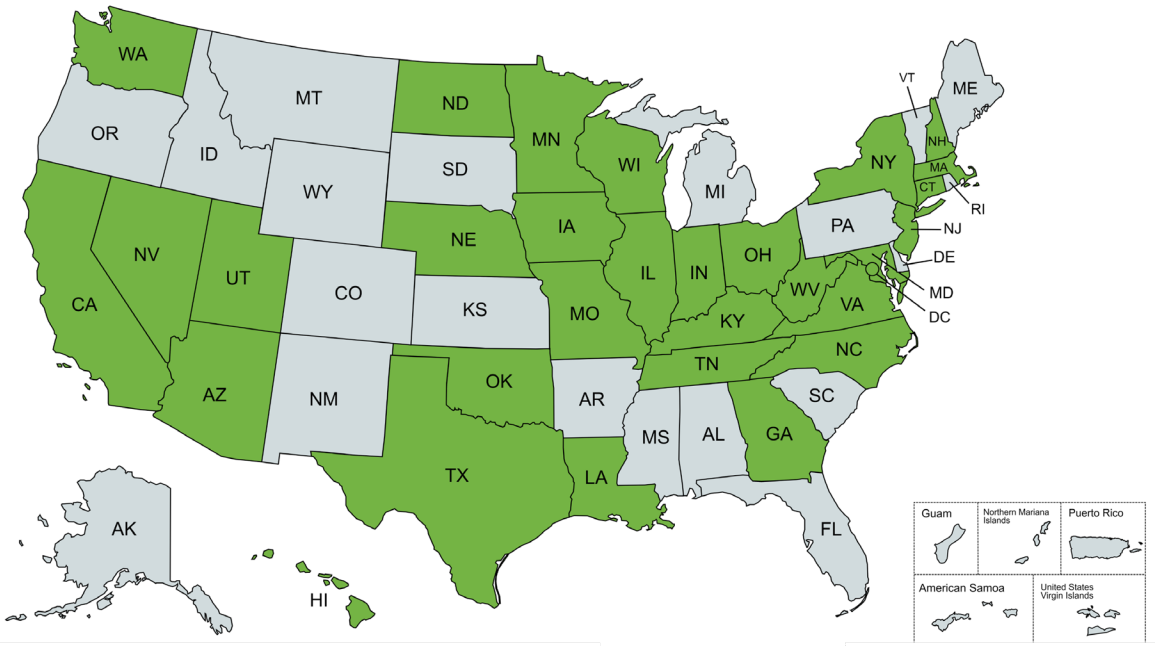
82 organizations were represented

Positives of participating in an ISO 35001 audit include:

*"[It] helps one **get material together** and **evaluate where they are** as they prepare [and it] **helps the institution to overcome their own biases**"*

-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 Canada and Mexico were also present at the session. Twelve 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.

Biorisk Management: Continuous Improvement

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ISO 35001: 2019 - Biorisk management for laboratories and other related organizations

Where are we?

