

# DLS ECHO Biosafety Session: February 27, 2024

## A Stepwise Process to Improve Biorisk Management Systems



**Eric Cook, MPH, CBSP**

Biosafety Officer, Global Chemical and Biological Security

Sandia National Laboratories

Albuquerque, NM



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# January Session Recap

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



65

participants attended the session

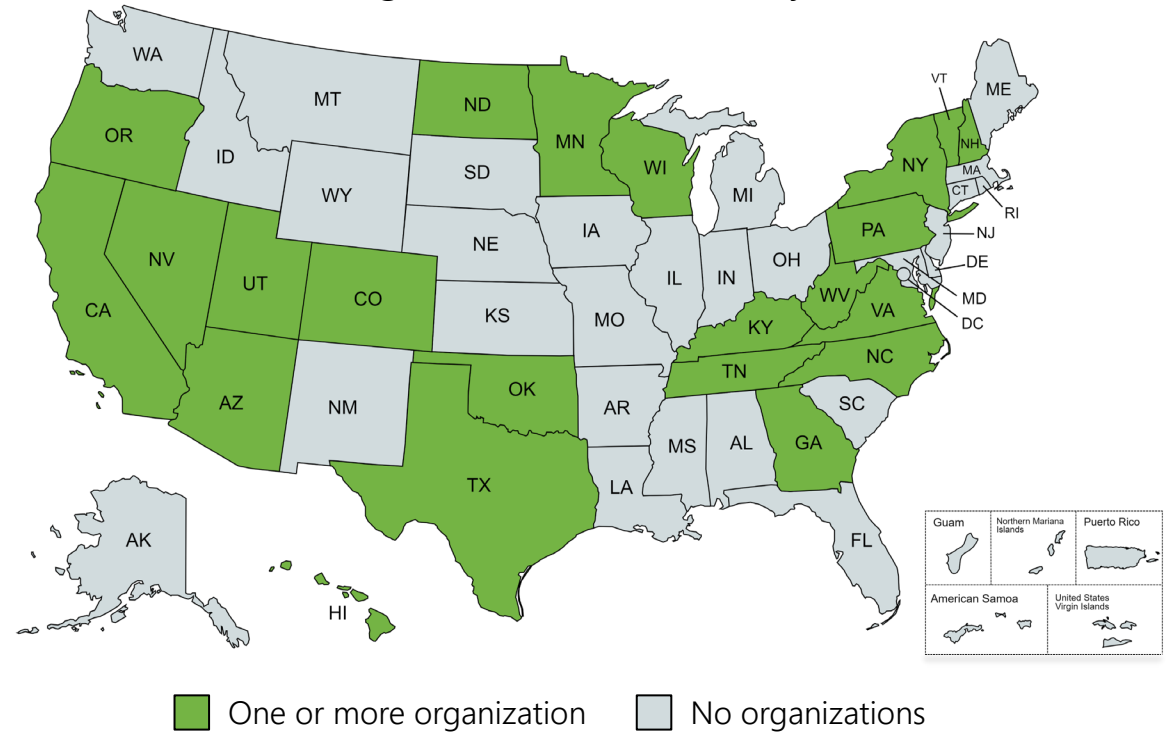


29

organizations were represented

“A biorisk plan helps keep people safe, especially when there is employee turnover. It also helps keep people from getting complacent with the organisms they work with daily. Having our laboratory scientists more involved in the safety process would be good.”  
-Session Participant

Organization Affiliation by State



Note: Attendees from at least one organization located in Belize and El Salvador were also present at the session.

# Agenda

- January Session Recap
- Speaker Introduction
- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders



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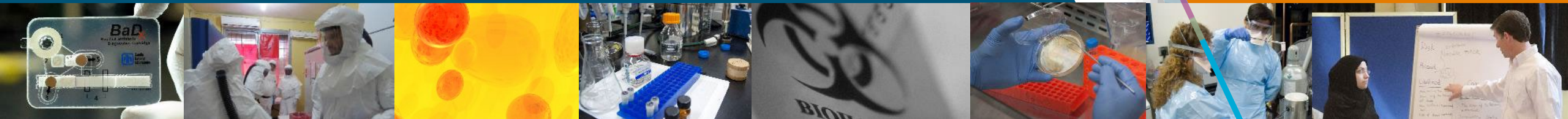
Albuquerque, NM



# A Simple Stepwise Implementation Process for BRM Systems Improvement

*Eric Cook, MPH, CBSP*

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## Objectives

- ❖ Apply the CWA and ISO Biorisk Management System Frameworks as a tool for systemic change
- ❖ Become familiar with resources and tools available for implementing a simple stepwise biorisk management system improvement process
- ❖ Introduce 4 simple steps for biorisk management system improvement process

# Agenda

- ❖ Review of BRM Systems – ISO 35001 and CWA 16393
- ❖ Cataract Hospital Scenario
- ❖ Step 1 – Prepare: Review standards and translate terminology
- ❖ Step 2 – Map: Assemble a diverse team with a variety of perspectives – map existing system structure to ISO
- ❖ Step 3 – Analyze: Identify opportunities to improve the existing system; brainstorm project ideas to match opportunities; prioritize project ideas – cost/benefit analysis
- ❖ Step 4 PDCA – Plan a project (Goals, Objectives, Roles, Responsibilities, and Performance Indicators [GORPPI]); implement the project; verify/check results; rinse and repeat

# Review of Biorisk Management Systems



## Key Messages

CWA 15793 and ISO 35001 are *BRM System Frameworks* designed to be compatible (not a replacement) with other ISO standards and international best practices.

These frameworks outline a process to **identify, assess, control**, and **monitor** the risks associated with hazardous biological materials. These documents are applicable to any laboratory or other organization that **works with, stores, transports**, and/or **disposes** of hazardous biological materials.

While not identical, ISO 35001 closely aligns with CWA 15793, which was used as a primary source document.

The two main principles that the both use are the Assessment, Mitigation, Performance (AMP) Model, and the Plan, Do, Check, Act (PDCA) Model.

## Management System

In the chat provide a few sentences that answer

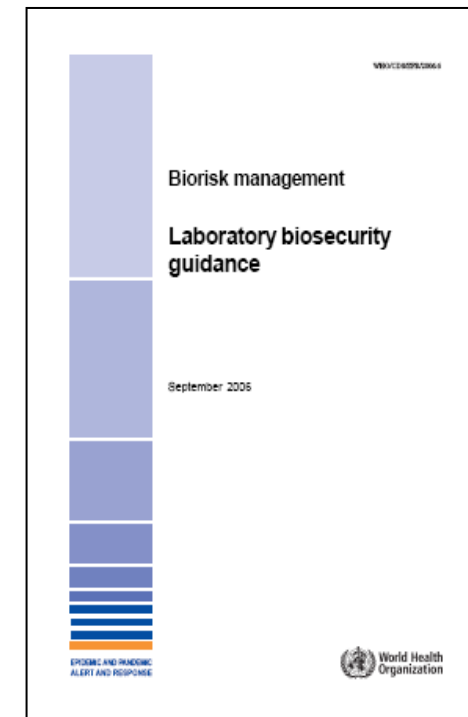
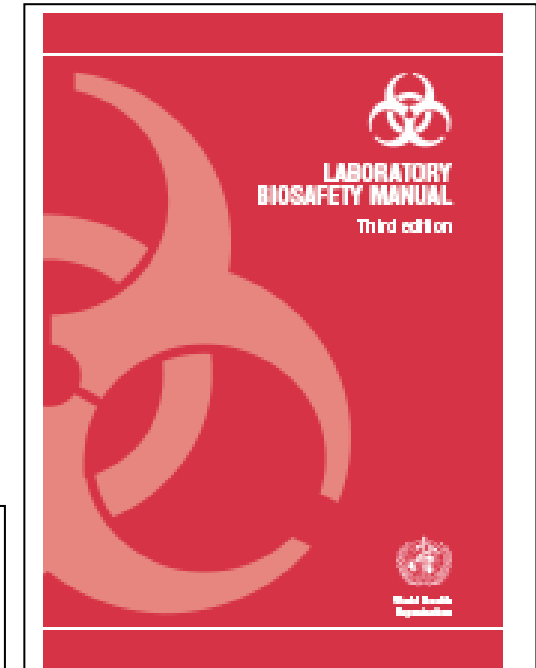
***What is a “management system”?***



