

DLS ECHO Biosafety Session: March 26, 2024

Leadership: Roles, Responsibilities, and Authorities



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February Session Recap:

“A Stepwise Process to Improve Biorisk Management Systems”



96
participants
attended the
session

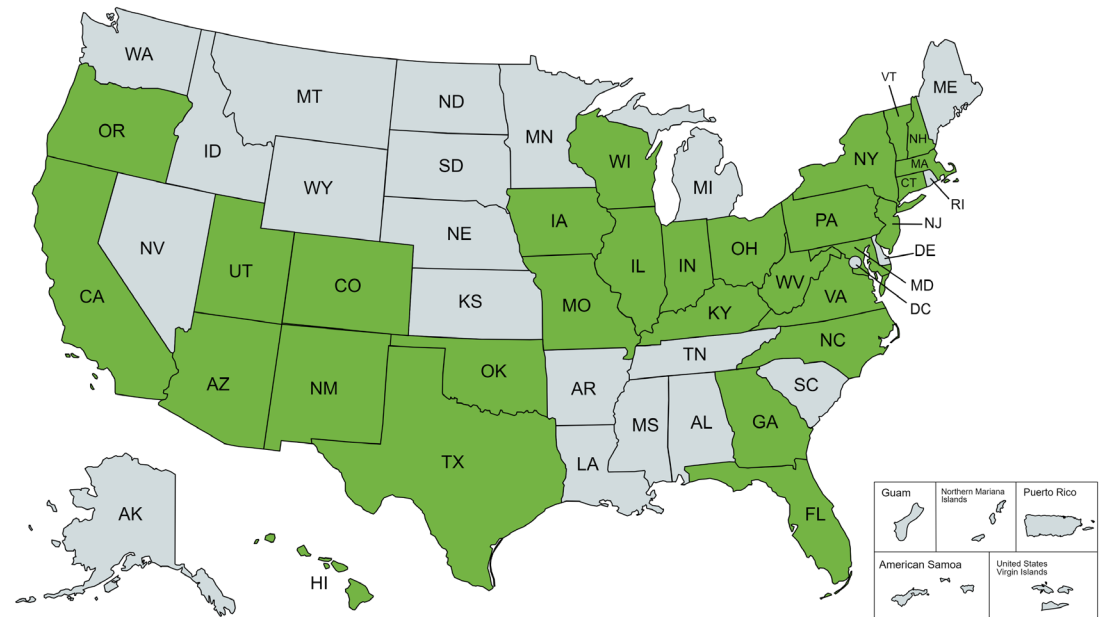


62
organizations
were
represented

Who should be involved in the biorisk management process?

- Facilities & engineers
- Principal investigators
- Responsible officials
- Technical supervisors
- Security managers
- Protocol committee chairs

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, Canada, El Salvador, and Italy were also present at the session. Five national organizations also attended this session.

Agenda

- February ECHO Biosafety Session Recap
- Speaker Introduction
- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders



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Biorisk Leadership

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Disclaimer

The views reflected in this presentation are solely my own personal views and do not necessarily reflect the views of ARS, the Department of Agriculture, or the United States Government.

Life Sciences Call to Leadership

“We need to develop leadership that represents and integrates technical and social expertise. Leaders must instill safety and security as core missions driving the work of scientific and political institutions. By supporting work to identify and mitigate risks, acknowledging failure and uncertainties, and facilitating participation of diverse experts, they can empower organizations to respond to new challenges.”

Palmer, Fukuyama and Relman

A more systematic approach to biological risk

12/15/2015, Science: Vol 350 Issue 6267

<https://www.science.org/doi/10.1126/science.aad8849>

Applicable to Biorisk Profession!