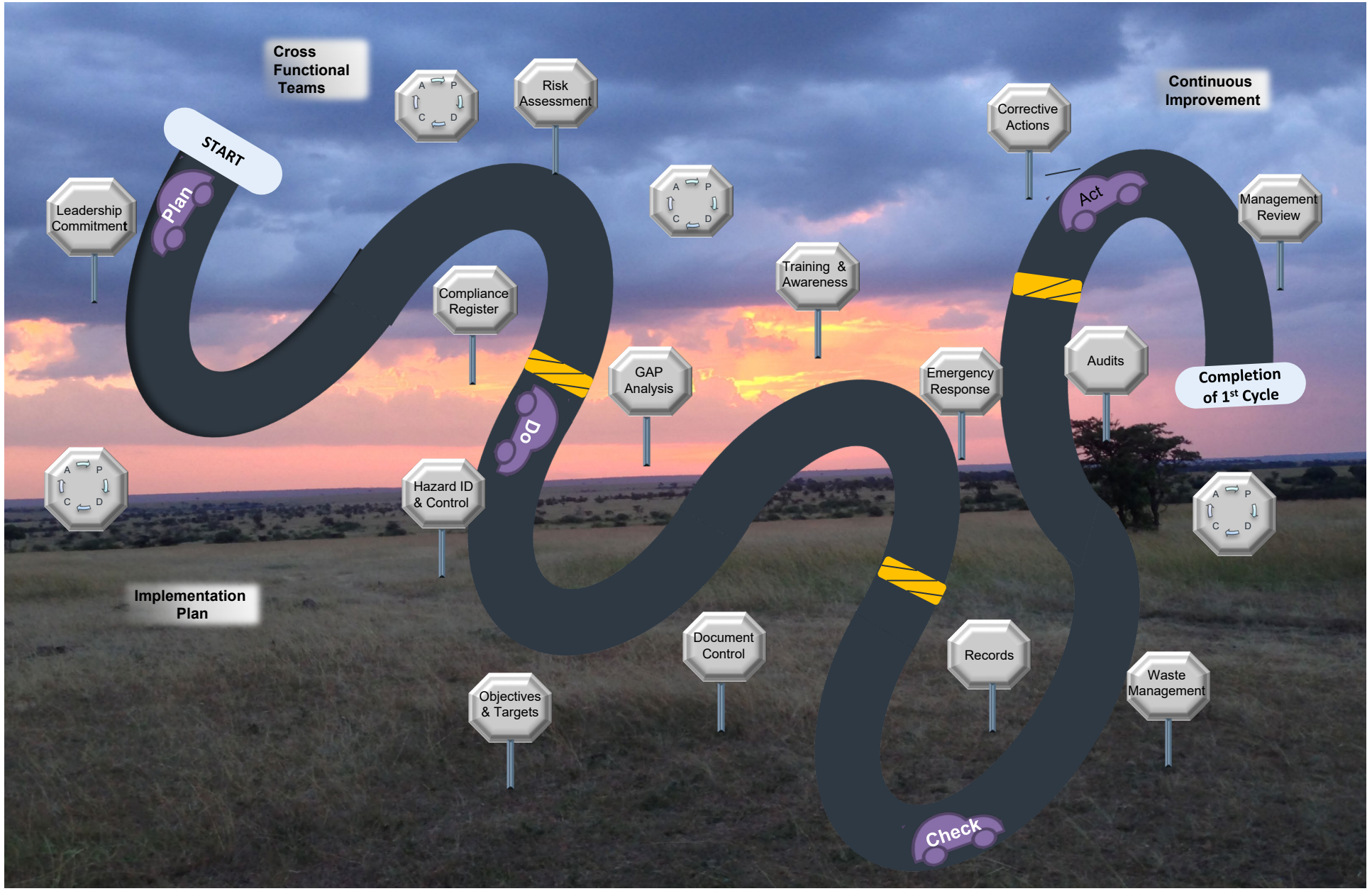
- *"Currently"* there is not a formal certification body?
- 1st class for ISO 35001 Lead Auditor Training will be held in Malta in February 17-21, 2025. https://bioriskinternational.com/about-page/
- Competency Standard ISO/TS 5441:2024 was published Summer of 2024.
- Implementation Standard, TS – ISO/TS 7446 expected to be published Spring of 2025.

Question

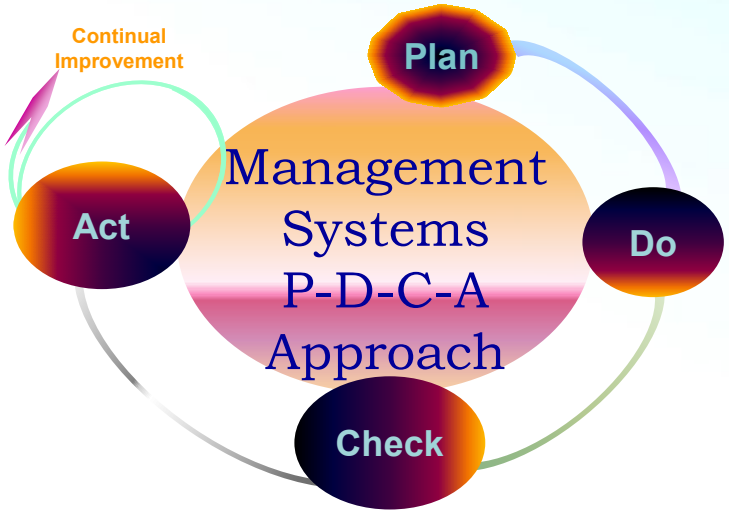
Are you currently implementing Biorisk Management Quality Systems in your Laboratory?

1. Yes! Fully in place.
2. Yes! In process.
3. No, no plans.
4. No, but are planning to.
5. Not sure where to start.

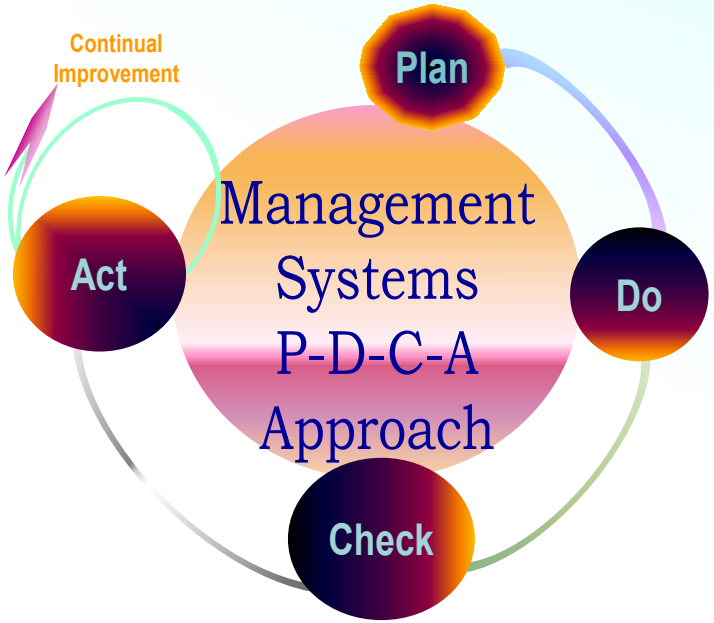
Biorisk Management Road Map For Implementation



