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INTERNATIONAL BIOLOGICAL and CHEMICAL THREAT REDUCTION

Integrated Laboratory Biosafety and Biosecurity and Global Health Security

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Outline

- Introduction
  - Sandia National Laboratories International Biological and Chemical Threat Reduction (IBCTR)
- What is laboratory biosafety and biosecurity ?
  - Laboratory biorisk management
- History of biosafety and biosecurity
- Paradigm shift from compliance-based to risk-informed performance-based
- Biosafety and biosecurity influences lab design and infrastructure
- Resources for biorisk management
- International Regulations, Guidance, and Standards for biorisk management

Sandia National Laboratories International Biological and Chemical Threat Reduction

INTRODUCTION

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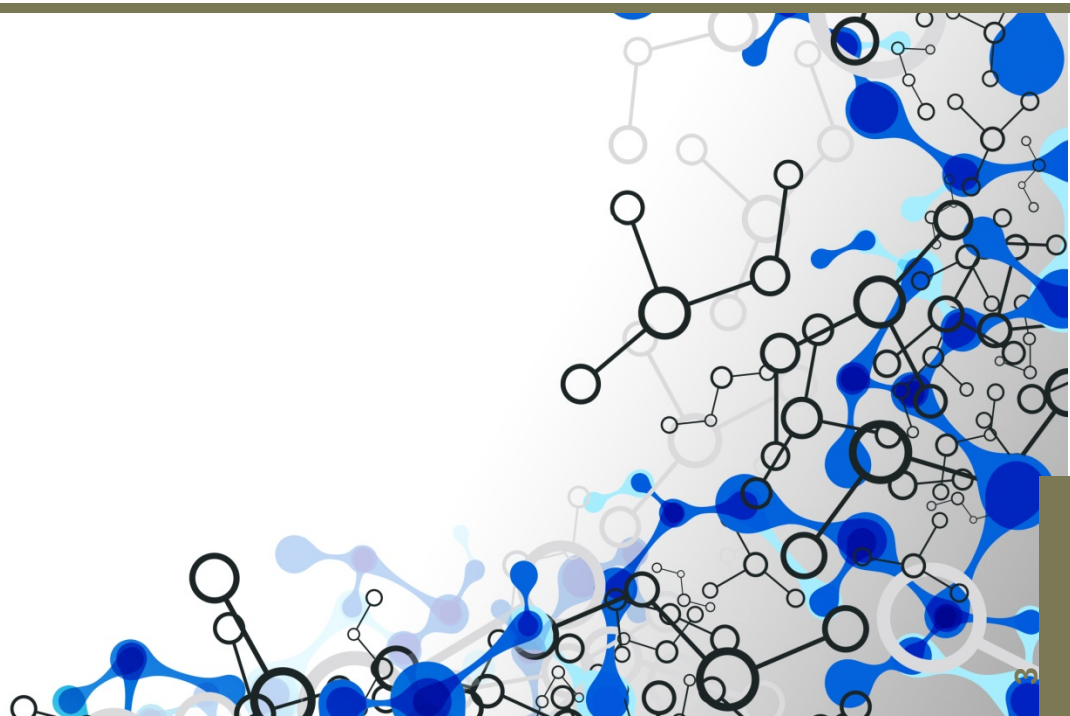

Innovative solutions for countering biological and chemical threats globally

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Strengthen capacities to safely, securely, and responsibly detect, handle, and control dangerous biological and chemical agents

- Promote the responsible use of biological and chemical agents, equipment, and expertise globally
- Improve understanding and management of the risks associated with accidental and deliberate misuse of biological and chemical agents.
- Encourage global partnerships and adherence to international risk management standards




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INTERPOL

Bioterrorism prevention

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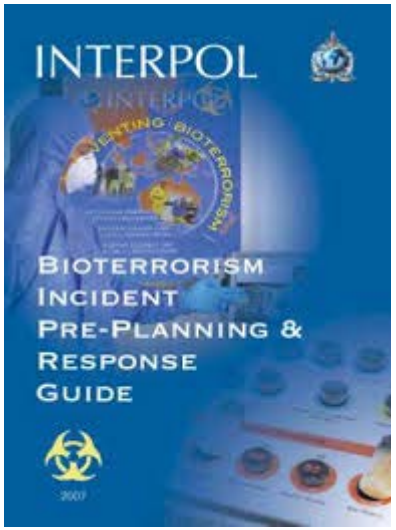

Training development and delivery

- Regional train-the-trainer sessions to promote interagency communication and collaboration
- Enhance safety and security of biological materials
- Operational response to biological incidents

Incident Response Guide Development

- Reference guide
- Bioterrorism preparedness and response

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IBCTR's global experience

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What is laboratory biosafety and laboratory biosecurity?

LABORATORY BIORISK MANAGEMENT

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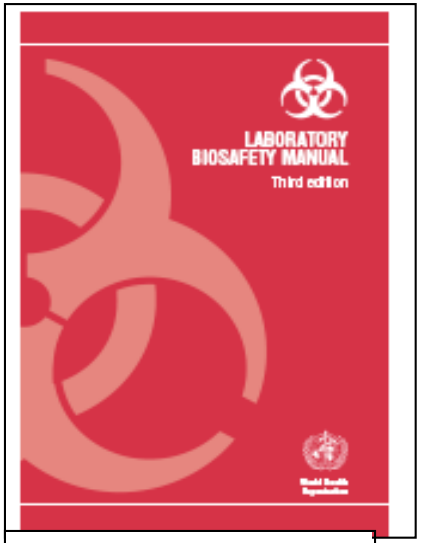
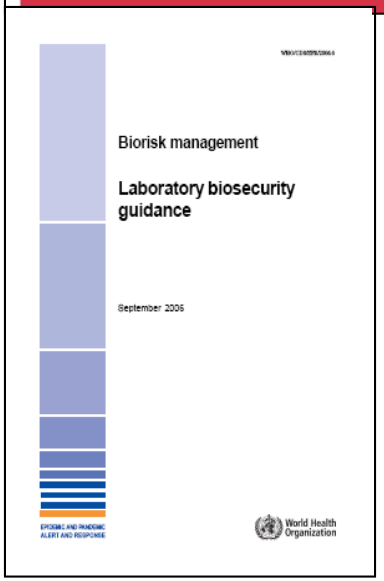
Definitions

Laboratory biosafety: containment principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release[1]

Laboratory 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)

Definitions continued

[1]**Biological Risk Management**: The analysis of ways and development of strategies to minimize the likelihood of the occurrence of biorisks (i.e. the probability or chance that a particular adverse event, including accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release, possibly leading to harm, will occur).

