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WORKSHOP

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AGREEMENT

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Laboratory biorisk management standard

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Foreword

CWA 15793:2008 was prepared by CEN Workshop 31 - Laboratory biosafety and biosecurity.

The CEN Workshop offers a mechanism whereby stakeholders can bring their standardization and specification requirements and develop a result by consensus, validated in an open process.

In a CEN Workshop all the decision-making powers rest with the interested parties themselves, the members of the Workshop. These include all stakeholders (for example industry representatives, service providers, administrators, users) and can come from any part of the globe. They are responsible for the funding and direction of the Workshop and for the approval of the deliverables.

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). The CWA is a voluntary standard applicable internationally and does not have the force of regulation.

For the development of this CWA, there were 76 participants from the following countries:

Argentina, Australia, Belgium, Canada, China, Denmark, Germany, Ghana, Hong Kong, Hungary, Ireland, Japan, Kazakhstan, Kyrgyzstan, Latvia, the Netherlands, Norway, Russia, Singapore, Spain, Sweden, Switzerland, the United Kingdom and the United States. A list of organizations participating in this Workshop and in support of this CWA is available from the CEN Management Centre. The WHO also participated in the Workshop.

There was also a public comment phase that brought comments from an additional 33 stakeholders from Argentina, Canada, Europe, Russia, Taiwan and the United States. More information on CEN and the CEN Workshops can be found at: www.cen.eu

NEN, the Dutch Standardization Institute, provided the secretariat of the Workshop.

The formal process followed by the Workshop in the development of the CEN Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of the CEN Workshop Agreement or possible conflict with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its members.

The final review/endorsement round for this CWA was successfully closed on 2007-12-24. The final text of this CWA was submitted to CEN for publication on 2008-01-14.

This CEN Workshop Agreement is publicly available as a reference document from the National Members of CEN: AENOR, AFNOR, ASRO, BDS, BSI, CSNI, CYS, DIN, DS, ELOT, EVS, IBN, IPQ, IST, LVS, LST, MSA, MSZT, NEN, NSAI, ON, PKN, SEE, SIS, SIST, SFS, SN, SNV, SUTN and UNI

Comments or suggestions from the users of the CEN Workshop Agreement are welcome and should be addressed to the CEN Management Centre.

Introduction

Management systems approach - Introduction

This laboratory biorisk management standard is based on a management system approach. This implies that identifying, understanding and managing a system of interrelated processes for a given objective, improves the organization's effectiveness and efficiency.

Application of the management systems approach principle leads to the following actions:

- a) defining the system by identifying or developing the processes that affect a given objective;
- b) structuring the system to achieve the objective in the most effective manner;
- c) understanding the interdependencies among the processes of the system;
- d) continually improving the system through measurement and evaluation, and;
- e) establishing resource constraints prior to action.

The systems approach outlined above has been successfully adopted by the International Organization for Standardization (ISO). Organizations which have already implemented systems for quality, environmental and/or occupational health and safety management, will find significant synergy between these systems and the one for biorisk management.

The management system approach enables an organization to effectively identify, monitor and control the laboratory biosafety and biosecurity aspects of its activities.

An effective management system approach should be 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 goals. This is known as the PDCA (Plan-Do-Check-Act) principle:

Plan:	Planning, including identification of hazard and risk and establishing goals,
Do:	Implementing, including training and operational issues,
Check:	Checking, including monitoring and corrective action,
Act:	Reviewing, including process innovation and acting to make needed changes to the management system.

In order to improve biorisk management the organization needs to focus on the causes of non-conformities and undesirable events. Systematic identification and correction of system deficiencies leads to improved performance and control of biorisk.

Keys to a successful biorisk management system

Some of the key factors in establishing and implementing a successful biorisk management system include:

- Commitment by top management:
 - providing adequate resources, prioritization and communication of biosafety and biosecurity policy;
 - integrating of biorisk management throughout the organization;
 - identifying opportunities for improvement and prevention, determining root causes and preventing recurrence.

- Focus on continual improvement:
 - making continual improvement an objective for every individual in the organization;
 - using periodic assessment against established risk-criteria to identify areas for potential improvement;
 - continually improving the effectiveness and efficiency of processes;
 - promoting prevention activities;
 - providing personnel in the organization with appropriate education and training including the methods and tools of continual improvement;
 - establishing measures and goals for improvement;
 - recognizing improvement.

Management system integration

This laboratory biorisk management standard is compatible with the EN ISO 9001:2000 (Quality), EN ISO 14001:2004 (Environmental) and OHSAS 18001:2007 (Occupational Health and Safety) management systems standards, in order to facilitate the integration of all such management systems of an organization.

Application

The requirements of this standard are generic and are intended to be applicable to all organizations handling biological agents and/or toxins, regardless of type, size and biological agents handled. This standard takes a riskbased approach but it does not employ biological agent risk classification or laboratory safety/containment levels, although such approaches can be entirely compatible with this standard.

Where any requirements of this standard cannot be applied due to the nature of the organization and its processes, this can be considered for exclusion. Where exclusions are made, claims of conformity to this standard are not acceptable, unless such exclusions do not affect the organization's ability or responsibility to control biorisk in the manner required by this standard. Any claims of exclusion shall be detailed and justification provided.

Compliance with national and local regulatory standards, regulations and requirements are of primary importance in any programme. Where any part of this standard is in conflict with any legal requirement, the conflicting part of the standard may be eligible for exemption if the legal requirement meets or exceeds the intent of this standard.

All organizations face challenges in putting the management system requirements of this standard in place. For small organizations the challenges are potentially greater due to minimal available resources, costs involved and difficulty in understanding and applying the standard. Small organizations are typically ones in which only a few people are involved, there is a simple communication flow and individuals undertake a wide variety of tasks. Decisions are made by just a few people. Small organizations should analyse each requirement clause of the standard and determine in which manner they can interpret and comply with it to suit the objective of the standard in identification and control of risk.

The more challenging requirement clauses in this respect may be the ones related to continual improvement. The organization should regard this as a recurring, step-by-step activity. When opportunities for improvement are identified, and justified, the organization needs to decide how they are to be implemented based on the available resources. The justification should be founded on an analysis of the potential gains in terms of improved control of risk. Improvements may typically address issues like:

- training and awareness programmes;
- internal communications;
- effectiveness of reviews;
- preventive actions;
- effectiveness of follow-up activities;
- documented procedures and instructions.

1 Scope

The scope of this laboratory biorisk management system standard is to set requirements necessary to control risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities.

The standard will enable organizations to:

- a) establish and maintain a biorisk management system to control or minimize risk to acceptable levels in relation to employees, the community and others as well as the environment which could be directly or indirectly exposed to biological agents or toxins;
- b) provide assurance that the requirements are in place and implemented effectively;
- c) seek and achieve certification or verification of the biorisk management system by an independent third party;
- d) provide a framework that can be used as the basis for training and raising awareness of laboratory biosafety and laboratory biosecurity guidelines and best practices within the scientific community.

The standard is performance-based and sets out requirements for and places responsibility on organizations to demonstrate that appropriate and validated risk reduction procedures have been established and implemented.

The standard is structured in a manner where the specific requirements pertaining to each individual clause are defined and stated in a frame-box. Informative guidance has been provided as an aid in interpreting the requirements where considered appropriate. This guidance is in the form of notes in association with the pertaining requirements clause and uses the terms “should” (recommendation), “may” (allowance) and “can” (possibility). Organizations wishing to implement this standard would be expected to consider all recommendations where the term “should” is used.

Contents of the notes shall not in any way be construed as being requirements.

2 Informative references

Two central guidance documents for biorisk management and the development of this standard are:

- WHO Laboratory biosafety manual, third edition, 2004, WHO/CDS/CSR/LYO/2004.11
- WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006, WHO/CDS/EPR/2006.6

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply to this standard:

3.1

accident

unintended event giving rise to harm

NOTE An accident is an incident which has resulted in harm.

3.2

audit (OHSAS 18001:2007)

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

NOTE 1 Independent does not necessarily mean external to the organization. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited.

NOTE 2 For further guidance on audit evidence and audit criteria, see EN ISO 19011:2002.

3.3

biohazard (adapted from ISO/IEC Guide 51:1999)

potential source of harm caused by biological agents or toxins

3.4

biological agent (adapted from EU Directive 2000/54/EC)

any microorganism including those which have been genetically modified, cell cultures and endoparasites, which may be able to provoke any infection, allergy or toxicity in humans, animals or plants

NOTE For the purpose of this standard prions are regarded as 'biological agents'.

3.5

biorisk (adapted from ISO/IEC Guide 51:1999)

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

NOTE The source of harm may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access or intentional unauthorized release.

3.6

biorisk assessment (adapted from OHSAS 18001:2007)

process of evaluating the biorisk(s) arising from a biohazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable

3.7

biorisk control (adapted from ISO/IEC Guide 73:2002)

actions implementing biorisk management decisions

NOTE Biorisk control may involve monitoring, re-evaluation, and compliance with decisions.

3.8

biorisk management committee

institutional committee of individuals competent in biorisk control, and other representatives as appropriate

3.9

biorisk management system (adapted from OHSAS 18001:2007)

part of an organization's management system used to develop and implement its biorisk policy and manage its biorisks

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.

3.10

biorisk management advisor

an individual who has expertise in the biohazards encountered in the organization and is competent to advise top management and staff on biorisk management issues

NOTE Depending on national guidelines and institutional traditions the role of a biorisk management advisor may be differently named e.g. biosafety officer, biosecurity officer, biorisk manager or biorisk management officer.

