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INTERNATIONAL BIOLOGICAL and CHEMICAL THREAT REDUCTION

Biorisk Management In Veterinary Laboratories and Animal Facilities

Regional Seminar for OIE National Focal Points for Veterinary Laboratories
Buenos Aires, Argentina

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OIE Collaborating Centre for Biorisk Management

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Need For Biorisk Management

Biological agents and toxins in a laboratory setting pose inherent risks to the health and safety of all personnel

All laboratories are responsible for biosafety and biosecurity that protects their workers, animal populations, and the environment from exposure or spread of pathogens.

- Public health concerns
- Biological threat reduction/terrorism

The guidance and information presented is in accordance with the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2015 edition

- Chapter 1.1.3. Biosafety and Biosecurity: Standard for Managing Biological Risk in the Veterinary Diagnostic Laboratory and Animal Facilities
  - *Adopted during the May 2015 General Session*

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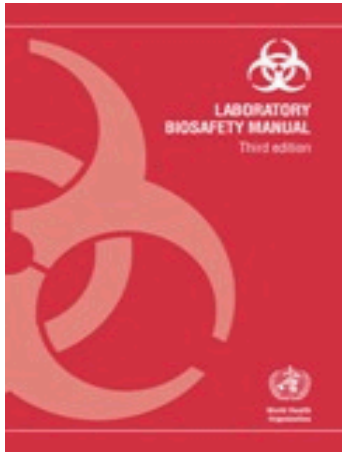
Biorisk Management

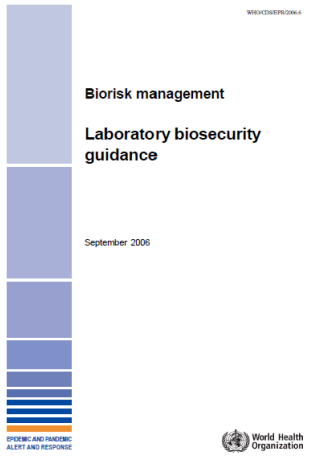


What are biorisks?

- What/Who are we protecting?
- Protecting from what?

Biosafety-containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]

Biosecurity-protection, control, and accountability for valuable biological materials within laboratories in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release[2]



1. Laboratory Biosafety Manual, Third Edition (World Health Organization, 2004)
2. Biorisk Management-Laboratory Biosecurity Guidance (World Health Organization, 2006)

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Biorisk Management

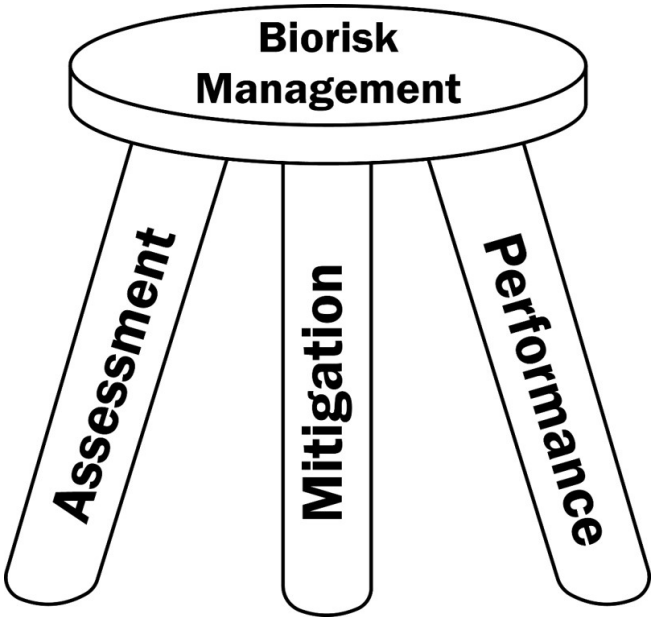
What is biorisk management?

