DLS ECHO Biosafety Session: May 30, 2024

Support: Resources, Competence, and Awareness

William Pinard, MS, BRM/BSEC (IFBA)
Principal Member of Technical Staff, Global Chemical and Biological Security
Sandia National Laboratories
Albuquerque, NM

Allison Treloar, MS, CMDA(ASQ), MB(ASCP), BRM(IFBA)
Principal Member of Technical Staff, Global Chemical and Biological Security
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Albuquerque, NM

April Session Recap:
Planning – Developing and Achieving Biorisk Management Objectives

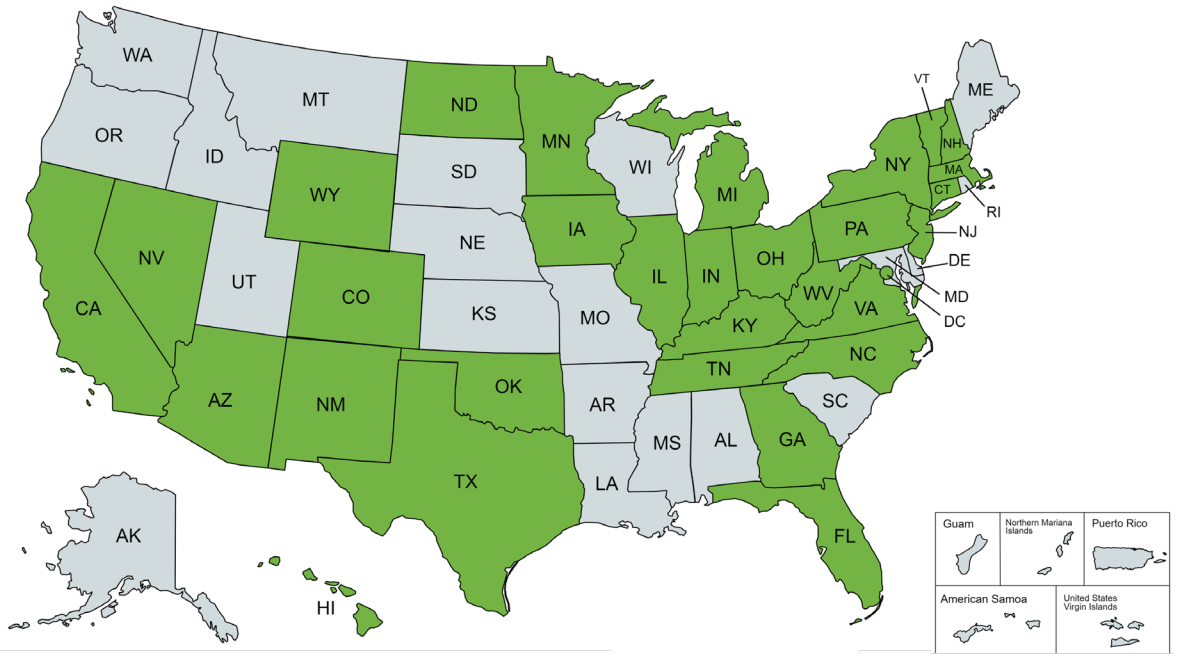
113 participants attended the session

70 organizations were represented

"We have job safety assessments annually where we perform risk assessments and ensure protections from risks are established. We do this for lab employees, office staff, warehouse workers, etc."

-Session Participant

Organization Affiliation by State



Note: States shaded in green had at least one organization located in that state in attendance at this session. Attendees from at least one organization located in El Salvador and Italy were also present at the session. Eight national organizations also attended this session.

Agenda

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

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

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Sandia National Laboratories

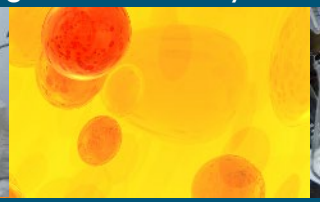
ECHO Biosafety Program

Support: Resources, Competence, and Awareness

Mr. William Pinard, Principal Member of the Technical Staff

Ms. Allison Treloar, Principal Member of the Technical Staff

Global Chemical and Biological Security, Sandia National Laboratories

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SAND2024-06361O

Mr. William J Pinard

(wjpinar@sandia.gov)

- Biorisk Management Trainer, Trainer Development and Mentorship Experience
- IFBA Certification Training Lead
- BRM Curriculum Development Team
- Laboratory Design, Maintenance, and Operations Experience
- Country Lead:
  - Current - GCC, Malaysia, Morocco, Türkiye
  - Former - Egypt, Jordan, and Pakistan
- Professionally Certified in Biorisk Management and Biosecurity

Principle Member of the Technical Staff in SNL/GCBS William has a background in genetics, microbiology,
and biological defense and has been promoting global laboratory BRM for 15 years, 13 with SNL/GCBS

Ms. Allison Treloar

(aftrelo@sandia.gov)

- Principal member of technical staff for SNL/GSBS
- Supports laboratory assessments, tailored BRM program development, BRM human capacity building activities, analysis projects, and development of tools
  - Topics of focus: ISO 35001 standard implementation, laboratory biosecurity, biosecurity risk assessment, laboratory design, and high containment.
- Country Lead for Kenya and deputy lead for Romania portfolios.
- 35+ years experience in academic and pharmaceutical research, independent diagnostic laboratories, and public health laboratories
  - Director. Office of Quality, Safety, Security, & Emergency Preparedness

- M.S. in Genetics from Southern Connecticut State University
- Boarded by the *American Society for Pathologists* as a Molecular Technologist and a Specialist in Laboratory Safety.
- Certified Medical Device Auditor through the *American Society for Quality*
- Certified in Biorisk Management by the *International Federation of Biosafety Associations*

Disclaimer – Resources, Certifications, and Training Programs listed here are not meant to be exhaustive. There are many resources available, more than can be included in a short program. These can serve as a launching point to go into greater detail on the subjects related to Biorisk Management.

Mentioning of any of these items should not be considered endorsement of a specific company, program, or product, but serve as an illustrative example of what is available through general public.

Additionally, the speakers make no claim on the accuracy of all of the information included in these documents, websites, and their sub sites. It is important to critically evaluate all information and determine if it is not only accurate, but appropriate for your situation.

Resources

Considerations for resource planning and allocation:

- Workers, skill sets, succession planning, anticipated turnover
- Expertise, SME, cross-training, competency assessment, mentoring, supervision, professional development
- Financial – capital improvements, maintenance, budgeting, forecasting
- Infrastructure, equipment, utilities, services, installation, validation, replacement, maintenance
- Adequate time to perform work
- Scheduling audits, performance review reporting, administrative support, IT functions
- Additional ?

POLL QUESTION #1

What resources are used in your organization for guidance in meeting standards and regulatory requirements?

