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Biorisk management

Laboratory biosecurity guidance

September 2006

EPIDEMIC AND PANDEMIC
ALERT AND RESPONSE

World Health Organization

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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.