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# Laboratory Biorisk Management

# **Strategic Framework for Action** 2012–2016

Applicable from 1st January 2012

International Health Regulations Coordination

World Health Organization

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# Acknowledgements

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# Abbreviations

| | |
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| 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)<br>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)<br>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.<br>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)<br>NOTE 1 An accident is an incident which has resulted in harm.<br>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".<br>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)<br>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.

# Background

## Biorisk Management and the International Health Regulations

Under the International Health Regulations (IHR (2005)), all State Parties have made a legally binding commitment to assess, develop and maintain their national core capacities for surveillance, assessment and response. Appropriate laboratory capacities are essential to a wide range of public health operations for all States Parties, and are specifically identified as IHR core capacities (IHR Annex 1A.6).

Laboratory services are essential to identify and confirm the agents involved in important public health events, including those which may cause public health emergencies of international concern (PHEIC. To meet IHR requirements, every State Party needs access to laboratory services, domestically or internationally.

Rapid access to laboratory services should rely on adequate sample collection and transport systems. Strong laboratory biorisk management measures and laboratory quality systems should ensure that laboratories release results in a safe, secure, timely and reliable manner.

The management of laboratory biorisk is addressed through the implementation of appropriate biosafety and laboratory biosecurity measures.

## Introduction to the WHO Biorisk Management Strategic Framework for Action

Although laboratory biosecurity is a relatively new concept to many, biosafety has been an established discipline for several decades. These fields have recently been elevated in prominence for a number of reasons, including laboratory acquired infections associated with SARS, the anthrax attacks in the US postal service, and renewed interest in the Biological Weapons Convention (BWC), together with emerging issues relating to the rapid growth of biotechnology and concerns over the potential for illicit use of such technologies.

However, despite significant investments in this field during the last decade, and progress made in strengthening biorisk management, many countries remain without effective regulatory and oversight mechanisms, and levels of awareness are often low amongst regulators and laboratory personnel alike. In addition, basic information relating to laboratory design and operating parameters is often confusing, with a lack of evidence to underpin many commonly used controls.

Developing countries in particular often struggle to implement solutions which have been designed for use in other parts of the world where different working conditions prevail. Adequate support services are also needed to operate laboratories. However, effective supplier networks, maintenance provision and other basic measures are often unavailable to those most in need.

At present there is no overarching framework or global strategy in this area to provide strategic direction to ensure that investments are planned and implemented appropriately to meet these needs. Without such strategic planning, biorisk management runs the danger of failing to meet the objective of delivering solutions that allow countries to build stand-alone capacity and capability.

This plan sets out a basis and rationale for WHO’s role in supporting the measures and mechanisms required to move towards the objective of supporting safe and secure environments in and around every laboratory in the world.

# Strategic Framework for Action 2012- 2016

## Objectives

The objectives of the WHO Biorisk Management Strategic Framework for Action (BRM SFA) are as follows:

- Coordinate the work of WHO towards improving biorisk management within the framework of an agreed five year plan, reviewed and updated on a biennial basis;
- Transfer knowledge to all Member States and ensure their ownership in so far as that is possible, enhancing local capacity and capability;
- Support development of appropriate national governance, provide guidance on technical issues, and raise biorisk management knowledge and awareness amongst all concerned stakeholders.

## WHO's primary responsibilities

The primary function of WHO is to act in a coordinating role, taking primary responsibility for:

- Development of the Framework in collaboration with stakeholders;
- Setting of targets and indicators, and monitoring progress towards achieving agreed milestones and objectives;
- Identification and coordination of required resources to meet the objectives of the Framework;
- Identification and engagement of delivery partners, best suited to implement planned activities.

The Biorisk Management Team (BMT) located at WHO Headquarters in the department of Global Capacities Alert and Response will facilitate the coordination.

## Stakeholders, partners, and key players

Partnerships will be developed at global, regional and national levels, including relevant groups within WHO (e.g. Regional and Country Offices, relevant disease specific programmes), WHO Collaborating Centres, Biosafety Associations, other key Organizations (e.g. the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization (FAO)), technical advisers, project delivery partners, together with donors and funding agencies from sectors including the health and security interface.

# Focus Areas

The Framework is based around the following distinct but interrelated Focus Areas, addressing issues from strategic to operational levels.

A. Leadership and Communication
B. Governance, Standards and Guidelines
C. Tools and Methodologies
D. Competence Development

## A. Leadership and Communication

***Objective***: To ensure WHO policy and strategy for biorisk management is developed, approved and effectively communicated to stakeholders through active participation at key fora, in collaboration with internal and external partners.

***Key activities***:

- Develop and advocate the WHO policy and strategy for biorisk management;
- Take a leading role in the discussion on development of risk-based approaches to manage biorisk;
- Engage and coordinate with internal and external stakeholders;
- Respond to incidents as they occur and provide appropriate guidance as and when necessary;
- Share good practice and experience within the international community.