# Definitions

**Laboratory biosafety:** containment principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release<sup>1</sup>

**Laboratory biosecurity:** protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or **intentional** release<sup>2</sup>



<sup>1</sup>Laboratory Biosafety Manual, Third edition (World Health Organization, 2004)

<sup>2</sup> Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

# What do we mean by Biorisks?

*Risks from working with biological materials*

**Biorisk = Biosafety + Biosecurity Risks**





# Laboratory Biorisk Management

CEN  
WORKSHOP  
AGREEMENT

CWA 15793  
February 2008

ICS 07.100.01

English version

Laboratory biorisk management standard

The 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.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN and neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

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Ref. No. CWA 15793:2008 CRP

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.

# CWA/ISO Biorisk Management Elements

No	Management Element
1	Institutional commitment to biorisk management; <b>policies</b> ; committees; documentation; scope of the BRM system
2	<b>Risk assessment program</b> , identifying, recording, analyzing biorisk
3	<b>Inspection/audit program</b> ; measurements of BRM system performance, goals and objectives for the BRM system, audits, inspections, continual improvement process.
4	<b>Training program</b> and competency assessments. Hazard and risk communication, communicating the policy, responsibilities, program elements.
5	<b>Occupational medicine program</b> , vaccination program, worker health monitoring and reporting
6	<b>Emergency response and incident tracking program</b> ; planning, Incident and accident tracking, response and planning, Identifying and tracking non-conformities
7	<b>Biosecurity program</b> , threat analysis, personnel reliability, access and authorization process. Inventory system, agent tracking, authorization and access process
8	<b>Infectious substance shipping and transport program</b>
9	<b>Biohazardous waste management program</b>
10	<b>PPE program</b>
11	<b>Good Laboratory Work Practices Program</b> ; SOPs; work planning; validation; Commissioning and decommissioning (both laboratory spaces and equipment)

# Cataract Hospital Case Study



**Scenario.** A public teaching hospital affiliated to the Cataract Ministry of Health conducts laboratory testing for SARS-CoV-2 in its Real-Time PCR Labs. They are receiving over a 1000 samples on a daily basis and producing large amounts of biological waste. This is much more than they normally work with. Prior to COVID-19, they typically worked fewer than 100 samples a day. The biosafety officer during her regular check to their labs noticed many issues related to biowaste management, she mentioned the following in her report.

**BSO Report.** *"Due to high workload, waste is overflowing. Bags and sharp containers are full most of the time, laboratory frequently runs out of appropriate supplies such as orange bags, marked containers, etc. Many bags and containers lack appropriate labels, but it is implicitly known as COVID-19 waste. There is one medium size autoclave inside the lab, but due to volume of waste they can only treat about half of the generated wastes before leaving the lab. There is limited facilities in the building for storing waste so the other half leaves without treatment. The autoclave was validated 2 years ago, and autoclave indicators (tape) are used when available to indicate treated waste and not treated waste. Custodians transport the COVID waste from the lab to a designated storage area in the back of the hospital (outdoors). From there the biological waste is stored for up to a week before being sent to the incinerator off-site for final treatment. The staff is not sure if they are following the right steps to handle generated biowaste, they said that they are using what is available; they are not aware of how they could be doing any differently, especially when working with uncommon agents (SARS-CoV2) or unprecedented work loads. Staff have not received any formal training on waste management."*

**Challenge.** The biosafety officer is seeking help to fix the situation since she is newly assigned to her position and does not have experience with biowaste management.

## Small Group Exercise - 10 Minutes

**Part 1:** Identify Biorisk Management System Problems (table)

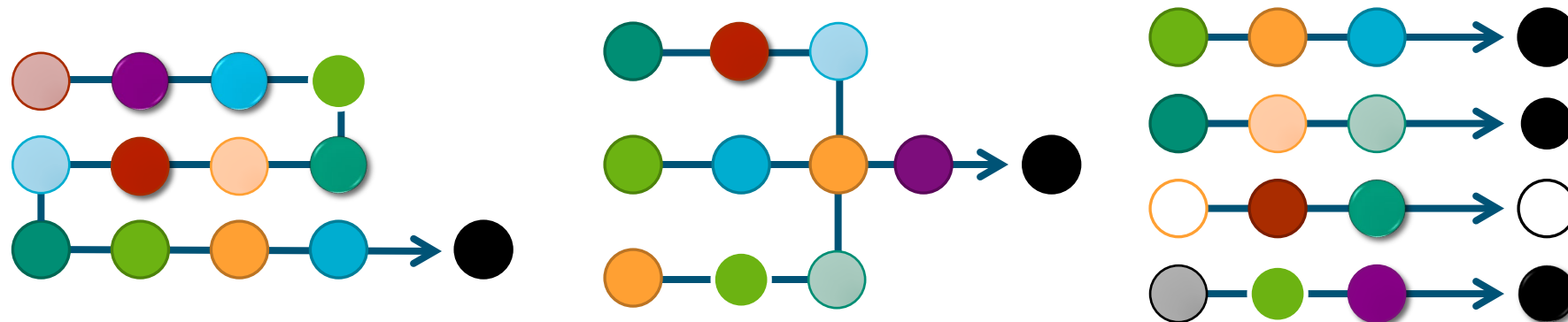
**Part 2:** Connect each problem to one of the eleven elements listed (or a specific section) of the CWA (table)

**Part 3:** Choose one problem from your list of problems and recommend specific changes in Biorisk Management that the leadership at Cataract Hospital can implement to address this problem (table).

# Implementation Pathway

There is no “ideal” route to successful CWA /ISO adoption or implementation

- Organization-specific process

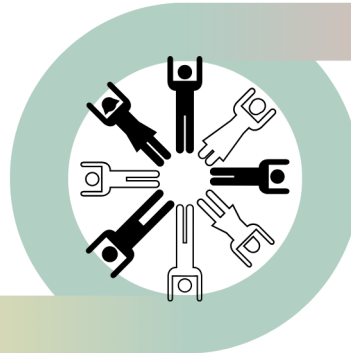


# 4 STEP PROCESS

Goals, Objectives, Roles, Responsibilities, and Performance Indicators (GORRPI)



- 1. Prepare**  
Review standards and translate terminology



- 2. Assemble a diverse team with a variety of perspectives**  
Map existing system structure to ISO

