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Biorisk management for laboratories and other related organisations

Système de management des biorisques en laboratoires et autres organismes associés

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The biorisk management system:

— establishes the biorisk management principles that enable laboratories and related facilities to achieve their biosafety and biosecurity objectives;

— defines the essential components of a biorisk management system framework to be integrated into a laboratory or other related organization's overall governance, strategy and planning, management, reporting processes, policies, values, and culture;

— describes a comprehensive biorisk management process that mitigates biorisks (biosafety and biosecurity risks); and

— provides guidance on the implementation and use of the standard, where appropriate.

The biorisk management system is based on a management system approach, which enables an organization to effectively identify, assess, control, and evaluate the biosafety and biosecurity risks inherent in its activities. As such, this document is intended to define requirements for a biorisk management system that is appropriate to the nature and scale of any organization. The biorisk management system is built on the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions that an organization undertakes to meet its goals. This is known as the Plan-Do-Check-Act (PDCA) principle.

The PDCA model is an iterative process used by organizations to achieve continual improvement of processes and products. It can be applied to a biorisk management system, and to each of its individual elements, as follows:

— Plan: establish objectives, programmes, and processes necessary to deliver results in accordance with the organization's biorisk management policy;

— Do: implement the processes as planned;

— Check: monitor and measure activities and processes with regard to the biorisk management policy and objectives, and report the results;

— Act: take actions to continually improve the biorisk management performance to achieve the intended outcomes.

Figure 1 illustrates the PDCA framework and how it relates to other requirements of this document.

NOTE Figure 1 is adapted from ISO 45001 *Occupational health and safety management system — Requirements with guidance for use*.

Biorisk Management System Model
[Top - Down Pyramid View]

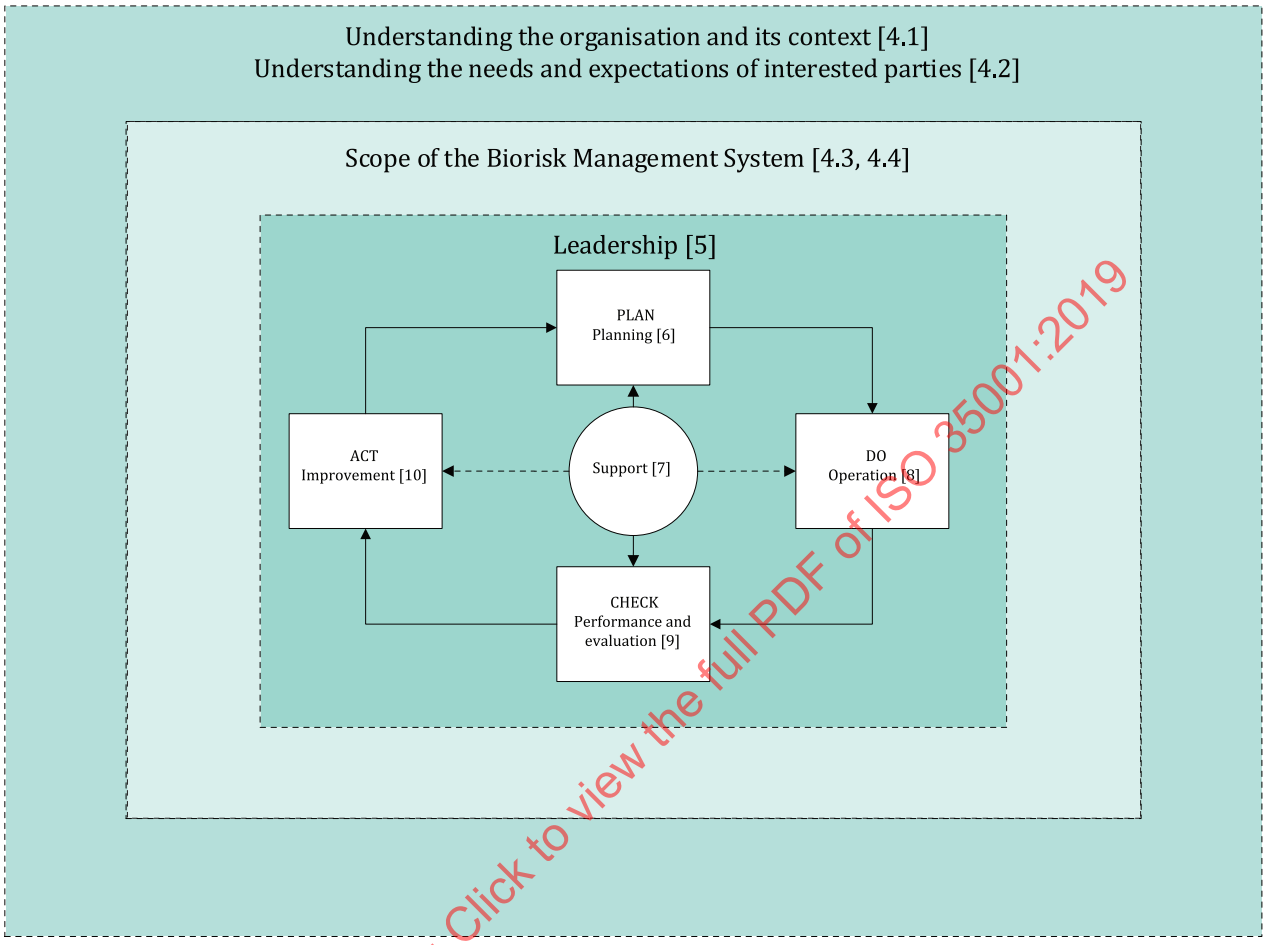

Figure 1 — Top down pyramid view of a biorisk management system model

Improving biorisk management requires attention to and understanding of the causes of nonconformities and incidents. Systematic identification and correction of system deficiencies leads to improved performance and control of biorisks.