ISO 35001

- Top Management – Essentially those that direct or control an organization...The C-suite
- Senior Management – Those with operational budgetary, HR responsibility and authority necessary for the safe and secure operation of the facility or facilities. ...Department/middle management
- Scientific Management – Responsible for the scientific program on day-to-day basis and will implement and monitor adherence to the BRM program....PI, lab managers, etc

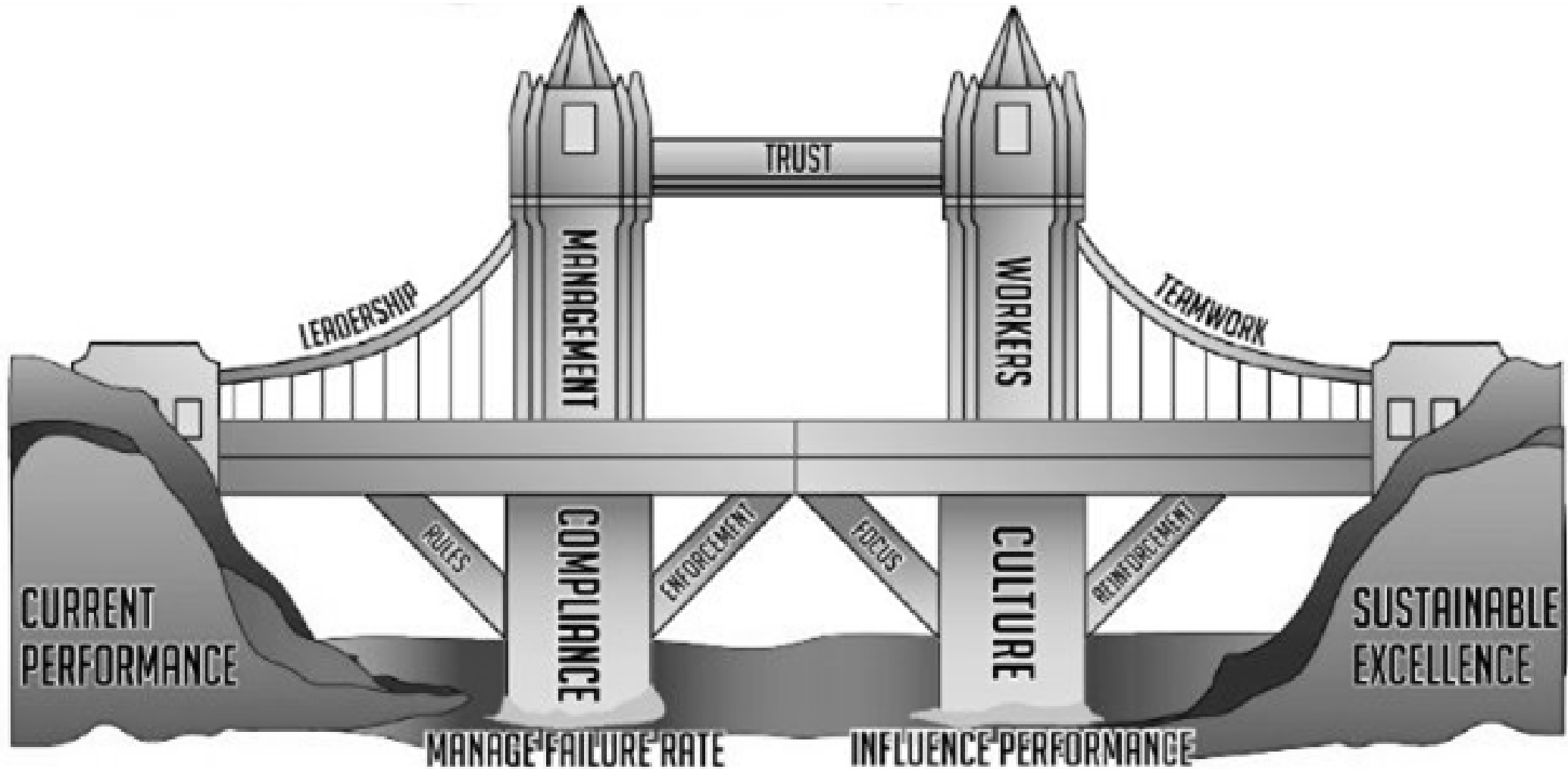
Biosafety Management Program Elements



Continual Improvement and PDCA



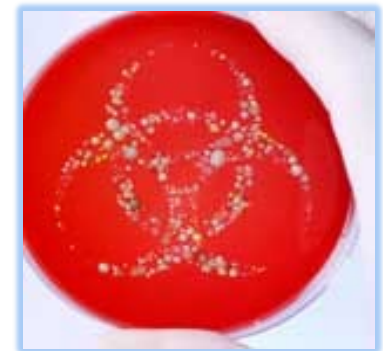
Compliance Vs. Culture



Mathis and Galloway, STEPS to Safety Culture Excellence,
Wiley and Sons, 2013

What is Culture

- ❖ Culture is the unwritten rules or the taken-for-granted values, underlying assumptions, expectations, collective memories, and definitions present in an organization.
- ❖ A culture of safety can be defined as the collective values, beliefs, attitudes and norms that shape individual safety-related behaviors in an organization.
- ❖ Safety Legend Dan Petersen once recounted talking to an employee, “That’s just how we do things around here.”
- ❖ Culture eats strategy for breakfast



What is Your Organizations Culture?

Take a couple of minutes and think about your organization and its culture (and answer the below questions on a piece of paper).

- ❖ Please share one or two things you like about your workplace culture, and one or two thing you would most like to change.
- ❖ If you wanted to improve your safety culture what would be the #1 thing you would focus on? What would you do?
- ❖ Is safety, biosafety and biosecurity an integral part of all operations? What are some of the other core values?
- ❖ Are all employees expected and encouraged to identify and report issues, hazards and accidents and take appropriate action?
- ❖ Is there clear accountability at all levels for following safety rules? Are safety elements included in everyone's performance plan?

Development of A Strategic Plan for Improving your Laboratory Biorisk Management Program

Plan Goals:

- ❖ Begin with the desired end in mind
- ❖ Align all biosafety, biocontainment, biosecurity and safety activities around the overarching biorisk management strategy
- ❖ Include appreciative words/language such as **excellence** in the safety/biosafety vocabulary of the plan...Words Matter
- ❖ The plan should be designed to serve as the institutional compass providing clear and consistent direction toward success



Vision Statement



*The **Biosafety Program** motivates all researchers to work safely and responsibly through knowledge of biological safety tenets and strength in communication*

- ⚠️ **A vision is a mental image of the possible and desirable future state of the organization.**
- ⚠️ **For a vision to have any impact on the employees of an organization, it has to be conveyed in a dramatic and enduring way**