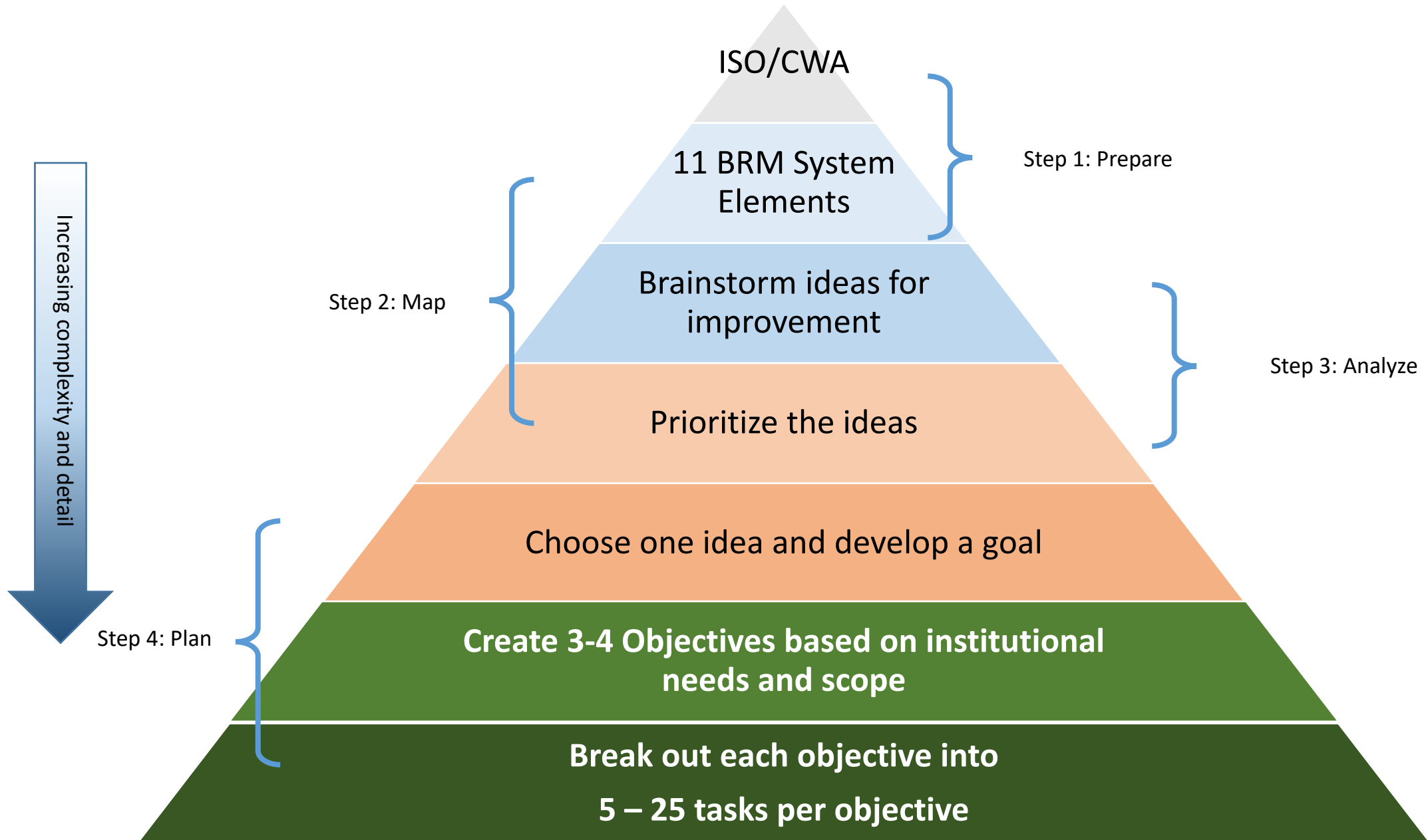


- 3. Analyze: Identify opportunities to improve the existing system;**  
Brainstorm project ideas to match opportunities; prioritize project ideas – cost/benefit analysis



- 4. PDCA**  
Plan a project (GORRPI); implement the project; verify/check results; rinse and repeat

# Stepwise Project Planning/Development Pyramid





# Case Study: National Animal Disease Diagnostic Laboratory

- ❖ Central disease diagnostic lab for the country
- ❖ 28 staff
- ❖ Animal disease outbreaks
- ❖ Import/Export
- ❖ Public health assurance through control of zoonotic diseases and food production from animal based products
- ❖ Virology and bacteriology
- ❖ Histology/pathology
- ❖ Vaccine efficacy testing
- ❖ Foodborne pathogen lab

## Step 1 – Prepare

Choose an appropriate standard(s) and translate the terminology into language used by your institution.



## Step I – Prepare

A. Identify a standard or system framework or target for your implementation project.

For example:

- ❖ ISO 35001
- ❖ CWA 16393
- ❖ Biosafety in Microbiological and Biomedical Laboratories
- ❖ WHO Laboratory Biosafety Manual
- ❖ Etc.

B. Translate the material into a mapping tool to compare existing systems with standard/framework requirements

For example:

- ❖ BRM system survey tool
- ❖ Sandia Question set
- ❖ Create your own

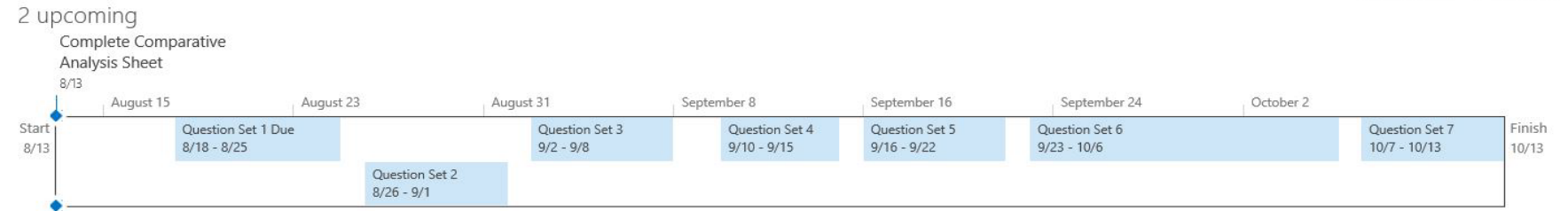
# Question Set and Project Timeline

Task	Duration	Deadline
✓ Kickoff Meeting		8/18/2020
✓ Analysis Question Set 1	1 week	8/25/2020
✓ Analysis Question Set 2	1 week	9/1/2020
✓ Analysis Question Set 3	1 week	9/8/2020
✓ Analysis Question Set 4	1 week	9/15/2020
✓ Analysis Question Set 5	1 week	9/22/2020
✓ <b>Analysis Question Set 6</b>	<b>2 weeks</b>	<b>10/6/2020</b>
✓ Analysis Question Set 7	1 week	10/13/2020
<input type="checkbox"/> Collating Recommendations & Document Cleanup	<b>1 week</b>	10/21/2020
<input type="checkbox"/> Finalize Confluence Document	1 week	10/28/2020
<input type="checkbox"/> Finalize Draft Report & Send out for Feedback	1 week	11/3/2020
<input type="checkbox"/> Receive Feedback of Draft Report	1 week	11/11/2020
<input type="checkbox"/> Finalize Report	1 week	11/19/2020

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## Project Summary

Question Set 7 due 3 days ago



- Create Project Timeline 8/13
- Create Section 4. Context of the organization 'Homework Assignment' 8/13

## Newsfeed

Start a conversation

- Huang, Foley  
Confluence Site: <https://snl-wiki.sandia.gov/pages/viewpage.action?pagelid=575183824>  
September 2 Like Reply Follow Huang, Foley ...
- Huang, Foley  
@**Jouravel, Natalie** you can do it this way if you want to reach certain folks.  
August 26 Like Reply Follow Huang, Foley ...

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- Comparative Analysis Sheet ...
- Question Sets ...
- Presentations ...
- 9. Performance evaluation ...
- 8. Operations ...
- 7. Support ...
- 6. Planning ...
- 5. Leadership ...
- 4. Context of the organization ...
- Standards ...

