Foundations of a Biomedical Research Laboratory Biorisk Management Program

June 16, 2022

VA Office of Research & Development
Biomedical Research Laboratory Biosafety and Biosecurity Program

- ✓ A recording of this session and the associated handouts will be available on ORPP&E's Education and Training website approximately one-week post-webinar
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- ✓ Please use the Q&A feature to submit questions.
  - ✓ **Please do not use Chat to send in questions.**
  - ✓ **Be sure to send questions to "All panelists".**
- ✓ We would be ever so grateful if you would complete the post-webinar evaluation survey that pops up once you exit the webinar.
- ✓ Experiencing sound issues – you can call in using the number included on the handouts and on your registration confirmation email that you received.

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Webinar #1 Reminder

ORD Biomedical Research Laboratory Biosafety and Biosecurity Program

ORD Biosafety and Biosecurity Program

- The ORD Biomedical Research Laboratory Biosafety and Biosecurity Program (BRLBBP) provides executive leadership in laboratory biosafety and biosecurity, including standardizing research laboratory biosafety and laboratory biosecurity policies and practices across the Agency
- BRLBBP also ensures VA research laboratories working with biohazards are operated in a safe and secure manner to protect:
  - Employees
  - Surrounding communities
  - Environment

https://www.research.va.gov/programs/biosafety/default.cfm

ORD Biosafety and Biosecurity Program

- Key Activities include:
  - Collaborate on the development of VHA biorisk management policy and written guidance
  - Communicating training requirements
  - Initiating training programs
  - Representing the VA perspective on biomedical research when participating on interagency work groups
  - Hiring of an ORD Research Biosafety Officer
- ORD contracted with Totally Joined for Achieving Collaborative Techniques, LLC (TJFACT) to support ORD's BRLBBP

ORD Biosafety and Biosecurity Program

- Collaborate with key stakeholders on the development and implementation of biorisk management program for biomedical research laboratories
- Utilize multiple types of communication mechanisms to enhance dissemination of information and networking:
  - Webinars
  - Dedicated email (VHACOORDBiosafety@va.gov) for inquiries/comments from the field on biosafety and biosecurity issues
  - Toolkit: Research Laboratory Biosafety and Biosecurity
  - Email distribution list for VA research safety staff and research oversight stakeholders

Educational Tools and Trainings

- Provide resources and guidance to VHA staff enhance biomedical research biosafety and biosecurity programs at VHA facilities
- Developed and published a Biosafety Toolkit that:
  - Provides resources for general biosafety and biosecurity information
  - Provides field programs with guidance and best practices
  - Serves as a training supplement for VHA staff
  - Assists in the development of Biomedical Research Laboratory Safety Manuals

https://www.research.va.gov/programs/orppe/education/toolkits/biosafety.cfm

Polling Question #1

Have you accessed ORD's new Biosafety Toolkit?

