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Competence requirements for biorisk management advisors

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Competence requirements for biorisk management advisors

Exigences de compétences pour les conseillers en management des biorisques

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Foreword

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

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Introduction

Principal factors in managing biorisks include, but are not limited to:

— establishing and maintaining comprehensive biorisk management;

— ensuring that there is qualified and competent advice and support for biorisk management.

Biorisk management advisors are competent individuals who provide advice, guidance, and assurance to the senior management of an organization on issues related to biorisk management.

Examples of biorisk management advisors can include biosafety professionals, biological safety officers, biosafety practitioners, biosafety coordinators, biosafety responsible officials, biosafety advisors, biosecurity officers, policy makers, employers (managers), contractors, consultants, trainers who provide a basis for curricular and learning objectives, recruitment requirements and assurance, and other individuals involved in biorisk management. Competence in biorisk management, within regular biosafety and biosecurity programmes, consisting of respective knowledge, skills and experience, is needed for an advisor to identify, assess, control, and monitor the risks associated with biological materials. Biorisk management competency is specified in this document, relating but not limited to ISO 35001.

This document is applicable to any laboratory or other related organization that handles, stores, transports, and disposes of hazardous biological materials, regardless of the type or size of the facility and biological materials used, where management has identified either the need for biorisk management advice or support or both. It also provides a framework for biorisk management advisors to demonstrate competence in biosafety and biosecurity and to identify areas for biorisk management competence development.

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Competence requirements for biorisk management advisors

1 Scope

This document defines the requirements for competence of individuals who provide advice, guidance, and assurance on processes to identify, assess, control, and monitor the risks associated with hazardous biological materials in a laboratory or other related organization that handles, stores, transports, or disposes of biological materials that can be potentially hazardous for people, animals, plants and the environment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 35001:2019, *Biorisk management for laboratories and other related organisations*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 35001 and the following apply.

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

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

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

3.1
attribute
inherent characteristic of a person

3.2
biorisk culture
set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting environment by individuals throughout the organization who work together to support or enhance best practice for laboratory biosafety and biosecurity

Note 1 to entry: This culture is crucial for the success of biorisk management and is built from mutual trust and the active engagement of all personnel across the organization, with a clear commitment from the organization's management.

3.3
biorisk management advisor
competent individual(s) providing unbiased advice, guidance, and assurance on biorisk management issues, reporting directly to the responsible senior management

3.4
competence
ability to apply knowledge, skills, and attributes to achieve intended results

Note 1 to entry: Competence is a specific combination of knowledge, skill, attributes and experience.

Note 2 to entry: The necessary knowledge and skills can vary from organization to organization and over time.

Note 3 to entry: An effective combination of competencies comprises overall competence.

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3.5
competent biorisk management advice
guidance or recommendations based on knowledge, skills and experience that accurately identify risks related to biological material, the potential consequences of these risks, the likelihood of their occurrence and mitigation strategies to reduce the risks to acceptable levels in a context meeting relevant regulatory requirements, standards, and their respective specifications

3.6
containment
set of measures, including practices, safety equipment and facility safeguards, that protect laboratory workers, the community, and the environment from exposure to biological material when stored or handled

3.7
containment level
set of standard microbiological practices, special practices, safety equipment, and laboratory facilities, including a composite of facility design and construction, equipment, practices, and operational procedures organized and characterized by the degree of protection provided to personnel, the environment, and the community

Note 1 to entry: Special practices address any unique risks associated with the handling of agents requiring increasing levels of containment. Appropriate safety equipment and laboratory facilities enhance worker and environmental protection.

Note 2 to entry: While containment levels can be a logical starting point for the handling and containment of biological agents in many countries, a correspondence between pathogenic microorganisms and laboratory biosafety levels is established for ease of administration. This thinking should not lead to the misconception that the risk group of a biological agent directly corresponds to the containment level of a laboratory. In fact, the actual risk of a given scenario is influenced not only by the agent being handled, but also by the procedure being performed and the competence of the laboratory personnel engaging in the laboratory activity.

Note 3 to entry: In most international systems, containment measures appropriate to protect humans, animals, plants, and the environment from exposure to biological materials are based on a category approach to cover the spectrum of risk to be managed.

