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Competence requirements for biorisk management advisors

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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*.

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

Introduction

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 organisation 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 programs, 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 organisation 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.

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 organisation that handles, stores, transports, or dis-poses 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 organisation 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 organisation, with a clear commitment from the organisation'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 organisation to organisation and over time.

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

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.

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 such as CEO, CTO, COO, CFO

Note 1 to entry: Senior management are sometimes referred to, within organisations, 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]

4 Context for biorisk management advice

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

An organisation'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 organisation 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 organisation 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 organisation 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 organisation, e.g. management, biorisk management committee, occupational health, environment, security;

— participating in the organisation biorisk management committee or equivalent;

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

— advising and assisting organisation 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.

NOTE Guidance on how to define which competencies are required for different organisational 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 bio-risk management advice relevant to the organisation'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 organisation'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 organisation.

Advice on biorisk management for an organisation 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 organisation.

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 organisation to be able to consult with all organisation management and staff.

The biorisk management advisor shall be aware of the need for a proactive ongoing hazard identification and assessment process for the organisation 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.

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.

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 organisation'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.

The biorisk management advisor shall be cognizant of the organisation'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 organisation.

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 decisions 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