Foundations of a Biomedical Research Laboratory Biorisk Management Program

ORD Biosafety and Biosecurity Webinar #2

Webinar Purpose & Objectives

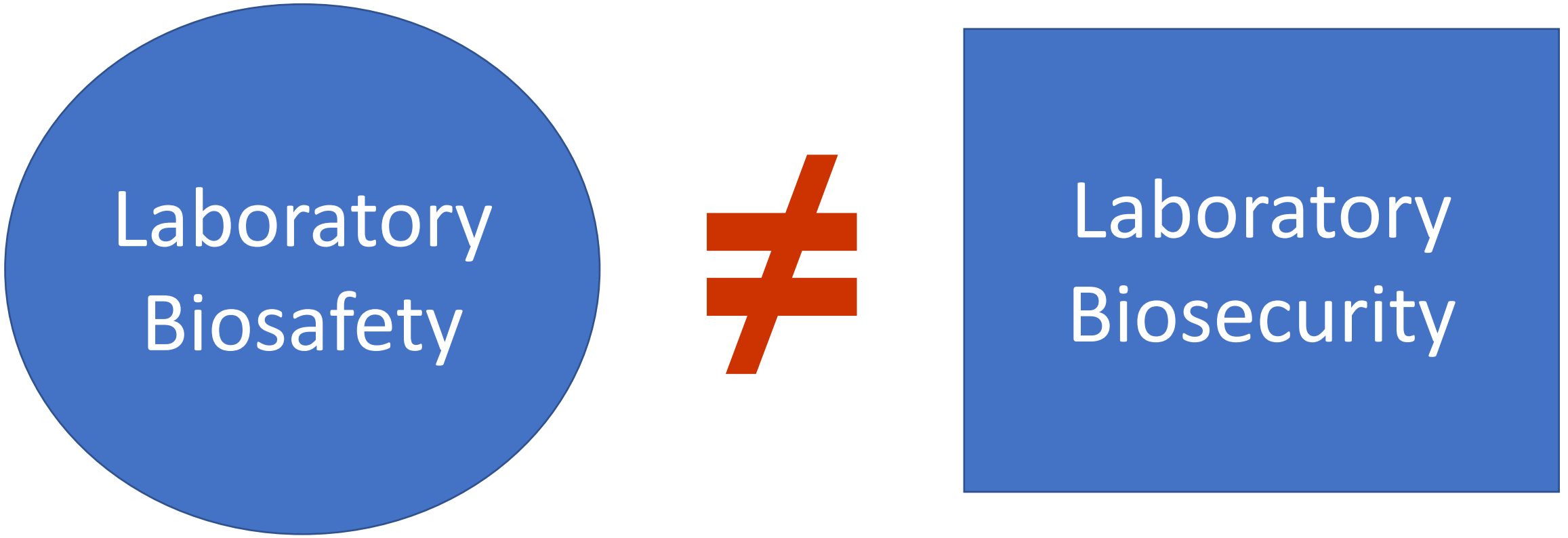
- Describe the purpose of a biomedical research laboratory biorisk management program (BRMP)
- Define important BRMP terminology and definitions
- Identify key responsibilities and activities that support research laboratory BRMP implementation and operation
- Identify general biosafety and biosecurity best practices to support a BRMP
- Recognize common biosafety and biosecurity challenges and solutions associated with BRMP implantation and operation