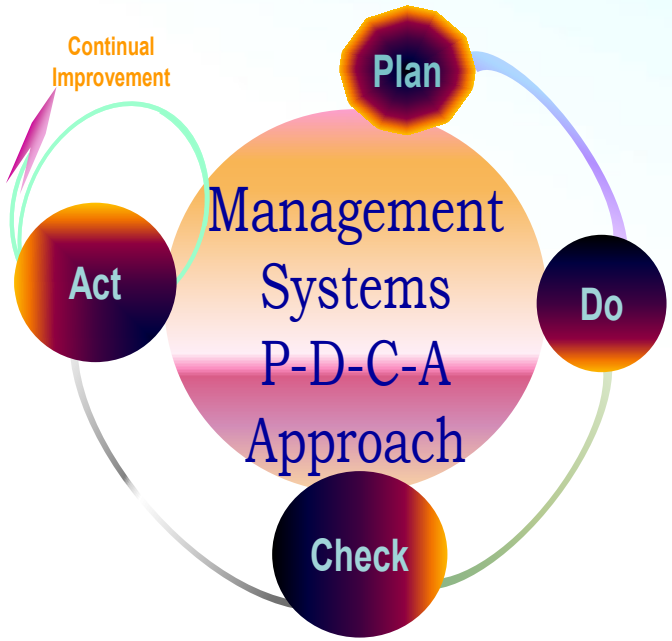
Biorisk Management implementation reflects ***accepted quality management principles based on the "Plan, Do, Check, Act," model*** using a standard process to identify current activities, establish goals, implement plans to meet the goals, determine progress, and make improvements to ensure *continual improvement.*



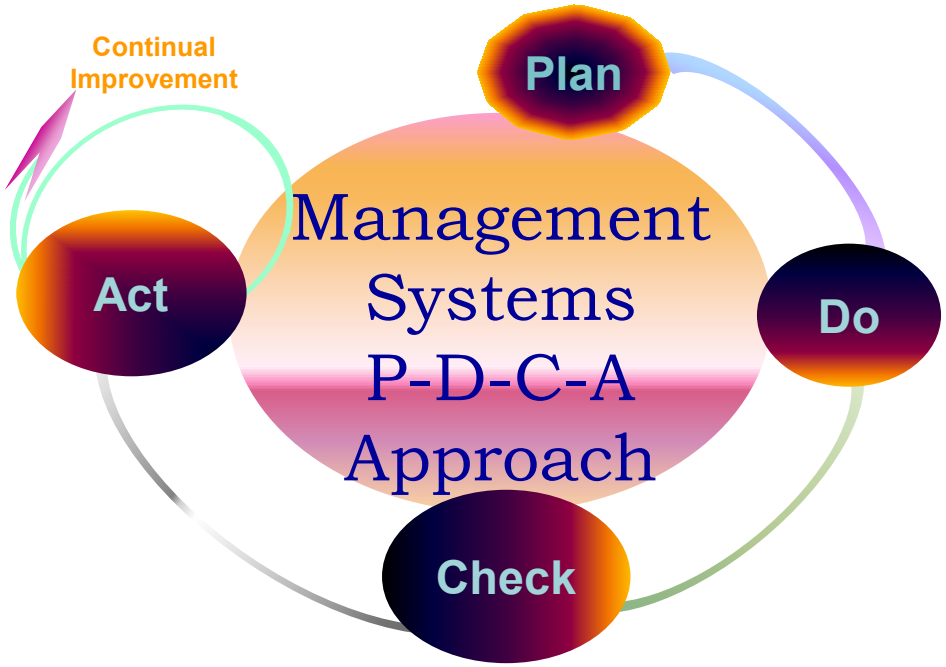
Implementation of a BRM System begins with a comprehensive evaluation of an organization's operations and activities to determine how they can or do impact the environment. The BRMS process then establishes goals and programs to address those impacts and improve efficiencies in the environmental footprint of the organization.



The resulting plans are deployed throughout the organization, **usually** through existing management mechanisms and operations. As the system evolves, it is continually evaluated to determine whether the goals are being met and, if necessary, plans are amended to achieve the intended goals and continue the improvement process. With the objective of making the organization more efficient and prepared to focus on its mission.



WOW! Easy! Right?



Plan – Do – Check - Act

- A fundamental principle of the scientific method and PDCA philosophy is iteration.
- Once a hypothesis is confirmed (or negated), executing the cycle again will extend knowledge further.
- Repeating the PDCA cycle can bring us closer to the goal.