- System or process to control safety and security risk associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities

Risk Characterization, Risk Management, Risk Communication

The AMP Model

- Assessment
- Mitigation
- Performance



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A Risk Analysis Approach- Biological Risk Assessment

An analytical procedure designed to identify and characterize biological risks in a facility, laboratory or a unit within it, or other type of operation dealing with pathogens or toxins

- Both biosafety AND biosecurity risks
- Should always be thorough and robust
- Allows a facility, laboratory, or other operation to determine the relative risk of its different activities pose, and helps guide risk mitigation decisions

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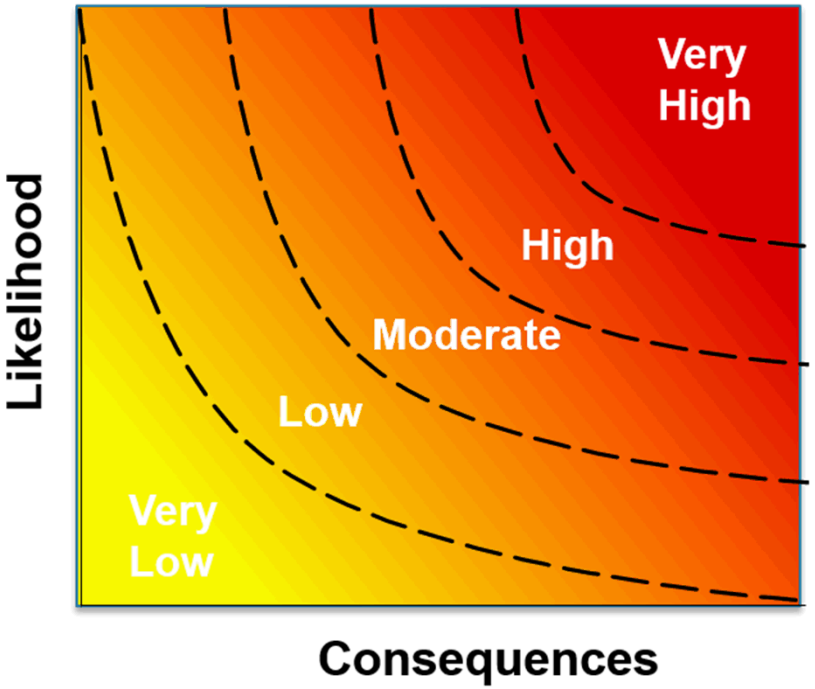
Biological Risk Assessment

Risk is defined as a combination of the likelihood (probability) of the occurrence and the severity of harm (or consequence) **RISK**

- Risk vs. threat
- Likeihood and consequences

Important factors to consider

- Characteristics of the agent
  - *Route of transmission*
  - *Pathogencity*
  - *Clinical signs/pathology*
  - *Available prophylactics/ treatment*
  - *Zoonotic potential*
- Laboratory Infrastructure
- Human Factors
- Operational Factors
- Environmental and Community Factors



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Risk Assessment-Characterization

Identifying the likelihood and the potential consequences associated with an adverse event (exposure ,release of the agent)

- human disease (probability and severity)
- animal disease (probability and severity)
  - *susceptible species in the vicinity*
  - *environmental factors in the vicinity*
    - Routes of transmission
    - Is the pathogen present and ubiquitous in the environment
- economic consequences of the disease
- Outbreak response (costs for investigation, surveillance, and control)
- potential for theft, misuse, or deliberate release.

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Biological Risk Assessment

The biological risk assessment allows a facility to determine if the work proposed poses an unacceptable risk to biosafety and biosecurity.

