SAND2011-1202C

Importance of Biorisk Management from National and International Perspectives

National Awareness Workshop on Improving Biosafety & Biosecurity at Veterinary Research Laboratories in Pakistan

March 1-2, 2011

International Biological Threat Reduction
Sandia National Laboratories

Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

International
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Key Concepts for Discussion

- **Introduction to International Obligations**
  - Biological Weapons Convention
  - UNSCR 1540
- **Introduction to Biorisk Management**
- **Importance of a National Biorisk Framework**
- **Benefits of One Health Approach**
  - Relationship of biorisk management to disease surveillance
  - Value of molecular diagnostics as a means of reducing biorisk

Spectrum of Biological Risks

Naturally occurring diseases	Re-emerging infectious diseases	Unintended consequences of research	Laboratory accident	Lack of awareness	Negligence	Deliberate misuse

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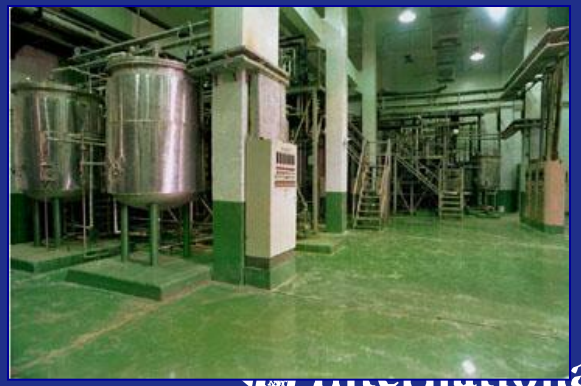
International Obligations

- **Biological Weapons Convention**
  - Prohibits the development, production, and stockpiling of biological weapons agents, toxins, equipment, and means of delivery by State Parties
  - Opened for signature April 1972; entered into force March 1975
  - No provisions for verification of compliance
  - Focus is on confidence building measures
- **UNSCR 1540**
  - "Take and enforce effective measures to establish domestic controls to prevent the proliferation of . . . biological weapons . . .; including by establishing appropriate controls over related materials"
  - Requires States to report efforts to 1540 Committee

Fermentation Vessels



BIOLOGICAL THREAT REDUCTION

Opportunity: Engaging a Multi-sectoral, Global Community

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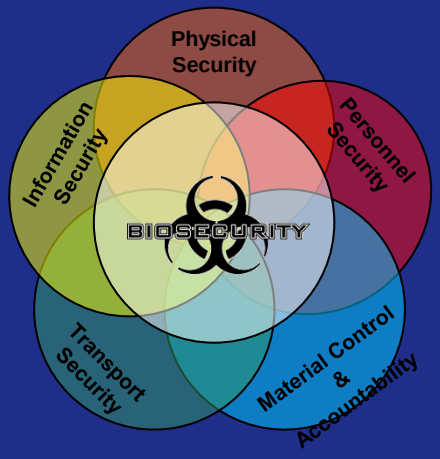
Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

Biorisk Management System

- **Seeks to effectively and efficiently manage an institution's biorisks**
  - Defines management practices for biosafety and biosecurity, location of the hazards, biological agents and their products
  - Establishes systems and policies to manage the laboratory biorisk
    - **Resources, institutional guidelines and operating procedures, training programs and oversight**
  - Integral in the day-to-day operations of the institute / organization, both in normal times and times of emergency



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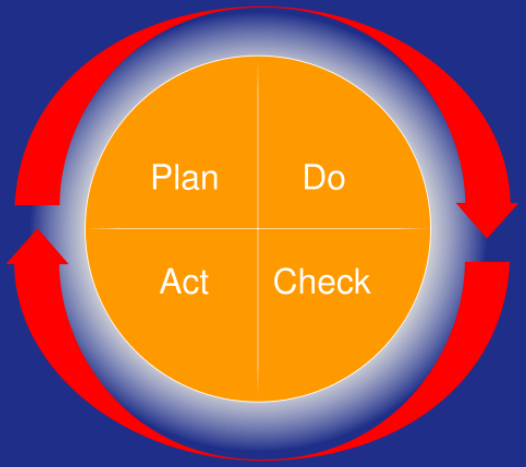
Requirements of a Management System

- **In a management system, all aspects of a PDCA cycle have to be addressed:**
  - Structured approach for achieving objectives and goals
  - Based on identified tasks and controls
  - Defined roles and responsibilities
  - Documented for reference and change control
  - Competence requirements, including on-going development
  - Records of controls, competence and performance

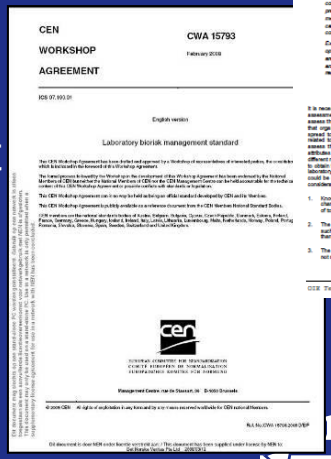


Utilizing Biorisk Management Systems:

- Control or minimize biosafety and biosecurity risks to acceptable levels to employees, the community and others
- Regulatory support and basis for new or revised legislation
- Provide assurance that the requirements are in place and implemented effectively
- Provide a framework that can be used as basis for training and awareness raising
- Audits and inspections
- Seek and achieve certification or verification by an independent third party
- Training
- International collaboration

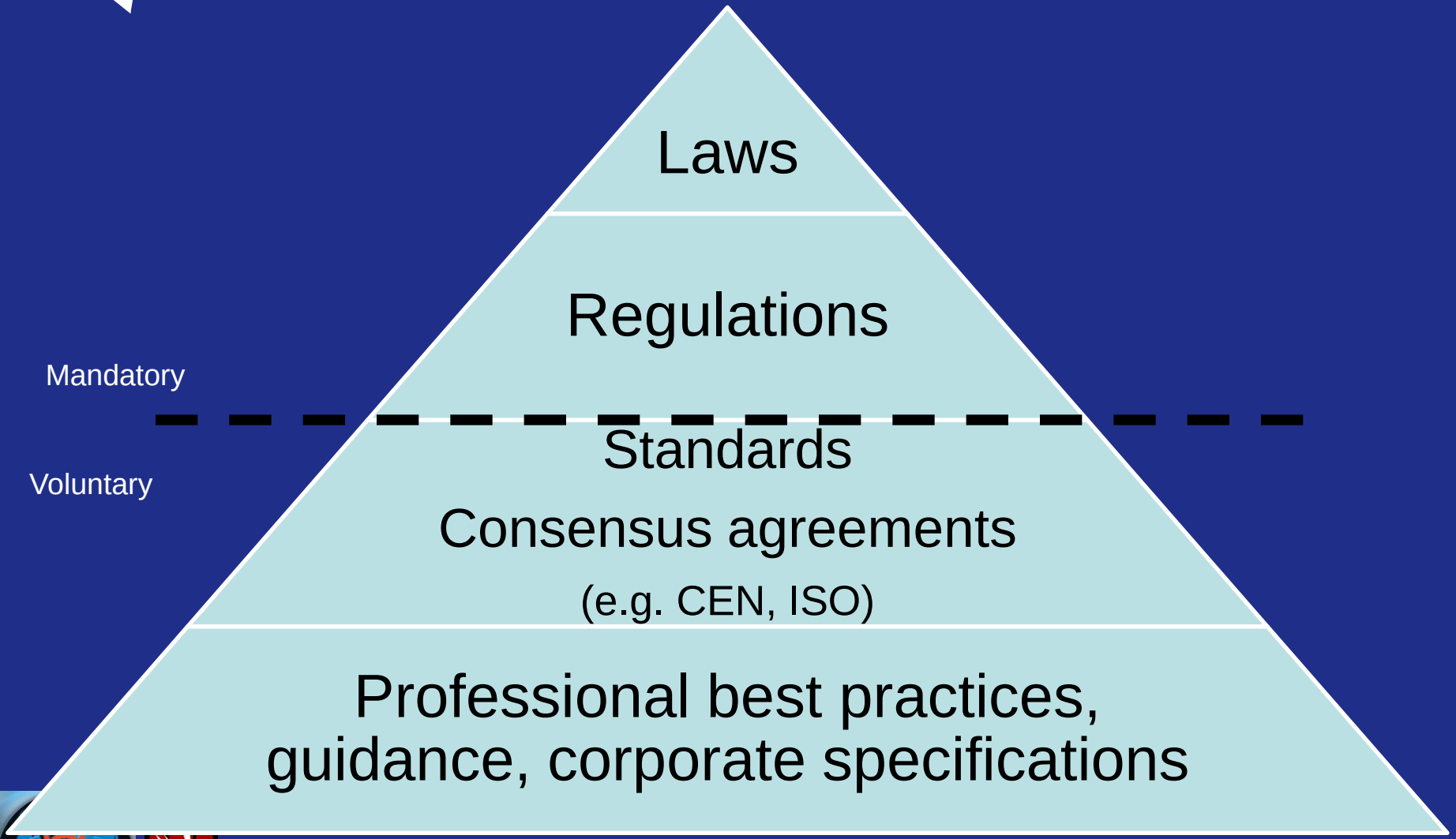
International Laboratory Biorisk Management Documents

- **Technical: OIE**
  - Chapter 1 .1.2-Biosafety and Biosecurity in the Veterinary Microbiology Laboratory and Animal Facilities
- **Technical: World Health Organization**
  - Laboratory Biosafety Manual
  - Biorisk Management: Laboratory Biosecurity Guidance
- **Management: CEN Workshop Agreements**
  - CWA 15793 Laboratory Biorisk Management Standard
  - CEN WS 55 – CWA 15793 Guidance Document (under development)
  - CEN WS 53 – Biosafety Professional Competence



Standards, Regulations, Best Practice

Standards, Regulations, Best Practice

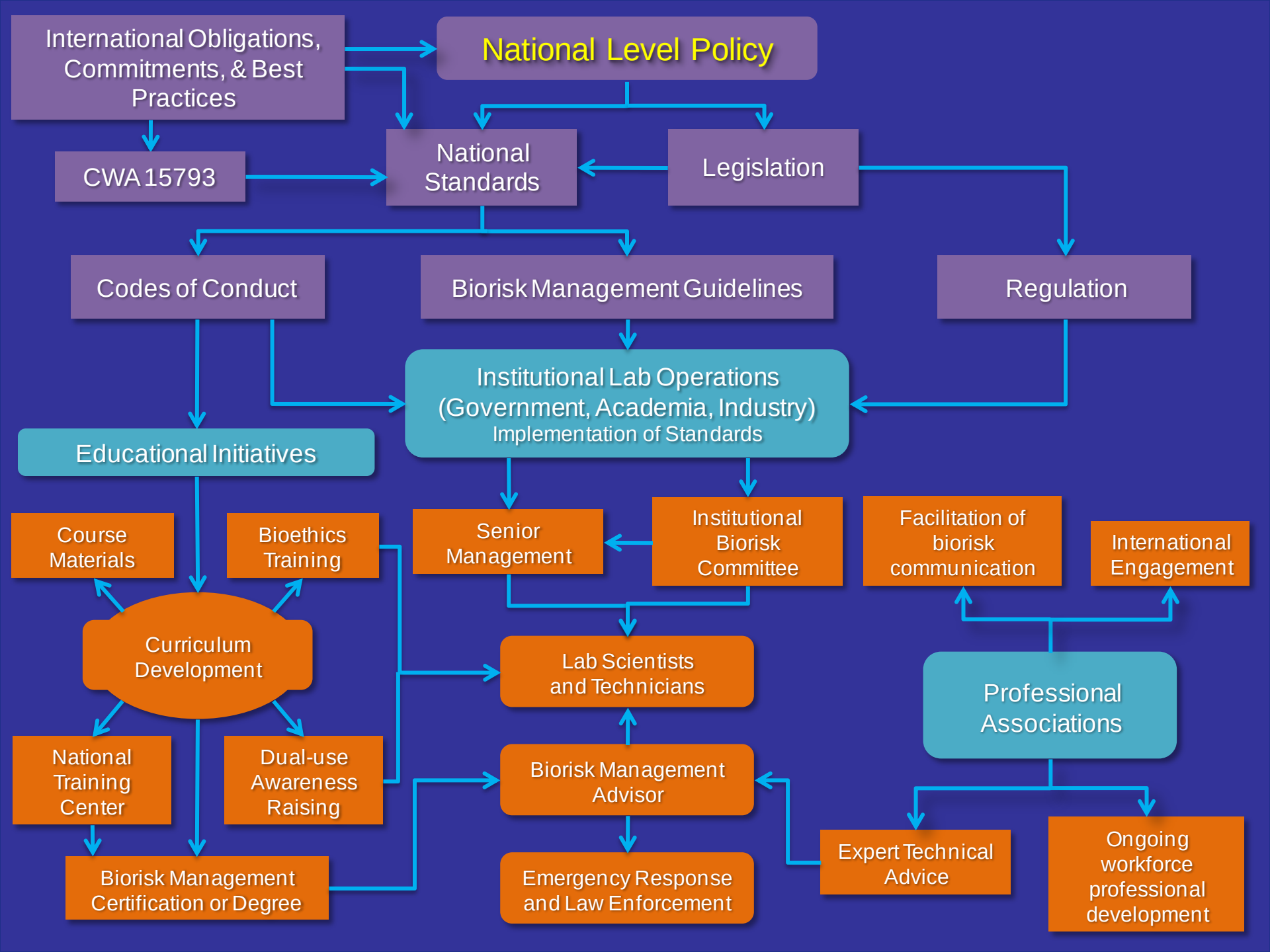


CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards such as**
  - ISO 9001 / 14001 and OSHAS18001
- **The Standard is performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization
- **Does not replace national regulations**
  - Compliance with regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs

Cooperation on National Biorisk Management Framework

- **Objectives:**
  - Develop overall framework for biorisk management (including a national strategy, standards, and guidelines) in Pakistan
    - **Framework should include coordination with and/or development of relevant legislation, regulations, and codes of conduct**
  - Ensure inter-ministerial coordination
- **First meeting of JBWG (Istanbul, September 2010)**
  - Initial action plan prepared
  - Framework schematic drafted (subsequently updated)
  - Path forward identified:
    - **National strategy on biorisk management**
    - **Development of national standards and guidelines**
    - **Awareness raising and leadership training**


International Obligations, Commitments, & Best Practices
National Level Policy
CWA 15793
National Standards
Legislation
Codes of Conduct
Biorisk Management Guidelines
Regulation
Institutional Lab Operations (Government, Academia, Industry)
Implementation of Standards
Educational Initiatives
Course Materials
Bioethics Training
Senior Management
Institutional Biorisk Committee
Facilitation of biorisk communication
International Engagement
Curriculum Development
Lab Scientists and Technicians
Professional Associations
National Training Center
Dual-use Awareness Raising
Biorisk Management Advisor
Biorisk Management Certification or Degree
Emergency Response and Law Enforcement
Expert Technical Advice
Ongoing workforce professional development

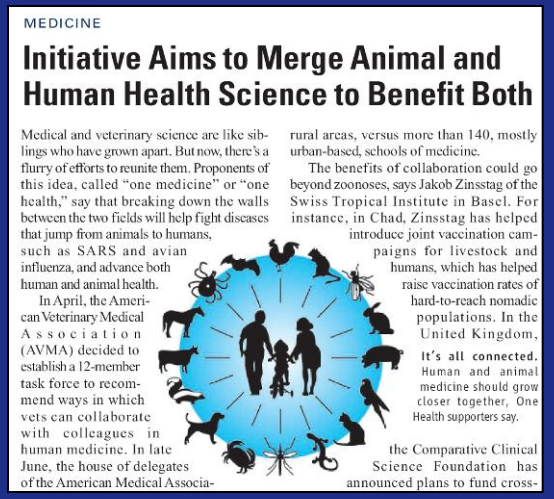
Definition:
One Health

One Health seeks to promote, improve, and defend the health and well-being of all species by enhancing cooperation and collaboration between physicians, veterinarians, and other scientific health professionals and by promoting strengths in leadership and management to achieve these goals.

One Health Initiative: http://www.onehealthinitiative.com/index.php

Benefits:
One Health

- **The Benefits of the One Health approach as proposed by the American Veterinary Medical Association (AVMA) in 2008**
  - Improving animal and human health globally through collaboration among the health sciences
  - Meeting new global challenges head-on through collaboration among multiple professions
  - Developing centers of excellence for education and training by developing collaborations between medical and veterinary colleges
  - Improved scientific knowledge to create innovative programs to improve health



MEDICINE

Initiative Aims to Merge Animal and Human Health Science to Benefit Both

Medical and veterinary science are like siblings who have grown apart. But now, there's a flurry of efforts to reunite them. Proponents of this idea, called "one medicine" or "one health," say that breaking down the walls between the two fields will help fight diseases that jump from animals to humans, such as SARS and avian influenza, and advance both human and animal health.