Key factors in establishing and implementing a biorisk management system include:

— Commitment by top management to:

  — provide adequate resources;

  — prioritize and communicate biosafety and biosecurity policy;

  — establish performance expectations and integrate biorisk management throughout the organization;

  — determine causes of incidents and nonconformities and prevent recurrence; and

  — identify opportunities for improvement and prevention.

— Focus on continual improvement to:

  — make continual improvement a priority for every individual in the organization;

- use periodic assessment against risk criteria established by the organization to identify areas for potential improvement;
- continually improve the effectiveness and efficiency of processes;
- take corrective action for unsafe or unsecure practices, and promote preventive activities;
- provide workers in the organization with appropriate education and training to support biorisk management, including the methods and tools of continual improvement;
- establish measures and goals for improvement; and
- recognize improvement.

A biorisk management program can assist an organization to fulfill its legal requirements and other requirements.

Biorisk management for laboratories and other related organisations

1 Scope

This document defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document is applicable to any laboratory or other organization that works with, stores, transports, and/or disposes of hazardous biological materials. This document is intended to complement existing International Standards for laboratories.

This document is not intended for laboratories that test for the presence of microorganisms and/or toxins in food or feedstuffs. This document is not intended for the management of risks from the use of genetically modified crops in agriculture.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
organization
person or group of people that has its own functions with responsibilities, authorities, and relationships to achieve its *objectives* (3.11)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity, or institution, or part or combination thereof, whether incorporated or not, public or private.

3.2
interested party
stakeholder
person or *organization* (3.1) that can affect, be affected by, or perceive themselves to be affected by a decision or activity

3.3
worker
person performing work or work-related activities under the control of the *organization* (3.1)

Note 1 to entry: Persons performing work or work-related activities under various arrangements, paid or unpaid, such as regularly or temporarily, intermittently or seasonally, casually, or on a part-time basis.

Note 2 to entry: Workers include *top management* (3.8), managerial, and non-managerial persons.

Note 3 to entry: The work or work-related activities performed under the control of the *organization* (3.1) may be performed by workers employed or contracted by the *organization* (3.1), or by a subcontractor.

[SOURCE: ISO 45001:2018, 3.3]

3.4
requirement
need or expectation that is stated, generally implied, or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1) and *interested parties* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in *documented information* (3.30).

3.5
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.10), *objectives* (3.11), and *processes* (3.31) to achieve those *objectives* (3.11)

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The system elements include the *organization's* (3.1) structure, roles and responsibilities, planning and operation.

Note 3 to entry: The scope of a management system may include the whole of the *organization* (3.1), specific and identified functions of the *organization* (3.1), specific and identified sections of the *organization* (3.1), or one or more functions across a group of organizations.

3.6
biorisk management
coordinated activities to direct and control an *organization* (3.1) with regard to *biorisk* (3.17)

[SOURCE: ISO Guide 73:2009, definition 2.1, modified — "risk" has been replaced by "biorisk."]

3.7
biorisk management system
management system (3.5) or part of a *management system* (3.5) used to establish *biorisk management* (3.6) *policies* (3.10), *objectives* (3.11), and *processes* (3.31) to achieve those *objectives* (3.11)

Note 1 to entry: A biorisk management system addresses the control of *biorisk(s)* (3.17).

3.8
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.1).

Note 2 to entry: If the scope of the *biorisk management system* (3.7) covers only part of an *organization* (3.1), then top management refers to those who direct and control that part of the *organization* (3.1).

3.9
effectiveness
extent to which planned activities are realized and planned results achieved

3.10
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.8)

3.11
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as financial, health and safety, and environmental goals) and can apply at different levels [such as strategic, organization-wide, project, product and *process* (3.31)].

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended outcome, a purpose, an operational criterion, or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *biorisk management systems* (3.7), objectives are set by the *organization* (3.1), consistent with the organization's *policy* (3.10), to achieve specific results.

3.12
environment
surroundings in which an *organization* (3.1) operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships

Note 1 to entry: Surroundings can extend from within an organization to the local, regional, and global system.

Note 2 to entry: Surroundings can be described in terms of biodiversity, ecosystems, climate, or other characteristics.

[SOURCE: ISO 14001:2015, 3.2.1]

3.13
biological agent
any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material that may be able to provoke infection, allergy, toxicity or other adverse effects in humans, animals, or plants

EXAMPLE Bacteria, fungi, viruses, viroids, endo-, and ectoparasites.