3.11

biosafety (adapted from: WHO/CDS/EPR/2006.6)

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

3.12

biosecurity (adapted from: WHO/CDS/EPR/2006.6)

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

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.

3.13

calibration (ISO/IEC 17025:1999)

correlation of the performance of equipment (e.g. readings of an instrument) to a standard

3.14

certification

systematic, documented process to ensure systems perform in accordance with available certification standards or applicable validation guidance

3.15

community

people outside the workplace potentially affected by the activities of the facility

3.16

competence (EN ISO 9000:2005)

appropriate education, training, skills and experience

3.17

containment (EN 12128:1998)

system for confining microorganisms or organisms or other entities within a defined space

3.18

continual improvement (adapted from OHSAS 18001:2007)

recurring process of enhancing the biorisk management system in order to achieve improvements in overall biorisk management performance consistent with the organization's biorisk management policy

Note The process need not take place in all areas of activity simultaneously

3.19

corrective action (OHSAS 18001:2007)

action to eliminate the cause of a detected nonconformity or other undesirable situation

NOTE 1 There can be more than one cause for nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

3.20

decontamination (from ISO 15190:2003)

procedure that eliminates or reduces biological agents and toxins to a safe level with respect to the transmission of infection or other adverse effects

3.21

disinfection (ISO 15190:2003)

process to reduce the number of microorganisms, but not usually of bacterial spores, without necessarily killing or removing all organisms

3.22

document (OHSAS 18001:2007)

information and its supporting medium

NOTE The medium can be paper, magnetic, electronic or optical computer disc, photograph or master sample, or a combination thereof.

3.23

event (adapted from ISO/IEC Guide 73:2002)

occurrence of a particular set of circumstances

3.24

facility

operational unit and associated buildings and equipment used to manage biological agents and toxins

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)

3.25

genetically modified microorganism (GMM) (EU Directive 98/81/EC)

microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination

3.26

good microbiological techniques (adapted from WHO/CDS/CSR/LYO/2004.11)

working methods applied to eliminate or minimize exposure to biological agents via e.g. aerosols, splashes, and accidental inoculation

3.27

harm (adapted from ISO/IEC Guide 51:1999)

adverse effect on the health of people, animals or plants, on the environment or on property

3.28

hazard (adapted from OHSAS 18001:2007)
source, situation, or act with a potential for causing harm

3.29

hazard identification (OHSAS 18001:2007)
process of recognizing that a hazard exists and defining its characteristics

3.30

incident
event with a potential for causing harm

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.

3.31

inspection (EN ISO 9000:2005)
conformity evaluation by observation and judgement accompanied as appropriate by measurement, testing or gauging

3.32

inventory
itemized record of stored supplies of biological agents or valuable biological materials

3.33

laboratory
room within a facility, designated for work on biological agents and/or toxins

3.34

microorganism (EU Directive 98/81/EC)
microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material including viruses, viroids, animal and plant cells in culture

3.35

nonconformity (OHSAS 18001:2007)
non-fulfilment of a requirement

NOTE A nonconformity can be any deviation from: relevant work standards, practices, procedures, legal requirements, etc.: biorisk management system requirements.

3.36

organization (OHSAS 18001:2007)
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

NOTE For organizations with more than one operating unit, a single operating unit may be defined as an organization.

3.37

personal protective equipment (PPE) (adapted from: ISO 15190:2003)

material, including clothing (e.g. gown, gloves, respirators, safety glasses), used to prevent exposure to or contamination of a person by chemical or biological matter

3.38

preventive action (OHSAS 18001:2007)

action to eliminate the cause of a potential nonconformity or other undesirable potential situation

NOTE 1 There can be more than one cause for a potential nonconformity.

NOTE 2 Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

3.39

procedure (adapted from OHSAS 18001:2007)

specified way to carry out an activity or a process

3.40

record (OHSAS 18001:2007)

document stating results achieved or providing evidence of activities performed

3.41

risk (ISO/IEC Guide 51:1999)

combination of the probability of occurrence of harm and the severity of that harm

3.42

risk assessment (OHSAS 18001:2007)

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

3.43

safety (ISO/IEC Guide 51:1999)

freedom from unacceptable risk

3.44

standard operating procedure (SOP)

set of written instructions that document a routine or repetitive activity followed by an organization

3.45

source (ISO/IEC Guide 73:2002)

item or activity having a potential for a consequence

3.46

toxin

substance, produced by a biological system, which in small or moderate amounts produces an adverse effect in humans, animals or plants. This definition includes substances and materials which may be contaminated with toxins (see also biohazard)

3.47

validation (adapted from EN ISO 9000:2005)

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

3.48

verification (adapted from ISO 9000:2005)

confirmation, through the provision of objective evidence that specified requirements have been fulfilled

3.49

workplace (OHSAS 18001:2007)

any physical location in which work-related activities are performed under the control of the organization

NOTE When giving consideration to what constitutes a workplace, the organization should take into account the OH&S effects on personnel who are, for example, travelling or in transit (e.g. driving, flying, on boats or trains), working at the premises of a client customer, or working at home.

4 Biorisk management system requirements

4.1 General requirements

4.1.1 Biorisk management system

The organization shall establish, document, implement and maintain a biorisk management system in accordance with the requirements of this Laboratory biorisk management standard.

4.1.2 Continual improvement

The organization shall continually improve the effectiveness of the biorisk management system through the use of the policy, objectives, self-audit programme, audit results, analysis of data, risk assessment, corrective and preventive actions and the management review.

NOTE The organization should strive to continue to develop and refine the systems in place to ensure that further opportunities to improve are identified and implemented. This may be achieved through goal setting and targets placed upon those working within the facility, and monitoring progress to ensure the goals are achieved.

4.2 Policy

4.2.1 Biorisk management policy

The organization's top management shall develop, authorize and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity). It shall clearly state the overall biorisk management objectives and a commitment to improving biorisk management performance.

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

- a) protecting staff, contractors, visitors, community and environment from biological agents and toxins that are stored or handled within the facility;
- b) reducing the risk of unintentional release of, or exposure to biological agents and toxins;
- c) reducing the risk to an acceptable level of unauthorized intentional release of hazardous biological materials, including the need to conduct risk assessments and implement the required control measures;
- d) complying with all legal requirements applicable to the biological agents and toxins that will be handled or possessed, and with the requirements of this standard;
- e) ensuring that the need for effective biorisk management shall take precedence over all non "health and safety" operational requirements;
- f) effectively informing all employees and relevant third parties and communicating individual obligations with regard to biorisk to those groups;
- g) continually improving biorisk management performance.

NOTE Biorisk management should be stated clearly as part of the organization's health, safety and environment (HSE) policies. Depending on the relevance of biorisk management to the organization, the biorisk management policy should complement the general HSE policies. As appropriate, the biorisk management policy may be integrated into the organization's HSE policies.

The policy should require all projects/work areas to be assessed for risks and a full assessment prepared before work is approved to commence.

4.3 Planning

4.3.1 Planning for hazard identification, risk assessment and risk control

4.3.1.1 Planning and resources

The organization shall ensure that a risk assessment system is established, implemented and maintained in accordance with this standard and that the performance of the risk management system is reported to senior management for review and as a basis for improvement.

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

NOTE The roles and responsibilities of personnel who perform and verify work affecting risk management should be defined and documented, particularly for people who need the organizational freedom and authority to do one of the following:

- a) initiate action to prevent or reduce the adverse effects of risk;
- b) control further treatment of risks until the level of risk becomes acceptable;
- c) identify and record any problems relating to the management of risks;
- d) initiate, recommend or provide solutions through designated channels;
- e) communicate and consult internally and externally as appropriate.

4.3.1.2 Risk assessment timing and scope

The organization shall ensure the approach to risk assessment is defined with respect to its scope, nature and timing so that it is proactive rather than reactive.

NOTE 1 The following should trigger either a new risk assessment or review of an existing one:

- a) commencement of new work or changes to the programme of work including the introduction of new biological agents or alterations to work flow or volume;
- b) new construction / modifications to laboratories, plant and equipment or its operation;
- c) introduction of altered and unplanned staffing arrangements (including contractors, visitors and other non-core personnel);
- d) significant alterations to Standard Operating Procedures (SOPs) or working practices (e.g. disinfection / waste management methodologies, PPE provision / usage entry / exit protocols, etc.);
- e) when unexpected events that may have relevance for the management of biorisks are observed;
- f) when actual or potential non-conformity with internal / external rules and regulations is identified (e.g. introduction of new legislation or major accident exposure);
- g) when considering emergency response and contingency planning requirements;
- h) as part of the existing management system review process (e.g. annually or at another appropriate and predetermined frequency).

NOTE 2 There are many defined methodologies and approaches available for conducting hazard identification, risk assessment and control and the approach taken will vary depending upon the nature of the situation and the level of detail required. One framework which organizations may consider adopting is outlined in Figure 1 below.