(Select all that apply)

1. Biosafety in Microbiological and Biomedical Laboratories (BMBL)
2. WHO Laboratory Biosafety Manual and associated monographs
3. National association/society guidance documents (APHL, ASM, etc.)
4. I rarely reference international resources.
5. I only reference regulations and inspection guidance documents (checklists)

Resources

International Resources

- ISO / CWA
- WHO
- (WOAH)
- ABSA, International
- IFBA
- PH Canada

National Resources

- CDC/NIH
  - BMBL
  - Biosafety Resources & Tools
  - Dual Use Research of Concern
  - NSABB

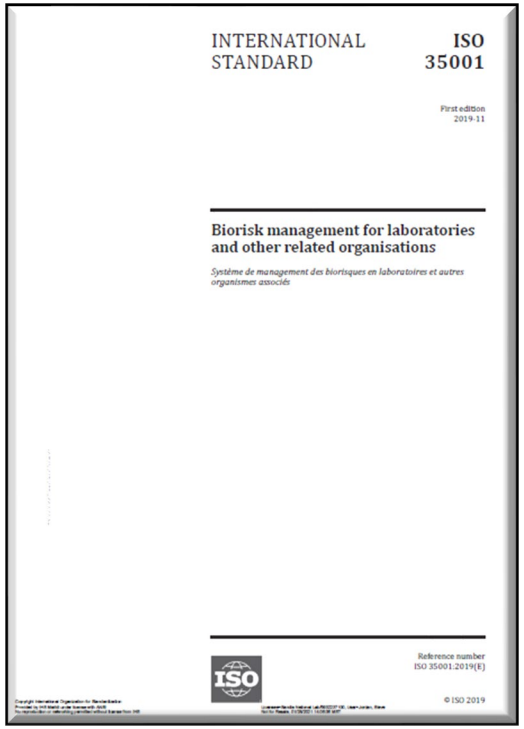
State Resources

Worker Health Programs

Vaccination of Workers

International Resources

- ISO 35001- Biorisk Management for Laboratories and Other Related Organizations
- European Standards Organization (CEN) Workshop Agreements (CWA)
  - CWA 15793 – Laboratory Biorisk Management (Expired)
  - CWA 16393 – Laboratory Biorisk Management – Guidance for the Implementation of CWA 15793:2008


INTERNATIONAL STANDARD

ISO 35001

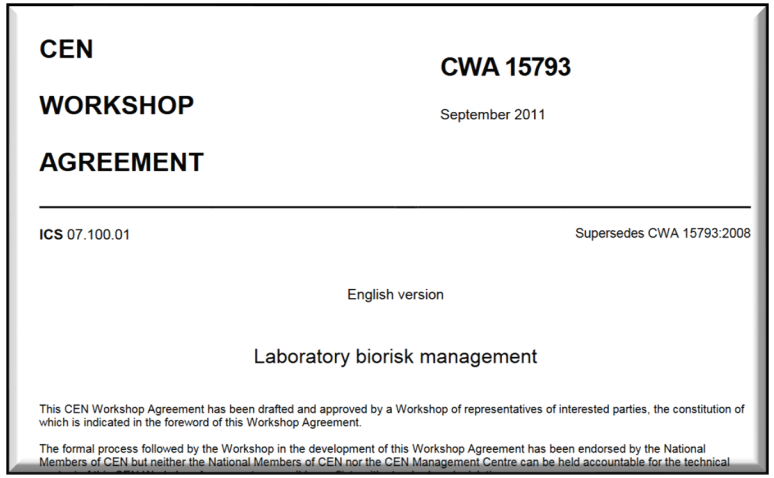
First edition 2019-11

Biorisk management for laboratories and other related organisations

Système de management des biorisques en laboratoires et autres organismes associés

Reference number ISO 35001:2019(E)

© ISO 2019


CEN WORKSHOP AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

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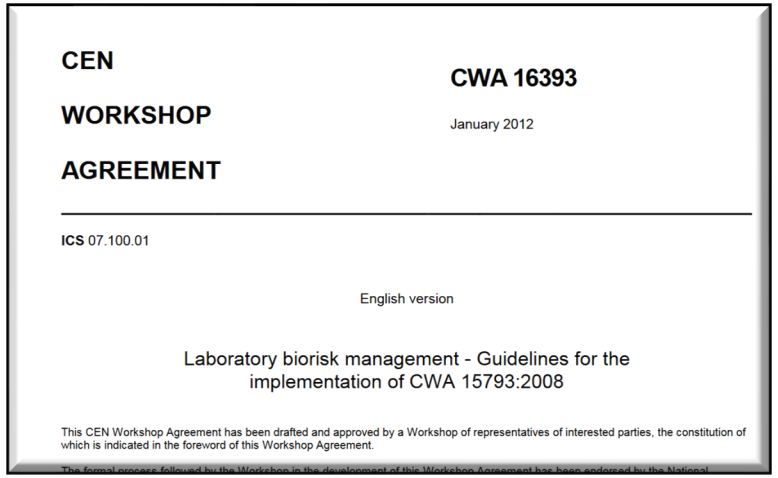
CEN WORKSHOP AGREEMENT

CWA 16393

January 2012

ICS 07.100.01

English version

Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008

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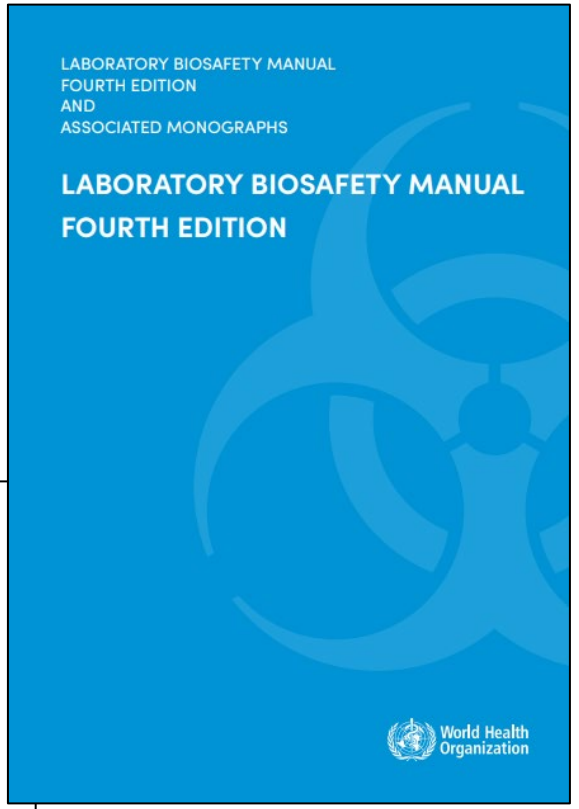
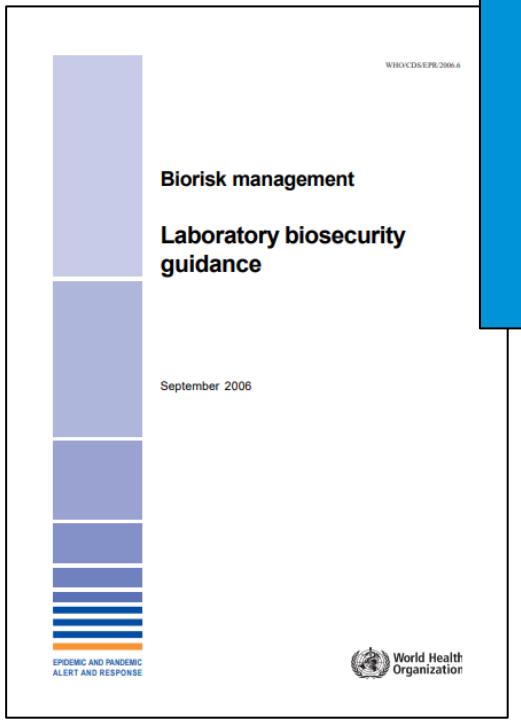
International Resources – World Health Organization

Laboratory Biosafety Manual, Fourth Edition and Accompanying Monographs

- Risk Assessment
- Laboratory Design and Maintenance
- Biological Safety Cabinets and Other Primary Containment Devices
- Personal Protective Equipment
- Decontamination and Waste Management
- Outbreak Preparedness and Resilience