Note 1 to entry: The definition of biological agents covers commonly used terms, such as pathogens, quarantine microorganisms, microorganisms of dual-use potential.

Note 2 to entry: For the purpose of this document, prions are regarded as biological agents.

Note 3 to entry: The term "engineered" includes biological agents that are synthetically derived.

3.14
biological materials
any material comprised of, containing, or that may contain *biological agents* (3.13) and/or their harmful products, such as *toxins* (3.15) and allergens

Note 1 to entry: Biological materials may be blood, secretions, or tissues of human or animal origin. Other biological materials include debris ororganic material from nature, culture, or preservation media, and/or cell cultures from human, animal, and plants.

Note 2 to entry: Animals and plants or parts thereof handled in relevant laboratories that may contain *biological agents* (3.13) or *toxins* (3.15) or biological agent vectors, such as arthropods, nematodes, and mites, are considered biological materials.

3.15
toxin
substance, produced by plants, animals, protists, fungi, bacteria, or viruses, which in small or moderate amounts produces an adverse effect in humans, animals, or plants

Note 1 to entry: This definition includes substances and materials, natural or as a result of biotechnology, that may contain toxins (see also *biohazard* (3.20)), any poisonous substance or any poisonous isomer, homologue, or derivative of such a substance.

[SOURCE: CEN Workshop Agreement 15793:2011, Laboratory biorisk management, 3.46, modified — clarified biological sources of toxins and added Note 1 to entry.]

3.16
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential "events" (as defined in ISO Guide 73) and "consequences" (as defined in ISO Guide 73), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73) of occurrence.

3.17
biorisk
effect of uncertainty expressed by the combination of the consequences of an event (including changes in circumstances) and the associated "likelihood" (as defined in ISO Guide 73) of occurrence, where *biological material* (3.14) is the source of *harm* (3.18)

Note 1 to entry: The *harm* (3.18) can be the consequence of an unintentional exposure, accidental release, or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.

3.18
harm
adverse effect on the health of people, animals, or plants, on the *environment* (3.12), or on property

3.19
hazard
source or situation with a potential for causing *harm* (3.18)

3.20
biohazard
potential source of *harm* (3.18) caused by *biological materials* (3.14)

3.21
threat
potential cause of an *incident* (3.39), which may result in harm to individuals, assets, a system, an organization, or the *environment* (3.12)

Note 1 to entry: In the context of *biosecurity* (3.23), the term threat is used to refer to an individual or group of people who have the motive, means, and opportunity to intentionally cause *harm* (3.18).

[SOURCE: ISO 28002:2011, 3.22, modified — Note 1 to entry has been added.]

3.22
biosafety
practices and controls that reduce the risk of unintentional exposure or release of *biological materials* (3.14)

3.23
biosecurity
practices and controls that reduce the risk of loss, theft, misuse, diversion of, or intentional unauthorized release of *biological materials* (3.14)

Note 1 to entry: In the context of this document, biosecurity does not include all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of non-indigineous species and pathogens.

3.24
physical security
combination of physical measures to reduce the *risk* (3.16) of unauthorized access, to safeguard assets and people, and to protect from a potential security *incident* (3.39)

Note 1 to entry: The term asset in this context refers to items or information of value, including *biological materials* (3.14), equipment, *laboratory* (3.28), *facility* (3.27), resources, and undocumented and *documented information* (3.30).

Note 2 to entry: Security *incident* (3.39) includes but is not limited to damage, loss, and theft of *biological materials* (3.14), equipment, or information.

[SOURCE: ANSI/ASIS PAP.1-2012, Security management standard: physical asset protection, C.47, modified — the term risk has been introduced, the overall definition condensed, and Notes 1 and 2 added.]

3.25
reliability
property of consistent intended behaviour and results

[SOURCE: ISO/IEC 27000:2018, 3.55]

3.26
information security
preservation of confidentiality, integrity, and availability of information

Note 1 to entry: Information security also includes preservation of authenticity, accountability, non-repudiation, and *reliability* (3.25) where necessary.

Note 2 to entry: The purpose of information security is protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction.

[SOURCE: ISO/IEC 27000:2018, 3.28, modified — Note 1 to entry has been modified and Note 2 to entry has been added.]

3.27
facility
operational unit and associated buildings and equipment used to manage *biological materials* (3.14)

Note 1 to entry: This includes the *laboratory* (3.28), together with the supporting infrastructure, equipment, and services, including ancillary rooms, such as airlocks, changing rooms, sterilizing rooms, and storage rooms.

Note 2 to entry: This document is applicable to other facility types that fall outside the definition of *laboratory* (3.28) (e.g. vivaria, aquaria, and greenhouses) but engage in relevant activities.

3.28
laboratory
room or clearly defined area within a *facility* (3.27) designated for work on *biological materials* (3.14)

3.29
competence
ability to apply knowledge and skills to achieve intended results

3.30
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— information on the *biorisk management system* (3.7), including related *processes* (3.31);

— information created in order for the *organization* (3.1) to operate (documentation);

— evidence of results achieved (records).