Once the biorisks have been identified and fully characterized, the facility can decide if the risk is acceptable and if the risk can be managed and mitigated appropriately to reduce the likelihood and consequences of injury, illness, or theft

- Diagnostic and research laboratories have to accept some risks due to their purpose and function within the public health sector

THERE IS NO WAY TO PERFORM WORK WITH BIOLOGICAL MATERIALS ABSENT OF RISK

Biorisks unique to veterinary/animal facilities

- Live animals on premises
- Animal bites/attacks/injuries to humans
- Necropsy/carcass disposal

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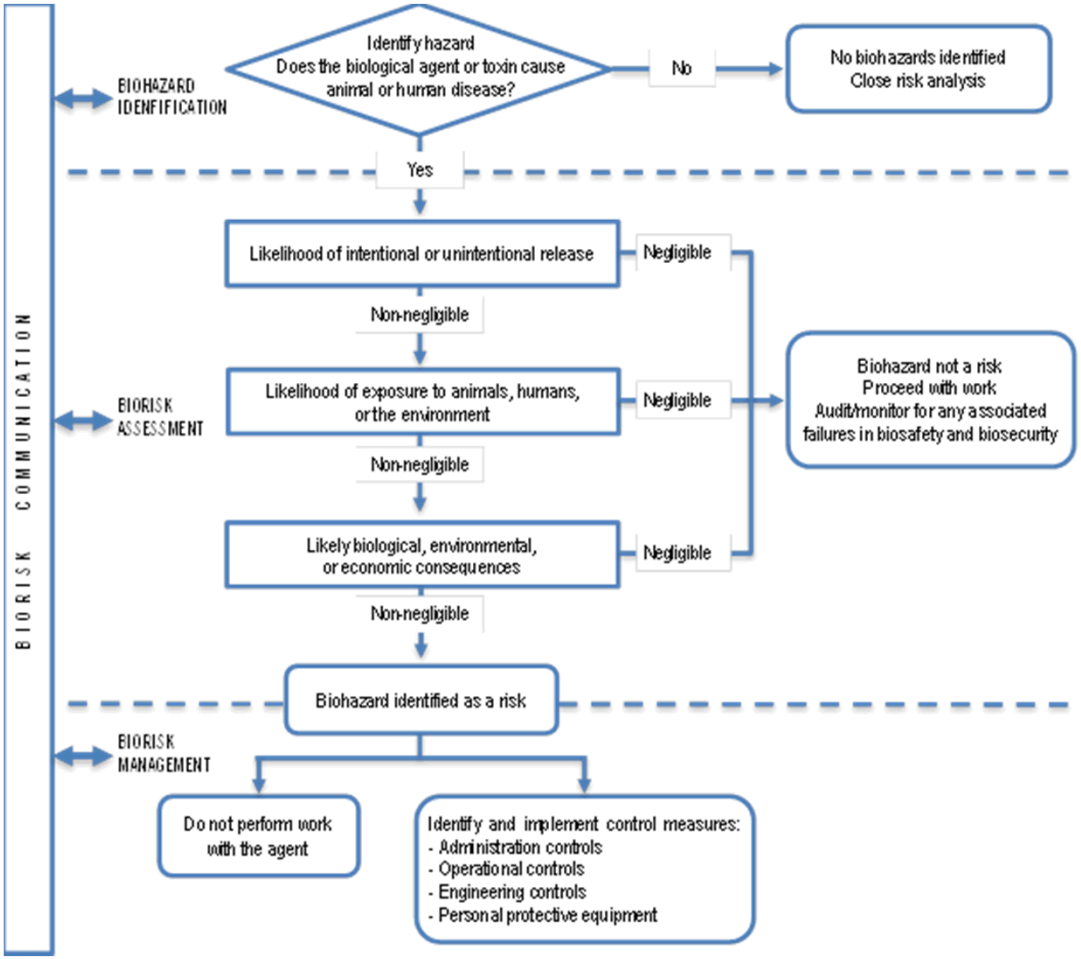
Risk Assessment Decision Matrix