In April, the American Veterinary Medical Association (AVMA) decided to establish a 12-member task force to recommend ways in which vets can collaborate with colleagues in human medicine. In late June, the house of delegates of the American Medical Associa-

rural areas, versus more than 140, mostly urban-based, schools of medicine.

The benefits of collaboration could go beyond zoonoses, says Jakob Zinsstag of the Swiss Tropical Institute in Basel. For instance, in Chad, Zinsstag has helped introduce joint vaccination campaigns for livestock and humans, which has helped raise vaccination rates of hard-to-reach nomadic populations. In the United Kingdom,

It's all connected. Human and animal medicine should grow closer together, One Health supporters say.

the Comparative Clinical Science Foundation has announced plans to fund cross-

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Impact of One Health on Infectious Diseases

- **Adapting One Health initiatives will integrate public and animal health sectors to help combat infectious diseases through:**
  - Improved detection of emerging and re-emerging infectious diseases in human and animal populations
  - Implementation of more effective control measures to combat zoonotic diseases globally
  - Enhanced public health through food safety
  - Broaden basic research in the area of zoonotic diseases

OIE

"One World One Health"

World Health Organization

"Veterinary Public Health"

Food and Agriculture Organization of the United Nations

for a world without hunger

"One World One Health"

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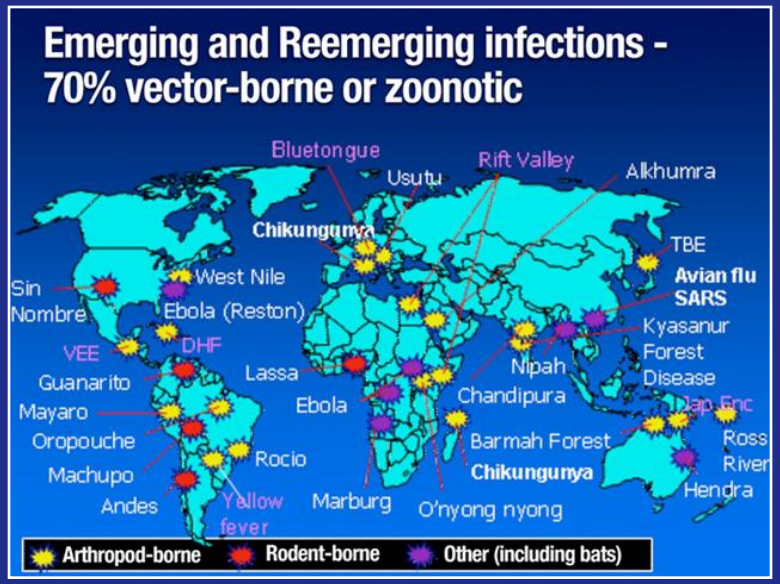
Emerging and Re-emerging Infectious Diseases

- **Recently the impact of infectious diseases of animal origin has become increasingly more apparent and more common**
  - 60% of human pathogens are zoonotic
  - 80% of animal pathogens are multi-host
  - 75% of emerging diseases are zoonotic
  - 80% of potential bioterrorism agents are zoonotic pathogens
- ***Nearly all new human (infectious) diseases that have emerged within the past 10 to 15 years have been found to have originated from animal reservoirs***



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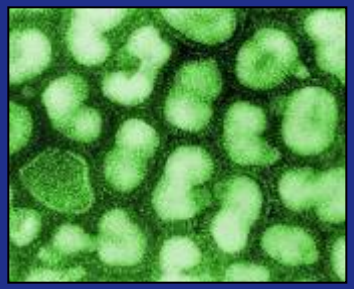
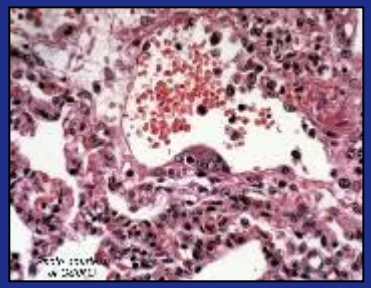
Detection of Emerging and Re-emerging Infectious Diseases

- **Developing partnerships between public and animal health sectors can facilitate the rapid detection of emerging and/or re-emerging infectious diseases**
  - Comprehensive surveillance programs
  - Open communication between public and animal health agencies to report outbreaks of zoonotic diseases
  - Collaborative efforts between public and animal health diagnostic laboratories to improve methods to detect and diagnose zoonotic pathogens

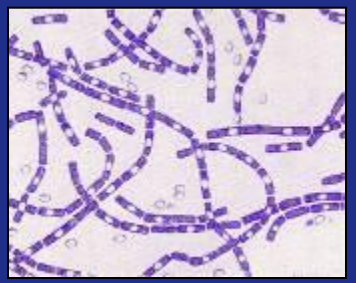


Avian influenza virus

SARS virus



Nipah virus in pig lung



Bacillus anthracis

Reducing Pathogen Quantities

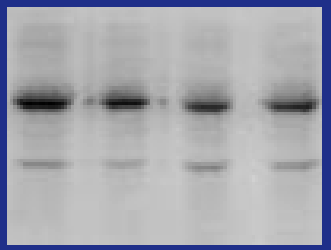
- Decreasing the quantity of dangerous pathogens in the laboratory will help reduce the likelihood of accidental exposure
- Decreasing the quantity of dangerous pathogens maintained in a laboratory will reduce the vulnerability to theft
- Laboratory procedures, techniques, or methods that minimize pathogen numbers in the laboratory with accomplishing the same goal will largely support laboratory biosafety and biosecurity

Methods to Minimize Pathogens in the Lab

- **The use of modern biotechnology can help reduce pathogen numbers in the laboratory**
  - Diagnostic medicine
    - **Biotechnology has provided many rapid and accurate methods to diagnose a number of infectious diseases without relying on conventional culture techniques**
  - Research
    - **Biotechnology has provided technologies to characterize pathogens phenotypically and genetically, study mechanisms of disease, and develop treatments, and do not require that pathogens be cultivated in large quantities**
- **Serology can provide extremely valuable diagnostic information without relying on conventional culture techniques**
  - Diagnostic applications
  - Epidemiology studies
  - Vaccine efficacy testing
- **Rapid diagnostic kits have also demonstrated utility in the biomedical profession primarily for diagnostic purposes**

Basic Molecular Methods Available

- **Utilization of the genetic material to identify a pathogen using genetic material**
  - *Polymerase chain reaction*
  - Restriction fragment length polymorphisms
  - DNA probes and microarray technology
- **Detection of protein**
  - Immunohistochemistry and immunoblotting
  - Antigen capture enzyme linked immunosorbentassay (ELISA)
  - Proteomics
- **Antibody detection**
  - Competitive ELISA



Reducing Pathogen Quantities

- Laboratory procedures, techniques, or methods that minimize pathogen numbers in the laboratory with accomplishing the same goal will largely support laboratory biosafety and biosecurity

- Numerous methods have been developed to aid in the identification and characterization of infectious pathogens that do not rely on isolation and culture techniques

- Unfortunately some of these technologies are difficult to sustain due to lack of training, cost, accessibility, and inability to repair equipment

Combined Control Measures to Combat Zoonotic Diseases

- **Animal interventions targeting zoonotic diseases have improved public health**
- **Prevention through awareness raising and outreach**
- **Comprehensive surveillance programs: FAO has implemented the Global Early Warning System (GLEWS) for major animal diseases and zoonosis**
  - GLEWS is a joint system that combines alert mechanisms of the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the World Organization for Animal Health (OIE) to assist in prevention and control of zoonotic disease threats through information sharing and risk analysis
  - http://www.glews.net/

Improved Food Safety

- **Establishing One Health practices can help minimize human exposures to infectious agents present in food**
  - Veterinarians can support the public health sector by improving animal health to help minimize food contamination by infectious pathogens
  - Veterinarians can help the public health sector provide outreach to educate the public on issues related to food contamination
  - Veterinarians can help educate public health professionals on food products that can be contaminated
  - Veterinarians and physicians can collaborate to resolve outbreaks of food borne illnesses

One Health:
Laboratory Biosafety and Biosecurity

- **Laboratory biosafety and biosecurity practices are largely pathogen driven and can support the One Health Concept but specific practices from relevant biomedical sectors may improve procedures and protocols**

- **The audience consists of biomedical professionals from both the public and animal health sectors**

  - How do you see One Health impacting your work from a safety and security perspective?

    - **Diagnostic medicine**

    - **Basic research**

    - **Health care providers**

Conclusions

- International obligations in biorisk management (BWC, UNSCR 1540) are aimed at protecting both dangerous materials and personnel working with dangerous materials
- Biorisk Management Systems act to effectively and efficiently manage an institution's biorisks
- A Pakistan national framework for biorisk management would coordinate the development of relevant legislation, regulations, and codes of conduct and ensure inter-ministerial coordination
- Approaches to laboratory biosafety and biosecurity are largely pathogen driven, supporting One Health initiatives which can enhance early detection and control of zoonotic diseases

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Discussion and Questions

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Basic Concepts of Biosafety and Biosecurity

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Key Concepts for Discussion

- Introduction to basic concepts and technical aspects of biosafety and biosecurity
- Importance of integrating biosafety and biosecurity to appropriately manage biorisks
- Introduction to AMP model of biorisk management
- Introduction to Biorisk Management Advisor (BRMA) and Committee (BRMC)

Laboratory Biosafety Concepts

- **Four different biosafety levels (BSLs) consist of combinations of laboratory practices, safety equipment, and laboratory facilities**

- **Proper assignment of a BSL is determined by a comprehensive risk assessment to include careful consideration of:**

  - Pathogen characteristics (infectious dose, route of transmission, etc.)
  - Procedures (high vs. low risk of aerosol production)
  - Personnel (host immune status)
  - Protective Equipment
  - Laboratory Facility
  - Environment-Agricultural Impact Issues

Laboratory Biosafety Concepts

- **Further consider the nature of the work and potential safety hazards includes**
  - Formation of aerosols
  - Work with large volumes and/or high concentrations of microorganisms
  - Workflow (clean to dirty)
  - Overcrowding and too much equipment
  - Infestation with rodents and arthropods
  - Unauthorized entrance

Laboratory Biosafety Concepts

- **Additional Design Features to be considered are:**
  - Equipment and Furniture
  - Adequate storage
  - Designation of Restricted or Dedicated Areas
  - Ventilation
  - Water Supply
  - Power
  - Security
  - Containment labs

Laboratory Biosecurity Concepts

- **Global events in the recent past have highlighted the need to protect laboratories and the materials they contain from being intentionally compromised in ways that may harm:**
  - People
  - Livestock
  - Agriculture
  - Environment

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Laboratory Biosecurity Concepts

- **Information that can be used to assess level of risk:**
  - Type of organisms available
  - Physical location
  - Personnel who require access
  - Personnel who are responsible
- **Carefully consider site-specific assessment results:**
  - Threat Assessment
  - Vulnerability Assessment
  - Risk Assessment and Management
- **Site-specific laboratory biosecurity program must consider:**
  - Requirements of the facility
  - Type of laboratory work conducted
  - Local conditions

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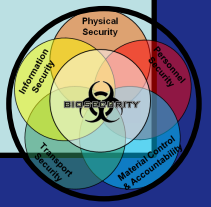
Biosecurity Supports Biosafety

- A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological hazard

Laboratory Biosafety

- A set of preventive measures designed to reduce the risk of intentional removal (theft) of a valuable biological material

Laboratory Biosecurity



- Implement graded levels of protection based on a risk management methodology

Common Biorisk strategy

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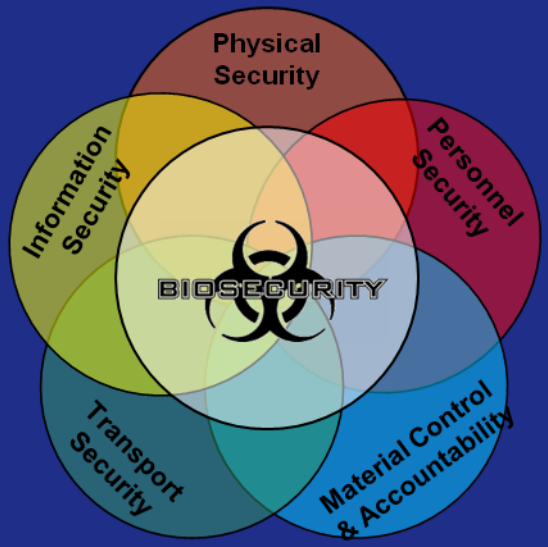
Biosecurity Supports Biosafety

- Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury



- Biosecurity and biosafety should be integrated systems that avoid compromising necessary infectious disease research and diagnostics

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Biosecurity Supports Biosafety

- **Many common elements to managing biosafety and biosecurity risks, such as**
  - Training
  - Manuals, documentation
  - Limiting access
  - Inventories
  - Knowledge of end user prior to shipping materials
  - Determining suitability of persons for job before granting access to the lab

- **Many bioscience laboratories have always protected their materials, protocols, and research**

Biosecurity Supports Biosafety

- **Laboratory biosecurity supports the laboratory biosafety agenda of preventing disease in people, animals, and plants and minimizing the risk of worker injury**

  - Limits the number of individuals who may be exposed to the hazards
  - Limits access to those who are professionally qualified and properly trained to be there
  - Access control procedures and records can be used to support investigations of laboratory safety or security incidents

Laboratory Biosecurity

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Biosafety System

- **Biosafety system components**
  - Microbiological risk assessment
  - Laboratory facility and containment principles
  - Laboratory and Safety Equipment
  - Laboratory work practices
  - Disinfection and sterilization
  - Waste Handling and disposal
  - Emergency procedures
  - Training
  - Program management practices

- **Each component implemented based on results of risk assessment**

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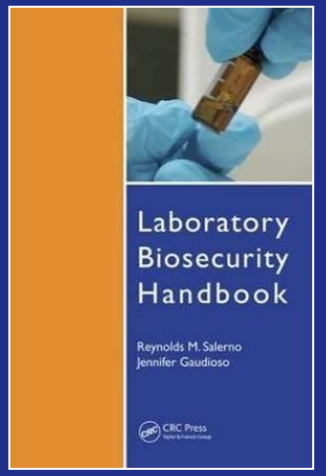
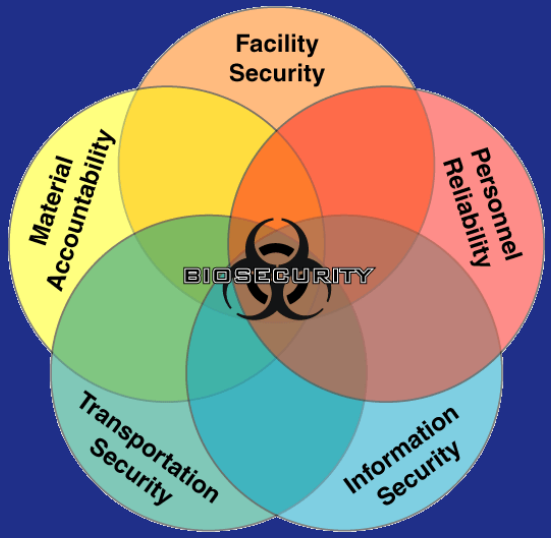
Biosecurity System

- **Biosecurity system components**
  - Physical security
  - Personnel security
  - Material handling and control measures
  - Transport security
  - Information security
  - Program management practices

- **Each component implemented based on results of risk assessment**





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Program Management System

- **Guides and provides oversight to both biosecurity and biosafety**
  - Defines program objectives
  - Ensures program has appropriate resources (financial and staffing)
  - Addresses sustainability of program

- **Delineated in a written plan or manual**
  - Comprehensive guidance
    - **Implementation**
    - **Roles and responsibilities**
    - **Policies and procedures**
  - Incident Response Plan

- **Manuals specific for each institution**
  - Should be based on laboratory-specific risk assessment
  - Standard operating procedures (SOPs)

Biorisk Management Systems

- Provide for the health and safety of laboratory workers and the environment
- Ensure the containment of hazardous infectious substances in laboratories
- Maintain citizens' confidence in the activities of the bioscience research community
- Increase transparency to investors in the biomedical and biotechnology industries
- Protect valuable research and commercial assets and reduce the risks of misuse

Conclusions

- **While technical elements available to biosafety and biosecurity are important, they are not the only consideration**
- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**
- **Risk assessment is the fundamental resource allocation tool**
  - For making decisions about which risks need to be protected against
  - Graded protection commensurate with risk
- **Biosecurity is a key part of laboratory operations**
- **Program management is an overarching component of both biosafety and biosecurity programs**

The probability of a laboratory security incident may be lower than a laboratory safety incident, but the consequences could be significantly greater.