[2]**Biorisk Management System**: (adapted from OHSAS 18001:2007) part of an organization's management system used to develop and implement its biorisk policy and manage its biorisks

[1]Global Health Security Agenda
http://www.cdc.gov/globalhealth/healthprotection/ghs/pdf/ghsa-action-packages_24-september-2014.pdf
[2]CWA 15793 Laboratory Biorisk Management (CEN 2011)

History of biosafety and biosecurity

RECENT BIOSAFETY AND BIOSECURITY INCIDENCES

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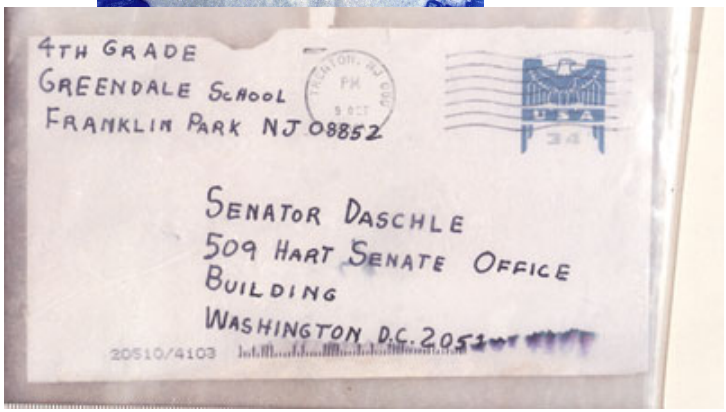
History of Biosafety

Laboratory-acquired infections

- 2001: first human case of glanders in the US in over 50 years
  - Situation: 33 year old microbiologist worked with *Burkholderia mallei* **did not routinely wear gloves**
- 1996: 6 of 19 medical technologists were infected and became ill with *Shigella sonnei*
  - Situation: cultured isolates indicated that the *Shigella* strain was nearly identical to a control strain kept by the laboratory
- 2004: **needle sticks** continue to be problematic in laboratories
  - Situation: a researcher received a needle prick in a biosafety level 4 working with mouse-adapted variant of Ebola Zaire
- 2000: 8 children ages 11-14 became ill after playing with a discarded smallpox vaccine vial
  - Situation: most likely **improper decontamination** and disposal procedure
- 2004: 2 laboratory workers contracted severe acute respiratory syndrome after working with improperly inactivated virus

History of Biosecurity

- 1996: Larry Wayne Harris ordered *Yersinia pestis* under **false pretenses**, USG enacted the select biological agent list to regulate transfer between facilities
- 2001: FBI claimed Bruce Ivins **mailed** several **letters** that contained anthrax spores resulting in 5 deaths with17 ill; USG revised select agent increasing number of agents and requiring specific security measures
- 2004: Texas Tech University professor Thomas Butler was sentenced to two years in jail after reporting **30 vials** of plague bacteria were **missing**
- 2009: former researcher at the National Microbiology Laboratory in Winnipeg, Canada **stole 22 vi**als of Ebola virus genetic material
- 2005-2009: series of **inventory discrepancies** in a variety of US laboratories



Compliance-based to risk-informed performance-based

CHANGING BEHAVIOR

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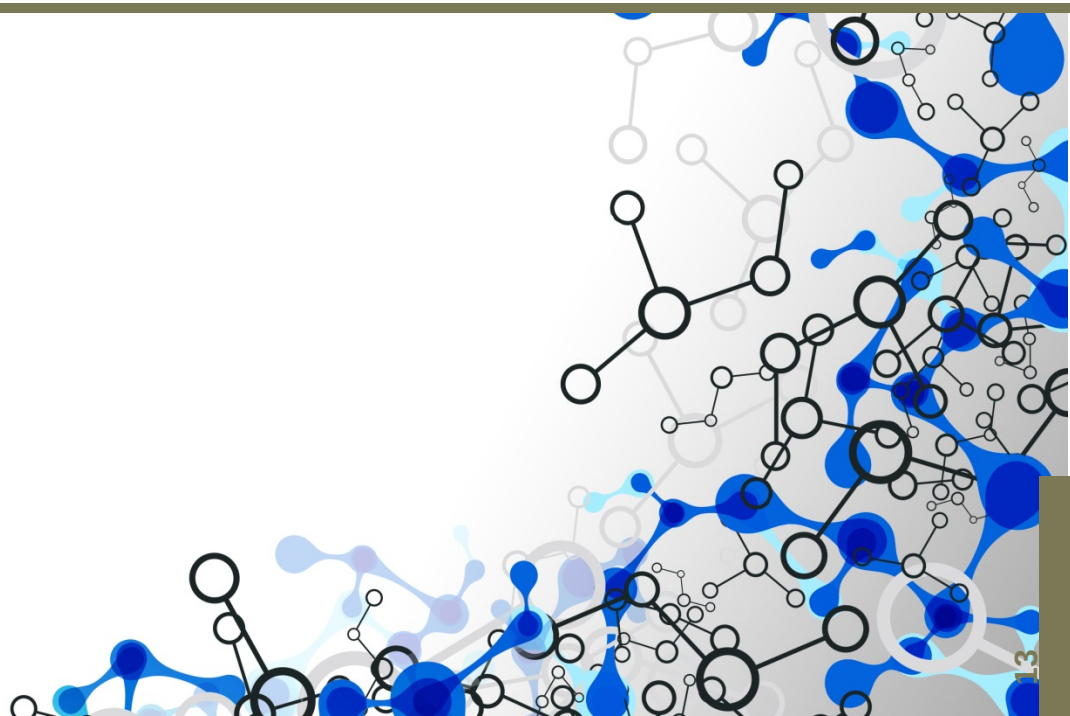

Biorisk Management
Integrating Biosafety and Biosecurity

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PERFORMANCE OBJECTIVE:

To minimize risks working with biological agents and toxins

INCIDENT:

Injury, loss of life, theft, loss of biological agent or toxin happens

RECOVERY:

New procedure, regulation, staff, requirement etc.