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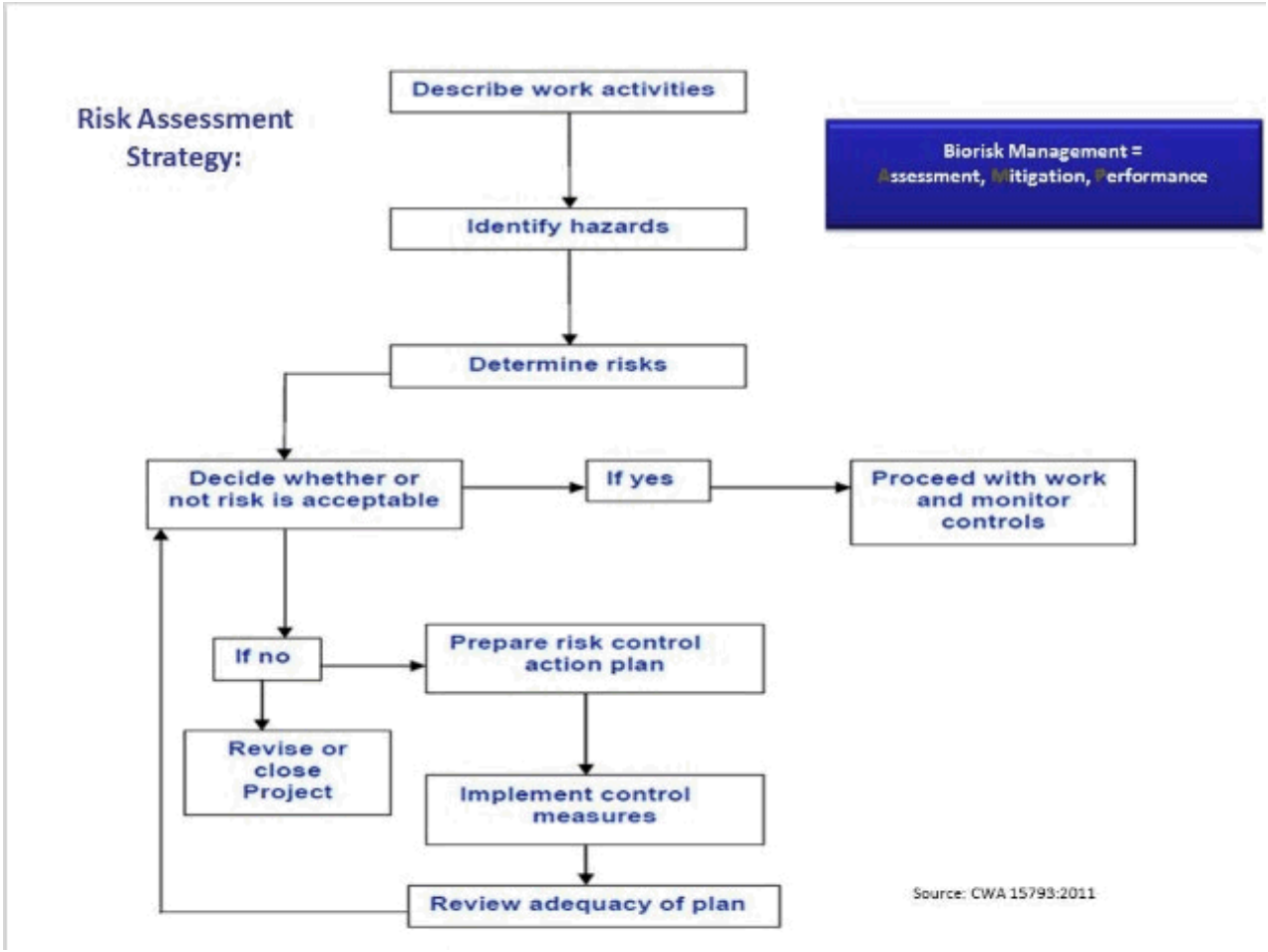
Risk Assessment Decision Matrix



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Mitigation Control Measures

Elimination or Substitution

- Decline to do the work or work with a similar pathogen with lower consequences
    - Sterne strain of *Bacillus anthracis*