Some Basic Questions

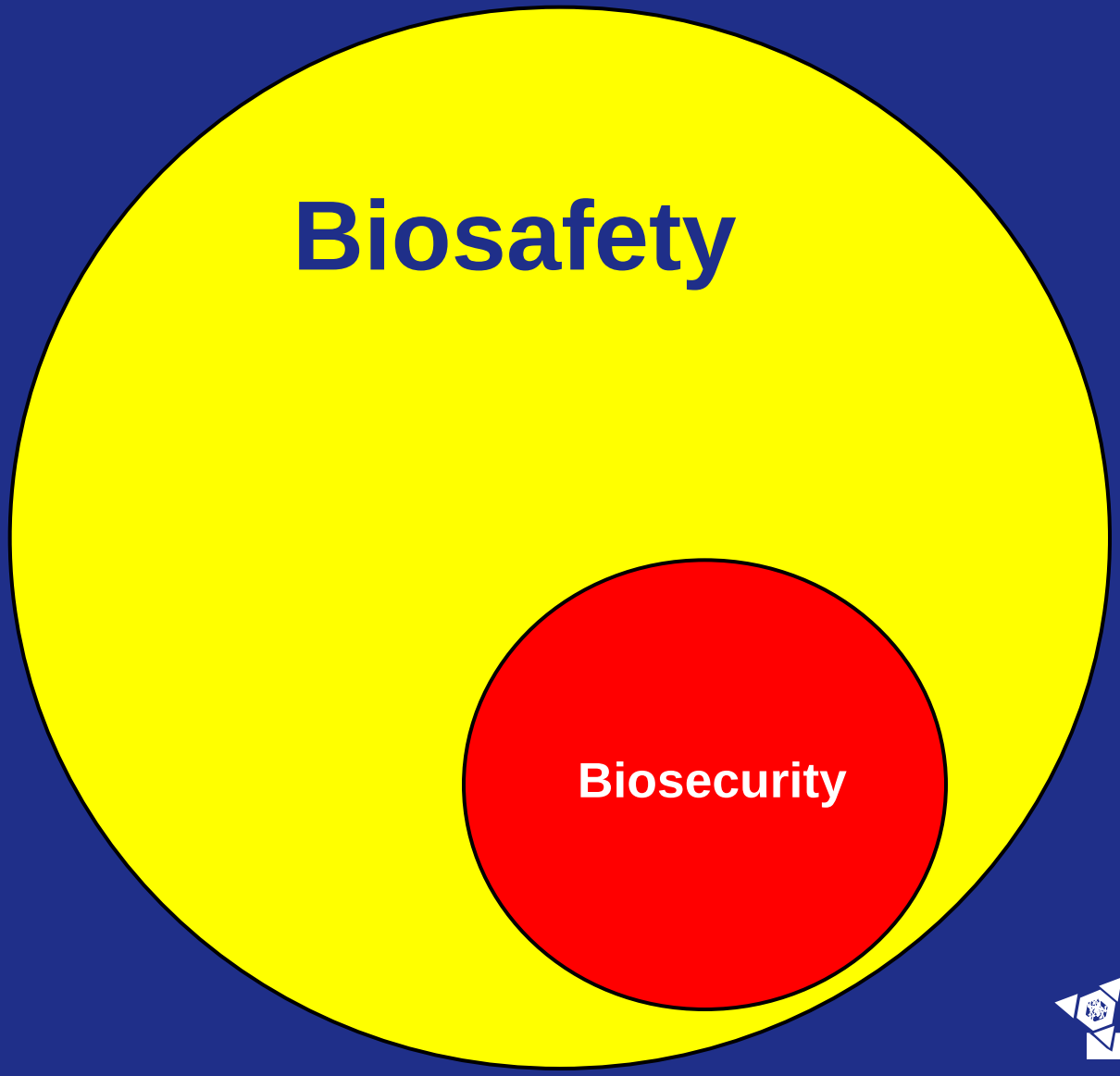
- Limits on who may enter the laboratories?
- Know who works in laboratories with dangerous pathogens?
- Entrust those persons to conduct their jobs well and responsibly?
- Have laboratory workers been appropriately trained to protect themselves, the environment, and the pathogens?
- Maintain and control collections of dangerous pathogens, inside and outside the laboratories?

A never-ending question:

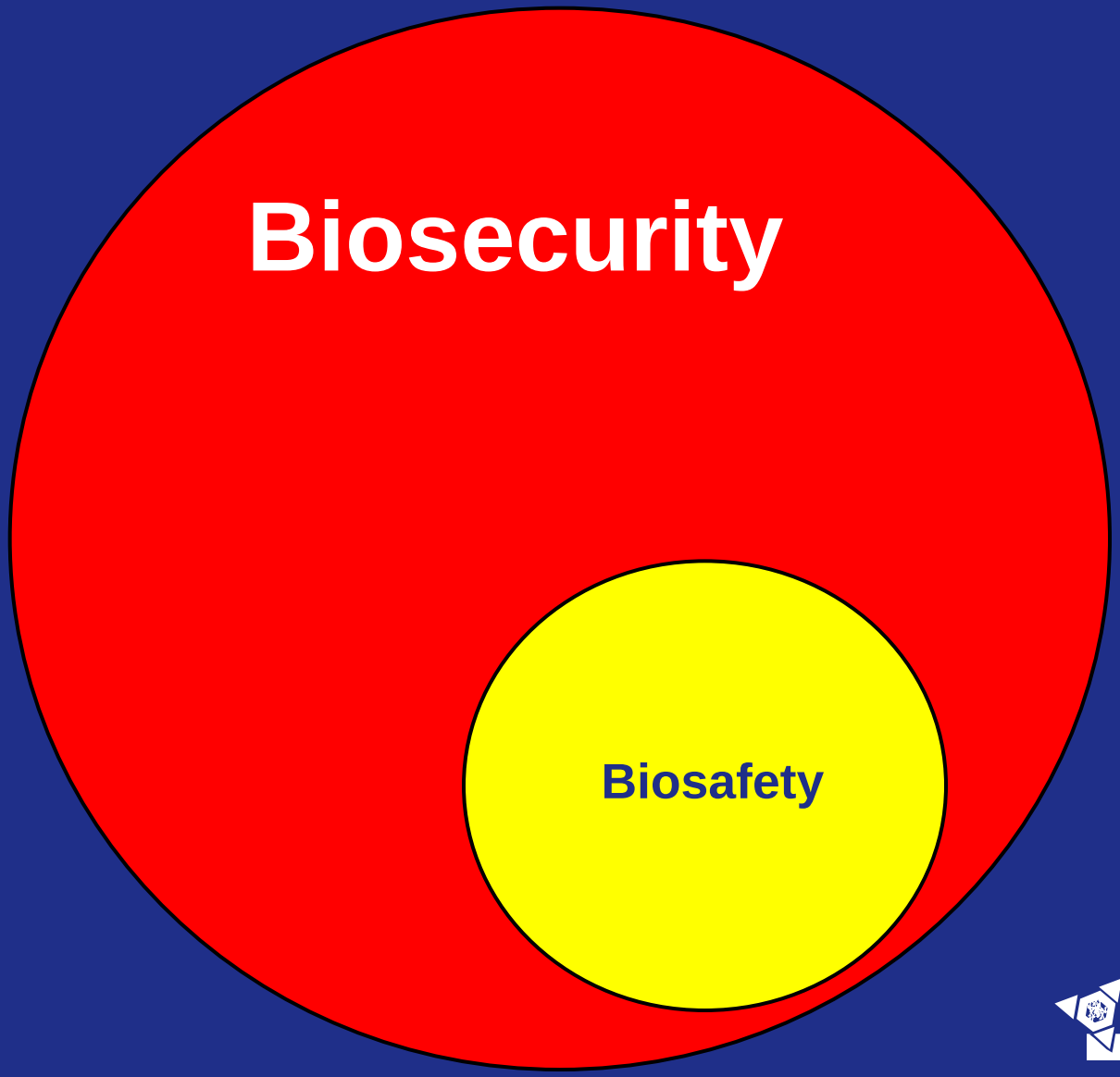
What is more important –

Laboratory Biosafety or Laboratory Biosecurity?

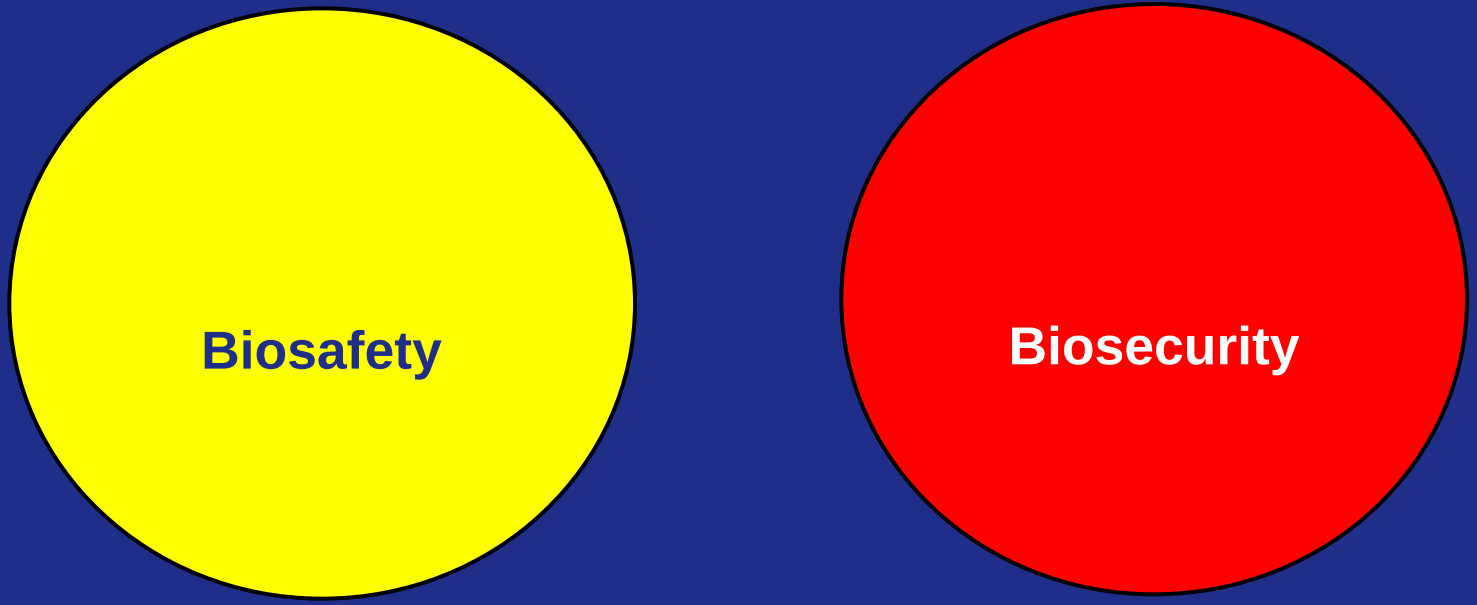
Is Biosafety More Important?



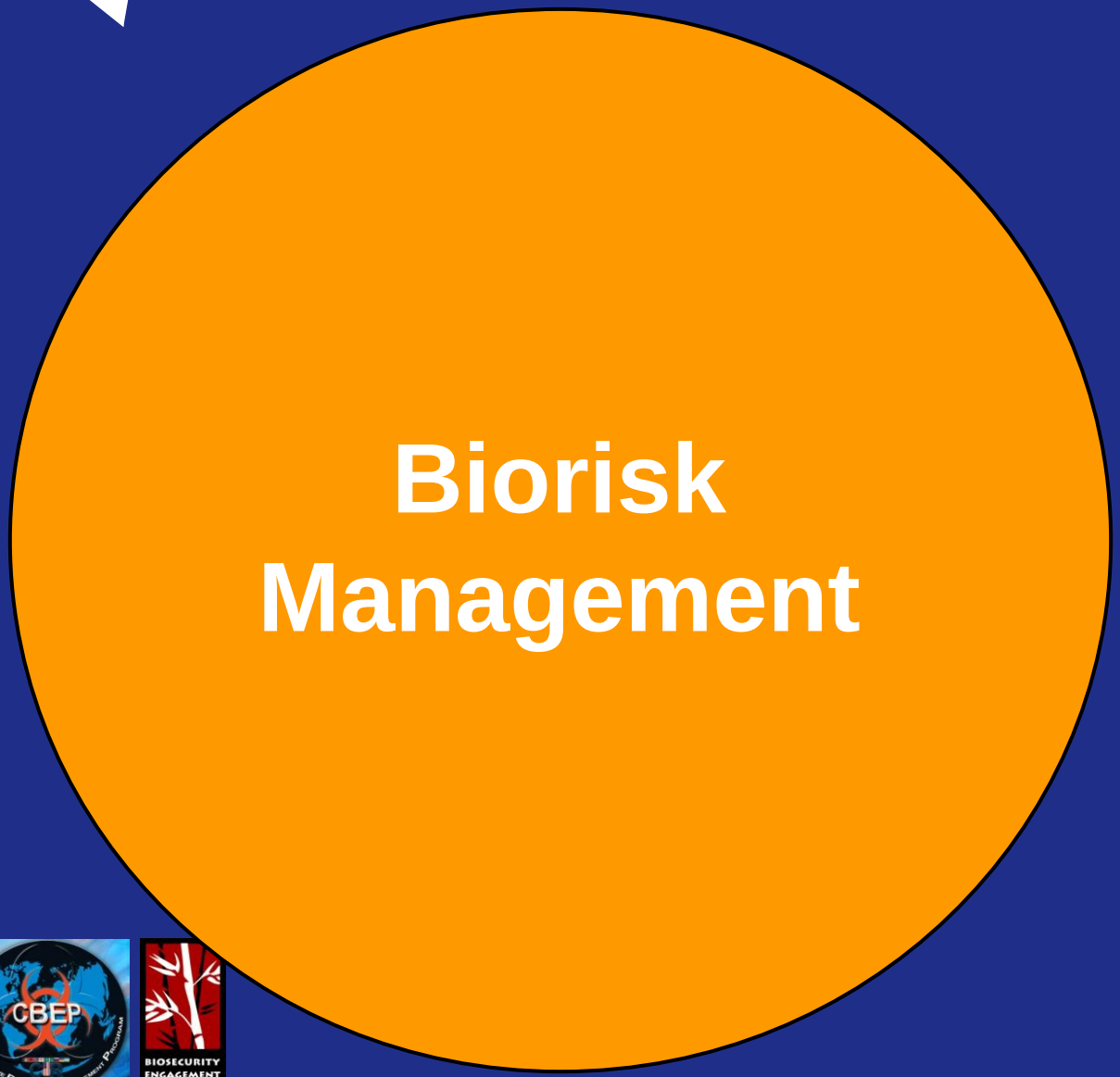
Is Biosecurity More Important?



Are They Separate Yet Equally Important ?



Are They Really Both a Part of a Single Objective?



"Security precautions should become a routine part of laboratory work, just as have aseptic techniques and other safe microbiological practices."

(WHO LBM 3rd edition)

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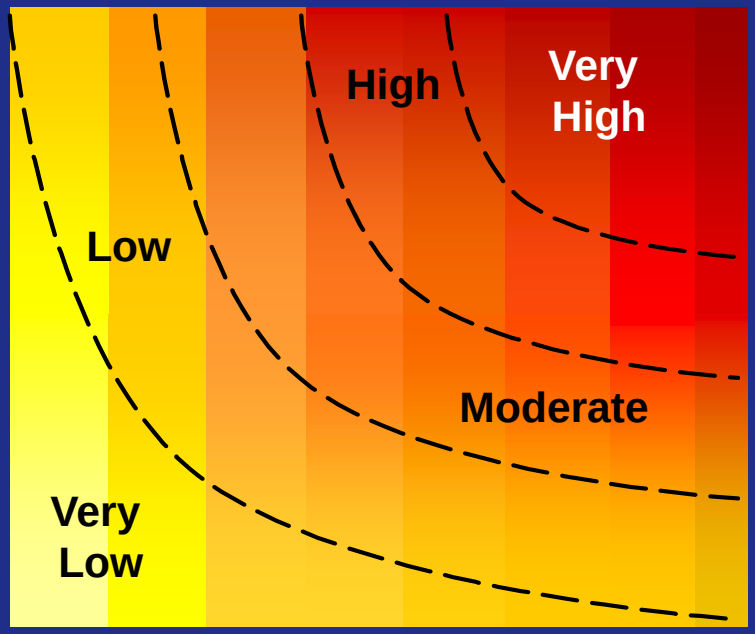
Biorisk Management =
Assessment Mitigation Performance

Hazard ID
Risk Assessment

Biorisk Control Measures
Risk Management

Processes
QA/QC
Objectives

Biorisk Assessment



- Risk of accidental infection to laboratory worker
- Risk of accidental infection to others at the institution
- Risk of accidental infection to outside community
- Risk of accidental infection in animal community
- Risk of theft and malicious use against humans
- Risk of theft and malicious use against animals

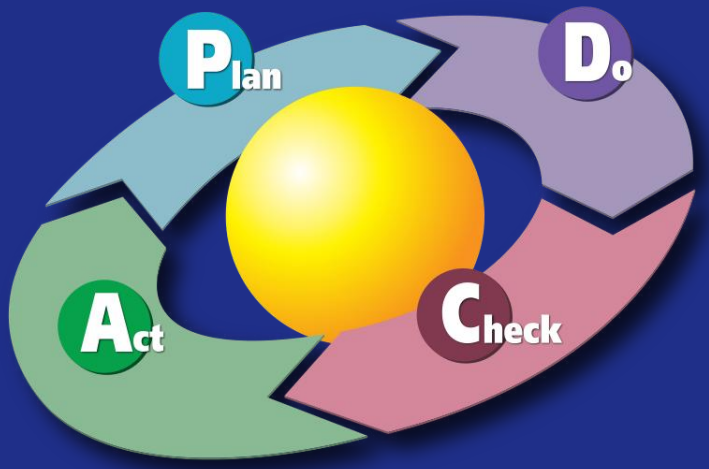
Biorisk Mitigation

- It is common for most laboratories to focus their attention and resources on mitigation, often neglecting assessment and management

- It is crucial to know why a mitigation is in use and if it is working as intended

Biorisk Management and Performance

- A biorisk management system seeks to effectively and efficiently manage an institution's laboratory biorisks
- Relies on a "Plan-Do-Check-Act" approach with the goal of continuous improvement



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Biorisk Management Committee (CWA 15793)

- **A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management, the committee shall:**
  - Have documented terms of reference;
  - Include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken;
  - Ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively;
  - Be chaired by a senior individual;
  - Meet at a defined and appropriate frequency, and when otherwise required.