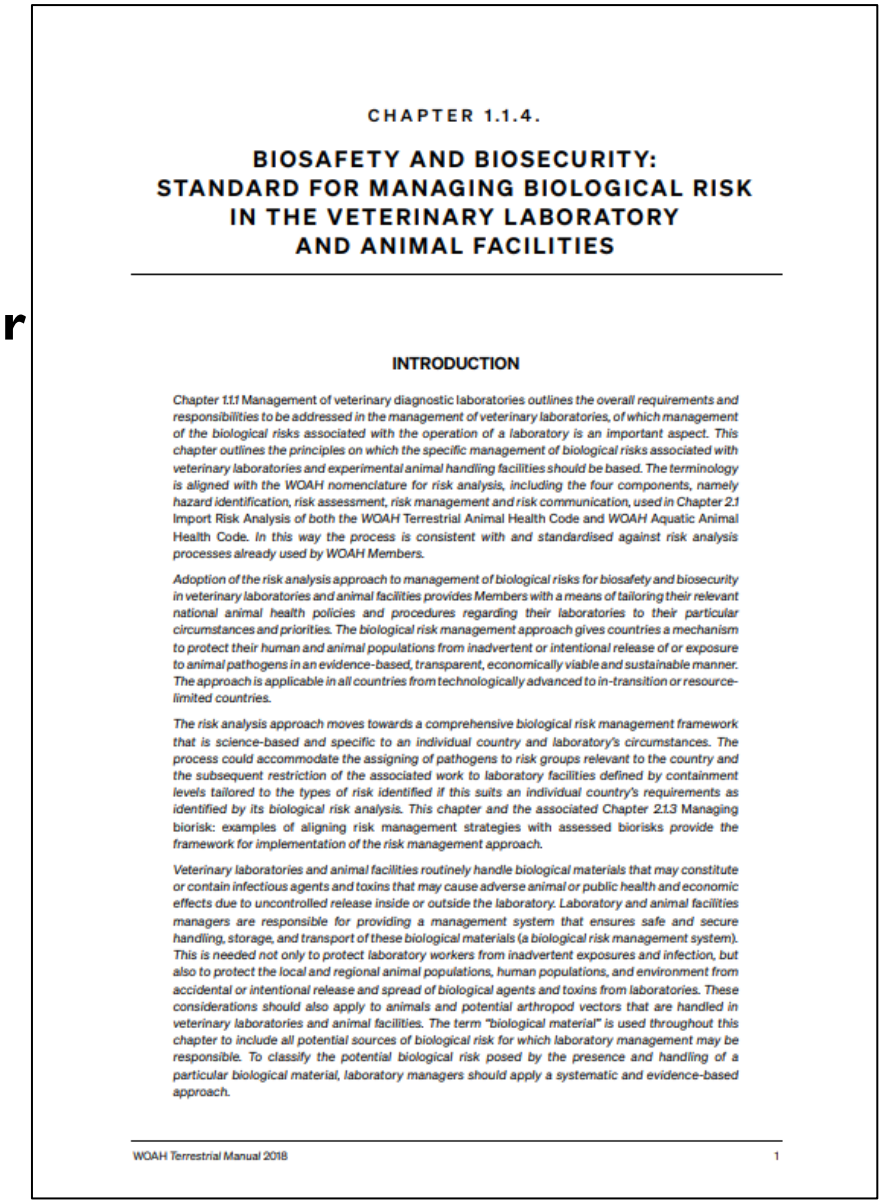
Biorisk Management: Laboratory Biosecurity Guidance



International Resources – World Organization for Animal Health

Manual of Diagnostic Tests and Vaccines for Terrestrial Animals

- Chapter 1.1.4. Biosafety and Biosecurity: Standard for Managing Biological Risk In the Veterinary Laboratory and Animal Facilities



CHAPTER 1.1.4.

BIOSAFETY AND BIOSECURITY: STANDARD FOR MANAGING BIOLOGICAL RISK IN THE VETERINARY LABORATORY AND ANIMAL FACILITIES

INTRODUCTION

Chapter 1.1.1 Management of veterinary diagnostic laboratories *outlines the overall requirements and responsibilities to be addressed in the management of veterinary laboratories, of which management of the biological risks associated with the operation of a laboratory is an important aspect. This chapter outlines the principles on which the specific management of biological risks associated with veterinary laboratories and experimental animal handling facilities should be based. The terminology is aligned with the WOAH nomenclature for risk analysis, including the four components, namely hazard identification, risk assessment, risk management and risk communication, used in Chapter 2.1* Import Risk Analysis *of both the WOAH* Terrestrial Animal Health Code and *WOAH* Aquatic Animal Health Code. *In this way the process is consistent with and standardised against risk analysis processes already used by WOAH Members.*

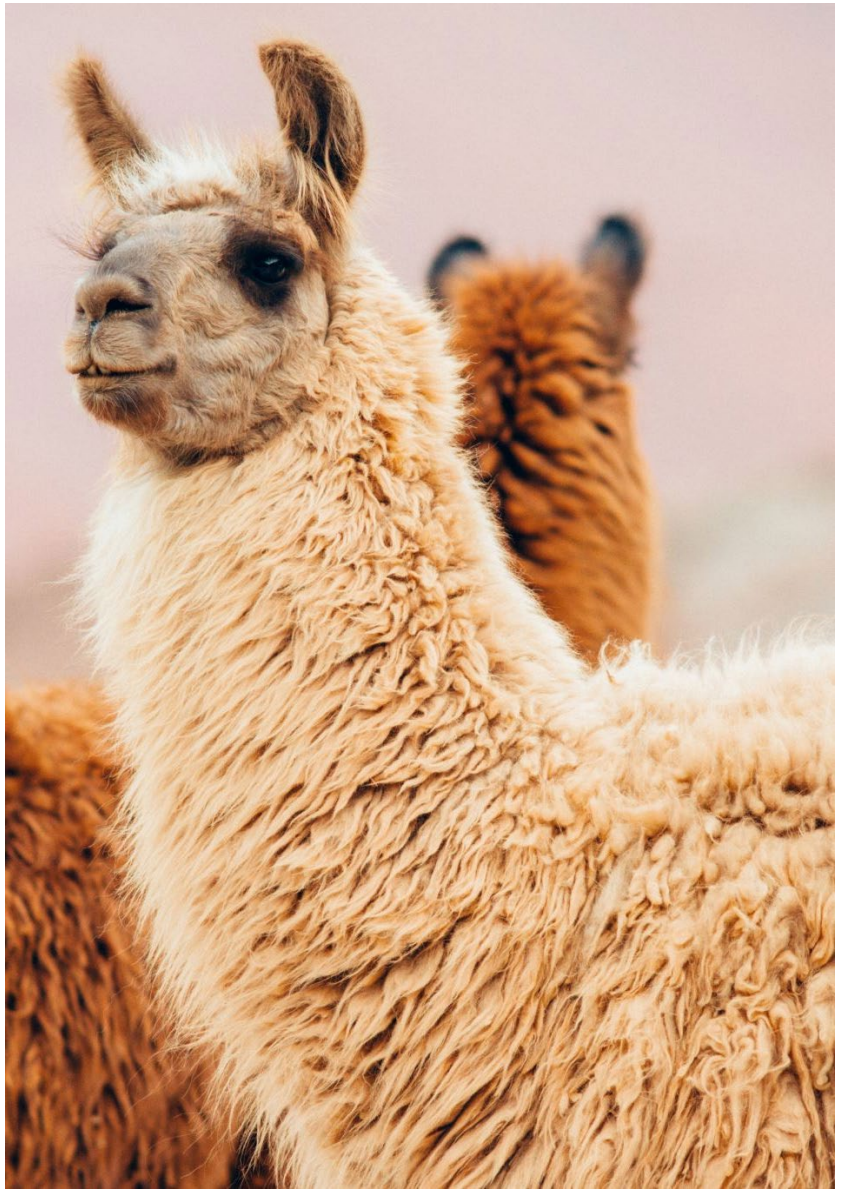
Adoption of the risk analysis approach to management of biological risks for biosafety and biosecurity in veterinary laboratories and animal facilities provides Members with a means of tailoring their relevant national animal health policies and procedures regarding their laboratories to their particular circumstances and priorities. The biological risk management approach gives countries a mechanism to protect their human and animal populations from inadvertent or intentional release of or exposure to animal pathogens in an evidence-based, transparent, economically viable and sustainable manner. The approach is applicable in all countries from technologically advanced to in-transition or resource-limited countries.