3.31
process
set of interrelated or interacting activities which transforms inputs into outputs

3.32
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to the management of activities, *processes* (3.31), products (including services), systems, or *organizations* (3.1).

3.33
outsource (verb)
make an arrangement where an external *organization* (3.1) performs part of an organization's function or *process* (3.31)

Note 1 to entry: An external organization is outside the scope of the *management system* (3.5) although the outsourced function or process is within scope.

3.34
monitoring
determining the status of a system, a *process* (3.31), or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

Note 2 to entry: Examples of monitoring processes include checking, supervising, and critically observing.

3.35
measurement
process (3.31) to determine a value

3.36
audit
systematic, independent, and documented *process* (3.31) for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

Note 3 to entry: "Audit evidence" and "audit criteria" are defined in ISO 19011:2018.

3.37
conformity
fulfilment of a *requirement* (3.4)

3.38
nonconformity
non-fulfilment of a *requirement* (3.4)

3.39
incident
occurrence arising out of, or in the course of, work that could or does result in *harm* (3.18)

Note 1 to entry: An incident where *harm* (3.18) occurs is referred to by some as an "accident."

Note 2 to entry: Although there can be one or more *nonconformities* (3.38) related to an incident, an incident can also occur where there is no *nonconformity* (3.38).

[SOURCE: ISO 45001:2018, 3.35 modified — 'harm' replaces 'injury and ill health', Note 2 to entry deleted.]

3.40
corrective action
action to eliminate the cause of a *nonconformity* (3.38) and to prevent recurrence

3.41
continual improvement
recurring activity to enhance *performance* (3.32)

3.42
decontamination
procedure that eliminates or reduces *biological agents* (3.13) and *toxins* (3.15) to a safe level with respect to the transmission of infection or other adverse effects

[SOURCE: ISO 15190:2003, 3.7, modified — terminology changed from 'microbial and toxic agents' to *biological agents* (3.13) and *toxins* (3.15)]

3.43
inspection
conformity (3.37) evaluation by observation and judgment accompanied as appropriate by *measurement* (3.35), testing, or gauging

3.44
personal protective equipment (PPE)
material used to prevent exposure to or contamination of a person by *biological materials* (3.14)

EXAMPLE Gowns, coats, gloves, respirators, safety glasses.

[SOURCE: ISO 15190:2003, 3.18, modified — *biological materials* (3.14) replaces 'biological matter', 'chemicals' removed.]

3.45
validation
establishment of the performance characteristics of a method and provision of objective evidence that the performance requirements for a specified intended use are fulfilled

[SOURCE: ISO 16140-1:2016, 2.81]

3.46
verification
demonstration that a validated method functions in the user's hands according to the method's specifications determined in the validation study and is fit for purpose

Note 1 to entry: Verification can also be applied to non-validated standardized reference methods (ISO 16140-1:2016, 2.59).

[SOURCE: ISO 16140-1:2016, 2.83]

4 Context of the organization

4.1 Understanding the organization and its context

The purpose and the mandate of the organization, its objective(s), and boundaries of its work shall be clearly defined and communicated throughout the organization.

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended outcome(s) of its biorisk management system.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

— the interested parties that are relevant to the biorisk management system;

— the relevant requirements of these interested parties.

4.3 Determining the scope of the biorisk management system

The organization shall determine the boundaries and applicability of the biorisk management system to establish its scope.

When determining this scope, the organization shall consider:

— the external and internal issues referred to in 4.1; and

— the requirements referred to in 4.2.

The scope shall be available as documented information.

4.4 Biorisk management system

The organization shall establish, document, implement, communicate, maintain, and continually improve a biorisk management system, including the processes needed and their interactions, in accordance with the requirements of this document.

5 Leadership

5.1 Leadership and commitment

Within the context of biorisk management, biosafety and biosecurity are complementary disciplines; it is important to align the mitigation of safety and security risks. Alignment can be enhanced through unity of oversight.

Top management shall demonstrate leadership and commitment with respect to the biorisk management system by:

— ensuring that the biorisk management policy and biorisk management objectives are established and are compatible with the strategic direction of the organization;

— ensuring the integration of the biorisk management system requirements into the organization's business processes;

— ensuring that the resources needed for the biorisk management system are available;

— communicating the importance of effective biorisk management and of conforming to the biorisk management system requirements;

— ensuring that the biorisk management system achieves its intended outcome(s);

— ensuring roles, responsibilities, and authorities related to biorisk management are defined, documented, and communicated to those who manage, perform, and verify work associated with biological materials;

— directing and supporting persons who contribute to the effectiveness of the biorisk management system;

— ensuring clear communication of the actions that need to be taken within the organization;

— promoting continual improvement; and

— supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE 1 Reference to "business" in this documentcan be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

NOTE 2 Overall responsibility for management of biorisk rests with top management, but tasks can be delegated through the organization provided that they are passed to competent individuals with adequate resources to perform the activities safely and securely. In smaller organizations, one individual can hold more than one role described in document.

NOTE 3 Resources include human resources and specialized skills, organizational infrastructure, technology, and financial resources.