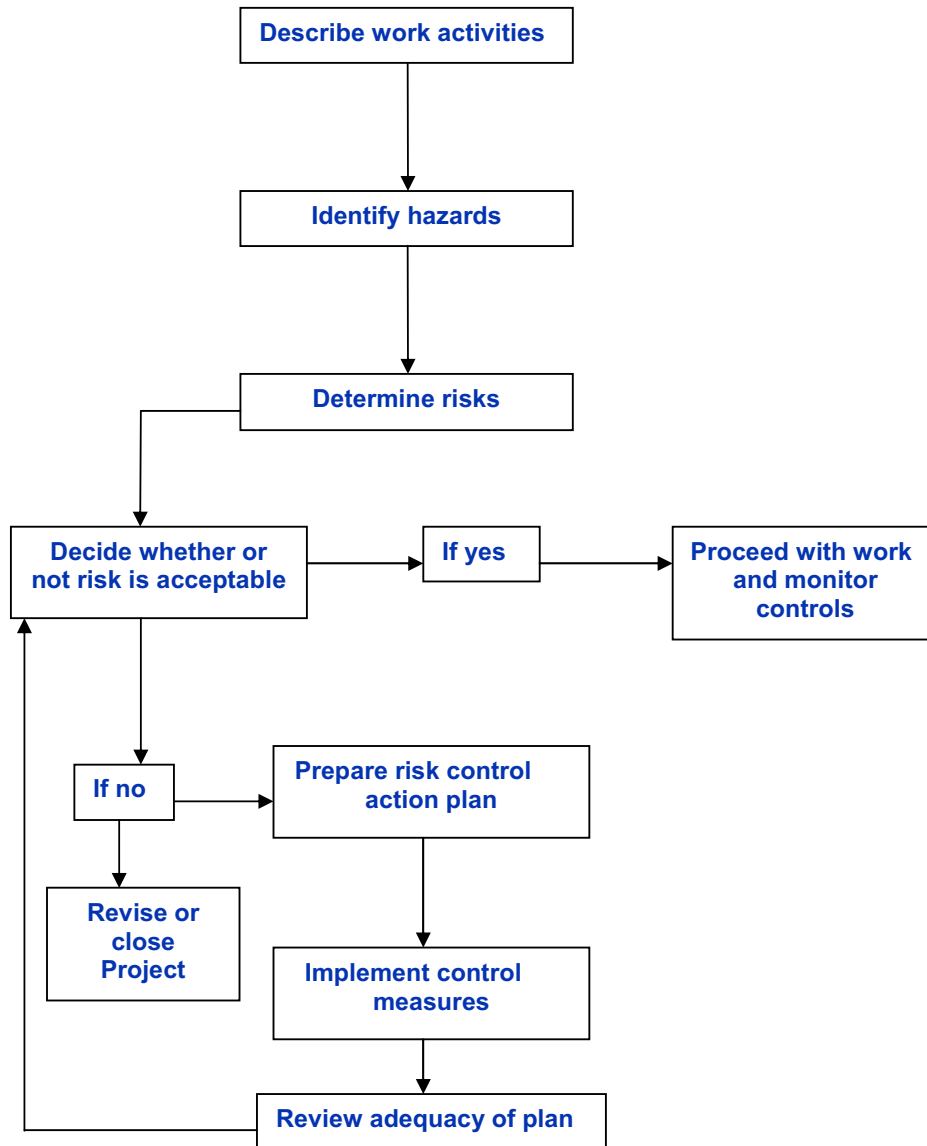


Figure 1 — Risk assessment strategy

4.3.1.3 Hazard identification

The hazards associated with proposed work shall be identified and documented.

NOTE The first stage in the risk management process is to identify all hazards that are relevant for biorisk. It is useful to involve the whole work team in this process and to use inputs from organizational experts on safety and risk management.

A hazard may be a physical situation (e.g. a fire or explosion), an activity (e.g. pipetting) or a material (in this case the principal hazard is most likely to be a biological agent or toxin, but others will include chemicals and asphyxiating gases such as nitrogen). The essence of a hazard is that it has the potential for causing harm, regardless of how likely or unlikely such an occurrence might be.

Biological hazards should be identified and assessed in relation to their potential damage to humans, animals, and the environment. Where hazardous materials are classified into hazard or risk groups based on international and/or foreign country classification schemes local diverging needs and constraints should be considered.

A hazard identification exercise should use information including:

- a) group experience and knowledge;
- b) external or specialized expertise not found in the facility;
- c) results of previous assessments;
- d) surveys of previous accidents/incidents;
- e) hazardous materials data;
- f) information on hazardous organisms;
- g) guidelines and codes of practice;
- h) facility drawings;
- i) SOPs, manuals, etc.;
- j) process maps.

Defined methodologies and approaches are available for conducting hazard identification exercises. Unless hazards are identified effectively, it is not possible to assess the risk associated with the facility and associated activities. Hazard identification should be appropriate in nature, structure and recorded to a level whereby others can review the process.

4.3.1.4 Risk assessment

The organization shall ensure that suitable methodologies for assessing and recording risks are identified, implemented and maintained.

NOTE The risk assessment should categorize risks to identify those which need to be eliminated or controlled. Descriptions of likelihood and consequence, together with the acceptability of risk levels should be defined and used in the assessment. Such a classification can be achieved for example through the use of a risk matrix identifying likelihood and consequence categories, ordered to illustrate those falling into high, moderate and low zones. However, other approaches may also be relevant and appropriate.

Assessments can be qualitative, semi-quantitative or quantitative, and a method suitable to the situation should be identified and followed. In conducting the assessment due consideration should be made of the inherent risk from the biological agents and toxins (e.g. from risk grouping descriptions, material safety data sheets etc.). After definition and implementation of control measures the risks should be reviewed to decide if the remaining risk is acceptable or whether additional controls need to be identified and implemented.

4.3.1.5 Risk management

The organization shall ensure suitable methodologies for the allocation of actions resulting from risk assessments, including time lines, responsible persons and associated reporting and approval mechanisms are identified, implemented and maintained.

NOTE The risk management approach should include a control plan to include:

- a) who is responsible and accountable for implementation of the plan;
- b) what resources are to be utilized (e.g. people, budget);
- c) timetable for implementation;
- d) details of the mechanism and frequency of review of compliance with the plan.

Risk management strategies should include the hierarchies of control. These are elimination of the work, substitution with an alternative organism/activity, isolation of the hazard, the use of engineering controls, administrative controls, or the reliance on personal protective equipment (PPE).

4.3.2 Conformity and compliance

The organization shall ensure that all relevant requirements are identified and fulfilled within the biorisk management system. Legal requirements include national / federal, regional / state, provincial, city and local regulatory requirements with which the organization shall comply.

NOTE The organization should adopt measures to identify legal and other requirements for the facility in relation to the biological agents and toxins that will be held and used, but also other regulations including for example: worker protection and rights, environmental impact and general health & safety (e.g. fire, electrical, etc.). There is a need to monitor for new and upcoming requirements, as well as those already in existence. This information should be kept up to date and the requirements incorporated into the biorisk management system of the facility.

4.3.3 Objectives, targets and programme

4.3.3.1 Biorisk control objectives and targets

The organization shall establish, implement and maintain documented biorisk control objectives and targets for an effective control of biorisk at relevant functions and levels in the organization.

4.3.3.2 Monitoring controls

Management shall establish the controls and put in place documented procedures for monitoring the effectiveness of the controls being applied to reduce or eliminate the hazards identified in the risk assessment process.

NOTE The controls can be monitored by regular audits, by utilizing corrective action reporting processes where problems have been identified, by investigation of incidents and accidents and improving controls and their implementation and by ensuring that adequate resources are provided to maintain the effectiveness of the controls.

4.4 Implementation and operation

4.4.1 Roles, responsibilities and authorities

4.4.1.1 Top management

Top management shall take ultimate responsibility for the organization's biorisk management system.

Top management shall ensure that roles, responsibilities and authorities related to biorisk management are defined, documented and communicated to those who manage, perform and verify work associated with the control of biological agents and toxins.

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

NOTE 1 Top management includes Officers (Director General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and Directors of the organization. Overall responsibility for management of biorisk rests with top management but tasks may 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 may hold more than one role described in the standard. It is important to define roles and responsibilities and that there is clear communication within the organization in terms of the actions that need to be taken, and who has the required authority.

NOTE 2 In assigning roles and responsibilities, potential conflicts of interest should be considered.

NOTE 3 This standard has identified roles that need to be covered in the organization and has only used titles to illustrate these roles; these titles may not be the same as the titles used in specific organizations.

NOTE 4 Resources include human resources and specialized skills, organizational infrastructure, technology and financial resources.

4.4.1.2 Senior management

A senior manager shall be designated with operational responsibility for overseeing the system for management of biorisk.

Functions of the system for the management of biorisk shall include:

- a) providing appropriate resources to ensure adequate provision of personnel, facilities and other resources deemed necessary for the safe and secure operation of the facility;
- b) reporting to top management on the performance of the biorisk management system and any need for improvement;
- c) ensuring promotion of the biorisk management system throughout the organization;
- d) instituting review, audit and reporting measures to provide assurance that the requirements of this standard are being implemented and maintained effectively.

NOTE Senior managers are those with significant operational, budgetary and personnel authority at the departmental or higher level, and may include members of top management. The senior management representative should be an

individual with decision making authority at a level whereby he/she can allocate resources and make decisions regarding the biorisk management needs of the facility (including required resources to conduct risk assessments and other management and administrative activities) independently of the need to implement the programme of work.

4.4.1.3 Biorisk management committee

A biorisk management committee shall be constituted to act as an independent review group for biorisk issues. Reporting to senior management, the committee shall:

- a) have documented terms of reference;
- b) include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken;
- c) ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively;
- d) be chaired by a senior individual;
- e) meet at a defined and appropriate frequency, and when otherwise required.