The risk analysis approach moves towards a comprehensive biological risk management framework that is science-based and specific to an individual country and laboratory's circumstances. The process could accommodate the assigning of pathogens to risk groups relevant to the country and the subsequent restriction of the associated work to laboratory facilities defined by containment levels tailored to the types of risk identified if this suits an individual country's requirements as identified by its biological risk analysis. This chapter and the associated Chapter 2.1.3 Managing biorisk: examples of aligning risk management strategies with assessed biorisks *provide the framework for implementation of the risk management approach.*

Veterinary laboratories and animal facilities routinely handle biological materials that may constitute or contain infectious agents and toxins that may cause adverse animal or public health and economic effects due to uncontrolled release inside or outside the laboratory. Laboratory and animal facilities managers are responsible for providing a management system that ensures safe and secure handling, storage, and transport of these biological materials (a biological risk management system). This is needed not only to protect laboratory workers from inadvertent exposures and infection, but also to protect the local and regional animal populations, human populations, and environment from accidental or intentional release and spread of biological agents and toxins from laboratories. These considerations should also apply to animals and potential arthropod vectors that are handled in veterinary laboratories and animal facilities. The term "biological material" is used throughout this chapter to include all potential sources of biological risk for which laboratory management may be responsible. To classify the potential biological risk posed by the presence and handling of a particular biological material, laboratory managers should apply a systematic and evidence-based approach.

WOAH *Terrestrial Manual 2018* 1

POLL QUESTION #2



Do you feel that your organization has adequate resources to assess biosecurity?

1. Yes. We have excellent resources.
2. Yes, but resources are limited for some aspects of biosecurity.
3. No. It is difficult for us to find ways to assess biosecurity.
4. No. We have no resources for assessment.

International Resources – ABSA International

Principles and Practices of Biosafety

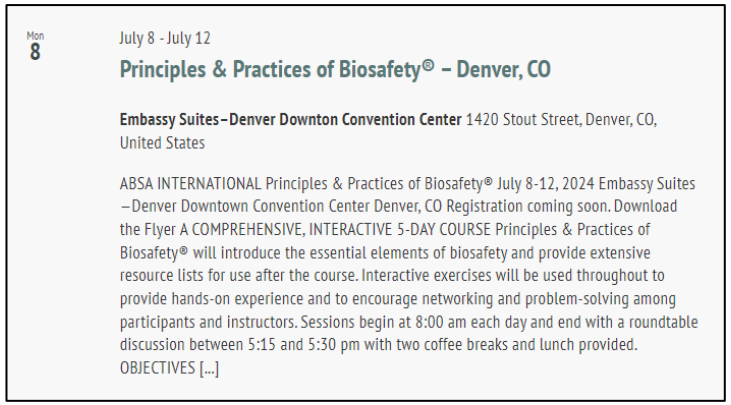
Annual Biosafety Conference

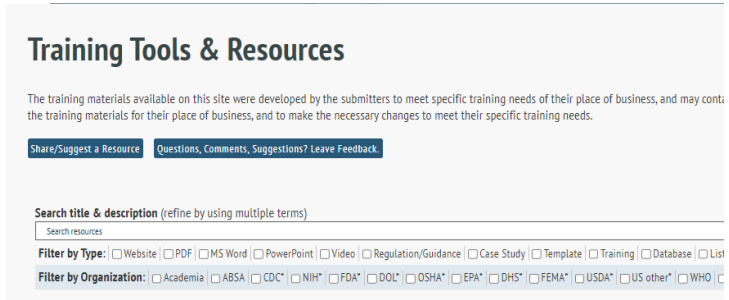
Biennial Biosecurity Symposium

Webinar Series

Training Tools and Resources

- https://absa.org/share-resource/





International Resources – Public Health Canada

Canadian Biosafety Handbook

Pathogen Safety Data Sheets

PSDS by Pathogen Name

A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | S | T | U | V

A

- *Acanthamoeba castellanii*
- *Actinobacillus spp.*
- *Actinomyces spp.*
- Adenovirus (types 1, 2, 3, 4, 5 and 7)
- Adenovirus (types 40 and 41)
- *Aerococcus spp.*
- *Aeromonas hydrophila*
- Alkhumra virus
- *Ancylostoma duodenale*
- *Angiostrongylus cantonensis*
- *Ascaris spp.*
- *Aspergillus spp.*

B

- *Bacillus anthracis*
- *Bacillus cereus*
- *Bacteroides spp.*

International Resources – Additional Resources

International Federation of Biosafety Associations

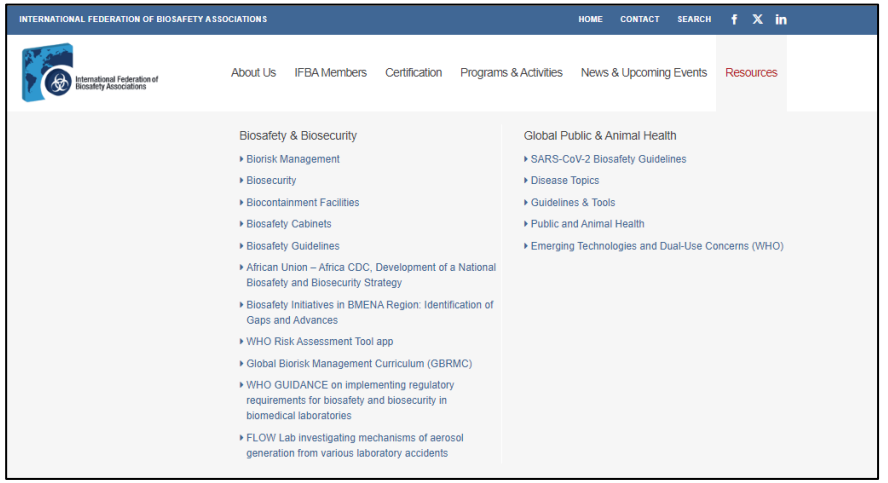
Association of Public Health Laboratories

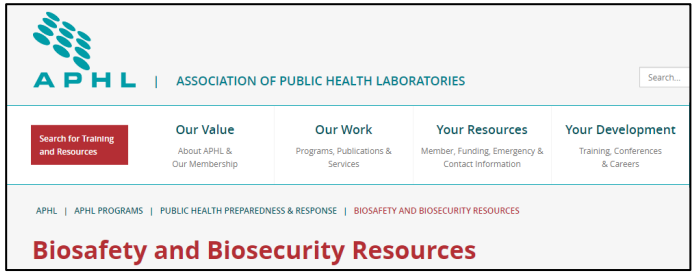
Biosecurity Central – Georgetown University