## Analysis Question Set 1

DUE: AM 8/25/2020

1. What are the policies that govern biorisk management at Sandia? (5.2)
  - ❖ Gather any documents or links or connections to biosafety/biosecurity specific policies. If no specific or separate biosafety/biosecurity policy then perhaps the policy is embedded in or describe in general EHS policies.
    - Policies
  - Evidence (supporting documents, links, connections, etc)
2. What are the boundaries, scope, applicability of the BRM system (may be part of the policy, part of the IBC charter, etc.)? (4.1, 4.2, 4.3)
  - ❖ Gather or note where this is documented.
    - Context/Boundaries/Scope
  - Interested Parties (external and internal)
  - Evidence (supporting documents, links, connections, etc)

## BIORISK MANAGEMENT SYSTEM SURVEY

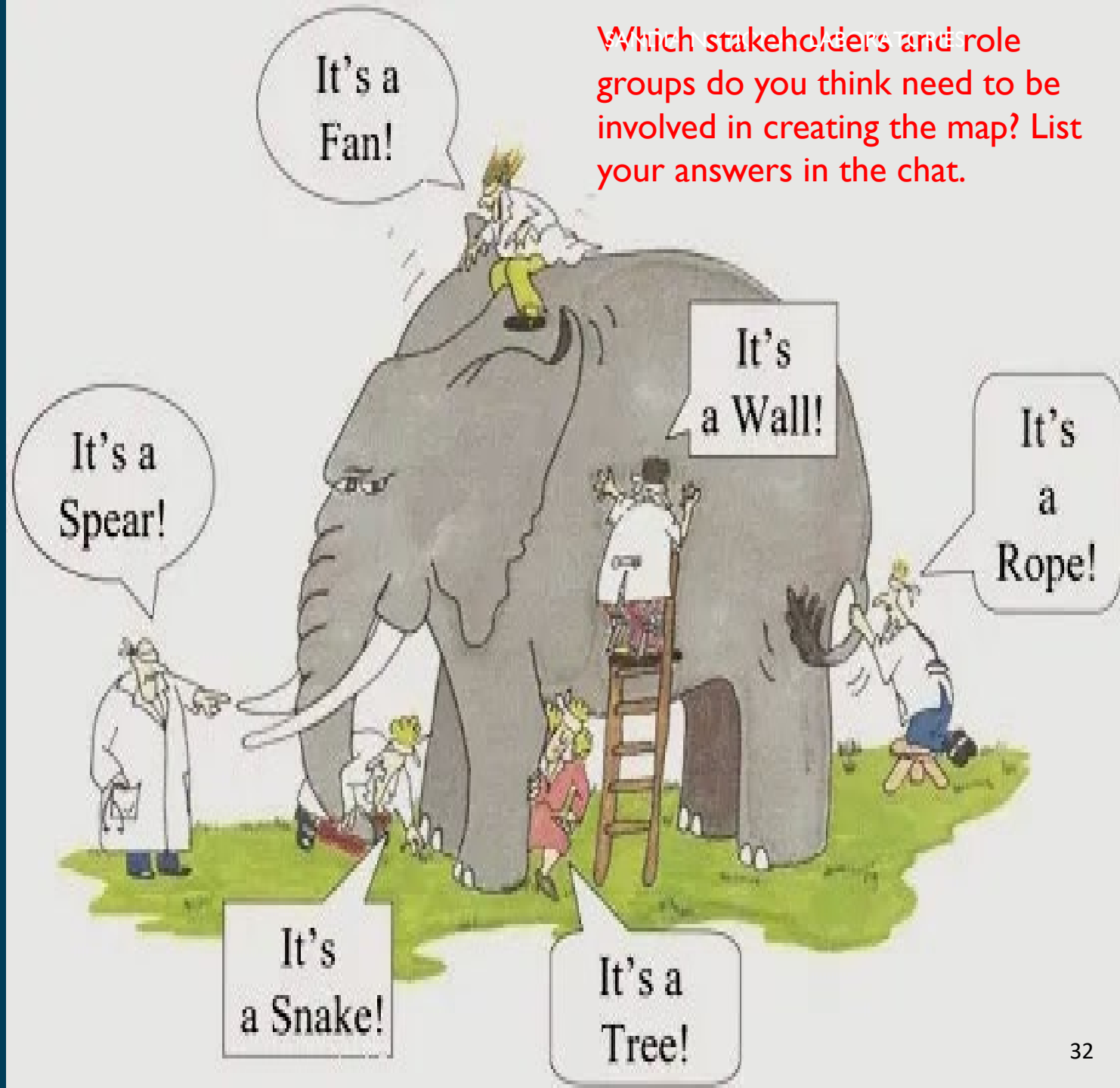
# Case Study: Using the BRM System Survey

Element	Question		
	1.1 Does your organization have a written/documentated statement or policy that outlines your organization's commitment, standards, and strategies to reduce the risk of <u>unintentional</u> release of, or exposure to, biological agents and/or toxins stored or handled at your institution?		51
	1.2 Does your organization have a written/documentated statement or policy that outlines your organization's commitment, standards, and strategies to reduce the risk of <u>intentional</u> release of, theft or misuse of biological agents and/or toxins stored or handled at your institution?		71
	1.3 Does your institution have established goals/objectives to improve safety? (e.g. is safety monitoring and improvement a part of work expectations)		71
	1.4 Does your institution have established goals/objectives to improve security? (e.g., is security monitoring and improvement a part of work expectations?)		44
	1.5 Does your organization have a document(s) that outlines the roles and responsibilities of members of your organization with regard to reducing the risk of <u>unintentional</u> release of, or exposure to, biological agents and/or toxins stored or handled at your institution?		64
	1.6 Does your organization have a document(s) that outlines the roles and responsibilities of members of your organization with regard to reducing the risk of <u>intentional</u> release of, theft or misuse of biological agents and/or toxins stored or handled at your institution?		64
	1.7 Has your supervisor provided you information on your specific roles and responsibilities regarding reducing the risk of <u>unintentional</u> release of, or exposure to, biological agents and/or toxins stored or handled in your work?		50
	1.8 Has your supervisor provided you information on your specific roles and responsibilities regarding reducing the risk of intentional release of, theft or misuse of biological agents and/or toxins stored or handled in your work?		50
	1.9 Does your organization have a person(s) or department(s) specifically trained in safety (of any kind - not just bio) such as a health and safety office or department, or a biosafety officer or biorisk management advisor?		63
	1.10 Does your organization have a person(s) or department(s) specifically trained in security (of any kind - not just bio) such as a security department, or a security guard/officer?		16

*Element 1:  
Institutional  
commitment to  
biorisk  
management*

## Step 2 – Map:

- A. Assemble a diverse team with a variety of perspectives – map existing system structure to chosen standards
- B. Gather information from different perspectives on the existing system using the ISO/CWA as a framework





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Existing projects: iterations of BSO triage then approve or else send to IBC for further review as described above.

### How are hazards identified, documented, mitigated/addressed, and effectiveness of controls? (6.1.1.) COMPLETE

#### Hazard Identifications and Documentation (6.1.2)

I have excluded the rest of the WPC process in my answers here, e.g. no mention of PHS, NEPA, etc.

IBC PR identifies and documents the hazards, personnel, rooms and SOPs by name, BRM system is applied to mitigate/control hazards, BSL containment, PPE, medical surveillance, biowaste and trainings are detailed.

Industrial Hygiene exposure assessment (IH EA) is not done per bio-activity or per bio-project, but done per L1s request for the room, it generally calls out biological hazards for the space but as a general class or type, e.g. risk groups 2 biological agents, cell lines.

Space walkthrough to ensure that the room(s) in question meets facility requirements; they don't expire; updated ad hoc (when risk changes). Risk changes are "never bio" to BSL1 or 2, BSL1 to BSL2, BSL2 to BSL1, BSL1 or 2 to "no more bio".

- using different checklist in CA and NM

#### Hazard mitigation (6.1.3)

IBC Project registration form, IH EAs in NM, relevant SOPs, WPC and TWDs.

