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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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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 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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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 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.

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.

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

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]

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.

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.

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 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.

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

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.

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;

— 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.

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.

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,

— 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.

Recognition of competence of a biorisk management advisor shall be reviewed and as necessary, adapted to changing needs in an organization.

NOTE 1 Competencies can be acquired through a variety of means such as training, consultation, and experience where training can be received in a combination of modalities.

NOTE 2 Competencies can, for example, be demonstrated by:

— an evidence portfolio of all relevant areas;

— preparing a range of practical examples such as:

  — preparation of a dossier;

  — completion of a risk assessment case or emergency scenario;

  — proof of certification for competencies.

NOTE 3 The context for the demonstration of competence can be organization and location specific in such cases where company, local, national, and regional requirements apply.

NOTE 4 Details to this clause are provided in Annex F.

Annex A
(informative)

The relationship between the clauses of ISO/TS 5441 (this document), ISO 35001 and the WHO laboratory biosafety manual

A.1 General

ISO 35001 defines a process and enables an organization to effectively identify, assess, control, and monitor the risks associated with hazardous biological materials. It is a management system standard and is intended to define requirements for a biorisk management system that are appropriate to the nature and scale of any organization.

The ISO 35001 biorisk MSS was designed to be compatible with the following ISO MSSs:

— ISO 9001

— ISO 14001

— ISO 15189

— ISO 15190

— ISO/IEC 17025

— ISO 31000

— ISO 45001

Development of ISO 35001:2019, a comprehensive biorisk MSS eliminated the need for any sector-specific biorisk MSSs.

A biorisk management system based on ISO 35001:2019, requires a pro-active, performance and evidence-based approach to biorisk management with defined accountabilities and improvement over time. ISO 35001 is built on the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions that an organization undertakes to meet its goals. In addition, this MSS relies on the integration of its parts including organizational leadership, policies, objectives, procedures, and processes. This is known as the Plan-Do-Check-Act (PDCA) principle.

The PDCA model is an iterative process used by organizations to achieve continual improvement of processes and products. It has been applied to this biorisk MSS, and to each of its individual elements, as follows:

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

— Do: implement the processes as planned;

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

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

The fourth edition of the WHO laboratory biosafety manual (LBM4) [2] adopts a risk- and evidence-based approach to biosafety rather than a prescriptive approach in order to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate and sustainable. Emphasis is placed on the importance of a "safety culture" that incorporates risk assessment, good microbiological practice and

procedure (GMPP) and SOPs, appropriate introductory, refresher and mentoring training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions. This approach aims to facilitate laboratory design that ensures greater sustainability while maintaining an appropriate control of biosafety. The WHO LBM4 is supportive of biorisk management programme(s) but does not address a biorisk management system

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 potentially hazardous biological materials. It is linked by intent and purpose to ISO 35001 and LBM4. Sections of the three documents are compared in Table A.1.

Table A.1 — Comparison by clause of ISO/TS 5441:2024 (this document), ISO 35001:2019 and the WHO laboratory biosafety manual[2]

ISO/TS 5441:2024 (this document)	ISO 35001:2019	WHO Laboratory Biosafety Manual 4th ed. [2]
7.2.1.1 Scientific and technical understanding	5.3.5 Scientific management	7.3.4 Laboratory personnel and support personnel
7.2.1.2 Biorisk management programme	4.4 Biorisk management system	7 Biosafety programme management
7.2.2 Planning of biorisk management	6 Planning	4.8 Emergency/incident response; 7.3 Assigned roles; 8.4 Personnel control
7.2.2.1 Competence to address risks and their management	6.1 Actions to address risks and opportunities	2 Risk assessment
7.2.2.2 Hazard and threat identification and analysis	6.1.1 Hazard and/or threat identification and analysis	2.1 Gather information
7.2.2.3 Risk assessment	6.1.2 Risk assessment	2.2 Evaluate the information
7.2.2.4 Risk mitigation	6.1.3 Risk mitigation	2.3 Develop a risk control strategy
7.2.3.1 Occupational health and occupational safety principles and regulatory framework	7.1.1 Worker health programme	3.9; 4.9; 5.9 Occupational health
7.2.3.2 Communication skills and information management	7.4 Communication 7.5 Documented information	7.6 Supporting plans
7.2.3.3 Training	7.3.1 Training	3.2 Personnel competence and training
7.2.3.4 Behavioural factors and worker management	7.2.1 Behavioural factors and worker management	8.4 Personnel control
7.2.3.5 Personal reliability measures	7.2.2 Personnel reliability measures 7.3 Awareness	
7.2.3.6 Personal security	7.7 Personal security	
7.2.3.7 Ethical concerns related to activities with biological material	7.2.2 Personnel reliability measures	

Table A.1 *(continued)*

ISO/TS 5441:2024 (this document)	ISO 35001:2019	WHO Laboratory Biosafety Manual 4th ed. [2]
7.2.3.8 Information management and security	7.5.4 Information security	8.3 Information control
7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance	8.2 Commissioning and decommissioning	3.3; 4.3; 5.3 Facility design
7.2.4.2 Containment principles	8.1 Operational planning and control	5.1 Operational working practices and procedures
7.2.4.3 Selection, verification, certification, and maintenance of equipment	8.3 Maintenance, control, calibration, certification, and validation	3.7; 4.7; 5.7 Laboratory equipment
7.2.4.4 Environmental safety	8.9 Emergency response and contingency planning	
7.2.4.5 Asset security	8.4 Physical security 8.10.1 Transport security	8.5 Physical security control
7.2.4.6 Inventory monitoring and control	8.5 Biological materials inventory	3.4; 4.4; 5.4 Specimen receipt and storage
7.2.5.1 Clothing and personal protective equipment	8.7 Clothing and personal protective equipment	3.6; 4.6; 5.6 Personal protective equipment
7.2.5.2 Good microbiological techniques	8.6 Good microbiological technique	3.1 Good microbiological practice and procedure
7.2.5.3 Infection control, disinfection, and decontamination	8.8 Decontamination and waste management	3.5; 4.5; 5.5 Decontamination and waste management
7.2.5.4 Biological waste management	8.8 Decontamination and waste management	3.5; 4.5, 5.5 Decontamination and waste management
7.2.5.5 Emergency preparedness and contingency planning	8.9 Emergency response and contingency planning 8.9.1 Emergency scenarios 8.9.2 Emergency plan training 8.9.3 Emergency exercises and simulations 8.9.4 Contingency plans	3.8; 4.8; 5.8; 8.7 Emergency/incident response
7.2.5.6 Transport of biological material	8.10 Transport of biological materials	6 Transfer and transportation
7.2.6.1 Audits and inspection	9.2 Internal audit 9.1 Monitoring, measurement, analysis, and evaluation	7.7.2 Audits and inspections 7.7 Reports and reviews

Table A.1 *(continued)*

ISO/TS 5441:2024 (this document)	ISO 35001:2019	WHO Laboratory Biosafety Manual 4th ed. [2]
7.2.6.2 Incident and accident investigation	10.2 Incident, nonconformity, and corrective action	

Annex B
(informative)

Guidance on how to determine the needs for competence in biorisk management advice in an organization

B.1 General

The organization should evaluate its activities in relation to biological material to understand its biorisk profile and the respective biorisk management needs, prior to engaging one or several biorisk management advisor(s).

This Annex will help an organization to determine the biorisk management competence needs and to formulate a profile for a job advertisement or call for bid.

Step 1 is to understand the level of complexity involved in the biorisk management by defining and listing the different biorisks linked to different types of activities at the organization.

Step 2 is to identify, based on Step 1, the range and level of competencies required to cover management of the different biorisks and need by the organization to acquire these competencies.

Step 3 is to apply the biorisk management complexity and competence needs to formulate the job requisition or call for bid and attract the matching competent biorisk management advisor(s).

Figure B.1 indicates the interrelationship between biorisk, activities with biological material and competence needs to manage these risks. In an organization with very limited activities in relation to biological material and very limited biorisks, the biorisk management competence needs are much more limited than in an organization with a high biorisk linked to a specific activity or with different biorisks of a large number of activities with different biological material.