## B. Governance, Norms and Standards

***Objective*:** To influence the development of appropriate standards, guidance and norms relating to biorisk management and participate in activities aimed towards their implementation, helping countries adopt appropriate strategies to reduce biorisk in laboratory environments.

***Key activities***:

- Participate in the development of appropriate standards, guidance and norms relating to biorisk management;
- Engage Member States, raise awareness on the need to identify appropriate and proportionate regulatory controls and mechanisms for biorisk management, and develop model frameworks and approaches for their implementation;
- Maintain key WHO publications and align with current best practice in biorisk management and developments in biological science;
- Coordinate activities within WHO and with partner organizations to develop biorisk management guidance on areas with particular focus on disease-specific issues and relevant resource-constrained environments.

## C. Tools and Methodologies

***Objective***: To develop and disseminate suitable tools and methodologies to help countries strengthen biorisk management capacities and capabilities.

***Key activities***:

- Develop tools and processes for laboratories seeking to adopt a biorisk management approach;
- Conduct pilot projects to refine approaches and demonstrate the benefits of biorisk management systems;

- Support the communication of good practices and lessons learnt to the wider biorisk management community.

## D. Competence Development

***Objective***: To support the development and use of appropriate training / competence development programmes and associated materials, to assist countries and institutions understand, adopt and implement biorisk management strategies.

***Key activities***:

- Assess competence development needs across the entire spectrum of roles and responsibilities relating to biorisk management (e.g. regulators, assessors, managers, scientists, students, support staff, first responders and the general public);
- Meet competence development needs through the provision of appropriate media, tools and communication channels;
- Transfer the required knowledge and skills to ensure competence development and local capacity building;
- Support development of capacity and capability through local, regional and global knowledge sharing and networking in the area of biorisk management.

# The Framework Implementation Process

A series of projects relating to the Focus Areas will be defined in order to meet the objectives of the Framework. Project implementation will require WHO, though GCR/SID/BMT, to assume an appropriate role in relation to the nature of the projects (e.g. delivery, coordination, participation, convener and/or observer). Each project will be allocated a focal point, responsible for coordinating activities and ensuring agreed deliverables are met in line with the Framework's objectives.

Resources will be directed towards:

- Effective planning and coordination of projects
- Research and development, piloting, or more widespread implementation of projects

*Research and Development* projects are those in the early stages and being explored for further implementation and roll-out. *Piloting* projects are those to be tested under field conditions, prior to wider roll-out, in order to ensure any lessons learnt are captured before the activity is extended to a wider target group. *Implementation* projects seek to scale initiatives to the widest possible target group (i.e. reaching out to all Member States), addressing the need to ensure communication, skills, processes and tools are made available globally wherever possible.

Projects will be defined according to the following criteria:

- Aim, objectives and targets
- Nature of WHO role and involvement
- Status and maturity level
- Milestones and timescales
- Resource allocation

Increasingly as projects are developed and scaled, activities may be conducted by parties external to GCR/SID/BMT, including additional WHO resources (e.g. WHO Regional Offices and disease-specific programmes), WHO Collaborating Centres, in-country governmental agencies, and other external partners. These groups will be identified as having the capacity, capability, local presence and other attributes required to achieve a successful outcome.

The monitoring and evaluation of projects will be defined within the detailed project descriptions, agreed with relevant stakeholders, and will form the basis of ongoing project management.

Projects associated with each of the described Focus Areas are listed in the following annexes. Indications are provided to describe WHO's role and individual projects' stage of development. Full project descriptions and updates including key targets and milestones may be provided separately, as appropriate, upon request. The list will be reviewed and revised on a regular basis.

Not all projects described in Annexes A-D may be underway. Unless dictated by extraordinary events, projects, and activities will be aligned with the Framework's aim, objectives and priorities.

# Annex A

# Leadership and Communication

**Objective:**
To ensure WHO policy and strategy for biorisk management is developed, approved and effectively communicated to stakeholders through active participation at key forums, in collaboration with internal and external partners.

**Projects:**

| No. | Project | WHO Role | Stage of development |
|---|---|---|---|
| A.1 | Consult with relevant WHO Departments to support the development of biorisk management strategies (e.g. IHR implementation, disease-specific networks and programmes, infection control) | Delivery | Ongoing |
| A.2 | Coordinate with project partners and collaborators (e.g. WHO Collaborating Centres, FAO, OIE, funding agencies, biosafety associations) | Delivery | Ongoing |
| A.3 | Communicate with international organizations and national regulatory agencies regarding the need for effective governance for biorisk management | Delivery | Ongoing |
| A.4 | Promote awareness of appropriate standards and norms, including CWA 15793, and encourage adoption and implementation at national level | Delivery | Ongoing |
| | | Coordination | Pilot |
| A.5 | Participate in discussions on the BWC, to ensure that WHO policy and position is communicated to Member States and collect feedback | Delivery | Ongoing |
| A.6 | Revise and update the WHO Biorisk Management Team web site | Delivery | Ongoing |

# Annex B

# Governance, Norms and Standards

**Objective:**
To influence the development of appropriate standards, guidance and norms relating to biorisk management and participate in activities aimed towards their implementation, helping countries adopt appropriate strategies to reduce biorisk in laboratory environments.