Laboratory Biosafety & Biosecurity

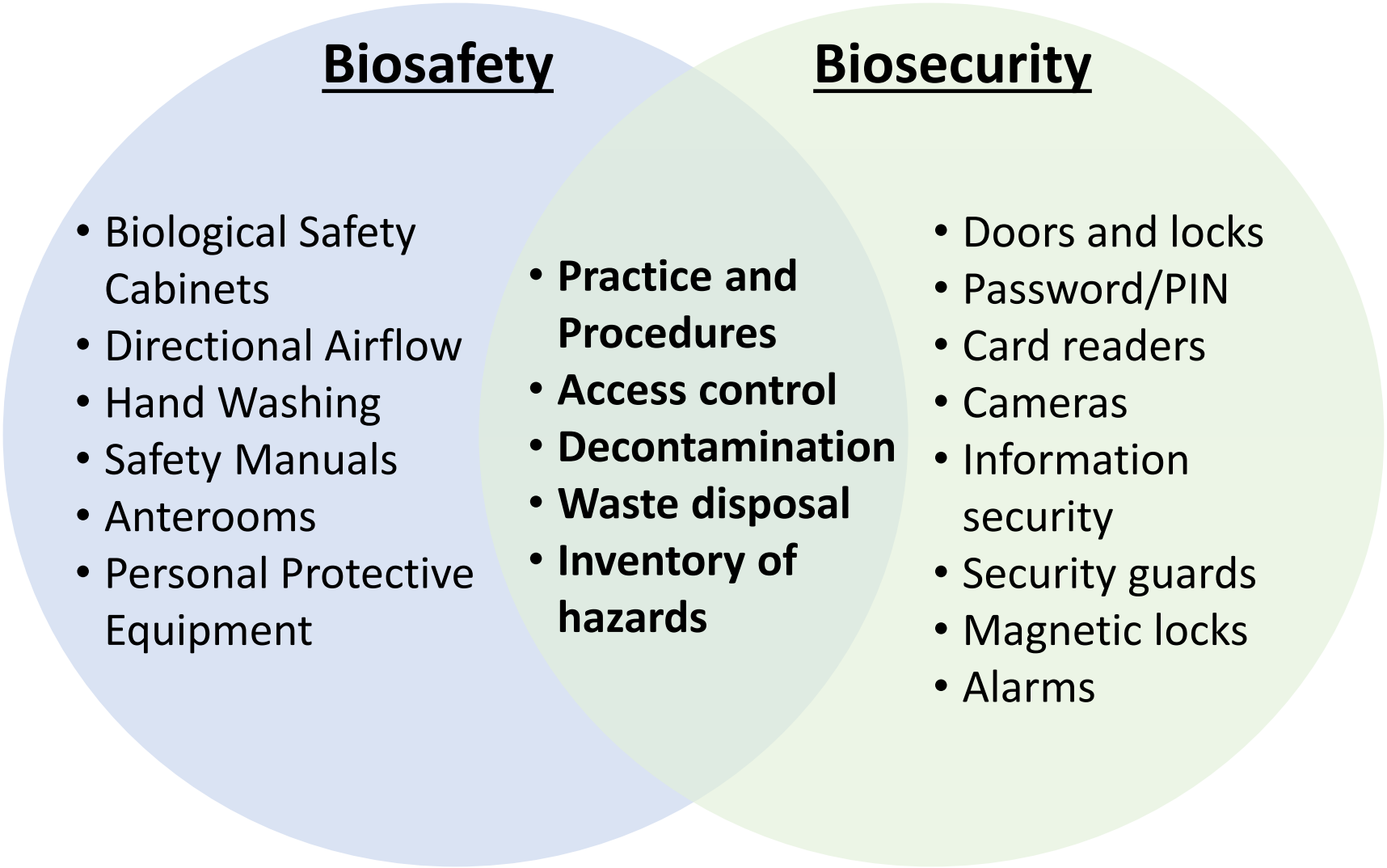
- **Laboratory Biosafety:** The consistent application of safety measures to minimize or prevent exposure to the person handling the agent, lab and building occupants, the community and the environment

- **Laboratory Biosecurity:** The risk- and threat-based control measures established to prevent the unauthorized access, misuse, loss, theft, diversion and intentional release of valuable biological materials, pathogens, toxins, information, expertise, equipment, technology and intellectual property that have the potential to cause harm to humans, animals, plants, the environment, public safety or national security.