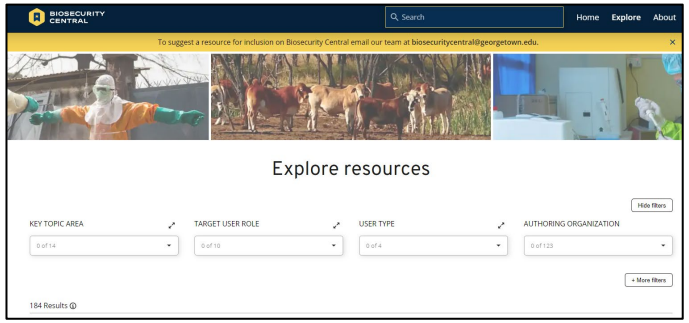
Canada Centre for Biosecurity

Denmark Center for Biosecurity and Biopreparedness

Netherlands Biosecurity Office







Global Chemical and Biological Security

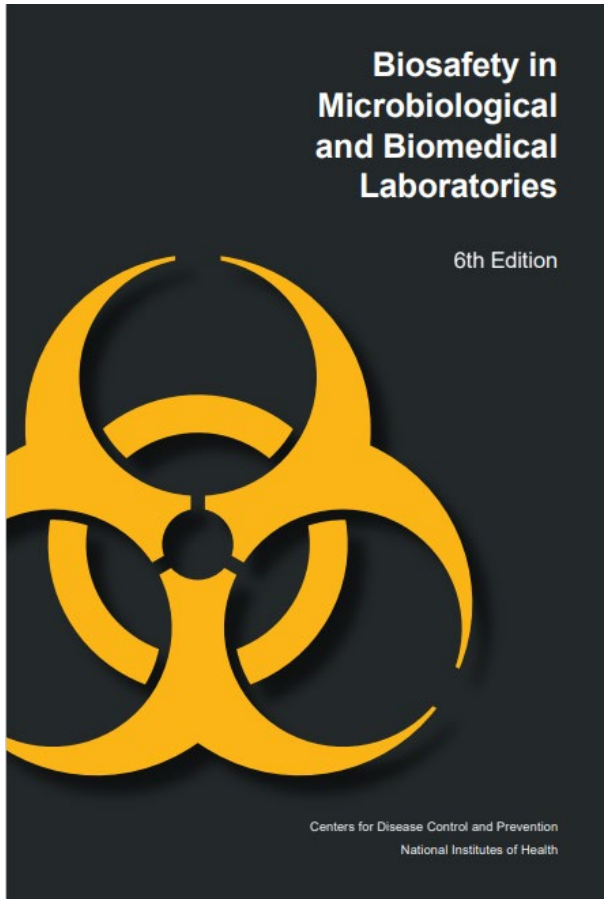
National Resources – CDC/NIH

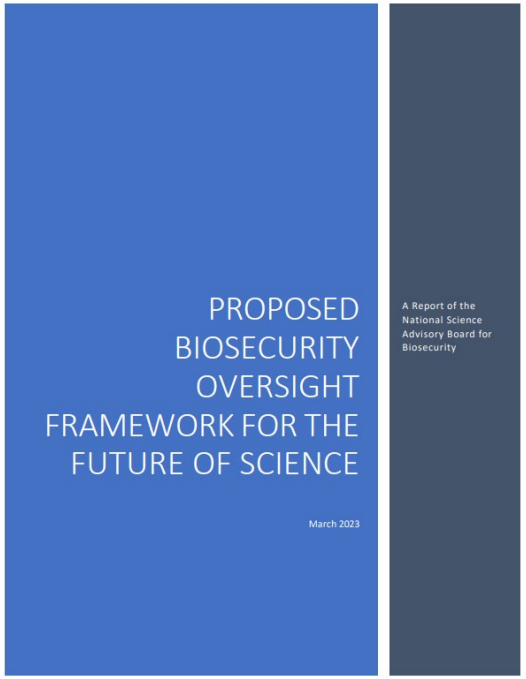
Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition

CDC Division of Laboratory Systems - Biosafety Resources & Tools

NIH Office of Science Policy

- Dual Use Research of Concern
- FAQs and Fact Sheets
- National Science Advisory Board for Biosecurity





Global Chemical and Biological Security

National Resources – Regional Associations & Other Government Entities

Affiliate Organizations

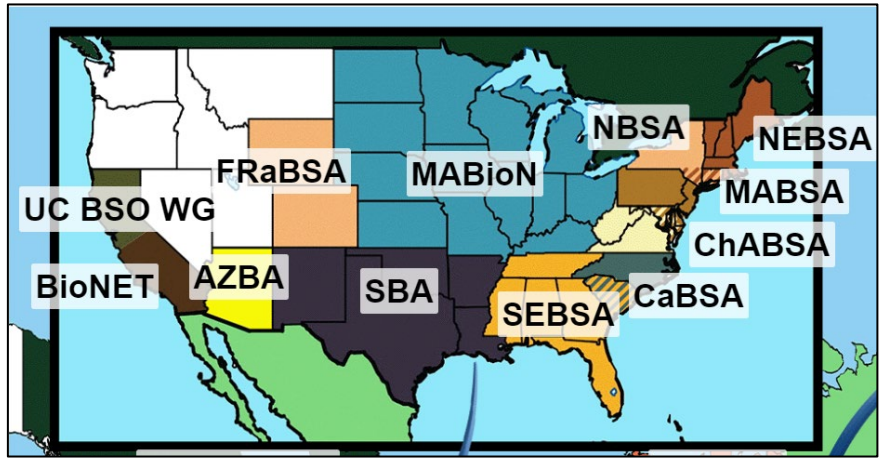
- New England Biological Safety Association
- Chesapeake Area Biological Safety Association
- Arizona Biosafety Alliance
- Front Range Biological Safety Association
- And MORE!

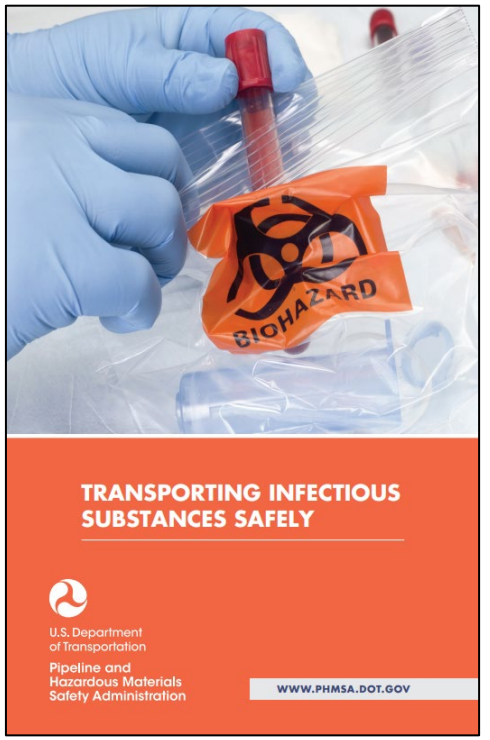
Department of Transportation

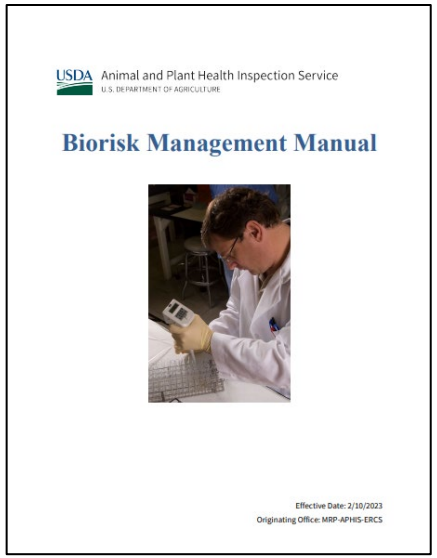
- Transporting Infectious Substances Safely

USDA

- ARS Annual Biosafety and Biocontainment Symposiums
  - Professional Development Courses
- Biorisk Management Manual







State Resources

At the Regional, National, and International Level, there is a plethora of resources and expertise available at the click of a button.