Biorisk Management Committee (CWA 15793)

- **Functions of the committee should include:**
  - Contributing to the development of institutional biorisk policies and codes of practice
  - Approving proposals for new work or significant modifications to the potential risk associated with existing activities
  - Reviewing and approving protocols and risk assessments for work involving biological agents and toxins
  - Reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs

Biorisk Management Advisor (CWA 15793)

- A competent individual(s) shall be designated to provide advice and guidance on biorisk management issues.
- This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so.
- This role shall be independent of those responsible for implementing the program of work.

Biorisk Management Advisor (CWA 15793)

- **Functions of the biorisk management advisor should include:**
  - Verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed
  - Advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / biorisk management committee
  - Ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other personnel as necessary
  - Advising on biorisk management issues within the organization
  - Contributing to the development and / or delivery of biorisk training activities
  - Ensuring that all relevant activities are performed in compliance with biorisk regulations and that required biorisk authorizations for work are in place

The CEN Workshop 53

- The objective of this CEN Workshop is to define the tasks and competency requirements of the biosafety professional
- Annexes contain model roles, tasks and training specifications
- Accreditation scheme is NOT provided, but may provide a framework to facilitate biosafety professional certification and education

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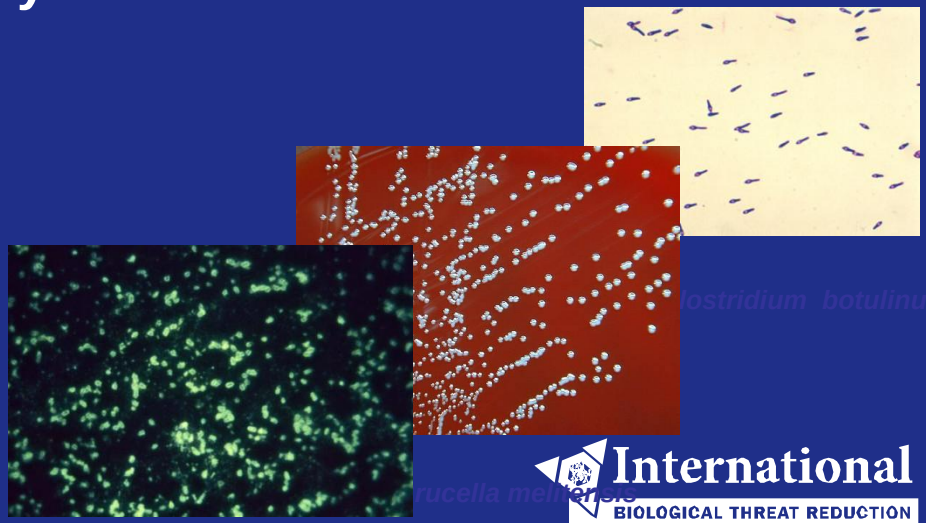
The CEN Workshop 53

- **23 Proposed Core Competencies Include:**
  - General principles of microbiology and cell biology
  - Containment principles
  - Biosafety and biosecurity risk assessment and management
  - Personal protective equipment (PPE)
  - Infection control, disinfection, decontamination and sterilization
  - Biosafety and biosecurity program management
  - Training
  - Communication skills and information / knowledge systems
  - International and national regulatory framework, standards, guidelines and conventions
  - Bioethics
- **Additional 8 Specialized Competencies for work with:**
  - Plants, Animals, Insects, Diagnostics, et .

Conclusions

- **Effective biosafety practices are the very foundation of laboratory biosecurity activities**
- **Effective biorisk management incorporates assessment, mitigation and performance**
- **Biorisk Management Advisor (BRMA) and Committee (BRMC) play essential roles in biorisk program management and need appropriate support and authority commensurate to their responsibility**

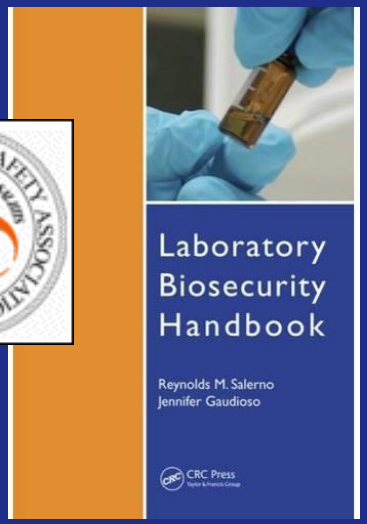


Resources

- **Laboratory Biosafety and Biosecurity Guidance**
  - Laboratory Biosecurity Handbook, 2007, CRC Press
  - WHO Laboratory Biosafety Manual, 3rd edition (Ch 9 is Laboratory Biosecurity)
  - WHO/FAO/OIE joint guidance – *Biorisk Management: Laboratory Biosecurity Guidance, 2006*
  - CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories*
    - **5th edition, 2006, extensive recommendations on biosecurity**
  - Canada's *Laboratory Biosafety Guidelines*, 3rd edition

- **Transport of Infectious Substances**
  - IATA guidance
  - WHO guidance

- **On the Web**
  - Biosecurity Engagement Program: www.BEPstate.net
  - Brazilian Biosafety Association: www.anbio.org.br
  - American Biological Safety Association: www.absa.org
  - Sandia National Laboratories: www.biosecurity.sandia.gov
  - European Biosafety Association: www.ebsa.be
  - Asia-Pacific Biosafety Association: www.a-pba.org



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Discussion and Questions

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Biorisk Assessment and Evaluation

National Awareness Workshop on Improving Biosafety & Biosecurity at Veterinary Research Laboratories in Pakistan

March 1-2, 2011

International Biological Threat Reduction

Sandia National Laboratories

Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

Key Concepts for Discussion

- Risk
- “Safety”
- Assessment of risk

Key Concepts for Discussion - Risk

- **Risk**
  - …is a function of probability and consequence
    - **Risk = *F* (Likelihood, Consequence)**
  - Takes into account several factors
    - **The agent**
    - **Host**
    - **Setting**

Key Concepts for Discussion - Safety

- **“Safety” risk**
  - Impact on human health
  - Release or exposure to a biological material
    - **There are other types of risk (e.g., compliance, security, perceived, environmental)**

Key Concepts for Discussion – Risk Assessment

- **Risk assessment**
  - Many tools are available
    - **HAZOP, HAZARD, SWIFT, BioRAM etc**
  - Most important tool - your brain!
    - **Professional experience**
    - **Judgement**

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Risk = *f* (Likelihood, Consequence)

Hazard, Threat, and Risk

- A **HAZARD** is a source or an object that can cause harm

- A **THREAT** is a person who has intent to cause harm to other people, animals, or the institution

- A **RISK** is the likelihood and consequences of an event with a hazard (or a hazard and threat)

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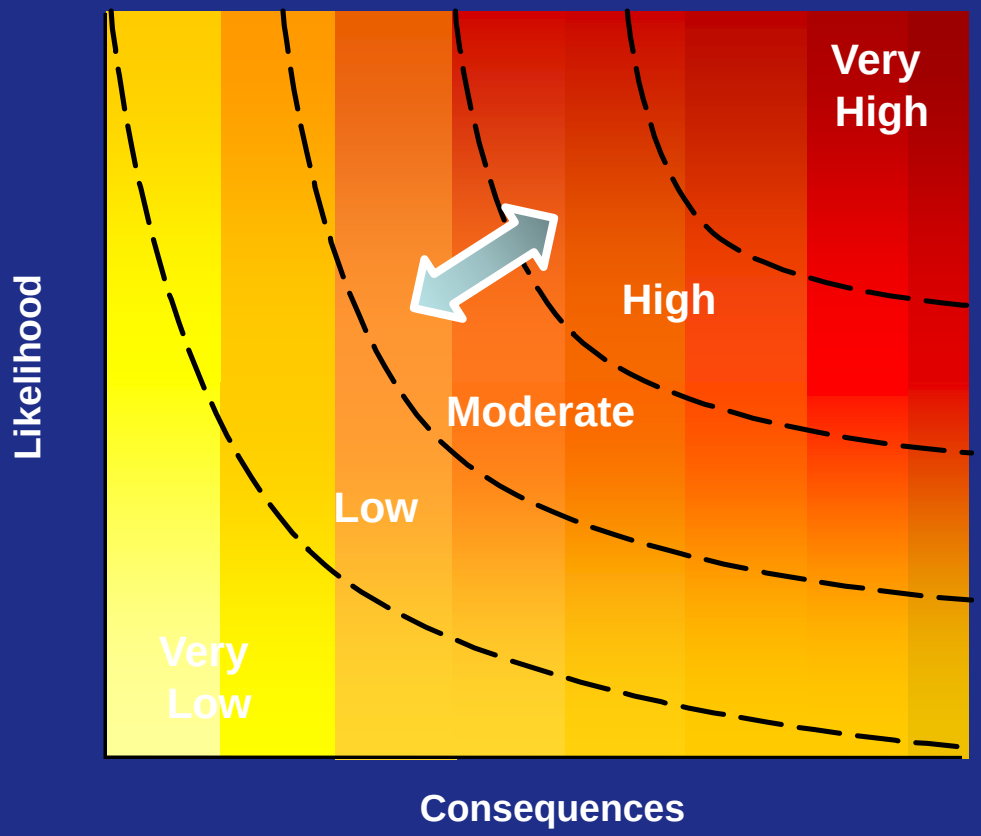
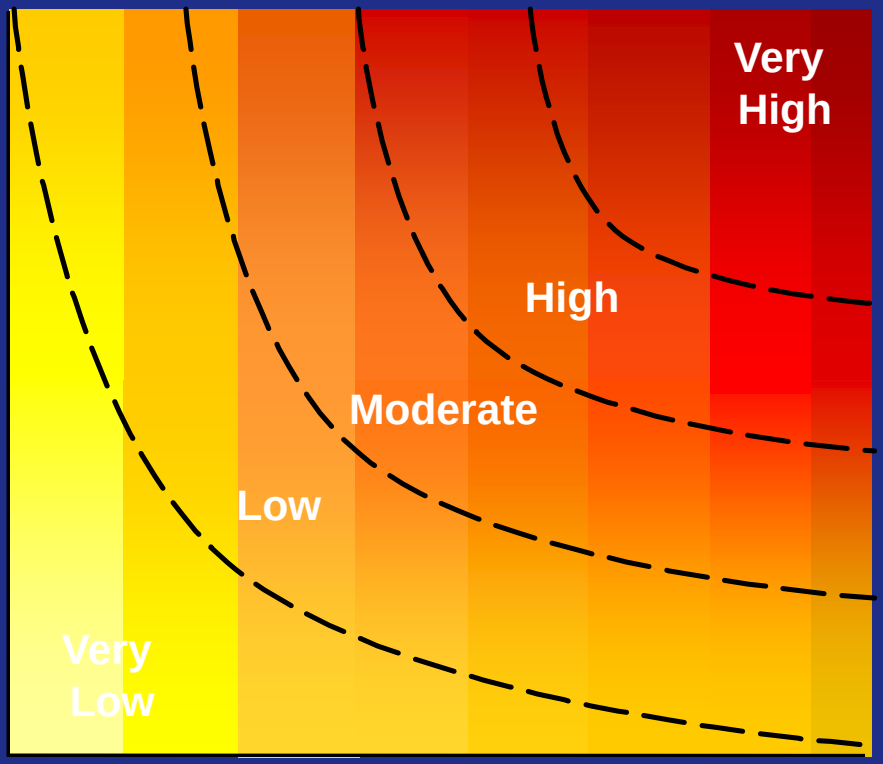
Acceptable risk



Risk when meeting a tiger in nature



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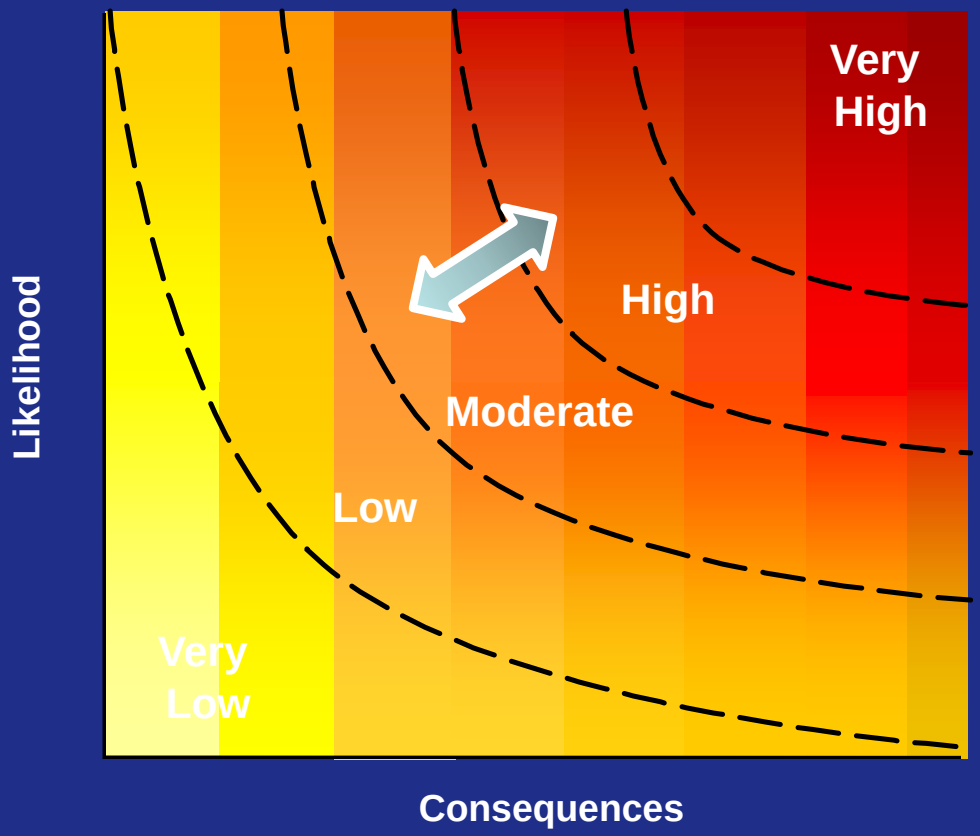
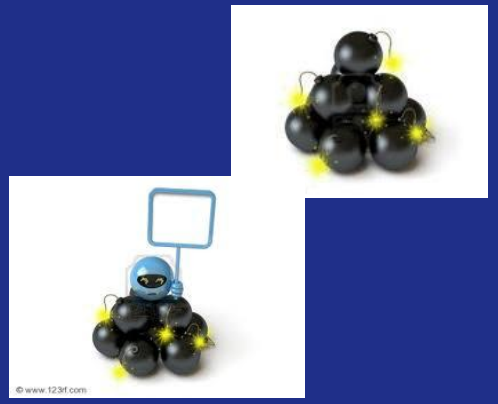
Risk is a function of likelihood and consequences



Risk Definitions

- **Risk Assessment**
  - Identify and explore (quantified terms)
  - Types
  - Intensities
  - Likelihood of the consequences related to a risk
- **Risk assessment comprises**
  - Hazard identification and estimate
  - Risk estimation
  - Exposure
  - Vulnerability assessment



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Risk Definitions

- **Risk Analysis**
  - Risk assessment
  - Risk management
  - Risk communication