NOTE 1 The biorisk management committee is often recognized as the Institutional Biosafety Committee and may be either a dedicated function, or the role can be addressed through a committee with a wider remit. Members may include the scientific manager, additional scientific specialists, the biorisk management advisor(s), security manager and the occupational health professional. Dependent on the nature of the agenda or nature of the work others may be included e.g. the facility manager and /or worker and community representatives.

Functions of the committee should include:

- a) contributing to the development of institutional biorisk policies and codes of practice;
- b) approving proposals for new work or significant modifications to the potential risk associated with existing activities;
- c) reviewing and approving protocols and risk assessments for work involving biological agents and toxins;
- d) reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs.

NOTE 2 The list of roles for the biorisk management committee is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed.

4.4.1.4 Biorisk management advisor

A competent individual(s) shall be designated to provide advice and guidance on biorisk management issues. This individual shall report directly to the responsible senior manager and have delegated authority to stop 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.

NOTE 1 The competent individual providing advice and guidance on biorisk management is often recognized as a biological safety officer (BSO) or biological safety advisor. This function should normally be regarded as an advisory position and not directly responsible for managing biorisk, as this rests with those conducting and managing the work within the organization (e.g. scientific director, principal investigator, department head, laboratory manager, group leader, etc). The role and knowledge of the biorisk advisor is important to develop, implement, maintain and continually improve a

biosafety and biosecurity programme based on a management system. The advisor should be competent to perform the role, and allocated sufficient time and other resources to do the job effectively. In the execution of his/her biorisk management duties the advisor should be independent from those responsible for implementing the programme of work and have direct access to the top management representative when necessary.

Functions of the biorisk management advisor should include:

- a) verifying, in conjunction with other relevant personnel, that all relevant biorisk considerations have been addressed;
- b) advising or participating in the reporting, investigation and follow-up of accidents / incidents, and where appropriate referring these to management / biorisk management committee;
- c) ensuring that relevant and up-to-date information and advice on biorisk management is made available to scientific and other personnel as necessary;
- d) advising on biorisk management issues within the organization (e.g. management, biorisk management committee, occupational health department, security);
- e) contributing to the development and / or delivery of biorisk training activities;
- f) ensuring that all relevant activities are performed in compliance with biorisk regulations and that required biorisk authorizations for work are in place.

NOTE 2 The list of roles for the biorisk management advisor is neither exhaustive nor comprehensive, but includes some of the main areas that should be addressed.

4.4.1.5 Scientific management

An individual(s) with responsibility for the scientific programme within the facility shall be designated with responsibilities relevant to biorisk management.

Functions shall include:

- a) ensuring that all work is conducted in accordance with established policies and guidelines described in this standard;
- b) supervising workers, including ensuring only competent and authorized personnel can enter and work in the facility;
- c) planning and conducting work activities, and ensuring adequate staffing levels, time, space and equipment are available;
- d) ensuring required authorizations for work are in place;
- e) ensuring laboratory biosafety and laboratory biosecurity risk assessments have been performed, reviewed and approved, and that the required control measures are in place;
- f) ensuring that all at-risk employees have been informed of risk assessments and/or provisions for any recommended precautionary medical practices (e.g. vaccinations or serum collections).

NOTE The scientific manager is the individual responsible for managing the scientific programme within the facility on a day to day basis, and for implementing and monitoring biorisk controls in association with other facility personnel (e.g. adherence to policies and procedures, monitoring staff performance and participation in inspections and audits). The individual would normally have an in-depth knowledge of the work programme and the facility and be in a supervisory / management position and may be referred to as Head of Department, Principal Investigator, Laboratory Supervisor / Manager or Group Leader. Competence will be required in technical / scientific aspects of the biological agents and toxins being used and their control, together with management of the facility, its personnel and systems. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined so as to avoid any omissions and ensure consistency.

4.4.1.6 Occupational health

The organization shall have access to appropriate occupational health expertise and establish an occupational health programme commensurate with the activities and risks of the facility.

NOTE The occupational health professional would normally be a medical doctor or occupational health nurse with understanding of the biological agents and toxins that are handled within the facility.

The role should include providing input into risk assessment from a worker health perspective, advising on first aid / emergency treatment measures and follow-up, liaising with external healthcare providers, and coordinating medical examinations, surveillance and vaccination programmes. Roles and responsibilities of the occupational health professional should be determined in light of requirements set out in this standard.

4.4.1.7 Facility management

Facilities manager(s) shall be appointed with responsibilities relevant to facilities and equipment determined in accordance with requirements set out in this standard.

NOTE The facilities manager would normally be an engineer or someone with an in-depth knowledge of laboratory facilities, containment equipment and buildings. The role should include providing input into risk assessment from a facility perspective, coordinating building and maintenance work, and liaising with contractors. Roles and responsibilities of the facilities management personnel should be determined in light of requirements set out in this standard. More than one individual may hold similar roles, but in such instances the responsibilities should be clearly defined so as to avoid any omissions and ensure consistency.

4.4.1.8 Security management

A security manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.

NOTE The security manager would normally be someone with an in-depth knowledge of laboratory and facility security, who should liaise with other personnel (e.g., biorisk management advisor) and implement effective and proportionate laboratory biosecurity measures, based on the biological risk. The role should include providing input into risk assessment and management from a security perspective. Roles and responsibilities of the security personnel should be determined in light of requirements set out in this standard.

4.4.1.9 Animal handling

In laboratories where animals are maintained, an animal care manager shall be designated with responsibilities determined in accordance with requirements set out in this standard.

NOTE The animal care manager would normally be someone with an in-depth knowledge of animal handling and zoonotic and animal diseases. The animal care manager should liaise with other personnel (e.g., biorisk management advisor, occupational health professional, etc) to implement effective and proportionate laboratory biosafety and laboratory biosecurity measures. A qualified veterinarian should be available for additional advice. The role should include providing input into risk assessment and management from an animal care and use perspective.

4.4.2 Personnel training, awareness and competence

The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so. Competence levels shall be judged on appropriate education, training and experience.

The organization shall define required competency levels and shall maintain records verifying that staff members have attained and demonstrated those levels of competency.

4.4.2.1 Recruitment

The organization shall ensure that qualifications, experience and aptitudes relating to biorisk are considered as part of the recruitment process.

NOTE Prior to taking up an appointment the organization should ensure that:

- a) all personnel should be subject to a formal selection process, including relevant background checks based on risk (e.g. employment references, security checks, etc.);
- b) appropriate controls are implemented if existing employees are transferred to areas where there may be an increased risk profile;
- c) an assessment is made of the need for the above controls for non-core personnel (e.g. contractors, visitors, students, etc.), and measures implemented to ensure they are applied where necessary.

4.4.2.2 Competence

The organization shall ensure that personnel conduct activities within the facility under close supervision until competency has been demonstrated.

NOTE Competence is defined in relation to appropriate education, training and / or experience, together with a demonstrable ability to perform the task in a safe / secure manner.

Procedures should address:

- a) definition of competency needs;
- b) demonstration of successful completion of required training;
- c) demonstration of ability to perform tasks under supervision and unsupervised;
- d) restrictions on personnel who have not demonstrated competence to ensure they do not perform tasks for which they are not eligible;
- e) maintenance of adequate records.

No worker should be exempt from demonstrating competence irrespective of rank, experience or background.

4.4.2.3 Continuity and succession planning

The organization shall ensure that adequate back-up and contingency measures are in place to address the need for continuity and succession planning.

NOTE The organization should identify roles and individuals and ensure that the integrity of the facility is not compromised through short or long-term absence. Such measures should include succession planning for personnel (technical, management and scientific, including contractors) to ensure that no individual holds critical knowledge regarding the safe and secure operation of the facility that is not available to others in the event of their departure or unavailability.

4.4.2.4 Training

The organization shall ensure that requirements and procedures for biorisk-related training of personnel are identified, established and maintained.

NOTE Procedures should address:

- a) definition of biorisk training needs;
- b) provision of required biorisk training;
- c) determination of effectiveness of biorisk training;
- d) provision of refresher biorisk training;
- e) restrictions on personnel to ensure they do not perform tasks for which they are not trained;
- f) maintenance of adequate records.

Training should include raising personnel awareness of biorisk issues including the relevance of human factors in biorisk management.

4.4.3 Consultation and communication

The organization shall ensure that relevant biorisk information relating to its activities is communicated to and from employees and other relevant parties.

Employee involvement and consultation arrangements shall be documented.

Personnel shall have access to adequate and up-to-date information pertaining to the biorisks of the organization.

NOTE 1 The organization should implement mechanisms to ensure that relevant and current information with the potential to affect workers and others is defined and delivered effectively at appropriate intervals. In the workplace this

could mean regular team meetings and briefings, as well as formal training sessions. In addition to facility personnel, it may also be appropriate to engage others including:

- a) local, national and international governmental organizations;
- b) relevant regulatory agencies;
- c) certifiers;
- d) emergency services and healthcare providers;
- e) contractors and suppliers (e.g. cleaners, maintenance providers, security personnel);
- f) local community representatives (e.g. through a community liaison committee).

NOTE 2 Systems should be set in place to identify existing or emerging technologies or other relevant information relating to the containment of the biological agents and toxins being handled or stored, and that this information is shared with relevant staff through the use of appropriate media. This may include circulation of appropriate signage, documents, team briefings and maintenance of reference libraries and other sources of information.