Continual Improvement

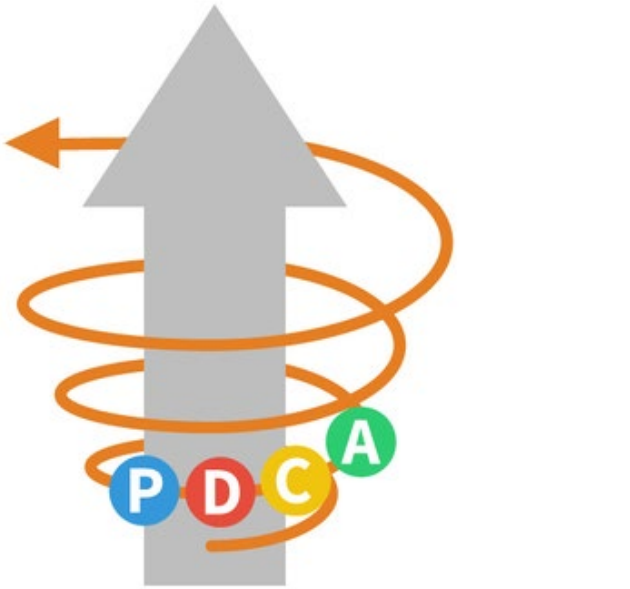
Spirals of Increasing Knowledge

- Envision an open coil or spring, with each loop being one cycle of the PDCA .
- Each cycle or loop bringing you closer to your goal.

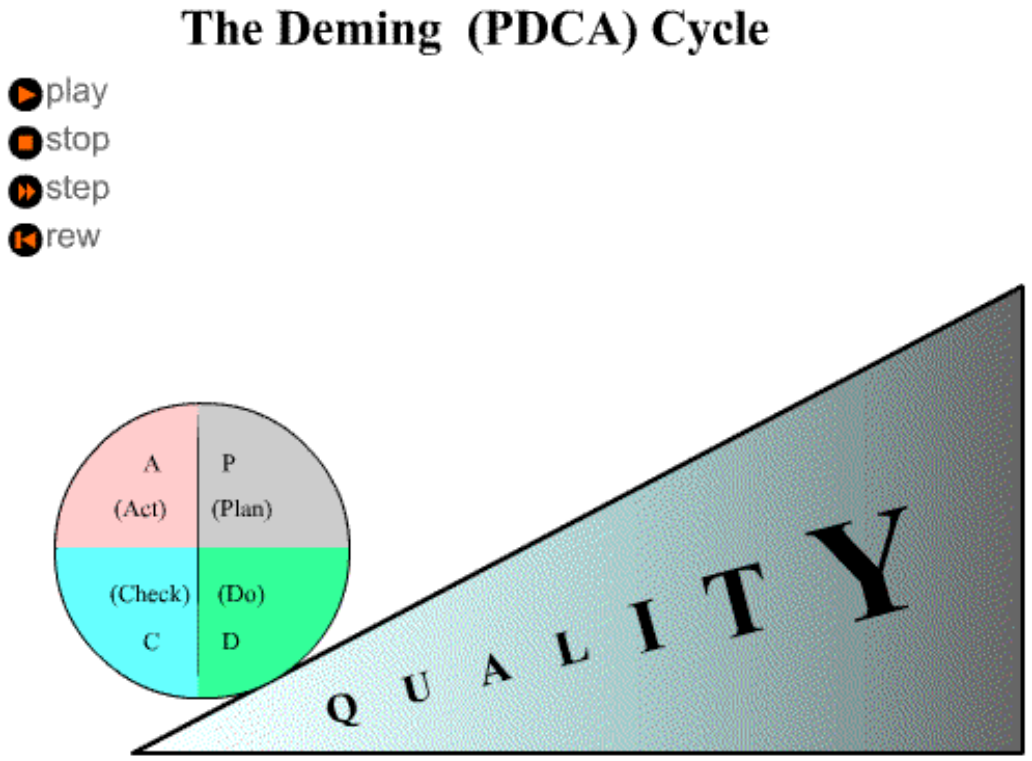
Spirals of Increasing Knowledge

The Management Systems approach is based on the belief that at the beginning of each cycle our knowledge and skills are limited, but improving. Especially at the start of a project.

Key information may not be known; the PDCA - scientific method - provides feedback to justify our guesses (hypotheses) and increase our knowledge.



PDCA = Continuous Improvement - Improved Quality



Scientific Method - PDCA

The power of Deming's concept lies in its apparent simplicity.

While easy to understand, it is often difficult to accomplish on an on-going basis.

Simplicity

- The concept of simplicity is something that is becoming increasingly relevant in today's world.
- ***As technology advances exponentially our minds are preoccupied with more and more information.***
- It is increasingly imperative that when you have people's attention, your message is clear and concise.
- The tolerance for mixed messaging is diminishing rapidly in our society.
- If you're introducing something new i.e. a new form, procedure, policy, etc. you must know what it is and what it stands for.