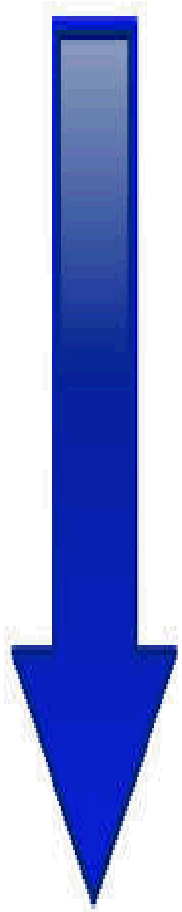
Engineering Controls

Administrative Controls

Practices and Procedures

Personal Protective Equipment

Generally, the control methods at the top of the list are more effective and protective than those at the bottom



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Engineering Controls

Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduces or prevents exposure to hazards

- Facility ventilation and air-flow
- Biological Safety Cabinets and glove boxes
    - *IMPORTANT that all equipment maintenance, calibration, and certification are a part of a complete biorisk management system*
- Barrier walls and shields for separation of incompatible activities
- Physical security:
    - *Facility and equipment locks with key control protocols*
    - *Badges and badge readers*
    - *Biometric devices*
    - *Detectors and sensors*
    - *Perimeter fences*
    - *Security guards*

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Administrative Controls

Policies, standards, and guidelines used to control risks

- Laboratory policies and management programs
  - *Biosafety officer*
  - *Biorisk management committees*
- Professionally qualified, trained, and competent personnel
- Training in the safe & secure handling of biological agents & toxins
- Health and safety programs (e.g. health care, vaccinations)
- Incident and accident investigation programs with emergency response and contingency plans
- Biological agents and toxin inventory management requirements
  - *"Cradle to the grave"*
  - *Access, storage, transfer, destruction, and audit*
- Waste management policies
- Security policies
  - *Badge requirements, visitor access procedures, personnel reliability, access to biological agents and toxins, data security (paper and electronic records)*

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Operational Controls/Practices and Procedures

Standard Operating Procedures for all biosafety and laboratory biosecurity-relevant processes

- Regular work practices
- Incidents
    - *Spills, injuries*
    - *Security Incidents*

Good Laboratory Work Practices

Appropriate disinfection and decontamination practices

Diagnostic sample transportation procedures for potentially infectious materials and specimens

- Secure packing
- Well defined diagnostic sample receiving procedures
- Trusted and verified means for secure transportation
- Chain of custody

Specimen and reagent handling and storage practices

Accident/incident reporting, response, and review protocols

Emergency exercise drills

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Personal Protective Equipment

Eye protection-Safety glasses, face shields

Respiratory protection-Face masks, N95 respirators, face shields, hoods, PAPRs

Hand protection-Gloves

- Latex, nitrile, chainmail, autoclave

Body protection-Laboratory coats, uniforms, coveralls, surgical scrubs, rubber boots, disposable shoe covers

Proper donning and doffing of PPE is crucial!

Significant advantage and disadvantage

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Biorisk Management-Performance

The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working as designed

- An ongoing process
- Regular monitoring and evaluation
    - *Drills, audits, documentation of incidents, equipment validation*
- When warranted, mitigation controls measures are added, adjusted, or removed to ensure their proper function and role in reducing biorisks

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Biorisk Communication

The interactive transmission and exchange of information and opinions throughout the risk analysis process about risk, risk-related factors and risk perceptions among risk managers, risk communicators, the general public, and other impacted parties.

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Biorisk Communication

Biorisk communication format and language is tailored to the intended audiences, including policy-makers, disease control authorities, animal care providers, and the public

The information is provided in a clear and understandable manner, including;

- the identification of the biohazard (agent or toxin)
- the benefits to the stakeholder gained by the laboratory working with the biohazard
- information indicating that a biorisk analysis was performed and is documented
- information indicating that the laboratory has control measures in place to mitigate against accidental or intentional release of the biological agent or toxin.

