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Competence requirements for biorisk management advisors

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

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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 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 [ISO Technical Specification document](#), relating but not limited to ISO ~~35001~~ *Biorisk management for laboratories and other related organisations*.

This [ISO Technical Specification 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.

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Competence ~~of~~ 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 ~~could~~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>~~<https://www.iso.org/obp>.
- ~~IEC Electropedia: available at <http://www.electropedia.org/>~~<https://www.electropedia.org/>.

3.1

able
having the power, skill, means, or opportunity to do something

3.2

allow
give (someone) permission to do something

3.3

attribute
inherent characteristic of a person

3.42

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.

3.53

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

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3.64

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 ~~(7-2)~~ comprises overall competence.

3.75

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

3.86

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

3.97

containment level

a 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 ~~may 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.

3.108

demonstrate

~~give a practical exhibition and explanation of (how a machine is operated, skill, or craft is performed)~~

3.11

dual-use research of concern potential

~~dual use research of concern is~~ 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 [\[SOURCE: WHO Laboratory Safety Manual 4th Edition 2020\]^{\[2\]}](#)

[\[SOURCE: WHO Laboratory Safety Manual 4th Edition 2020\]](#)

ISO/DTS 5441:(en)

3.129
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]]

3.1310
knowledgeable

intelligent and well informed

3.1411
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).

[SOURCE: ISO Directive 1]

3.1512
management system standard
MSS

standard for a management system

[ISO/DTS 5441](#)

[SOURCE: ISO Directive 1 (Annex SL 2.1)]

3.1613
participate

take part in an action or endeavour

3.1714
programme
work 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.

3.1815
risk group
RG

~~hazard group~~

classification of biological agents based upon each agent's characteristics and epidemiological profile

Note 1 to entry: The higher the risk ~~or hazard group~~, 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]

3.1916
senior management

individual or group(s) who directs and controls an organization including strategic level management positions such as CEO, CTO, COO, CFO, ~~etc.~~

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

3.2017
skills

ability to apply knowledge and use know-how to complete tasks and solve problems[SOURCE: CEN Guide 14 [3]][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 ~~is-~~ ~~ssues~~ 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.

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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 C-Annex B](#).

NOTE 3 Two internationally published documents provide international laboratory biosafety (the WHO Laboratory Safety Manual [\[2\]\]](#) and biosecurity (ISO 35001 [Biorisk management for laboratories and other related organisations](#) [\[1\]\]](#)) guidance and define a process to identify, assess, control, and monitor the risks associated with hazardous biological materials. This [ISO Technical Specification document](#) elaborates competencies for the biorisk management advisor in the context of biorisk management as presented in these documents. [Annex A-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;
- ~~assist~~ assisting or ~~participate~~ 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-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.

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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 ~~may~~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~~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 ~~section 7.2.7.2~~. 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~~Annexes C to ~~E~~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 ~~relevant~~linked to ~~address section~~ISO 35001:2019, 5.3.4 (Biorisk management advisor) ~~of ISO 35001~~.

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