#### Evaluations of effectiveness of controls (6.1.4)

BSOs, Line, and IBC voting. Occurrences and QA elements.

SMEs and IBC through human interaction, documented in IBC Project Registration form.

Management Surveillance performed annually

Industrial Hygiene exposure assessment (IH EA)

Group/User Meetings

IBC annual renewal/review of IBC projects (**3 year review in NM**)

**Recommendation: Biosafety focused inspection (annually)? Integrate current processes into biosafety/risk; develop a single biosafety checklist resource surveillance; evaluation of different site checklists**

Documents of Interest:

Space tools

ISO/CWA Elements/References	Current Practices	Local regulations requirements	Differences or gaps	Recommendations
Roles and responsibilities				
Written policies				
Waste management system/practices				
PPE policies and practices				
Etc.				

Priority	Difficulty	Impact	Recommendations	Related ISO 35001.2019 Clauses
<b>High</b>	<b>Policy and Leadership Considerations</b>			
Low	Hard	Low	If ISO35001:2019 Certification is long term goal for our lab, evaluate if a <u>separate Biorisk management policies</u> should be developed and inserted into existing Institutional policies OR developed as standalone policy.	4.3. Determining the scope of the <u> biorisk management system</u>
High	Hard	High	Review <u> biorisk management policy</u> and scope outlined in the Biological Hazards Chapter of the ES&H Manual, the IBC Charter, and the Biosafety Manual is consistent.	4.3. Determining the scope of the <u> biorisk management system</u> ; 5.2. Policy
High	Hard	High	Review and update the Biological Hazards chapter of the ES&H Manual for accuracy and changes by BSOs.	4.4. <u> Biorisk management system</u>
High	Easy	Low	Add annual IBC review cycle in IBC charter, Biosafety Manual, and Biological Hazards chapter of the ES&H Manual.	4.4. <u> Biorisk management system</u>
High	Hard	High	Update the roles/responsibilities in the IBC Charter, Biosafety Manual, and Biological Hazards chapter of the ES&H Manual for consistency and verify terminology usage throughout all documents. Map ISO terms to institutional policy terms in roles and responsibility section of Biosafety Manual and IBC Charter (organizational chart) to be consistent with ISO standard terminology.	5.3. Roles, responsibilities, and authorities
<b>Moderate</b>	<b>Planning</b>			
High	Easy	High	Update and refine the language to defines projects that the BSOs are empowered to approve on behalf of the IBC and which projects IBC is required to review in the IBC OP, IBC Charter, and Biosafety Manual.	6.1.1. Hazard and/or threat identification and analysis
Moderate	Hard	High	Integrate current processes into biosafety/risk; develop a single biosafety checklist resource for management surveillance and evaluate different site checklists for best practice.	6.1.4. Performance evaluation
Low	Easy	Low	Evaluate if industrial hygiene (IH) exposure assessment process is aligned with biosafety assessment. If processes are not aligned, update IH exposure assessment process to align with <u> biorisk requirements</u> .	6.1.4. Performance evaluation

## Case Study – Step 2 Mapping Results

## Step 3 – Analyze Results:

- A. Identify opportunities to improve the existing system;
- B. Brainstorm project ideas to match opportunities;
- C. Prioritize project ideas – cost/benefit analysis



## Step 3 – Analyze

### A. Identify areas, systems, elements, topics to improve.

- II System Elements
- Sections of the CWA/ISO

### B. For each system or element identified above, brainstorm project ideas that could be implemented to improve existing system

- See list of existing ideas

### C. Risk/Cost/benefit analysis of each idea to create a priority list.

- Cost = effort, resources, needs, etc
- Benefit = Impact of the project on reducing biorisk
- Risk = what if we don't change? What if we do change?

# ISO 35001 – Evaluation/Implementation

How to evaluate your systems against the ISO standard?  
How would you eat a dinosaur?



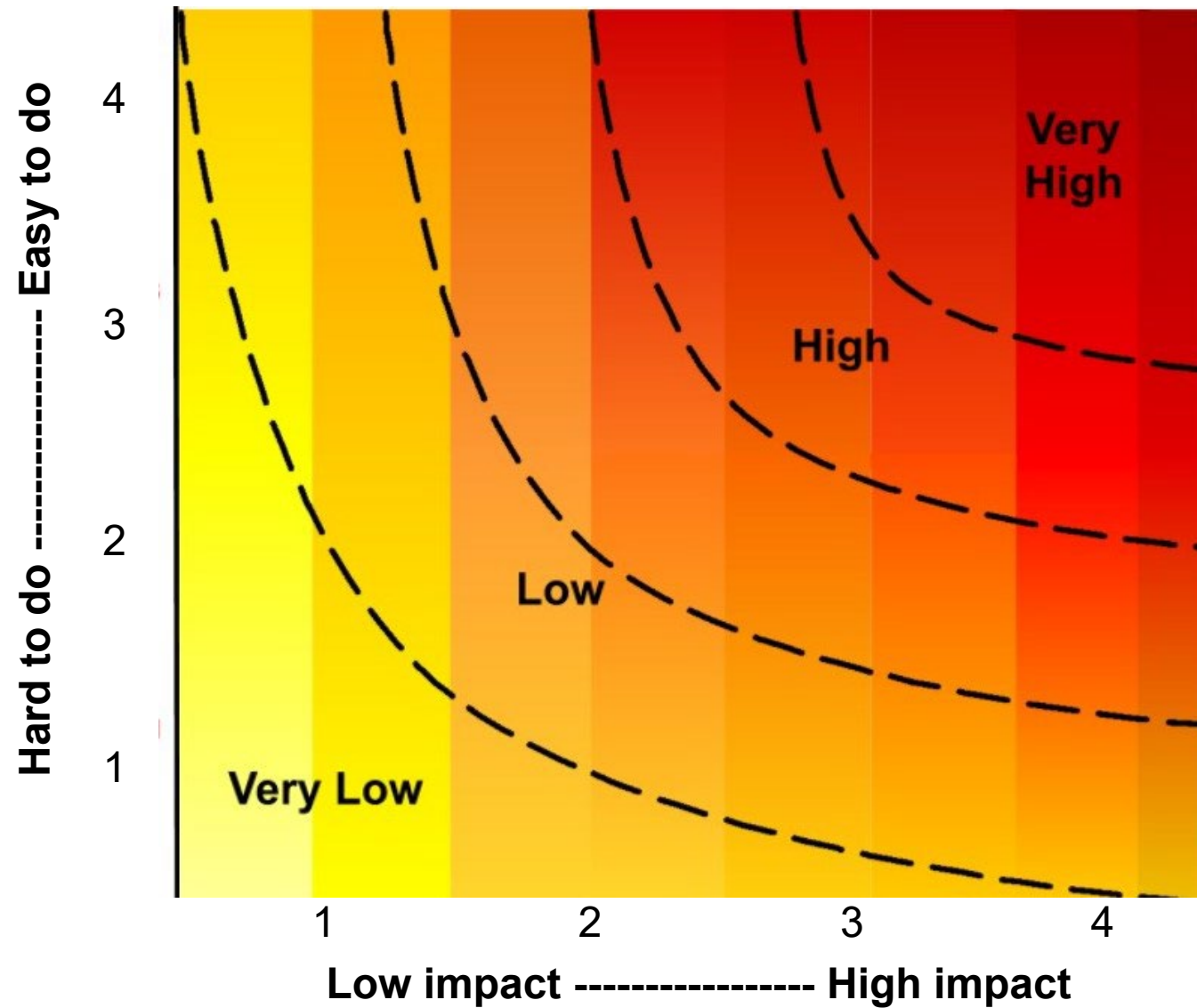
# ISO 35001 – Evaluation/Implementation

How to evaluate your systems against ISO35001?  
One bite at a time





## A simple method to determine priorities



# A simple method to determine priorities

<b>Ease</b>	<b>Measured by: The number of people it will take, the amount of time, the amount of resources, amount of effort</b>
4 (very easy)	One person job; few resources needed; little time (days) and effort; single input (one time only) does not need continuous effort/input
3	One or two person job; some resources needed; more time (weeks) and effort; may require occasional inputs to maintain
2	Several people will need to put significant time into this project; a lot of resources needed; months of effort; may require sustained or continuous input from a single person to maintain
1 (very hard)	Will involve teams of people or organization wide effort; will require extensive resources or difficult to obtain supplies and will need commitment/dedication to achieve; months or years of effort; may require sustained or continuous input from a multiple people to maintain