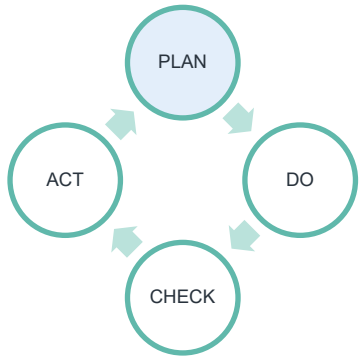
Biorisk Management System Steps

- Plan
  - Policy (Plan)
  - Planning (Plan)
- Do
  - Implementation (Do)
- Check
  - Monitoring & Measuring (Check/Study)
- Act
  - Corrective & Preventive Action (Act)
  - Program and Management Review (Act/Plan)

Continual Improvement

Plan

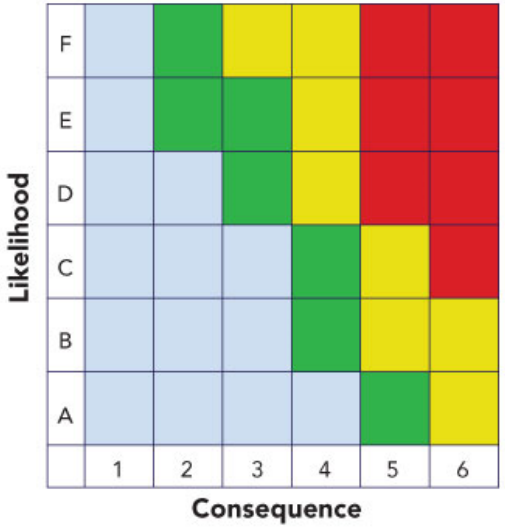
You need to know where you are in the forest to know the best direction to get out.



Risk Assessment – GAP Analysis

Critically important.

- Gap Analysis is all about evaluating and improving performance.
- It is an assessment of the current state of an organizations program against a known set of requirements.
- Once you know where your gaps are, an organization can take steps to fill them.
- Risk Assessent - A methodology which systematically analyzes a process to:
  - Identify and assess hazards
  - Determine risks
  - Develop improvements



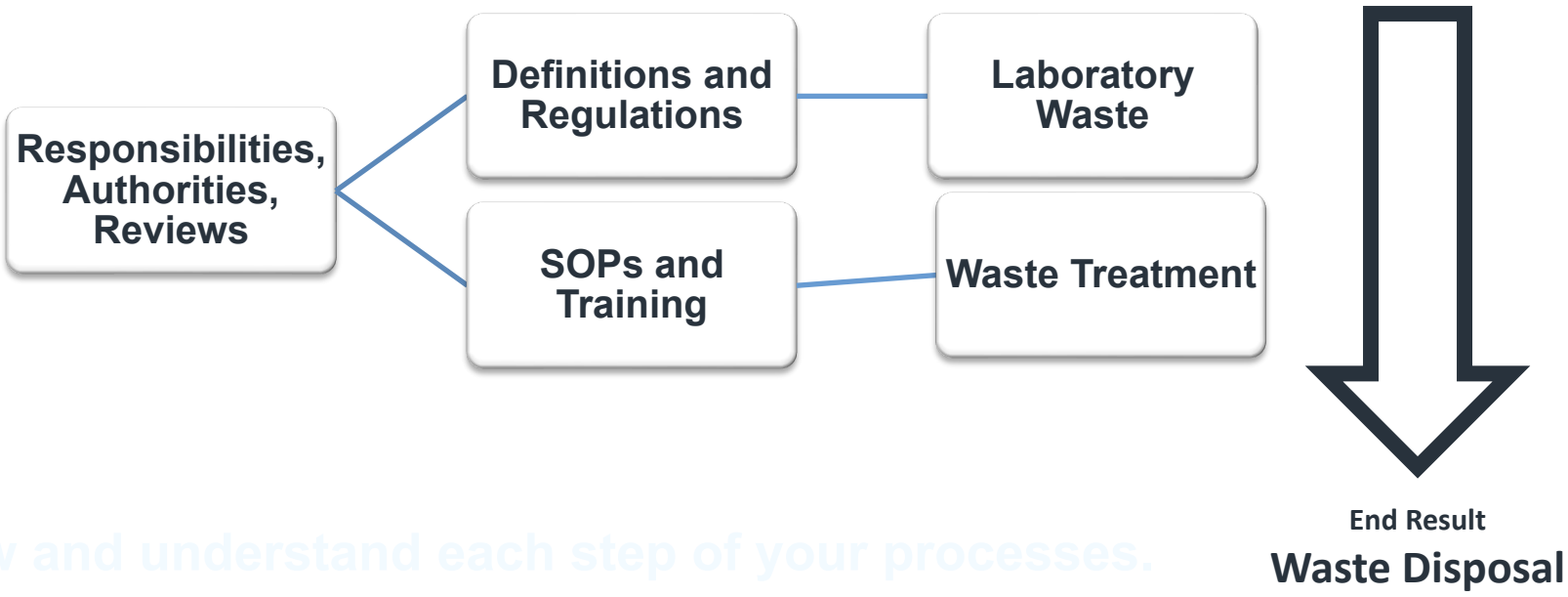
	Extreme Risk & Priority – Requires immediate review.
	High Risk & Priority – Extensive noise risk controls required.
	Moderate Risk & Priority – Some noise controls required
	Low Risk & Priority – Acceptable level of noise control, *Qzone Compliant*

Question?!?!?!