5.2 Policy

Top management shall establish a biorisk management policy that:

— is appropriate for the purpose of the organization;

— provides a framework for setting biorisk management objectives;

— includes a commitment to satisfy applicable requirements;

— includes expectations for biorisk assessment, control measures to mitigate risk, and performance evaluation at all levels of the organization; and

— includes a commitment to continual improvement of the biorisk management system.

The biorisk management policy shall:

— be available as documented information;

— be communicated within the organization; and

— be available to interested parties, as appropriate.

The policy shall be appropriate to the nature and scale of the biorisks associated with the facility and associated activities. The policy shall commit the organization to:

— protecting workers, visitors, and the environment from exposure to and/or contamination by the biological materials that are stored or handled at the facility;

— assessing and prioritizing the risks associated with specific activities that involve biological materials;

— reducing the risks of unintentional or deliberate release, theft, loss, or exposure to biological materials through the implementation of specific control measures;

— designing and implementing processes to continually evaluate and improve the effectiveness of the biorisk management system;

— ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements; and

— effectively informing all employees and relevant third parties, and communicating individual obligations with regard to biorisk management to those groups.

5.3 Roles, responsibilities, and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organization, including to those who manage, perform, and verify work associated with the control of biological materials.

Top management shall assign the responsibility and authority for:

a) ensuring that the biorisk management system conforms to the requirements of this document; and

b) reporting on the performance of the biorisk management system to top management.

NOTE The roles and responsibilities described in this subclause can be fulfilled by many or a few individuals as long as conflicts of interest are managed.

5.3.1 Top management

Top management shall take ultimate responsibility for the organization's biorisk management system. Top management shall not delegate its ultimate responsibility, but may delegate authority.

Top management shall demonstrate its commitment by ensuring the availability of resources to establish, implement, maintain, and improve the biorisk management system.

5.3.2 Senior management

Senior management shall be designated with operational responsibility for overseeing the biorisk management system and ensuring the implementation of the operational function of the biorisk management system.

These functions include:

— ensuring the provision of appropriate and adequate workers, facilities, and other resources deemed necessary for the safe and secure operation of the facility;

— reporting to top management on the performance of the biorisk management system and any need for improvement;

— ensuring promotion of the biorisk management system throughout the organization; and

— instituting review, audit, and reporting measures to provide assurance that the requirements of this documentare being implemented and maintained effectively.

5.3.3 Biorisk management committee

A biorisk management committee shall be established in support of the biorisk management system. Where feasible based on the nature of the organization and its activities, the committee shall consist of members who are independent of activities being reviewed for biorisk issues.

The committee shall establish a mechanism by which committee members shall recuse themselves from participation in committee decision-making procedures (e.g. a vote) on issues where real or perceived conflicts of interest exist.

Reporting to senior and/or top management, the committee shall:

— have documented terms of reference;

— include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken;

— ensure issues addressed are formally recorded, including the assignment, tracking, and completion of all actions;

— be chaired by someone appointed by senior and/or top management (see 5.3.1 and 5.3.2); and

— meet at a defined and appropriate frequency, and when otherwise required.

NOTE The responsibilities of the committee can be assumed by other existing committee(s), such as an Institutional Biosafety Committee (IBC) or other biosafety committee.

5.3.4 Biorisk management advisor

Where applicable, a competent individual(s) shall be designated to provide advice, guidance, and assurance on biorisk management issues. This individual shall report directly to the responsible senior management and have delegated authority to prohibit work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.

Functions of the biorisk management advisor should include:

— verifying, in conjunction with other workers, that all biorisks have been addressed;

— advising or participating in the reporting, investigation, and follow-up of accidents, incidents, and, where appropriate, referring these to management/biorisk management committee;

— ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other workers as necessary;

— advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security);

— contributing to the development and/or delivery of biorisk management training activities; and

— advising and assisting organization management in ensuring that required authorizations for work are in place.

NOTE Examples of biorisk management advisor roles include biosafety professionals, biological safety officers, biosafety practitioners, biosafety coordinators, biosafety responsible officials, biosafety advisors, or equivalent.

5.3.5 Scientific management

Where applicable, an individual(s) with responsibility for all or part of the science programme at the facility shall also be designated with specific biorisk management responsibilities.

Functions shall include:

— planning and coordinating work activities, and ensuring adequate staffing levels, time, space, and equipment are available;

— ensuring (where necessary in consultation with the biorisk management advisor), that hazard identification and risk assessments have been performed, reviewed by all affected workers, subjected to approvals required by the biorisk management system, and that the required control measures are in place;

— ensuring required authorizations for work are in place;

— ensuring that all at-risk workers have been informed of risk assessments and control measures, and/or provisions for any recommended precautionary medical practices;

— ensuring that all work is conducted in accordance with established policies and guidelines described in this document;

— supervising workers, including ensuring only competent and authorized workers have access and can work in areas under supervision; and

— ensuring that processes are in place to routinely measure the effectiveness of the control measures, and to change the control measures as appropriate to improve biorisk management performance.

6 Planning

6.1 Actions to address risks and opportunities

The organization shall plan how to mitigate biorisks most effectively. This is accomplished by defining the actions required to identify, assess, and prioritize the biorisks, implementing measures to mitigate the biorisks, integrating those actions into the organization's biorisk management system process, and evaluating the effectiveness of these actions.