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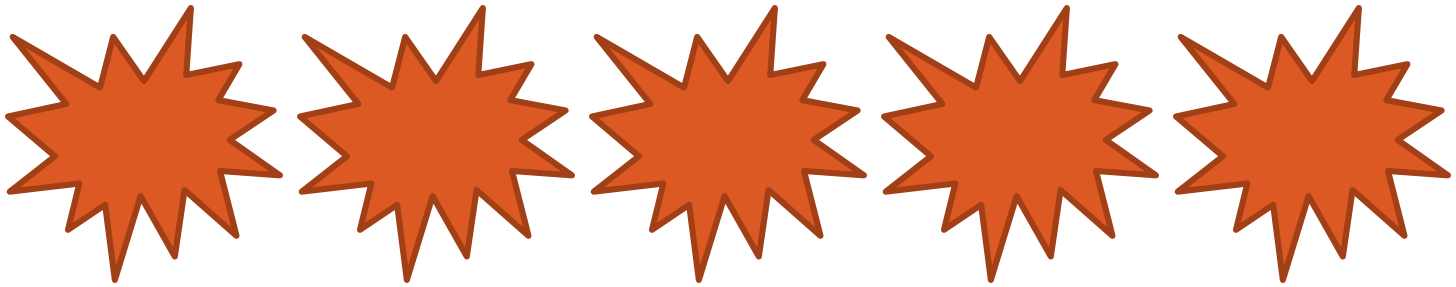
Lapses in biosafety & biosecurity

Biosafety and biosecurity incidences are recent!

Lack of Behavior to meet performance objective found to be, in part:

- Lapses in fundamental biosafety good practices
  - *hand washing, not wearing PPE, following procedures*
- Lapses in personnel management, material control & accountability, overall program management resulting in
  - *Theft, loss of material*



WHY?

Compliance-based versus Performance-based

- **Lack** of site-specific / work-activity biosafety and biosecurity risk assessment

- **Lack** of personnel management and program management

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Most laboratories handling potentially dangerous biological materials are stuck in compliance mode.[1]

Without clear understanding of performance objectives

1. Tim Trevan "Biological research: Rethink biosafety" *Nature* November 12, 2015:527,155-158 www.nature.com/news/biological-research-rethink-biosafety-1.18747

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Critical Elements for Success

Integrated Biosafety & Biosecurity: Biorisk Management

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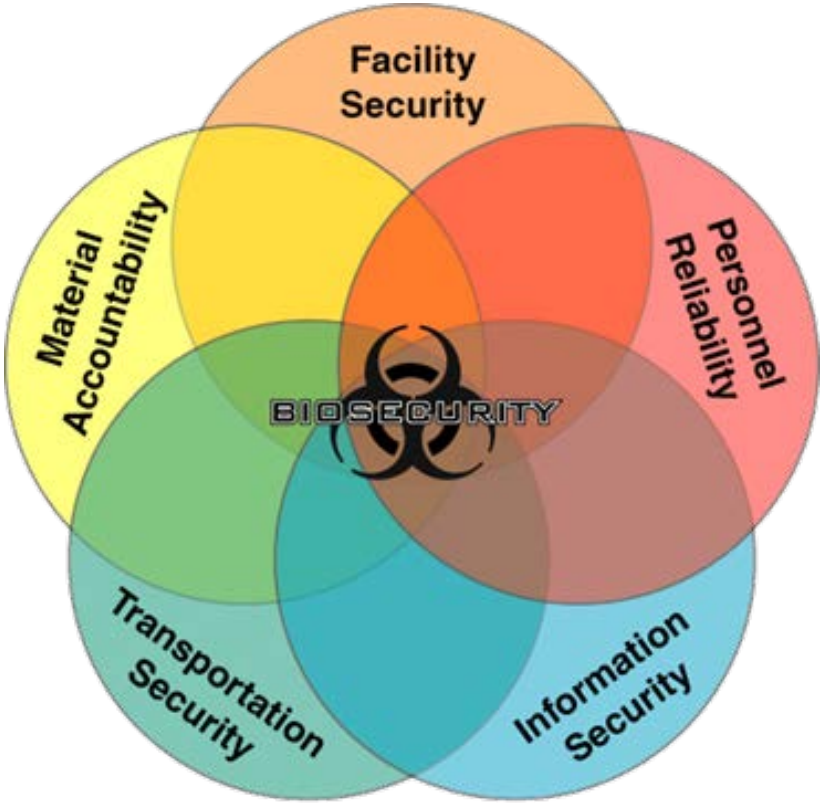

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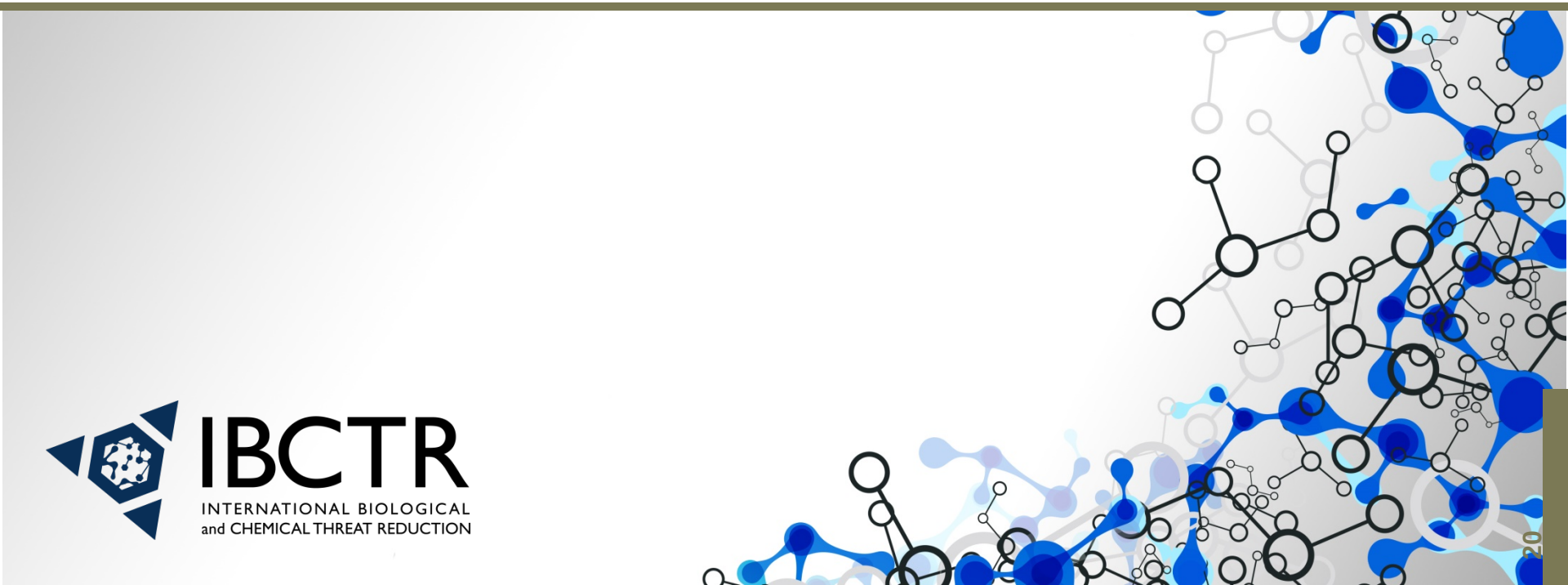
Biosafety and biosecurity influences lab design and infrastructure