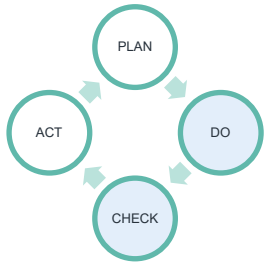
Do you feel comfortable with the concept of Risk Assessment?

- Yes
- No
- Kind of?

Processes Mapping



Know and understand each step of your processes.



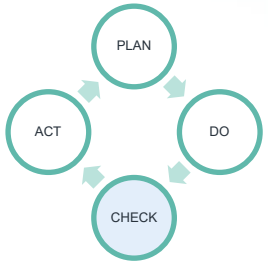
Question?!?!?!

Have you ever used Process Mapping to evaluate a program or process?

- Yes
- No

Check/Study

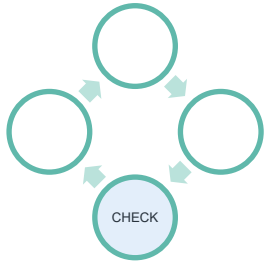
- Gather data
- Analyze the data
- Measures
- Validate/Verify
- Study/Check



Check
Auditing and Inspection Programs

- Audit programs are a way for an organization to catch items that don't always fall into the normal chain of process flow….. Programmatic gaps.

- From a risk management standpoint GAPS are scary.
  - As the risk increases, the gaps must be filled.



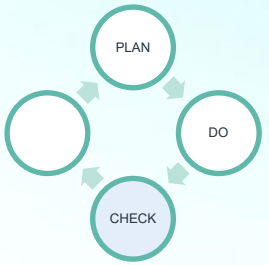
Integrated Audit Programs

Don't just check boxes.

Develop a program that provides multiple purposes.

Make it simple, flexible, and provide a strong foundation build on.

- **Validation**
- **Verification**
- **Training**
- **Knowledge assessment**
- **Cultural / Behavior assessment**
- **Measures / metrics**
- **Risk assessment basics?**



Question?!?!?!

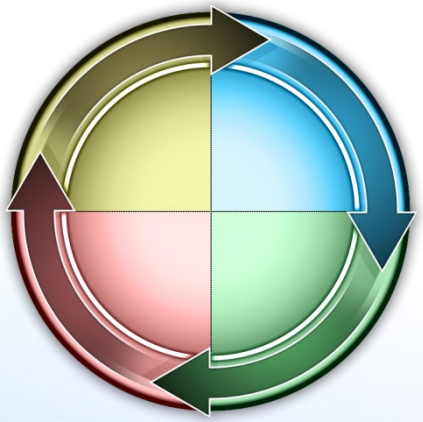
Do you feel your Biorisk Audit Program performs the way you want it to? Providing you with information to better your overall program?

- Yes
- No, and would like to learn more on how.
- Kind of? We can do better!

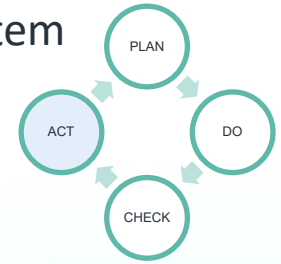
Management Review

•The Management Review is a specific Biorisk Management System element and requirement. Its goal is to provide a means to systematically identify and proactively manage issues that can impact an organization's biorisk performance, especially in relationship to mission requirements and accomplishments.

•The Biorisk Management System - Management Review is designed to ensure ongoing and practical involvement by the top management of an organization. The Management Review offers top leadership the opportunity to determine:



•Is the current Biorisk Management System suitable, adequate and effective for its intended purposes?
•What decisions or actions relative to the Biorisk Management System need to be made to ensure continual improvement?