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Role of Training

Training is an extremely vital part of implementing a biorisk management system

- Raises safety and security awareness
- Diagnosis tool
    - *Many facilities know they can work safer and more secure but don't know where to start*
- Conduit for inquiry
    - *Novel concept for some facilities and laboratorians*
    - *No direct translation for "biosafety" or "biosecurity" in some languages*
    - *Paradigm shifts and changes in long standing practices and workplace cultures*

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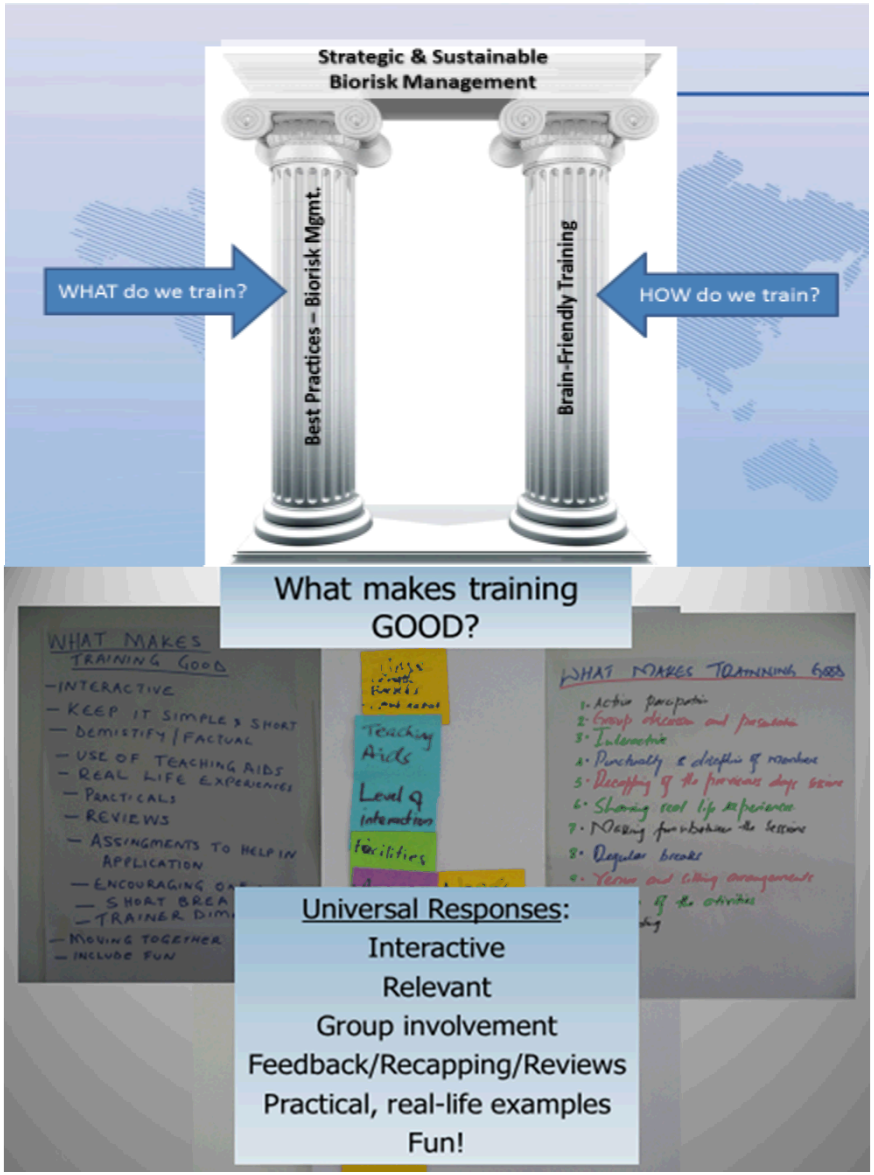
Training Students, Not Topics

Effective training takes a student centered approach

- Brain-based teaching methodology that builds critical thinking skills
- “How should I behave when I encounter a certain situation?”
- Moving away from checklist approach & “Death by PowerPoint”
- Should increase retention and promote “curiosity gap” which will lead to independent study