# A simple method to determine priorities

<b>Impact</b>	<b>Measured by: The number of people it will affect, the amount or degree of safety/security improvement</b>
1 <small>(little impact)</small>	Will only impact one person or one room/space. Implementation will result in a small increase in safety or security.
2	Will impact several people, or a small department/ team or section. Several rooms/spaces. Will have a moderate increase to safety/security
3	Will impact a large department, many people, a whole building. Will have a significant impact to safety or security.
4 <small>(great impact)</small>	Will impact the entire organization and the community around the organization. Will have a major impact on reducing safety/security risks.

New waste  
management program

4, 1

Create an Institution  
Biorisk Management  
Committee

3, 3

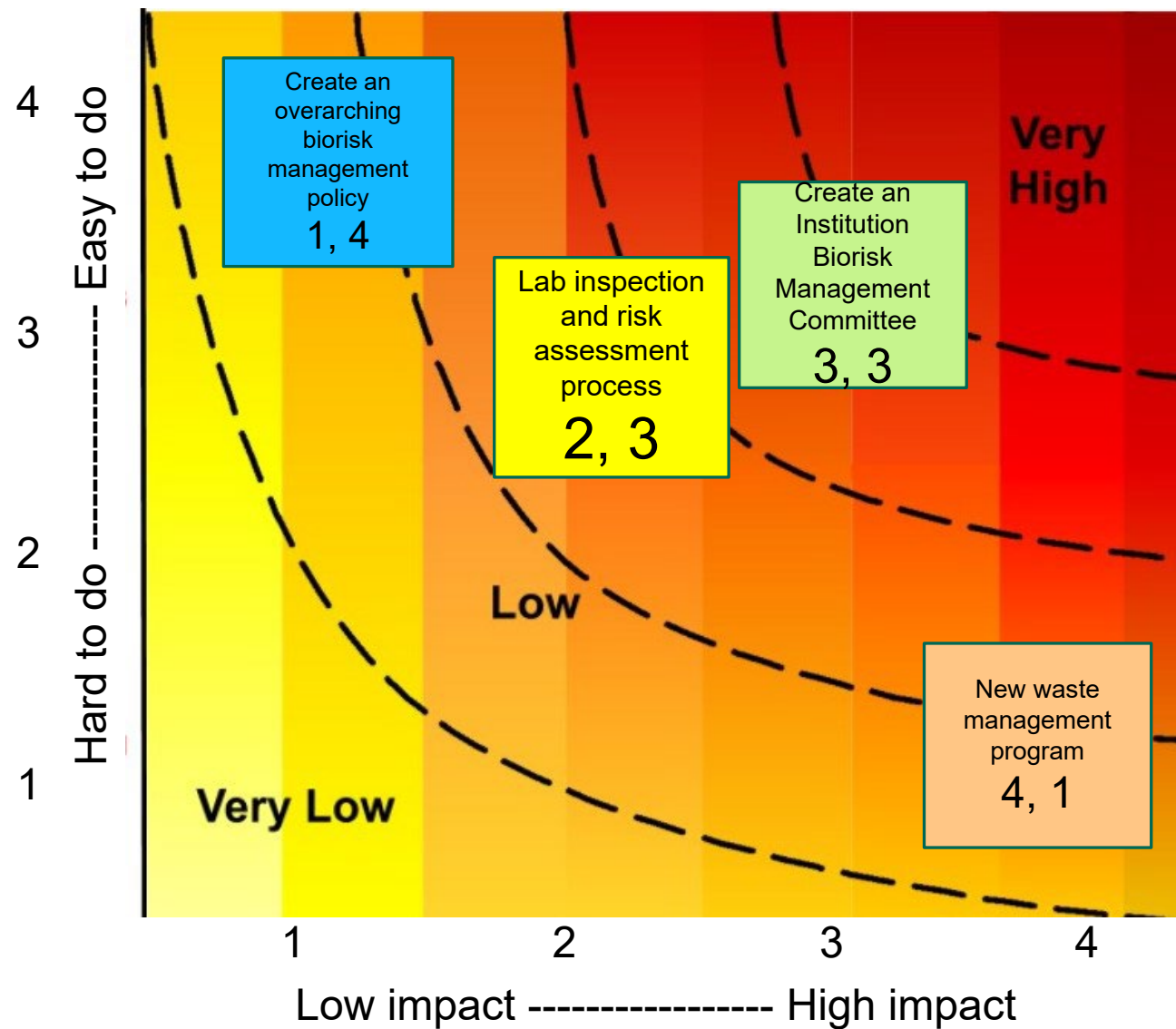
Lab inspection and  
risk assessment  
process

2, 3

Create an overarching  
biorisk management  
policy

1, 4

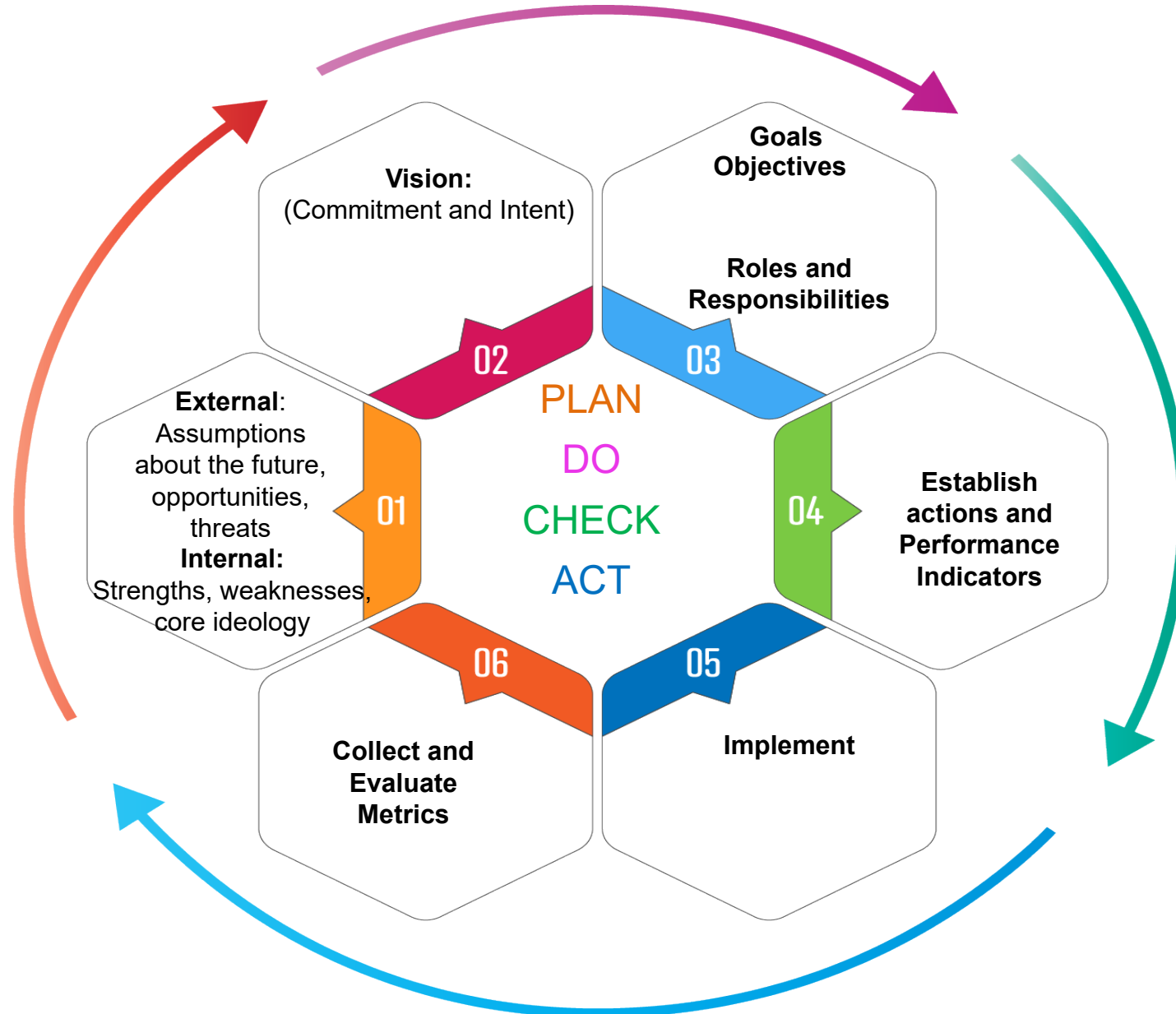
# A simple method to determine priorities