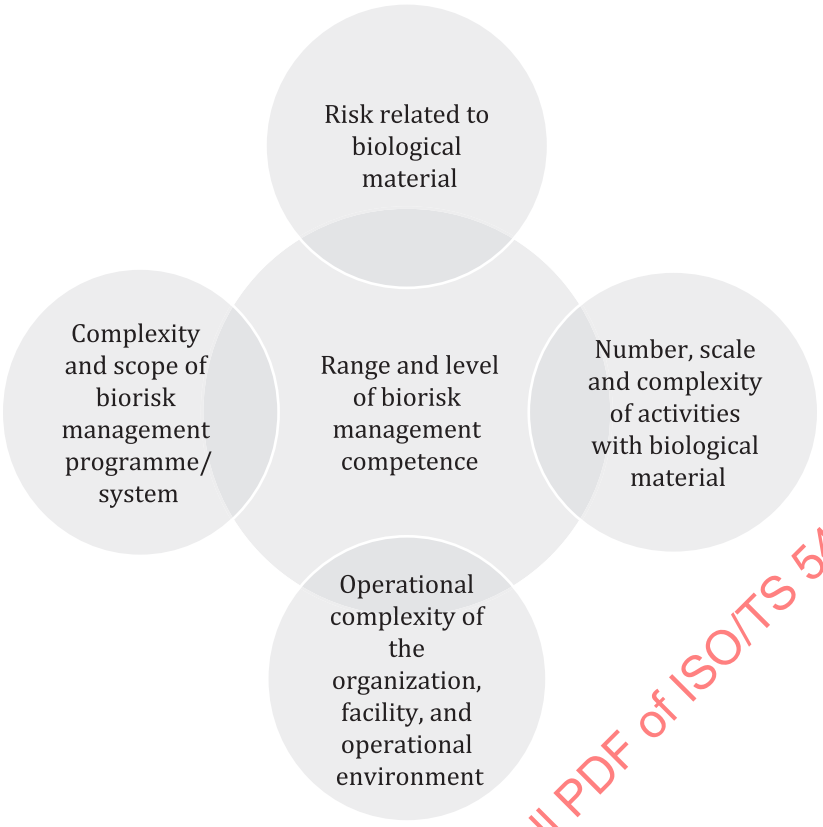

Figure B.1 — Interrelationship between biorisk, activities with biological material and competence needs to manage these risks

A biorisk management system such as the one described in ISO 35001 should define a number of essential components. These are policies, leadership requirements and responsibilities. The biorisk management system directs the implementation of the organizational biorisk management programme. Figure B.2 illustrates the relationship between a comprehensive biorisk management system and its respective biorisk programmes. Light grey circles comprise the biorisk management programme.

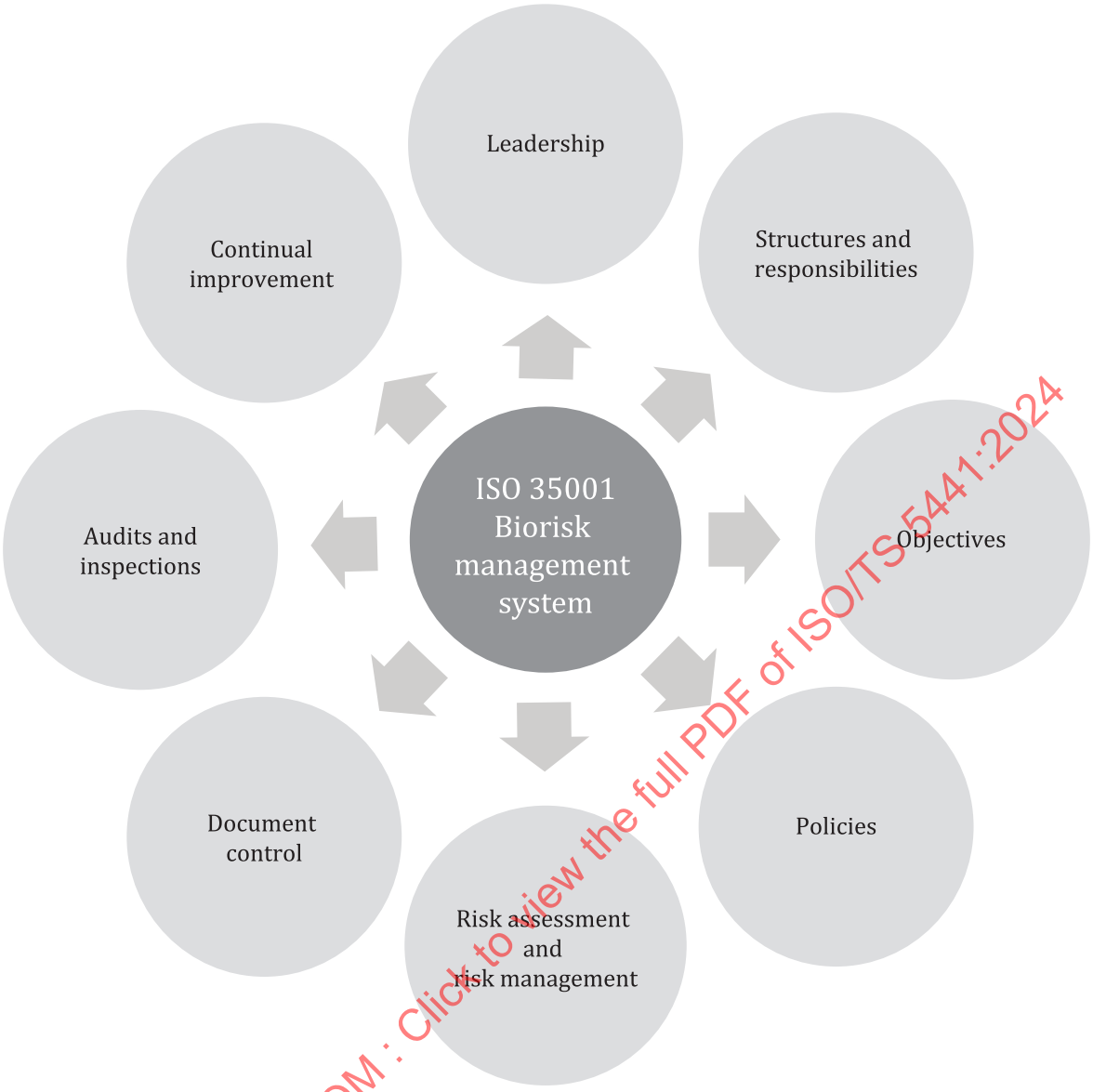

Figure B.2 — Components of an ISO 35001 biorisk management system

B.2 Determination of complexity of biorisk management

B.2.1 General

Below are guidelines to assess what level of expertise may be required of (a) biorisk management advisor(s) based on the level of complexity of the biorisk management.

For this assessment, the list of attributes for each segment of biorisk management should be reviewed to determine its complexity (basic or complex).

B.2.2 Basic biorisk management

Basic biorisk management is sufficient if the following points apply:

— low risk work (RG1 and RG2);

— limited number or scale of activities with biological material;

— limited need for coordination of biosafety and biosecurity or need for biorisk management limited to a specific section of complex biorisk management when under the lead of organizational biorisk management advice;

— organization operates in one country or region.

B.2.3 Complex biorisk management

Biorisk management is complex if one or several of the following points apply:

— medium to high-risk work (work with RG2 through RG3 or RG4 biological materials/agents);

— medium to high complexity biorisk management, for example:

  — type of facility(s): greenhouses, aquaculture, parasites, large and/or small animal facilities, clinics or hospital settings, clinical sample analysis labs, research and development facilities, manufacturing facilities, fieldwork, etc.;

  — scale of work: small vs. large scale (>10 litre) or both;

  — type of work: GMOs, recombinant, gene engineering, clinical, siRNA, viral vectors, etc.;

  — regulatory complexity: permitting (import, export, GMOs), dual use, etc.;

— need for lead biorisk management advice for the organization;

— need for coordination of biorisk management using a management system approach (ISO 35001);

— biorisk management advice needing to address issues across organizational and national boundaries;

— need for biorisk subject matter expert on engineering project teams for new or renovated biological facilities.

B.3 Competence guidance

Based on the evaluation of the complexity of biorisk management and need for biorisk management advice, an organization can consult Tables B.1 to B.5 to identify attributes that can be required for (a) biorisk management advisor(s) to be sufficiently competent in providing the biorisk management advice needed in the organization.