Plenary Discussion:

What type of documents and resources do you see at the State level that allows you to better implement safe and secure practices in the your laboratories?

Do you rely more on local resources or national resources to improve your biorisk management? What resources do you find the most helpful?

State of New Mexico Resources

Bureau of Health Emergency Management (BHEM)

- State-wide incident management, Hazardous material response, radiation detection and response

Department of Homeland Security and Emergency Management

- Emergency management and preparedness training

FBI, Weapons of Mass Destruction Coordinator

- Facility security, personal reliability

Environment Department

- Hazardous waste bureau, OSHA, radiation control

Department of Health

- Vaccinations, occupational health specialists, epidemiologists

WORKER HEALTH PROGRAMS

"The organization shall ensure that risks to worker health are managed effectively…"

Determine the **scope and components** of the program **based on the risk assessment**.

- Pre-employment health check?
- Prior exposures or existing disease?

Worker medical history (example):

- Identification of personnel who could have potential exposure?
- Mitigation measures (vaccination, PPE)?
- Emergency measures (isolation, transportation)?
- Prophylaxis or post-exposure treatment?
- Record types and retention requirement?

Outputs (example):

- A program that incorporates biorisks, relying on prevention, with contingency plans.
- Contingency plans that cover contractors and visitors
- Increased awareness or provision of information to workers on potential risks, signs/symptoms, consequences of exposure
- Metrics to measure program effectiveness

VACCINATION PROGRAMS

Vaccination is a risk mitigation strategy.

Based on risk assessment and cover workers who may be potentially exposed

Identify workers, visitor, contractors and other personnel who may be exposed and are eligible for vaccination based on exposure risk.

Control access to areas where work requires vaccination

Titer check schedule, efficacy and safety information.

Conditions for pre- or post-employment vaccination

Procedures for declination and non-responders

Record retention information

Competence

CWA 16335 and **ISO 81240**

ABSA

- CBSP
- RBP

IFBA

- Professional Certification in Biorisk Management
- Six Level II PCs

ASCP

- QLS

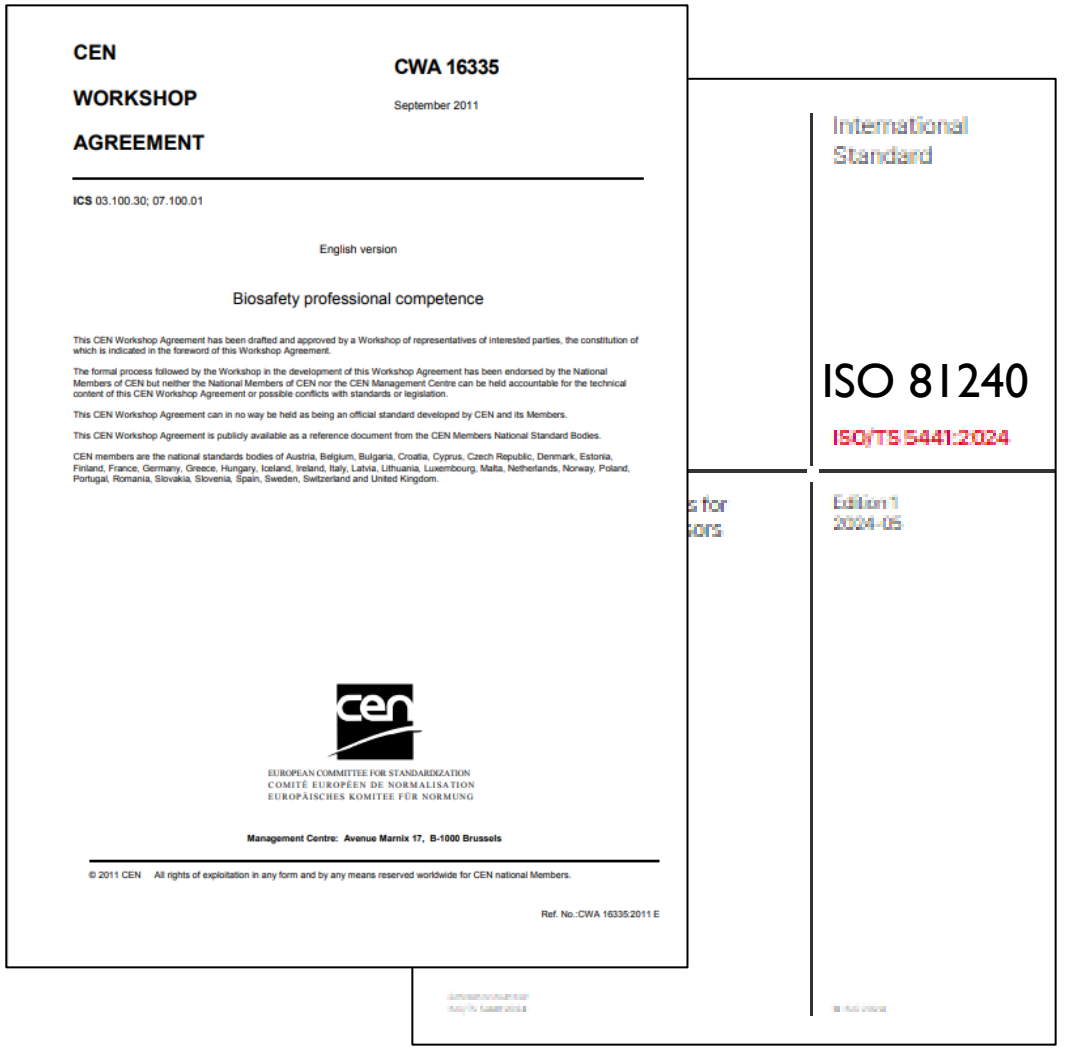
Behavioral Factors and Worker Management

Personnel Reliability Measures

Competence - European Standards Organization

CWA 16335 – Biosafety Professional Competence

- Role of Biosafety Professional in an Organization
- Biosafety Professional Background Qualifications
- Competencies
  - General
  - Core
    - General principles of microbiology, biochemistry, and cell biology
    - General principles of molecular biology and genetic engineering
    - Biological and other hazards in the work area
    - Occupational health and biosafety
    - Human factors
    - Etc. (25 Core Competencies Listed)
  - Specialized competencies – based on type of work and risk level
  - Continuing professional development
- Annexes
  - Model role profile of biosafety professional in an organization
  - Model tasks of the biosafety professional in an organization
  - Model training specifications
  - Example of a portfolio of achievements to demonstrate relevant experience of biorisk management


CEN

WORKSHOP

AGREEMENT

CWA 16335

September 2011

ICS 03.100.30; 07.100.01

English version

Biosafety professional competence

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No.:CWA 16335:2011 E

International Standard

ISO 81240

ISO/TS 5441:2024

Edition 1
2024-05

POLL QUESTION #3

Do you feel that external worker certification or credentialing would help to promote a culture of biosecurity and biosafety in your organization?