When planning for the biorisk management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2, and then determine the risks and opportunities that need to be addressed to:

— give assurance that the biorisk management system can achieve its intended outcome(s);

— prevent or reduce undesired effects;

— achieve continual improvement.

The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

— integrate and implement the actions into its biorisk management system processes; and

— evaluate the effectiveness of these actions.

Key components of a biorisk management programme include hazard and/or threat identification, risk assessment, risk mitigation, and performance evaluation (see 7.4 for details of risk communication).

NOTE 1 In the context of this document, opportunities refers to the options available to identify, assess, control, and monitor the risks associated with hazardous biological materials.

NOTE 2 Effects include actual or potential effects or nonconformities.

6.1.1 Hazard and/or threat identification and analysis

The biorisk-related hazards and/or threats associated with proposed work shall be identified and documented.

The first stage in the biorisk management process is to identify all biological hazards and/or threats that could be the basis for an incident. It is useful to involve the whole work team in this process, and to use inputs from organizational experts on biosafety and biorisk management.

The second stage in the biorisk management process is to determine how the hazard and/or threat could produce a negative outcome. This step involves producing a comprehensive understanding of the hazard and/or threat. Biohazards should be identified based on their potential to cause harm to humans, animals, plants, and the environment. In particular, the inherent characteristics of the biological hazards should be documented and considered.

6.1.2 Risk assessment

The organization shall ensure that suitable methodologies for assessing and prioritizing biorisks are identified, implemented, maintained, and documented.

Biorisk assessments shall take into account activity- or protocol-specific information, and should be based on the unique context of those activities and protocols, including factors related to facility, environment, and personnel.

The biorisk assessment shall identify all potential scenarios of a particular activity that could produce a negative outcome. The biorisk assessment shall prioritize the biorisks based on an evaluation of the likelihood and consequences of each of the biorisks. The biorisk assessment shall determine the most appropriate control measures, and how the system will measure the effectiveness of those control measures.

The organization shall ensure approaches to biorisk assessment are defined with respect to scope, nature, and timing in order to be proactive rather than reactive. Assessments can be qualitative, semiquantitative, or quantitative, and a method suitable to the situation should be identified and followed.

6.1.3 Risk mitigation

The identification and implementation of control measures shall be based on the results of the biorisk assessment. Control measures shall be designed to eliminate or mitigate biorisks to an acceptable level. Assessed biorisks that are not mitigated shall be documented, along with a rationale for the decision. After identification and implementation of control measures, the organization shall determine if the remaining biorisks are acceptable, or whether additional controls need to be identified and implemented.

The organization shall ensure that its biorisk management system includes a control plan.

The organization shall ensure that processes managed by outsourced service providers are controlled in a manner consistent with being performed within the organization, to the extent possible.

6.1.4 Performance evaluation

The organization shall ensure the biorisk management system includes a process to measure the effectiveness of the control measures implemented to mitigate biorisks.

The performance of all of the control measures shall be evaluated on a routine basis, and the results of that evaluation shall be documented. The evaluation methodology can be quantitative, semiquantitative, or qualitative.

The results of this evaluation shall be used to enhance or change the control measures, and as the basis for continually improving the biorisk management system.

The performance evaluation shall be communicated to those members of the organization whose work may be affected by the biorisks, and reviewed by all relevant supervisors, managers, and organizational leadership. Top management may designate certain supervisors, managers, and/or leaders to approve the performance evaluation and oversee the implementation of measures to improve the biorisk management system.

6.2 Biorisk management objectives and planning to achieve them

The organization shall establish biorisk management objectives at relevant functions and levels.

The biorisk management objectives shall:

a) be consistent with the biorisk management policy;

b) be measurable (if practicable);

c) take into account applicable requirements;

d) be monitored;

e) be communicated;

f) be updated as appropriate.

The organization shall retain documented information on the biorisk management objectives.

When planning how to achieve its biorisk management objectives, the organization shall determine:

— what will be done;

— what resources will be required;

— who will be responsible;

— when it will be completed;

— how the results will be evaluated.

The organization shall ensure that its biorisk management system includes a control plan that addresses:

— responsibility and accountability for implementation of the plan;

— resources to be utilized (e.g. people, budget);

— timetable for implementation;

— adequate training provided in an effective way to workers in order to mitigate risk from the potential failure of any aspect of the biorisk management system plan;

— integration of risk control measures designed for biosafety and biosecurity;

— communication of the control plan across the organization; and

— mechanism and frequency for reviewing and assessing compliance with the plan.

7 Support

7.1 Resources

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance, evaluation, and continual improvement of the biorisk management system.

The organization shall identify resource requirements and provide adequate resources, including the assignment of trained workers for management, performance of work, and verification activities, including internal review.

7.1.1 Worker health programme

The organization shall ensure that risks to worker health are managed effectively, including consideration for preventive and protective measures. All workers whose health could be directly impacted by exposure to biological materials shall be included in the worker health programme.