An organization can need basic or complex biorisk management competence depending on its situation and range of biological materials used. The need for biorisk management competence can be somewhere in between basic and complex but is always adapted to the type and use of biological material.

Table B.1 indicates the degree and education of a biorisk management advisor based on the complexity of the biorisk management in an organization (also refer to F.1.4).

Table B.1 — Experience and education of a biorisk management advisor

Experience/ Education	Basic biorisk management	Complex biorisk management
Are biosafety credentials required?	Preferred but not essential unless required by local law	Has appropriate credentials according to country or region-specific certifications or registrations
What educational background is recommended?	3 year to 4 year degree in applicable Life Sciences or equivalent	Life Sciences graduate degree or equivalent. Advanced degree (e.g. Master's or PhD) or equivalent in microbiology, virology, molecular biology, cell biology, bacteriology, mycology, parasitology, transmissible spongiform encephalopathies, cell culture, biological toxins, biotechnology, or other relevant programme preferred
Is hands-on relevant laboratory or other related organization experience required?	Minimum of 2 years	8 years to 10 years
What professional memberships are recommended?	Member or associate of a local or national biological safety association	Member of a local or national biological safety association with active support/ participation preferred

Table B.2 indicates the level of competence required in an organization depending on the complexity of biorisk management. Column 1 lists the competences of 7.2, column 2 lists the level of competence needed for basic biorisk management and column 3 lists the level of competence needed for complex biorisk management.

Table B.2 — Competence elements

Competence (clause number in this document)	Competence need	
	Basic biorisk management	Complex biorisk management
7.2.1.1 Scientific and technical understanding	Limited to basic scientific and technical knowledge of biological material and the potential hazards and risks adapted to the biological materials handled by an organization.	Proficient scientific and technical understanding of biological material and the potential hazards and risks related to these materials handled by an organization so that biorisk management advisor is able to provide consultation with all organization management and staff.
7.2.1.2 Biorisk management programme	Limited to basic experience developing, establishing, and supporting the implementation of a basic biorisk management programme to fit an organization where biological risks are limited.	Proficient in developing, establishing, and supporting the implementation of a comprehensive or complex biorisk management programme or integrate biorisk management into a management system.
7.2.2 Planning of biorisk management	Limited to basic experience with biorisk management planning in an organization where biological risks are limited.	Proficient with biorisk management planning including hazard and threat identification and analysis, risk assessment and risk mitigation.
7.2.2.1 Competence to address risks and their management	Limited to basic experience conducting suitable biorisk assessments and determining effective risk mitigation strategies. Aware of knowledge gaps and aware for which biological risks additional expertise should be requested.	Proficient with conducting a suitable biorisk assessment and determining effective risk mitigation strategies where a variety of biological risks have to be addressed and managed consistently. Provides guidance on risk assessment of different types of biological materials and their management to project leaders, principal investigators, management, and other relevant personnel.

Table B.2 *(continued)*

Competence (clause number in this document)	Competence need	
	Basic biorisk management	**Complex biorisk management**
7.2.2.2 Hazard and threat identification and analysis	Able to provide limited to basic guidance to an organization on the respective biological hazard and threats and to recommend additional guidance for hazard and threat identification competence if needed.	Proficient in identification of the whole range of different biological hazards and threats present in an organization. Provides expert guidance to project leaders, principal investigators, management and other relevant personnel on biological hazard identification and threats.
7.2.2.3 Risk assessment	Limited to basic skills to assess and document risks of well-known biological materials using suitable methods.	Proficient to assess, and document biological risks using suitable risk assessment methodologies. Proficient to address biological risks related to unknown/emerging hazardous biological material applying the necessary scientific background. Proficient to recognize uncertainties related to risks of biological material and how to address these uncertainties.
7.2.2.4 Risk mitigation	Limited to basic skills to evaluate and implement the organization's mitigation plan to ensure that the measures are adequate to reduce biorisk to acceptable levels.	Proficient to evaluate, develop and implement the organization's control plan to ensure that measures best suited and most effective are implemented and controlled to adequately mitigate biorisk to acceptable levels.
7.2.3.1 Occupational health and occupational safety principles and regulatory framework	Limited to basic understanding of requirements in occupational health and occupational safety (ISO 45001) and how they relate to biological safety.	Understanding the requirements of application of the principles of occupational health and occupational safety (ISO 45001) including measures as they relate to the safe handling of biological material both in the laboratory, in the workplace and in the outside environment.
7.2.3.2 Communication skills and information management	Skills to communicate on biological risk related issues applicable in an organization to the line manager or entity to report to.	Effective communicator able to transfer information clearly, understandably, and effectively and modify the communication to suit the targeted audience, such as management, laboratory workers, ancillary personnel, and external parties.
7.2.3.3 Training	Basic knowledge of training principles to appropriately identify training needs and to provide an internal biosafety and biosecurity training programme tailored to effected audiences in an organization with limited biorisk management needs.	Proficient knowledge of training principles to prescribe training needs and to develop, deliver and validate an internal biosafety and biosecurity training programme tailored to different audiences in an organization with complex biorisk management needs.
7.2.3.4 Behavioural factors and worker management	Limited to basic skills to influence behaviours and risk perception and be persuasive in adhering to good biosafety and biosecurity practices considering cultural and socio-economic considerations in an organization with limited biorisk management needs.	Proficient understanding of the importance of establishing and maintaining a biorisk culture. Understanding of shared values, patterns of behaviour and perceptions and their importance for safety and security making laboratory personnel more likely to conduct their work safely and maintain a safety culture in the laboratory. Possesses the skills and attributes to influence behaviours and risk perception and be persuasive in promoting good biosafety and biosecurity practices considering cultural and socio-economic considerations in an organization with complex biorisk management needs.

Table B.2 *(continued)*

Competence (clause number in this document)	Competence need	
	Basic biorisk management	**Complex biorisk management**
7.2.3.5 Personal reliability measures	Limited to basic understanding of personnel reliability and how this relates to insider and outsider threats.	Proficient understanding of 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. Competent interaction with management responsible for reliability issues in an organization with complex biorisk management needs.
7.2.3.6 Personal security	Basic understanding of worker security on or away from the job related to the specific biorisk issues of an organization. Basic understanding of the need for personal security support to workers and understanding for which biorisk issues additional support services are required in an organization.	Proficient understanding of worker security on or away from the job recognizing that workers can be vulnerable because of their function or position. Understanding of the importance of establishing and maintaining a programme to provide personal security support services to workers applicable to organization with complex biorisk management needs. Knowledgeable interaction with security services of an organization.
7.2.3.7 Ethical concerns related to activities with biological material	Basic knowledge concerning scientific integrity, and ethical considerations for responsible use of biological materials. Developing the ability to assist in the development and maintenance of an ethics framework that supports an ethical biosafety and, if applicable, biosecurity culture.	Proficient knowledge concerning scientific integrity, and ethical considerations for responsible use of biological materials. Proficient to assist in the development and maintenance of an ethics framework that supports an ethical biosafety and biosecurity culture. Knowledgeable about ethical or practical code of conduct guidance documents including international agreements and able to make proposals on integrating this into a complex biorisk management programme or organizational management system.
7.2.3.8 Information management and security	Basic understanding of the importance of establishing and maintaining an information security programme to identify, protect, and control access to sensitive information related to the biorisk management programme.	Proficient understanding of the importance of establishing and maintaining an information security programme to identify, protect, and control access to sensitive information related to the biorisk management programme and ability to contribute to the establishment and maintenance of information management and security in such a programme.
7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance	Basic knowledge to recognize the need for integration of biosafety and biosecurity aspects into technical facility design and construction. Basic knowledge on construction requirements relevant to biorisk management and assessment of need for additional respective expertise. Developing knowledge of basic systems and design features of a typical facility; limited to basic understanding of the construction, commissioning, and validation processes.	Proficient knowledge to identify technical facility design and construction requirements relevant for biorisk management including all biosafety and biosecurity aspects determined by a preceding risk assessment process. Understanding the basic systems and design features of a typical facility. Understanding the construction, commissioning, and validation processes. Knowledgeable about basic (re)design features relevant to the organizations facility types. Ability to participate in planning and implementation of system modifications, commissioning, and de-commissioning.