3.8
dual-use potential
life sciences research that, based on current understanding, has the potential to provide knowledge, information, products, or technologies that can be directly misapplied to create a significant threat with potential consequences to public health and safety, agricultural species and other plants, animals, and the environment[SOURCE: WHO Laboratory Safety Manual 4th Edition 2020][2]

3.9
knowledge
outcome of the assimilation of information through learning

Note 1 to entry: Knowledge is the body of facts, principles, theories, and practices that is related to a field of work or study.

[SOURCE: CEN Guide 14][3]

3.10
knowledgeable
intelligent and well informed

3.11
management system
set of interrelated or interacting elements of an organization to establish policies and objectives, as well as processes to achieve those objectives

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

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

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Note 3 to entry: The management system of an organization establishes, documents, implements, and maintains that it is capable of supporting and demonstrating the quality and consistent achievement of the requirements of its biorisk management programme.

Note 4 to entry: A biorisk management system addresses the control of biorisk(s).

3.12
management system standard
MSS
standard for a management system

3.13
participate
take part in an action or endeavour

3.14
programme
set of related measures or activities with a particular long-term aim

Note 1 to entry: The terms "management system" and "programme" refer to biorisk management in this document.

Note 2 to entry: The term "biorisk management system" applies only to the context for which it is used.

3.15
risk group
RG
classification of biological agents based upon each agent's characteristics and epidemiological profile

Note 1 to entry: The higher the risk, the higher the likelihood that the agent will cause and spread infection in humans or animals in the country, and/or the more severe the consequences of that infection will be to individual and public health, if it were to occur.

Note 2 to entry: Risk Group 1 (no or low individual and community risk): A microorganism that is unlikely to cause human or animal disease.

Note 3 to entry: Risk Group 2 (moderate individual risk, low community risk): A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory personnel, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Note 4 to entry: Risk Group 3 (high individual risk, low community risk): A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

Note 5 to entry: Risk Group 4 (high individual and community risk): A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

[SOURCE: WHO Laboratory Safety Manual 4th Edition 2020][2]

3.16
senior management
individual or group(s) who directs and controls an organization including strategic level management positions

EXAMPLE Chief Executive Officer (CEO), Chief Technology Officer (CTO), Chief Operating Officer (COO), Chief Financial Officer (CFO).

Note 1 to entry: Senior management are sometimes referred to, within organizations, as executive management, top management, upper management and higher management.

3.17
skills
ability to apply knowledge and use know-how to complete tasks and solve problems[SOURCE: CEN Guide 14][3]

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4 Context for biorisk management advice

Requirements for competent biorisk management advice shall be defined based on the context of the organization and the nature of its activities, including but not limited to, governance, planning, management, reporting, policies, values, and culture.

An organization's objective(s) and scope of activities, with respect to its requirements for biorisk management is its context for biorisk management advice. This context shall be clearly defined and effectively communicated.

In its selection of biorisk management advice, an organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve effective biorisk management.

Biorisk management advice can be provided to that particular organization by individuals who are knowledgeable, skilled, and experienced in biorisk management.

NOTE 1 The required advice can range from basic biorisk management advice to comprehensive and integrated biorisk management advice developed for a single field of use of biological material, e.g. safety, industrial hygiene, engineering or for single or multiple use of biological materials supplemented by appropriate additional levels of biorisk management advice.

NOTE 2 Guidance for how to define the competencies required for the context of the organization is provided in Annex B.

NOTE 3 Two internationally published documents provide international laboratory biosafety (the WHO Laboratory Safety Manual) [2] and biosecurity (ISO 35001) [1] guidance and define a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This document elaborates competencies for the biorisk management advisor in the context of biorisk management as presented in these documents. Annex A is provided to show the relationships between the chapters and sections of each of these documents.

5 Functions of biorisk management advisor(s)

Functions of the biorisk management advisor(s) should include:

— verifying, in conjunction with other workers, that all biorisk has been appropriately addressed;

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

— ensuring that relevant and up-to-date information and advice on biorisk management, i.e. biosafety and biosecurity issues, are made available to scientific, technical personnel and other workers as necessary;

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

— participating in the organization biorisk management committee or equivalent;

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

— advising and assisting organization management so that the required authorizations for work with biological material are in place;

— assisting or participating in laboratory biosafety inspection, internal audits, management review and other activities, including nonconformance management;

— providing support in the design, implementation, and monitoring of efficient biorisk management programmes and management systems, that include change control;

— providing support in the design, (re)construction, and (de)commissioning of biocontainment facilities and infrastructure so that biorisk requirements are met;

— actively contributing to the organizational biorisk management programme and management system.