Laboratory Biosafety & Biosecurity



Laboratory Biosafety & Biosecurity



Laboratory Biorisk Management

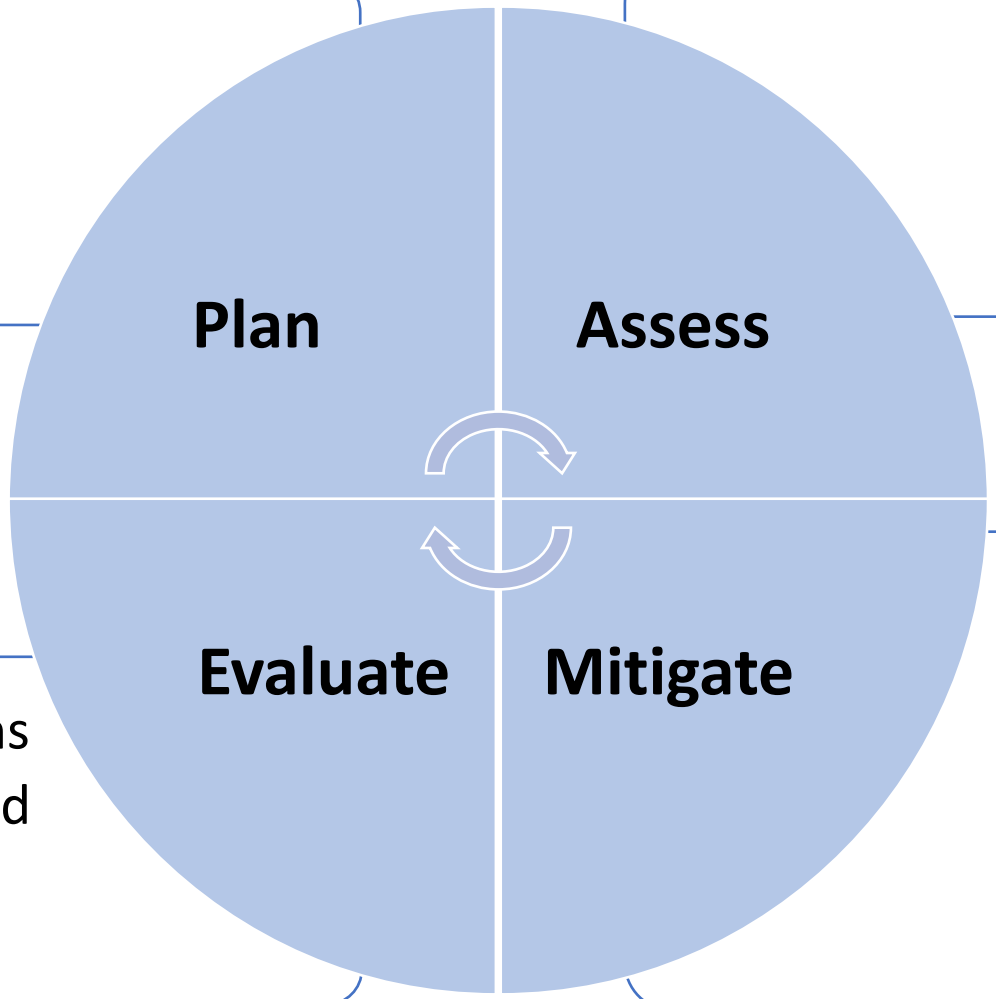
- **Biorisk:** The effect of uncertainty expressed by the combination of the consequences of an event and the associated likelihood of occurrence, where biological material is the source of harm.

Biorisk = Biosafety + Biosecurity Risks

- **Biorisk management:** Coordinated activities to direct and control an organization regarding biorisk.

Laboratory Biorisk Management Approach

- Biosafety and Biosecurity Policies
- Roles and Responsibilities



- Hazard Identification
- Biosafety Risk Assessment
- Biosecurity Risk Assessment

- Laboratory Inspections
- Incident Reporting and Response
- Management Review

- Biosafety Manuals
- Biosecurity Plans
- SOPs
- Trainings
- Waste Management
- Facility/laboratory Besign

Biorisk Management Program Planning

- Establish BRM polices and objectives
- Identify and ensure the resources needed to support the BRM program are available
- Define roles, responsibilities, and authorities
  - Management and Leadership
  - Principal Investigators
  - Biorisk Management Committees
  - Research Staff
  - Other Facility Personnel
- Ensure clear communication of the actions that need to be taken in support of the BRM program
- Promote the continual improvement of the BRM program

Biorisk Assessment

- **Hazard:** Source or situation with a potential for causing harm.
  - Biological
  - Chemical
  - Radiological
  - Physical
  - Other

- **Risk:** A combination of the consequences of an event and the associated "likelihood" of occurrence.
  - RISK = f (probability) x (consequence)