1. Yes.
2. No.
3. Maybe.

Competence – ABSA International

Professional Credentialling

- For years the practitioners of biosafety have come from many different disciplines. It was usually determined that there was a need for someone to oversee the institution's biohazards operations. It was a position born out of necessity and was usually given over to either a senior research scientist with some background in microbiology or to the safety professional with no background in biological work. The field of biosafety has become defined and refined over the years. Research has become very complicated with rDNA work and highly infectious organisms, the threat of bioterrorism, and emerging diseases. Many institutions now require that individuals overseeing biohazard and rDNA work be competent, educated, and have proper experience.

A **Certified Biosafety Professional** (n=227)

- is an individual with a documented microbiology foundation and experience overseeing a biosafety program. Recipients are internationally recognized by their commitment to professional development to biosafety. The CBSP designation awarded upon application approval and passing the certification exam.

Registered Biosafety Professional (n=480)

- is an individual with documented university education or specialized training in relevant biological safety disciplines. A RBP has an understanding of infectious diseases, their transmission, and the application of methods to safely control infectious materials in research, clinical, production, testing, educational, developmental, and other work environments. RBPs understand the need for and application of biological safety principles and practices. They have detailed knowledge of regulatory guidelines and standards impacting work with infectious agents and materials.

Competence – International Federation of Biosafety Associations

Level I Professional Certification

- Biorisk Management (n=1552)

Level II Professional Certifications

- Biosecurity (n= 185)
- Biological Waste Management (n=69)
- Biosafety Cabinet Selection, Installation and Safe Use (n=41)
- Biocontainment Facility Design, Operations & Maintenance (n=24)
- Biological Risk Assessment (n= 76)
- Cybersecurity (n=22)

Competence – American Society of Clinical Pathologists

Qualification in Laboratory Safety – QLS

Professionals involved in any phase of laboratory safety, including compliance, training, developing, and/or managing safety programs for laboratory employees, trainees, and/or students.

ASCP BOC ASCP BOARD OF CERTIFICATION

Competency topics:

- Management (regulatory agencies, regulations, and guidelines)
- General Safety (ergonomics, fire, electrical, compressed gasses, radiation, work practices, spills)
- Chemical Safety (classifications, incompatible mixtures, signs and labels, management)
- Biohazard Control (infection control, protocols)
- Physical Environment (equipment, disinfection/decontamination, disposal and waste management)

Competence - Behavioral Factors and Worker Management

Addressing biorisks associated with inappropriate behavior or human factors.

Preventative approach to managing risks associated with individuals and including these issues in risk assessments.

Multidisciplinary approach to managing behavioral risks:

- Documents, procedures, checklists, SOPs
- Occupational health and safety program
- Manager training in observation and recognition of behaviors
- Promoting personal reliability (see something, say something)
- Establishing communication, consultation, and feedback processes
- Conflict management and resolution processes
- Respecting individual privacy and dignity

Competence - Personnel Reliability Measures

*"…provide assurance that workers are **reliable, trustworthy, and competent**, and to identify individuals who may pose a biosecurity or biosafety risk…"*

Determined by the risk assessment.

Management ultimately responsible for establishing a policy and program.

- Define personal reliability requirements for each position in the organization.
- Control access to materials and locations based on risk.
- Establish screening program (identity verification, education, employment, etc.) with periodic reviews at changes in responsibility.
- Measures should determine the willingness of personnel to support a strong safety and security culture.

Requirements should be consistent, transparent, and documented.

Treat screening results as sensitive and personally identifiable information.

POLL QUESTION #4

What resources are available to you for training?

(Select all that apply)

1. Organization-provided
2. External subject matter experts
3. National societies/association material
4. Other laboratories'/universities' material
5. Subscriber-based programs
6. Regulator/certifier programs
7. Self-study programs

Awareness

How are staff made aware of BRM program elements?

Training

- CDC/NIH
  - Division of Laboratory System Biosafety Trainings
  - NBBTP/IRTA
- **IFBA Related Credentialling Trainings**
  - Frontline Foundation
  - Professional Associations
  - Biosafety Training Institute
- **SNL**
  - GBRMC
  - Core Documents

Awareness

Resources and Competencies are critical for the effective design and development of a strong biorisk management system. All of the preparation in the world will be useless if it is not properly distributed to the working staff at an institution.

PLENARY

- **How is facility staff at your institution made aware of your biorisk management system, policy, investigation outcomes, performance, nonconformities, and/or legal responsibilities?**
- **Who is responsible for ensuring that the staff is aware of the above?**
- **What does BRM training look like in your facility?**

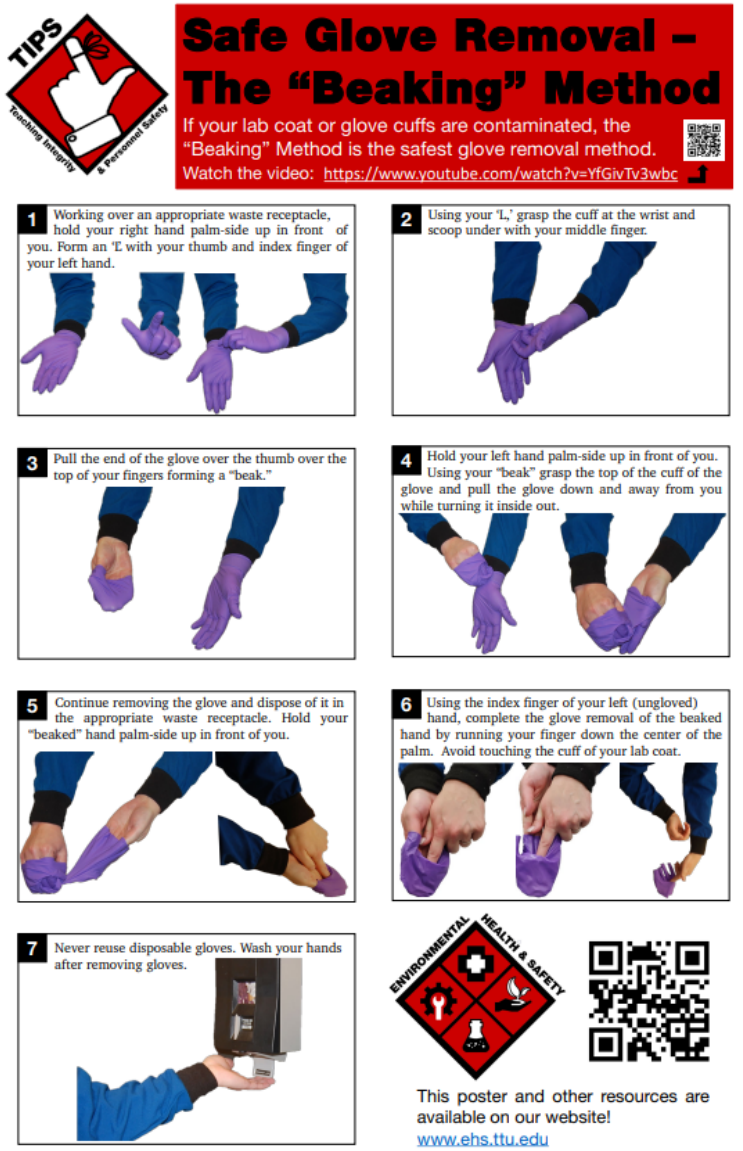
Awareness - Training

Internal Trainings and Awareness Raising

- Official Staff Training Events – Onsite or Offsite
- Dedicated Meeting Time – Training Topics
- Lunch and Learns
- Announcements
  - Fliers, Posters, Emails, Listservs