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NOTE Guidance on how to define which competencies are required for different organizational work situations is provided in Annex C.

6 Biorisk management advisor knowledge, skills, and experience

The biorisk management advisor shall have appropriate knowledge and skills to effectively provide biorisk management advice relevant to the organization's activities with hazardous biological material.

The biorisk management advisor should have relevant experience handling or managing activities with biological material. The knowledge, skills and experience required shall be sufficient to demonstrate competence that is commensurate with the risk. Additional experience is required as risk increases.

Combinations of one or more competencies can be necessary to meet an organization's needs for biorisk management advice.

NOTE Guidance on how to define which competencies are required for different work environments is provided in Annex C.

7 Competence

7.1 General prerequisites

Biorisk management advice requires an understanding of the potential risks and threats associated with handling, storing, securing, transporting, and disposing of biological materials and understanding the strategies and practices for risk and threat mitigation. Competence for a biorisk management advisor shall include a fundamental understanding of the basic characteristics of biological materials, and their potential to cause harm to humans, animals, plants, and the environment and the ability to provide effective biorisk management advice for the organization.

Advice on biorisk management for an organization can require one or several biorisk management advisors with fundamental and specific competencies comprising only a few or all the competencies of 7.2. The biorisk management advisor's competence shall be actively maintained and documented.

NOTE 1 Different skills and knowledge are required when providing advice, guidance, and assurance on biorisk management issues in different environments where activities with biological material occur. The extent of knowledge and skills required increases as the risk of the activity increases.

NOTE 2 Basic knowledge in related areas such as in occupational health and safety, chemical safety, radiation safety, and security can also be required by an organization.

NOTE 3 Details on this clause are described in Annexes C to E.

7.2 Range and subject matter of competencies

7.2.1 Scientific, technical and management background

7.2.1.1 Scientific and technical understanding

The biorisk management advisor shall have sufficient scientific and technical understanding of biological material and the potential hazards and risks related to the materials handled by an organization to be able to consult with all organization management and staff.

The biorisk management advisor shall be aware of the need for a proactive ongoing hazard identification and assessment process for the organization with respect to emerging scientific and technical developments. The biorisk management advisor shall be able to oversee and coordinate relevant processes that are performed, and implemented according to the biorisk management programme, and that provide required control measures for health and safety and prevention of environmental release.

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The biorisk management advisor should have knowledge and understanding of past and current incidents both within and outside of an organization involving hazardous biological materials that led to the development of specific biosafety and biosecurity practices and that can inform biorisk management practices within an organization.

NOTE 1 This competence is also linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.1.2 Biorisk management programme

The biorisk management advisor shall be competent in developing, establishing, and supporting the implementation of biorisk management programmes and understanding how the elements, e.g. physical, personnel, and informational biosafety and biosecurity measures of the programme, are interrelated to achieve the objectives of the programme and its implementation.

When biorisk in an organization is managed as a management system, i.e. ISO 35001, the biorisk management advisor shall understand and apply the core principles and practices associated with the management system approach, i.e. PDCA, objectives and policies, structure and responsibilities, risk management and its documentation.

The biosafety management advisor shall be competent in setting priorities for actions to implement and communicate the biosafety and biosecurity policy.

NOTE 1 This competence is linked to ISO 35001:2019, 4.4 (Biorisk management system) and 5.3.4 (Biorisk management advisor).

NOTE 2 When using a management system, e.g. ISO 35001, for developing a biorisk management programme, an understanding of the structure of the biorisk management system including but not limited to providing documentation, risk management, defining of objectives and key results, establishing policy and assigning responsibilities is relevant.

NOTE 3 Details to this clause are provided in Annexes C and D.

7.2.2 Planning of biorisk management

7.2.2.1 Competence to address risks and their management

The biorisk management advisor shall demonstrate an ability to conduct a suitable risk assessment for a given situation and determine mitigation strategies. The biorisk management advisor can provide guidance on risk assessment and management to project leaders, principal investigators, management, and other relevant personnel.