Hazard ≠ Risk

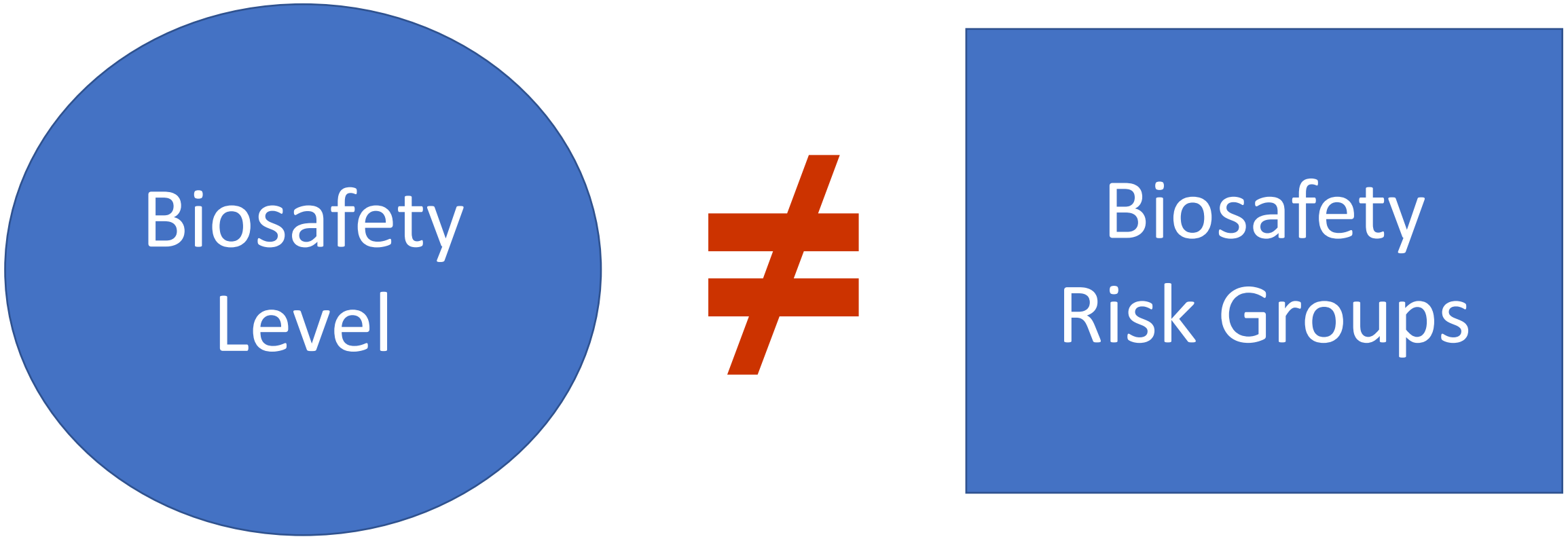
Biorisk Assessment

- Biosafety Risk Assessment
  - Characterize and evaluate safety risks
  - Agents (hazards), Activities, & Procedures
  - Ensures safety of staff, families, community and environment
- Biosecurity Risk Assessment
  - Characterize and evaluate security risks
  - Agents (assets) & Threats
  - Ensures security of the samples from theft, loss, and misuse

Biorisk Mitigation – Laboratory Biosafety

Engineering	Physical changes to workstations, equipment, materials or any other relevant aspect of the work environment that reduce or prevent exposure to hazards
Administrative	Policies, standards and guidelines used to control risks
Practices and Procedures	Processes and activities that have been shown in practice to be effective in reducing risks
Personal Protective Equipment	Devices worn by the worker to protect against hazards in the laboratory

Common Biosafety Misconception



Laboratory Biosafety Levels (BSL)

BSL-1

Well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present **minimal potential hazard** to laboratory personnel and the environment

BSL-2

Agents associated with human disease and pose **moderate hazards** to personnel and the environment

BSL-3

Indigenous or exotic agents; may cause **serious or potentially lethal disease** through the inhalation route of exposure

BSL-4

Dangerous and exotic agents that pose high individual risk of aerosol-transmitted laboratory infections and **life-threatening disease** that are frequently fatal for which there are no vaccines or treatments