- ⚠️ **A mission statement is an organization's vision translated into written form. It should be a short and concise statement of goals and priorities.**
- ⚠️ **Is clear enough to provide guidance in decision making but general enough to allow individual initiative and adapt to changing conditions**
- ⚠️ **Communicate your vision constantly linking current events to your vision and the relationship between the two.**

Mission Statement



A mission statement should be a short and concise statement of goals and priorities

The purpose of the Biorisk Management Program is to prevent or minimize employee exposures or the accidental environmental release of hazardous biological agents through the promotion of safe laboratory practices, procedures and proper use of containment equipment and facilities by employees, students, visitors and contractors.

Goals of a Biosafety Program

- ☠ Prevent employees and their families from acquiring laboratory-associated infectious diseases**
- ☠ Prevent contamination of the environment and promote environmental quality**
- ☠ Comply with all applicable National, International and Local guidelines and regulations for the use of biohazardous materials**
- ☠ Conform to prudent biosafety practices**
- ☠ Expand the research community's awareness of the importance of biological safety in the conduct of good science through effective communication**

Biorisk Policy

- ❖ Clearly state the direction and intent of the organization's top management
 - State the commitment to implement, maintain and improve upon the BRM System.
- ❖ Appropriate to the Nature and scope of the biorisks at the organization.
- ❖ Define roles and responsibilities at all levels of the organization
- ❖ identify a chain of responsibility for information on biorisk related issues:
 - Risk assessment and risk management processes
 - Establish objectives and establish metrics to assess success
 - Compliance strategy for relevant legal requirements applicable to the biological material stored or manipulated within the organization/facility
 - Define procedures for the conduct and documentation of inspections, audits and corrective actions
 - Define requirements and procedures for reporting incidents, accidents, non-conformance as well as investigating and development of corrective actions
 - Shipping, receiving and inventory processes
 - Risk communication and training
 - Requirements for biosafety, biocontainment and biosecurity plans
 - Document control

Biosafety Policy Advice

- ❗ Start with the end in mind.
- ❗ Your written policy is just another means of communicating “The Policy”
- ❗ The real policy is management and your attitude toward employee’s safety.
- ❗ What management and you do or fail to do, speaks louder than what is written.
- ❗ A safety culture is created by what we and other managers demonstrate personally and what we reward and tolerate in others.