Risk Definitions

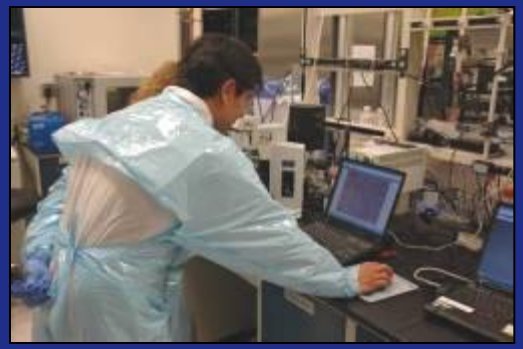
- **Risk Prevention**
  - **Measures to stop a risk being realized;**
  - typically means stopping the activity giving rise to the risk

Risk Definitions

- **Risk Reduction**
  - Measures to reduce the ***level*** of risk
  - Reducing the ***likelihood*** of the risk being realized
  - Reducing the ***impact*** of the risk

Using a Risk Assessment Process

- **A standardized biological risk assessment process allows the risk assessments to be:**
  - Repeatable
  - Quantifiable



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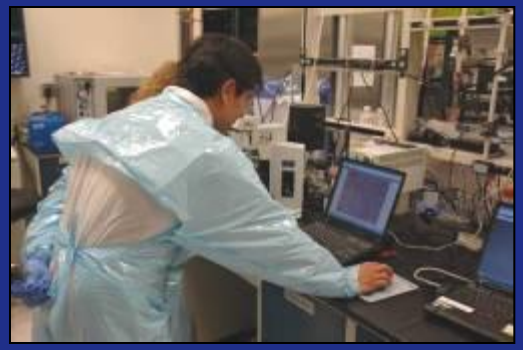
Using a Risk Assessment Process

- **A systematic, standardized approach should include:**
  - Accepted ***criteria*** for assessing the risk
  - A ***standardized approach*** for evaluating the situation against the criteria (“scoring system”)



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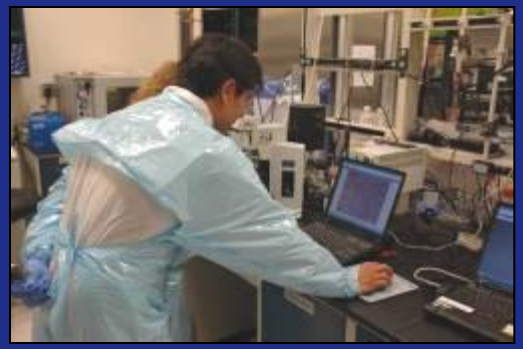
Using a Risk Assessment Process

- **Ideally this process results in a system that:**
  - Allows analysis of the risk to identify driving factors and allow better realization of mitigation measures
  - Enables better communication of risk
  - Help to define what is acceptable risk



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Risk Assessment Principles

- **Define the problem**
- **The problem should drive the choice of method for the assessment**
- **The risk assessment method should be *as simple as possible***
  - Elaborate when needed
- **Those conducting risk assessments should be explicit about uncertainties**
- **Risk assessment methods can incorporate one or more approaches**
- **Document it!**

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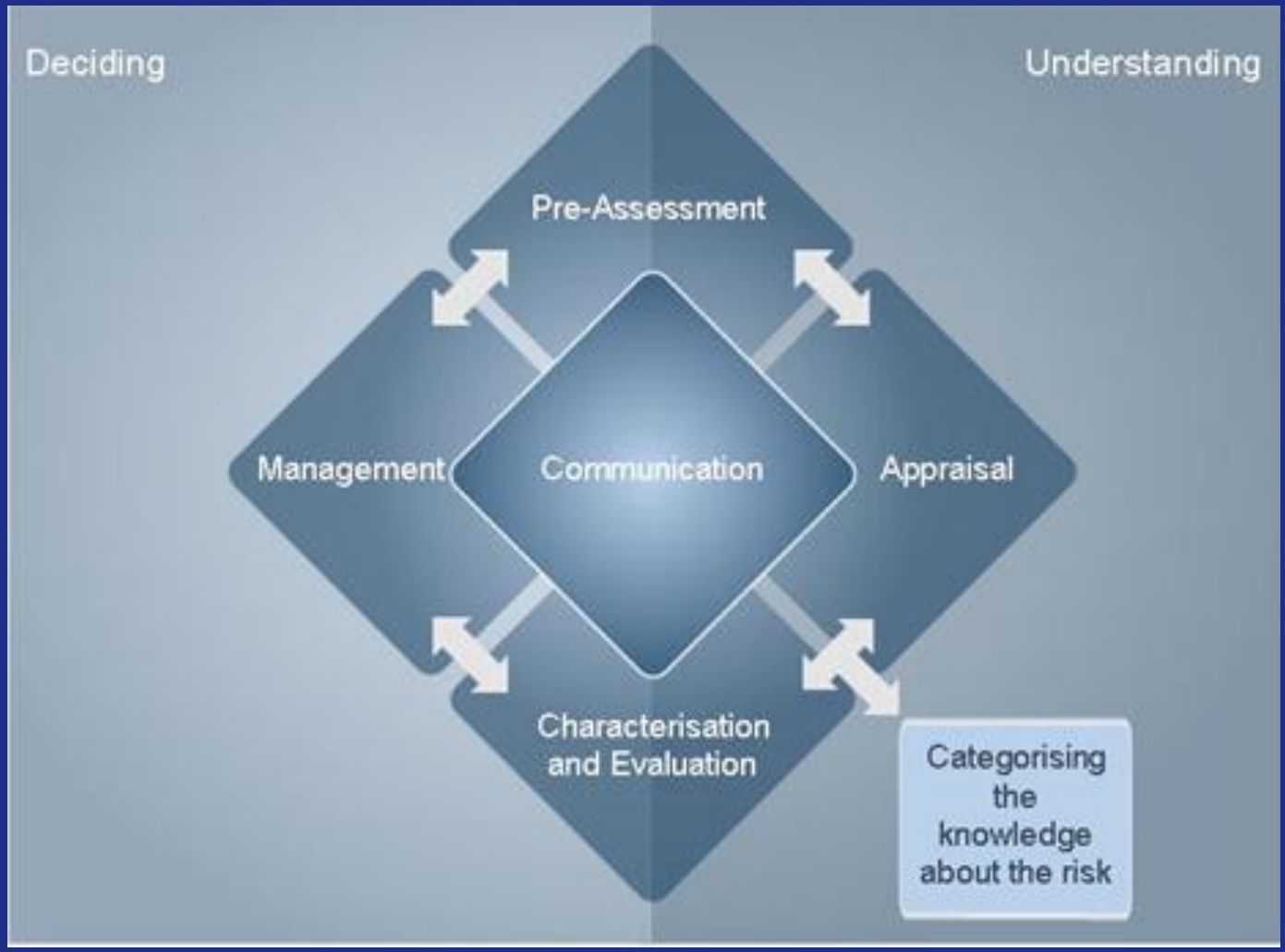
Risk Governance Process



Laboratory Biosafety Risk

- **Likelihood**
  - The likelihood of infection by the agent
  - The likelihood of exposure through an infectious route
    - **- based on the procedures and work practices**

- **Consequences**
  - Of disease from accidental exposure

- **Risks**
  - To laboratory workers
    - **Researchers**
    - **Animal care workers**
    - **Technicians**
    - **Engineers**
  - Risk of accidental exposure to community
  - Risk of accidental exposure to animal community

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Likelihood of infection

- **Routes of infection of the agent (and infectious dose via that route)**
  - Inhalation
  - Ingestion
  - Contact
  - Percutaneous
  - Vector-Borne
- **Stability of the agent**
- **Infection mitigation measures (existence of prophylaxis)**

Likelihood of exposure (based on the routes of infection)

- **Potential of inhalation exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of ingestion exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of percutaneous exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures
- **Potential of contact exposure to laboratory workers and to the community**
  - Procedures
  - Mitigation measures

Consequence of disease

- **Agent properties**
- **Morbidity**
- **Mortality**
- **Consequence mitigation measures**
- **Potential for secondary transmission**
  - Communicability (host to host)
  - Transmissibility (route of infection between hosts)

Laboratory Biosecurity Risks for Dangerous Pathogens

- **Likelihood**
  - The likelihood of ***theft*** from a facility
  - The likelihood an agent can be ***used as a weapon***
- **Consequences**
  - Of a bioattack with the agent
- **Risks**
  - Persons in area of attack
  - Persons in larger community from secondary exposure
  - Animals in area of attack
  - Animal in larger community from secondary exposure

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Conclusions

- **Risk assessment and risk decision are *the critical foundations* for the design of a laboratory biosafety and biosecurity program**
- **Technical risk assessments generally do not include perceived social, cultural, political concerns and risk acceptance will depend on the 'owner' of the risk: risk averse or risk tolerant**
- **A systematic, standardized biological risk assessment process enables:**
  - The analysis of the risk to identify driving factors and allow better realization of mitigation measures
  - Enables better communication of risk
  - Helps to define what is acceptable risk
- **Biorisk can be strengthened by standard risk governance approaches**

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So, how should a laboratory biorisk assessment be conducted?

Traditional Biorisk Assessment Methods

- **Typical risk assessment approaches use pure opinion to define the risk**
  - Lacks ability to repeat
  - Can not be compared
  - Difficult to communicate
- **Laboratories often default to regulations to define biorisk practices**

Pure Quantitative Risk Assessment?

- **In a quantitative scheme, the risk assessor assigns numerical values to the likelihood and consequences of the adverse event**
  - All data in the model should be quantitative

- **For laboratory biorisks, currently there is limited data to numerically define the probability of an infection, exposure, release, theft, or loss**

- **Likewise, there is limited data existing to quantify the consequences of disease**

Key things to think about regarding biorisks

- **Biorisk and scientific expert opinions are valuable**
- **The overall biorisk(s) for any process is made up of multiple factors**
  - Agent factors like route of infection, impact of disease on a host, etc
  - Laboratory factors like equipment in use, animals in use, in place biosafety practices, etc
  - Environmental factors like susceptible hosts, endemicity, etc
  - Threats for intentional (biosecurity) risks
- **Not all factors impact the risk in the same way**

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One risk assessment option

- **Multiple criteria decision making has been widely accepted as a method to capture, compare, and aid in complex decision making processes**
- **Criteria can be organized in terms of likelihood and consequence**
  - And can be arranged in a hierarchy by relationships
- **Criteria can be weighted to reflect the variance of impact**
- **Criteria can be defined using absolute values**

Laboratory Biosafety Risk Assessment Project (Biosafety RAM)

Risk = *f* (Likelihood, Consequence)

- **Likelihood**
  - The likelihood of infection by the agent and the likelihood of exposure through an infectious route based on the procedures and work practices
- **Consequences**
  - Of disease from accidental exposure
- **Risks**
  - To laboratory workers
  - Risk of accidental exposure to human and animal community
  - Risks of secondary infection

LDRD LABORATORY DIRECTED RESEARCH & DEVELOPMENT

Public Health Agency of Canada / Agence de la santé publique du Canada

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NIID NATIONAL INSTITUTE OF INFECTIOUS DISEASES

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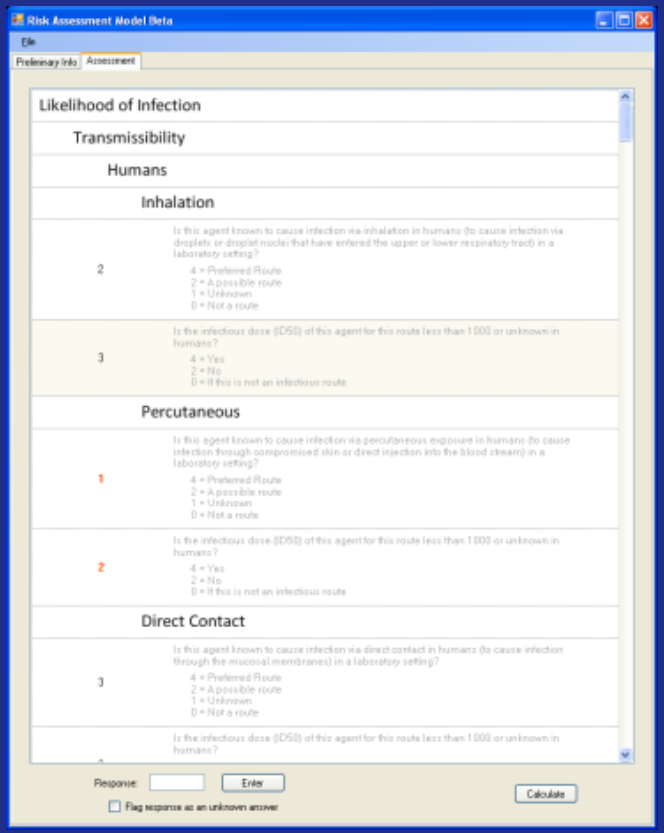
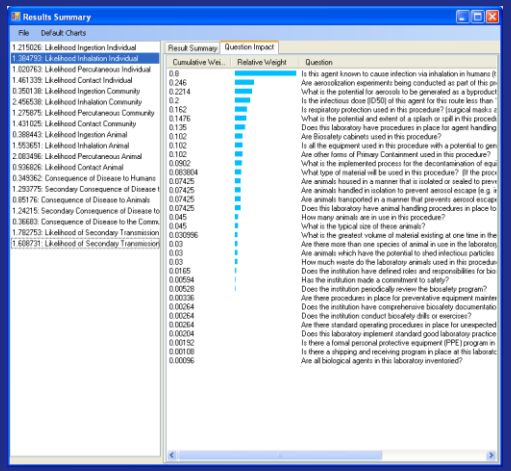
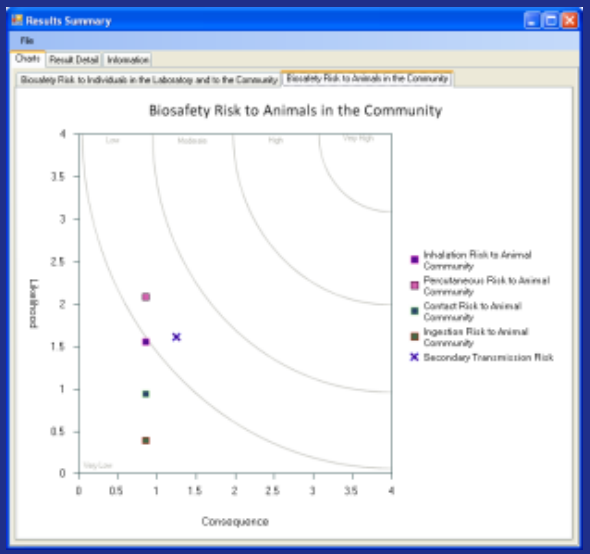
Biosafety RAM

- **Risks based on routes of exposure**
  - Inhalation
  - Ingestion
  - Contact
  - Percutaneous







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Laboratory Biosecurity Risk Assessment Project (BioRAM)

Risk = *f* (Likelihood, Consequence)

- **Likelihood**
  - The likelihood of targeting a laboratory based upon the agent's potential for malicious use and the likelihood of successful acquisition of the agent from the laboratory
- **Consequences**
  - Of disease from malicious release
- **Risks**
  - Risks to human and animal community

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Conclusions

- **There are multiple risk assessment models and methods which can be used to conduct biorisk assessments**

- **The key points for conducting a risk assessment are:**
  - Risk is a function of both the likelihood and the consequences
  - Regulations or risk group definitions are not enough
  - A risk assessment should be repeatable, comparable, and support risk management decision making

- **The approach used should clearly answer the question**
  - What is the risk of a laboratory acquired infection to someone working on this research project in my lab?
  - What is the risk of an environmental exposure from this research project?
  - What is the risk of theft of this valuable biological material from my laboratory?

