LABORATORY BIOSAFETY MANUAL
FOURTH EDITION
AND
ASSOCIATED MONOGRAPHS

BIOSAFETY PROGRAMME MANAGEMENT

World Health Organization

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Biosafety programme management

(Laboratory biosafety manual, fourth edition and associated monographs)

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Glossary of terms

Accident: An inadvertent occurrence that results in actual harm such as infection, illness, injury in humans or contamination of the environment.

Aerosol: Liquid or solid particles suspended in air and of a size that may allow inhalation into the lower respiratory tract (usually less than 10 micrometres in diameter).

Aerosol/airborne transmission: The spread of infection caused by the inhalation of aerosols.

Aerosol-generating procedure: Any procedure that intentionally or inadvertently results in the creation of liquid or solid particles, which become suspended in the air (aerosols).

Antimicrobial: An agent that kills microorganisms or suppresses their growth and multiplication.

Biological agent: A microorganism, virus, biological toxin, particle or otherwise infectious material, either naturally occurring or genetically modified, which may have the potential to cause infection, allergy, toxicity or otherwise create a hazard to humans, animals or plants.

Biosafety: Containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

Biosafety committee: An institutional committee created to act as an independent review group for biosafety issues, reporting to senior management. The membership of the biosafety committee should reflect the different occupational areas of the organization as well as its scientific expertise.

Biosafety officer: An individual designated to oversee facility or organizational biosafety (and possibly biosecurity) programmes. The person fulfilling this function may also be termed biosafety professional, biosafety advisor, biosafety manager, biosafety coordinator, or biosafety management advisor.

Biosafety programme management: The development, implementation and oversight of biosafety at the organizational level using a variety of information that includes institutional policies, guidance documents for practices and procedures, planning documents (training, recruitment, emergency/incident response) and record keeping (personnel, inventories, incident management).

Biosecurity: Principles, technologies and practices that are implemented for the protection, control and accountability of biological materials and/or the equipment, skills and data related to their handling. Biosecurity aims to prevent their unauthorized access, loss, theft, misuse, diversion or release.

Calibration: Establishment of the relationship between the measurement provided by the instrument and the corresponding values of a known standard, allowing correction to improve accuracy. For example, laboratory equipment such as pipetting devices may need calibration periodically to ensure proper performance.

Certification: A third-party testimony based on a structured assessment and formal documentation confirming that a system, person or piece of equipment conforms to specified requirements, for example, to a certain standard.

Code of practice (code of conduct, code of ethics): Non-legislated guidelines for behavioural and practical standards that are voluntarily accepted as best practice and are thus followed by one or more organizations and/or individuals.

Communicability: Capability of a biological agent to be transmitted from one person or animal to another, either through direct or indirect transmission. This is often related to/represented by an epidemiological measurement called the basic reproduction number (R_0) which is an average number of secondary infections generated by a single infected individual in a fully susceptible population.

Containment: The combination of physical design parameters and operational practices that protect personnel, the immediate work environment and the community from exposure to biological agents. The term "biocontainment" is also used in this context.

Contamination: The introduction of undesired biological agents into tissues and specimens or onto surfaces.

Core requirements: A set of minimum requirements defined in the fourth edition of the World Health Organization (WHO) *Laboratory biosafety manual* to describe a combination of risk control measures that are both the foundation for, and an integral part of, laboratory biosafety. These measures reflect international standards and best practice in biosafety that are necessary to work safely with biological agents, even where the associated risks are minimal.

Decontamination: Reduction of viable biological agents or other hazardous materials on a surface or object(s) to a pre-defined level by chemical and/or physical means.

Disinfectants: Agents capable of eliminating viable biological agents on surfaces or in liquid waste. These will have varying effectiveness depending on the properties of the chemical, its concentration, shelf life and contact time with the agent.

Disinfection: A process to eliminate viable biological agents from items or surfaces for further safe handling or use.

Dual use items: Certain materials, information and technologies that are intended for benefit, but which might be misapplied to do harm.

Emergency/incident response: An outline of the behaviours, processes and procedures to be followed when handling sudden or unexpected situations, including exposure to or release of biological agents. The goal of an emergency/incident response is to prevent injuries or infections, reduce damage to equipment or the environment, and accelerate resumption of normal operations.

