



Laboratory Biorisk Management **Strategic Framework for Action** 2012–2016

Applicable from 1st January 2012

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Management
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for Action
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Abbreviations

BRM	Biorisk Management
BRM ATP	Biorisk Management Advanced Trainer Programme
BWC	Biological Weapons Convention
CEN	European Committee for Standardization
CWA	CEN Workshop Agreement
IHR	International Health Regulations
FAO	Food and Agriculture Organization
ISST	Infectious Substances Shipping Training
MLB	Managing Laboratory Biorisk
OIE	World Organisation for Animal Health
PHEIC	Public Health Emergencies of International Concern
WHA	World Health Assembly
WHO	World Health Organization
/HSE	Health Security and Environment Cluster
/GCR	Department of Global Capacities Alert and Response
/SID	Support for IHR Capacity Development Unit
/BMT	Biorisk Management Team

Terms and Definitions

accident	unintended event giving rise to harm (from CWA 15793:2011) NOTE An accident is an incident which has resulted in harm.
biorisk	combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological agent or toxin (from CWA 15793:2011) NOTE The source of harm may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.
biorisk management	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 top management to demonstrate that appropriate and valid biorisk mitigation strategies are established, documented, implemented, maintained and continually improved. (adapted from: WHO/CDS/EPR/2006.6)
biorisk management system	part of an organization's management system used to develop and implement its biorisk policy and manage its biorisks (from CWA 15793:2011) NOTE 1 A management system is a set of interrelated elements used to establish policy and objectives and to achieve those objectives. NOTE 2 A management system includes organizational structure, planning activities (including for example, risk assessment and the setting of objectives), responsibilities, practices, procedures, processes and resources.
biosafety	laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or their accidental release (adapted from: WHO/CDS/EPR/2006.6)
biosecurity	laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized

	access or intentional unauthorized release (adapted from: WHO/CDS/EPR/2006.6) NOTE In the context of this standard biosecurity is restricted to laboratory biosecurity; laboratory includes animal and manufacturing facilities, and does not include all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of alien species and pathogens.
certification	systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance (from CWA 15793:2011)
community	people outside the workplace potentially affected by the activities of the facility (from CWA 15793:2011)
competence	appropriate education, training, skills and experience (from CWA 15793:2011)
facility	operational unit and associated buildings and equipment used to manage biological agents and toxins (from CWA 15793:2011) NOTE 1 This includes the laboratory, together with the supporting infrastructure, equipment and services including ancillary rooms such as airlocks, changing rooms, sterilizing rooms and storage rooms. NOTE 2 In the context of this standard additional facility types may also need to be considered which fall outside the definition of "laboratory" (e.g. vivaria, aquaria and green houses).
hazard	source, situation, or act with a potential for causing harm (from CWA 15793:2011)
incident	event with a potential for causing harm (from CWA 15793:2011) NOTE 1 An accident is an incident which has resulted in harm. NOTE 2 An incident where no harm is caused may also be referred to as a "near miss", "near hit", "close call" or "dangerous occurrence". NOTE 3 An emergency situation is a particular type of incident.
inspection	conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging (from CWA 15793:2011)
laboratory	room within a facility, designated for work on biological agents and/or toxins (from CWA 15793:2011)
organization	company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration (from CWA 15793:2011) NOTE For organizations with more than one operating unit, a single operating unit may be defined as an organization.
record	document stating results achieved or providing evidence of activities performed (from CWA 15793:2011)
risk	combination of the probability of occurrence of harm and the severity of that harm (from CWA 15793:2011)
risk assessment	process of evaluating the risk(s) arising from a hazard(s), taking into account the adequacy of any existing controls and deciding whether or not the risk(s) is acceptable (from CWA 15793:2011)
safety	freedom from unacceptable risk (from CWA 15793:2011)

Aim

This document presents a strategic framework, aimed towards the development of sustainable global, regional and national plans relating to laboratory biorisk management.

Vision

"Safe and secure environments in and around every laboratory in the world"

Mission

- Lead, participate and collaborate in advancing biorisk management, including biosafety and laboratory biosecurity.
- Provide frameworks, expertise and tools to inform, guide, and support WHO's Member States in protecting the health of people in and around laboratory environments through appropriate biorisk management.
- Establish a positive and growing culture towards responsible biorisk management worldwide.

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