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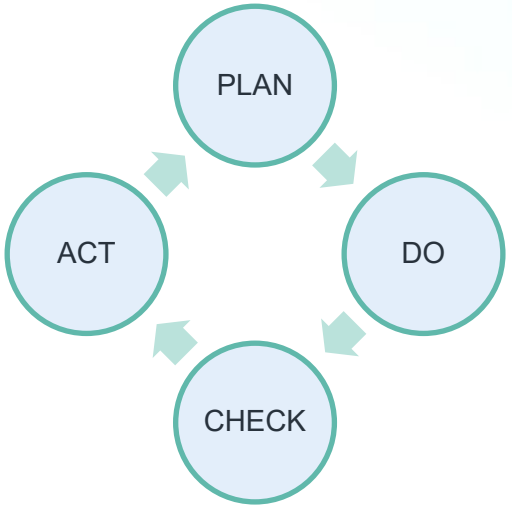
Continual Improvement

PDCA Example: Emergency Preparedness & Response

- Plan, Plan, Plan
  - Emergency response plans
  - Spill response plans
  - Medical emergency response plans
  - Security Plans
- Do, Do, Do
  - Communicate plan
  - Train – responders, employees, etc.
- Check
  - Conduct drills
  - Actual emergencies
- Act
  - Evaluate performance in drills and actual emergencies.
  - Adjust plans when and where necessary

Start Thinking PDCA Cycles

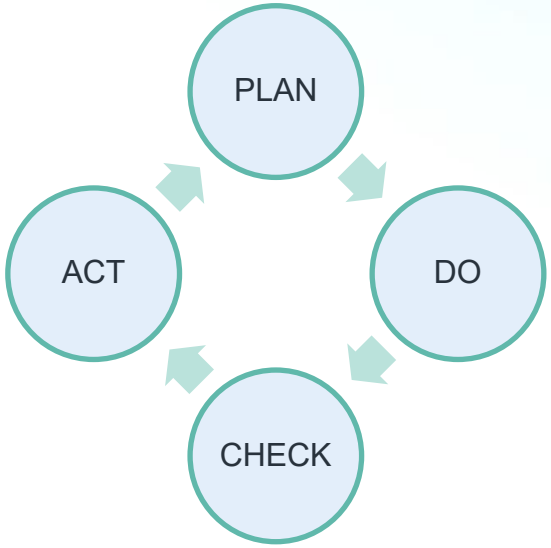


Question???

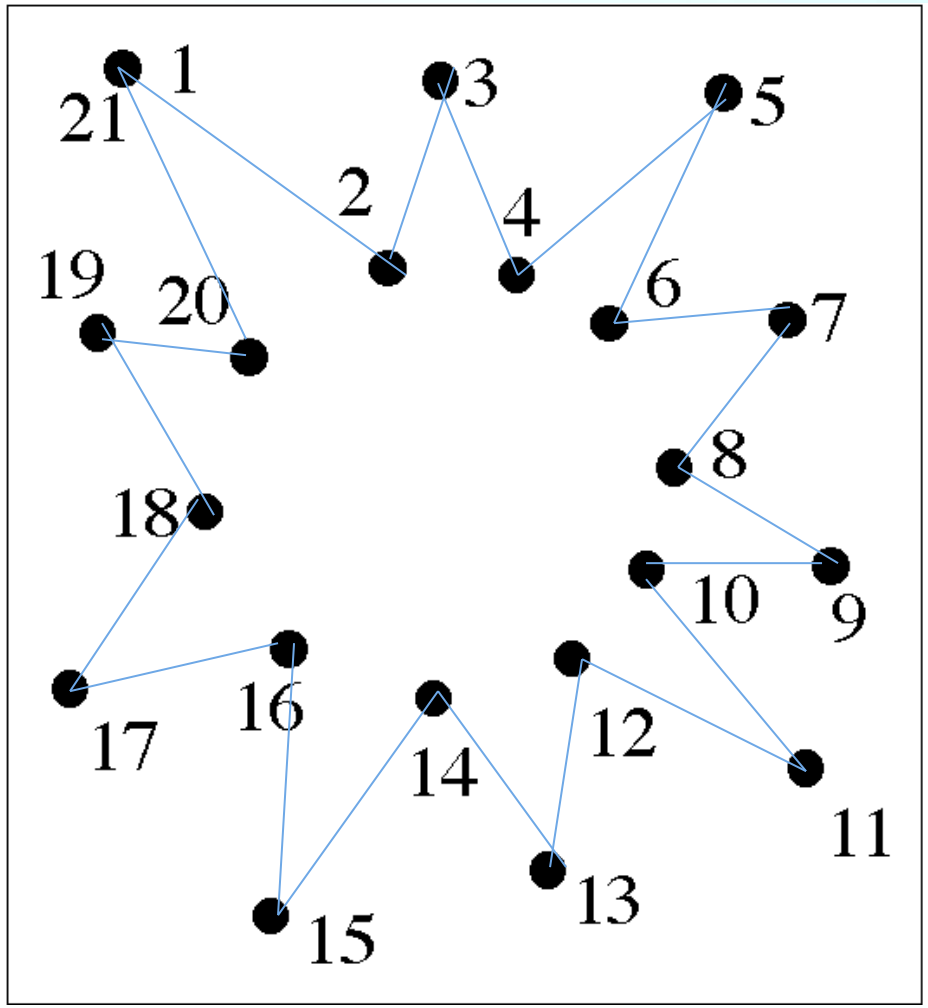
What are other examples that fit into this outline?