The requirements of the worker health programme, including requirements for records management and confidentiality, shall be determined by a defined hazard and/or threat identification and biorisk assessment process that involves all relevant workers.

7.1.1.1 Vaccination of workers

The organization shall:

— establish and implement vaccination policy as part of the worker health programme;

— ensure that the required and/or recommended vaccines and its information are made available to the worker(s);

— maintain immunization records in accordance with national, regional, and local requirements;

— ensure access to work areas and/or activities is controlled for individuals including visitors and workers based on the vaccination policy of the organization; and

— identify and implement alternative measures to protect non-responders to vaccination and/or person(s) with vaccine contraindications.

7.2 Competence

The organization shall:

— determine the necessary competence of person(s) who work under its control and affect its biorisk management performance;

— ensure that these persons are competent on the basis of appropriate education, training, or experience;

— ensure that all workers are under close supervision until they demonstrate the ability to perform activities in a safe and secure manner;

— ensure that the competence of a worker transferred into another position is re-evaluated;

— where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;

— retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.

7.2.1 Behavioural factors and worker management

The organization shall address biorisks associated with human behaviour in the biorisk management plan, including how workers interact with the facility, its equipment, and coworkers.

The organization shall provide individual support and effective management of these behavioural factors.

7.2.2 Personnel reliability measures

The organization shall implement personnel reliability measures to determine and provide assurance that workers are reliable, trustworthy, and competent, and to identify individuals who may pose a biosecurity or biosafety risk to the organization.

The organization shall:

— establish policy and procedures to guide implementation of personnel reliability measures;

— control individual's access to facilities or work according to the established policies and procedures;

— determine personnel reliability measures based on local and national areas of concern for the types of agents and type of work being conducted;

— balance the requirements for maintaining effective personnel reliability measures, and the need to cultivate an atmosphere of trust and confidence in workers; and

— ensure all measures taken are lawful and ethical.

7.3 Awareness

Persons who work under the organization's control shall be aware of:

— the biorisk management policy;

— the requirements of the organization's biorisk management plan, including any updates to the biorisk management plan;

— the outcomes of investigations of relevant incidents and accidents;

— their contribution to the effectiveness of the biorisk management system, including the benefits of improved performance;

— the implications of not conforming with the biorisk management system requirements;

— the legal requirements that govern biorisk management.

7.3.1 Training

The organization shall ensure that requirements and procedures for biorisk management training of workers are identified, established, and maintained.

The procedures shall include, but not be limited to:

— identification of biorisk training needs;

— provision of programmes based on biorisk training needs;

— provision of required biorisk training in line with biorisk management plans;

— determination of effectiveness of biorisk training;

— provision of refresher biorisk training on a consistent basis;

— assessment to ensure that workers are competent to perform assigned tasks; and

— maintenance of biorisk training records.

7.4 Communication

The organization shall determine the need for internal and external communications and consultations relevant to the biorisk management system, including but not limited to:

— what it will communicate or consult;

— when to communicate and consult;

— with whom to communicate and who to consult:

  — internally among the various levels and functions within the organization,

  — with stakeholders, and

  — with other interested parties;

— how to communicate:

  — verbal communication (e.g. team briefing, conference call), and

  — non-verbal communication (e.g. posting of signage, document circulation, reference library).

The organization shall:

— ensure that appropriate and effective communication processes are established between the workplaces within the facility in line with organization's information security programme (7.5.4);

— ensure two-way directional communication is established with, and access to up-to-date information is provided to, workers on relevant biorisks;

— implement communication process for interested parties on its role, responsibility, needs, and biorisk management activities;

— ensure that internal and external communication plans and training are in place to support emergency response and contingency planning (8.9); and

— ensure a record of communications and meetings is kept.

7.5 Documented information

7.5.1 General

The organization's biorisk management system shall include:

— documented information required by this document, including but not limited to policies, plans, procedures, protocols and records; and

— any other documented information determined by the organization as being necessary for the effectiveness of the biorisk management system.

NOTE The extent of documented information for a biorisk management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products, and services;

— legal or other requirements;

— the complexity of processes and their interaction; and

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

— identification and description (e.g. a title, date, author, or reference number);

— format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

— review and approval for suitability, accuracy, and adequacy;

— review and approval for suitability for public release; and

— security and protection of sensitive information.

7.5.3 Control of documented information

Documented information required by the biorisk management system and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity);

c) it reflects the most current policies, plans, procedures, protocols, records, and other information associated with the biorisk management system.

For the control of documented information, the organization shall address the following activities, as applicable:

— distribution, access, retrieval, and use based on risk;

— storage and preservation, including preservation of legibility;

— control of changes (e.g. version control) and status (e.g. draft, interim, final);

— retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the biorisk management system shall be identified, as appropriate, and controlled.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

7.5.4 Information security

The organization shall establish and maintain an information security programme to identify, protect, and control access to sensitive information related to the biorisk management system.

The information security programme shall include policies and procedures to manage the identification, handling, storage, transmission, access control, and destruction of sensitive information.

As part of the information security programme, a review and approval process shall be used to prevent the unauthorized or unintended disclosure of sensitive information.