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Risk-based design process

Biosafety and Biosecurity risk assessments used to identify, evaluate, and prioritize biosafety and biosecurity risks present in the facility

1. Nature of the agents or toxins present
2. Scientific procedures used
3. Risk of exposure to staff working in the facility
4. Risk to environment or persons outside of facility
5. Risk of theft of biological agents or toxins
6. Risk to the facility and users from outside threats

Biosafety and Biosecurity Principles for Laboratory Design and Infrastructure

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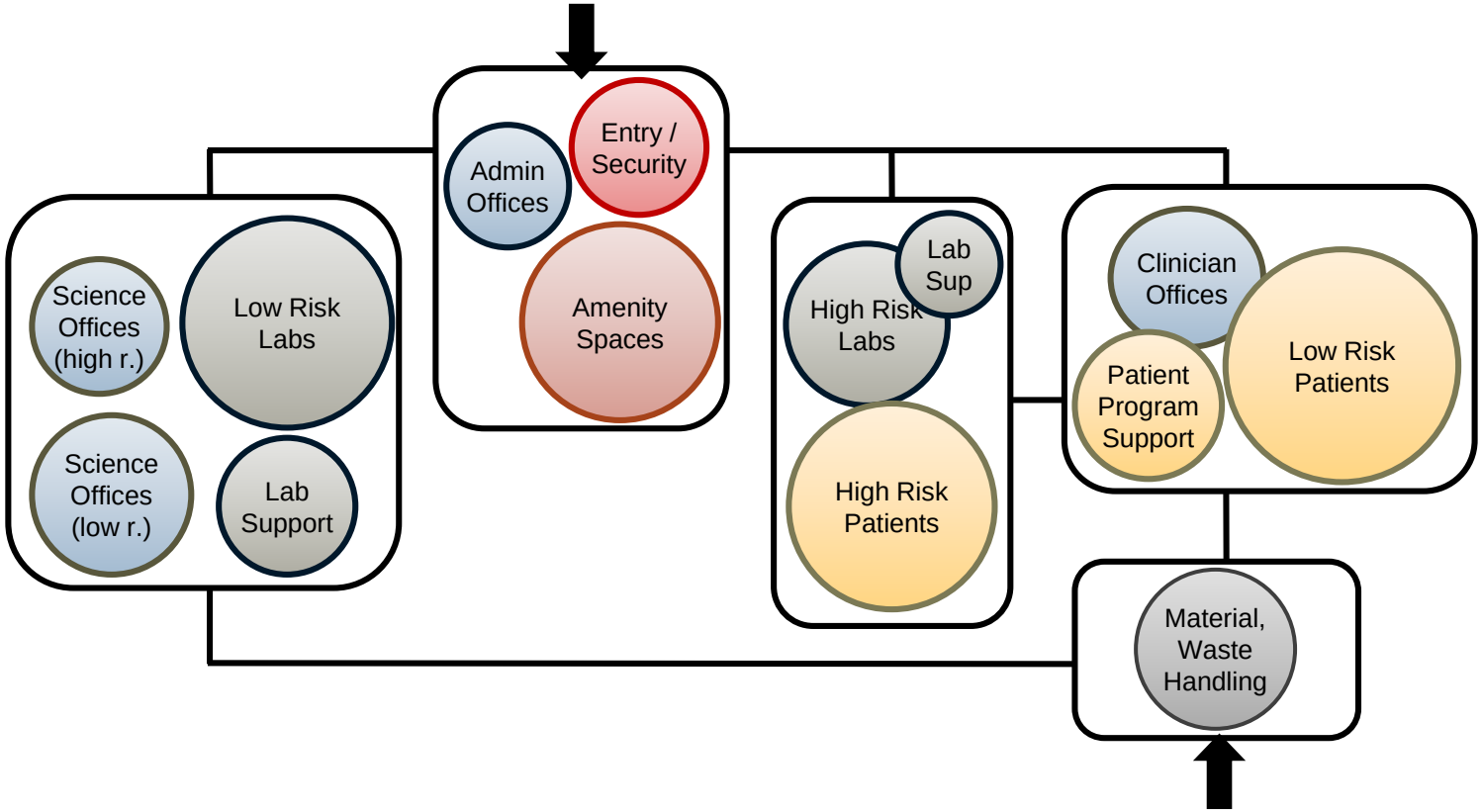
Zoning and Organization - Higher Risk Areas Consolidated



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Biosafety and Biosecurity Mindfulness -Balancing Laboratory Design with Protocols