Discussion and Questions

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Biorisk Mitigation Measures

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Key Concepts for Discussion

- The need to conduct risk assessment prior to mitigation measure selection
- Escalating hierarchy of controls for risk mitigation
- Human error, poor laboratory techniques and misuse of equipment cause the majority of laboratory injuries and work-related infections
- The most important element of safe work with biohazards is strict adherence to good microbiological practices and techniques
- Employees must be aware of the potential hazards and trained and proficient in the proper work practices for safely handling biohazards

Technique vs. Technology

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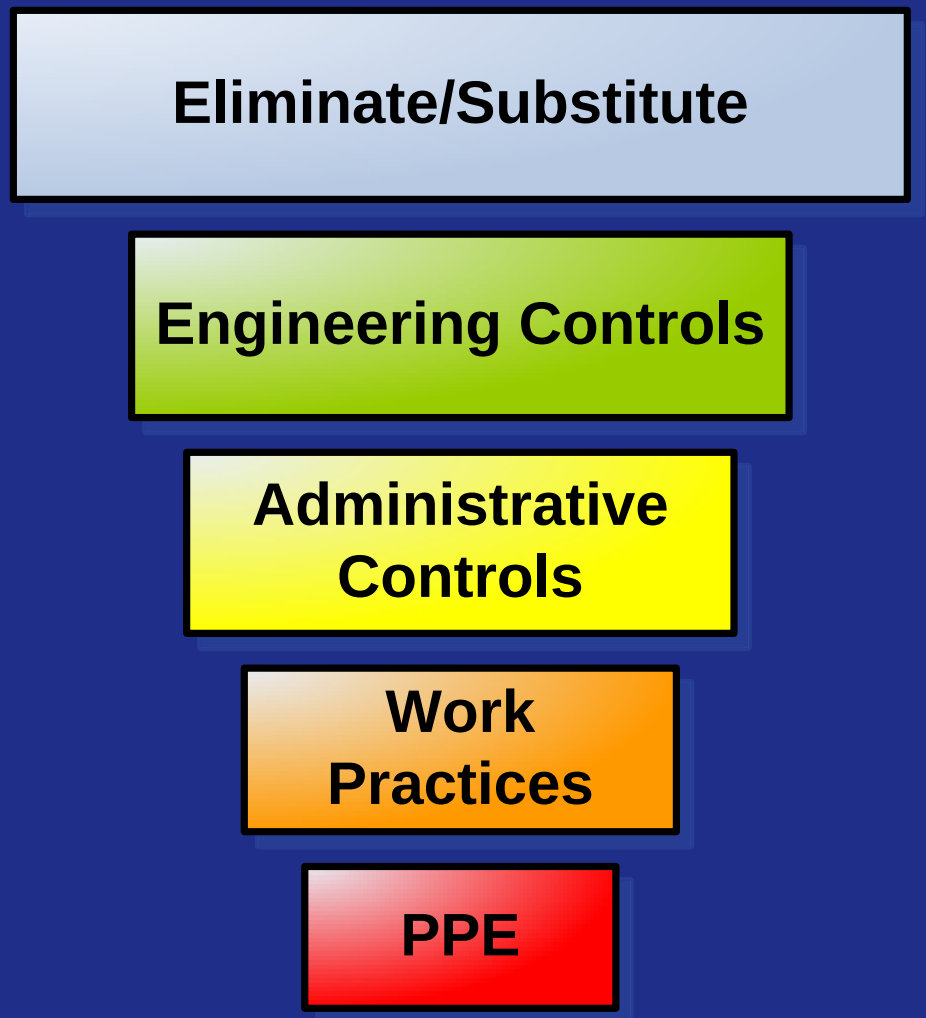
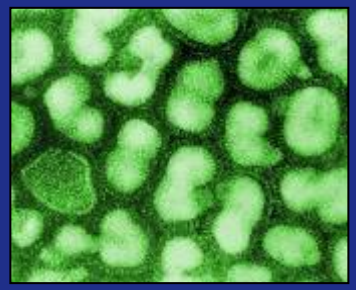
Hierarchy of Controls for Risk Management



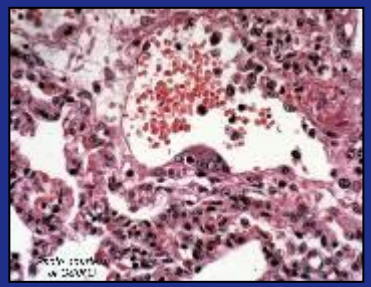
Examples of Elimination/Substitution

- **Reducing the quantity of pathogenic material handled**
  - Utilization of assays and technology that do not involve propagation or culture
- **Actions to reduce the risk associated with the biohazard by using a different or altered agent**
  - Less pathogenic species
  - Attenuated strains
  - Genetically modified organisms
  - Fragments of the organism or agent



Avian influenza virus

SARS virus



Nipah virus in pig lung

Bacillus anthracis

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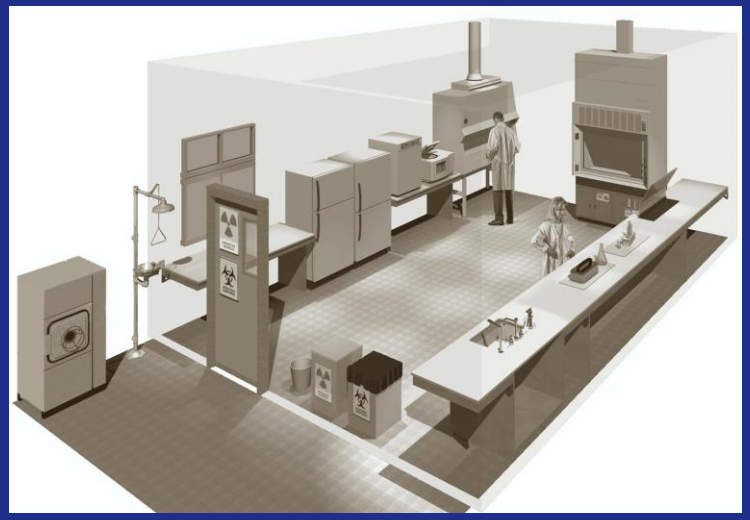
Definitions for Mitigation Control Measures

Engineering Controls	• *Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards*
Administrative Controls	• *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*

Examples of Biosafety Engineering Controls

- **Primary Containment**
  - BSC
  - Sealable Containers including rotor cups
  - Cages
- **Secondary Containment**
  - Facility layout and construction
  - Airflow
  - Doors (with locks and access controls)
  - Sealable rooms
- **Waste**
  - Autoclave/Incinerator
  - Sharps Container



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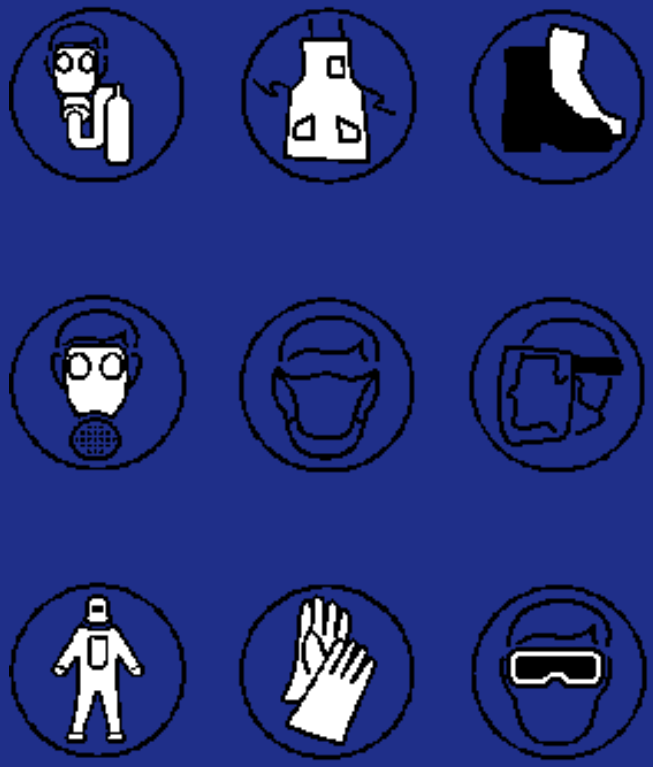
Examples of Biosafety Administrative and Procedural Controls

- **Personnel Management**
  - Training
  - Integrity verification
  - Medical clearance and Occupational Health
- **Good Lab Practices**
  - No eating or drinking /No mouth pipetting
  - Hand washing
  - Spill cleaning / standard cleaning
  - Sharps handling
  - Aerosol prevention
  - Inventory
  - Documentation
  - Waste handling
  - Entry and Exit procedures

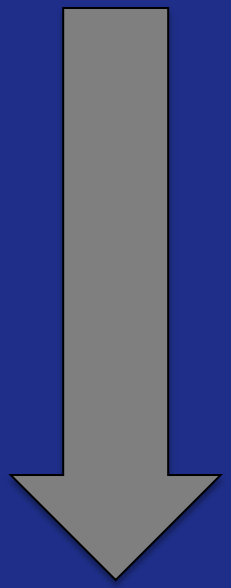
Examples of Personal Protective Equipment (PPE)

- Gloves
- Coats
- Gowns
- Shoe covers
- Boots
- Face shields
- Safety glasses
- Goggles
- Respirators



Advantages/Disadvantages

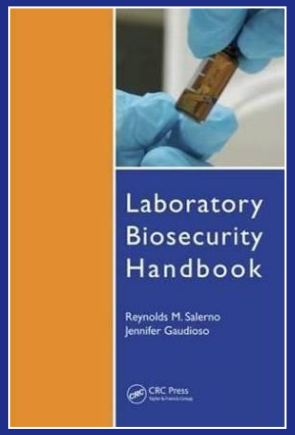
Control Measure	Advantages	Disadvantages
Elimination or Substitution	Most effective at removing risk	May not be feasible, or may impede laboratory work
Engineering	Efficient, eliminates hazard	Cost, complexity
Administrative	Authority approach	Indirect approach, primarily addresses the human factor
Practices & Procedures	SOP based (standardized approach)	Training and supervision requirements
PPE	Ease of use, relative cost	Does not eliminate hazard, PPE fails exposure happens, uncomfortable, limits ability

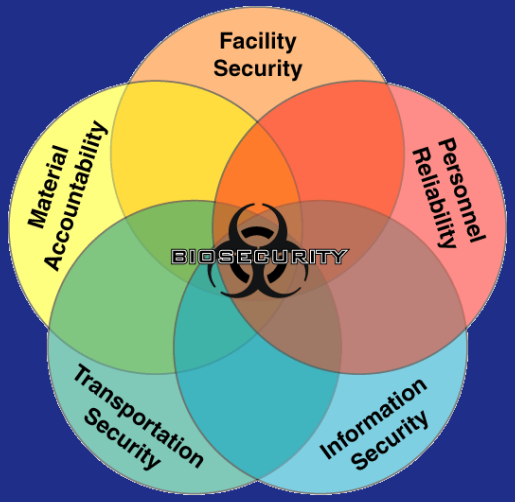


Biosecurity Systems

- **Biosecurity system components**
  - Physical security
  - Personnel security
  - Material handling and control measures
  - Transport security
  - Information security

- **Each component implemented based on results of risk assessment**



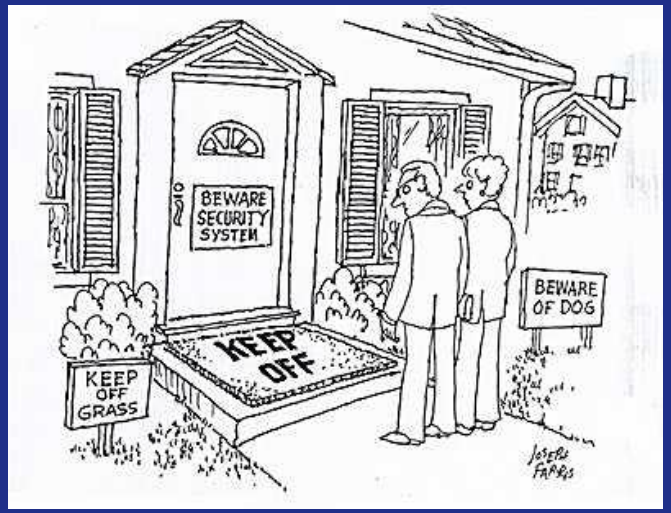


Elements of a Physical Security System

- Graded protection
- Access control
- Intrusion detection
- Response force

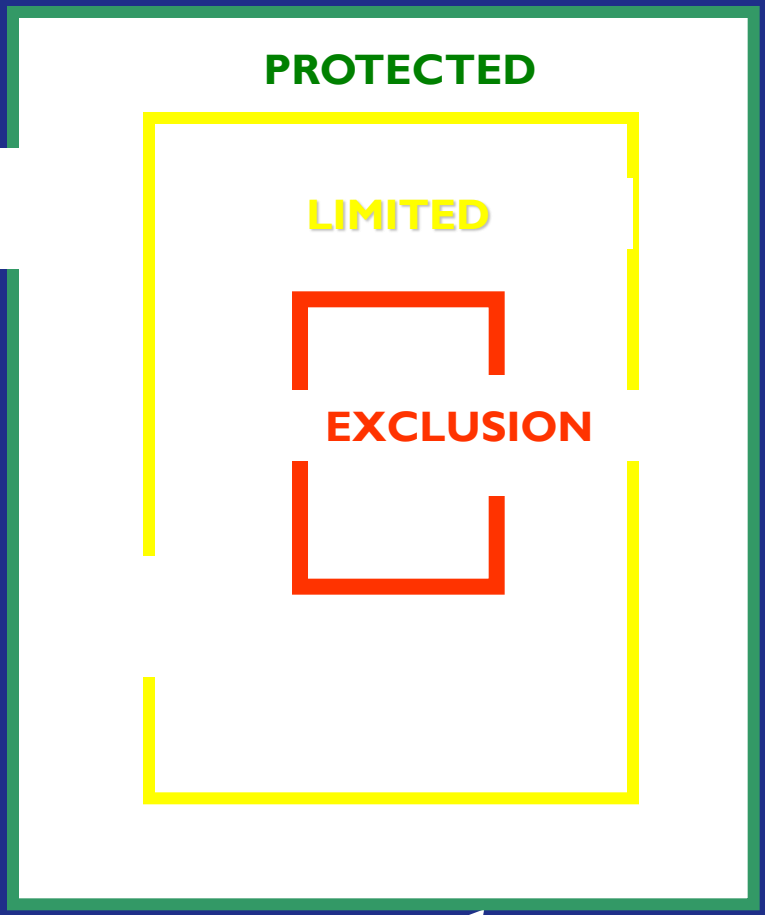
Define System Objectives

- **There must be a security system strategy:**
  - Deny: prevent adversary from gaining access to particular pathogen or toxin
  - Contain: prevent adversary from leaving facility while in possession of stolen pathogen or toxin
  - Deter: discourage adversary from stealing a particular pathogen or toxin by making theft of that agent appear very difficult



Graded Protection for Bioscience Laboratories

- **Property Protection Areas**
  Low risk assets
- **Limited Areas**
  Moderate risk assets
- **Exclusion Areas**
  High risk assets



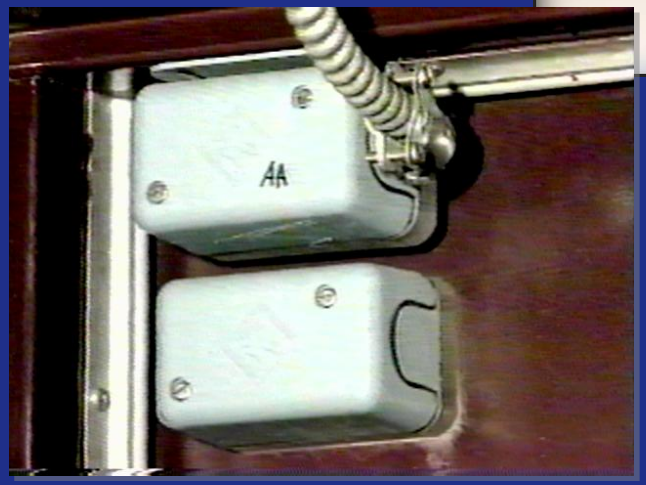
Basis of Access Controls

- **Allow entry of Authorized persons**
- **Prevent entry of Unauthorized persons**
- **Allow exit of Authorized persons**

- **Something you have**
  - Key
  - Card
- **Something you know**
  - Personal Identification Number (PIN)
  - Password
- **Something you are**
  - Biometric feature (i.e., fingerprints, face)

Intrusion Detection

- **Detect unauthorized access**
- **Many types of intrusion detection**
  - Personnel notice unauthorized access
  - Electronic Sensor



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Response Force

- **On-site guard force**
  - Patrols perimeter and buildings
  - Summons and directs local law enforcement
  - Deters
  - Can be the primary response depending on the motives of the adversary
  - Information gathering for secondary response

- **Local law enforcement**
  - Secondary response
  - Reinforce on-site guard force
    - **Respond according to plan when summoned**
    - **Equipped and authorized to confront adversary**

Personnel Security

- **Personnel Screening**
  - Help to judge a person's integrity to reduce the risk of theft, fraud or misconduct
  - In-processing, during employment, out-processing procedures
- **Badges**
  - Issued to authorized individuals accessing restricted areas
- **Visitor Control**
- **Training**

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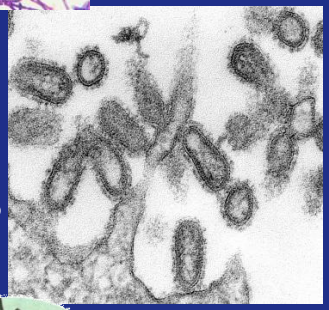
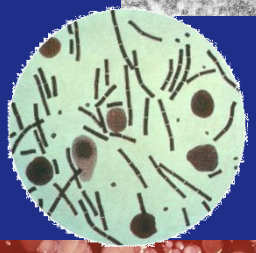
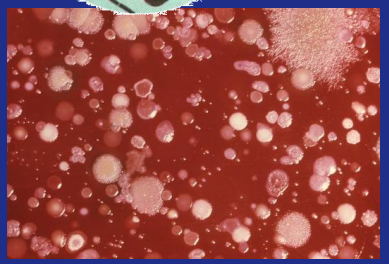
Material Handling and Control Measures