NOTE 1 This competence is linked to ISO 35001:2019, 6.1.2 (Risk assessment) and 6.1.3 (Risk mitigation).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.2.2 Hazard and threat identification and analysis

The biorisk management advisor shall provide guidance to project leaders, principal investigators, management and other relevant personnel on biological hazard identification and threats. This guidance should include an analysis of how these hazards and threats can produce a negative outcome.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor).

NOTE 2 Details to this clause are provided in Annexes C and D.

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7.2.2.3 Risk assessment

The biorisk management advisor shall have the competence to assess, implement, maintain and document biorisks using suitable methods.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.2.4 Risk mitigation

The biorisk management advisor shall have the knowledge and competence to evaluate and implement the organization's control plan to ensure that the measures are adequate to mitigate biorisk to acceptable levels applying the hierarchy of controls and understanding its principles.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor) and 6.1.3 (Risk mitigation).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3 Support of personnel

7.2.3.1 Occupational health and occupational safety principles and regulatory framework

The biorisk management advisor shall understand the requirements of occupational health and occupational safety (ISO 45001)[4] including safe handling of biological material, assessment of specific biorisks, and definition and implementation of biorisk mitigation measures, both in the laboratory, in the workplace and in the outside environment (ISO 15190)[5].

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor) and 7.1.1 (Worker health programme).

The biorisk management advisor should have the authority to advise personnel to inform their medical provider of the nature of their work with hazardous biological materials.

The biorisk management advisor should be able to identify issues where medical input, e.g. occupational health and safety is required.

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3.2 Communication skills and information management

The biorisk management advisor shall have the competence to transfer information clearly, understandably, and effectively and modify their communication style to suit the targeted audience, such as management, laboratory workers, ancillary personnel, and external parties.

The biorisk management advisor should be knowledgeable about various strategies for communication and outreach training including laboratory-specific standard operating procedures (SOPs), interactive team discussions, job aids and posters, generic awareness-raising through short publications, e.g. pamphlets, handouts, briefings and electronic notifications, e.g. social media or email.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor) and 7.4 (Communication).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3.3 Training

The biorisk management advisor shall have sufficient knowledge of training principles, e.g. adult learning and training to recognize training needs and develop, deliver, implement, and validate an internal biosafety and biosecurity training programme tailored to different audiences.

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The biorisk management advisor shall be cognizant of the organization's responsibility to provide and arrange the appropriate training of all personnel based on their functional roles and responsibilities in support of the biorisk management programme or biorisk management system.

The biorisk management advisor shall be competent to determine and define requirements and procedures for biorisk management training of workers and that these requirements are identified, established, documented, and maintained, including the methods and tools for continual improvement.

The biorisk management advisor shall have the competence to assess the quality of biorisk management training activities and evaluate their suitability for the organization.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor), 7.3.1 (Training) and 7.3.3 (Awareness).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3.4 Behavioural factors and worker management

The biorisk management advisor shall understand the importance of establishing and maintaining a biorisk culture effective for developing and implementing a successful biorisk management programme and a biorisk management system.

The biorisk management advisor shall understand shared values, patterns of behaviour and perceptions of the importance of safety and security that make laboratory personnel more likely to conduct their work safely and maintain a safety culture in the laboratory.

The biorisk management advisor should have the skills and attributes to influence behaviours and risk perception and be persuasive in promoting good biosafety and biosecurity practices while considering cultural and socio-economic principles.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor and 7.2.1 (behavioural factor and worker management).

NOTE 2 The following personal attributes are relevant for a biorisk management advisor, i.e.:

— open minded – willing to consider alternative ideas or points of view;

— diplomatic – tactful in dealing with people;

— tenacious – persistent, focused on achieving objectives;

— decisive – able to reach timely conclusions based on logical reasoning, objective evidence, and analysis;

— self-reliant – able to act and function independently while interacting effectively with others;

— ethical – fair, truthful, sincere, honest, and discreet;

— morally courageous – willing and able to act in a fair and impartial manner, despite pressure generated by the need to take what may often be unpopular positions that can lead to confrontation;

— organized – able to effectively prioritize, in relation to the use of time and other resources, to ensure the scope of work is completed effectively and areas of risk are addressed appropriately;

— communicative – able to communicate effectively to the intended audience.