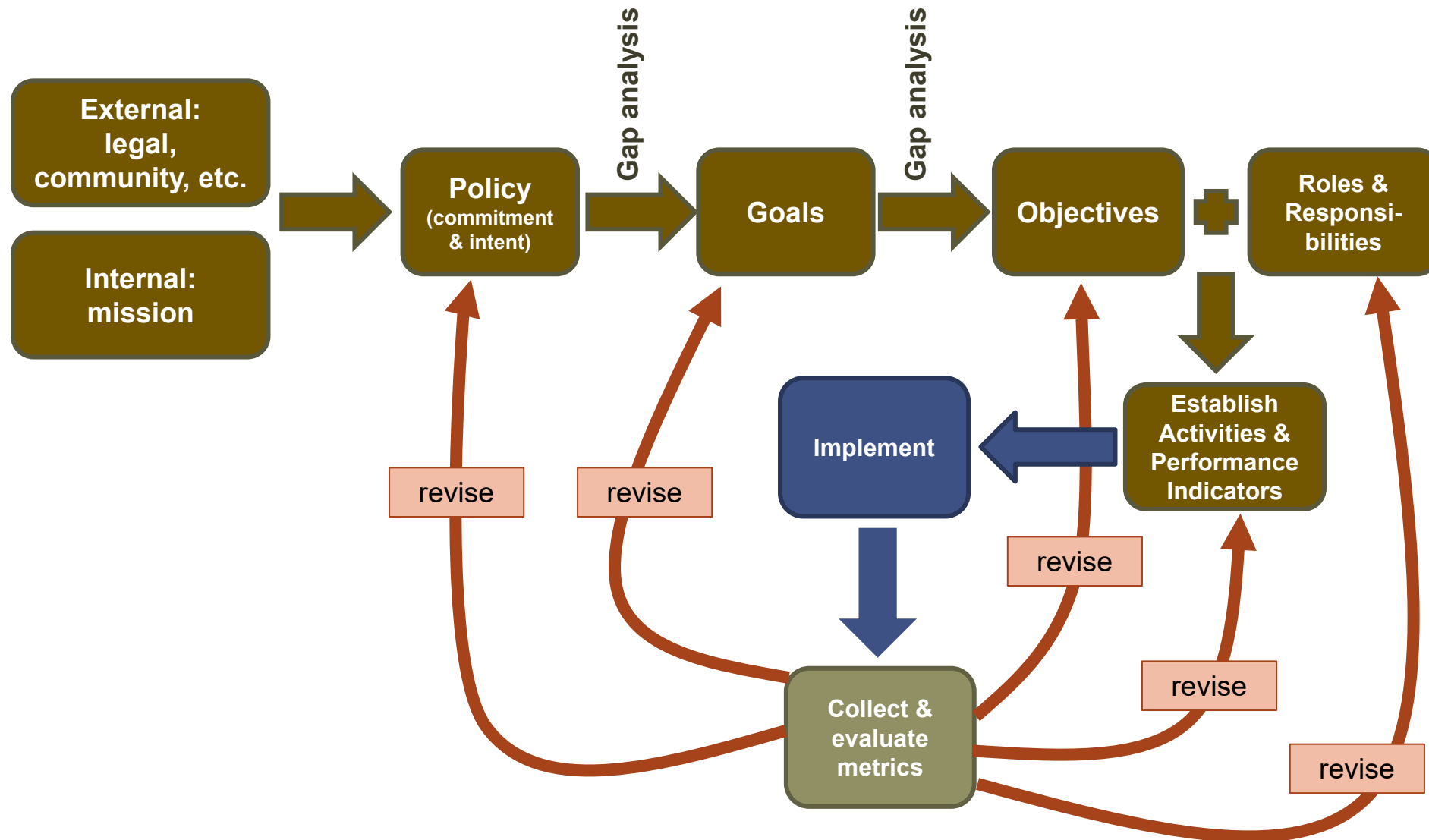
## Step 4 – Plan and implement a project:

- A. Choose an idea;
  - B. Plan the project (GORRPI);
  - C. Implement the project
- A. Validate the results; rinse and repeat