4.4.4 Operational control

The organization shall identify those operations and activities that are associated with possible biological risk and where control measures shall be applied.

The organization shall plan these activities, including maintenance, and ensure that they are carried out under specified conditions.

4.4.4.1 General safety

The organization shall ensure that a formal process is in place to identify and manage risk associated with general safety.

NOTE The organization should adopt a preventive and proactive approach to managing such sources of risk, both to protect workers from the direct hazards associated with their work and to address the implications for biorisk in the event of an accident / incident resulting from such sources. Measures should be identified and implemented to detect, mitigate and respond to emergencies, taking into consideration potential implications for biological agents and toxins control in such measures.

Issues addressed should include but are not limited to:

- a) general laboratory safety;
- b) fire safety;
- c) electrical safety;
- d) radiation safety;
- e) chemical safety;
- f) use of gasses (including risk of asphyxiation);
- g) hot work and cold work;
- h) equipment under pressure;
- i) laboratory animal care and use;
- j) general housekeeping, including storage requirements and tidiness.

4.4.4.2 Biological agents and toxin inventory and information

The organization shall ensure that an accurate and up-to-date biological agents and toxin inventory is established and maintained.

It shall ensure that records relating to the inventory of biological agents and toxins are current, complete and stored securely with adequate backup provision.

It shall ensure that transfers of biological agents and toxins between laboratories at the facility or into and out of the facility are recorded and controlled in line with the level of the risk.

NOTE 1 The inventory process should be based on risk and include:

- a) identifying all biological agents and toxins held, including cultures, specimens and other sources (e.g. infected tissues / samples or animals);
- b) restricting access to biological agents and toxins to authorized individuals with a demonstrable legitimate need;
- c) implementing effective physical security measures according to risk (e.g. locks, alarms, access controls, etc.);
- d) developing and maintaining a reliable sample identification system;
- e) segregating and storing biological agents and toxins according to risk;
- f) determining what materials should be controlled (e.g. seed stocks, working stocks, infected animals) and what level of information should be captured in the inventory for those materials.

NOTE 2 Inventory information should include:

- a) the name(s) of and contact information for the individuals(s) responsible for the material and details of other personnel with access to the materials or immediate area based on the level of the risk;
- b) restricted access to the detailed inventory records to those individuals whose work requires access to that information;
- c) legible and robust identification numbers and other relevant identifiers;
- d) records of quantities / volumes of biological agents and toxins at an appropriate level and based on risk (i.e. for certain biological agents, location and responsible individual may be adequate while for others more detail may be necessary);
- e) records of materials consumed, destroyed or removed from the facility where appropriate.

NOTE 3 Controls should be set in place to ensure that all the necessary checks and documented assurances are received to ensure that requests for biological agents and toxins originate from legitimate facilities and individuals. Material may only be brought into the facility or sent elsewhere if authorized by those responsible for the facility. For materials deemed high risk, more stringent controls including shipment tracking and verification of receipt are important considerations.

4.4.4.3 Work programme, planning and capacity

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

The organization shall establish criteria for work that requires prior approval.

It shall ensure there is sufficient resource capacity and capability to manage workflow, whether planned or unplanned.

NOTE 1 The programme of work should include the nature of the activities authorized to be conducted in the facility and their definitions (e.g. diagnostics, research, small scale / large scale, etc). All activities associated with the work programme should be specified and supported by formal SOPs approved in accordance with the requirements for controlled documents as defined by this standard. Any changes to the programme of work should be subject to a formal change management process.

NOTE 2 The resources needed to implement and maintain the biorisk management system and continually improve its effectiveness, should be determined and provided.

4.4.4.4 Change management

The organization shall ensure that all changes associated with the design, operation and maintenance of the facility are subject to a defined and documented change management process.

NOTE The changes should be reviewed, verified and validated as appropriate, and approved before implementation. This should include evaluation of the effect of the changes on the risk assessment.

The following are examples of changes that should be subject to the change management process:

- a) modifications to buildings and equipment or their operation, which may or would have an effect on biorisk;
- b) introduction of altered staffing arrangements (such as temporary presence of on-site contractors or students, temporary reassignments of personnel);
- c) changes to the programme of work, including alterations to work flow or volume which may or would have an effect on biorisk;
- d) alterations to SOPs, including significant changes in materials or reagents;
- e) modifications to entry / exit protocols;
- f) modifications to personnel policies and visitor protocols;
- g) modifications to disinfection and other waste management methodologies;
- h) changes associated with PPE provision and usage.

4.4.4.5 Work practices, decontamination and personnel protection

4.4.4.5.1 Good microbiological technique

The organization shall ensure that all personnel handling biological agents and toxins are competent in good microbiological techniques and that appropriate resources (including time and equipment) are available to ensure such practices can be adhered to effectively.

NOTE As appropriate, procedures should address risks associated with but not limited to the following:

- a) animal handling;
- b) centrifugation;
- c) control of needles and sharps;
- d) correct use of vacuum pumps;
- e) culture, purification and storage techniques;
- f) minimization /containment of aerosols;
- g) pipetting;
- h) sonication and other mechanical forms of cell / tissue disruption;

- i) use of biological safety cabinets;
- j) use of disinfectants, including spill control, routine decontamination, hand washing and showering.

This list is neither exhaustive nor comprehensive and identifies only some activities that may be employed during typical laboratory work. These activities should be undertaken in association with appropriate procedures and working practices to ensure the control measures are effective under all foreseeable and credible operating scenarios. Appropriate control measures should be identified during risk assessments, and these will vary depending on the biological agents and toxins being used and the activities to be undertaken.

4.4.4.5.2 Inactivation of biological agents and toxins

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

The organization shall ensure that all contaminated or potentially contaminated waste items have been identified and documented (including those that may result from an emergency), and that effective procedures are put in place to devise effective decontamination and other appropriate treatments.

NOTE 1 Sources of contamination that should be considered include:

- a) personnel;
- b) clothing and PPE;
- c) glassware;
- d) equipment;
- e) cultures and associated materials;
- f) spill clean-up materials and equipment;
- g) possibly infectious microorganisms and toxins and contaminated materials;
- h) paper and plastic waste;
- i) needles, syringes and sharps;
- j) waste water, including that from sinks and showers;
- k) air;
- l) filters and air handling systems;
- m) discarded equipment used in the facility;
- n) animals exposed to laboratory biological agents or toxins;
- o) animal carcasses and bedding;
- p) facilities.

All potential waste streams and other sources of contamination should be identified and documented.

Contaminated personnel may include core personnel working within the facility, contractors and emergency response personnel. Cultures and associated materials may be a source of contaminated supernatants, aspirates and culture media. Infected biological materials may also include infectious human, animal or plant specimens. In some instances it may be necessary to hold contaminated dedicated equipment such as fire fighter apparel or ambulance tools on site if they cannot be effectively decontaminated.

Risk assessment should be an integral part of the process to identify and develop effective decontamination regimes.

NOTE 2 Whatever the biological agents and toxins handled, it is likely that a number of effective inactivation methods will be available. The organization should ensure that there are data available to demonstrate that the methodology selected is capable of inactivating the biological agents and toxins under the specific conditions encountered in the facility. Validation measures should consider issues including;

- a) the nature of the material being treated (e.g. volume, presence of protein / other potentially inhibitory substances);
- b) contact times, materials compatibility issues (e.g. interaction with stainless steel or rubber seals);
- c) potential health hazards associated with the disinfectant;
- d) the need to maintain the required level of active compound, including deterioration over time.

In planning and conducting decontamination activities the organization should consider:

- i) ensuring all disinfectants used contain sufficient active compound to address the working conditions under which they will be applied, and that such concentrations are maintained throughout the process, including conducting specific validation activities where necessary;
- ii) providing adequate facilities and procedures for the storage of waste (including short term storage);
- iii) ensuring methods are available for effective decontamination of mixed waste (e.g., infected animals that have received radioactive materials);
- iv) ensuring that where appropriate, methods are available for decontamination of sensitive equipment or that which is not suitable for autoclaving (e.g. computers);
- v) implementing monitoring measures to ensure the methods have been effective (e.g. cycle recording and use of indicators in autoclaves);
- vi) decontaminating protective clothing by appropriate means prior to leaving the facility;
- vii) ensuring adequate methods and resources are available to deal with routine work and any spillages or other incidents during handling and transport of materials inside and outside the facility;
- viii) implementing programmes to ensure the amount of contaminated waste is minimized.

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

NOTE The organization should have a validated procedure for the inactivation of biological agents and toxins waste products.

The following elements should be considered for a waste management policy:

- a) ensure programme is in place to minimize the waste production;
- b) ensure effective waste audit trails are in place and documented;
- c) provide adequate facilities and procedures for the storage of waste (including short term storage);
- d) ensure methods are available for effective segregation and decontamination of mixed waste (e.g., infected animals that have received radioactive materials);
- e) ensure appropriate packaging material is used to contain the waste and to maintain its integrity during storage and transportation.

4.4.4.5.4 Clothing and Personal Protective Equipment (PPE)

The organization shall ensure that PPE needs are identified and suitable equipment is specified, made available, used and maintained appropriately within the facility.