NOTE 3 Details to this clause are provided in Annexes C and D.

7.2.3.5 Personnel reliability measures

The biorisk management advisor shall understand personnel reliability with respect to insider and outsider threats, personnel screening, and the evaluation of personnel performance issues to provide assurance that workers are dependable, trustworthy, and competent. This understanding can include knowledge of

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counter threat surveillance and effectively implementing security training and personnel evaluation such as background checks and security clearances.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor) and 7.2.2 (Personnel reliability measures).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3.6 Personal security

The biorisk management advisor should understand personal security which is concerned with security of workers during on-duty and off-duty hours while away from the facility because workers can be vulnerable because of their function or position.

The biorisk management advisor should understand the importance of contributing to the assessment and prioritization of potential threats to workers and mitigating their potential vulnerabilities. As appropriate the biorisk management advisor should support respective services to establish and maintain personal security protocols and standard operating procedures for workers.

NOTE 1 This competence is linked to ISO 35001:2019, 7.7 (Personal security).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.3.7 Ethical concerns related to activities with biological material

The biorisk management advisor shall have knowledge concerning good practices, scientific integrity, and ethical considerations for responsible activities with biological materials.

The biorisk management advisor in conjunction with leadership and workers should have the competence to assist in the development and maintenance of an ethics framework that supports ethical use of biological materials.

The biorisk management advisor shall have knowledge of ethics and code of conduct guidance documents including relevant standards and local, national and international regulations or agreements and can make proposals for appropriately integrating them into the organizational biorisk management system.

NOTE 1 This competence is linked to ISO 35001:2019, 5.3.4 (Biorisk management advisor), 7.2.2 (Personnel reliability measures), 7.3 (Awareness) as well as 7.7 (Personal security).

NOTE 2 The organizational biorisk management programme can include appropriate committees and evaluations of which the biorisk management advisor can be a participant.

NOTE 3 International treaties, conventions and protocols can influence specific national legislation.

NOTE 4 Details to this clause are provided in Annexes C and D.

7.2.3.8 Information management and security

The biorisk management advisor should understand the importance of establishing and maintaining an information and information technology security programme to identify, protect, and control access to sensitive information and information technology affecting biorisk management.

NOTE 1 This competence is linked to ISO 35001:2019, 7.5.4 (Information security).

NOTE 2 Details to this clause are provided in Annexes C and D.

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7.2.4 Controls and containment

7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance

The biorisk management advisor shall have knowledge to identify facility design and construction requirements and issues relevant to biorisk management including physical security aspects determined by the risk assessment process.

The biorisk management advisor shall understand the basic systems and design features of a typical facility, understand the construction, commissioning, decommissioning and validation processes, and should have knowledge of basic (re)design features of the most important types of facilities.

The biorisk management advisor shall have knowledge to identify and describe the biosafety and biosecurity requirements and issues relevant to preventive and corrective maintenance and operations.

The biorisk management advisor shall have knowledge of the formal commissioning and decommissioning processes of the relevant facilities from conception, design, during build phases and validation and testing of systems to decommissioning and the implications on the effectiveness of biorisk management.

The biorisk management advisor shall participate in planning and implementation of any system modifications and any system commissioning that is within the biorisk management programme including de-commissioning.

NOTE 1 This competence is linked to ISO 35001:2019, 8.1 (Operational planning and control) and 8.2 (Commissioning and decommissioning).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.4.2 Containment principles

The biorisk management advisor shall understand the risks, details and limitations of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological material. Knowledge of regulations, whether local, national, or international should also be considered as part of the biorisk management advisor's portfolio because these regulations can affect specific practices associated with the containment of biological material.

NOTE 1 This competence is linked to ISO 35001:2019, 8.3 (Maintenance, control, calibration, certification, and validation).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.4.3 Selection, verification, certification, and maintenance of equipment

The biorisk management advisor shall understand the biosafety and biosecurity implications of equipment in the facility and advise on choice, correct use and limitations, installation, validation, certification, and maintenance.