Good microbiological practice and procedure (GMPP): A basic laboratory code of practice applicable to all types of laboratory activities with biological agents, including general behaviours and aseptic techniques that should always be observed in the laboratory. This code serves to protect laboratory personnel and the community from infection, prevent contamination of the environment, and provide protection for the work materials in use.

Hazard: An object or situation that has the potential to cause adverse effects when an organism, system or (sub)population is exposed to it. In the case of laboratory biosafety, the hazard is defined as biological agents which have the potential to cause adverse effects to personnel and/or humans, animals, and the wider community and environment. A hazard does not become a "risk" until the likelihood and consequences of that hazard causing harm are taken into account.

Heightened control measures: A set of risk control measures as described in the WHO *Laboratory biosafety manual* that may need to be applied in a laboratory facility because the outcome of a risk assessment indicates that the biological agents being handled and/or the activities to be performed with them are associated with a risk that cannot be brought below the risk tolerance level with the core requirements only.

Inactivation: Removal of the activity of biological agents by destroying or inhibiting reproductive or enzyme activity.

Incident: An occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm.

Infectious dose: The amount of biological agent required to cause an infection in the host, measured in number of organisms. Often defined as the ID_{50}, the dose that will cause infection in 50% of those exposed.

Laboratory-associated infection: Any infection acquired or reasonably assumed as a result of exposure to a biological agent in the course of laboratory-related activities. A person-to-person transmission following the incident may result in linked secondary cases. Laboratory-associated infections are also known as laboratory-acquired infections.

Maximum containment measures: A set of highly detailed and stringent risk control measures described in the fourth edition of the WHO *Laboratory biosafety manual* that are considered necessary during laboratory work where a risk assessment indicates that the activities to be performed pose very high risks to laboratory personnel, the wider community and/or the environment, and therefore an extremely high level of protection must be provided. These are especially needed for certain types of work with biological agents that may have catastrophic consequences if an exposure or release were to occur.

Pathogen: A biological agent capable of causing disease in humans, animals or plants.

Personal protective equipment (PPE): Equipment and/or clothing worn by personnel to provide a barrier against biological agents, thereby minimizing the likelihood of exposure. PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators.

Primary containment device: A contained workspace designed to provide protection to its operator, the laboratory environment and/or the work materials for activities where there is an aerosol hazard. Protection is achieved by segregation of the work from the main area of the laboratory and/or through the use of controlled, directional airflow mechanisms. Primary containment devices include biological safety cabinets (BSCs), isolators, local exhaust ventilators and ventilated working spaces.

Prophylaxis: Treatment given to prevent infection or to mitigate the severity of the disease if infection were to occur. It can be delivered before possible exposure or after exposure before the onset of infection.

Risk: A combination of the likelihood of an incident occurring and the severity of the consequences (harm) if that incident were to occur.

Safety culture: A set of values, beliefs and patterns of behaviour instilled and facilitated in an open and trusting atmosphere by individuals and organizations working together to support or enhance best practice for laboratory biosafety, irrespective of whether it is stipulated in applicable codes of practice and/or regulations.

Sharps: Any device or object that is a puncture or wound hazard because of its pointed ends or edges. In the laboratory, sharps can include needles, syringes with attached needles, blades, scalpels or broken glass.

Standard operating procedures (SOPs): A set of well-documented and validated stepwise instructions outlining how to perform laboratory practices and procedures in a safe, timely and reliable manner, in line with institutional policies, best practice and applicable national or international regulations.

Transmission: The transfer of biological agent(s) from objects to living things, or between living things, either directly or indirectly via aerosols, droplets, body fluids, vectors, food/water or other contaminated objects.

Validation: Systematic and documented confirmation that the specified requirements are adequate to ensure the intended outcome or results. For example, in order to prove a material is decontaminated, laboratory personnel must validate the robustness of the decontamination method by measurement of the remaining biological agents against the detection limit by chemical, physical or biological indicators.

Verification: Confirmation that a given item (product, process or system) satisfies the specified requirements. For example, verification that the performance of an autoclave meets the standards specified by the manufacturer should be performed periodically.

Zoonotic disease (zoonosis): Infectious disease that is naturally transmitted from animals to humans and vice versa.