External Trainings

- Subject Matter Experts from outside the facility conducting training
  - Roadshows
  - Nonprofits
  - Associations
  - Governmental Bodies
  - Private Companies
    - Specific Equipment Demo/Training



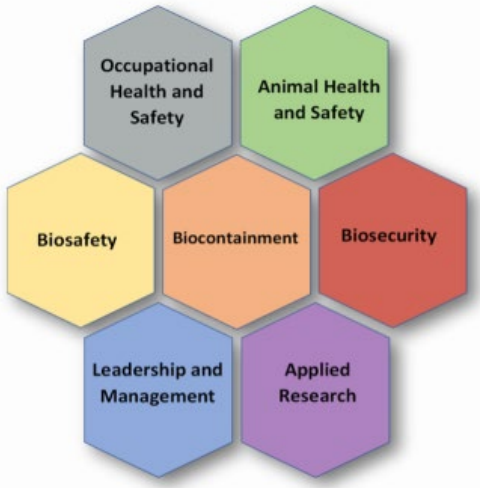
Awareness – Training – CDC & NIH

Division of Laboratory System Biosafety Trainings

- Fundamentals of Chemical Fume Hood Safety
- Fundamentals of Centrifuge Safety
- Fundamentals of Working in a Biological Safety Cabinet
- Introduction to Laboratory Risk Management
- Additional Course

Exploring the dexterity in personal protective equipment by performing various tasks in a simulated environment.

Credit: NBBTP/IRTA



Hexagonal grid displaying the seven core components of the NBBTP curriculum

Credit: NBBTP/IRTA

NBBTP / IRTA

- The **National Biosafety and Biocontainment Training Program** (NBBTP)/Intramural Research Training Award (IRTA) Fellowship is a two-year program designed to train Fellows specifically to support high containment research environments by acquiring knowledge and skills necessary to meet the scientific, regulatory, biocontainment, biosafety, engineering, communications, management, and public relations challenges associated with the conduct of research in these facilities.
- The mission of the NBBTP/IRTA is to prepare biosafety and biocontainment professionals of the highest caliber to meet the needs of the biomedical emerging disease and civilian biodefense research communities through the 21st century.

Awareness – Training – IFBA Credentialling Related Training

Frontline Foundation Online Training

- Online Programs
- Six courses available, including Biorisk Management, Biosecurity, and Biohazardous Waste Management
- 2-8 Hour Duration

Biosafety Training Institute

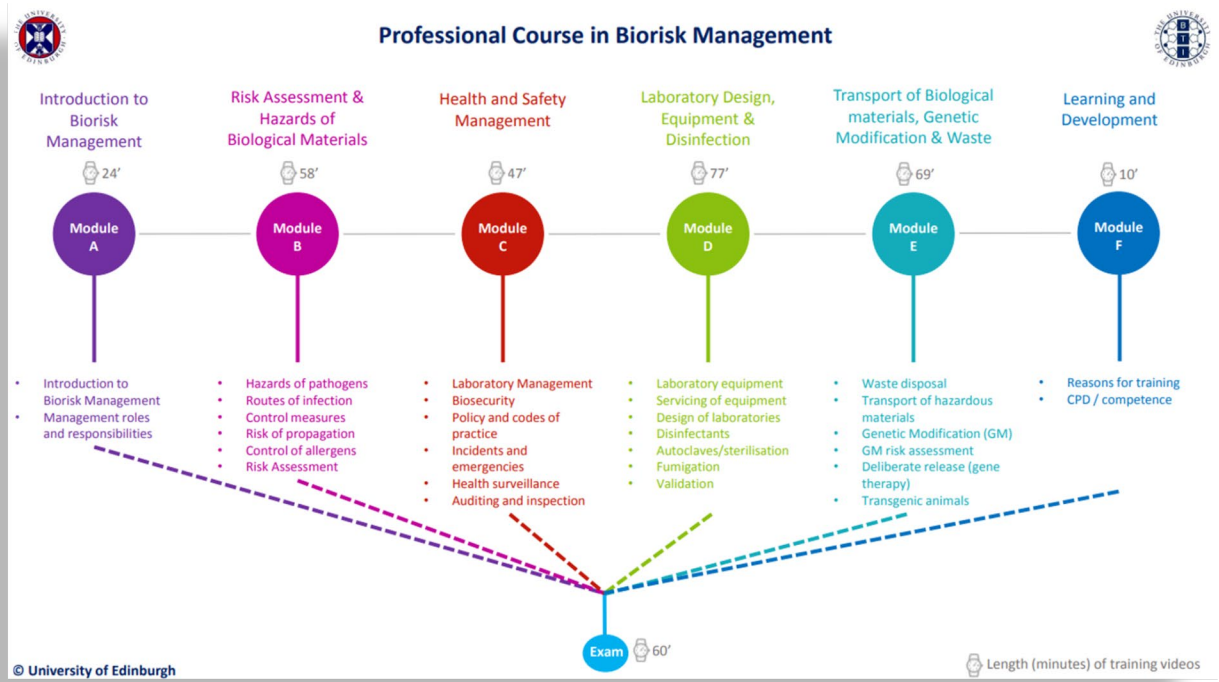
- Six Modules
- Approximately 6 hours over up to three months

Professional Associations

- Typically International Biosafety Associations
- Target specific population for opportunities
- Focused on one exam topic

Sandia National Laboratories

- Biorisk Management and Biosecurity
- 12 week, six sessions
- Currently requires special access



Awareness – Training – Sandia National Laboratories

Global Biorisk Management Curriculum (GBRMC)

- 42 Courses, plus draft, piloting courses, and guided exercises
- Four "tracks"
  - Foundational
  - Laboratory-level
  - Management and Leadership
  - Laboratory Design (Further restricted)
- 4-8 hours each
- Requires trainer development orientation to access

Core Document Library

- SOP Templates
- Program Plan Templates
- Manual Templates

Wrap Up

Resources

- Having the right resources for your facility is essential for the safe and secure operation of your laboratory.
- It is the responsibility of the organization to provide appropriate resources for a BRM system.
- Organizations around the world have put together content to support the strong development of a BRM system so there is no need to reinvent the wheel.

Competency

- Understanding and documenting a facilities competency needs is critical.
- Credentialling programs exist to ensure minimum standards are met.
- Behavioral and other human factors are a growing field to ensure personnel reliability needs are met to protect the workforce and facility.

Awareness

- Creating a BRM system will not improve safety or security if the staff does not know what the system is.
- Preview for upcoming sessions, COMMUNICATION is a critical piece of awareness raising.
- Understanding the different training requirements of different staff members is essential to establishing a well organized and structured BRM system.

Questions?

Post-session Survey

- Takes 2 minutes to complete and helps improve ECHO Biosafety Program and CoP
- Participation is voluntary
- Responses are anonymous and feedback will be summarized in aggregate
- Questions? Contact DLSbiosafety@cdc.gov

DLS ECHO Biosafety Session: June 25, 2024

Support: Communication and Documented Information

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