NOTE Measures in place should include:

- a) ensuring adequate information is used in selecting PPE (e.g. risk assessments, review and analysis of tasks, employee feedback, etc.);
- b) ensuring all personnel who have to use PPE (including scientific staff, visitors and contractors) are identified and supplied with correct fitting equipment and clothing;
- c) explicitly addressing selection and use of PPE in SOPs, training and competency assessments;
- d) defining and conducting an appropriate programme to ensure that routine checks and maintenance of PPE are defined and carried out;
- e) defining and addressing the need for and provision of replacement and spare PPE;
- f) identifying and controlling the hazards associated with PPE itself (e.g. impaired dexterity or visibility);
- g) providing adequate PPE for use during both normal and emergency working conditions;
- h) ensuring procedures are in place for the cleaning and if appropriate the validated decontamination of used PPE including the safe storage prior to decontamination.

Personal protective equipment should be used in conjunction with, but never as a substitute for, reasonable and appropriate administrative and engineering controls. PPE should be used in accordance with established standards and manufacturers specifications. PPE should be made available by the employer at no cost to the employee.

4.4.4.6 Worker health programme

The organization shall ensure that risk to worker health, and that of other personnel whose health could be directly impacted by exposure to biological agents and toxins, is managed effectively including prevention and protection measures.

The requirements of the health surveillance programme shall be determined by a defined health hazard identification and risk assessment process involving all relevant personnel.

NOTE Relevant personnel that may be consulted by the programme include:

- a) the biorisk management advisor;
- b) the occupational health professional;
- c) facility personnel and employee representatives;
- d) external experts, including emergency responders;
- e) biorisk management committee members;
- f) veterinary and animal care facility staff;
- g) human resources representatives;
- h) communicable disease specialist;
- i) scientific management.

The programme should address the needs of all individuals who may be associated with the facility, including providing assurance that contractors and visitors receive the required level of protection in line with the activities they will perform, as well as safeguarding workers' families.

Personnel considered to have significant risk of exposure should be identified and their healthcare needs assessed. This should include the need for vaccination, PPE provision and emergency measures that encompass isolation / testing in the event of exposure. The health including the immune status of the individual should be considered and periodic checks as appropriate to work conditions should be established.

Although the primary focus of the assessment is exposure to the biological agents and toxins being handled, other conditions that could impact personnel associated with the facility should also be addressed. These may include medical conditions that could affect the work (e.g. epilepsy, heart attack, impaired vision, physical mobility / dexterity), the ability to use appropriate PPE safely, or factors affecting general well-being (e.g. stress, depression, pregnancy, immune status, etc.).

Information covered by the worker health programme should be treated in confidence. All individuals should have access to healthcare consultation either with a corporate or institutional occupational health facility or an independent health care provider, and be informed as to the nature of any treatments / vaccinations they may receive and the inherent risks and benefits of these treatments/vaccinations.

4.4.4.6.1 Vaccination of personnel

Based on risk, the need for vaccination shall be identified and shall cover groups identified as being potentially exposed to biological agents or toxins.

The organization shall ensure that a vaccination policy be defined and implemented, and that access to laboratories or work is controlled for individuals until they comply with the policy.

NOTE Measures should be implemented to identify non-responders to vaccination when needed (depending on the response rate of the vaccine) and a policy should be in place to address these individuals. Individuals considered unfit for work in the facility on health grounds should be identified and prevented from accessing areas where there are risks of exposure. Areas requiring vaccinations to enter should be posted.

Visitors, contractors and other non-core personnel should provide evidence of vaccination or evidence of established immunity in accordance with the above requirement. Based on risk, reasonable measures should be taken to ensure that the vaccinations have been given and current certificates are valid. This may include examination of original certificates and crosschecking with medical practices responsible for administering the vaccine. The organization should ensure that the required or recommended vaccines are made available to the concerned personnel. Vaccination should be seen as a risk mitigation strategy and its use should in no way infer that other controls such as the use of Good Microbiological Technique or use of PPE can be relaxed.

4.4.4.7 Behavioural factors and control of workers

The organization shall establish and maintain a programme to address risk associated with human behaviour, including the management of how workers interact with the facility and its equipment.

NOTE The organization should ensure that factors associated with behaviours, and the need for individual support and communication are managed responsibly, both to protect workers from direct hazards and to ensure they can function optimally within the facility. Many laboratory incidents are caused by inappropriate behaviour or human frailties, and a preventive and proactive approach to managing risk associated with the individual should be pursued, including the specific inclusion of such issues in risk assessments. The use of competent experts in assessing this area should be considered.

Measures should be set in place to address:

- a) human reliability and behavioural safety, including adherence to procedures;
- b) communication, consultation and feedback;
- c) conflict management and resolution;
- d) empowerment, including authority to stop work if potentially unsafe or unsecure conditions are identified;
- e) avoidance of "blame culture", including willingness to report accidents, incidents or unsafe conditions / behaviours, and protection of workers who do so;
- f) ergonomics, including equipment and work practice design to take account of individual needs;
- g) respect for individual privacy and dignity.

4.4.4.7.1 Personnel reliability

The organization shall ensure that a personnel reliability policy is defined and implemented, and that access to facilities or work is controlled for individuals according to the policy.

NOTE 1 The nature and extent of the personnel reliability assessment measures required should be determined as part of the risk assessment process. In some instances, few checks may be required other than collection of employment references, whereas in others more in-depth screening may be deemed necessary.

NOTE 2 Where lawful and appropriate as determined by risk assessment, screening may include such checks as identity and immigration status, membership of organizations hostile to biological research, criminal records and financial probity.

4.4.4.7.2 Contractors, visitors and suppliers

The organization shall ensure that suppliers, contractors, visitors and sub-contractors adhere to the requirements of established management systems and do not compromise biorisk management of the facility.

4.4.4.7.3 Exclusion

The organization shall ensure that measures are set in place for the removal and exclusion of personnel (both temporary and, if appropriate, permanent) from the facility where deemed necessary through risk assessment.

NOTE The procedures should address:

- a) removal of access to the facility (e.g. removal of passes, changes of keys, access codes and other security devices, etc.);
- b) removal of access to information relating to the facility including documentation, computerized records and data;
- c) immediate physical removal of personnel if deemed necessary.

4.4.4.8 Infrastructure and operational management

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

4.4.4.8.1 Planning, design and verification

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

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

The design process shall identify and consult all relevant parties associated with the facility and its operation.

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.

NOTE A formal design process means a structured and documented approach whereby the needs of the facility are determined through risk assessment. Engineering and operational solutions shall be incorporated that are consistent with the risk posed by the properties of materials that will be stored and handled in the facility and the nature of the work to be carried out.

The design process should include the identification and review of relevant legislation and codes of practice (including building codes as well as those relating to laboratory biosafety / laboratory biosecurity) and risk assessments. The requirements identified from these sources should be incorporated into the design plans. The design should be fully documented, including a description of the tests and the standards of acceptance to assure performance. The process should be documented and transparent to provide an assurance that it has been comprehensive and thorough.

The design process should include the identification of and consultation with individuals involved in planning, construction and operation of the facility.

The following roles / individuals should be considered in terms of information requirements and need for consultation:

- a) scientific personnel and other end users;
- b) biorisk management advisor, biorisk management committee;
- c) biosecurity and/or security personnel;
- d) designers (architects and engineers);
- e) constructors;
- f) maintenance engineers;
- g) materials and equipment suppliers;
- h) commissioning agents;
- i) certifiers;
- j) regulators;
- k) first responders;
- l) other relevant parties identified in risk assessments.

If justified on the basis on the nature of the work, a peer review process involving independent, competent third parties should be conducted to ensure the design specification;

- 1) is in line with accepted good practice;
- 2) incorporates features capable of providing assurance for control of biological agents and toxins;
- 3) ensures relevant legislative requirements, and, standards, and risk assessment findings have been incorporated into the design.

4.4.4.8.2 Commissioning and decommissioning

The organization shall ensure that there is a formal process for initial commissioning of new facilities and the final decommissioning of existing ones.

NOTE Commissioning will ensure that the facility is constructed and performs as intended. The commissioning process should start at the design phase at the first stage of science programme definition to assure that the expectations for the building are achievable. The commissioning plan should develop in detail in parallel with the physical concept to assure that the expectations for the building are measurable. The commissioning plan should clearly identify, with examples, all steps from beginning to end including conditions of acceptance of each step, as a pre-requisite of proceeding to the next. The commissioning plan should identify all steps required before operation is commenced initially or resumed after temporary shut down.

The commissioning process should provide the benchmark for acceptable facility operation and the description of the programme to be put in place to maintain that level of performance.

The decommissioning process should identify the decontamination procedures and security-related measures that have to be in place for temporary or final shut down of the facility. The de-commissioning programme should not only describe the procedures to be undertaken, but also, the standards of acceptance when those procedures are performed. This may be documented through clearance certificates and permits to work, which identify when and under what conditions the decommissioned facility can be re-entered.

4.4.4.8.3 Maintenance, control, calibration, certification and validation

The organization shall establish and maintain documented procedures to ensure equipment and elements of the physical plant that may impact on biorisk be identified, purchased, maintained, calibrated, certified or validated in a manner consistent with the intent and requirements of the biorisk management programme.

NOTE 1 The maintenance programme should apply to all aspects of the physical structure (including finishes and seals where appropriate) and equipment therein. All materials used should be specified to ensure they can perform in line with predetermined criteria. An appropriate maintenance plan will be addressed as part of that specification process.