Executive summary

A facility's biosafety programme is comprised of foundational elements that are implemented to protect personnel, the public and the environment from exposure to, or inadvertent release of, harmful biological agents. An effectively managed biosafety programme is essential to ensuring that programme objectives continue to be met. The plan–do–check–act programme management cycle is a standardized method that can be used to efficiently manage a facility's biosafety programme. This monograph describes how the plan–do–check–act programme management cycle supports the development, implementation and continuous improvement of the biosafety programme in a risk- and evidence-based way. The targeted readership for this monograph is biosafety officers, laboratory personnel and laboratory managers who implement a biosafety programme in their laboratories.

The information in this monograph on biosafety programme management is designed to accompany and support the fourth edition of the WHO *Laboratory biosafety manual* (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach in order to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable. Emphasis is placed on the importance of a "safety culture" that incorporates risk assessment, good microbiological practice and procedure and standard operating procedures, relevant introductory, refresher and mentoring training of personnel, and prompt reporting of incidents and accidents followed by appropriate investigation and corrective actions. This new approach aims to facilitate laboratory design and ways of operating that ensure greater sustainability while maintaining adequate and appropriate control of biosafety.

The other associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment, laboratory design and maintenance, biological safety cabinets and other primary containment devices, personal protective equipment, decontamination and waste management, and outbreak preparedness and resilience.

This monograph provides information on how to establish a strong biosafety culture within a facility and laboratory. The roles and responsibilities of personnel in an organization and their contribution to the biosafety programme are described. Key considerations for the foundational elements of a biosafety programme in different types of facilities are discussed. In addition, standardized templates of documentation needed for an effective biosafety programme are provided to support the development and implementation of a biosafety programme that is based on risk and evidence, and reflects the intent of the programme.

SECTION 1

INTRODUCTION

The development and implementation of a robust biosafety programme is intended to protect personnel, the public and the environment (including animal populations) from release of and/or exposure to harmful biological agents. This programme is multifaceted and integrates a variety of elements to enhance its effectiveness.

The information in this monograph on biosafety programme management is designed to accompany and support the fourth edition of the WHO *Laboratory biosafety manual (1)* (core document) and other associated monographs. The manual and the monographs adopt a risk- and evidence-based approach to biosafety rather than a prescriptive approach in order to ensure that laboratory facilities, safety equipment and work practices are locally relevant, proportionate to needs and sustainable.

The other associated monographs provide detailed information and help implement systems and strategies on the following specialized topics: risk assessment *(2)*, laboratory design and maintenance *(3)*, biological safety cabinets and other primary containment devices *(4)*, personal protective equipment *(5)*, decontamination and waste management *(6)*, and outbreak preparedness and resilience *(7)*.

A biosafety programme is a collection of information and associated actions that include:

- an institutional policy to describe the scope, purpose and objectives of the biosafety programme;
- clearly defined terminology;
- clearly defined roles and responsibilities within the organization;
- a biosafety manual that outlines risk control measures for the risks associated with biological hazards; and
- comprehensive procedures to support the safety policy.

The level of complexity of a given biosafety programme depends on the nature of the organization, including its size and structure, as well as the work performed within it (for example, research versus diagnostics). A comprehensive biosafety programme has many foundational elements (described in subsection 5.1); proactive and systematic management of these elements is essential for the success of a biosafety programme.

As annexes to this monograph, a number of templates are provided, which are designed to give information and considerations on key aspects of a biosafety programme. The templates can and should be modified for use as needed for various types of facilities to support the development of a comprehensive biosafety programme.

SECTION 2

BIOSAFETY PROGRAMME MANAGEMENT CYCLE

Effective management of a biosafety programme can be achieved by implementing the following project management cycle: planning – assessment – implementation – review and improvement. The four stages of the cycle should be carried out in all types of facilities and the elements associated with each stage should be defined and represented. Figure 2.1 gives an example of how the foundational elements are managed within the biosafety programme management cycle.