NOTE 1 This competence is linked to ISO 35001:2019, 8.3 (Maintenance, control, calibration, certification, and validation).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.4.4 Environmental safety

The biorisk management advisor shall:

— be knowledgeable about specific biological materials, the types of activities that will be performed with them, the applied procedures, and the environments in which the activities will take place;

— understand the risks for unintentional environmental release because of work involving biological materials;

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— be knowledgeable about the implementation of good microbiological practices and procedures;

— be knowledgeable of suitable monitoring strategies to evaluate and prevent environmental release;

— be knowledgeable of suitable risk and mitigation practices and strategies;

— be able to prepare appropriate responses for emergencies and incidents involving an environmental breach involving biological hazards;

— understand specific laboratory environmental exposure routes to mitigate the associated consequences.

NOTE 1 This competence is linked to ISO 35001:2019, 5.2 (Policy), 6.1.2 (Risk assessment) and 6.1.3 (Risk mitigation).

NOTE 2 Environment in this context is anywhere outside of the immediate area of control.

NOTE 3 Details to this clause are provided in Annexes C and D.

7.2.4.5 Asset security

The biorisk management advisor shall understand the importance and aspects of security measures used to protect assets that include physical security, information technology management security (7.2.3.8), inventory monitoring and control, transport security, personal security (7.2.3.6) and personnel reliability measures.

The biorisk management advisor shall understand the importance of implementing and maintaining mitigation measures determined as part of the risk assessment process and communicate it to the senior management.

NOTE 1 This competence is linked to ISO 35001:2019, 8.4 (Physical security).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.4.6 Inventory monitoring and control

The biorisk management advisor shall be knowledgeable of the risks associated with inventory control, e.g. loss, theft; be able communicate the importance of maintaining an accurate inventory of biological material in use or stored and can recommend the associated controls commensurate with the risk.

NOTE 1 This competence is linked to ISO 35001:2019, 8.5 (Biological materials inventory).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.5 Operation and safe practices

7.2.5.1 Clothing and personal protective equipment (PPE)

The biorisk management advisor shall be competent to advise, assess and evaluate the appropriate types of PPE required for given situations and discuss potential problems and solutions when PPE is introduced and used.

NOTE 1 This competence is linked to ISO 35001:2019, 8.7 (Clothing and personal protective equipment).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.5.2 Good microbiological techniques (GMT)

The biorisk management advisor shall be able to guide staff to apply GMT and enable staff to create and maintain a safe working environment including their workplace and workflows.

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The biorisk management advisor shall be competent in GMT and methods to eliminate or minimise exposure to biological material including manipulation and aseptic technique, identification of biorisks, hygiene, organization of work, and practices that prevent contamination and misidentification.

NOTE 1 This competence is also linked to ISO 35001:2019, 8.6 (Good microbiological techniques) .

NOTE 2 A description of GMT is described in the WHO Laboratory Biosafety Manual.[2] The main subjects cover laboratory techniques, contingency plans and emergency procedures, disinfection and sterilization, decontamination and final disposal, and introduction to transport of infectious substances.

NOTE 3 Details to this clause are provided in Annexes C and D.

7.2.5.3 Infection control, disinfection and decontamination

The biorisk management advisor shall understand the fundamentals of infection control, disinfection, and decontamination, as well as their efficacy. The biorisk management advisor shall be competent to advise on selection and correct use of methods and products.

NOTE 1 This competence is linked to ISO 35001:2019, 8.8 (Decontamination and waste management).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.5.4 Biological waste management

The biorisk management advisor shall be competent to identify and develop a biological waste management plan, including validation and verification, and provide advice on implementation of the plan.

NOTE 1 This competence is linked to ISO 35001:2019, 8.8 (Decontamination and waste management).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.5.5 Emergency response and contingency planning

The biorisk management advisor shall be competent to advise, support development and implement an emergency preparedness and response plan for biorisk management, including training and exercises for emergency scenarios.

The biorisk management advisor shall understand the biorisk aspects of contingency planning, and the importance of implementing and maintaining a business continuity plan for continued operation of the organization.

NOTE 1 This competence is linked to ISO 35001:2019, 8.9 (Emergency response and contingency planning).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.5.6 Transport of biological material

The biorisk management advisor should be competent to identify and understand all applicable international, national, and local transportation requirements for safe and secure internal and external transport.

The biorisk management advisor shall understand the pertinent requirements for import and export, including documentation, correct packaging, labelling and means of transport for biological material and be experienced in supporting persons responsible for such transport.