Biological Agent Risk Groups

Risk Group 1 (RG1)	Risk Group 2 (RG2)	Risk Group 3 (RG3)	Risk Group 4 (RG4)
Agents are not associated with disease in healthy adult humans	Agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available	Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available	Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

Biorisk Mitigation – Laboratory Biosecurity

Physical Security	Personnel Security	Material Control & Accountability	Transport Security	Information Security
• Graded Protection • Wall, fences and gates • Access controls • Alarms • Security guards	• Roles and responsibilities • Employee vetting and screening polices and procedures • Visitor management	• Inventory management • Documentation and reporting requirements • Accountability policies and procedures • Storage/Disposal requirements	• Shipping policies and procedures • Internal vs. External • Training certification	• Identification of sensitive information • Marking and labeling of sensitive information • Storage requirements

Laboratory Biosecurity - Challenges

- Securing dangerous biological materials can be difficult considering:
  - Viruses and bacteria are difficult to count and track
  - Small amounts can be multiplied to have severe consequences
  - Relatively inexpensive to produce
  - Detection can be a challenge without sufficient information and resources
- Dangerous biological materials can be found in many locations:
  - Research and diagnostic laboratories
  - Culture collections and repositories
  - Environment
  - People and animals
  - Waste
- Many laboratories are not accustomed to worrying about or prioritizing security and may need to intentionally increase raising security awareness among staff.

Other Challenges
&
Best Practices

Establishment of a Culture Safety and Responsibility

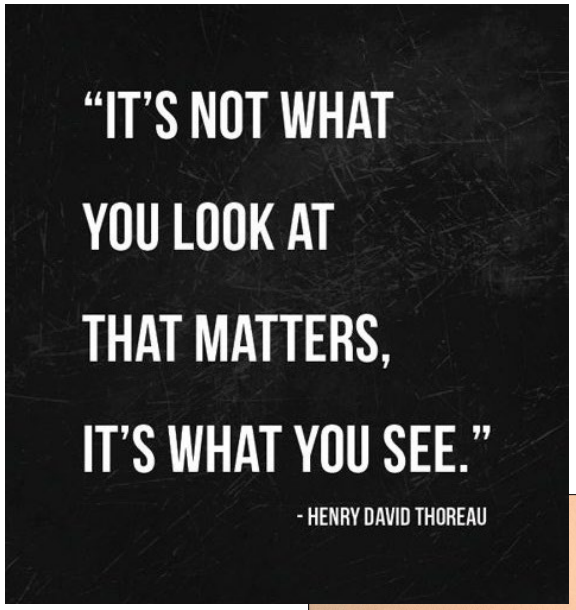
- A perspective whereby employees and leadership share common beliefs, values, and norms about safety and take responsibility for their role in these fundamental practices.
- Individual and organizational attitudes about safety and responsibility will influence all aspects of laboratory conduct, including whether individuals will:
  - Comply with safety and security measures and procedures
  - Report biosafety or biosecurity incident, near-misses, and concerns without fear of retribution or ridicule
  - Respond appropriately to incidents
  - Communicate risks to each other and to managers in a timely and accurate manner

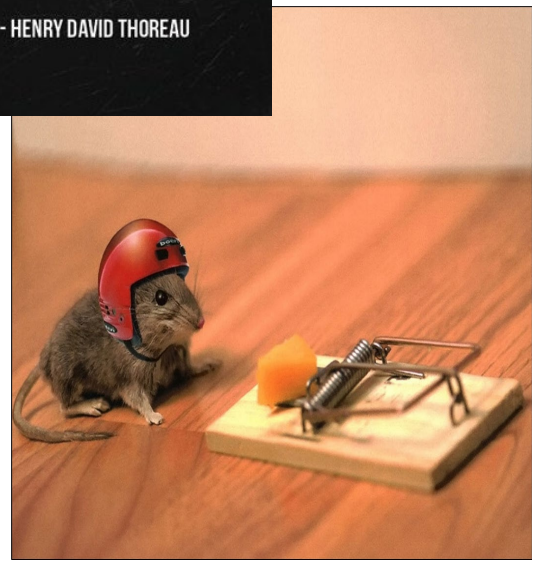
Establishment of a Culture Safety and Responsibility