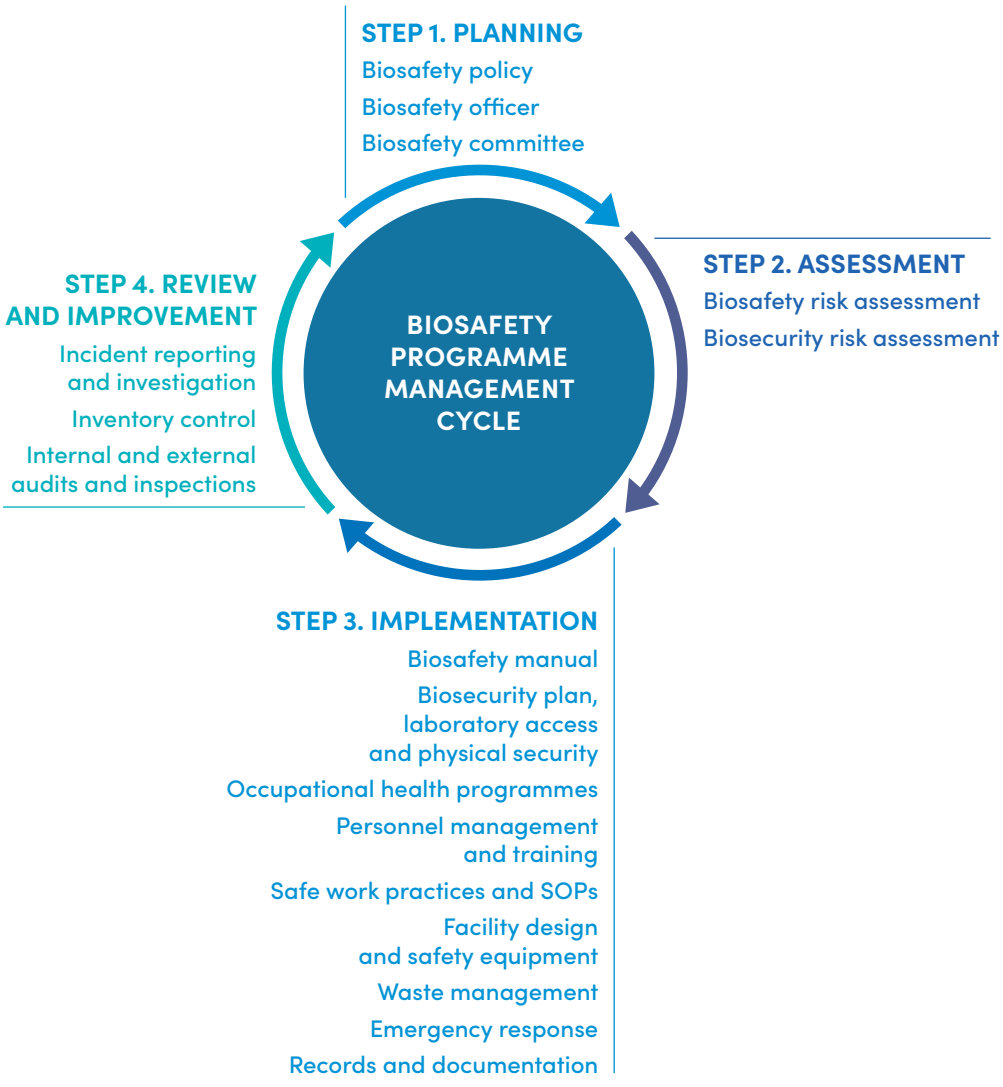


Figure 2.1 Biosafety programme management cycle

4 BIOSAFETY PROGRAMME MANAGEMENT

SECTION 3

ESTABLISHING A STRONG BIOSAFETY CULTURE

Creating and cultivating a strong biosafety culture is critical for the success of a biosafety programme. Cultivating a biosafety culture is not a defined step within the biosafety programme management cycle, but starts in the planning phase and is developed, reinforced and maintained in all laboratory activities. Commitment of senior management is essential to build a strong biosafety culture as it demonstrates that the identification and control of risks posed by hazardous biological agents are a priority at all levels of the organization. A biosafety culture is not easily achieved. It requires time, commitment and diligence from all personnel, supervisors and senior management, in an environment of respect and trust. The following best practices are recommended for developing and sustaining a strong biosafety culture.

3.1 Demonstrated commitment of senior management

- The active and visible participation of senior management in biosafety-related activities demonstrates a top-down institutional commitment (such as membership of the institutional biosafety committee, participation in regular biosafety meetings).
- Commitment can also be demonstrated through the senior management's approval and endorsement of institutional biosafety policies, as well as the assurance of financial and human resources to manage a biosafety programme.
- Commitment to an open and transparent environment is also needed where biosafety issues can be raised and discussed without fear of reprisal.