Table B.2 *(continued)*

Competence (clause number in this document)	Competence need	
	Basic biorisk management	**Complex biorisk management**
7.2.4.2 Containment principles	Basic understanding of the details of physical design parameters and operational practices that protect personnel, the immediate work environment, the community, and the environment from exposure to biological material. Understanding of the risks related to limitations of physical design parameters and operational practices and ability to recognize areas of need for support.	Proficient understanding of the details of physical design parameters and operational practices that contain biological material to protect personnel, the immediate work environment, the community, and the environment from exposure to this biological material. Proficient understanding of the risks related to limitations of physical design parameters and operational practices and how to address these limitations.
7.2.4.3 Selection, verification, certification, and maintenance of equipment	Basic understanding of the need to address biosafety and biosecurity aspects when selecting equipment. Able to offer basic advice on choice, correct use and limitations, installation, validation, certification, and maintenance.	Proficient understanding of the implications of selection of safe equipment in the facility, its verification, certification and maintenance on biosafety and biosecurity. Knowledgeable to advise on choice, correct use and limitations of equipment, its installation, validation, certification, and regular maintenance.
7.2.4.4 Environmental safety	Basic knowledge of: — the hazards of the specific biological materials used, and their potential hazards to the environment; — the risks for unintentional environmental release as a result of work involving these biological materials.	Proficient knowledge of: — the 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; — the risks for unintentional environmental release as a result of work involving biological materials; — implementation of good microbiological practices and procedures; — suitable monitoring strategies to evaluate and prevent environmental release and mitigation practices and strategies; — how to prepare appropriate responses for emergencies and incidents involving an environmental breach of biological material; — specific laboratory environmental exposure routes to mitigate the associated consequences.
7.2.4.5 Asset security	Basic understanding of the importance and aspects of security measures used to protect assets that include physical security, information management security, inventory monitoring and control, transport security, personal security and personnel reliability measures and interrelationship with biosafety and biosecurity.	Proficient understanding of the importance and aspects of security measures used to protect assets that include physical security, information management security, inventory monitoring and control, transport security, personal security and personnel reliability measures. Competent to implement and maintain the mitigation measures determined as part of the risk assessment process. Effective risk/ risk control strategy communication to senior management.

Table B.2 *(continued)*

Competence (clause number in this document)	Competence need	
	Basic biorisk management	**Complex biorisk management**
7.2.4.6 Inventory monitoring and control	Basic knowledge of the importance of inventory control commensurate with mitigation of risks related to hazardous biological material. Ability to provide support for the establishment and maintenance of an accurate inventory of biological material used or stored if needed by the organization.	Proficient knowledge of the importance of inventory control commensurate with mitigation of risks related to hazardous biological material. Ability to communicate the importance of maintaining an accurate inventory of biological material used or stored at an organization and the importance of establishing a tracking system.
7.2.5.1 Clothing and personal protective equipment (PPE)	Ability to advise, assess and evaluate the appropriate types of PPE required for a given situation with specific biological material used in an organization with basic biorisk management. Ability to discuss potential problems and solutions when PPE is introduced and used.	Competent to advise, assess and evaluate the appropriate types of PPE required for a given situation and discuss potential problems and solutions when it is introduced and used addressing different types of hazards of biological materials used in an organization with complex biorisk management needs.
7.2.5.2 Good microbiological techniques (GMT)	Basic experience in GMT and the methods to eliminate or minimise exposure to biological material including; handling and aseptic technique, identification of biorisks, hygiene, organization of work, and practices that prevent contamination and misidentification, adapted to the specific need of an organization. Basic knowledge on how to guide staff to apply GMT and enable them to create and maintain a safe working environment (workplace and workflow).	Proficient in GMT and the methods to eliminate or minimise exposure to biological material including; handling and aseptic techniques, hygiene measures, organization of work, and safe practices to prevent contamination and misidentification. Proficient in advising on the application of GMT for work processes with different types of biological material used in an organization with complex biorisk management needs. Proficient in supporting to create and maintain a safe working environment (workplace and workflow).
7.2.5.3 Infection control, disinfection, and decontamination	Understanding of the fundamentals of infection control, disinfection, and decontamination, as well as their efficacy, adapted to the specific biological material used and the limited need of an organization for biorisk management.	Proficient understanding of the fundamentals of infection control, disinfection, and decontamination, as well as their efficacy. Proficient to advise on selection and correct use of methods in an organization where a wide variety of biological materials are used and biorisk management is complex.
7.2.5.4 Biological waste management	Basic understanding for the need to identify and implement biological waste management adapted to the specific biological material used in an organization Knowledgeable to engage in a discussion on validation and verification of the biological waste management methods.	Proficient to develop a comprehensive biological waste management plan, including validation and verification, addressing the variety of biological materials used in an organization demanding for specific treatments adapted to the biological material. Experienced on advising on implementation of the biological waste management plan.
7.2.5.5 Emergency preparedness and contingency planning	Basic understanding in how to develop an emergency preparedness and contingency plan addressing biological risks, including training and exercises for emergency scenarios.	Proficient to support development of an emergency preparedness and contingency plan, including training and exercises for emergency scenarios and advise on its implementation in an organization where biorisk management is complex. Understanding the aspects of business continuity, and the importance of implementing and maintaining a business continuity plan for the continued operation, including biorisk operations, of the organization during an emergency.

Table B.2 *(continued)*

Competence (clause number in this document)	Competence need	
	Basic biorisk management	**Complex biorisk management**
7.2.5.6 Transport of biological material	Basic understanding of how to identify and understand all applicable international, national, and local transportation requirements for safe and secure internal and external transport. Knowledgeable on where to find information on requirements for import and export of biological material, including documentation, correct packaging, labelling and means of transport.	Proficient to identify and understand all applicable international, national, and local transportation requirements for safe and secure internal and external transport. Understanding the requirements for import and export, including documentation, correct packaging, labelling and means of transport for biological material. Experienced in supporting persons responsible for such transport.
7.2.6.1 Audits and inspection	Basic understanding of how to conduct biorisk management audits and inspections, and identify failures, non-conformities with defined requirements, areas for improvement and the need for corrective actions in an organization with a limited need for biorisk management. Able to communicate and document audit findings, the need for corrective actions and their timely implementation.	Proficient to conduct biorisk management audits and inspections, and identify failures, non-conformities with defined requirements, areas for improvement and the need for corrective actions in an organization with complex biorisk management. 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 timely implementation.
7.2.6.2 Incident and accident investigation	Basic understanding to establish, support and provide oversight for an incident-reporting system (including near misses) for organizations with limited biorisk management needs.	Proficient to establish, support and provide oversight for an incident-reporting system (including near misses) for organizations using different types of biological materials requiring complex biorisk management. Experienced in incident and accident investigative review processes required to update and improve emergency response. Skilled in providing training on lessons learned to prevent future occurrences. Able to report, receive reports, investigate, and follow up on accidents or incidents related to biological materials, use the results from incident investigations to update laboratory procedures and emergency/incident response plans.
7.2.7 Regulatory framework, standards, guidelines, and conventions	Basic understanding of the applications of international frameworks of biorisk management, including national regulation and standards, guidelines, treaties, and conventions, in all areas of biosafety and biosecurity to ensure compliance in an organization with limited needs for biorisk management.	Proficient understanding of the applications of international frameworks of biorisk management, including national regulation and standards, guidelines, treaties, and conventions, in all areas of biosafety and biosecurity to ensure compliance in an organization with complex biorisk management.

The type of biological material and methodologies used have a significant impact on the biorisk management complexity and competence needs.

Table B.3 indicates additional competence considerations based on the biorisk profile of an organization.

Table B.3 — Additional competence considerations based on the biorisk profile of the organization

Which of the following biological materials or technologies is the organization working with?	Applicable to the organization? (Yes or No)
Work with genetically modified organisms/ recombinant technology (e.g. gene editing, gene drives, xenobiotics, animal cloning, siRNA)	
Dual use agents or technology	
Protein synthesis	
Work in large scale production (bioprocessing; >10 litres in any one vessel or container)	
Work with biological materials (e.g. human or animal cell lines, tissues, blood)	
Work involving toxins of biological origin and other hazards products from microorganisms	
Animals where health status in unknown	
Work with small animals (rodents)	
Work with large animals (cattle, swine, equine)	
Work with large animals infected with high-risk pathogens	
Work with small animals infected with high-risk pathogens	
Work with microbial pathogens	
Work with protists	
Work with fungi	
Work with plant pathogens and allergens	
Work with aquatic pathogens and allergens	
Work with animal pathogens and allergens	
Work with prions and prion-like proteins	
Work with non-human primates	
Work with parasites and arthropods	
Work in controlled environments e.g., GLP, Good Manufacturing Practice (GMP) or Clean Room.	
Work in a diagnostic laboratory	
Work in the context of clinical trials	
Work under high containment	
Work under maximum containment	
Work related to medical and veterinary services	
Work in greenhouses	
Environmental sampling	
Mobile and field laboratories	

Table B.4 helps evaluate the competence requirements for experience with regulations (see also 7.2.7) related to biorisk management complexity in an organization.

