

Biorisk management

Laboratory biosecurity guidance

September 2006



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Abbreviations

BSL3	Containment laboratory – Biosafety Level 3
BSL4	Maximum containment laboratory – Biosafety Level 4
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically modified organism
LBM3	Laboratory biosafety manual, third edition, 2004
LBG	Biorisk management: laboratory biosecurity guidance, first edition, 2006
OIE	World Organisation for Animal Health
VBM	Valuable biological materials
WHO	World Health Organization

Definitions

The following terms are defined in the context in which they are used in this document.

Accountability

Accountability ensures that valuable biological materials (VBM, see definition below) are controlled and traced as intended, by formally associating the specified materials with the individuals who provide oversight and are held responsible for them.

Bioethics

The study of the ethical and moral implications of biological discoveries, biomedical advances, and their applications as in the fields of genetic engineering and drug research (adopted from 1). In this document, bioethics is one of the three components that contribute to a successful biorisk management culture.

Biological laboratory

A facility within which microorganisms, their components or their derivatives are collected handled and/or stored. Biological laboratories include clinical laboratories, diagnostic facilities, regional and/national reference centres, public health laboratories, research centres (academic, pharmaceutical, environmental, etc.) and production facilities (manufacturers of vaccines, pharmaceuticals, large scale GMOs, etc) for human, veterinary and agricultural purposes.

Biorisk

The probability or chance that a particular adverse event (in the context of this document: accidental infection or unauthorized access, loss, theft, misuse, diversion or intentional release), possibly leading to harm, will occur.

Biorisk assessment

The process to identify acceptable and unacceptable risks (embracing biosafety risks (risks of accidental infection) and laboratory biosecurity risks (risks of unauthorized access, loss, theft, misuse, diversion or intentional release)) and their potential consequences.

Biorisk management

The analysis of ways and development of strategies to minimize the likelihood of the occurrence of biorisks. The management of biorisk places responsibility on the facility and its manager (director) to demonstrate that appropriate and valid biorisk reduction (minimization) procedures have been established and are implemented. A biorisk management committee should be established to assist the facility director in identifying, developing and reaching biorisk management goals.

Biosafety

Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release (2).

Code of conduct, code of ethics, code of practice

Non-legislated guidelines which one or more organizations and individuals voluntarily agree to abide by, that set out the standard of conduct or behavior with respect to a particular activity (adopted from 1).

Control

Control is the combination of engineered and procedural measures that ensure valuable biological material (VBM, see definition below) are used only as intended.

Dual-use

Initially used to refer to the aspects of certain materials, information and technologies that are useful in both military and civilian spheres. The expression is increasingly being used to refer not only to military and civilian purposes, but also to harmful misuse and peaceful activities (adopted from 1).

Genetically modified organisms (GMO)

Organisms whose genetic material has been altered using techniques generally known as "recombinant DNA technology". Recombinant DNA technology is the ability to combine DNA molecules from different sources into one molecule in a test tube. GMOs are often not reproducible in nature, and the term generally does not cover organisms whose genetic composition has been altered by conventional cross-breeding or by "mutagenesis" breeding, as these methods predate the discovery (1973) of recombinant DNA techniques.

Hazard

A danger or source of danger; the potential to cause harm.

Laboratory biosecurity

Laboratory biosecurity describes the protection, control and accountability for valuable biological materials (VBM, see definition below) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.

Misuse

The misuse of valuable biological materials (VBM, see definition below) describes their inappropriate or illegitimate use, despite existing and subscribed agreements, treaties and conventions (3).

Threat

The likelihood for an adverse event to occur, as an expression of intention to inflict evil, injury, disruption or damage.

Transfer of VBM

Legal and/or administrative policies and procedures relating to the oversight and approval process for the transfer of custody and/or ownership of valuable biological materials (VBM, see definition below) between countries, entities (organizations, institutions, facilities, etc.) or individuals.

Transport of VBM

Procedures and practices to correctly categorize, package, document and safely and securely transport valuable biological materials (VBM, see definition below) from one place to another, following applicable national and/or international regulations.

Valuable biological materials (VBM)

Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.

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