3.2 Demonstrated commitment to biosafety throughout the organization

- An endorsed institutional code of practice can outline the roles, responsibilities and expectations of all personnel within the organization to support an effective biosafety programme.
- A clear, appropriate, timely and evident response to biosafety concerns raised by personnel demonstrates an ongoing commitment to the safety of the working environment.

3.3 Active engagement of laboratory personnel and support personnel

- Early consultation with and cooperation between those responsible for the development of a biosafety programme and those directly affected by or working within this programme will support a successful working relationship where the common goal of biosafety is achieved.

- Encouragement and support by members of the institutional biosafety committee and biosafety officer(s) of the active involvement of laboratory directors, laboratory managers, principal investigators, laboratory personnel, support personnel and students to influence and inform biosafety policies and the biosafety programme as a whole will increase a sense of ownership, which supports engagement in the biosafety culture.

3.4 Ongoing communication and promotion of biosafety

- Regular and transparent communication builds trust between senior management, the institutional biosafety committee, the biosafety officer(s) and personnel.

- An effective communication process, which promotes open dialogue, reassures personnel when seeking advice, raising biosafety concerns or reporting incidents.

SECTION 4

ROLES AND RESPONSIBILITIES

An effective biosafety programme promotes a culture of safety, integrity and excellence in science, and accuracy in diagnostics. The programme should be exemplified by openness, honesty, accountability and responsibility. The following subsections describe the key roles and responsibilities of institutional personnel in the development and maintenance of the organization's biosafety programme. Depending on the size and complexity of the organization, roles and responsibilities may overlap. For example, in a smaller facility, the laboratory director may also be a member of the organization's senior management team, and the responsibilities of the biosafety officer may be performed by laboratory personnel (quality manager) or amalgamated with other aspects of safety (such as chemical, ergonomic, electrical) in the role of an overarching safety officer.

4.1 Senior management

Senior management is ultimately responsible for the safety of all personnel, contractors and visitors to the organization. It is also responsible for protecting the health and safety of the public from the risks associated with the work being performed within the organization. As the highest level of management within an organization, the composition of senior management will depend on the size and complexity of the organization. In a smaller organization, senior management may include the director or head of the institute or of the laboratory. In a larger organization, it may be composed of a team that is far removed from daily laboratory activities and so may rely more heavily on advice from biosafety personnel. Regardless of the size and complexity of the organization, senior management must ensure that appropriate risk assessments are performed and that appropriate resources are available to control identified risks. Senior management may have the following responsibilities:

- defining the organization's commitment to biosafety through a policy and possibly a code of practice;
- making decisions on compliance with applicable legislative or regulatory requirements, based on the organization's internal recommendations;
- allocating sufficient funds and resources to support biosafety within the organization;
- being aware of the overall institutional risks related to hazardous biological agents, and ensuring completion of relevant risk assessments by appropriate individuals;

- defining the roles and responsibilities for biosafety of all personnel within the organization;
- defining the components and procedures (such as emergency/incident response, communication plan, and occupational health and safety plan) that incorporate feedback from frontline personnel to support the biosafety programme; and
- providing oversight of the biosafety programme through participation in review processes and committees.

4.2 Biosafety committee

The biosafety committee should represent a cross-section of institutional expertise that reflects the size and complexity of the organization, the types of biological agent in use and the activities being carried out. The committee acts as an independent review group for issues related to biosafety and reports to senior management. It may have the following responsibilities:

- contributing to the development of institutional biosafety policies and codes of practice;
- reviewing new research projects involving infectious agents, animals, recombinant DNA and genetically modified materials;
- identifying, assessing, and mitigating potential dual-use risks in the research process (proposal/design stage), during research conduct, and at all communication stages (for example, manuscripts, conferences, presentations);
- reviewing accidents and incidents;
- performing risk assessments; and
- acting as an impartial mediator in disputes over biosafety matters.

4.3 Biosafety officer

A knowledgeable and capable biosafety officer will support the development, implementation, maintenance and continuous improvement of the organization's biosafety programme. Whether a full-time or part-time employee or contractor, the biosafety officer should have the necessary expertise to advise all personnel and management on biosafety issues and concerns.