7.6 Non-employees

The organization shall ensure that oversight for visitors, suppliers, and other non-employee personnel is equivalent to the requirements of established management systems and does not compromise biorisk management of the facility.

7.7 Personal security

The organization shall have a programme in place to provide personal security support services to workers, based on an assessment and prioritization of threats to workers and potential vulnerabilities.

The programme shall include, where appropriate, personal security awareness training and other measures to address priority threats and vulnerabilities based on the assessment.

NOTE Personal security is concerned with security of workers during on-duty and off-duty hours while away from the facility. Workers can be vulnerable because of their function or position.

7.8 Control of suppliers

The organization shall determine and apply processes for the acquisition of products and services from suppliers to ensure conformance to specified requirements depending on their potential impact on the biorisk management system. The organization shall ensure suppliers are evaluated and selected based on their ability to provide products/services that meet the requirements of this standard and the objectives of the organization's biorisk management system. The organization shall establish criteria for selection, evaluation, and re-evaluation of suppliers. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

8 Operation

8.1 Operational planning and control

The organization shall ensure that facilities, equipment, and processes are designed, operated, and maintained in a safe and secure way with respect to biorisk management.

The organization shall ensure that a formal planning, design, and redesign process is adopted for the facility based upon an assessment of risks associated with the materials to be used and activities undertaken.

The design process shall identify and incorporate all relevant legislative requirements, and take account of information from recognized standards, guidelines, industry good practices, facility processes, and facility-specific risk assessments.

The design process shall identify and include consultation with all interested parties associated with the facility and its operation and use. All design features, construction techniques, materials, and equipment selected shall be documented in line with the need to provide sufficiently specific and detailed instruction and information on the design specification.

The organization shall ensure that new construction and physical facility modifications are carried out according to an approved plan.

The organization shall ensure that the programme of work for the facility is defined, documented, and reviewed.

The organization shall identify those operations and activities that are associated with potential biorisks and where control measures shall be applied.

The organization shall plan, implement, and control the processes needed to meet requirements, and to implement the actions determined in Clause 6, by:

— establishing criteria for initiating the processes to be performed (including criteria for work that requires prior approval);

— implementing control of the processes in accordance with the established criteria; and

— keeping documented information to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled.

8.2 Commissioning and decommissioning

The organization shall ensure, based on risk assessment, that:

— both commissioning and decommissioning of facilities, or areas therein, are included as a part of the formal and documented planning stages, and not considered solely towards the end of construction; and

— there is a formal process for commissioning of new or significantly renovated facilities, or areas therein, and the final decommissioning of facilities prior to being taken out of service, repurposed, or deconstructed.

NOTE For the purposes of this document, “significantly renovated” refers to any renovation that impacts measures that mitigate biosafety or biosecurity risks.

8.3 Maintenance, control, calibration, certification, and validation

The organization shall establish and maintain documented procedures to ensure that equipment and elements of the facilities, including any ancillary support facilities that may impact on the organization's biorisks, are identified, purchased, maintained, and calibrated, certified, or validated in a manner consistent with the intent and requirements of the biorisk management programme.

8.4 Physical security

The organization shall ensure that control measures for the physical security of biological materials are determined, implemented, and maintained on the basis of the biorisk assessment process.

The organization shall establish a plan and procedures to regularly verify that the physical security system is performing according to design requirements, taking into account operational experience. The organization shall test the system regularly to ensure its operability and performance. Maintenance and repair of the physical security system shall be an element of the organization's maintenance plan.

To support the physical security system, the organization shall ensure that control measures are in place for removal and exclusion of person(s) from the facility where it is deemed necessary.

8.5 Biological materials inventory

The organization shall ensure that an accurate, verifiable, and up-to-date inventory, or itemized record, of biological materials with biological agents and toxins specified, is established and maintained based on the organization's biorisk assessment.

The organization shall determine the biological agents, toxins, and other biological materials handled and stored, and which of these will be accounted for and controlled through the inventory based on the organization's biorisk assessments and other requirements, as applicable.

Based on the organization's biorisk assessments, the organization shall determine a process for checking, reviewing, updating, and reporting the biological materials inventory.

8.6 Good microbiological technique

The organization shall ensure that all workers who handle biological materials are competent in performing good microbiological technique – the working methods applied to eliminate or minimize exposure to biological materials, such as described in the WHO *Laboratory biosafety manual* (most recent edition), and ISO 15190:2003. Good microbiological technique ensures quality of science as well as the application of the necessary safeguards to mitigate the identified biorisks. The organization shall ensure that appropriate resources (including time and equipment) are available to ensure workers are trained in such practices, and that the practices are effectively respected.

8.7 Clothing and personal protective equipment (PPE)

The organization shall ensure that suitable selection and provision of equipment, including PPE, is specified based on the biorisk assessments. The organization shall ensure that PPE is maintained and used appropriately, including cleaning and decontamination. The organization shall make PPE available and provide appropriate training for the use of PPE to relevant workers. The organization shall consider applicable regulations for the maintenance and use of PPE.

8.8 Decontamination and waste management

The organization shall establish and maintain validated procedures to ensure that appropriate methods for decontamination and inactivation are chosen and implemented effectively.