- Laboratories should develop a culture of safety and responsibility that promotes communication, encourages questions, and welcomes evaluation of its institutional practices
- Laboratory workers should commit to supporting a culture of safety and responsibility, be aware of the risks associated with work performed, and act in ways that strengthen safety and security
- Laboratory workers have the responsibility to report their concerns to their supervisors and the right to express their concerns without fear of reprisal
- Supervisors have the responsibility to address the concerns that are raised.

Risk Perception and Tolerance

- Determining “acceptable” risk is a subjective process
- Different people perceive risk differently
- A “safe” activity is one in which risks are considered to be acceptable
- Everyone has different perception and tolerance of risk and what is “acceptable”
- Drives investment decisions within an institution
  - Risk-averse institutions will spend more resources attempting to reduce the risks it faces.
  - Risk-tolerant institutions may proceed with procedures others may find too dangerous.





Communication

- Ensure all staff are aware of an institutions biorisk management objectives, policies, and procedures
- Ensure all staff are aware of their roles and responsibilities within the biorisk management program
- Define communication procedures and utilize multiple communication strategies
  - Web-based (e.g. websites, list serves, email)
  - Verbal communication (e.g. team briefing, conference call, virtual platform
  - Non-verbal communication (e.g. posting of signage, document circulation, reference library)
- Ensure internal and external communication plans and training are in place to support emergency response and contingency planning

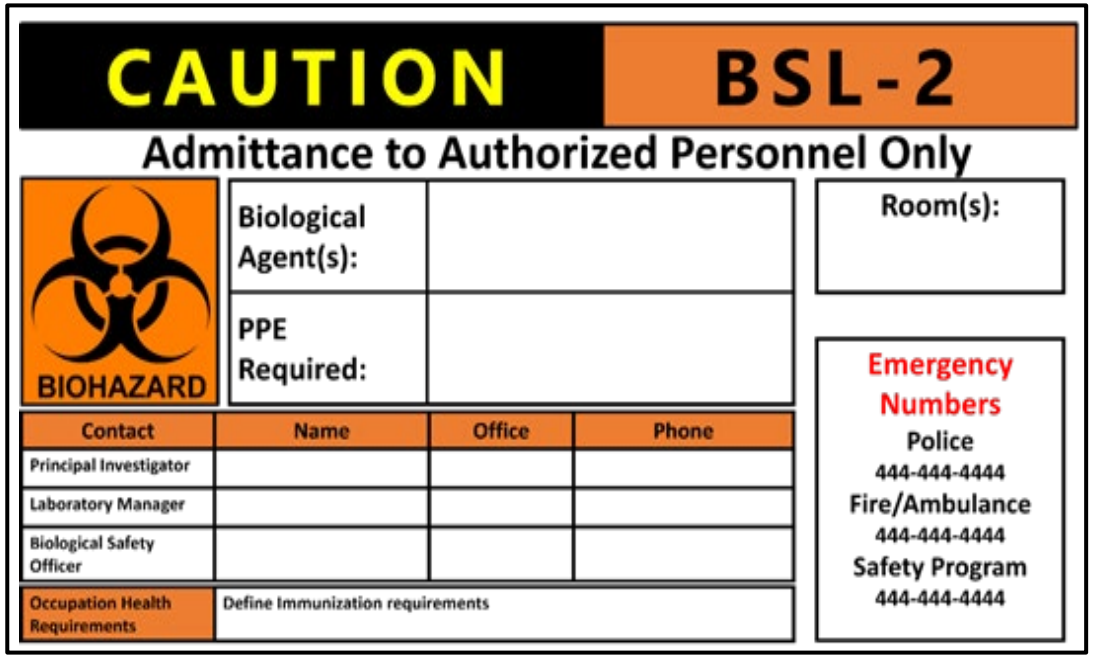
Next Steps & Action Items
(How does this apply to us?)
(What can we do?)