In planning and conducting maintenance activities the organization should consider:

- a) adequately maintaining the physical integrity of the facility and its fixtures and fittings;
- b) ensuring maintenance activities are performed by competent individuals, and that risks associated with the work have been subjected to risk assessment;

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- c) identifying and recording maintenance requirements at time of construction of facilities, or purchase / acquisition of equipment;
- d) creating and maintaining a maintenance register for all applicable equipment;
- e) identifying and conducting planned maintenance activities at an appropriate frequency;
- f) ensuring adequate provision for unplanned (breakdown) maintenance to ensure integrity of the facility is maintained at all times;
- g) determining and monitoring predictive maintenance requirements and associated indicators and monitors;
- h) ensuring essential spare parts are available in line with a frequency appropriate to the risk of failure and need for replacement;
- i) a pest control programme.

NOTE 2 In planning and conducting equipment controls, the organization should consider:

- a) identifying equipment in line with identified work needs, which can be demonstrated as fit for purpose;
- b) controlling purchase / acquisition of equipment to ensure all necessary risk assessments are completed and approval is authorized by competent personnel;
- c) controlling entry and exit of equipment to and from the facility, including decontamination requirements (e.g. air locks and decontamination).

NOTE 3 In planning and conducting calibration activities, the organization should consider:

- a) identifying and recording calibration requirements at time of purchase / acquisition;
- b) identifying the standards / tests that will be used to ensure the equipment is correctly calibrated;
- c) creating a documented and up-to-date calibration register for all applicable equipment;
- d) ensuring calibration is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment.

NOTE 4 In planning and conducting certification activities the organization should consider:

- a) identifying and recording certification requirements at time of purchase / acquisition of equipment, including relevant and current standards against which to certify;
- b) ensuring competent and independent certifiers are used for the certification process;
- c) ensuring certification is scheduled and conducted in line with manufacturer's requirements and / or other specified intervals as identified by risk assessment.

NOTE 5 In planning and conducting validation activities, the organization should consider:

- a) identifying and recording validation requirements at time of purchase/acquisition;
- b) identifying the standards/tests that will be used to ensure the equipment is correctly validated;
- c) creating a documented and up-to-date validation register for all applicable equipment;
- d) ensuring validation is scheduled and conducted in the line with manufacturer's requirements and / or other specified intervals as identified by risk assessment;
- e) ensuring competent and independent validation companies are used for the validation process.

For physical security systems, the analogous concept is performance testing; evaluating the entire physical security system (equipment, policies, procedures, and people) to ensure the system works as designed

4.4.4.8.4 Physical security

The organization shall ensure that the controls for the physical security of cultures, specimens, samples and potentially contaminated materials or waste determined as part of the risk assessment process are implemented and maintained.

NOTE 1 Measures should be set in place to minimize the potential for release or removal of biological agents from the facility due to a breach in security. This should involve proactive measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms.

In planning and conducting security risk assessments the organization should consider:

- a) theft or diversion of biological agents and toxins or related equipment, documents or data;
- b) sabotage including vandalism and tampering;
- c) break-in and intrusion;
- d) labour issues and disputes;
- e) weather-related emergencies (i.e., earthquake, tsunami, flood, tornado, and hurricane);
- f) workplace violence;
- g) utilities failure;
- h) picketing, occupation and barricade;
- i) screening and isolation of suspect packages;
- j) acts of terrorism;
- k) civil unrest or war.

NOTE 2 Care should be taken to coordinate biosecurity measures with those of biosafety to manage and minimize conflicting priorities.

4.4.4.8.5 Information security

The organization shall have a policy and procedure in place to identify sensitive information; a review and approval process shall be used to control access to such information.

NOTE The information generated by a laboratory can be as valuable and/or dangerous as the biological agents and toxins stored at the facility. Adequate measures to prevent unauthorized release of such information are critical.

Procedures addressing information security should consider:

- a) secure storage of all sensitive written records and data, including electronic records and electronic signatures;
- b) computer security including robust internet firewalls and encryption protocols;
- c) strict policies regarding PC's, laptop computers, storage media, cameras, etc. entering or leaving the facility;
- d) thorough destruction of paper files to be discarded and complete erasure of unwanted electronic files;
- e) security measures and procedures.

4.4.4.8.6 Control of supplies

The organization shall ensure that purchases (including services) conform to specified requirements. Controls shall be applied depending on potential impact on the biorisk involved.

The organization shall ensure suppliers are evaluated and selected based on their ability to provide products / services that meet the requirements of this standard. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

NOTE While not all suppliers will provide products / services that may impact on biorisk, there are many that may. Suppliers that should be considered include, but are not limited to, those that provide:

- a) cleaning services;
- b) laboratory equipment;
- c) waste management or disposal services;
- d) IT support services;
- e) equipment and facility maintenance services;
- f) security services.

4.4.4.9 Transport of biological agents and toxins

The organization shall ensure that procedures for the safe and secure transport of cultures, specimens, samples and contaminated and potentially contaminated materials are established and maintained in accordance with legal requirements for the transport of dangerous goods.

NOTE In planning and conducting transport activities the organization should consider:

- a) ensuring transport requirements are identified and implemented, including legal requirements and national and international guidelines;
- b) ensuring adequate packaging systems, materials, labels, PPE and documentation are available and used as part of the transportation process;
- c) selecting a reliable, trustworthy carrier that is qualified to handle the package safely and securely;
- d) whether a request for biological agents and toxins or material that may contain viable biological agents and toxins is being made by an approved facility for a legitimate reason, and equivalent controls are applied to importation of material to the facility;
- e) the need is identified for formal documented transfer forms signed by the responsible management representative authorizing movement of materials.
- f) document control that allows traceability of material movements;
- g) identifying and implementing adequate and proportionate emergency response and contingency plans associated with transportation, including adequate precautions for handling suspicious packages, quarantine areas and appropriate explosive stand-off..

4.4.4.10 Personal security

The organization shall have a policy in place to provide personal security support services to staff members that include, where appropriate, personal security awareness training.

NOTE Personal security is concerned with staff security during off-duty hours while away from the facility. During these times, staff members are vulnerable because of their function or position.

4.4.5 Emergency response and contingency plans

The organization shall establish and maintain plans and procedures to identify the potential for incidents and emergency situations involving biological agents, toxins and materials, to prevent their occurrence, to respond to emergency situations and to limit the likely illness or other damage that may be associated with them.

Emergency planning shall cover all aspects of biorisk and include general safety, security and medical issues.

4.4.5.1 Emergency scenarios

The organization shall ensure that all credible and foreseeable emergency scenarios that may impact the organization's biorisks have been identified.

NOTE In order that emergency planning can take place, it is necessary to consider all credible emergency scenarios. It is unlikely that all potential scenarios will be credible; however, all reasonable threats should be considered and recorded and, where appropriate, the rationale as to why issues were dismissed.

Scenarios considered should include:

- a) infected / potentially infected worker or other contact (e.g. family member, emergency responder or community member);
- b) accident or illness to worker and need for evacuation;
- c) fire;
- d) flood;
- e) breach of security;
- f) explosion;
- g) potential loss of biological agents or toxins through theft or any other reason;
- h) unexpected virulence (unknown biological agents or biological agents expected to be avirulent);
- i) physical facility and equipment failure, including control system failure;
- j) failure of disinfection regime;
- k) utility failure including electricity, gas, steam and water supplies;
- l) major spillage / aerosol release;
- m) environmental release;
- n) natural disaster (e.g. earthquake, extreme weather conditions, disease pandemics etc.);
- o) act of terrorism or deliberate vandalism;
- p) intense media attention.

4.4.5.2 Emergency plans

The organization shall ensure that biorisks are taken into account when preparing and implementing emergency plans.

The organization shall ensure a system is established to effectively manage medical and/or environmental emergencies, including, but not limited to, the identification of potentially infected workers and provision of immediate medical care to exposed, ill or injured workers.

The organization shall also ensure that control measures in place can be demonstrated as being reasonable and proportionate to the scale and nature of the emergency.

Emergency plans shall be effectively communicated to all employees and relevant third parties, and tested, with the intention that everyone is aware of their obligations.

NOTE 1 The organization should ensure that plans address as a minimum:

- a) the identification of those responsible for devising, implementing and testing the control measures specified;
- b) the need to respond during out-of-hours emergencies as well as those that occur during normal working hours;
- c) provision for periods of reduced staff availability (e.g. during weekends and holiday periods);
- d) the need for emergency access / exit, including the ability to override access controls as appropriate;
- e) the need for emergency exit routes to avoid evacuating people through areas of higher biosafety or biosecurity;
- f) the provision for safe removal, transport, transfer, treatment and accommodation of contaminated persons, objects.

In the event of an emergency situation there may be a requirement to involve parties external to the organization. Based upon the credible scenarios identified, the organization should identify such agencies to establish their role in responding to a given situation. The organization may choose to sign memoranda of understanding or agreements with key local responders. It may also be necessary to inform and educate such parties as to their role and any risk exposures they may face and ensure that their actions will not unnecessarily increase the risk associated with the emergency (e.g. uncontrolled use of fire water). Contact information should be documented and made available to personnel responsible for coordinating the emergency response activity.

External agencies consulted may include:

- a) police and security services;
- b) fire services;
- c) ambulance and local hospitals / healthcare providers;
- d) transport providers / couriers;
- e) local and national government officials;
- f) environmental authorities.

