

IZSLER

IMPROVING SAFETY AND SECURITY

ELEMENTS OF A LABORATORY BIOSECURITY PLAN

ÉLÉMENTS D'UN PLAN DE BIOSÉCURITÉ EN LABORATOIRE



Biosafety and Biosecurity Compliance

OIE Terrestrial Manual 2014 - CHAPTER 1.1.3 and 1.1.3a

BIOSAFETY AND BIOSECURITY IN THE VETERINARY MICROBIOLOGY LABORATORIES AND ANIMAL FACILITIES

http://www.oie.int/fileadmin/Home/eng/Health_standards/tahm/1.01.03_BIOSAFETY.pdf

STANDARD FOR MANAGING BIORISK IN THE VETERINARY LABORATORY AND ANIMAL FACILITIES

http://www.oie.int/fileadmin/Home/fr/Health_standards/tahm/1.01.03a_BIOSAFETY.pdf

World Health Organization (WHO)

LABORATORIES BIOSAFETY MANUAL - Third edition, Geneva, 2004

<http://www.who.int/csr/resources/publications/biosafety/en/Biosafety7.pdf>

BIORISK MANAGEMENT - LABORATORY BIOSECURITY GUIDANCE - SEPT. 2006

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

The European Commission for the control of Foot-and-Mouth disease (EuFMD)

MINIMUM BIORISK MANAGEMENT STANDARDS FOR LABORATORIES WORKING WITH FOOT-AND-MOUTH DISEASE VIRUS

(40th General Session of the EuFMD, 2013)

http://www.fao.org/fileadmin/user_upload/eufmd/Lab_guidelines/FMD_Minimumstandards_2013_Final_version.pdf

SYSTEM

Biorisk policy	Mission and means to realize it
Delegation of responsibilities and communication	"Who does what"
Biorisk Officer(BRO)	Responsible for coordinating
Formal process of Risk assessment/threat assessment	"Know what you are doing"
Standard operating procedure (SOP)	"How to do it"
Record keeping	"Record what happen"
Accident / incident reporting system	
Accident / Incident review system	
System to review biorisk changes	"Learn from what you recorded"
System for continual improvement	
Recording receipt of BA containing materials	Traceability of submissions
Accessibility to live Biological Agents (BA)	Control and Protection of biologicals
Emergency plans (+ contingency plans)	"How to ensure continuity"
Access to site	"Who is where, and why"
Training	Motivated and skilled personnel only
Threat reduction/control measures	Known or predictable threats
Emergency procedures	"How to react in case of .."
Communication	Active communication channels for transparence and notifications

Basic documentation

Biorisk policy	Mission and means to realize it
Delegation of responsibilities and communication	"Who does what"
Biorisk Officer(BRO)	Responsible for coordinating

➤ **Biorisk Policy**

Site Administrator's declaration regarding the authorization to the manipulation of dangerous biological agents, and resources that the administration makes available to ensure

- staff protection
- laboratory and environment protection
- continuity of the relevant services
- security of the site

➤ **Delegation of responsibilities and communication**

Availability of an organizational chart setting out the referents for

- scientific activities (normally the chief scientist, head of the department etc.)
- animal experimentation (if applicable)
- safety and security management,

together with a clear identification of their responsibilities

The communication of the above definitions to the staff and to the relevant monitoring bodies

➤ **Biorisk Officer (BRO)**

Appointment of a Biorisk Officer, with the indication of relevant duties and prerogatives

Formal process of Risk assessment/threat assessment

"Know what you are doing"