NOTE 1 This competence is linked to ISO 35001:2019, 8.10 (Transport of biological materials).

NOTE 2 Details to this clause are provided in Annexes C and D.

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7.2.6 Performance evaluation and improvement

7.2.6.1 Audits and inspections

The biorisk management advisor shall be competent to conduct biorisk management audits and inspections, identify failures and non-conformities with defined requirements, areas for improvement and the need for corrective actions.

The biorisk management advisor shall be able to communicate and document audit findings and the need for corrective actions comprehensively placing them into context with the biological risks and requirements for their timely implementation.

NOTE 1 This competence is linked to ISO 35001:2019, 9.2 (Internal audit).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.6.2 Incident and accident investigation

The biorisk management advisor shall demonstrate competence and capacity to establish, support and provide oversight for a voluntary, anonymous, non-punitive incident-reporting system for laboratories that is designed to exclude sensitive and classified information and protect, to the extent permitted by law, any sensitive or private information that is inadvertently submitted. In developing this system, the biorisk management advisor should be able to cover all incidents, including near misses.

The biorisk management advisor should understand the incident and accident investigative review processes required to update and improve emergency responses and provide training opportunities on lessons learned to prevent future occurrences.

The biorisk management advisor should be able to report, receive reports, investigate and follow up on accidents or biosafety incidents, use the results from incident investigations to update laboratory procedures and emergency/incident response and potentially publish in-house validation of risk control in peer-reviewed journals so that others can benefit from the conclusions of the studies: strong communication practices help establish good reporting mechanisms for any incidents, accidents or inefficiencies of the risk control measures.

NOTE 1 This competence is linked to ISO 35001:2019, 8.9 (Emergency response and contingency planning).

NOTE 2 Details to this clause are provided in Annexes C and D.

7.2.7 International and national regulatory framework, standards, guidelines, and conventions

The biorisk management advisor should demonstrate a detailed understanding of the applications of relevant national regulations, standards and guidelines to the biorisk management programme or biorisk management system to ensure compliance.

The biorisk management adviser should also demonstrate a level of understanding of international biosafety and biosecurity treaties, conventions, standards and guidelines, appropriate to the needs of the organization.

NOTE 1 Details to this clause are provided in Annexes C and D.

7.3 Competencies relevant for specific work areas

The principles of biorisk management can apply to a wide range of specialized work areas depending on the organization. When providing advice for these specific work areas, the biorisk management advisor can be required to obtain consultative advice, gain training or acquire and demonstrate additional knowledge in these work areas.

Specialized work competency should be considered when work is performed:

— with small animals e.g. rodents, fish,

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— with large animals e.g. cattle, swine, equine,

— with non-human primates,

— with arthropods,

— with parasites,

— with plants,

— with fungi,

— with cell cultures, tissues, and blood,

— with prions and prion-like proteins,

— with biological toxins and other hazardous products from microorganisms,

— in large scale production (bioprocessing),

— in controlled environments, e.g. Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP) or Clean Room,

— in a diagnostic laboratory,

— in the context of clinical trials,

— under high containment,

— under maximum containment,

— that is related to medical and veterinary services,

— in greenhouses,

— with environmental sampling, and

— in mobile and field laboratories.

NOTE 1 Details to this clause are provided in Annex E.

7.4 Competence documentation including continuing professional development

Different competences are required for biorisk management advisors based on the biorisk management needs of an organization. The depth and coverage of knowledge and skills required can increase as the risk of the activity increases.

The biorisk management advisor may not have relevant knowledge, skills, and experience in all areas. In situations where this expertise is needed, appropriate training, consultative and management assistance can be sought to help meet the biorisk management needs of the organization.

Competence shall be demonstrable and correlate to the biorisk management needs of an organization. To this aim, biorisk management advisors can maintain a portfolio of their achievements to demonstrate relevant knowledge, skills, and experience in biorisk management.

To maintain competence, the biorisk management advisor shall engage in continuing professional development to maintain requisite knowledge, skills, and experience needed to manage a biorisk management programme.

While a biorisk management advisor is still receiving training to achieve the competencies required for their organization, the competence gaps can be addressed by the organization temporarily engaging a biorisk management advisor with the necessary competencies.

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