List them in the Chat!

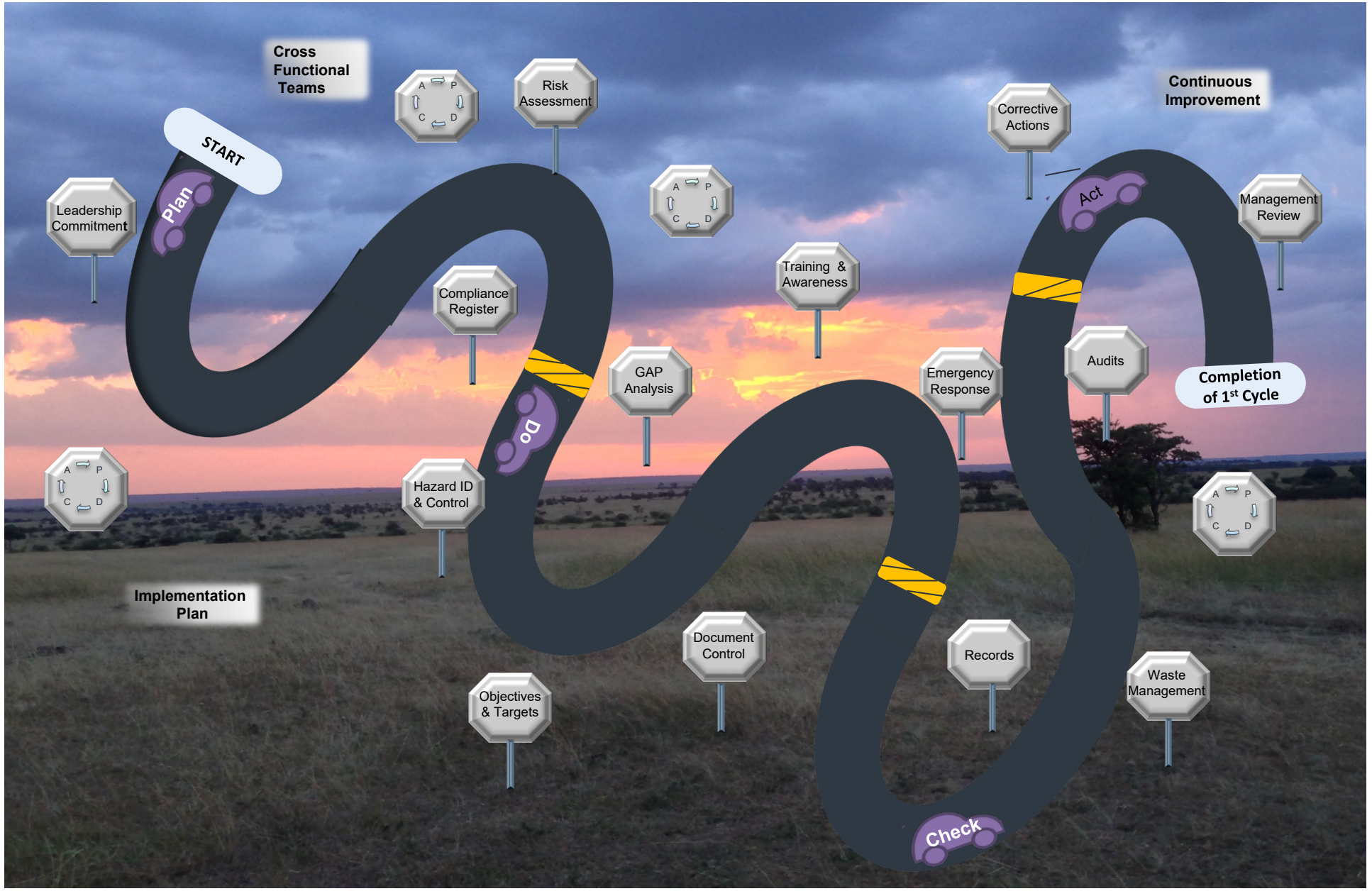
Start Thinking PDCA Cycles



Implementing a management system can be described as a connect the dots picture. You have the pieces. By connecting the dots you have a better idea of what you have.



Biorisk Management Road Map For Implementation



Question?!?!?!

One FINAL Question!

Do you have a Road Map for Implementation of your Biorisk Management System?

- Yes
- No
- Working on it!

Patience.

Quality programs are built on the philosophy of continual improvement and teamwork. All that is good takes time.

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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 December 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.

Scan here to view instructions

DLS supports the enhancement of biorisk management in laboratories and encourages your institution to participate. For questions, contact DLSBiosafety@cdc.gov.

Thank You and See You in 2025!

- ECHO Biosafety sessions will resume in 2025 – stay tuned for updates!
- Your feedback and participation are key to the success of these sessions
- Access materials from previous ECHO Biosafety sessions: https://www.cdc.gov/safe-labs/php/echo-biosafety/

Scan here to access the ECHO Biosafety website