Laboratory Signage Review Initiative

- Review your local biomedical Research Laboratory Safety Manual hazard signage posting procedures
  - Verify the accuracy and clarity of local signage procedures
  - Review available tools/guidance to aid in the development of laboratory signage (e.g., Laboratory Biosafety Signs Template)
  - Develop and/or modify existing signage procedures to address the gaps identified
- Survey your biomedical research laboratory space(s) to determine laboratory usage and if the signage accurately reflects the activities occurring in the spaces
  - Establish a list of active and inactive biomedical research laboratories in your building(s)

Laboratory Signage Review Initiative

- Ensure Hazard Signage SOP includes signage requirements for:
  - Biological hazards
  - Chemical hazards
  - Radiological hazards
  - Other physical hazards (e.g lasers, sounds)
- Review (PIs and Research Safety) the hazards present in the laboratories
  - Create/modify laboratory signage if needed
  - Post updated signage on all laboratory doors
- Establish a requirement to review/update laboratory signage on a recurring basis



Biological Safety Cabinet (BSC) Review Initiative

- Review existing local biomedical research laboratory BSC procedures and training materials
  - Identify gaps in existing BSC procedures and training materials
  - Reference available tools/guidance to aid in the development of a BSC procedures and training materials (e.g., ORD Guidance Biological Safety Cabinets)
  - Develop and/or modify existing BSC procedures and training materials to address the gaps identified
- Survey your biomedical research laboratory space(s) to identify existing BSCs usage and/or need for BSC usage
  - Establish a list of actively used and/or inactive BSCs in your laboratories

Biological Safety Cabinet (BSC) Review Initiative

- Create and/or modify an existing BSC Operations and Maintenance SOP to include procedures for:
  - Proper Usage – start-up, use, shutdown
  - Decontamination – spill clean-up, repairs, HEPA filter exchanges, and relocation
  - Certification – annual or otherwise as needed
  - Repairs – service request reporting and tracking
- Develop and track BSC training for current and new research staff on the proper use of BSCs
- Establish a local requirement to regularly review proper BSC usage, training, certification, and maintenance (e.g., inspections)

ORD Biosafety and Biosecurity Webinar Series

- Webinar #1 – Introduction to ORD's Biosafety and Biosecurity Program: New Initiatives for VA Facility (4/28/2022)
- Webinar #2 – Foundations of a Biomedical Research Laboratory Biorisk Management Program (6/16/2022)
- **Webinar #3 – Topic To Be Determined**

Participant feedback from today's webinars will help determine the focus of future webinars

BRLBBP: Biosafety Mailbox for Queries

VHACOORDBiosafety@va.gov

- VA designated email address to submit biosafety and biosecurity questions
- Biosafety subject matter experts (SMEs) will respond with an initial or final response within 7 calendar days
- SMEs will provide responses on biomedical research laboratory topics related

  - Biosafety and biosecurity risk assessment practices
  - Handling and management of infectious microorganisms
  - Biohazard and chemical waste management
  - Personal protective equipment (PPE)
  - Biosafety and biosecurity best practices
  - Other biosafety and biosecurity topics

- ***NOTE: Biomedical research related biosafety and biosecurity questions should initially be addressed to your local Biosafety POC and/or local Subcommittee on Research Safety (SRS).***

References

- ORD Biomedical Research Laboratory Biosafety and Biosecurity Program
- Toolkit: Research Laboratory Biosafety and Biosecurity
- VHA Directive 1200.08. Safety of Personnel and Security of Laboratories Involved in VA Research, Veterans Health Administration, January 8, 2021.
- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Ed., Centers for Disease Control and Prevention and National Institutes of Health, 2020.
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), National Institutes of Health, 2019.
- ABSA International - The Association for Biosafety and Biosecurity

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Questions and Answers

Please Complete the Survey!

Thank you!