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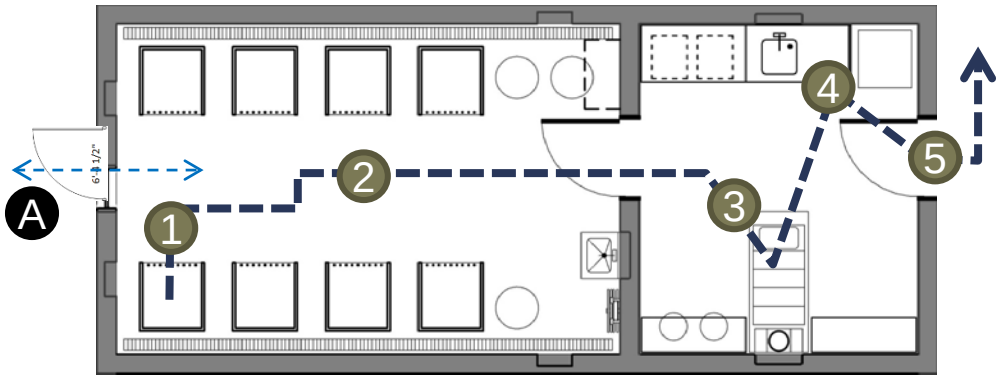
Protocol mapping

- Mapping out step by step protocols identifies areas of risk and uncovers needs
- When risks are discovered design team works with the scientific & biosafety personnel to solve with a combination of design and protocols



A. Patient entry and exit
1. Patient in waiting room
2. Patient moves to procedure room
3. Patient seated in chair or on table
    a. Clinical sample taken
4. Sample packaged at bench and placed in double container
5. Sample taken from procedure area to lab for analysis

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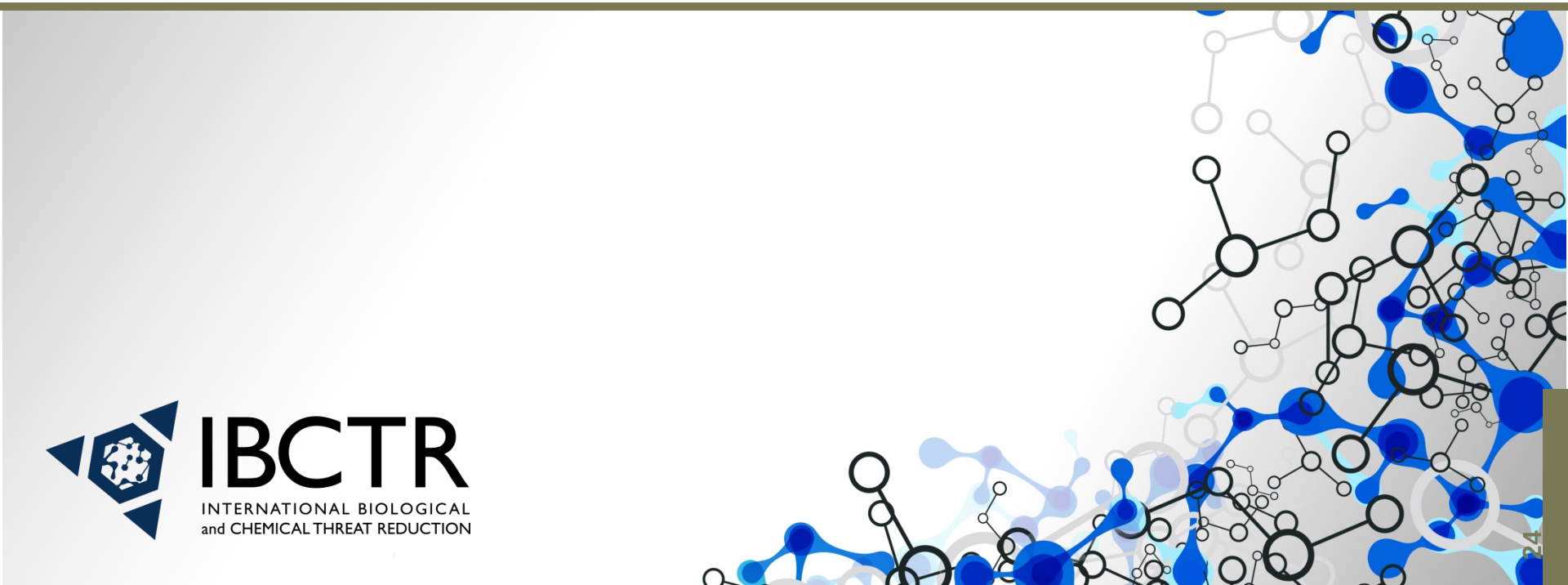
Resources for biorisk management



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Global Health Security Agenda (GHSA)

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The Global Health Security Agenda	The Global Health Security agenda is an effort between the U.S. government, other nations, international organizations and public and private stakeholders, to accelerate progress toward a world safe and secure from infectious disease threats and to promote global health security as an international security priority.

Action Package Prevent-3
Biosafety and Biosecurity

http://www.globalhealth.gov/global-health-topics/global-health-security/

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Kenya & GHSA AMR and BS&S Action Packages

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ANTIMICROBIAL RESISTANCE ACTION PACKAGE PREVENT-2

1. PLAN OF ACTION FOR INTERNATIONAL HEALTH REGULATIONS(2005) IMPLEMENTATION
2. National Integrated Disease Surveillance & Response Strategic Plan 2013-2018
3. STATUS OF IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005) IN KENYA 2014
4. National Strategic Plan for Infection Prevention and Control 2014-2018
5. National Infection Prevention and Control Guidelines for Health Care Services in Kenya, December 2010

BIOSAFETY & BIOSECURITY ACTION PACKAGE PREVENT-3

1. PLAN OF ACTION FOR INTERNATIONAL HEALTH REGULATIONS(2005) IMPLEMENTATION
2. National Integrated Disease Surveillance & Response Strategic Plan 2013-2018
3. STATUS OF IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005) IN KENYA 2014
4. Veterinary Policy Draft Two July 2012
5. National Infection Prevention and Control Guidelines for Health Care Services in Kenya, December 2010
6. NATIONAL PUBLIC HEALTH LABORATORY SERVICES STRATEGIC PLAN, 2014-2019

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East Africa Biorisk Management Training Community