*In this case –
little brother is watching!*

Policy Statement Example

It is the policy of this Institute to provide a safe and healthful work environment to all of its employees, to be a responsible steward of the environment and a good neighbor to the citizens of the communities in which our facilities are located. To this end, a biorisk management program has been established with the following objectives to:

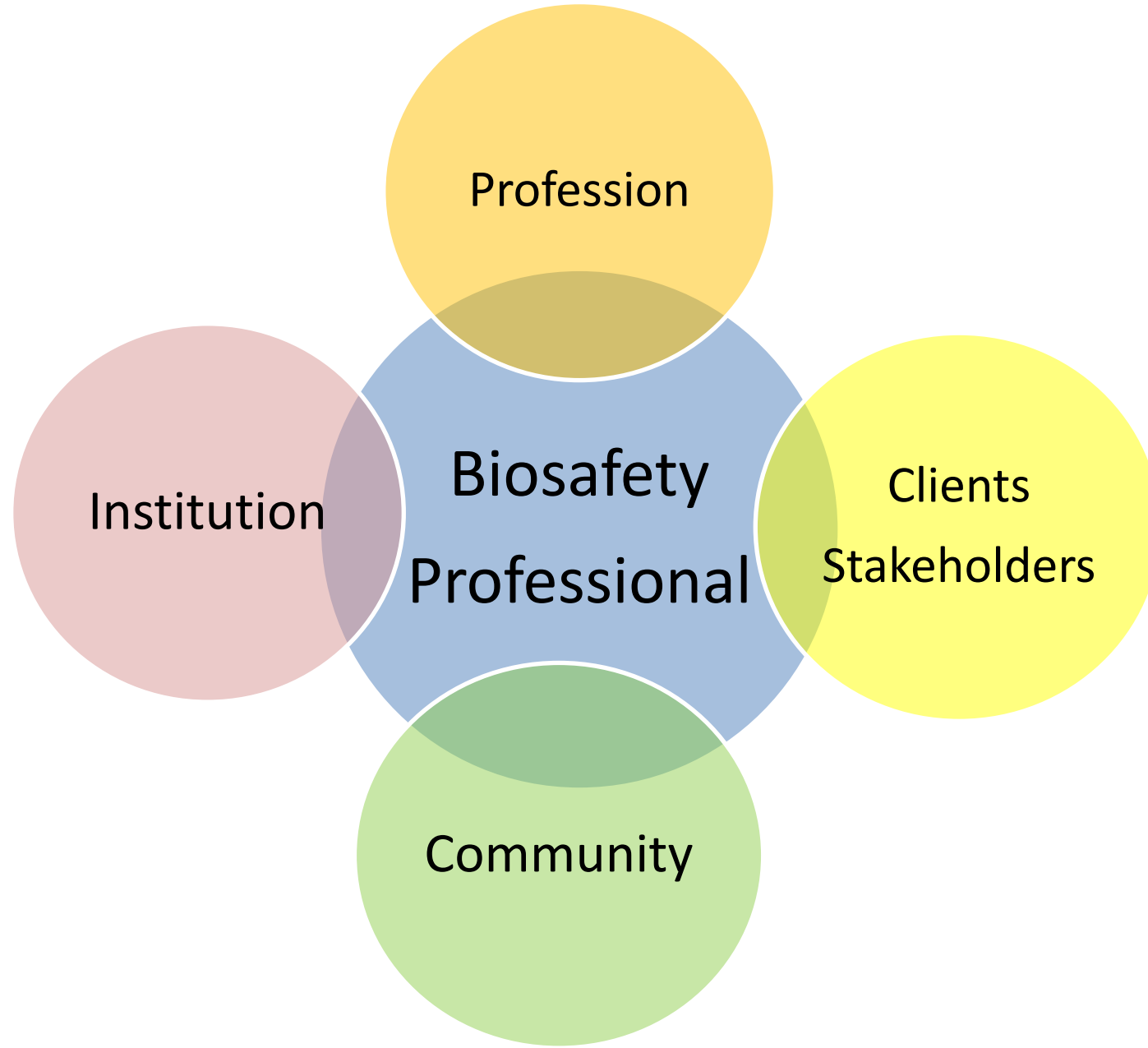
- ☣ Identify, evaluate, control and prevent biological hazards.
- ☣ Minimize and prevent the occurrence of accidents and illnesses from biological agents used in research.
- ☣ Meet or exceed the requirements of Federal, State and local regulations affecting biological and laboratory safety.