1st step → Bio-hazard identification

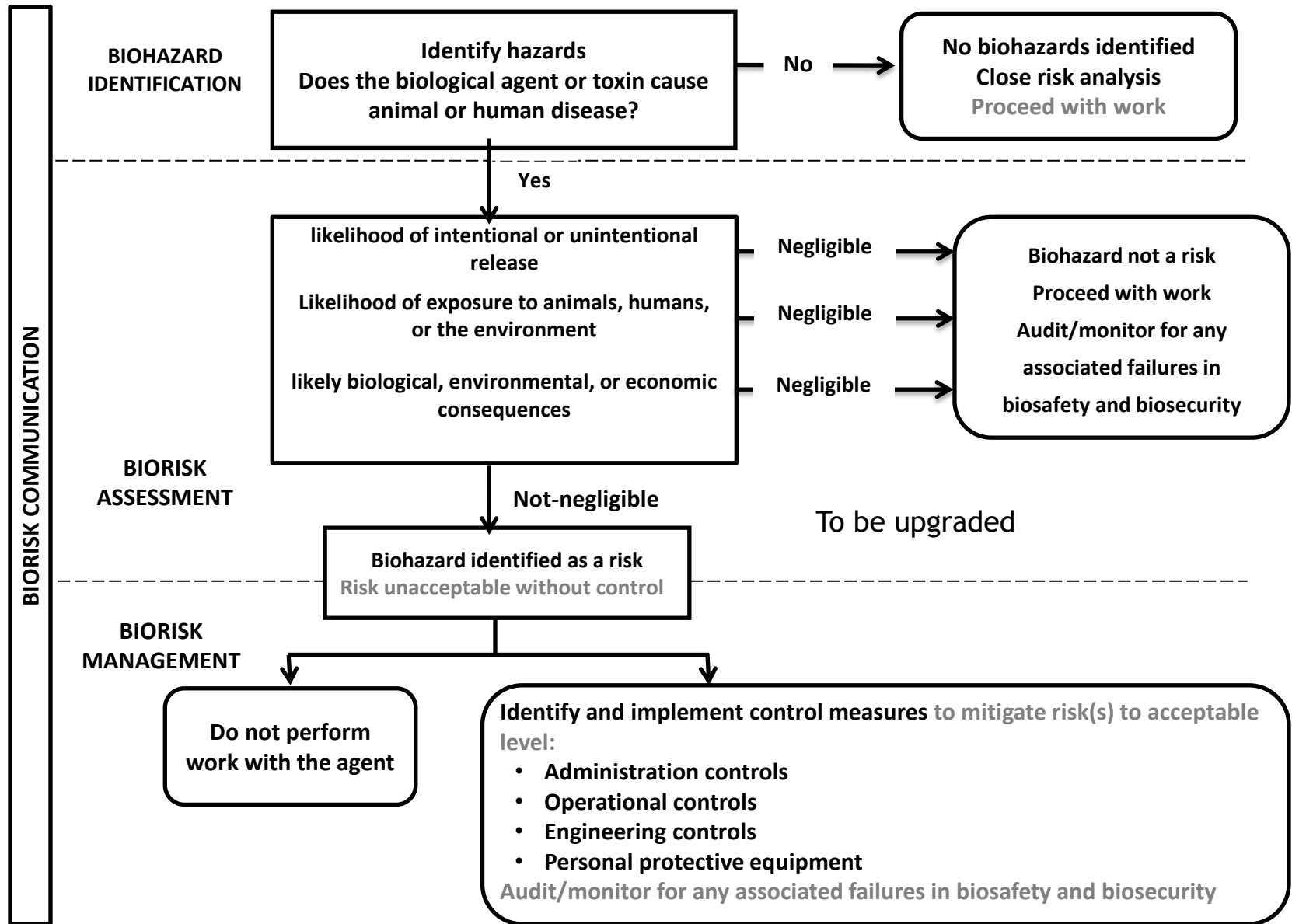
- Pathogens identification and characterisation
- Inventory of biological materials held and/or manipulated
- Diagnostic specimens
- Pathogen storage
- Pathogen transportation
- Physical and chemical hazard
- Laboratory animals

2nd step → Bio-risk assessment

Qualitative or Quantitative

- Biosafety → Exposure (personnel/environment)
Release (inside/outside)
 - Biosecurity → Threats: theft, misuse, deliberate release
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Risk analysis



Management

Standard operating procedure (SOP)	"How to do it"
Record keeping	"Record what happen"
Accident / incident reporting system	
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General requirements -