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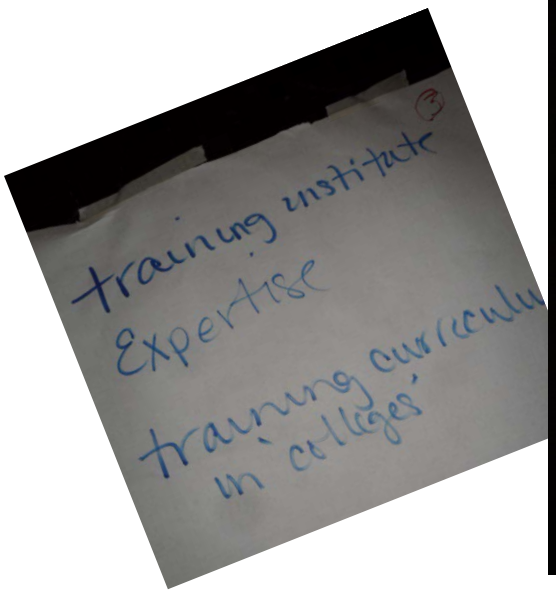
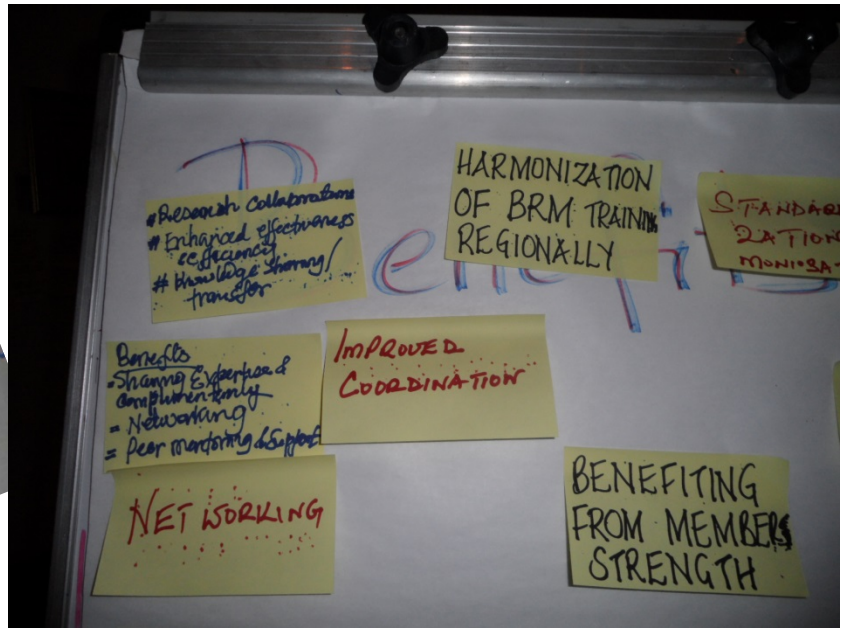
Objective: Create a regionally recognized network of biorisk management expertise

- Deliver biorisk management training with partners from (*to date* Kenya, Uganda, Ethiopia, Tanzania, Rwanda, South Africa, West Africa)
- Develop regional trainers and a sustainable trainer development plan
- Develop mechanisms and opportunities to integrate biorisk management into higher education





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Global Biorisk Management Curriculum
(GBRMC)

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Biosafety and Biosecurity training materials

- Strategic, sustainable
- Anywhere, anytime
- Well-branded, well-managed
- Customizable

Network of trainers

- In over 51 countries
- Since 2012, taught >700 times to >3700 students

GBRMC

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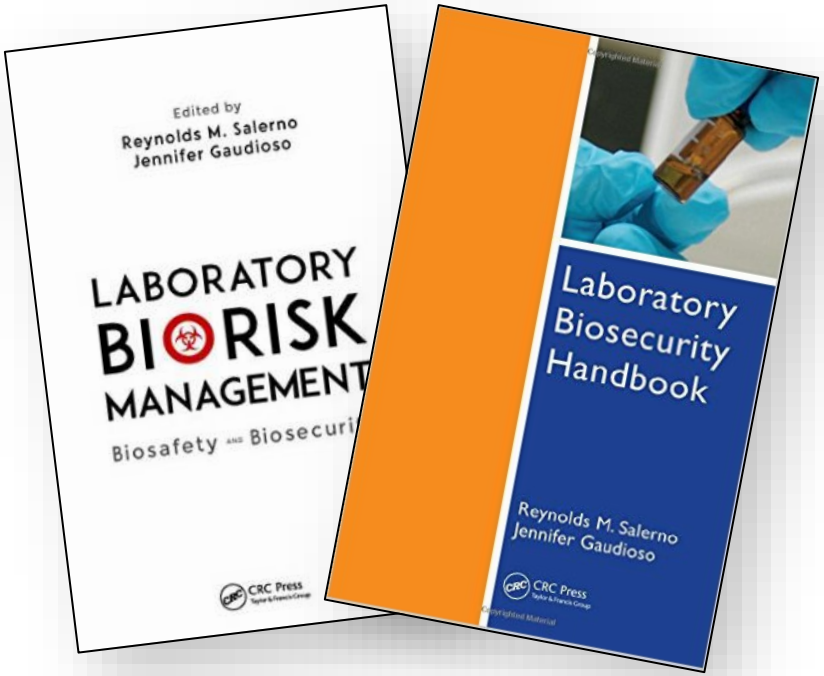
Laboratory Biorisk Resources

LABORATORY BIORISK MANAGEMENT (2015)



Both books focus on

- Rigorous risk assessment
- Deciding how to mitigate those risks deemed to be unacceptable
- Establishing mechanisms to constantly evaluate the effectiveness of the control measures

LABORATORY BIOSECURITY (2007, 2nd ED. IN PREPARATION)

IBCTR's Risk Assessment Methodologies

Vision

- Create a standardized approaches to risk assessment for chemical and biological safety and security
- Create a tool for understanding prioritization and communication