Management's Responsibility For Compliance

- Ensuring staff are prepared (everyday)
- Ensuring facility is prepared (everyday)
- Highlight these aspects in routine communications
- Have a procedure (SOP) in place regarding regulatory inspections and ensure staff are well aware of their roles and responsibilities.
- Rehearsal / dry run (preparation)

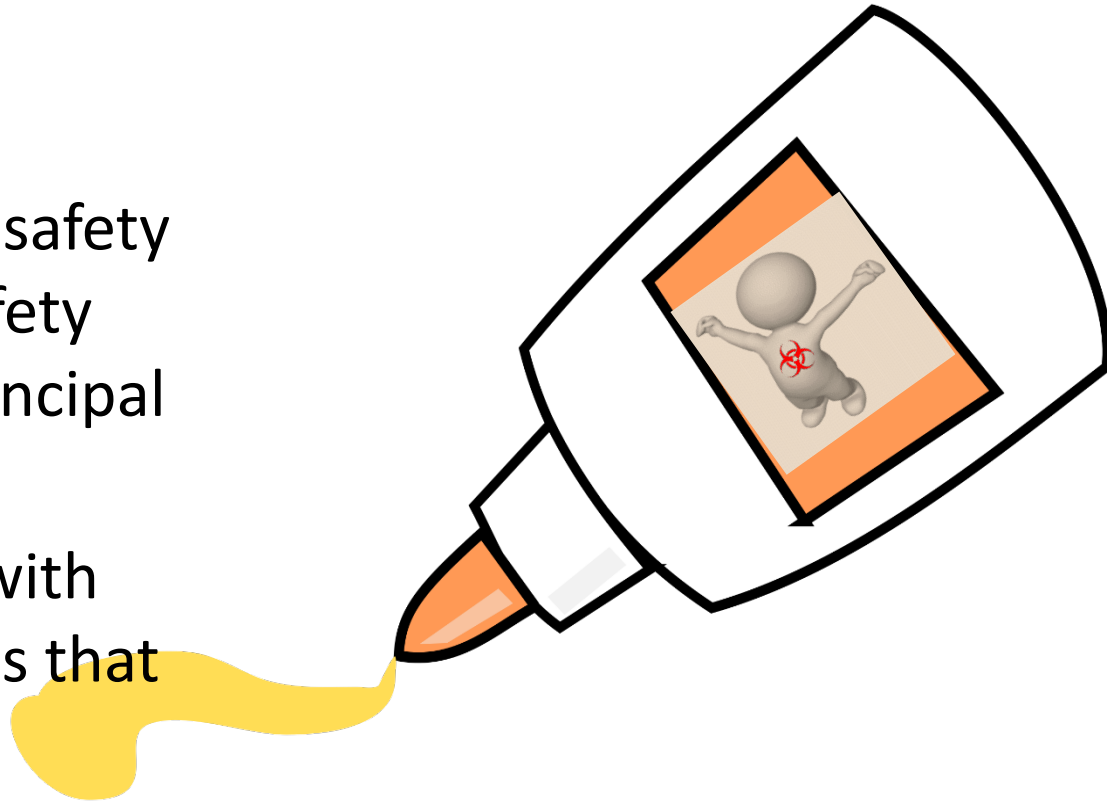


SERVICE: To Lead Is To Serve



Biosafety/Biorisk Professional

- ❖ Manages the Biosafety Program
- ❖ Provides technical leadership in risk assessment and biosafety principles for biosafety committees and principal investigators
- ❖ Establishes liaison with service departments that support research laboratories



Professional Credibility

- ❏ Well versed in the technical core competencies
- ❏ Develop expertise in one or more technical areas (publications, courses)
- ❏ Continual Learning

Fortune favors the prepared mind.
Are you adequately prepared to take those opportunities which arise to showcase your technical knowledge and leadership abilities?