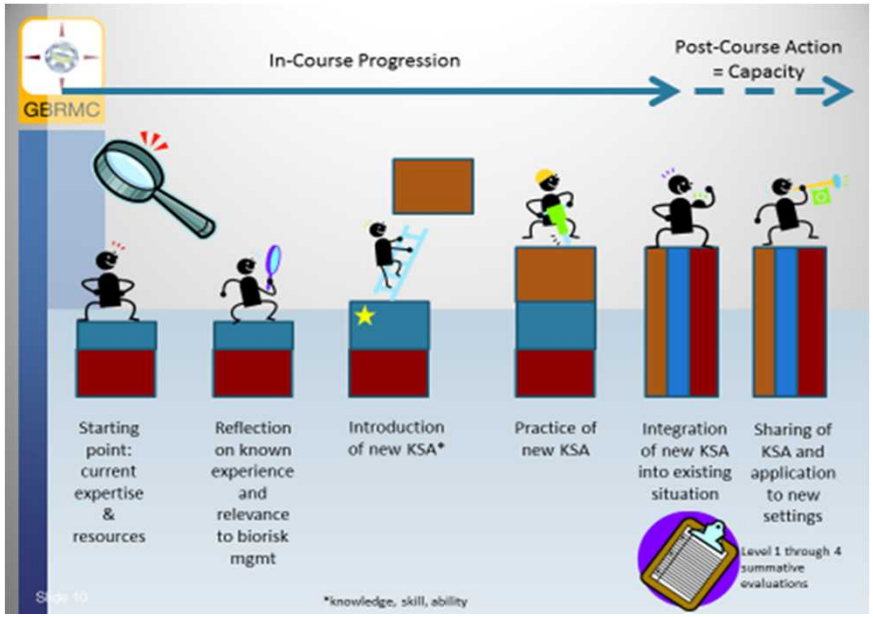


Global BioRisk Management Curriculum (GBRMC)

The GBRMC library is a technically relevant, consistent, and credible resource addressing existing and emerging biorisk management training needs around the world.

To provide core materials for training biorisk management principles and practices.

- Common messages to be presented "anywhere, anytime" by trainers all over the globe using international best practices in biorisk management
- Allows trainers to focus their expertise on local or situation-specific training to augment the core biorisk management message
- Allows trainers to couple locally-appropriate training materials with standardized core principles
- Access to an expansive library of GBRMC Core Documents that can be used as templates for the development of facility specific biorisk management plans
    - *SOPs for work tasks and incident response*
    - *Laboratory inspection forms*
    - *Respiratory protection and fit testing*



Global BioRisk Management Curriculum (GBRMC)

Basic track-all employees

Laboratory Level track- Biorisk Management Advisors, Scientific/Laboratory Management, Lab Workforce

Management and Leadership Track-Policy Makers, Top Management, Biorisk Management Advisors, Scientific/Laboratory Management

GBRMC Trainer Development

- Participants with a strong desire to improve biorisk management locally can become GBRMC Trainers
- Builds an independent and sustainable network of trainers that can expand training on the local, provincial, and national level that will lead to improvements in BRM
- Trainers granted access to the curriculum to use materials, customize for local audiences, give feedback, and make improvements

Challenges to Biorisk Management Implementation

Shifting to critical thinking
- Can be challenging to consider every single situation and every single risk
- A “compliance mindset”
- Have to understand “why”

Management Involvement
- Decisions are made from the top down
- “Buy In”
- Management’s awareness and knowledge of BRM

Containment Creep
- Risk based decision making leading to over-mitigation
- “Now I need a BSL-4!”
- All mitigation controls must be appropriate
    - *Based on a thorough and robust risk assessment*

Resource availability
- A strong consideration in underdeveloped countries and resource limited environments
- BRM is somewhat dependent on financial resources but not wholly
    - *Importance of operational controls/practices and procedures*
    - *Making decisions from a risk based assessment and analysis*
- Requesting and allocating the appropriate mitigation measures
    - *Blind or uninformed donations from donors*
    - *No considerations of maintenance and sustainability*

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Successes In Biorisk Management

How can you measure?

- Surveys?
- Training Evaluations?

Every facility and every laboratorian starts at different levels

Behavior Changes?

Institutional/Organizational Changes?