<u>Components</u>	<u>Biosafety</u>	<u>Biosecurity</u>
➤ Facility	○ Access - authorized personnel only	○ Access - anti intrusion measures
➤ Activity	○ Hazard identification ○ Risk analysis ○ Complete set of Procedures (POS)	○ Risk Mangement <ul style="list-style-type: none"> ▪ Verification, Corrective actions, continuous improvement, Risk Communication, regular reports, documents review
➤ Containment measures	○ Shower facility (personnel) ○ Negative pressure ○ Exhaust air filtration ○ Waste decontamination ○ Materials decontamination ○ Continuous monitoring ○ Maintenance	○ Risk assessment (yearly) ○ Scheduled overall controls <ul style="list-style-type: none"> ▪ Verification, Corrective actions, continuous improvement
➤ Equipment	○ Complete, according to Risk assessment ○ Regularly controlled	○ Contingency plans (reviewed) ○ Regular check of cleaning effectiveness
➤ Laboratory design	○ Building tightness ○ Comfortable, ergonomic ○ Easily cleanable, protected	○ Regular check of tightness ○ Regular check of cleaning effectiveness
➤ Personnel	○ Identified ○ Trained ○ Protective garments ○ Personal/collective protective equipment	○ Identification + authorization ○ Skillness improvement on the containment issues ○ Quarantine

DEFINITIONS

- 1. A biosecurity plan contains all the measures that are utilised to mitigate the risks of disease entry or spread. The plans/statements must undergo ongoing review and maintenance.**
 - 2. A biosecurity plan is implemented to prevent theft, misuse or intentional release of pathogens. The type of biosecurity plan implemented will depend on the nature of the facility, type of research and diagnostics conducted and the local environment.**
 - 3. The intention of a biosecurity plan is to protect the pathogens from theft, misuse or intentional release. The biosecurity plan must be specific to the nature of each facility, the type of research and diagnostics conducted and the local environment. The specific requirements must include physical protection, personnel suitability/reliability, pathogen accountability and plans for biosecurity incident and emergency response.**
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Biosecurity plan

Biorisk Officer(BRO)	Responsible for coordinating
Accessibility to live Biological Agents (BA)	Control and Protection of biologicals
Emergency plans (Intruders)	"How to ensure continuity"
Access to site	"Who is where, and why"
Training	Motivated and skilled personnel only
Threat reduction/control measures	Known or predictable threats
Emergency procedures	"How to react in case of .."
Communication	Active communication channels for transparency and notifications

A Biosecurity plan should include:

1. BA inventory
2. Records
2. Facility security
3. Emergency protocols (Events, incidents...),
4. Personnel
5. Communication

1) Biological materials inventory

- Inventory all stored vials, plates and tubes.
Working solutions of the agents that are currently being used for on-going experiments do not need to be inventoried.
- access to the pathogens restricted to specific trained laboratory personnel.
- tracking system to determine if vials are unaccounted for.
- personnel who do have access to the pathogens must be documented and kept on file

2) Records

- Record of transfers within or outside the site (inventory changes)
 - Record of personnel access (movements traceability)
 - Disposal records including date and decontamination method
 - Labelling of samples
 - BRO notification in case of loss, theft, misuse
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2) Facility Security

Strategies used to prevent the entry of unauthorized personnel and the theft of pathogens must be examined.

- Restricted access to the site ,
- Restricted access to the pathogens ,
- facility's specific security protocols to minimize the entry of unauthorized personnel

3) Protocols for Emergencies

Emergency protocol in place for

- Intruders,
- Samples/stored material stolen
- BA misuse,
- Intentional release

4) Personnel

Approval to the access to BA require:

- Personnel qualification and training
- Background checks and security clearances where needed
- Periodic investigations
- Escort and badges for non approved personnel
- Identification such as badges

5) Communication

Clearly indicate who must be informed in case of

- unauthorized personnel inside the site
- Intruders
- Theft
- Stored material loss
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THANK YOU FOR THE ATTENTION



Istituto Zooprofilattico Sperimentale
della Lombardia e dell'Emilia-Romagna
"B. Ubertini"