Communication Skills

- ❌ Interpersonal
- ❌ Written Communication
- ❌ Conversational
- ❌ Public Speaking



Communication is the essence of good leadership. You can not impart your vision, without letting people understand what you're trying to do, how you're going to get there and what their role will be. Not to mention motivating them on the task at hand.

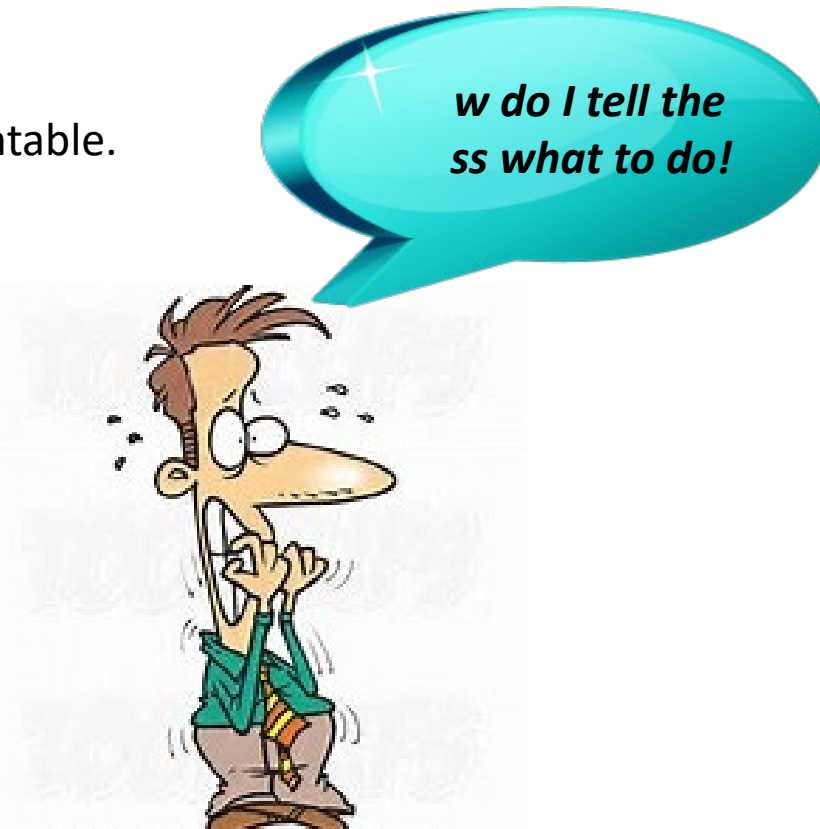
Leading Up



- ❖ A Biosafety/Biorisk Professional can assist their organization's leadership in three leadership activities:
 - Saying the right things about Biosafety
 - Measuring the right things; and
 - Holding his/her lieutenants accountable.

- ❖ Management Issues and Concerns:
 - Multiple competing priorities
 - Impact on bottom line
 - Regulatory vs. Good Practice
 - Accountability
 - Perceptions

- ❖ What does Safety mean to them?



Big Three Questions/Getting to Yes

When a decision maker listens to your idea there are three things that they consider?

- ❏ Why?
- ❏ Is It Worth It?
- ❏ Are You The Right Champion?



Tips For Communicating with Upper Management

- ❗ Brevity versus incompleteness
- ❗ Know your facts
- ❗ Provide references: historical or regulatory
- ❗ Use units and language they understand
- ❗ Offer options to a particular problem
- ❗ Prioritize: urgent, essential economically desirable, desirable
- ❗ Keep your cool
- ❗ Respect their time