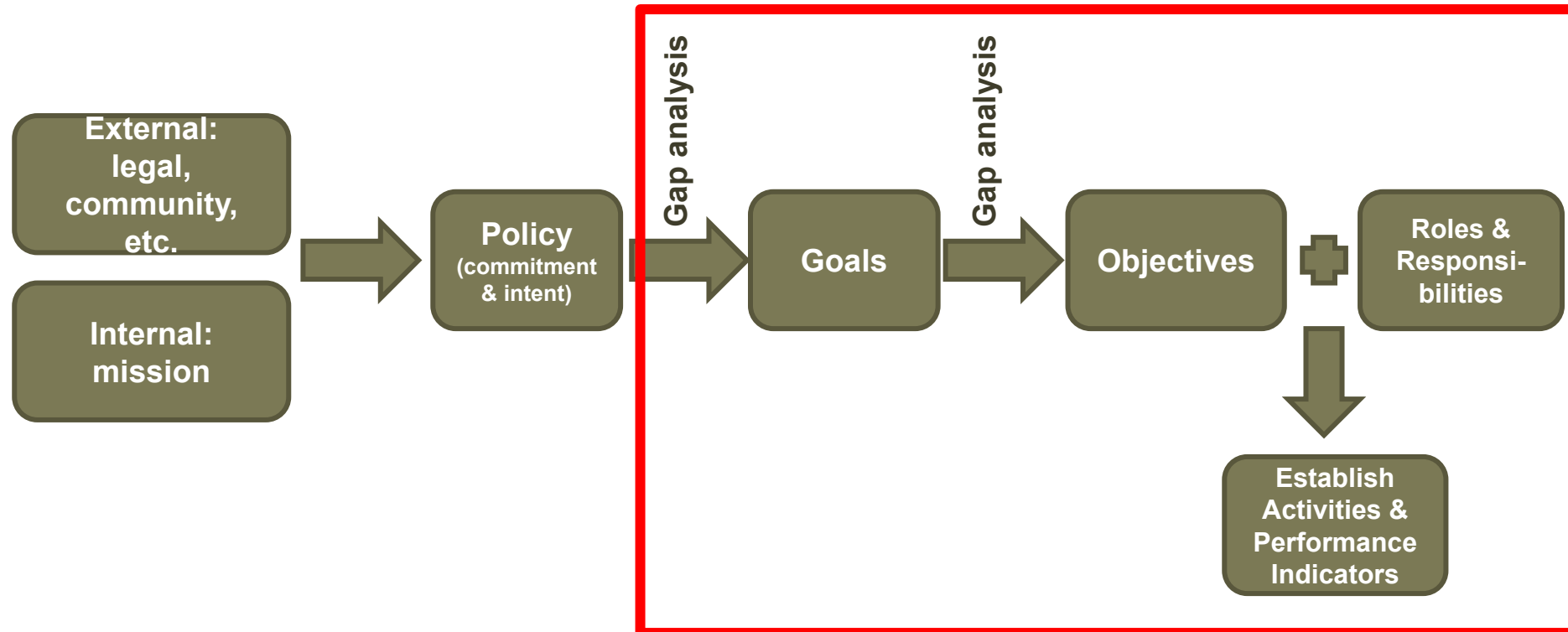


# Plan-Do-Check-Act

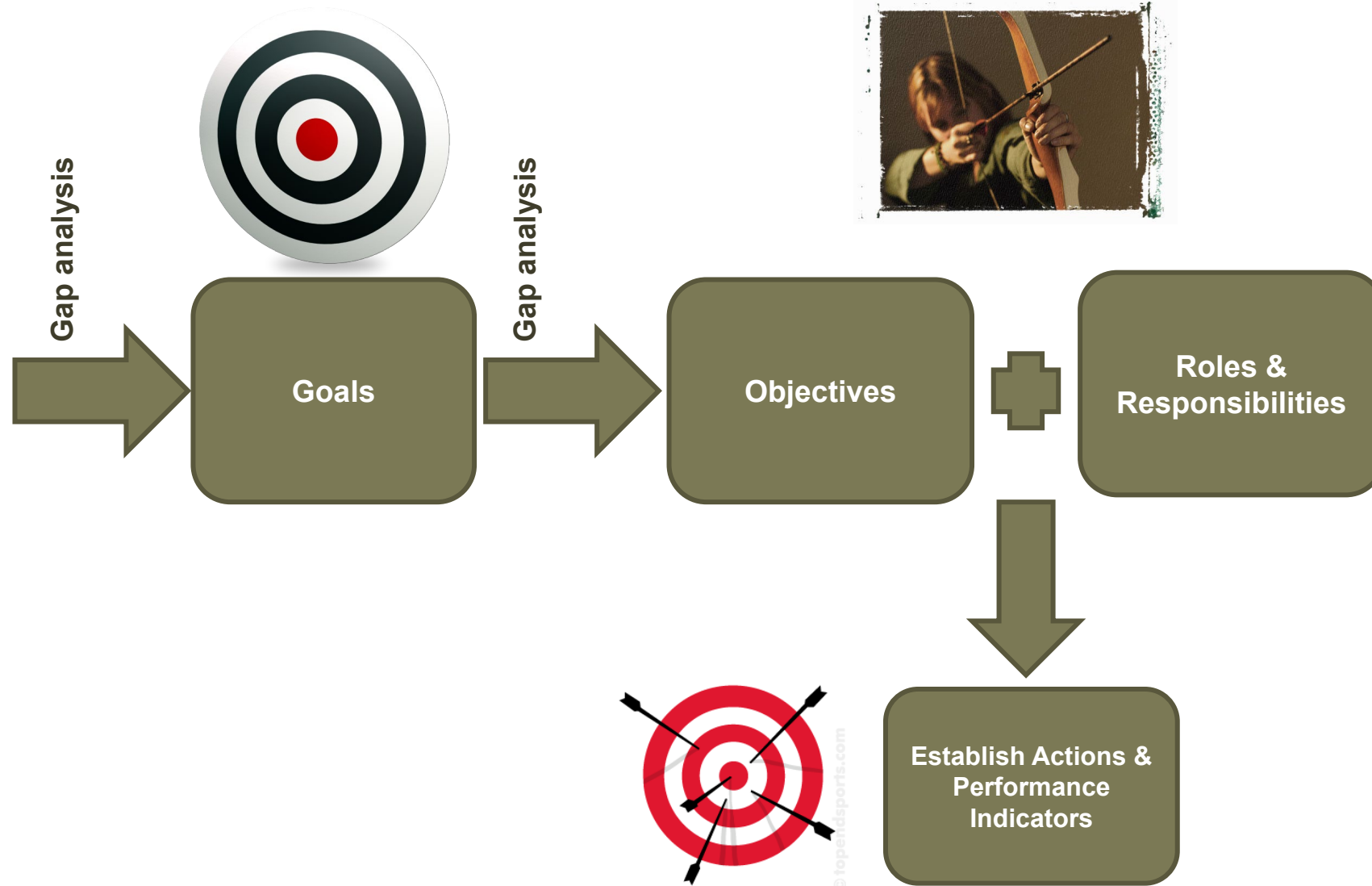




# Plan



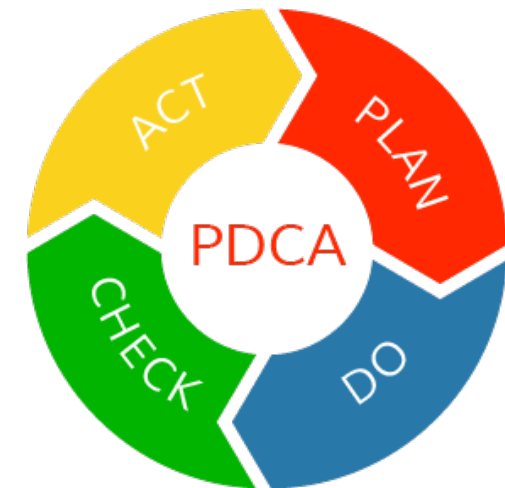
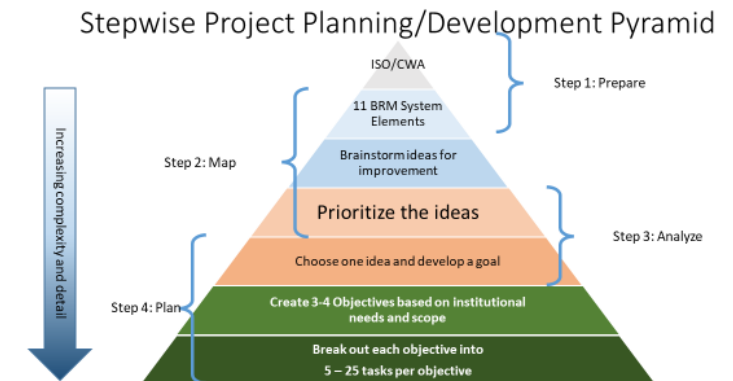
# Goals, Objectives, Roles, Responsibilities, and Performance Indicators (GORRPI)



# Case Study – Final Project Plan

## Four Step process summary

- ❖ Step 1 – Prepare: Choose a standard, choose a tool or create your own
- ❖ Step 2 – Map: (Gap analysis). Use the tool, gather a variety of perspectives.
- ❖ Step 3 – Analyze: Don't find gaps, find opportunities to improve brainstorm ideas for projects to match the opportunities; priority – cost/benefit analysis
- ❖ Step 4 – Take one bite at a time: PDCA - Plan a project (GORRPI); implement the project; verify/check results; rinse and repeat



# Q&A



# DLS ECHO Biosafety Session: March 26, 2024

## Leadership: Roles, Responsibilities, and Authorities



**Joseph P. Kozlovac, MS, RBP, CBSP, SM(NRCM)**

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