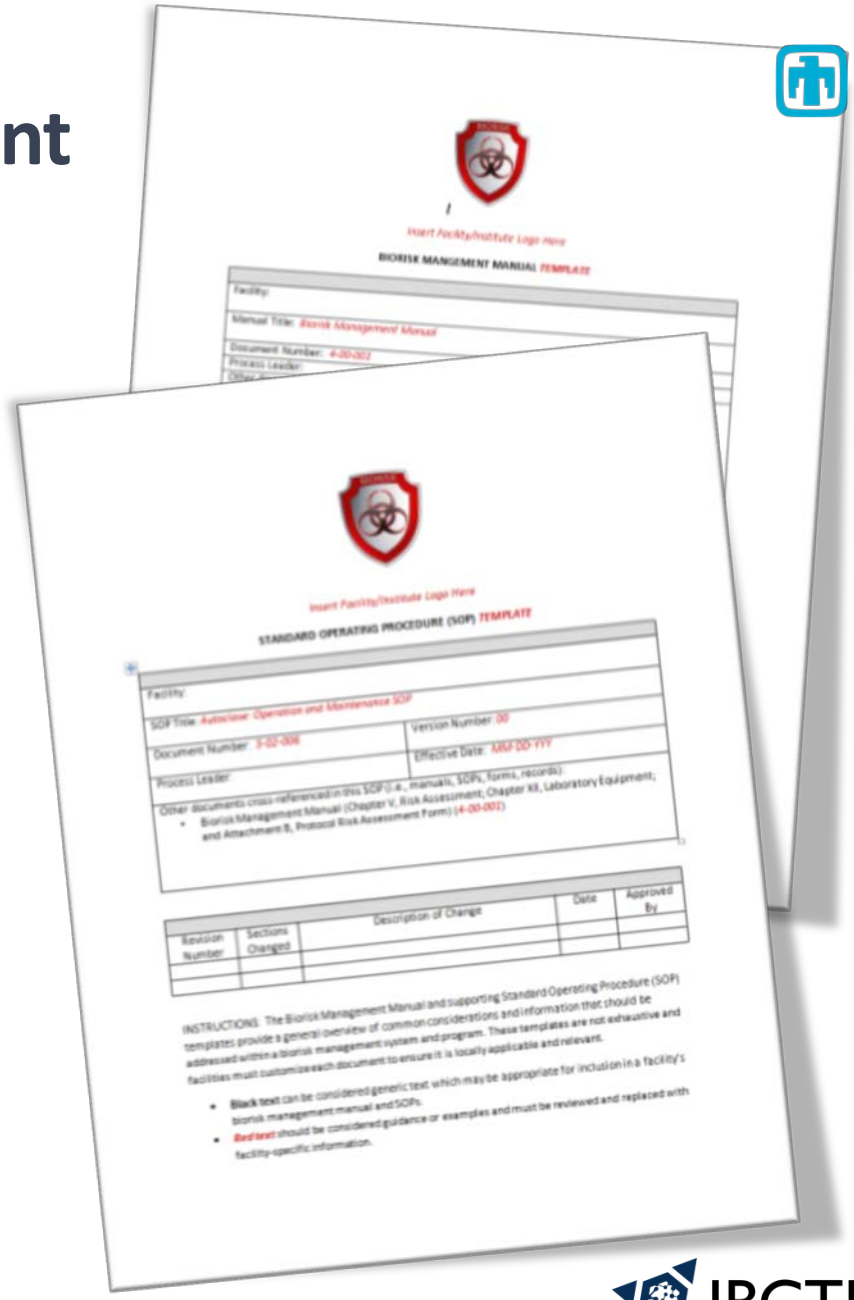
The Tools

- Biosafety RAM
- Biosecurity RAM
- Chem SAM

Tools for risk management

Library of Core Documents for risk management

- Biorisk Management Manual template
- Operations and Maintenance Manual template
- SOP templates including
  - Autoclaves
  - Biosafety Cabinet
  - Personal Protective Equipment
  - Spill Response
  - Waste Handling
  - Inventory Management
  - Chemical Hygiene Plan



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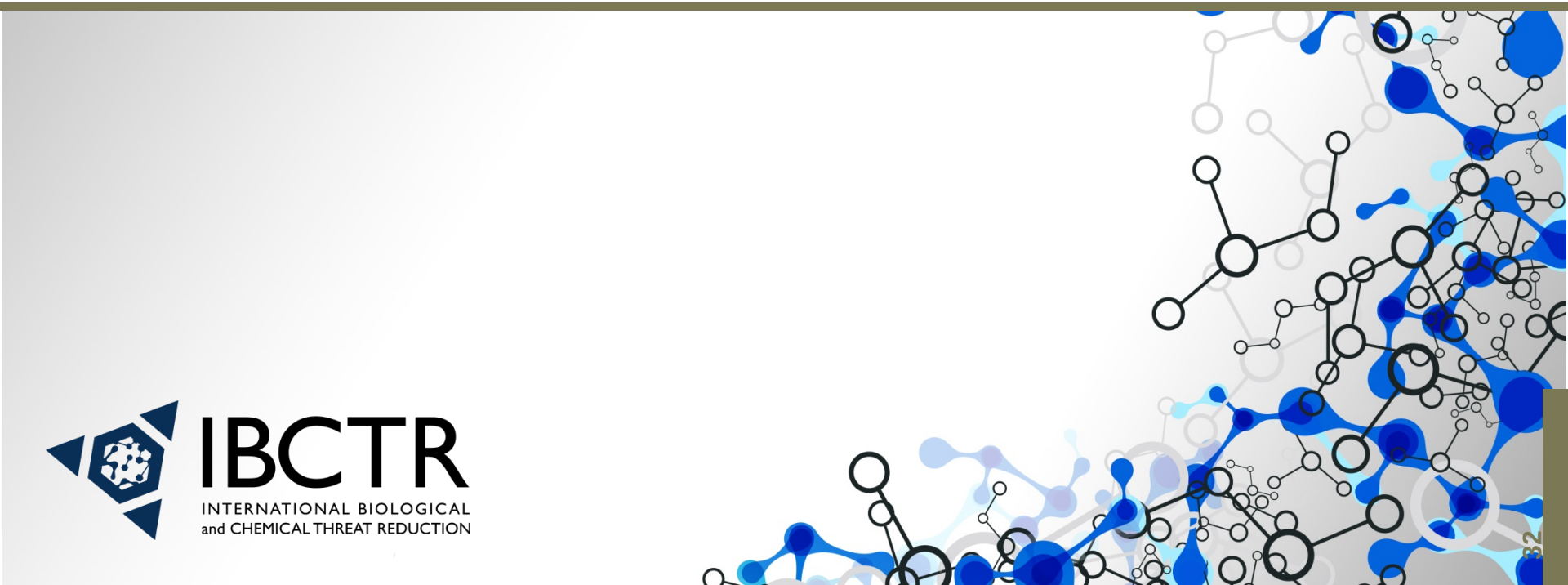
International References, Guidance, and Standards for biorisk management



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International Biosecurity References

- CWA 15793: Laboratory Biorisk Management
    - *Participating in the conversion to an ISO 35001 standard*
- UN Security Council 1540, 2004
- Biological & Toxin Weapons Convention (BWC), 1972
- Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document (International Federation of Biosafety Associations)