Creating Safety Leadership Champions

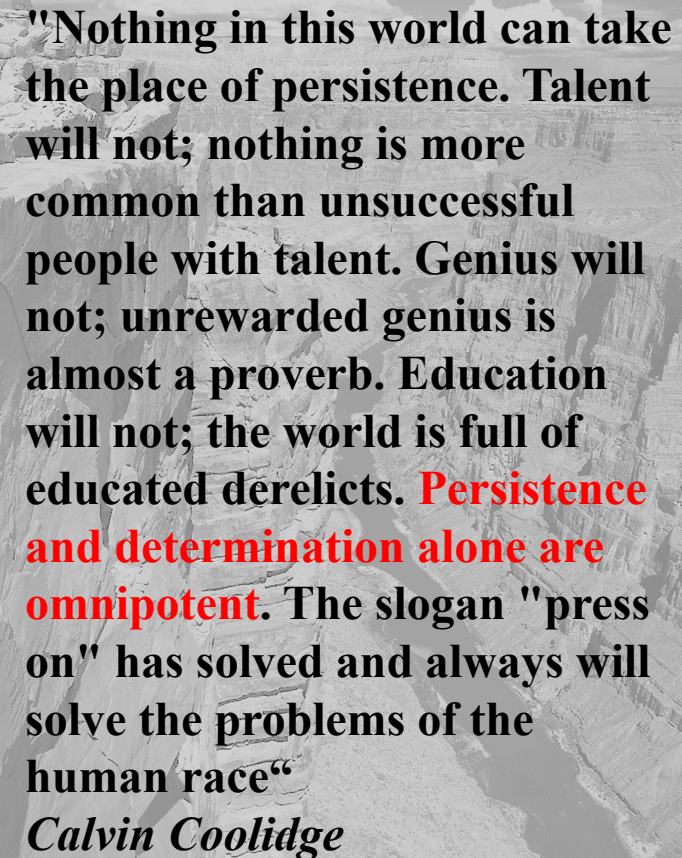


Members of the USDA ARS Biosafety, Safety and Health Leadership Steering Committee (BSHLSC)

- ❖ BSO must develop key relationships with various leadership staff (Build trust)
- ❖ Coach and assist champions in communicating their support of the safety program and safety culture
 - Roles and responsibilities
 - Metrics and accountability
 - Stories used to reinforce perceptions or change them