Table B.4 — Experience with regulations and their implementation

Regulation	Applicable to the organization? (Yes or No)	Basic biorisk management	Complex biorisk management
Country specific regulations for regions where organization operates		Understand where to find applicable regulations	Proficient knowledge and application of regulations for each country where the organization operates
Permission to work with genetically modified organisms		Understands permitting expectations and requirements but may require some support with execution	Proficient knowledge and experience applying and obtaining GMO permits
Import / export-controlled biological materials (e.g. animal health certificates, CITES, phytosanitary requirements)		Understands what import or export controlled biological materials are and the process for obtaining required permits or registrations	Proficient knowledge and experience identifying and working with export controlled biological materials; experience applying for applicable export permits or registrations
Transport of biological materials nationally or internationally (e.g. road, rail, air, sea)		Is aware of key logistical requirements for transporting of biological materials or has access to subject matter experts for support	Proficient knowledge and experience transporting of biological materials
Biological waste inactivation and disposal (e.g. wastewater, incinerator, autoclaving, digester)		Is aware of key requirements for infectious waste treatment relevant to the organization or has access to subject matter experts for support	Proficient knowledge and experience with infectious waste management including treatment and inactivation of waste as relevant to the organization's operations

Table B.5 provides a checklist for attributes related to management skills that can be needed to complement biorisk management competencies. These attributes are also described in 7.2.3.4, NOTE 2, Behavioural factors and worker management.

Table B.5 — Management skills to complement biorisk management competencies

Which of the following management skills are most important for this role?	Applicable to the role (Yes or No)
Planning and time management	
Leadership	
Open minded	
Diplomatic	
Tenaciousness	
Decisive	
Self-reliant	
Ethical	
Morally courageous	
Organized	
Communicative (verbal and written)	

B.4 Model job requisition

Once the organization has defined the competence and attributes that can be required for a candidate or applicant to be successful as a Biorisk Management Advisor in the organization, a respective job requisition or invitation to apply can be designed to attract the right talent.

Annex C
(informative)

Competencies for biorisk management advice required for specific work environments in an organization

C.1 General

This Annex provides guidance to an organization in how to define the requirements for competent biorisk management advice based on the nature of its activities (Clause 4).

A compilation of the biological material used, the range of activities performed, and the specific work environment in place, is a prerequisite for a definition of biorisk management competence needs.

Based on this compilation, an organization can look for the required competencies using Table C.1 to Table C.3, which relate competence needs to biological material used, activities performed, and work environments in place. Depending on the nature of activities, a combination of competencies from more than one column can apply.

Table C.1 refers to work with various types of biological materials, animals, and low to maximum containment.

Table C.2 refers to work in various activity environments.

Table C.3 refers to work in minimal containment or highly specialized fields such as biosecurity or import, export and transport of biological material.

See Clause 7, Annex D and Annex E for detailed descriptions of competencies. Within each competence, there are several topics and the degree of knowledge, skill and experience to support that activity can vary. A periodical review is necessary to adapt the need for biorisk management advice to changes in the biological risk, the type of activities performed, and the specific work environment.

An organization can prioritise the different competencies for its biorisk management programme or, if applicable, its management system. Priorities can vary between different organizations as a result of the biological risks and scale of activities.

Whether competencies for biorisk management advice are covered by one or several biorisk management advisors is at the discretion of the organization.

Table C.1 — Competence requirements to work with various biological materials, animals, and low to maximum containment

Competence requirements to work with various biological materials including: Bacteria, viruses, fungi, plant pathogens, genetically modified plants, prions/prion-like proteins, and biological toxins in research and development
— All competence subclauses from 7.1 to 7.2.7
Competence requirements to work with animals including: Large and small animals, non-human primates, arthropods, and parasites
— All competence subclauses from 7.1 to 7.2.7, except 7.2.5.2
Competence requirements to work in low containment to maximum containment e.g. CL/BSL2, CL/BSL3 and CL/BSL4
— All competence subclauses from 7.1 to 7.2.7

Table C.1 *(continued)*

Competence requirements to work in medical and veterinary services
— All competence subclauses from 7.1 to 7.2.7
NOTE 7.2.7 on regulatory framework is relevant to all environments.

Table C.2 — Competence requirements to work in various activity environments

Competence (subclause numbers in this document)	**GMP / clean room**	**Diagnostic / GLP testing**	**Clinical trials**	**Quality and analysis**	**Large scale production bioprocessing**	**Environmental sampling**
7.1 General prerequisites: an understanding of risks and threats associated with biological materials	+	+	+	+	+	+
7.2.1.1 Scientific and technical understanding	+	+	+	+	+	+
7.2.1.2 Biorisk management programme	+	+	+	+	+	-
7.2.2.1 Competence to address risks and their management	+	+	+	+	+	+
7.2.2.2 Hazard and threat identification and analysis	+	+	+	+	+	+
7.2.2.3 Risk assessment	+	+	+	+	+	+
7.2.2.4 Risk mitigation	+	+	+	+	+	+
7.2.3.1 Occupational health and occupational safety principles and regulatory framework	-	+	+	+	+	+
7.2.3.2 Assessment of workplace attitude and culture in an organization	+	+	+	+	+	+
7.2.3.3 Training	+	+	+	+	+	+
7.2.3.4 Communication skills and information / knowledge systems	+	+	+	+	+	+
7.2.3.5 Ethical concerns related to activities with biological material	-	-	+	-	-	-
7.2.3.6 Information management and security	-	+	+	+	+	+

Table C.2 *(continued)*

Competence (subclause numbers in this document)	GMP / clean room	Diagnostic / GLP testing	Clinical trials	Quality and analysis	Large scale production bioprocessing	Environmental sampling
7.2.3.7 Personal security	+	+	+	-	+	+
7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance	+	+	-	+	+	-
7.2.4.2 Containment principles	+	+	-	+	+	-
7.2.4.3 Environmental safety	+	+	-	+	+	+
7.2.4.4 Inventory monitoring and control	+	+	+	+	+	+
7.2.4.5 Selection, verification, certification, and maintenance of equipment	+	+	+	+	+	+
7.2.4.6 Asset Security	+	+	+	+	+	+
7.2.5.1 Clothing and personal protective equipment	+	+	-	+	+	+
7.2.5.2 Good microbiological techniques	+	+	-	+	+	-
7.2.5.3 Infection control, disinfection, and decontamination	+	+	+	+	+	+
7.2.5.4 Biological waste management	+	+	+	+	+	+
7.2.5.5 Emergency preparedness and response	+	+	+	+	+	-
7.2.5.6 Transport of biological material	+	+	+	+	+	+
7.2.6.1 Audits and inspections	+	+	+	+	+	-
7.2.6.2 Incident and accident investigation	+	+	+	+	+	+
NOTE 7.2.7 on regulatory framework is relevant to all fields.						

Table C.3 — Competence requirements to work in minimal containment or specialized fields

Competence (subclause number in this document)	CL / BSL1	Mobile laboratory	Biosecurity	Facility management	Import, export / transport
7.1 General prerequisites: an understanding of risks and threats associated with biological materials	+	+	+	-	+
7.2.1.1 Scientific and technical understanding	+	+	+	-	-
7.2.1.2 Biorisk management programme	+	+	+	+	-
7.2.2.1 Competence to address risks and their management	+	+	+	-	+
7.2.2.2 Hazard and threat identification and analysis	+	+	+	-	+
7.2.2.3 Risk assessment	+	+	+	+	+
7.2.2.4 Risk mitigation	+	+	+	+	+
7.2.3.1 Occupational health and occupational safety principles and regulatory framework	-	+	-	+	-
7.2.3.2 Assessment of workplace attitude and culture in an organization	+	+	+	-	-
7.2.3.3 Training	+	+	+	+	+
7.2.3.4 Communication skills and information / knowledge systems	+	+	+	+	+
7.2.3.5 Ethical concerns related to activities with biological material	-	+	-	-	-
7.2.3.6 Information management and security	-	-	+	+	+
7.2.3.7 Personal security	-	+	+	-	-
7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance	+	-	+	+	-
7.2.4.2 Containment principles	+	+	+	+	+
7.2.4.3 Environmental safety	-	+	-	-	-
7.2.4.4 Inventory monitoring and control	-	+	+	-	-

Table C.3 *(continued)*

Competence (subclause number in this document)	CL / BSL1	Mobile laboratory	Biosecurity	Facility management	Import, export / transport
7.2.4.5 Selection, verification, certification, and maintenance of equipment	+	+	+	+	-
7.2.4.6 Asset security	-	+	+	+	+
7.2.5.1 Clothing and personal protective equipment	+	+	-	-	+
7.2.5.2 Good microbiological techniques	+	+	-	-	-
7.2.5.3 Infection control, disinfection, decontamination, and sterilization	+	+	-	-	+
7.2.5.4 Biological waste management	+	+	-	+	-
7.2.5.5 Emergency preparedness and contingency planning	+	+	+	+	+
7.2.5.6 Transport of biological material	+	+	+	-	+
7.2.6.1 Audits and inspections	+	-	+	+	+
7.2.6.2 Incident and accident investigation	+	+	+	+	+

Annex D
(informative)

Detailed description of competencies

D.1 General

Table D.1 details of specific competences to provide a better understanding of each competence. They are aligned with the competencies in Clause 7 of this document and expand on them, but do not replace them. Also, they do not claim to be complete and should be extended depending on the context of the organization.

Table D.1 — Detailed description of competencies listed in Clause 7 of this document

7.2.1	Scientific, technical and management background
7.2.1.1 Scientific and technical understanding	**Knowledge** General principles of microbiology, biochemistry, and cell biology: — biochemistry, — cell biology, — bacteriology, — virology, — mycology, — parasitology, — transmissible spongiform encephalopathies (TSE), — cell cultures, — biological toxins. **Skills** Evaluation of basic characteristics of the principal types of biological material and their risks; i.e. main factors that contribute to the ability of biological agents to cause disease, main toxin producing organisms. Evaluation of techniques in molecular biology and genetic engineering and how they can potentially result in basic characteristics of biological material. **Experience** Application of fundamentals and techniques in molecular biology and genetic engineering besides manipulation of non-modified biological material.
7.2.1.2 Biorisk management programme	**Knowledge** Coordination of biosafety and biosecurity in a biorisk management programme for the management of biological risks in an organization. Foundation for a biorisk management programme through assessment and management of risk arising from the organization's activities with hazardous biological material. It includes the biosafety and biosecurity policy appropriate to the nature and scale of the biological risks associated with the work to be performed in an organization. The policy sets the biosafety and biosecurity goals and objectives for the organization. Application of the concept of continual improvement through a cycle of planning, implementing, reviewing, and improving the processes and actions whenever a management system approach with policies, objectives and processes (i.e. ISO 35001) is used, in addition to the other components of the system.

Table D.1 *(continued)*

	Skills Develop and support the implementation of a biorisk management programme appropriate to the nature and scale of the identified and potential biological risks. Establish, document, implement, communicate, maintain, and continually improve biorisk management if a management system is applied, including the processes needed and their interactions, in accordance with the requirements of an organization. **Experience** Awareness and understanding of the need for practical applicability of the biorisk management programme and its adaptation to changes of activities with biological materials and risks related to them. Experienced in applying a management system in accordance with the requirements of an organization, if applicable.
7.2.2 **Planning of biorisk management**	
7.2.2.1 Competence to address risks and their management	**Knowledge** Awareness and general insight on potential issues related to activities with biological material which could lead to biological risk and the consequential management of these risks. **Skills** Ability to use foundational knowledge to anticipate, address and communicate potential issues related to activities with biological material, including the capabilities and limitations of the ability of the organization to implement management strategies. **Experience** Recommend appropriate and reasonable strategies to the organization.
7.2.2.2 Hazard and threat identification and analysis	**Knowledge** Knowledge of hazards and threats associated with work with biological material and consideration of other hazards: — microorganisms and occupational infections - Laboratory Acquired Infection (LAI), — toxins, — allergens, — blood borne pathogens, — potentially infected material, e.g. blood, body fluids, soil samples, — modes of transmission means and routes, — infectious dose, — emerging and re-emerging diseases, — parasites, — cell lines (e.g. primary, permanent, immortalized, engineered), — dual-use potential, — other hazards associated with the use of biological material, e.g. chemical, gases, radiological, fire, mechanical, electrical, liquid nitrogen. **Skills** Addressing issues related to hazards and threats associated with biological material. **Experience** Informed decision when expert help is needed to address or expand hazards and threats associated with work with biological material.
7.2.2.3 Risk assessment	**Knowledge** Theoretical background on how to perform a systematic evaluation of factors and identify those which pose risk for a given situation:

Table D.1 *(continued)*

	— risk group classification systems (e.g. WHO:– human, animal, plant pathogens), — hazard identification (e.g. mode of transmission, infectious dose), — sources of lists of controlled biological agents and their historical context, — task risk assessment/job hazard analysis, — determination of risk group for unclassified organisms, — biosafety risk assessment (including engineered organisms), — biosecurity risk assessment, including controls of people, physical measures, and data/information. **Skills** Ability to conduct a systematic evaluation of relevant and cross-sectional factors, including those of both biological and non-biological nature, in order to identify real and potential risks for a given situation. **Experience** Assessment of biological risks of all biological materials used in an organization and addressing biological risk resulting from the combined use of genetic modification of this material.
7.2.2.4 Risk mitigation	**Knowledge** Understand the need for a risk mitigation plan taking into account: — risk reduction methods based on biological risks, — hierarchy of controls of methods for risk reduction, — national implementation of conventions, accountability, and restrictions, — risk mitigation measures proposed by international guidelines. **Skills** Ability to identify risks that require mitigation and develop mitigation strategies that are appropriate and reasonable for a given situation. **Experience** Identification of mitigation strategies to address hazards and threats associated with work with biological material
7.2.3 **Support of personnel**	
7.2.3.1 Occupational health and occupational safety principles and regulatory framework	**Knowledge** Awareness of prevention and surveillance measures to keep laboratory workers healthy: — relevant information on occupational health: — prevention of occupational risks, — medical surveillance, — incident / accident response, — allergens and hypersensitivity, — medical issues related to the use of PPE (e.g., respiratory protection), — immunocompromised workers, — pregnant workers, — partnership between occupational health provider, health safety and environment and biorisk management.

Table D.1 *(continued)*

	Skills Interaction with the occupational health provider on the prevention and surveillance measures contributing the biorisk management perspective. **Experience** Taking into account occupational health and occupational safety principles in: — a plan for prevention, treatment, post-exposure prophylaxis, monitoring, and surveillance to meet requirements of the workplace, — an emergency preparedness plan for potential exposure to hazardous biological material.
7.2.3.2 Communication skills and information management	**Knowledge** Identification of elements of biosafety and biosecurity that are required in the overall risk communication strategy of the organization. **Skills** Ability to effectively communicate in the identified local written language(s) in a manner that is accurate, relevant, and understandable by those within the organization. Development of written documents to maintain an accurate and historical record of biorisk management for the organization. Communication of the elements of biosafety and biosecurity that contribute to the overall culture of safety and security using a range of communication strategies: — communication skills, — conflict resolution strategies, — knowledge systems (e.g. the internet), — information systems (e.g. scientific journal, printed and e-books, PubMed, colleagues), — social computing tools (e.g. social media, email). **Experience** Communication of risk control measures, information about their purpose, function and use to all personnel concerned so that these measures are understood, implemented correctly and are effective.
7.2.3.3 Training	**Knowledge** Need for a biorisk management programme to address the respective audience: — principles of adult education, learning methodologies and presentation skills, — contents of an internal biosafety and biosecurity training programme, — select appropriate tools and learning situations (when and how to train), — whom to train – categories of people within an organization (e.g. management, principal investigators, lab workers, animal facility workers, maintenance workers, cleaning personnel, security personnel, contractors, visitors, students), — trainee progress assessment / competence, — trainer and training course evaluation. **Skills** Assessment of the content and quality of the biorisk management training activities and evaluate their suitability for the organization. **Experience** Provision or organization of biorisk management training adapted to the need of biorisk management in an organization.

Table D.1 *(continued)*

7.2.3.4 Behavioural factors and worker management	**Knowledge** Knowledge on how behavioural factors can lead to intentional and unintentional errors in biorisk management. **Skills** Integration of behavioural factors to risk assessment, accident investigation, training, and other relevant areas of biorisk management. **Experience** Persuasion in promoting good biosafety and biosecurity practices considering cultural and socio-economic considerations.
7.2.3.5 Personnel reliability measures	**Knowledge** Recognition of critical importance of personnel reliability, defined as the quality or state of being reliable, by demonstrating dependability, responsibility, and trustworthiness, in implementation of biorisk management. Awareness of how personal reliability influences the performance level of biorisk management. **Skills** Evaluation whether insufficient biorisk management processes result in lack of personal reliability. Persuasion in promoting good biosafety and biosecurity practices considering cultural and socio-economic differences treating others with respect and seeking win-win outcomes to the biorisk management challenge. **Experience** Addressing personal reliability issues when these are considered as reason for areas of biorisk management not adequately implemented.
7.2.3.6 Personal security	**Knowledge** Recognition of the need for personal security in the context of biorisk management and the need for precautions and response to personal threats based on the biological risks of an organization. **Skills** Definition of the need for personal security based on the biological risks and the context of an organization, including assessment of critical assets that might lead to personal threats. **Experience** Participation in establishment of effective personal security measures based on assessment of the biorisk related threat evaluation of the organization.
7.2.3.7 Ethical concerns related to activities with biological material	**Knowledge** Awareness of the moral principles or values governing, or distinctive of, life sciences research and the moral or societal implications of certain biological research procedures, technologies, or treatments. Awareness of the ethical values that should be considered by an ethical review process of activities with biological material: — gain of function research of concern, — synthetic genomics, — work with select agents, — specimen collection and medical records in clinical laboratories. Understanding the norms of safe and responsible conduct in life sciences critical to counteracting the diversion of biological materials, equipment, or technologies for harmful purposes. Familiarity with applicable legislation and codes of conduct related to scientific integrity and responsible life science, i.e.:

Table D.1 *(continued)*

	— code of conduct, that is statement of values and professional practices of a group of individuals with a common focus, — animal welfare, — declaration of Helsinki, — access and benefit sharing of genetic resources, — clinical trial registration and performance, — studies involving human embryos, gametes, and stem cells. **Skills** Awareness raising to ethical issues that might be related to life science research, taking into account bioethical dilemmas shaped by life sciences professionals' cultural values and beliefs about the concepts of biosafety, biosecurity, and responsible conduct of research. Assistance in the development and maintenance of an ethics framework that supports an ethical biorisk management culture. Participation in risk and benefit consideration of biological research in the organization providing the biorisk management perspective. **Experience** Participate in committees addressing ethical frameworks by contributing the biorisk management perspective.
7.2.3.8 Information management and security	**Knowledge** Understanding of the components of information security including cybersecurity and data security to protect information from unauthorized release and ensure that the appropriate level of confidentiality is preserved to prevent loss of data and sabotage of computer systems. Understanding of the methods of data management and security. **Skills** Performance of risk assessment related to potential loss of valuable biological material and methods and results on research with these materials. Approval of acquisition, possession, use, storage, and transfer of any biological material with misuse potential as part of information management. **Experience** Liaison with IT and/or security subject matter experts as appropriate on measures to be implemented to prevent unauthorized release of sensitive information (e.g. inventories, data, security plans, access codes).
7.2.4 **Controls and containment**	
7.2.4.1 Facility (re)design, construction, commissioning, decommissioning, validation, operation, and maintenance	**Knowledge** Consideration of biorisk management in preventive and corrective maintenance, operations, and decommissioning: — the design team (e.g. architects and engineers, principal investigators, users, management, safety, maintenance, communication), — basic design features of the most important types of facilities, — technical drawings (blueprint reading), — Heating, Ventilation and Air Conditioning (HVAC) systems, — High Efficiency Particulate Air (HEPA) filtration [room and biological safety cabinet (BSC)], — plumbing and vacuum systems, — pressure and airflow monitoring system, — waste disposal and wastewater treatment systems,

Table D.1 *(continued)*

	— auxiliary facilities such as power, water, and gas supply, — access control systems, — construction materials and finishes, — laboratory containment levels 1 and 2, — small animal facilities containment levels 1 and 2, — plant facilities (greenhouses, growth chambers), — large scale bioprocessing principles, — fire protection, escape, and rescue routes – impact on biosafety and biosecurity, — construction process, responsibilities, supervision, liabilities, — testing, validation, and commissioning, — facility operations, maintenance, biosafety, and biosecurity issues (under normal conditions), — facility breakdown and biosafety and biosecurity issues (under emergency conditions, including earthquake, tornados, floods, etc.). **Skills** Ability to review technical documents with an understanding of the basic systems (e.g. HVAC), understand the construction commissioning and validation processes in order to identify the basic design features relevant to that type of facility. **Experience** Consultation with those responsible for the design, construction, transformation, or relocation (e.g. architects, building site management, authorities, project leaders) of facilities.
7.2.4.2 Containment principles	**Knowledge** Understanding the concept of containment, its limitations and the most important types of containment: — primary containment (e.g. Biological Safety Cabinet, isolator, bioreactor, kill tank, IVC), — secondary containment (e.g. laboratory facility), — filtration (e.g. air, vacuum), — air flow and pressure differentials, — biological containment, — safe working practices. **Skills** The ability to apply the knowledge of containment principles to the identified risks which require mitigation through containment practices. The ability to develop appropriate and reasonable emergency response measures which directly relate to the malfunctioning of containment equipment and facility. **Experience** Consultation with those responsible for installation, validation and maintenance of containment equipment and those responsible for participating in emergency response procedures related to the equipment and facility.
7.2.4.3 Selection, verification, certification, and maintenance of equipment	**Knowledge** Overview on the impact on biorisk management resulting from choice, installation, validation, reception of product certificate, and maintenance of equipment:

Table D.1 *(continued)*

	— safety equipment (e.g. biological safety cabinets, autoclaves, isolators, small animal cage systems, dunk tanks – selection, installation, how it works, associated biosafety issues.), — special laboratory equipment (e.g. centrifuges, FACS, homogenizers, microtomes, mechanical pipettors, microscopy and histology – associated biosafety and biosecurity issues), — validation, certification, and maintenance of safety equipment. **Skills** Ability to provide support with selection, verification, certification and maintenance of equipment. **Experience** Consultation with those responsible for the selection, verification, certification and maintenance of equipment.
7.2.4.4 Environmental safety	**Knowledge** Understanding of the environmental risk related to unintentional and accidental release of biological material into the environment. Understanding the impact of the receiving environmental habitats, including air, water, soil, biodiversity, surrounding an organization, from which biological material may be released. Understanding the applicable legislations related to intentional biological release and the impact of compliance on the organization. **Skills** Collection of all relevant information on environmental risks, including: — identification on environmental issues for a given situation, i.e., — animal and plant pests (e.g. mode of transmission, vectors, mode of dispersal, survival in the environment, endemic or exotic), — gene flow, — protection goals, — a plan for prevention, monitoring and surveillance in place, — an emergency preparedness plan for potential unintentional releases of hazardous biological material. **Experience** Integration of environmental safety issues to the biorisk management programme of an organization.
7.2.4.5 Security	**Knowledge** Recognize the need for security and implementation of effective control and monitoring mechanisms based on the biological risks of an organization that contribute to the effectiveness biorisk management. **Skills** Be able to identify the potential for threats based on the biological risks and the context of an organization, including assessment of critical assets that might lead to threats. Identification of targets and weakness of a given facility, the resulting potential threats and how to mitigate them. **Experience** Participate in establishment of effective security measures based on assessment of the threat evaluation of the organization contributing the biorisk management perspective.

Table D.1 *(continued)*

7.2.4.6 Inventory monitoring and control	**Knowledge** Understanding the need and impact of a biological material inventory and the safe and secure storage of biological material. **Skills** Ability to identify information relevant for the biorisk management programme and attributes of that information which may require update. Examples of such records are inventories of (hazardous) biological materials, responsibilities of the staff and training, SOPs, audits and reviews, license applications, notifications, and renewals. **Experience** Consultation with those responsible for biological material inventory on content, methods and update of such an inventory.
7.2.5 Operation and safe practices	
7.2.5.1 Personal protective equipment	**Knowledge** Understanding appropriate types of PPE and their limitations, which may be required for a given situation: — PPE fundamentals, — clothing, — gloves (e.g. lab, hot/cold, animal handling, chemicals), — face and eye protection, — respiratory protection (e.g. types, medical clearance, fit testing, maintenance, training), — shoes and boots. **Skills** The ability to identify PPE which are appropriate for mitigation of exposure risk, based on a given situation. **Experience** Consultation with users and providers of PPE about the appropriate type of PPE based on the biological risk in an organization.
7.2.5.2 Good microbiological techniques	**Knowledge** Components of a safe working environment for a given situation (workplace and workflow): — personal hygiene, — routine housekeeping plan, — planning and preparation of workflow and job assignments, — organizing the workplace, — minimizing aerosols, safe use of sharps and techniques to prevent other types of exposures, — selection and use of appropriate PPE, — selection and use of appropriate safety equipment, — decontamination, cleaning, and waste disposal when finishing work. **Skills** The ability to identify good microbiological techniques, including emergency response measures, which are appropriate for the identified risks associated with the biological material and the context of its intended use. **Experience** Consultation with users on specific work processes requiring specific elements of good microbiological techniques.

Table D.1 *(continued)*

7.2.5.3 Infection control, disinfection, and decontamination	**Knowledge** Understanding of the most essential elements of infection control, disinfection and decontamination, as well as their efficacy: — fundamentals of hygiene, infection control, disinfection, decontamination, and sterilization, — infection and pest control programme, — disinfection methods including selection of materials and reagents, — decontamination methods including selection of materials and reagents, — sterilization methods, — spill management, — validation principles and methods, — monitoring. **Skills** The ability to design a disinfection plan, including validation, for the biological material used in an organization. The ability to communicate to relevant personnel who may be involved in the monitoring, maintenance and repair of equipment which may require to be disinfected or decontaminated. **Experience** Integrate disinfection plan into the biorisk management programme of an organization and relate to other parts of the plan such as, assessment of characteristics of biological material, good microbiological techniques, biological waste management, and relocation of equipment.
7.2.5.4 Biological waste management	**Knowledge** Understanding of the most essential elements of methods of biological waste management and sterilization, as well as their efficacy: — fundamentals of waste collection, labelling, handling, storage, treatment, transport and final disposal, — waste treatment methods and validation, — solid waste, — sharps, — liquid, wastewater treatment, — mixed waste (e.g. biological-chemical, biological-radioactive, biological-chemical-radioactive). Awareness of local requirements on waste management and disposal. **Skills** The ability to identify legislative requirements and develop local processes to securely segregate, inactivate (including validation), package and dispose biological waste. The ability to identify legislative requirements and develop local process to security segregate and package live waste for transport of final decontamination, destruction, and disposal. **Experience** Consultation with users and waste specialist on specific biological waste segregation, treatment and disposal processes for the type biological waste generated in an organization.
7.2.5.5 Emergency preparedness and contingency planning	**Knowledge** Understanding of the content of an emergency preparedness and contingency plan related to the biological risk in an organization:

Table D.1 *(continued)*

	— definitions of biosafety, biosecurity and biothreats, — fundamentals of emergency preparedness and response (integrates approach for all aspects of safety and security, coordination with other agencies/partners), — emergency preparedness (biosafety and biosecurity), — fundamentals of contingency planning/business continuity, — emergency response, — crisis management, — risk communication, — facility protection and surveillance (including environmental threats), — occupational health considerations associated with an emergency, — national biothreat response. **Skills** The ability to identify and communicate emergency preparedness and response needs based on the identified biological risks relevant to the organization. The ability to design and communicate procedures to prevent and manage major emergency situations, e.g. major spills and other unintentional releases, fire, medical, power failures, security incidents, natural disasters, and any other emergency situations which have or may have an element of biological risk. The ability to design table top tutorials and practical drills related to emergency response which have or may have an element of biological risk. **Experience** Integrate emergency preparedness and response plans into the biorisk management programme of an organization. Consultation of emergency preparedness and response plans with first responders, occupational health providers, emergency services, fire brigade.
7.2.5.6 Transport of biological material	**Knowledge** Awareness of relevant requirements and restrictions on transport, and need for import and export permits (license) of biological material, including: — fundamentals of packaging systems and transportation, — practical guidance and documentation, — different modes of transport (e.g. air, road, rail, and water), — procedures for spill, broken containers, and leaks. **Skills** The ability to identify and communicate legislative requirements and containment needs applicable to the identified biological risks to ensure secure and compliant packaging, labelling and means of transport prior to offering for transport. The ability to develop local procedures for management of issues (loss of containment, misdirection, exposure) related to biological risk which may arise as a result of receipt of biological material. **Experience** Informed engagement with users facilitating the application of correct packaging, labelling and means of transport for specific biological material. Information management regarding import and export permits and licenses for biological material.
7.2.6 **Performance evaluation and improvement**	
7.2.6.1 Audits and inspection	**Knowledge** Knowledge of constituents of audits and inspections:

Table D.1 *(continued)*

	— inspection versus audit, — elements, methods and evaluation of an audit, — elements, methods, and evaluation of an inspection, — distinction between non-compliance and non-conformance, — management programme audits, — audit preparation and plan, — combination of document and on-site audits, — communication and performance during an audit, — how to resolve non-compliance and lack of cooperation, — audit reports and corrective actions. Knowledge on systematic approach how the implementation and efficacy is probed during an audit or inspection and actions for improvement. **Skills** The ability to identify, communicate and carry out biorisk management audits based on the biorisk management programme of an organization. **Experience** Planning and realization of biorisk management audits based on the biorisk management programme of an organization.
7.2.6.2 Incident and accident investigation	**Knowledge** Understand the need and content of voluntary, anonymous, non-punitive incident-reporting to cover all incidents and accidents, including near-misses. **Skills** The ability to collect and evaluate relevant facts, and propose corrective actions to prevent or mitigate recurrent accidents or incidents related to biological risk: — incident and accident fact collection, analysis, and evaluation, — record keeping, report writing and reporting, — identify and implement effective corrective actions. **Experience** Integration of incident and accident reporting into emergency preparedness and response plans, preparation of reporting forms and communication to all involved parties of an organization.
7.2.7 International and national regulatory framework, standards, guidelines, and conventions	**Knowledge** Familiarity, understanding, and application of the regulatory framework, including standards and guidelines, in all areas of biorisk management. **Skills** The ability to monitor changes in local, national, and international legislation and guidelines which are or may be relevant to the biorisk management programme. The ability to adapt or make recommendations for adaptation of the biorisk management programme to reflect those changes. This list is indicative only and not all inclusive:

Table D.1 *(continued)*

- worker protection (prevention of occupational risks):
- regulations for contained activities:
  - working with pathogens (human, animal, opportunistic) – worker protection (lab and hospital environment),
  - working with engineered organisms,
  - working with animals (including animal care issues),
  - working with plants (environmental protection, phytosanitary regulations).
- deliberate release and field activities:
  - microbiological issues,
  - plant issues (e.g. risk assessment),
  - animal issues (e.g. risk assessment).
- international and national transport, import, export regulations:
  - International Air Transport Association (IATA)[6],
  - International Civil Aviation Organization (ICAO)[7],
  - International Maritime Organization (IMO)[8],
  - import regulations,
  - UN Model Regulations for the Transport of Dangerous Goods[9].
- other regulations:
  - gene therapy,
  - emergencies,
  - waste regulations,
  - dual use / select agent regulations.
- conventions:
  - Convention on Biological Diversity (CBD)[10],
  - Access and Benefit Sharing of Genetic Resources (ABS)[11],
  - Cartagena Protocol on Biosafety[10],
  - Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters[11],
  - Biological and Toxin Weapons Convention (BTWC)[12],
  - UN Security Council Resolution 1540 (2004)[13],
  - Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)[14],
  - International Plant Protection Convention (IPPC)[15].