CEN

WORKSHOP AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

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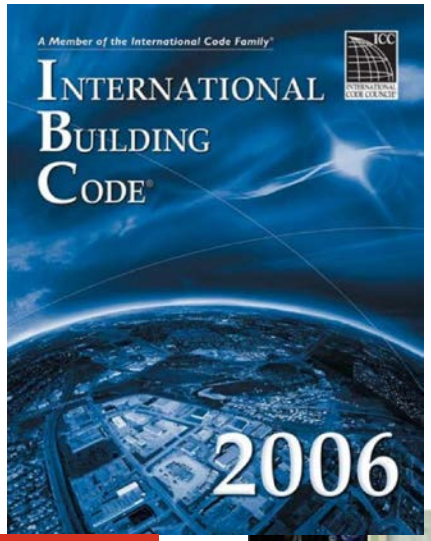
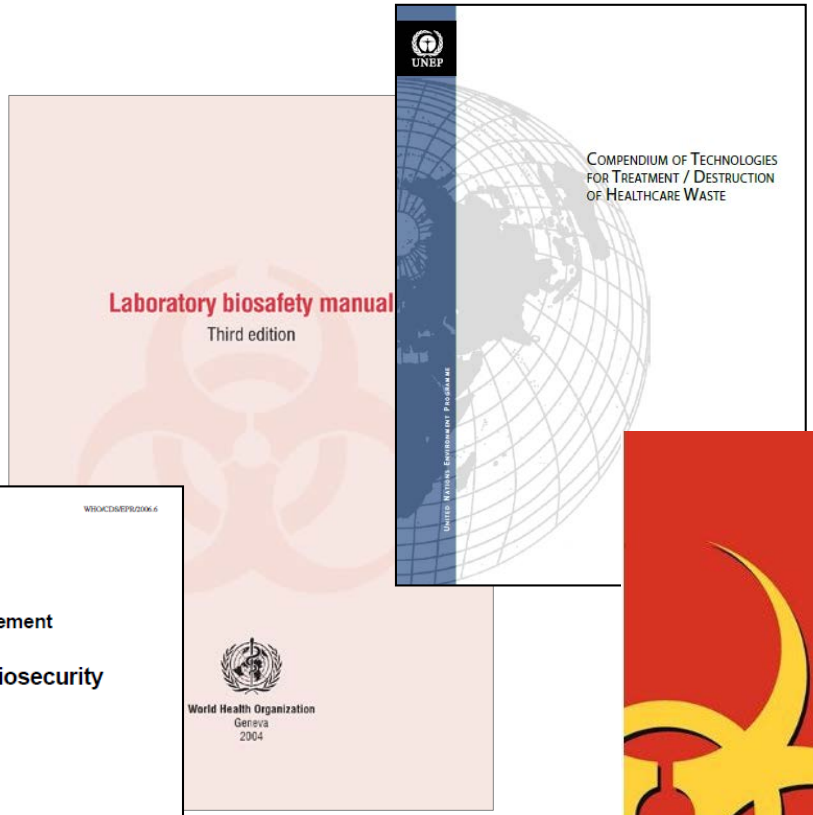
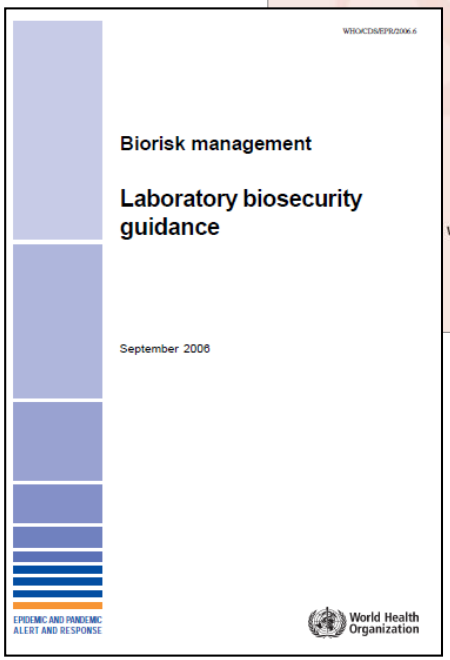
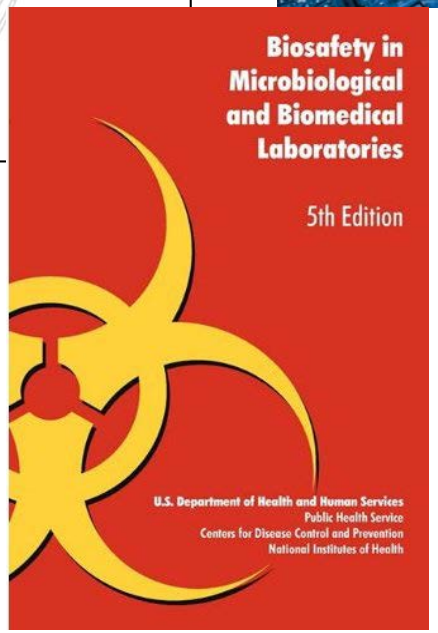
International Federation of Biosafety Associations

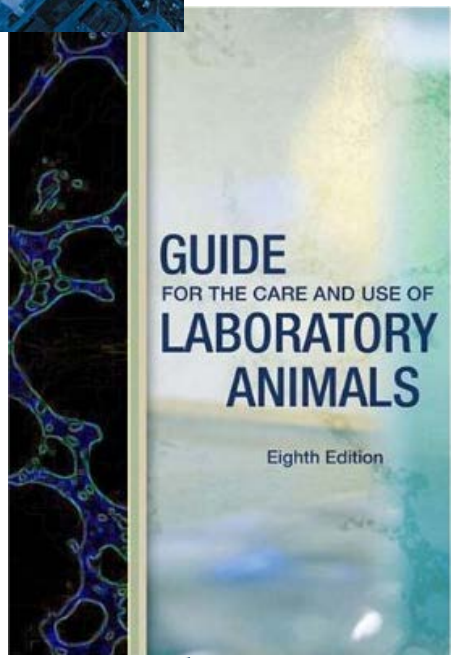
Codes, Regulations, Guidelines











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BEP

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Overlap of Biosafety and Biosecurity Mitigations