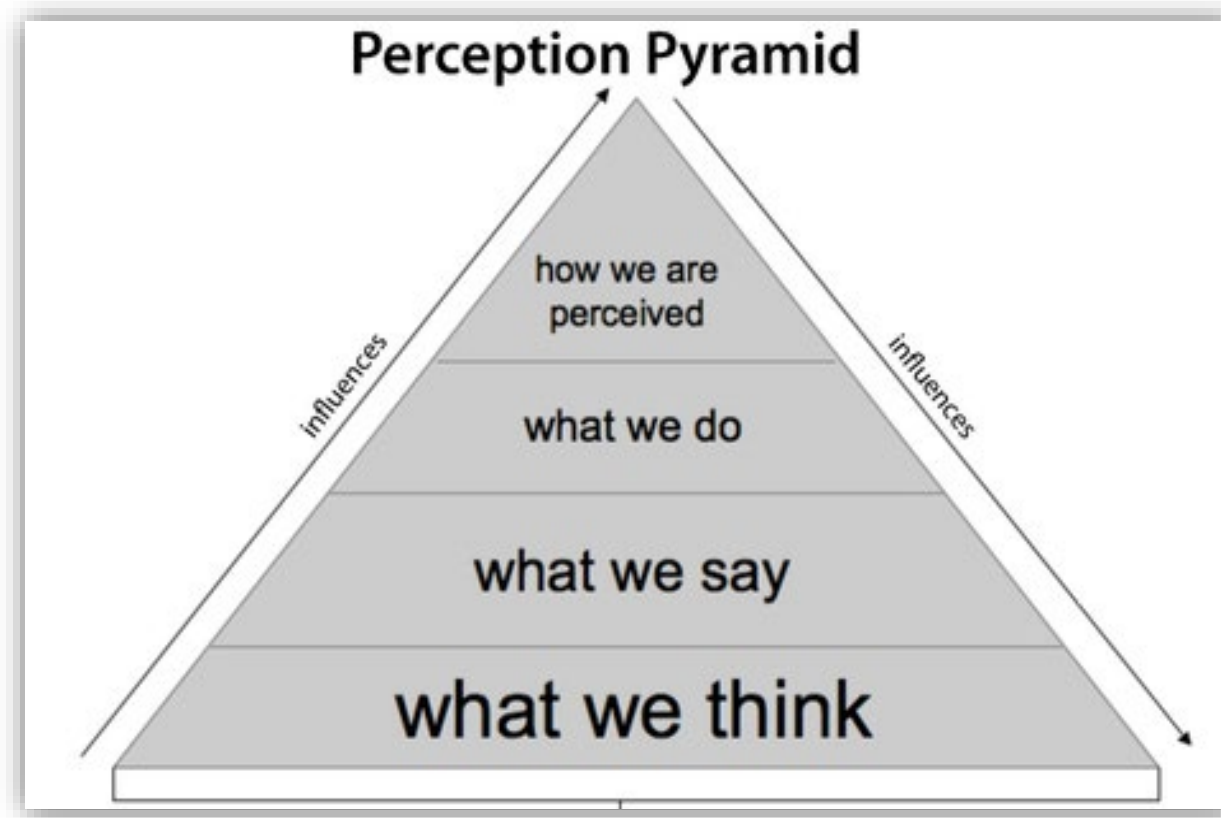
Pleasant Persistence

- ❏ Define what you want to accomplish.
- ❏ Prepare for “NO”, obstacles and other setbacks
- ❏ Review, reevaluate and revise
- ❏ Be Patient
- ❏ Follow up
- ❏ Provide value
- ❏ Keep focused
- ❏ Eventually Succeed and Enjoy!



"Nothing in this world can take the place of persistence. Talent will not; nothing is more common than unsuccessful people with talent. Genius will not; unrewarded genius is almost a proverb. Education will not; the world is full of educated derelicts. **Persistence and determination alone are omnipotent. The slogan "press on" has solved and always will solve the problems of the human race"**
Calvin Coolidge

How do we improve biosafety programs and culture?



We change perceptions!

Final Thoughts

- ❖ Biorisk Management Professionals need to engage in leadership at their institution and profession
- ❖ Continually develop technical and leadership competencies
- ❖ Clear, consistent communication is essential
- ❖ Active participation by leadership/champions is essential and must be sustained
- ❖ Use pleasant persistence
- ❖ Pursuit of biosafety excellence is a path to be followed rather than a destination.....Continual Improvement is the goal!



Group Exercise

You are the Biological Safety (Biosafety) Officer (BSO) at a Medical School with a staff of 500 professional and support personnel. Basic research and diagnostic work is carried out biosafety level (BSL) 2 principles, practices and facilities. In comparison to previous years, you noticed during the past 12 months, there has been an increase in the number of incidents, significant near-misses, and laboratory-associated infections (LAIs). You report your findings to your supervisor, the Dean of Research. She reviews your data and within a day asks you to develop a *Plan* consisting of your approach to improve the safety culture in the Medical School community in order to mitigate the events you reported. What is your approach to this situation?

- NOTE: Be cognizant of personnel and fiscal constraints. Having more people and funding may help. However, you must be able to address this situation using your current level of personnel and funds. Regardless of the cliché “Do more with less,” you cannot do more with less, but you must be practical and reasonable in your approach(es)!
- How should I develop the *Plan* to assure that I can sell the *Plan* to upper management? What can I do to convince them to “buy-into” the *Plan* so they have “ownership” and champion the *Plan*?
- How can we have leadership demonstrate their commitment to improving biosafety to the workforce?

Questions?



DLS ECHO Biosafety Session: April 30, 2024

Planning: Developing and Achieving Biorisk Management Objectives



Michael J. Stevenson, PhD

Deputy Lab Director

New Hampshire Public Health Laboratories

Beltsville, MD





Risk Assessment in Clinical Laboratories

March 27, 2024, 12:00 – 1:00 pm ET

When Ebola entered the United States in 2014, healthcare workers were faced with the very real threat of a deadly exotic disease presenting itself anywhere at any time.

This revealed the importance of needing to be prepared and ready to respond.

Laboratory professionals have since been tasked with performing a risk assessment in an effort to protect themselves and their communities from laboratory-associated infections.

Participants of this webinar will be reminded of how to identify and assess for hazards and mitigate risk and will learn of resources available to assist in what can seem like a daunting process.





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