- New found awareness with dedicated staff (Biosafety officers, biosafety committees)

Time is a factor

A lack or reduction of incidences is a goal but not a reliable indicator of successful implementation of a biorisk management system

- The responses to those incidences can be…

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OIE Biosafety and Biosecurity Resources

http://www.oie.int/publications-and-documentation/general-information

Health standards

Terrestrial Animal Health Code, Aquatic Animal Health Code

OIE Quality Standard & Guidelines for Veterinary Laboratories:

- Management Requirements, Technical Requirements

Manual of Diagnostic Tests for Aquatic Animals

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

- Chapter 1.1 .1 - Collection and Storage of Diagnostic Specimen
- Chapter 1.1.2 - Transport of Specimens of Animal Origin
- Chapter 1.1.3 and 1.1.3a
    - *Individual Agent and Disease chapters*

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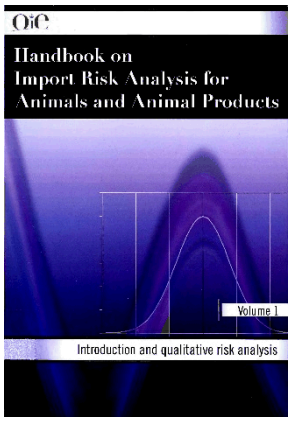
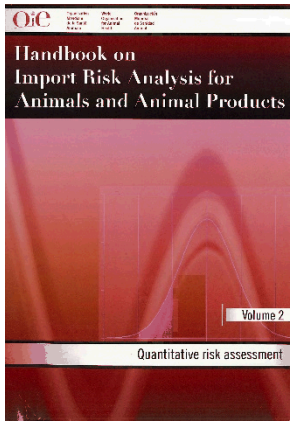
OIE Reference Materials and Handbooks

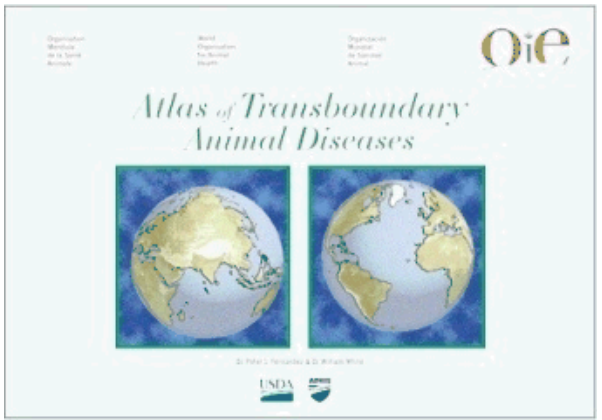
- Handbook on Import Risk Analysis for Animals and Animal Products
  - *Introduction and qualitative risk analysis (v.1)*
  - *Quantitative Risk Assessment (v.2)*

OIE Biological Threat Reduction Strategy

Atlas of Transboundary Animal Diseases







OIE Biosafety and Biosecurity Resources

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OIE Periodicals

Scientific and Technical Review

OIE Bulletin

Disease Information (available on the WAHID interface)

World Animal Health (Annual Global Disease Summary)

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Additional Resources on Biosafety and Biosecurity

European Committee for Standardization CEN Workshop Agreement CWA 15793(2011) – A management systems approach to Laboratory Biosafety.

CDC Biosafety in Microbiological and Biomedical Laboratories(BMBL) 5th Edition (2009)

- http://www.cdc.gov/biosafety/publications/bmbl5/

WHO Laboratory Biosafety Manual 3rd Edition (2004)

- http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

Laboratory Biorisk Management: Biosafety and Biosecurity-Salerno and Gaudioso (2015)

Laboratory Biosecurity Handbook-Salerno and Gaudioso (2007)

BioRAM-Biorisk management modeling tool developed at SNL

- http://bioram.swcp.com to request the latest version of the software

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GBRMCNet and Core Documents

- https://connect.sandia.gov/sites/GBRMCNet/Resource Library/Forms/User.aspx

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