The responsibilities of a biosafety officer could include advising on and/or contributing to:

- biosafety, biosecurity and technical consultations;
- apprising senior management and/or the biosafety committee of safety-related issues within the organization;
- ensuring risk assessments and authorizations for work are in place;
- developing and/or delivering safety-related training activities;
- periodic laboratory inspections, audits and assessments;
- reporting, investigating and following up on accidents or biosafety incidents;
- developing and maintaining the biosafety manual and standard operating procedures (SOPs) related to biosafety and biosecurity;
- promoting and monitoring compliance with legislative or regulatory requirements; and
- communicating with personnel at all levels of the organization about biosafety.

4.4 Laboratory personnel

The laboratory director or manager is responsible for implementing processes within the facility or laboratory that comply with the organization's biosafety policies. They may also have the following responsibilities:

- being aware of and complying with the organization's biosafety policies and procedures;
- ensuring that adequate and timely resources are made available for the elements of the biosafety programme (for example, performing risk assessments, attending training);
- working closely with biosafety personnel to ensure that appropriate risk control strategies are implemented;
- contributing to the development of facility- or laboratory-specific SOPs;

- ensuring and supporting adherence to safety policies and procedures by all personnel they manage; and
- promoting ongoing communication between senior management, the biosafety officer and laboratory personnel.

All other laboratory personnel within the organization, including personnel, students and volunteers, are responsible for supporting and contributing to a robust biosafety programme. Personnel have a responsibility to: adhere to institutional policies; complete required training; follow SOPs and other operational working practices; and report to the biosafety officer any contravention of these procedures and practices, any areas for improvement, or any incidents with hazardous biological materials.

4.5 Support personnel

Security and maintenance personnel, administrators and additional support personnel who are not directly involved in laboratory work but have access to the laboratory space or the biological agents (for example, shipping and receiving personnel) have a role in supporting the biosafety programme. Support personnel are responsible for: completing training to understand and identify potential hazards; communicating identified hazards to the biosafety officer; applying work practices that prevent exposure to themselves or others; and following the security measures in place to limit laboratory access.

SECTION 5

DEVELOPING A BIOSAFETY PROGRAMME

5.1 Foundational elements of a biosafety programme

A biosafety programme is an organization-wide system that includes biosafety elements that protect personnel, the public and the environment from exposure to hazardous biological agents. When developing a biosafety programme, key considerations include:

- size, complexity and scope of the facility,
- availability of resources, both financial and human, for implementation of a biosafety programme,
- gaps or deficiencies in financial and human resources, and
- whether the biosafety programme should be part of an overarching health and safety programme or a stand-alone programme.

Regardless of the size and complexity of the organization, the foundational elements of a biosafety programme remain the same. All stages of the biosafety programme management cycle (planning, assessment, implementation, and review and improvement) should be carried out in all facility types, and the elements associated with each phase should be defined and represented. What these elements look like and how they are implemented will vary between organizations, facilities and individual laboratories.

Table 5.1 outlines the foundational elements of a biosafety programme within the four stages of the programme management cycle and the key factors to consider for each element.