**Tasks and Projects:**

| No. | Project | WHO Role | Stage of development |
|---|---|---|---|
| B.1 | Publish a WHO Laboratory Biorisk Management Manual, incorporating biorisk management principles. (Managing Laboratory Biorisk, MLB1) | Delivery | Planned |
| B.2 | Publish an updated WHO Biorisk Management: Laboratory Biosecurity Guidance document | Coordination | Proposed |
| B.3 | Collaborate/consult with relevant WHO disease specific programmes to develop specific guidance, including emergency plans in the event of a pandemic or similar crisis | Delivery | Proposed |
| B.4 | Develop guidance for risk-based approaches to laboratory and equipment design, operation, use, maintenance and certification | Participation / observer | Proposed |
| B.5 | Participate in the process to develop and revise CWA 15793 and related documents | Observer | Ongoing |
| B.6 | Participate in the process to develop an international biorisk management accreditation / certification scheme based on CWA 15793 | Observer | Planned |
| B.7 | Revise the publication “Guidance on Regulations for the Transport of Infectious Substances” | Delivery | Ongoing |
| B.8 | Support Member States in the development and implementation of regulations for the transport of infectious substances | Participation | Ongoing |
| B.9 | Where appropriate, adapt the *Design for Biorisk Management* approach to laboratory construction, based on principles developed for the construction/renovation of healthcare facilities in resource constrained countries | Coordination | Planned |
| B.10 | Collaborate with the partner organization setting standards in animal health (OIE) to develop common strategies, standards, guidance and norms, where appropriate, for public health and veterinary laboratories and to promote international guidance and standards and their implementation. | Partner | Ongoing |

# Annex C

# Tools and Methodologies

**Objective:**
To develop and disseminate suitable tools and methodologies to help countries strengthen biorisk management capacities and capabilities.

**Tasks and Projects:**

| No. | Project | WHO Role | Stage of development |
|---|---|---|---|
| C.1 | Develop concept, processes and tools for implementing a biorisk management system approach at country and facility level | Coordination | Ongoing |
| C.2 | Develop concept and tool for recording and analysing laboratory accidents and incidents | Observer | Proposed |
| C.3 | Develop concept and tool for facilities to assess infrastructure, equipment and maintenance | Coordination | Proposed |
| C.4 | Develop concept and tool for laboratory risk assessment | Coordination | Proposed |
| C.5 | Develop tools to ensure safe transport of infectious substances | Coordination / Delivery | Ongoing |
| C.6 | Develop tools and processes to raise awareness on responsible life science research | Coordination | Ongoing |

# Annex D

# Competence Development

**Objective:**
To support the development and use of appropriate training / competence development programmes and associated materials to assist countries and facilities understand, adopt and implement biorisk management strategies.

**Tasks and Projects:**

| No. | Project | WHO Role | Stage of development |
|---|---|---|---|
| D.1 | Review globally available biorisk management training offerings and develop a delivery database | Observer | Proposed |
| D.2 | Assess baseline competencies and training needs in biorisk management (biosafety, laboratory biosecurity, 2011) | Observer | Proposed |
| D.3 | Re-assess competency requirements in biorisk management (2015) | Observer | Proposed |
| D.4 | Develop and deliver a risk assessment training programme | Coordination | Ongoing |
| D.5 | Develop and deliver courses on laboratory operations and maintenance, engineering, design and construction | Coordination | Proposed |
| D.6 | Develop and deliver training in shipping of infectious substances (ISST) | Coordination / Delivery | Ongoing |
| D.7 | Develop workshop-in-a-box self-assessment tool | Participation | Ongoing |
| D.8 | Deliver biorisk management advanced trainer programme (BRM ATP) course for trainers | Coordination / Delivery | Ongoing |
| D.9 | Develop BRM electronic training tool | Coordination | Ongoing |
| D.10 | Deliver BRM short course for users | Coordination / Delivery | Ongoing |
| D.11 | Develop biosafety campaign themes | Coordination | To be started soon |
| D.12 | Expand BRM training to include module on responsible life science research | Coordination / Delivery | Ongoing |
| D.13 | Elaborate educational curricula and recognition schemes for biorisk management professionals | Observer | Proposed |

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