- **Ensure complete and timely knowledge of:**
  - What materials exist
  - Where the materials are
  - Who is accountable for them
  - NOT: to detect whether something is missing



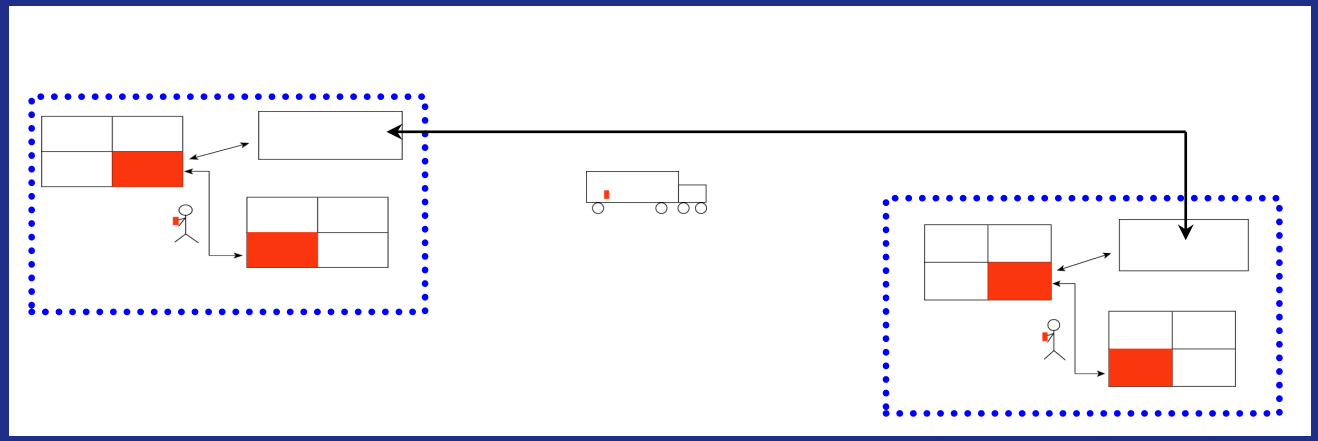
- **The operating procedures associated with the materials**
  - Where they can be stored and used
  - How they are identified
  - How inventory is maintained and reconciled
  - Documentation and reporting requirements





Transport Security

- **Transport – movement of biological material outside of a restricted area**
- **Transport can occur**
  - Across international borders
  - Within a country
  - Within a facility
- **Protection while in transport should be comparable that in the restricted area**
  - May require a documented chain of custody



Information Security

- **Protect information that is too sensitive for public distribution**
  - Label information as restricted
  - Limit distribution
  - Restrict methods of communication
  - Implement network and desktop security
- **Biosecurity-related sensitive information**
  - Security of dangerous pathogens and toxins
    - **Risk assessments**
    - **Security system design**
  - Access authorizations

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Conclusions

- **Implementing biosafety and biosecurity mitigation controls**
  - Should first consider elimination or substitution
  - A combination of control measures should be used based on their effectiveness and your ability to implement them
  - Should be based on the results of the risk assessment to a minimum, acceptable level of risk
- **Compliance with proper work practices is the most important aspect of containment**
- **Work practices can be used to build redundancy in protection**
- **Proper mentoring and proficiency demonstration are key for compliance**

Discussion and Questions

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Developing Biorisk Management Programs at Veterinary Laboratories and Institutions

National Awareness Workshop on Improving Biosafety & Biosecurity at Veterinary Research Laboratories in Pakistan

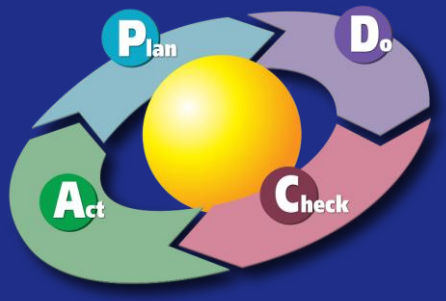
March 1-2, 2011

International Biological Threat Reduction
Sandia National Laboratories

Sandia National Laboratories is a multi-program laboratory managed and operated by Sandia Corporation, a wholly owned subsidiary of Lockheed Martin Corporation, for the U.S. Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

Key Concepts for Discussion

- **Biorisk management system implementation (CWA 15793)**
  - Plan, Do Check, Act



- **Utilization of AMP Performance Systems**
  - Maximize protection of valuable biological materials
  - Foster a culture of awareness and compliance

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Biorisk Management =
Assessment Mitigation Performance

Hazard ID
Risk Assessment

Biorisk Control Measures
Risk Management

Processes
QA/QC
Objectives

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Processes
QA/QC
Objectives

How Do You Avoid Biorisk Management Problems at Your Institution?

- **Laboratory biorisk management programs need:**
  - Appropriate resources
  - Institutional guidelines and operating procedures
  - Training
  - Oversight

- **But… How do you:**
  - - decide to allocate your scare resources?
  - - determine what needs to be addressed in operating procedures?
  - - determine which training is required for whom?
  - - determine what level of oversight is appropriate?

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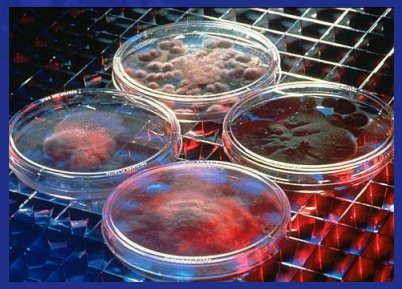
What is Program Management?

- **A laboratory program which seeks to effectively and efficiently manage an institution's laboratory biorisks**
- **Effective program management is central to the success of implementing biosafety and biosecurity in any laboratory!**
- **Laboratory biorisk management programs need:**
  - Resources
  - Institutional guidelines and operating procedures
  - Training
  - Oversight



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Biosecurity Engagement Program

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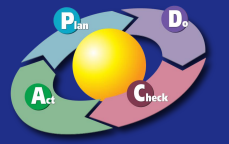
Program Management Roles and Responsibilities

- **Numerous stakeholders in program management**
  - Ensure each component of biosafety and biosecurity are implemented and function optimally
  - Thoroughly understand and implement the risk assessment process
  - Decide which risks should be mitigated, and allocate resources accordingly
  - Clearly delineate the roles and responsibilities of laboratory personnel

Biorisk Management Systems Approach



- **All rely on a "Plan-Do-Check-Act" approach with the goal of continuous improvement**

- **Plan**
  - Planning, including identification of hazards and risks and establishing program goals
- **Do**
  - Implementing, including training and operational issues
- **Check**
  - Checking, including monitoring and corrective action
- **Act**
  - Reviewing, including process innovation and acting to make needed changes to the management system.

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Plan

- Define specific Biorisk Program objectives
- Ensure compliance with all national and international requirements
- Effectively allocate limited resources to address highest risks first
- Perform a risk assessment
- Make risk mitigation decisions

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Do

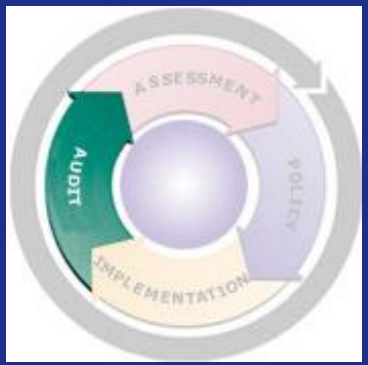
- **Determine roles and responsibilities**
  - Biorisk manager
  - Scientific manager
  - Biorisk management committee
  - Top management
  - Employees
  - Technical staff, maintenance

Do

- **Provide standard training**
  - Although this is NOT sufficient
- **Provide personnel knowledge and skills**
- **Implement training initiatives**
- **Implement risk mitigation measures**
- **Perform Facility maintenance**

Check

- Biorisk management program must be documented
- Documents need to be reviewed and updated at regular intervals, and after any incidents
- Regular audits are vital tools to assess program effectiveness, and evaluate opportunities for improvement



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Internal Inspections: Discussion

- What are the objectives of an internal inspection?
- What should an internal inspection focus on?
- Who should carry out an internal inspection?
- With what frequency?
- How should the results of internal inspections be communicated, documented, and followed up?

External Inspections: Discussion

- What are the objectives of an external inspection?
- What should an external inspection focus on?
- Who should conduct external inspections?
- What triggers an external inspection? With what frequency are they carried out?
- How should the results of external inspections be communicated, documented, and followed up?

Act

- **Biorisk management program should be regularly reviewed and updated**

- **Review information should include**
  - Audit results
  - Work activities
  - Status of risk assessment activities
  - Status of preventative and corrective actions
  - Follow-up actions from previous management reviews
  - Results of incident investigations
  - Changes that could impact program

- **Review should lead to decisions and actions to improve**

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System Effectiveness: Discussion

- **What metrics might be used to measure the effectiveness of a facility's risk management system?**
  - Management performance indicators?
  - Operational performance indicators?
  - Biorisk status indicators?
- **Can the same metrics be used for biosafety and biosecurity?**

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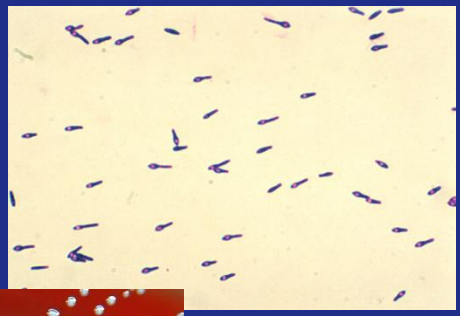
Conclusions

- **Program management is an overarching component of both biosafety and biosecurity programs!**

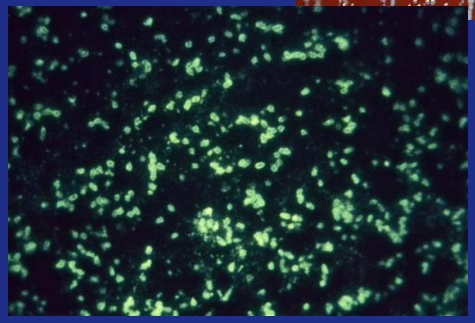
- **Ensures success of the programs by**
  - Planning
  - Staffing
  - Funding
  - Training

- **Should address every element of the biorisk program**



Clostridium botulinum

Brucella melitensis



Yersinia Pestis

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What program management systems and resources are available for biorisk?

Laboratory Biorisk Management Standard
CWA 15793:2008

- **International Approach**
  - Not country specific
  - Based on international acceptable best practices
  - Local solutions possible
  - The Standard is based around the current WHO Biosafety and Biosecurity Guidelines
  - Contains definitions, requirements and notes for guidance
  - Consistent with other international standards
    - **ISO 9001 / 14001 and OSHAS18001**


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Laboratory biorisk management standard

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Laboratory Biorisk Management Standard
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- **Management System Standard**


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  - The Standard is <u>not</u> a technical document
  - The Standard is Performance oriented
  - Describes what needs to be achieved
  - How to do It … is up to the organization
  - The Standard is not intended to replace any national or sub-national regulatory requirements that may apply to the laboratory/facility
  - Compliance with regulatory requirements is mandatory

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Laboratory Biorisk Management Standard
CWA 15793:2008

- **Examples of topics covered:**
  - Biorisk Management Policy
  - Hazard identification, risk assessment and risk control
  - Roles, responsibilities and authorities
  - Training, awareness and competence
  - Operational control
  - Emergency response and contingency plans
  - Inventory monitoring and control
  - Accident and incident investigation
  - Inspection and audit
  - Biorisk management review


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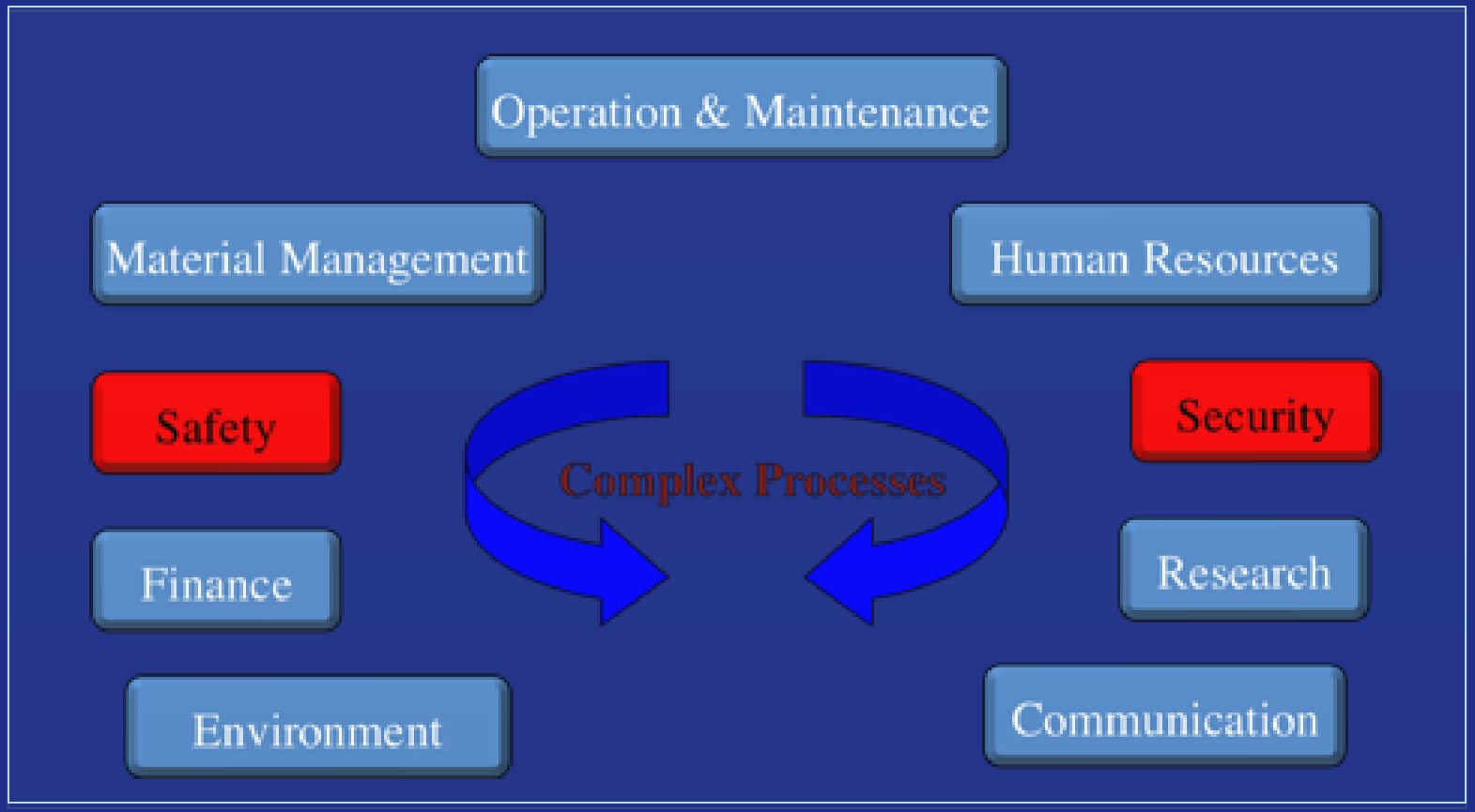

Laboratory Biorisk Management Standard
CWA 15793:2008

- **The Standard can be used for:**
  - Improving overall laboratory biorisk performance
  - Increasing awareness of biosafety and biosecurity risk
  - Effective management of complex laboratory safety and security processes
  - Improving international laboratory collaboration and safety harmonization
  - Basis for new or revised legislation or regulations
  - Support laboratory certification/accreditation, audits/inspections