NOTE 2 Procedures should ensure that there is adequate emergency planning provision to address worker health needs in the event of an accident or emergency situation. This provision should extend to first responders and their families, members of the broader community and to environmental conditions that may have been affected by the incident. This should include the identification of emergency scenarios, including infected worker / family member, together with the necessary support measures (e.g. liaison with emergency services / local authorities), provision of equipment and other resources required to manage the emergency (e.g. prophylaxis, post-exposure treatment, disinfectants, isolation requirements, vaccines, etc.). The necessary plans and other materials for managing medical emergencies should be prepared, tested and maintained.

Procedures should ensure that adequate first aid provision is available in relation to credible accident scenarios as identified during risk assessment. The procedures should address the need for adequate provision of trained personnel and their availability, as well as equipment and other materials that may be required in the provision of treatment.

Procedures should ensure that additional competent medical support is identified and made available (e.g. hospitals, isolation units, etc.).

4.4.5.3 Emergency exercises and simulations

The organization shall ensure that structured and realistic emergency exercises and simulations, including security drills are conducted at regular intervals, based on risk, to test the plans, prepare personnel, and learn from any good practices or deficiencies identified.

NOTE Exercises and simulations should be conducted in order to provide an assurance that plans are effective and to learn from any lessons that arise.

Exercises should be planned and every effort made to ensure they are realistic representations of the events they are designed to simulate. However, such activities should also be conducted under controlled conditions and not be allowed to become a source of risk in their own right. The results of the exercise should be documented and reviewed for lessons learned, and feedback provided to appropriate personnel on performance. Any actions arising should be recorded, allocated to named individuals and measures set in place to ensure they are closed out effectively.

4.4.5.4 Contingency plans

The organization shall ensure that in the event of an emergency, adequate contingency measures shall be in place to ensure the safety and security of continued operations.

NOTE In the event of an emergency or unforeseen event there may be disruption to normal operating conditions. This could range from the need to safely shut down work in the event of a power failure, to obtaining alternative storage conditions in the event of a breakdown. Such eventualities should be considered proactively and contingency plans set in place. Activities should address the need for adequate redundancy, replacement and other measures, which could involve the availability of alternative facilities or personnel, the introduction of backup systems (e.g. power supplies), alternative means of decontaminating materials in the event of failure of critical systems or equipment (e.g. kill tanks or autoclaves), or the complete safe shut down of operations in extreme situations.

4.5 Checking and corrective action

4.5.1 Performance measurement and analysis of data

The organization shall ensure that appropriate data are determined, collected and analysed to assess the suitability and effectiveness of the biorisk management system and to evaluate where continual improvement of the system can be made.

NOTE The analysis should include data generated as a result of monitoring, measurement, audits, and analysis and from other sources. Such analyses should be conducted at least annually and more often if justified by the risks and the scope of operations. The results of the analysis should be applied in the management review.

4.5.2 Records, document and data control

The organization shall ensure that records, documents and data are established, controlled and maintained to provide evidence of conformity to the requirements of this standard and that they remain legible, readily identifiable and retrievable.

NOTE Where appropriate, documents should be identified and controlled based upon the nature of the work and need for record keeping.

Controlled documents may include:

- a) risk assessments, standard operating procedures (SOPs) and safety manuals;
- b) job hazard analyses and charts of authority;
- c) design records and commissioning / test plans, maintenance plans and records and all associated data;
- d) audit and inspection checklists;
- e) laboratory biosecurity manuals and risk assessments, authorizations and other security documents;
- f) training records;
- g) containment equipment certifications.

The list of controlled documents is neither exhaustive nor comprehensive but includes some of the main areas that should be formally recorded and subject to document control. Data should be construed as documents in this context. A procedure should be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposal of records. A procedure should be established to define the controls needed to approve documents prior to issue or public release to ensure sensitive information such as specific freezer locations of pathogen repositories is not inadvertently released. Procedures should also be established to define the controls for review, update and re-approval of documents, and for the change control and revision process.

4.5.3 Inventory monitoring and control

The organization shall ensure that a review of the inventory is conducted at predetermined intervals based on risk and at a level and frequency whereby materials can be accounted for in an appropriate manner.

The organization shall ensure that the measures are put in place to minimize the quantities of biological agents and toxins that make up the inventory.

NOTE The nature of the inventory and associated controls should be based upon the nature of the material held and the risk of harm should it be misplaced or removed with the intention of misuse. For many biological agents and toxins, the checks may be of a lower frequency and stringency than for others with greater potential for causing harm. Such measures may include numbered sequences of tubes, periodic inspections and crosschecks with records of materials held.

The organization should demonstrate proactive measures towards the reduction of risk through elimination, substitution or minimization of volumes / quantities of biological agents and toxins used, and the number of manipulations conducted.

Procedures should be in place to investigate potentially missing biological agents appropriate for the level of risk.

4.5.4 Accident and incident investigation, non-conformity, corrective and preventive actions

4.5.4.1 Accident / incident investigation

The organization shall establish and maintain documented procedures to define, record, analyse and learn from accidents and incidents involving biological agents and toxins.

NOTE Procedures should be set in place to ensure that what constitutes an accident or incident is clearly defined and communicated to all relevant personnel, and may include events of exposure and accidental release. Accidents and incidents provide an indication that the systems designed to manage biorisk may have failed, and it is essential that lessons are learned and improvements are made where possible.

As a minimum, the accident / incident investigation process should include:

- a) identifying those responsible for maintaining the accident / incident reporting system;
- b) defining what constitutes an accident / incident, and what triggers recording and reporting;
- c) specifying required documentation to support the system;
- d) identifying the reports that will be generated, their frequency and distribution;
- e) ensuring analysis of trends;
- f) identifying root causes using individuals trained in investigation techniques;
- g) providing feedback at regular intervals and action tracking mechanisms to ensure that lessons learned result in action to avoid the repeat of such events and / or minimize their potential impact;
- h) identifying where it may be appropriate or necessary, for security professionals may be required to coordinate with law enforcement.

4.5.4.2 Control of nonconformities

The organization shall ensure that situations that do not conform to the requirements of this standard are identified and controlled to prevent undesirable consequences. Records of the nature of the non-conformity and any subsequent action taken shall be maintained.

NOTE The controls and related responsibilities and authorities for dealing with non-conforming situations should be defined in a procedure.

4.5.4.3 Corrective action

The organization shall ensure action is taken to eliminate the causes of non-conformities with the requirements of this standard in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

NOTE A procedure should be established to define requirements for:

- a) reviewing the non-conformities;
- b) determining the cause of non-conformities;
- c) evaluating the need for action to ensure that non-conformities do not recur;
- d) determining and implementing action needed;
- e) recording results of action taken;
- f) reviewing corrective actions taken.

4.5.4.4 Preventive action

The organization shall ensure action is taken to identify and eliminate the causes of potential non-conformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential nonconformities.

NOTE A procedure should be established to define requirements for:

- a) determining the potential non-conformities and their causes;
- b) evaluating the need for action to prevent occurrence of non-conformities;
- c) determining and implementing action needed;
- d) recording of the results of action taken;
- e) reviewing preventive action taken.

4.5.5 Inspection and audit

The organization shall ensure that a programme of inspection and audit is conducted which is appropriate to the risk associated with the facility.

Inspections and audits shall be conducted at planned intervals to determine if the biorisk management system conforms to the documented plans and to the requirements of this standard, and that it is effectively implemented and maintained.

Management responsible for the area being inspected / audited shall ensure that any actions are taken without undue delay to eliminate detected non-conformities and their causes. Follow-up activities arising shall include the verification of the actions taken and the reporting of verification results.

NOTE Inspections may be frequent checks on specific areas conducted to ensure sufficient standards are being maintained (e.g. disinfectant levels / concentrations and air exchange rates / maintenance of directional air flow), or more extensive but less frequent inspections of laboratories, facilities or other operations. Random, unannounced inspections and inventory audits can help ensure compliance at all times, not just in time for scheduled inspections. Audits should be performed by competent individuals who are independent of the activity being audited. Records should be maintained of findings of inspections / audits, including action taken to close out any non-conformities or improvement opportunities.

4.6 Review

4.6.1 Biorisk management review

Top management shall review the organization's biorisk management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the system, procedures, policies and objectives. Records from the management review shall be maintained.

NOTE The management review should be conducted at a defined frequency determined by the needs of the organization, but at least annually.

The review input should include information on:

- a) results of audits;
- b) compliance to SOPs and work instructions;
- c) status of risk assessment activities;
- d) status of preventive and corrective actions;
- e) follow-up actions from previous management reviews;
- f) changes that could affect the system;
- g) recommendations for improvement;
- h) results of accident / incident investigations.

The review output should include decisions and actions related to:

- i) improvement of the effectiveness of the biorisk management system;
- ii) improvement related to the requirements and risk assessments;
- iii) resource needs.

Bibliography

- [1] EN ISO 9001:2000, Quality management systems - Requirements (ISO 9001:2000)
- [2] EN ISO 14001:2004, Environmental management systems - Requirements with guidance for use (ISO 14001:2004)
- [3] OHSAS 18001:2007, Occupational health and safety management systems - Requirements
- [4] EN ISO 9000:2005, Quality management systems - Fundamentals and vocabulary (ISO 9000:2005)
- [5] EN ISO 19011, Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)
- [6] ISO/IEC Guide 51:1999, Safety aspects - Guidelines for their inclusion in standards
- [7] EU Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work
- [8] ISO/IEC Guide 73:2002, Risk management - Vocabulary - Guidelines for use in standards
- [9] ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories
- [10] EN 12128:1998, Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements
- [11] ISO 15190:2003, Medical laboratories - Requirements for safety
- [12] EU Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms