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AGREEMENT

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Biosafety professional competence

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

The main activity of a CEN Workshop is the development and publication of the CEN Workshop Agreement (CWA). The CWA is a voluntary agreement applicable internationally and does not have the force of regulation. The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN-CENELEC Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation. This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

This CEN Workshop commenced in December 2009 with a combined kick-off and first plenary meeting. It had its third and final plenary meeting in May 2011. There was also a public comment phase. More information on CEN and the CEN Workshops can be found at: www.cen.eu

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties on 2011-06-30, the constitution of which was supported by CEN following the public call for participation made on 2009-12-17.

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

A list of the individuals and organizations which supported the technical consensus represented by the CEN Workshop Agreement is available to purchasers from the CEN Management Centre. These organizations were drawn from the following economic sectors: American Biological Safety Association (ABSA), Basler & Hofmann AG, CH, Bayer CropScience, BE, Belgian Biosafety Professionals (BBP), BE, BioSafety Solutions (LLC), US, Biosafety training & consultancy (BT&C), NL, Bundesforschungsinstitut für Tiergesundheit (FLI), DE, Centro Nacional de Biotecnología (CSIC), ES, Centro de Investigación en Sanidad Animal, ES, Chinese Center for Disease Control and Prevention, CN, Det Norske Veritas (DNV), NO, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, DE, European Biosafety Association (EBSA), Federal Ministry for Health and Women, AT, Federal Office of Public Health, CH, GlaxoSmithKline, ES, Hannover Medical School, DE, Health Protection Agency, GB, Instituto de Diagnóstico y Referencia Epidemiológicos (InDRE), MX, Instituto Valenciano de Investigaciones Agrarias (IVIA), ES, Institute of Reference Materials and Measurement, BE, Institute of Infectious Diseases Japan, JP, Institute of Safety in Technology and Research, GB, International Federation of Biosafety Associations (IFBA), Karolinska Institutet, SE, Leids Universitair Medisch Centrum (LUMC), NL, Medical Research Council, GB, Mexican Biosafety Association, MX, National Institute for Occupational Safety and Health at Work, ES, Public Health Agency of Canada, CA, Sandia National Laboratories, US, Sanofi-Aventis, FR, Statens Serum Institute, DK, Swedish Institute for Infections, SE, Swiss Federal Office for the Environment, Office of waste, water, energy and air Kanton Zürich, CH, Telstar Projects (Tpro), ES, University of Edinburgh, GB.

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The final review/endorsement round for this CWA was started on 2011-05-11 and was successfully closed on 2011-06-30.The final text of this CWA was submitted to CEN for publication on 2011-07-26.

This CEN Workshop Agreement is publicly available as a reference document from the CEN National Members of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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

“With the support of the Prevention, Preparedness and Consequence Management of Terrorism and other Security-related Risks Programme
European Commission - Directorate-General Home Affairs"

"This project has been funded with the support of the Prevention, Preparedness and Consequence Management of Terrorism and other Security-related Risks Programme European Commission - Directorate-General Home Affairs". This publication [communication] reflects the views only of the author, and the Commission cannot be held responsible for any use which may be made of the information contained therein".

Introduction

This CEN Workshop Agreement (CWA) addresses the broad range of competences and abilities required by individuals who advise management and personnel on the safe and secure use of biological material and who manage and support the development and implementation of relevant management programmes or systems. It takes into account the roles that these individuals play in the workplace and the tasks that they are required to perform. While this document is primarily intended for biosafety professionals, it will also be of interest for employers (managers) and trainers.

As stated by WHO (WHO/CDS/CSR/LYO/2004.11, 2004), “effective biosafety practices are the very foundation of laboratory biosecurity activities”, hence biosafety and biosecurity cannot be dissociated. The application of biosafety and laboratory biosecurity management, also called biorisk management (CWA 15793:2008), is the working area of the biosafety professional.

The job titles of persons with relevant biosafety and biosecurity responsibilities show significant variation from organization to organization. Moreover, within a given organization there may be more than one person assigned relevant responsibilities which, especially in larger and/or more complex organizations may vary according to their specific roles. In many organizations, the roles will include responsibilities for both biosafety and biosecurity. Irrespective of this variability there are common elements of competence and this document lists the requirements to ensure that such individuals, however their job is titled, have appropriate attributes that can be recognized at all levels, within an organization and across regional or national borders.

This CWA was developed in response to identified needs across the international community informed by the experience of practitioners through professional organizations and WHO.

While this CWA is not intended to provide guidance on certification or accreditation of courses or programmes, it is written and structured in such a way that it could provide a means to facilitate future initiatives of this type. In this context it may be useful in the development of new programmes as well as courses integrated into existing certified trainings.

Application

This document is intended to provide a framework for those who work in the biosafety and biosecurity fields to evaluate their competence as a professional and to identify areas for development. In the context of this document biosecurity is restricted to laboratory biosecurity.

The requirements of this CWA are intended to be applicable to all organizations, regardless of type or size of the facility and biological materials used, where the management has identified the need to appoint a biosafety professional. In general, a biosafety professional is appointed where the risk posed by the work with biological materials requires biosafety and biosecurity measures.

This document does not in itself impose any obligation upon anyone to follow it. However, such an obligation may be imposed, for example, by legislation or by a contract. In order to be able to claim compliance with this document, the user needs to be able to identify the requirements he/she is obliged to satisfy. The user also needs to be able to distinguish these requirements from other provisions where there is a certain freedom of choice.

This document is structured in a manner where the specific requirements pertaining to each individual clause are defined and stated in regular text. A requirement is indicated by use of the verbal form "shall". Informative guidance has been provided as an aid in interpreting the requirements where considered appropriate. This guidance is in the form of notes, in association with the pertaining requirements clause and uses the terms “should” (recommendation), “may” (allowance) and “can” (possibility). Contents of the notes shall not in any way be construed as being requirements; the same is valid for the text in the informative Annexes.

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

Where any requirements of this document are not applicable, these can be considered for exclusion. Where exclusions are made, claims of conformity to this CWA are not acceptable, unless such exclusions do not affect the biosafety professional's ability to perform in the manner required by the CWA. Any claims of exclusion shall be explained and documented.

Compliance with national and local regulatory standards and regulations is a requirement for any organization. International, national or regional regulations or directives may address specific topics covered in this CWA. Where any part of this document is in conflict with any legal requirement, the conflicting part of the document may be eligible for exemption. If the legal requirements neither meet nor exceed the intent of the CWA, compliance with the CWA cannot be claimed.

1 Scope

This CEN Workshop Agreement (CWA) describes competence areas of a biosafety professional. International, national or regional regulations or directives take precedence over this CWA.

This CWA provides in informative annexes a model role profile and model tasks of a biosafety professional in an organization; these help to define competence requirements. It also provides model training specifications for reaching competence.

2 Informative references

Three central guidance documents for biosafety professional competence and the development of this CWA are:

— CWA 15793:2008 Laboratory biorisk management standard;

— WHO Laboratory Biosafety Manual (WHO/CDS/CSR/LYO/2004.11, 2004);

— WHO Biorisk Management: Laboratory Biosecurity Guidance (WHO/CDS/EPR/2006.6, Sept. 2006).

3 Terms and definitions

For the purposes of this document, the terms and definitions given in CWA 15793:2008 apply except where they have been adapted and are defined below.

3.1
biological agent
naturally occurring or genetically modified organism, capable of replication or transferring genetic material and potentially able to provoke infection, allergy or toxicity in humans, animals or plants. This includes bacteria, fungi, viruses, viroids, prions, endoparasites, human, animal and plant cell cultures

3.2
biological material
any material which includes:

— biological agents;

— any substance that may contain biological agents;

— any substance produced by or derived from a biological agent that may present a hazard to health (for example toxins, allergens) or the environment;

— animals and plants or parts thereof that may contain biological agents;

— animals and plants or parts thereof that are genetically modified;

— animals and plants or parts thereof that may provoke infection, allergy or toxicity in humans, animals or plants.

3.3
biorisk management
management of risks arising from adverse events, including accidental release, unintentional exposure, loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release

3.4
biosafety
containment principles, technologies and practices that are implemented to prevent the unintentional exposure to biological material, or their accidental release

[adapted from: WHO/CDS/EPR/2006.6]

3.5
biosafety professional
individual who has a broad range of competences and abilities to advise management and personnel on the safe and secure use of biological material and to manage and support the development and implementation of relevant management programmes or systems

NOTE 1 This individual may be employed under a variety of titles such as biosafety officer, biosafety advisor, biosafety manager, biosafety coordinator, biorisk management advisor.

NOTE 2 A biosafety professional may be working in an organization applying a management system such as ISO 9001, ISO 14001, OHSAS 18001, CWA 15793.

3.6
biosecurity
protection, control and accountability for biological materials within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release

NOTE In the context of this document, biosecurity is restricted to laboratory biosecurity. Laboratory includes animal and manufacturing facilities. Use of the term in this document does not encompass all aspects of biosecurity in the sense of national or regional control measures to prevent the dissemination of alien species and pathogens.

[adapted from: WHO/CDS/EPR/2006.6]

3.7
competence
demonstrated ability to apply knowledge, skills and attitudes for achieving observable results

NOTE With reference to this CWA to be competent means to have knowledge, skills and experience to perform designated task(s).

[from CEN Guide 14:2010]

3.8
containment
set of measures including biological containment, practices, safety equipment and facility safeguards that protect laboratory workers, the community and the environment from exposure to biological material when stored or worked with

3.9
containment level
containment level designations are based on a composite of facility design and construction, equipment, practices and operational procedures required for working with a range of biological material

In most international systems, containment measures appropriate to protect humans, animals, plants and the environment from exposure to biological materials are based on a four category approach to cover the spectrum of risk to be managed. In this document containment level 1 represents the lowest and containment level 4 represents maximum containment.

3.10
dual-use
work, materials or technologies that can be reasonably anticipated to provide knowledge or products that could be deliberately misapplied by others to pose a threat to public health, agriculture, plants, animals or the environment

[adapted from NSABB]

3.11
facility
operational unit and associated building(s) and equipment

NOTE 1 This includes the laboratory, together with the supporting infrastructure, equipment and services including ancillary rooms such as airlocks, changing rooms, sterilizing rooms and storage rooms.

NOTE 2 In the context of this CWA additional facility types may also need to be considered which fall outside the definition of “laboratory” (e.g. vivaria, aquaria and green houses).

[adapted from CWA 15793:2008]

3.12
knowledge
outcome of the assimilation of information through learning. Knowledge is the body of facts, principles, theories and practices that is related to a field of work or study

[from CEN Guide 14:2010]

3.13
laboratory
room within a facility, designated for work with biological material

[adapted from CWA 15793:2008]

3.14
qualification
skill, training, knowledge, experience for personnel to properly perform to a particular level

[adapted from EN 4179:2005]

3.15
senior manager
manager with significant operational, budgetary and personnel authority at the departmental or higher level. This may include members of top management

[from CWA 15793:2008]

3.16
skills
ability to apply knowledge and use know-how to complete tasks and solve problems

[from CEN Guide 14:2010]

3.17
top management
top management includes Officers (Director General, Chief Executive Officer, Chief Operating Officer, Chief Financial Officer, etc.) and Directors of the organization

[from CWA 15793:2008]

4 Abbreviations

A & E – Architects and Engineers

ABS – Access and Benefit Sharing of genetic resources

BMBL – Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH)

BSC – Biological Safety Cabinet also known as microbiological safety cabinet

BTWC – Biological and Toxins Weapons Convention

CBD – Convention on Biological Diversity

CDC (US) – Centers for Disease Control and Prevention (US)

CEN – Comité Européen de Normalisation (European Committee for Standardization)

CITES - Convention on International Trade in Endangered Species of Wild Fauna and Flora

CWA – CEN Workshop Agreement

FACScan – Fluorescence Activated Cell Sorting Scan flow cytometry

GM – Genetically Modified

GMM – Genetically Modified Microorganisms

GMO – Genetically Modified Organism

GMP – Good Manufacturing Practices

GMT – Good microbiological techniques

HEPA – High Efficiency Particulate Air

HSE – Health Safety and Environment

HVAC – Heating, Ventilation and Air Conditioning

IATA – International Air Transport Association

IEC – International Electrotechnical Commission1

IPPC – International Plant Protection Convention

ISTR – Institute of Safety in Technology and Research (GB)

LAI – Laboratory Acquired Infection

NIH – National Institutes of Health (US)

NSABB - US National Science Advisory Board for Biosecurity

OIE – World Organisation for Animal Health

PI – Principal Investigator

POR – Prevention of Occupational Risks

PPE – Personal Protective Equipment

SOP – Standard Operating Procedure

TSE – Transmissible Spongiform Encephalopathies

WHO – World Health Organisation

5 Role of the biosafety professional in an organization

The biosafety professional shall

— give advice and guidance to management and personnel on biosafety and biosecurity issues;

— support the design, implementation and monitoring of efficient biorisk management programmes or systems;

— be able to work with occupational health, safety, environmental and other professionals to ensure that suitable biosafety and biosecurity preventive measures are in place.

NOTE 1 CWA 15793 states “This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.”

NOTE 2 To achieve this, organisations may need a fulltime appointment in a large organization or a part-time appointment of a trained and experienced laboratory worker in smaller sized operations or an external consultant. Because of this, it is not possible to specify a single role profile, however, a model role profile of the biosafety professional is given in informative Annex A of this document.

6 Biosafety professional background qualifications

6.1 The biosafety professional shall have relevant education to ensure safe and secure handling of biological material.

NOTE The biosafety professional should have an education in the life sciences or other relevant fields (e.g. safety, industrial hygiene, engineering) supplemented by appropriate levels of biology. This individual should also have appropriate knowledge to understand the activities performed in a facility.

6.2 The biosafety professional shall have relevant experience working at, or overseeing facilities using biological material. The experience required shall be sufficient to demonstrate competence and will depend on risk level with increasing experience required as the risks increase.

NOTE The experience should include working at or overseeing work at the highest biosafety containment level established at the workplace or, where a well established network is available to support his/her day to day work, at one containment level lower.

7 Competences

7.1 General

Different competences are required for working under different environments. Also, the depth of knowledge and skills required will increase as the risk of the activity increases. This section addresses core competences (7.2) and additional specialized competences (7.3) as well as continuing professional development (7.4).

NOTE Examples of different work environments include but are not limited to:

— laboratories at different containment levels (including GMO work);

— activities with animals at different containment levels (including infected animals and GMOs);

- activities with plants at different containment levels (conventional, GM, noxious weeds, pests and diseases);
- activities with arthropods at different containment levels;
- activities with parasites at different containment levels;
- clinical/diagnostic laboratories;
- gene therapy activities;
- large scale activities;
- activities related to facility infrastructure (kill tanks, HEPA filter banks, HVAC, etc.).

7.2 Core competences

All biosafety professionals shall be able to demonstrate the core competences listed below.

NOTE The competences listed below are required to carry out the tasks described in informative Annex B (Model tasks of the biosafety professional in an organization) and these competences can be acquired in part by training programmes such as those set out in informative Annex C (Model training specifications). An overview of the relationship between competences, tasks and training specifications are presented in informative Annex E.

7.2.1 General principles of microbiology, biochemistry and cell biology

The biosafety professional shall be able to understand

- the basic characteristics of the principal taxonomic groups of biological agents;
- the main factors that contribute to their ability to cause disease;
- the effects of biological toxins.

NOTE This competence is relevant to task B.2 (Biorisk assessment and management) of Annex B and can be fulfilled by training specification C.2.1.1.1 (General principles of microbiology, biochemistry and cell biology) of Annex C.

7.2.2 General principles of molecular biology and genetic engineering

The biosafety professional shall be able to understand genetic modification technology and describe the potential risks to workers and the environment.

NOTE This competence is relevant to task B.2 (Biorisk assessment and management) of Annex B and can be fulfilled by training specification C.2.1.1.2 (General principles of molecular biology and genetic engineering) of Annex C.

7.2.3 Biological and other hazards in the work area

The biosafety professional shall be able to

- understand the risks associated with the use of biological material and be aware of other hazards in the workplace;
- be aware of occupational infections that have led to the development of current biosafety practices.

NOTE This competence is relevant to task B.2 (Biorisk assessment and management) of Annex B and can be fulfilled by training specification C.2.1.2.1 (Biological and other hazards in the work area) of Annex C.

7.2.4 Occupational health and biosafety

The biosafety professional shall be able to understand the importance of occupational health as relevant for the safe handling of biological material.

NOTE This competence is relevant to task B.13 (Occupational health) of Annex B and can be fulfilled by training specifications C.2.1.2.2 (Occupational health and biosafety) and C.2.1.2.3 (Human factors) of Annex C.

7.2.5 Human factors

The biosafety professional shall be able to understand human factors (e.g. behaviour, reliability, ergonomics) leading to intentional and unintentional errors. The biosafety professional shall have the skills to influence behaviours and risk perception, and be persuasive in promoting good biosafety and biosecurity practices taking into account cultural and socio-economic considerations.

NOTE This competence is relevant to task B.14 (Human factors), B.2 (Biorisk assessment and management), B.6 (Biosecurity), B.13 (Occupational health) and B.18 (Decontamination) of Annex B and can be fulfilled by training specification C.2.1.2.3 (Human factors) of Annex C.

7.2.6 Containment principles

The biosafety professional shall understand the concept and details of various types of containment and their limitations (see definition of containment in 3.8).

NOTE This competence is relevant to task B.2 (Biorisk assessment and management), B.15 (Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance), B.16 (Selection, validation, certification and maintenance of equipment) and B.17 (Personal protective equipment (PPE)) of Annex B and can be fulfilled by training specification C.2.1.2.7 (Facility design, construction, commissioning, decommissioning, validation, operation and maintenance), C.2.1.2.8 (Selection, validation, certification and maintenance of equipment), C.2.1.2.9 (Good microbiological techniques (GMT)) and C.2.1.2.10 (Personal protective equipment (PPE)) of Annex C.

7.2.7 Biorisk assessment and management

The biosafety professional shall be able to carry out a risk assessment for a given situation and decide on mitigation strategies. The biosafety professional shall be able to provide guidance on biological hazard identification, risk assessment and management to project leaders, principal investigators, management and other relevant personnel.

NOTE This competence is relevant to task B.2 (Biorisk assessment and management) and B.6 (Biosecurity) of Annex B and can be fulfilled by training specification C.2.1.2.5 (Biorisk assessment and management) of Annex C.

7.2.8 Environmental safety

The biosafety professional shall be able to:

— understand the risks for the environment associated with work involving biological material;

— design suitable measures to prevent the escape of biological material into the environment;

— design suitable monitoring strategies to evaluate prevention measures.

NOTE This competence is relevant to task B.21 (Environmental safety) of Annex B and can be fulfilled by training specification C.2.1.2.6 (General principles of environmental safety) of Annex C.

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

The biosafety professional shall be able to identify facility design and construction issues that are relevant to biorisk management including physical security aspects determined by the risk assessment process. The biosafety professional shall be able to understand the basic systems and design features of a typical facility; understand the construction, commissioning and validation processes; and shall have knowledge on basic (re)design features of the most important types of facilities. The biosafety professional shall also be able to identify and describe the biosafety and biosecurity issues in preventive and corrective maintenance, operations and decommissioning.

NOTE This competence is relevant to task B.15 (Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance) and B.16 (Selection, validation, certification and maintenance of equipment) of Annex B and can be fulfilled by training specification C.2.1.2.7 (Facility design, construction, commissioning, decommissioning, validation, operation and maintenance), and C.2.1.2.8 (Selection, validation, certification and maintenance of equipment) of Annex C.

7.2.10 Selection, validation, certification and maintenance of equipment

The biosafety professional shall be able to understand the biosafety and biosecurity implications of equipment in the facility and to advise on choice, correct use, installation, validation, certification and maintenance.

NOTE This competence is relevant to task B.6 (Biosecurity) and B.16 (Selection, validation, certification and maintenance of equipment) of Annex B and can be fulfilled by training specification C.2.1.2.8 (Selection, validation, certification and maintenance of equipment) of Annex C.

7.2.11 Good microbiological techniques (GMT)

The biosafety professional shall be able to understand and apply good microbiological techniques in order to guide staff to enable them to create and maintain a safe working environment (workplace and workflow).

NOTE 1 A description of good microbiological techniques is provided in the WHO Laboratory Biosafety Manual (WHO/CDS/CSR/LYO/2004.11, 2004). The main subjects cover laboratory techniques, contingency plans and emergency procedures, disinfection and sterilisation and introduction to transport of infectious substances.

NOTE 2 This competence is relevant to task B.4 (Guidance, best practices and standard operating procedures (SOPs)) of Annex B and can be fulfilled by training specification C.2.1.2.9 (Good microbiological techniques (GMT)) of Annex C.

7.2.12 Personal protective equipment (PPE)

The biosafety professional shall be able to advise on the appropriate types of PPE required for a given situation, and discuss potential problems and solutions when the equipment is introduced and used.

NOTE This competence is relevant to task B.17 (Personal protective equipment (PPE)) of Annex B and can be fulfilled by training specification C.2.1.2.10 (Personal protective equipment (PPE)) of Annex C.

7.2.13 Infection control, disinfection, decontamination and sterilisation

The biosafety professional shall be able to understand the most important elements of infection control, disinfection, decontamination and sterilisation, as well as their efficacy. The biosafety professional shall be able to advise on choice and the correct use of methods.

NOTE This competence is relevant to task B.18 (Decontamination), B.2 (Biorisk assessment and management), B.4 (Guidance, best practices and standard operating procedures (SOPs)), B.10 (Accident / incident reporting and investigation), B.13 (Occupational health) and B.19 (Biological waste management) of Annex B and can be fulfilled by training specification C.2.1.2.11 (Infection control, disinfection, decontamination, and sterilisation) of Annex C.

7.2.14 Biological waste management

The biosafety professional shall be able to develop a biological waste management plan, including validation and verification, and advise on implementation of the plan.

NOTE This competence is relevant to task B.18 (Decontamination) and B.19 (Biological waste management) of Annex B and can be fulfilled by training specification C.2.1.2.11 (Infection control, disinfection, decontamination, and sterilisation) and C.2.1.2.12 (Biological waste management) of Annex C.

7.2.15 Emergency preparedness and response

The biosafety professional shall be able to develop an emergency preparedness and response plan and advise on its implementation.

NOTE This competence is relevant to task B.7 (Emergency plans and exercises) of Annex B and can be fulfilled by training specification C.2.1.2.13 (Emergency preparedness and response) of Annex C.

7.2.16 Incident and accident investigation

The biosafety professional shall understand methods of incident (including near misses) and accident investigation and shall be able to apply them and shall contribute to actions to prevent reoccurrence.

NOTE This competence is relevant to task B.10 (Accident / incident reporting and investigation) of Annex B and can be fulfilled by training specification C.2.1.2.14 (Incident and accident investigation) of Annex C.

7.2.17 Biorisk management programme

The biosafety professional shall be able to develop and support the implementation of a biorisk management programme and understand how the elements (e.g. physical, personal and informational biosecurity measures) in such a programme are interrelated so as to achieve the objectives of the programme. The biosafety professional shall be able to understand and apply the core principles and practices associated with a management system approach that incorporates continual improvement and be able to communicate them.

NOTE This competence is relevant to task B.1 (Biorisk management programme) B.6 (Biosecurity) and B.11 (Records) of Annex B and can be fulfilled by training specification C.2.1.2.15 (Biorisk management programme) of Annex C.

7.2.18 Inventory monitoring and control

The biosafety professional shall be able to understand and communicate the importance of maintaining an accurate inventory of biological material used and/or stored at the site and the associated controls commensurate with risk.

NOTE This competence is relevant to task B.1 (Biorisk management programme), B.6 (Biosecurity) and B.11 (Records) of Annex B and can be fulfilled by training specification C.2.1.2.15 (Biorisk management programme) of Annex C.

7.2.19 Physical security

The biosafety professional shall be able to understand and communicate the importance of implementing and maintaining the physical security measures determined as part of the risk assessment process.

NOTE This competence is relevant to task B.1 (Biorisk management programme), B.2 (Biorisk assessment and management), B.6 (Biosecurity), B.15 (Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance) of Annex B and can be fulfilled by training specification, C.2.1.2.5 (Biorisk assessment and management), C.2.1.2.7 (Facility design, construction, commissioning, decommissioning, validation, operation and maintenance) and C.2.1.2.15 (Biorisk management programme) of Annex C.

7.2.20 Training

The biosafety professional shall have sufficient knowledge on training principles in order to understand training needs and to develop, deliver and validate an internal biosafety and biosecurity (re)training programme tailored to different audiences.

NOTE This competence is relevant to task B.8 (Training) of Annex B and can be fulfilled by training specification C.2.1.2.16 (Training) of Annex C.

7.2.21 Communication skills and information / knowledge systems

The biosafety professional shall be able to transfer information clearly and convincingly to an audience including management, laboratory workers, ancillary personnel and external parties. The biosafety professional shall be able to communicate with personnel at all levels with the proper degree of understanding and sensitivity.

NOTE This competence is relevant to task B.9 (Communication) of Annex B and can be fulfilled by training specification C.2.1.2.17 (Communication skills and information / knowledge systems) of Annex C.

7.2.22 Audits and inspections

The biosafety professional shall be able to carry out biosafety and biosecurity audits and inspections, identify failures, non-conformities, areas for improvement and monitor corrective actions.

NOTE This competence is relevant to task B.11 (Records) and B.12 (Audits and inspections) of Annex B and can be fulfilled by training specification C.2.1.2.18 (Audits and inspections) of Annex C.

7.2.23 Packaging, shipping, transport, import and export of biological material

The biosafety professional shall be able to identify and understand the need to apply relevant regulations and guidelines on safe and secure transport, import and export, including correct packaging, labelling and means of transport for biological material and be able to support persons responsible for such transport

NOTE This competence is relevant to task B.20 (Transport / export / import) of Annex B and can be fulfilled by training specification C.2.1.2.19 (Packaging, shipping, transport, import and export of biological material) of Annex C.

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

The biosafety professional shall be able to demonstrate understanding and applicability of national and international regulatory frameworks, including standards, guidelines and conventions, in all areas of biosafety and biosecurity to ensure compliance.

NOTE This competence is relevant to task B.3 (Regulations and guidelines, permits) and B.4 (Guidance, best practices and standard operating procedures (SOPs)) of Annex B and can be fulfilled by training specification C.2.1.3.1 (International regulatory framework, standards, guidelines and conventions) and C.2.1.3.2 (National regulatory framework, standards and guidelines) of Annex C.

7.2.25 Bioethics

The biosafety professional shall be aware of bioethics issues applicable to the organisation’s field of activities and be able to demonstrate familiarity with applicable bioethics legislation and codes of conduct.

NOTE This competence is relevant to task B.3 (Regulations and guidelines, permits) and B.4 (Guidance, best practices and standard operating procedures (SOPs)) of Annex B and can be fulfilled by training specification C.2.1.3.3 (Bioethics) of Annex C.

7.3 Specialized competences

Different or more complex and/or higher risk environments shall require demonstration by the biosafety professional of additional specialized competences.

NOTE 1 Examples of these may include knowledge of, or experience in:

— laboratory experiments with small animals (e.g. rodents, fish); large animals (e.g. cattle, swine, equine); and non-human primates;

— working with plants, plant pests, pathogens and diseases;

— working with arthropods;

— Transmissible Spongiform Encephalopathies (TSE);

— large scale production (bioprocessing);

— biosafety and Good Manufacturing Practices (GMP);

— clinical / diagnostic laboratory activities;

— gene therapy activities;

— high containment.

NOTE 2 Core and additional competences can be acquired through a variety of means such as training and experience.

Knowledge and competence may, for example, be demonstrated by:

— an evidence portfolio of all relevant areas, e.g. ISTR portfolio scheme listed in Annex D

— preparing a range of practical examples such as:

- preparation of a dossier;
- completion of a risk assessment case or emergency scenario.

7.4 Continuing professional development

To maintain competence, the biosafety professional shall engage in continuing professional development to maintain requisite knowledge and qualifications needed to manage the biorisk management programme.

Annex A
(informative)

Model role profile of biosafety professional in an organization

A.1 General

The safe and secure handling of biological material is the responsibility of the management of an organization handling such material. However, associated tasks can be delegated to a biosafety professional. The organisation may need a fulltime biosafety professional or multiple appointments in a large or more complex organization, e.g. university, national institute or pharmaceutical company; a part-time appointment of a trained and experienced laboratory worker in smaller sized operations; or an external consultant. Because of this it is not possible to specify a single role profile, but the following key elements should be addressed.

A.2 The biosafety professional should be appointed by top/senior management

There should be a written appointment by top/senior management in which the tasks of the biosafety professional are described as well as his/her responsibilities and authority. This should cover at least the tasks and authority defined in national/local legislation.

A.3 The biosafety professional should have an independent position in the organization

The biosafety professional should be able to maintain an independent position regarding his/her role that is based on scientific information, regulatory requirements and internationally recognized best practices.

The biosafety professional should be respected as a competent professional, based on education and experience, and be free to express honest, objective and expert opinion within the organisation.

A.4 The biosafety professional should report to and advise the responsible top/senior manager

The biosafety professional should have a direct reporting line or access to top/senior management on subjects of biosafety and biosecurity.

A.5 The biosafety professional should be the point of contact for all biosafety matters, internally as well as externally

It should be ensured that the biosafety professional is the key contact person for biosafety within the organization (for management, principal investigators, technical staff, etc.). He/she should also normally be the first point of contact for regulators, external inspectors, and may be the first point of contact for other third parties in all biosafety matters.

A.6 The biosafety professional should be a member of the team(s) that ensures safety and security within an organisation

The function of the biosafety professional should not be seen as an isolated role within an organisation. The biosafety professional needs to coordinate his/her activities with those responsible for other areas including

health, safety and environment management and occupational health. Preferably, the biosafety professional should be a member of and/or have a key role within the organisation's health, safety and environment function.

Risks associated with the security of biological material are just one element of the security risk profile of an organisation. While other elements do not generally require input from the biosafety professional, where there is a significant risk from relevant material, the key role of the biosafety professional must be recognised. The biosafety professional should know all activities involving biological material of dual use potential and should be involved in the approval of acquisition, use, storage and disposal of such material.

Annex B
(informative)

Model tasks of the biosafety professional in an organization

B.1 Biorisk management programme

The biosafety professional should assist management to develop a biosafety and biosecurity policy appropriate to the nature and scale of the risk associated with the organisation and the work to be performed. The policy should set the biosafety and biosecurity goals and objectives for the organization.

The biosafety professional should, together with the senior management, project leaders and technical services personnel, develop a biorisk management programme appropriate to the nature and scale of the work with hazardous biological material planned and performed by the organization.

B.2 Biorisk assessment and management

The foundation for a biorisk management programme is the management of risk arising from the organization's activities. The biosafety professional should provide guidance on hazard identification, risk assessment and control to the management, project leaders and other relevant personnel.

B.3 Regulations and guidelines, permits

The biosafety professional should work with senior managers to monitor changes in relevant national and international legislation and guidelines and ensure that these are reflected in the biorisk management programme. The biosafety professional should make relevant information available, e.g. official notification, permit requirements, changes in regulations, to principal investigators and management. The biosafety professional should maintain and facilitate the interaction with authorities on biosafety and biosecurity matters.

B.4 Guidance, best practices and standard operating procedures (SOPs)

The biosafety professional should provide guidance to laboratory staff and ancillary personnel on best biosafety and biosecurity practices for the development of standard operating procedures.

B.5 Biosafety Committee

The biosafety professional should advise the management on the establishment and role of a biosafety committee, addressing all biological materials. The biosafety professional should be a member and can be the convenor of the biosafety committee.

B.6 Biosecurity

Laboratory biosecurity should be an integral part of the security plan of an organization based on risk and threat assessment, including physical, personnel and data considerations, to prevent loss, theft, unauthorised possession, misuse, or diversion of biological material with dual-use potential. Laboratory biosecurity should be coordinated with the biosafety activities. The biosafety professional should raise awareness of dual-use potential of biological material. The biosafety professional should be involved in the approval of acquisition,

possession, use, storage and transfer of any biological material with misuse potential. A biological material inventory and the safe and secure storage of biological material should be included in the security plan.

The biosafety professional should advise senior management on measures to be implemented to minimize the potential for unauthorized release or removal of biological materials from the facility. This should involve appropriate measures to identify vulnerabilities and implementation of effective control and monitoring mechanisms.

The biosafety professional should liaise with IT and/or security subject matter experts as appropriate to advise senior management on measures to be implemented to prevent unauthorized release of sensitive information (e.g., inventories, data, security plans, access codes).

B.7 Emergency plans and exercises

The biosafety professional should ensure development and review of procedures and the provision of instructions in order 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, involving biological material. The biosafety professional should be involved in a training programme for emergency preparedness. Any training programme should include practical exercises.

B.8 Training

The biosafety professional should

— ensure that information on hazards associated with biological material and advice on biosafety and biosecurity is provided to all employees, sub-contractors and visitors, including maintenance and cleaning staff, students and temporary staff;

— ensure there is an awareness of the risks and responsibilities involved;

— coordinate training and retraining on biosafety and biosecurity procedures and practices, e.g. risk assessment methodology, the use of safety equipment and personal protective equipment (PPE), and the safe use of new appliances and methods.

B.9 Communication

Communicating biosafety and biosecurity information to staff and to the community is the responsibility of the management of an organisation. The biosafety professional should provide information and advice on biosafety and biosecurity to corporate and local communications functions for dissemination internally and externally where required.

B.10 Accident / incident reporting and investigation

The biosafety professional should ensure there is a documented procedure to define, record, analyze and learn from accidents and incidents. The biosafety professional should ensure that laboratory staff and ancillary personnel will be trained to recognize and report any accident/incident that might have an implication for exposure to biological material. The biosafety professional should ensure that all accidents and incidents relating to use or misuse of biological material are investigated, the results recorded and that any recommendations are implemented by changes in the work practices, SOPs and reflected in the risk assessment. All findings and decisions should be communicated to laboratory staff and management. Reporting to the management should be made at regular intervals and immediately when deemed necessary.

B.11 Records

The biosafety professional should ensure that records relevant for the biorisk management programme are kept and up-dated. 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.

B.12 Audits and inspections

The biosafety professional should ensure that there is an appropriate plan for regular internal inspections and audits in locations where biological material is in use to monitor the compliance with safety and security measures. There should be feedback through a comprehensive inspection/audit documented report with recommendations on actions to be taken and a follow-up on these actions. The biosafety professional should provide guidance and/or recommendations with respect to setting appropriate corrective actions to management with a timescale for implementation.

B.13 Occupational health

The biosafety professional should work with the occupational health provider and human resources to ensure that

— relevant information on occupational health is provided;

— a plan for prevention, treatment, post-exposure prophylaxis, monitoring and surveillance is in place to meet requirements of the workplace;

— an emergency preparedness plan is developed for potential exposure to hazardous biological material.

NOTE Occupational health measures should be provided by an occupational health professional who will make pre-employment evaluation, if deemed necessary, and provide health and medical surveillance.

B.14 Human factors

The biosafety professional should ensure that human factors (e.g., behaviour, reliability, ergonomics) leading to intentional and unintentional errors are reflected in risk assessment, accident investigation, training and other relevant tasks.

B.15 Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance

The biosafety professional should participate in the planning and (re)design of facilities. The biosafety professional should provide advice on the measures necessary to ensure biosafety and biosecurity in consultation with those responsible for the design, construction, transformation or relocation (architects, building site management, authorities, project leaders, etc.) of facilities. The biosafety professional should provide input to the commissioning process as well as operations, maintenance and decommissioning.

B.16 Selection, validation, certification and maintenance of equipment

The biosafety professional should provide advice on the choice and installation of appropriate equipment that may impact biosafety and biosecurity, e.g. autoclaves, biological safety cabinets, access controls. The biosafety professional should ensure validation and/or certification prior to use, at suitable intervals and following maintenance, relocation and/or reinstallation.

B.17 Personal protective equipment (PPE)

The biosafety professional should provide advice and guidance on selection, use and maintenance of appropriate PPE having regard to regulations, risk assessment and up-to-date knowledge of the biological material and programmes in place. Management should ensure that the selected PPE is easily available and accessible to personnel and should ensure it is used.

B.18 Decontamination

The biosafety professional should provide advice on effective decontamination procedures and their implementation as well as selection and use of disinfectants. The biosafety professional should provide advice to and liaise with the relevant maintenance staff to monitor maintenance and whenever necessary the decontamination of installations and equipment when biological safety is concerned.

B.19 Biological waste management

The biosafety professional should advise on biological waste management principles and ensure all waste streams are defined and biological waste is decontaminated or inactivated prior to leaving the facility. If any biological waste has to leave the facility without validated decontamination or inactivation, appropriate measures should be taken to ensure safe and secure transport to the point of final decontamination and disposal/destruction.

B.20 Transport / export / import

The biosafety professional should ensure that instructions are provided for safe and secure on-site and off-site transport; export and import; and packaging and permitting of biological material, e.g. cultures, specimens and any potentially contaminated material, in accordance with national and international regulations and requirements.

B.21 Environmental safety

The biosafety professional should work with the environmental safety provider to ensure that

— relevant information on environmental risks is provided;

— a plan for prevention, monitoring and surveillance is in place to meet the requirements of the workplace;

— relevant environmental safety expertise is available and made known to management;

— an emergency preparedness plan is developed for potential unintentional releases of hazardous biological material.

Annex C
(informative)

Model training specifications

C.1 Training specifications

Different competences are required for working under different environments. Also, the depth of knowledge and skills required will increase as the risk of the activity increases. All biosafety professionals should be able to demonstrate the core competences. Different or more complex and/or higher risk environments require demonstration by the biosafety professional of additional specialized competences.

— Experience and/or training should be adequate to reach competence as described in Clause 7;

— Relevant experience of biorisk management as listed below should be demonstrated through a portfolio of achievements, e.g. ISTR portfolio scheme listed in Annex D;

— Training can be provided in a combination of modalities, including the following:

- face to face course work, continuous or, for example, one per week;
- partly face to face and partly distance learning mode with home work;
- through courses taken from competent providers over a period of time;
- other training modalities.

C.1.1 Core competences

— Training duration should be adequate to reach competence as described in Clause 7 and core training specifications of this annex;

— Basic knowledge of microbiology, biochemistry, cell biology and molecular biology is required.

C.1.2 Specialized competences

Greater knowledge and depth of understanding are required to achieve competence in the specialized areas of this annex.

C.2 Modules

C.2.1 Core training specifications

Required for all biosafety professionals working with biological agents (genetically modified or not), plants and/or small animals. This core training specifications could be all that is needed for the biosafety professional working at containment levels 1 and 2.

C.2.1.1 Fundamentals

C.2.1.1.1 General principles of microbiology, biochemistry and cell biology

— Biochemistry;

— Cell biology;

— Bacteriology;

— Virology;

— Mycology;

— Parasitology;

— Transmissible Spongiform Encephalopathies (TSE);

— Cell cultures;

— Biological toxins.

Objectives: The participant should be able to describe the basic characteristics of the principal taxonomic groups of pathogenic microorganisms and parasites; explain main factors that contribute to their ability to cause disease; describe main toxin producing organisms and their effects.

C.2.1.1.2 General principles of molecular biology and genetic engineering

— Fundamentals and techniques in molecular biology and genetic engineering;

— Viral vectors.

Objectives: The participant should be able to understand current methods of genetic modification technology and potential risks to workers and the environment.

C.2.1.2 Principles of biosafety and biosecurity

C.2.1.2.1 Biological and other hazards in the work area

— Microorganisms and occupational infections (LAI - Laboratory Acquired Infection);

— Genetically modified organisms;

— Toxins;

— Allergens;

— Bloodborne pathogens;

— Potentially infected material, e.g., blood, body fluids, soil samples, etc.;

— Modes of transmission: means and routes;

— Infectious dose;

— Emerging and re-emerging diseases;

— Parasites;

— Cell lines (e.g. primary, permanent, immortalized, GM);

— Aerosols;

— Other hazards associated with the use of biological material, e.g. chemical, gases, radiological, fire, mechanical, electrical, liquid nitrogen, etc.

Objectives: The participant should be able to understand the risks associated with work with biological agents and consideration of other hazards. She/he could describe some occupational infections that have led to the development of current biosafety and biosecurity practices and should be able to decide when expert help is needed to address a specific issue.

C.2.1.2.2 Occupational health and biosafety

— Prevention of occupational risks (POR);

— Medical surveillance;

— Incident / accident response;

— Allergens and hypersensitivity;

— Medical issues related to the use of personal protective equipment (e.g. respiratory protection);

— Immunocompromised workers;

— Pregnant workers;

— Partnership between occupational health provider, Health Safety and Environment and Biosafety.

Objectives: The participant should be able to understand the working relationship with the occupational health provider and of the prevention and surveillance measures to keep laboratory workers healthy.

C.2.1.2.3 Human factors

— Behaviour-based safety, including reliability and errors;

— Working in a team;

— Stress;

— Ergonomics.

Objectives: The participant should be able to understand human factors (e.g. behaviour, reliability, ergonomics) leading to intentional and unintentional errors. The participant should have the skills to influence behaviours and risk perception, and be persuasive in promoting good biosafety and biosecurity practices taking into account cultural and socio-economic considerations.

C.2.1.2.4 Containment principles

— Primary containment (e.g. Biological Safety Cabinet, isolator, bioreactor, kill tank);

— Secondary containment (e.g. laboratory facility);

— Filtration (air, vacuum, etc.);

— Air flow and pressure differentials;

— Biological containment;

— Safe working practices.

Objectives: The participant should be able to understand the concept of containment and its limitations and be able to discuss the most important types of containment.

C.2.1.2.5 Biorisk assessment and management

— Risk group classification systems (WHO and others – human, animal, plant pathogens);

— Hazard identification (e.g. mode of transmission, infectious dose, etc.);

— 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 GMOs);

— Biosecurity risk assessment, including controls of people, physical measures and data/information;

— Risk management, risk reduction methods and hierarchy of controls;

— National implementation of Conventions and accountability and restrictions.

Objectives: The participant should be able to contribute to a security plan for biological materials with other stakeholders and integrate it into the biorisk management programme. The participants should be able to carry out a risk assessment for a given situation and decide on mitigations strategies taking into account hierarchy of controls.

C.2.1.2.6 General principles of environmental safety

— Animal and plant pests: mode of transmission, vectors, mode of dispersal, survival in the environment, endemic or exotic, etc.;

— Gene flow;

— Protection goals.

Objectives: The participant should be able to identify environmental issues for a given situation and advise on mitigation strategies.

C.2.1.2.7 Facility design, construction, commissioning, decommissioning, validation, operation and maintenance

— The design team (architects and engineers, principal investigators, users, management, safety, maintenance, communication);

— Technical drawings (blueprint reading);

— HVAC (Heating, Ventilation and Air Conditioning) systems;

— HEPA (High Efficiency Particulate Air) filtration (room and Biological Safety Cabinet (BSC));

— Plumbing and vacuum systems;

— Access control systems;

— Construction materials and finishes;

— Laboratory containment levels 1 and 2;

— Small animal facilities 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.).

Objectives: The participant should be able to read a technical drawing and understand the basic systems (HVAC, etc.), understand the construction commissioning and validation processes and have knowledge of basic design features of the most important types of facilities. The participant should be able to consider the biosafety and biosecurity issues in preventive and corrective maintenance, operations and decommissioning.

C.2.1.2.8 Selection, validation, certification and maintenance of equipment

— Safety equipment: e.g. biological safety cabinets, autoclaves, isolators, small animal cage systems, dunk tanks – selection, installation, how it works, associated biosafety issues, etc.;

— Special laboratory equipment: centrifuges, FACS, homogenizers, microtomes, mechanical pipetters, microscopy and histology – associated biosafety and biosecurity issues;

— Validation, certification and maintenance of safety equipment.

Objectives: The participant should be able to understand the impact on biosafety and biosecurity when using these pieces of equipment and advise on choice, installation, validation, certification and maintenance.

C.2.1.2.9 Good microbiological techniques (GMT)

— 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.

Objectives: The participant should be able to identify components of a safe working environment for a given situation (workplace and workflow).

C.2.1.2.10 Personal protective equipment (PPE)

— PPE fundamentals;

— Clothing;

— Gloves (lab, hot/cold, animal handling, chemicals, etc.);

— Face and eye protection;

— Respiratory protection (types, medical clearance, fit testing, maintenance, training);

— Shoes and boots.

Objectives: The participant should be able to advise on the appropriate types of PPE required for a given situation, based on theoretical and practical experience, and discuss potential problems and solutions when the equipment is introduced and used.

C.2.1.2.11 Infection control, disinfection, decontamination, and sterilisation

— Fundamentals of infection control, disinfection, decontamination, and sterilisation;

— Infection control programme;

— Disinfection methods;

— Decontamination methods;

— Sterilisation methods;

— Spill management;

— Validation principles and methods;

— Monitoring.

Objectives: The participant should be able to describe the most important elements of infection control, disinfection, decontamination and sterilisation, as well as their efficacy and could draw up a disinfection plan, including validation, for a given situation.

C.2.1.2.12 Biological waste management

— Fundamentals of waste collection, labelling, handling, storage, treatment, transport and final disposal;

— Waste treatment methods and validation;

— Solid waste;

— Sharps;

— Liquid, waste water treatment;

— Mixed waste (bio-chem, bio-rad, bio-chem-rad).

Objectives: The participant should be able to develop and implement a biological waste management plan including validation for a given situation for the safe and secure disposal of biological material.

C.2.1.2.13 Emergency preparedness and response

— 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.

Objectives: The participant should be able to propose an emergency preparedness and response plan for a given situation. The participant should also be able to identify targets and weakness of a given facility, the resulting potential threats and how to mitigate them.

C.2.1.2.14 Incident and accident investigation

— Incident and accident fact collection, analysis and evaluation;

— Record keeping, report writing and reporting;

— Identify effective corrective actions.

Objectives: The participant should be able to collect relevant facts, evaluate them and propose corrective actions to prevent or mitigate recurrent accidents or incidents.

C.2.1.2.15 Biorisk management programme

— Understand the principles of management systems;

— Responsibilities within the hierarchy (including managers and committees);

— Policies, programmes, manuals;

— SOPs and work instructions;

— Occupational health monitoring and management;

— Audits and inspections – principles;

— Training programme;

— Traceability of biological material;

— Record keeping and reporting skills;

— Biosafety Committee;

— Conflict management and resolution;

— Communication and motivation skills;

— Working in a team, stress, poor conditions;

— Bioethics.

Objectives: The participant should be able to develop and implement a biorisk management programme, including identifying who is accountable, who has the competence, and who is controlling which elements. The participant should be able to determine who can develop a SOP or work instruction, how to review a SOP or work instruction. The participant should be able to know how to implement a SOP or work instruction, how to develop supporting training for competence improvement. The participant should have a general view on how to conduct an internal safety audit and an inspection, and how to set up a training programme.

C.2.1.2.16 Training

— 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 (management, principal investigators, lab workers, animal facility workers, maintenance workers, cleaning personnel, security personnel, contractors, visitors, students, etc.);

— Trainee progress assessment / competence;

— Trainer and training course evaluation.

Objectives: The participant should be able to understand the basic principles of training to allow him/her to develop and carry out an internal biosafety and biosecurity (re)training programme tailored to different audiences and ascertain the competence of the trainees.

C.2.1.2.17 Communication skills and information / knowledge systems

— 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. Twitter, Facebook, email, LinkedIn).

Objectives: The participant should be able to transfer information clearly and convincingly to an audience including management, laboratory workers, and external parties. The participant should be able to communicate with personnel at all levels with the proper degree of understanding and sensitivity. The participant should understand how knowledge/information systems can benefit a biorisk management programme.

C.2.1.2.18 Audits and inspections

— Management systems;

— Responsibilities;

— Inspection versus audit;

— Elements of an audit;

— Methods for auditing;

— Evaluation of an audit;

— Elements, methods and evaluation of an inspection;

— How to resolve non-compliance and lack of cooperation.

Objectives: The participant should be able to apply the elements of a management system or other systematic approach, to understand how the implementation and efficacy is probed during an audit or inspection and to propose actions for improvement.

C.2.1.2.19 Packaging, shipping, transport, import and export of biological material

— Fundamentals of packaging systems and transportation;

— Practical guidance and documentation;

— Different modes of transport (air, road, rail, and water);

— Spill procedures;

— Training needs;

— International and national transport, export, import regulations are listed under C.2.1.3.1.

Objectives: The participant should be able to identify relevant requirements and restrictions on transport, import and export and to determine when an export or import permit (license) is needed and how to obtain it. The participant should be able to propose correct packaging, labelling and means of transport for a given situation.

C.2.1.3 Biosafety and biosecurity laws, regulations, standards and guidelines, conventions and codes of conduct

C.2.1.3.1 International regulatory framework, standards, guidelines and conventions

This list is indicative only and not all inclusive.

— Worker protection (prevention of occupational risks);

— Regulations for contained activities;

- Working with pathogens (human, animal, opportunistic) – worker protection (lab and hospital environment);
- Working with genetically modified organisms;
- Working with animals (including animal care issues);
- Working with plants (environmental protection, phytosanitary regulations);

— Deliberate release and field activities;

- microbiological issues;
- plant issues (risk assessment, etc.);
- animal issues (risk assessment, etc.);

— International and national transport, import, export regulations;

- IATA – International Air Transport Association;
- ICAO – International Civil Aviation Organization;
- IMO – International Maritime Association;
- RID – Regulations for International carriage of Dangerous Goods by Rail;
- ADR – European Agreement on International Carriage of Dangerous Goods by Road;
- ADNR – European Agreement on carriage of Dangerous Goods by Inland Waterways;
- Import regulations;
- Export regulations (dual-use, Cartagena and others);
- UN Model Regulations for the Transport of Dangerous Goods;

— Other regulations;

- Gene therapy;
- Emergencies;
- Waste regulations;
- Dual use / select agent regulations;

— Conventions;

- Convention on Biological Diversity (CBD);
  - — Access and Benefit Sharing of Genetic Resources (ABS);
  - — Cartagena Protocol on Biosafety;
- Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters;
- Biological and Toxin Weapons Convention (BTWC);
- UN Security Council Resolution 1540 (2004);
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);
- International Plant Protection Convention (IPPC);
- UN Subcommittee of Experts on the Transport of Dangerous Goods;

— Biosafety-related standards;

- OIE – World Organisation for Animal Health Codes and Standards;
- CEN biosafety, clinical, microbiological and biotechnology standards;
- ISO biosafety, clinical, microbiological and biotechnology standards;
- FDA standards;

— Management systems standards;

- ISO 9001 Quality management standard;
- ISO 14001 Environmental standard;
- OHSAS 18001 Occupational Health standard;

— International and national guidance documents, guidelines, manuals (e.g., National Institutes of Health (NIH) recombinant DNA Guideline, Biosafety in Microbiological and Biomedical Laboratories (BMBL), Public Health Canada Laboratory Biosafety Guidelines, WHO Laboratory Biosafety Manual, WHO Guidance on biosecurity).

Objectives: The participant should be able to demonstrate familiarity, understand and apply the regulatory framework, including standards and guidelines, in all areas of biosafety and biosecurity.

C.2.1.3.2 National regulatory framework, standards and guidelines

As above but adapted to the national requirements.

C.2.1.3.3 Bioethics

— Code of conduct;

— Animal welfare;

— Helsinki convention;

— Access and benefit sharing of genetic resources.

Objectives: The participant should be able to demonstrate familiarity with applicable legislation and codes of conduct.

C.2.2 Specialist training specifications

This list is indicative and not all inclusive. These are special topics related to specific activities or work environments to supplement the core training specifications. They should be chosen according to the specific facility where the biosafety professional will carry out his/her activities. Each of these modules should contain the elements listed in C.2.1 (Core training specifications) where applicable.

C.2.2.1 Laboratory animal experiments – small animals (rodents, fish, etc.)

— Animal models /animal use in research;

— Working with GM animals;

— Working with animal pathogens (GM and non-GM);

— Control of arthropods causing disease in animals, and arthropods acting as vectors for other animal pathogens;

— Animal care and use;

— Occupational health issues associated with the use of animals;

— Biosafety issues associated with the use of animals;

— Biosecurity issues associated with the use of animals;

— Facility requirements;

— Waste handling;

— OIE diseases lists;

— OIE biological containment recommendations;

— Quarantine, import, export.

Objectives: The participant should be familiar with different small animal applications and their related biosafety and biosecurity issues and how to address them.

C.2.2.2 Laboratory animal experiments – large animals (cattle, swine, equine, etc.)

— Facility and engineering-related biosafety and biosecurity aspects;

— Biosecurity issues associated with the use of animals;

— Special operating procedures;

— Animal housing, care, management and impact on work and biosafety;

— Waste handling;

— Working with GM animals;

— Working with animal pathogens (GM and non-GM);

— Control of arthropods causing disease in animals, and arthropods acting as vectors for other animal pathogens;

— Occupational health issues associated with the use of animals;

— OIE diseases lists;

— OIE biological containment recommendations;

— Quarantine, import, export.

Objectives: The participant should be able to describe how a facility for large animal is designed and operated and how biosafety and biosecurity related issues could be addressed.

C.2.2.3 Laboratory animal experiments – non-human primates

— Animal care and use issues and impact on biosafety;

— Biosecurity issues associated with the use of animals;

— Working with animal pathogens (GM or non-GM);

— Control of arthropods causing disease in animals, and arthropods acting as vectors for other animal pathogens;

— Occupational health issues and zoonosis;

— Facility requirements;

— OIE diseases lists;

— OIE biological containment recommendations;

— Quarantine, import, export.

Objectives: The participant should be able to describe how a non-human primate animal facility is designed and operated and how biosafety and biosecurity related issues could be addressed.

C.2.2.4 Working with plants

— Fundamentals of working with plants;

— Biosecurity issues associated with the use of plants;

— Facility requirements;

— Plant pathogens (working with bacteria, fungi, viruses, insects, quarantine organisms, dual use organisms, GM) and containment;

— Insects causing disease in plants and insects acting as vectors for other plant pathogens;

— Contained use of genetically modified plants;

— Waste handling (liquids and solid, bulk, etc.);

— Deliberate release of genetically modified plants;

— Risk assessment methods related to release into the environment;

— Compliance and monitoring related to field releases;

— Overview of regulatory framework for commercial release;

— Cartagena Protocol on Biosafety;

— Phytosanitary issues;

— Noxious weeds;

— Movement of plants and seed (transport, export, import).

Objectives: The participant should be able to describe how a plant facility is designed and operated and how biosafety and biosecurity related issues could be addressed as well as the use of plants in the environment (GM and non-GM).

C.2.2.5 Working with arthropods

— Fundamentals in working with arthropods;

— Facility design and containment requirements related to biosafety and biosecurity issues;

— Biosecurity issues associated with the use of arthropods;

— Occupational health issues associated with the use of arthropods;

— GM arthropods.

Objectives: The participant should be able to describe how an insect facility is designed and operated and how biosafety and biosecurity related issues could be addressed.

C.2.2.6 Transmissible Spongiform Encephalopathies (TSE)

— Introduction to TSE;

— Law and regulations;

— Research, development and diagnosis;

— Exposure and risk assessment;

— Safety measures;

— Containment levels;

— SOPs;

— Inactivation;

— Waste handling.

Objectives: The participant should be able to set up and maintain a safety management system for work with TSEs.

C.2.2.7 Large scale production (bioprocessing)

— Definition of large scale;

— Bioreactors and monitoring/control systems;

— Culture methods for different organisms (GM and non-GM) and applications;

— Downstream processing;

— Scaling up;

— Facility design;

— Biosafety measures and procedures;

— Biosecurity measures and procedures;

— Biosafety and GMP;

— Accidents/spills management;

— Waste management.

Objectives: The participant should be able to understand the principles of bioprocessing, the equipment used and the specific biosafety and biosecurity issues and should be able to explain an industrial process.

C.2.2.8 Biosafety and Good Manufacturing Practices (GMP)

— Fundamental principles of GMP;

— GMP management systems;

— GMP facility requirements;

— Conflicts and solution between GMP and biosafety.

Objectives: The participant should be able to explain how a GMP facility is designed and operated, could identify areas of conflict with biosafety principles and could suggest solutions.

C.2.2.9 Clinical/diagnostic laboratories

— Micro-organisms and occupational infections (LAI);

— Bloodborne pathogens;

— Potentially infected materials;

— Safety equipment;

— Special laboratory equipment.

Objectives: The participant should be able to recognize the potential hazards associated with the work in a clinical laboratory.

C.2.2.10 Gene therapy activities

— Fundamentals of gene therapy and biosafety considerations during;

  - vector creation;
  - vector administration;
  - post administration (e.g., waste management, containment of patient excretion);

— Occupational health issues;

— Regulations.

Objectives: The participant should be able to recognize the potential biosafety hazards associated with vector creation and administration.

C.2.2.11 Containment level 3 activities

These are the topics required for all biosafety professionals working in containment level 3 facilities, regardless of the type of facility (human pathogens, animals, GMOs, animal pathogens). This is an additional training to core training specifications and applicable special topics. Subjects to be covered at greater depth than in the core training specifications. Visit to at least two working containment level 3 facilities is recommended.

— Biorisk assessment and management;

— Facility design (e.g. airlocks (personnel and material), pass-throughs, change rooms), facility construction, validation and commissioning;

— Facility operations, maintenance and periodic verification of facility performance – including emergency power, filtration, pressure differentials and air exchanges;

— Use of animals, including facility design and animal care;

— Laboratory and safety equipment – including equipment repair management;

— PPE;

— Infection control, disinfection, decontamination, sterilisation – including double-door autoclaves and kill tanks;

— Management of the facility – including entry/exit procedures;

— Personnel selection and training (including Train-the-Trainer for laboratorians) – including maintenance and emergency personnel training;

— Manuals, SOPs and work instructions;

— Occupational health;

— Accidents, incidents and spill decontamination;

— Waste management (biological and mixed waste);

— Emergency response;

— Audits and inspections.

Objectives: The participant should be able to understand the additional aspects that are required for biorisk management at containment level 3.

C.2.2.12 Containment level 4 activities

These are the topics required for all biosafety professionals working in containment level 4 facilities, regardless of the type of facility (human pathogens, animals, GMOs, animal pathogens). This is an additional training to core training specifications and applicable special topics. Subjects to be covered at greater depth than in the Core Training Specifications. Visit to at least two facilities working at containment level 4 facilities is recommended.

— Biorisk assessment and management;

— Facility design (e.g. airlocks (personnel and material), pass-throughs, change rooms), suit vs cabinet lab, facility construction, validation and commissioning;

— Facility operations, maintenance and periodic verification of facility performance – including emergency power, filtration, pressure differentials and air exchanges;

— Use of animals, including facility design and animal care;

— Laboratory and safety equipment – including Class III biosafety cabinet or glove box set up, equipment repair management;

— PPE – including positive pressure suit;

— Infection control, disinfection, decontamination, sterilisation – including double-door autoclaves and kill tanks;

— Management of the facility (including entry/exit procedures);

— Personnel selection and training, including maintenance and emergency personnel;

— Manuals, SOPs and work instructions;

— Occupational health;

— Accidents, incidents and spill decontamination;

— Waste management (biological and mixed waste);

— Emergency response;

— Audits and inspections.

Objectives: The participant should be able to understand the additional aspects that are required for biorisk management at containment level 4.

Annex D
(informative)

Example of a portfolio of achievements to demonstrate relevant experience of biorisk management

D.1 General

This Annex contains an example of a portfolio of achievements to demonstrate relevant experience of biorisk management. It is based on a scheme from the Institute of Safety in Technology and Research (ISTR), for more information see [9].

For Table D.1, the following definitions apply.

General awareness (GA)

The applicant will be able to demonstrate sufficient familiarity with a subject to the point of being able to "interpret" related documents for the benefit of others, including their own employer, and to be able to identify the need for and sources of information.

Basic understanding (BU)

The work submitted must contain evidence that the applicant has a broad understanding of the subject area. It should offer evidence of understanding beyond that of general awareness to the point where the individual is able to offer generic advice and participate in informed discussion, but not necessarily be regarded as an expert in the subject.

Detailed understanding (DU)

The evidence presented will provide strong support for regarding the applicant as an expert in the chosen area and apply basic principles to novel situations. This may include the ability to train others, or write papers, or offer expert advice within their own employment or to third parties.

Table D.1 — Portfolio of achievements to demonstrate relevant experience of biorisk management

Unit		Topic		Evidence of experience or application in the workplace	
Mandatory unit					
1	Basic underpinning knowledge	a.	Microbiology and infectious diseases	Demonstration of an understanding of the scientific basis of biological risks by formal training to degree level or equivalent and/or scholarly publications in relevant subject	BU
		b.	Scientific trends	Provision of advice on recent developments, attendance at conferences & courses	GA

2	Organisational arrangements	a.	Development of policy, standards or codes of practice	Writing of policy and codes of practice: e.g. policy documents that candidate has authored, minutes of meetings at which candidate has made significant contribution	DU
		b.	Influencing a change in safety culture	Evidence for managing an improvement: inspection reports and/or follow up reports that demonstrate improvements achieved, evidence of increased awareness in workplace through candidate's efforts	DU
		c.	Development of a safety or 'compliance' management system	For example, a system for submission and approval of GM risk assessments or for performance validation of autoclaves	DU
		d.	Record keeping at the institutional level	Implementation of new systems and/or maintenance of an appropriate existing system	BU
		e.	Inspection and auditing	Developing systems, programmes as well as in conducting inspections and audits	DU
		f.	Dealing with overlapping or third-party organisations or individuals	Evidence of managing co-operation between employers including transfer arrangements for materials or waste, service level agreements, decontamination certificates or Permits-to-Work. Examples could include contributing to documentation pertaining to shared responsibilities.	DU
		g.	Dealing with the enforcement agencies	Details of preparation as well as response. Examples could include facilitating inspection visits, submitting notifications, responding to requests for information etc.	BU
		h.	Incident reporting and investigation	Examples of investigation reports; developing systems for reporting and investigation, including meeting the legal reporting requirements	DU

	Unit	Topic	Evidence of experience or application in the workplace	
3	The law	a. A detailed understanding of health and safety law as applied specifically to biological agents hazardous to human, animal and plant health	Interpretation and application of the law. Examples may include (a) securing significant expenditure or changes in established work practice to ensure compliance; (b) involvement in the mitigation case following enforcement action; (c) acting as an expert witness in the Courts; (d) development of workplace specific guidance/systems for ensuring legal compliance with these regulations	DU
		b. Regulatory environment	Demonstration of an understanding of the interaction with other legislation associated with biosafety e.g. Human Tissue Act, Anti-Terrorism (Crime and Security) Act	BU

4	Communication and training	a. Safety communication within the workplace	Development and implementation of communication processes with scientists, PIs, laboratory managers etc. and with other stakeholders for example the Trade Unions. Examples include safety notices or other communications instigated or authored by the candidate.	DU
		b. Maintaining professional competence	Examples of course attendance, further relevant qualification, conference participation etc.	DU
		c. Safety training	Development (including training needs analysis) and delivery of a training programme. Examples include course training materials, dates of delivery and feedback from trainees	DU
		d. Communication outside of the organisation	Development of links with appropriate people and groups on health and safety matters & speaking at conferences, etc.	BU
		e. Influencing skills	Attainment of required level in formal course and/or examples of success in influencing for positive change, either through effecting positive changes in awareness and compliance in the workforce or through influencing senior management to effect a positive change in safety culture	BU

	Unit	Topic	Evidence of experience or application in the workplace	
5	Biological risk management	a. Risk assessment methodology and application	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training	DU
		b. Control measures according to hierarchy of control; includes selection, testing and maintenance	Determining and advising on appropriate control measures, for example; selection and testing of engineering controls; routine disinfection, sterilisation and decontamination; barrier systems; waste management; ergonomics and their incorporation into Codes of Practice and Local Rules	DU
		c. Emergency preparedness and response	Preparation of emergency plans; examples of managing real events (through actual experience or training exercises)	DU
		d. Security	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training	BU

6	Occupational Health	a. Understanding the biosafety requirements for Occupational Health (OH) and/or Industrial/Occupational Hygiene provision and the organisational relationship between them and biosafety.	Health surveillance: legal requirements and relationship with Occupational Health department or provider Identifying OH needs and providing advice on specific hazards and risk factors, including vulnerabilities affecting immunity, resistance to biological agents and the need to refer to the OH provider and/or Industrial/Occupational Hygienist	BU

	Unit		Topic	Evidence of experience or application in the workplace	
Optional units					
1	Work at Containment Level 3 or 4 (including animal pathogens)	a.	Facility design and operation	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		b.	Risk assessments and Codes of Practice	Provision of advice, development of written guidance, development of institutional procedures	DU
		c.	Selection, use, maintenance and testing of control measures	Provision of advice, development of written guidance, development of institutional procedures	DU
		d.	Fumigation, including testing for sealability	Development of procedures, including planned and/or emergency shut down	DU
		e.	Training	Provision of training in use of the facility	DU
		f.	Emergency response	Hands on experience or participation in training exercises	DU
2	Animal facilities NOTE: Evidence may be based on experience involving one or more of the following: mammals, fish, reptiles, insects etc., including those genetically modified	a.	Facility design and operation	Provision of advice on specific projects, development of written guidance, development of institutional procedures, provision of training; ergonomic design	DU
		b.	Risk assessments and Codes of Practice	Id.	DU
		c.	Selection, use, maintenance and testing of control measures	Id. To include where appropriate, determining quarantine measures; work with infected animals; animal allergens	DU
		d.	Monitoring performance	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		e.	Emergency response	Hands on experience	DU

	Unit	Topic	Evidence of experience or application in the workplace	
3	Genetic modification NOTE: Evidence may be based on experience involving one or more of the following types of activities: i). Contained Use of genetically modified micro-organisms ii). Contained Use of genetically modified animals iii). Contained Use of genetically modified plants iv). Gene therapy v). Deliberate release of GMOs	a. Facility design and operation	Provision of advice on specific projects, development of written guidance/Codes of Practice, development of institutional procedures	DU
		b. Risk assessments.	Provision of advice on and/or conducting of risk assessments for work involving GMOs	DU
		c. Training	Provision of specific training in risk assessment for work with GMOs and in safe use of the facility	DU
		d. Notifications	Management of notification process	DU
4	Transport of biological materials	a. Transport	IATA Class 6.2/9 certification + demonstration of understanding of application to road, rail and sea by development of guidance or policy or provision of advice, including other dangerous materials associated with the transport of biological materials, e.g. dry ice	DU
		b. Import/export	Provision of advice on the regulatory requirements for the import/export of biological material to or from the UK	DU
		c. Emergency response	Hands on experience or participation in training exercises	DU

	Unit	Topic	Evidence of experience or application in the workplace	
5	Enforcement agencies/legal proceedings	a. Enforcement agency inspections	Demonstration of a lead role in the preparation for and response to enforcement agency inspections	DU
		b. Civil or criminal action	Contribution to the defence or prosecution of health and safety civil or criminal action and/or attendance at an approved course	DU
6	Plant Pathogens	a. Materials prohibited under Plant Health Orders	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		b. Facility design and operation and maintenance (greenhouses, waste and bulk treatment)	Id.	DU
		c. Working with contained plant/pathogens	Provision of advice on quarantine, vectors, soil, parasites, controls, development of written guidance, development of institutional procedures	DU
		d. Genetically modified plants	Provision of advice on international and national regulation including Cartagena Protocol, permits, licences, transgenic	DU
		e. Deliberate release	Provision of advice on risk assessment, field release, commercial release	DU
		f. Containment Principles	Provision of advice on specific projects, development of written guidance, development of institutional procedures	DU
		g. Import and Export	Id. Specific projects interaction with inspectors, development of plant materials transport	DU
		h. Waste management	Id.	DU
		i. Training	Provision of training in use of the facility or other safety procedures	DU
		j. Risk assessment	Management of full range of safety within these facilities	DU

	Unit	Topic	Evidence of experience or application in the workplace	
7	Large scale production	a. Facility design and operation	Provision of advice on design and/or operation of specific large scale projects; development of written guidance/Codes of Practice; development of institutional procedures, including planned and/or emergency shut down	DU
		b. Risk assessments	Provision of advice on and/or conducting of risk assessments for work at large scale.	DU
		c. Selection, use, maintenance and testing of control measures	Provision of advice development of written guidance/institutional procedures on specific large-scale issues	DU
		d. Training	Provision of training in safe use of the facility	DU
		e. Waste management	Provision of advice on specific issues relating to inactivation and disposal of bulk culture fluids. Development and/or implementation of validation procedures	DU
		f. Emergency response	Hands on experience or participation in training exercises	DU

8	Biosecurity	a. Legal context	Provision of advice on specific projects, development of written guidance. Demonstration of understanding of definitions and legal requirements	DU
		b. Physical measures	Demonstration of understanding of available technologies, either through course attainment or the provision of advice	DU
		c. Security plans	Demonstration of the contribution to the development of site security plans	DU
		d. Assessment	Demonstration of ability to assess the threat and the risk of loss. Demonstration of the ability to determine measures to reduce risk where weaknesses identified.	BU
		e. Personnel security	Demonstration of contribution to determining access control and understanding of the requirements for personnel screening	BU
		f. Proportionate application	Demonstration of the proportionate application of Biosecurity measures, including physical and biological barriers	DU

	Unit	Topic	Evidence of experience or application in the workplace
9	Others e.g. clinical, bioethics, aerobiology, toxins,	a. Application can be made on a case by case basis for other specialist aspects of biological safety	

Annex E
(informative)

Overview of the relationship between competences, tasks and training specifications

Core competences (clause 7.2)		**Recommended to perform tasks** (Annex B)		**Can be acquired by training** (Annex C)	
7.2.1	General principles of microbiology, biochemistry and cell biology	B.2	Biorisk assessment and management	C.2.1.1.1	General principles of microbiology, biochemistry and cell biology
7.2.2	General principles of molecular biology and genetic engineering	B.2	Biorisk assessment and management	C.2.1.1.2	General principles of molecular biology and genetic engineering
7.2.3	Biological and other hazards in the work area	B.2	Biorisk assessment and management	C.2.1.2.1	Biological and others hazards in the work area
7.2.4	Occupational health and biosafety	B.13	Occupational health	C.2.1.2.2 C.2.1.2.3	Occupational health and biosafety Human factors
7.2.5	Human factors	B.14 B.2 B.6 B.13 B.18	Human factors Biorisk assessment and management Biosecurity Occupational health Decontamination	C.2.1.2.3	Human factors
7.2.6	Containment principles	B.2 B.15 B.16 B.17	Biorisk assessment and management Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance Selection, validation and certification, and maintenance of equipment Personal protective equipment (PPE)	C.2.1.2.7 C.2.1.2.8 C.2.1.2.9 C.2.1.2.10	Facility design, construction, commissioning, decommissioning, validation, operation and maintenance Selection, validation, certification and maintenance of equipment Good microbiological techniques (GMT) Personal protective equipment (PPE)

7.2.7	Biorisk assessment and management	B.2 B.6	Biorisk assessment and management Biosecurity	C.2.1.2.5	Biorisk assessment and management
7.2.8	Environmental safety	B.21	Environmental safety	C.2.1.2.6	General principles of environmental safety
7.2.9	Facility (re)design, construction, commissioning, decommissioning, validation, operation and maintenance	B.15 B.16	Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance Selection, validation and certification, and maintenance of equipment	C.2.1.2.7 C.2.1.2.8	Facility design, construction, commissioning, decommissioning, validation, operation and maintenance Selection, validation, certification and maintenance of equipment
7.2.10	Selection, validation, certification and maintenance of equipment	B.6 B.16	Biosecurity Selection, validation and certification, and maintenance of equipment	C.2.1.2.8	Selection, validation, certification and maintenance of equipment
7.2.11	Good microbiological technique (GMT)	B.4	Guidance, best practices and standard operating procedures (SOPs)	C.2.1.2.9	Good microbiological techniques (GMT)
7.2.12	Personal protective equipment (PPE)	B.17	Personal protective equipment (PPE)	C.2.1.2.10	Personal protective equipment (PPE)
7.2.13	Infection control, disinfection, decontamination and sterilisation.	B.18 B.2 B.4 B.10 B.13 B.19	Decontamination Biorisk assessment and management Guidance, best practices and standard operating procedures (SOPs) Accident / incident reporting and investigation Occupational health Biological waste management	C.2.1.2.11	Infection control, disinfection, decontamination, and sterilisation
7.2.14	Biological waste management	B.18 B.19	Decontamination Biological waste management	C.2.1.2.11 C.2.1.2.12	Infection control, disinfection, decontamination, and sterilisation Biological waste management

7.2.15	Emergency preparedness and response	B.7	Emergency plans and exercises	C.2.1.2.13	Emergency preparedness and response
7.2.16	Incident and accident investigation	B.10	Accident / incident reporting and investigation	C.2.1.2.14	Incident and accident investigation
7.2.17	Biorisk management programme	B.1 B.6 B.11	Biorisk management programme Biosecurity Records	C.2.1.2.15	Biorisk management programme
7.2.18	Inventory monitoring and control	B.1 B.6 B.11	Biorisk management programme Biosecurity Records	C.2.1.2.15	Biorisk management programme
7.2.19	Physical security	B.1 B.2 B.6 B.15	Biorisk management programme Biorisk assessment and management Biosecurity Facility planning, (re)design, commissioning, decommissioning, validation, operations and maintenance	C.2.1.2.5 C.2.1.2.7 C.2.1.2.15	Biorisk assessment and management Facility design, construction, commissioning, decommissioning, validation, operation and maintenance Biorisk management programme
7.2.20	Training	B.8	Training	C.2.1.2.16	Training
7.2.21	Communication skills and information/knowledge systems	B.9	Communication	C.2.1.2.17	Communication skills and information / knowledge systems
7.2.22	Audits and inspections	B.11 B.12	Records Audits and inspections	C.2.1.2.18	Audits and inspections
7.2.23	Packaging, shipping, transport, import and export of biological material	B.20	Transport / export / import	C.2.1.2.19	Packaging, shipping, transport, import and export of biological material
7.2.24	International and national regulatory framework, standards, guidelines and conventions	B.3 B.4	Regulations and guidelines, permits Guidance, best practices and standard operating procedures (SOPs)	C.2.1.3.1 C.2.1.3.2	International regulatory framework, standards, guidelines and conventions National regulatory framework, standards and guidelines
7.2.25	Bioethics	B.3 B.4	Regulations and guidelines, permits Guidance, best practices and standard operating procedures (SOPs)	C.2.1.3.3	Bioethics

Bibliography

[1] Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJEC 21.5.2009 – L 125/75-97)

[2] http://eur-lex.europa.eu/en/index.htm

[3] Council Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work (Official Journal of the European Community 17.10.2000 L262/21-45)

[4] ISO 9000:2005, Quality management systems - Fundamentals and vocabulary

[5] CEN Guide 14:2010, Common policy guidance for addressing standardisation on qualification of professions and personnel

[6] NSABB, US National Science Advisory Board for Biosecurity, Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information, June 2007, http://oba.od.nih.gov/biosecurity/biosecurity_documents.html

[7] ISO 14001:2004, Environmental management systems - Requirements with guidance for use

[8] BS OHSAS 18001:2007, Occupational Health and Safety Management systems Requirements

[9] http://www.istr.org.uk/biosafac.shtml

[10] ISO 15190:2003, Medical laboratories – Requirements for safety

[11] EN 4179:2005, Aerospace series – Qualification and approval of personnel for non-destructive testing