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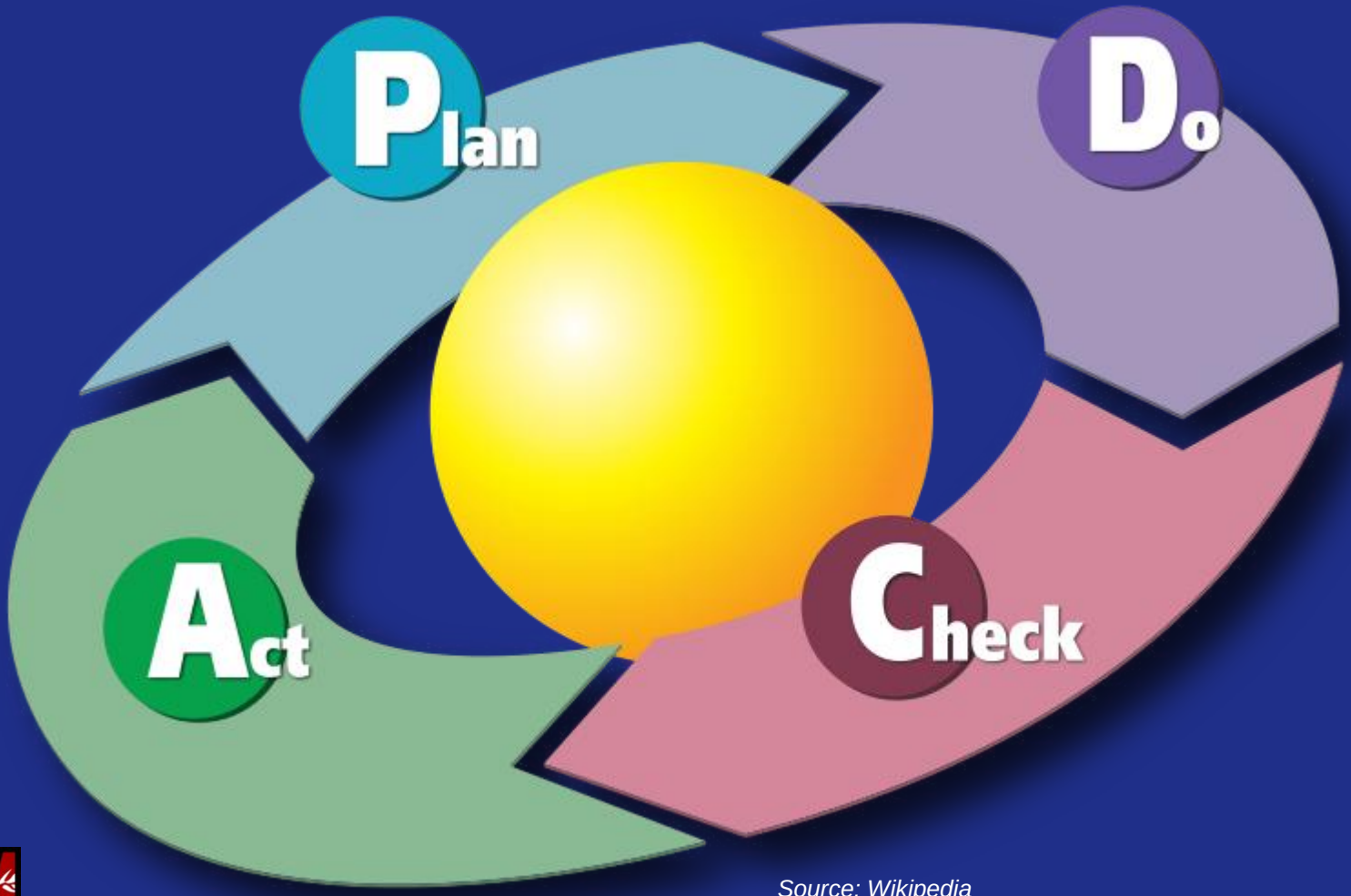
Systematic Approach



Source: Wikipedia

The AMP Model

- **Assessment = Plan, Do, Check, Act**
- **Mitigation = Plan, Do, Check, Act**
- **Performance = Plan, Do, Check, Act**
- **Mitigation is improved and sustained when performance measures are included**
- **Three components of performance:**
  - Apply, assure, and advance

The AMP model

- **How does performance improve biorisk management?**
  - Evidence that your system is working properly and sustainable
  - Indicates that the level risk is acceptable
  - Will assist in creating a culture of awareness through implementation of continual improvement programs (reporting and analysis of incidents, near misses, lessons learned for corrective action)
  - Should add value without being unnecessarily burdensome
  - Can be applied to all Valuable Biological Materials protect all assets for robust business practices and safe/secure/successful laboratory operations

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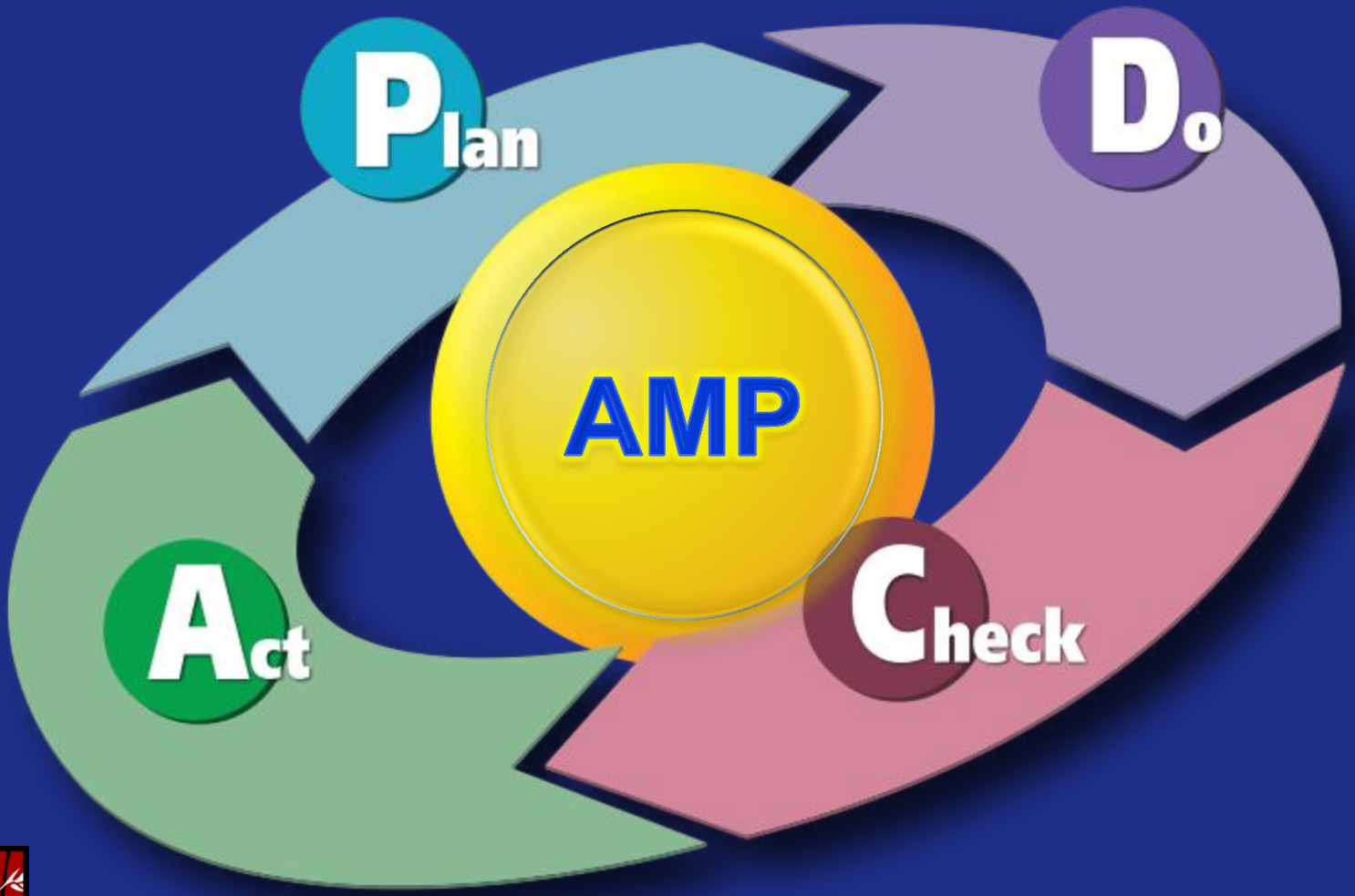

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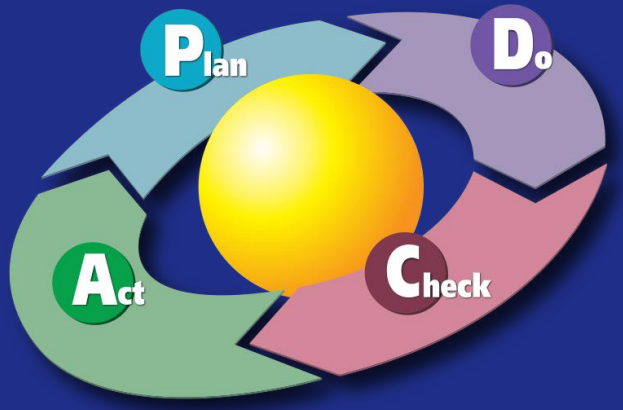
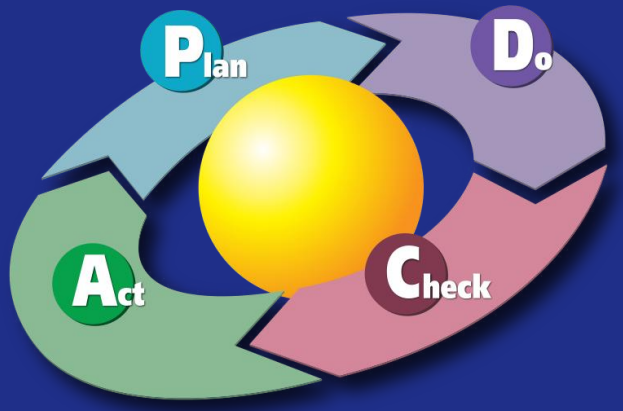
Conclusions

- **Adoption and implementation of the CWA 15793:2008 will be an integral part of the future biorisk management agenda for laboratories worldwide and a necessity to protect people and the environment as well as building community confidence**



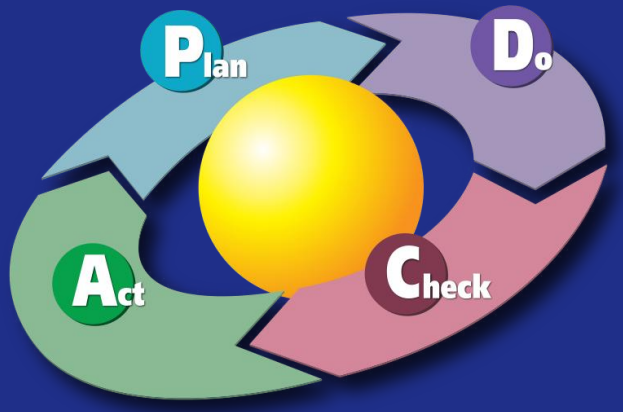
Conclusions

- **The AMP Model will ensure that your management systems is functional, successful and sustainable and valuable biological materials are protected**



Conclusions

- **Implementation of continual improvement and corrective action programs will facilitate employee buy-in and create a culture of awareness**



Discussion and Questions

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International
BIOLOGICAL THREAT REDUCTION

Workshop Outcomes and Way Forward

National Awareness Workshop on Improving Biosafety & Biosecurity at Veterinary Research Laboratories in Pakistan

March 1-2, 2011

International Biological Threat Reduction

Sandia National Laboratories

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Key Concepts for Discussion

- Consensus Definitions
- Consensus Concepts
- Consensus Operations
- Consensus Roles and Responsibilities
- Consensus Way Forward

Consensus Definitions

- **VETERINARY LABORATORY BIOSAFETY**
  - IMPLEMENTATION OF CONTAINMENT PRINCIPLES, TECHNOLOGIES, AND PRACTICES TO PREVENT UNINTENTIONAL EXPOSURE TO VETERINARY PATHOGENS AND TOXINS OR THEIR ACCIDENTAL RELEASE

- **VETERINARY LABORATORY BIOSECURITY**
  - INSTITUTIONAL AND PERSONAL SECURITY MEASURES DESIGNED TO PREVENT THE LOSS, THEFT, MISUSE, DIVERSION OR INTENTIONAL RELEASE OF VETERINARY PATHOGENS AND TOXINS

CBEP
Cooperative Biological Engagement Program
BIOSECURITY ENGAGEMENT PROGRAM
International BIOLOGICAL THREAT REDUCTION

Consensus Concepts

- SAFETY OF LABORATORY WORKERS IS OUR TOP MOST PRIORITY
- LABORATORY BIOSAFETY MEASURES MUST BE BASED ON MICROBIOLOGICAL RISK ASSESSMENT SPECIFICALY KEEPING IN VIEW THE PATHOGENICITY OF THE AGENT AND POTENTIAL OUTCOME OF ITS EXPOSURE
- IT IS BETTER TO PREVENT OCCURANCE OF BIOHAZARD AT VETERINARY LABORATORY THROUGH APPLICATION OF BIOSECURITY MEASURES
- USING MODERN TECHNOLOGIES CAN MINIMIZE BIORISK BY REDUCING THE QUANTITY OF PATHOGEN BEING WORKED WITH IN THE LABORATORY

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Consensus Operations

- **TO MINIMIZE BIOHAZARD, UN-AUTHORIZED PERSONS SHOULD NOT BE ALLOWED TO ENTER THE LABORATORY WORKING AREA**

- **FUNDAMENTAL ELEMENTS OF LABORATRY BIOSAFETY**
  - GOOD MICROBIOLOGICAL TECHNIQUES
  - APPROPRIATE USE OF BIOSAFETY EQUIPMENT
  - LAB STAFF WELL TRAINED IN BIOSAFETY PROCEDURES

Consensus Roles and Responsibilities

- **EACH VETERINARY LABORATORY SHOULD APPOINT A LABORATORY BIOSAFETY OFFICER:**
  - PLAN & CONDUCT BIOSAFETY TRAINING FOR LAB STAFF
  - DEVELOP & IMPEMENT BIOSAFETY OPERATIONAL MANUAL
  - CONDUCT REGULAR HEALTH SURVEILLANCE OF ALL LABORATORY WORKERS & ARRANGE TREATMENT IN CASE OF NEED

- **EACH VETERINARY RESEARCH INSTITUTION SHOULD HAVE AN INSTITUTIONAL BIORISK MANAGEMENT COMMITTEE TO ASSIST THE SENIOR MANAGEMENT IN:**
  - REVIEWING THE LABORATORY PROTOCOLS & ENSURING COMPLIANCE WITH INSTITUTIONAL BIORISK MANAGEMENT POLICIES
  - CONDUCTING INSTITUTIONAL BIORISK ASSESSMENTS
  - COORDINATING ACROSS THE INSTITUTION AND WITH OUTSIDE STAKEHOLDERS ON BIORISK MANAGEMENT RELATED ISSUES
  - MONITORING THE IMPLEMENTATION OF BIORISK MANAGEMENT STANDARDS GUIDELINES

Potential Way Forward-1

Establish Ministry and Institutional level support for Biorisk Management Advisors (BRMA) and Biorisk Management Committees (BRMC)

Potential Way Forward-2

Adopt management systems and performance-based programs as tools to address the National Biorisk Management Framework and/or Policy (i.e., CEN Workshop Agreement (CWA) 15793, Laboratory Biorisk Management standard)

Potential Way Forward-3

Adopt the risk assessment process as the basis for selection and implementation of biorisk management and mitigation measures

Potential Way Forward-4

Consider the benefits of a One Health Initiative to streamline technical approaches related to pathogens and regulatory oversight/management via inter- or multi-agency discussions (Ministries of Livestock and Dairy Development, Food and Agriculture, Health)

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International
BIOLOGICAL THREAT REDUCTION

Definitions

- Veterinary Laboratory Biosafety – Implementation of containment principles, technologies, and practices to prevent unintentional exposure to veterinary pathogens and toxins or their accidental release.
- Veterinary Laboratory Biosecurity – Institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release of veterinary pathogens and toxins.

Concepts

- Safety of Laboratory workers is our top priority
- Laboratory biosafety measures must be based on a microbial risk assessment, specifically keeping in view the pathogenicity of the agent and potential outcome of its exposure
- It is better to prevent the occurrence of biohazard at a veterinary laboratory through application of biosecurity measures
- Using modern technologies can minimize biorisk by reducing the quantity of pathogen being worked with in the lab

Operations

- To minimize biohazard, un-authorized persons should not be allowed to enter the laboratory working area.
- Fundamental Elements of Laboratory Biosafety
    - Good microbiological techniques
    - Appropriate use of biosafety equipment
    - Lab staff should be well trained in biosafety procedures

Roles and Responsibilities

- Each veterinary laboratory should appoint a Laboratory Biosafety Officer:
    - Plan and conduct biosafety training for lab staff
    - Develop and implement Biosafety Operational Manual
    - Conduct regular health surveillance of all laboratory workers and arrange treatment in case of need
- Each veterinary research institution should have an Institutional Biorisk Management Committee to assist senior management in:
    - Reviewing the laboratory protocols and ensuring compliance with institutional biorisk management policies
    - Conducting institutional biorisk assessments
    - Coordinating across the institution and with outside stakeholders on biorisk management related issues

- Monitoring the implementation of biorisk management standards and guidelines