Table 5.1 Foundational elements of a biosafety programme

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 1: PLANNING		
Biosafety policy	A biosafety policy is the main biosafety programme guidance document. It should outline an organization's commitment to managing the risks posed by biological agents by setting clear biosafety objectives and targets. A policy will establish an internal accountability system whereby the roles in managing biological risks are defined for all individuals. A strong code of practice, and clear roles and responsibilities throughout the organization will help build a strong biosafety culture.	▪ Does my laboratory or organization have a safety policy? ▪ Is biosafety included in this policy, and should this be further developed? ▪ Does the policy include well-defined objectives that are clear, realistic and measurable?
Biosafety committee	A biosafety committee may be established as an advisory body for biosafety-related matters, or may be part of an overarching safety committee. The committee may develop institutional policies, review risk assessments, approve protocols, identify potential dual-use or advise on biosafety-related issues.	▪ Does my laboratory or organization have a committee to oversee safety; if so, does this committee oversee biosafety? ▪ What are the roles and responsibilities of the biosafety committee? ▪ Does the committee review and approve research and projects before they start, throughout their implementation and before publication/dissemination of results? ▪ What expertise is required for members of the committee? ▪ Is the expertise representative of the biological agents and work being performed in the laboratory? ▪ Are there independent experts in associated fields, local authorities or national regulatory bodies that can be approached for additional advice?
Biosafety officer	The role of the biosafety officer is to develop, implement, maintain and improve an organization's biosafety programme. While they may be employed under a variety of titles (for example, safety officer/adviser, biosafety adviser, biosafety manager, biosafety coordinator, biorisk management adviser, quality manager or biosafety professional), the individual should have the appropriate expertise and knowledge for the activities being performed with biological agents within the institution.	▪ Does my laboratory or organization have an individual identified to oversee safety; if so, does this person oversee biosafety? ▪ What are the roles and responsibilities of the biosafety officer?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 2: ASSESSMENT		
Biosafety risk assessment	Biosafety risk assessment is a systematic framework that determines the likelihood and consequences of inadvertent exposure or unintended release by evaluating the inherent characteristics of biological agents and the activities being performed. It is intended to select and apply appropriate risk control measures, including physical containment design, safety equipment and operational practices, to reduce risks to an acceptable risk.	▪ Which personnel will contribute to the risk assessment? ▪ What types of laboratory activities are conducted? ▪ How many laboratories within the organization work with hazardous biological agents? ▪ Which biological agents are handled or stored within the laboratory or organization, and what are the risks of these agents? ▪ What types of laboratory activity are being performed with these agents? ▪ What type of equipment does the facility have? ▪ What is the scope of the facility? Are there special considerations related to the facility design? ▪ Who will perform the activities with biological agents, and what is their competency, training or other personal considerations? ▪ What is the likelihood of the identified consequences happening? ▪ What, and in which situations, are risk control strategies required to prevent personnel exposure and release of or exposure to pathogens in the community? ▪ Are there regulations (such as national legislation) to be considered? ▪ Are there approval processes before the work can proceed? ▪ How will the hazards, risks and risk control measures be communicated? ▪ How often, or under what circumstances, will a risk assessment be reviewed?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 2: ASSESSMENT		
Biosecurity risk assessment	A biosecurity risk assessment is a systematic framework performed to identify risks and determine risk control strategies that protect biological agents and other assets from theft, misuse, diversion (to unauthorized laboratories/people) or intentional release.	▪ Which biological agents in the laboratory or organization are a biosecurity threat (for example, those with dual-use potential), what is their physical location and who requires access to them? ▪ What other assets (for example, information, equipment) are also a biosecurity threat? ▪ What risk control strategies protect against theft, misuse, diversion or intentional release? ▪ How often, or in what circumstances, will a risk assessment be reviewed? ▪ What checks will be in place to confirm compliance? ▪ What will be the consequences of non-compliance?
STEP 3: IMPLEMENTATION		
Biosafety manual	A biosafety manual describes the foundational elements of a biosafety programme (such as policies, programmes, standard operating procedures (SOPs)). It is the most effective tool for documenting and communicating the elements and objectives of a biosafety programme.	▪ What are the outputs of the biosafety and biosecurity risk assessments? ▪ Given the size and complexity of the laboratory or organization, is a dedicated biosafety manual required, or should this information be included in an overarching health and safety manual? ▪ Are biosafety elements adequately captured in the overarching health and safety manual? ▪ What should be included in the biosafety manual?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Biosecurity plan, laboratory access and physical security	A biosecurity plan outlines the security measures to be implemented to prevent the theft, misuse, diversion or intentional release of hazardous biological agents. This includes the process by which laboratory access is determined, personnel security, and medical and training requirements. The biosecurity plan also details physical security countermeasures to prevent unauthorized access, which promotes biosecurity objectives and biosafety by limiting access to the laboratories and other potentially hazardous areas.	▪ What are the outputs of the biosecurity risk assessment? ▪ What are the assets, threats and vulnerabilities within the laboratory or organization? ▪ Who is responsible for authorizing access? ▪ Are there written procedures and/or forms available to facilitate and document laboratory access requests and results? ▪ What are the access requirements for administrative (that is public) and restricted (that is laboratory) areas within the facility? ▪ How do cleaning and maintenance personnel access the laboratory or other secure areas? ▪ Are there secure areas within the laboratory? ▪ What risk control measures are in place to regulate access? ▪ Who manages access risk control measures (that is key custodian)? ▪ When are keys/codes changed? ▪ How are unauthorized personnel or unauthorized access detected? ▪ Is there a guard, commissionaire or emergency response force (that is police, fire)?
Occupational health programme	A function of an occupational health programme is to prevent illness resulting from laboratory exposure to biological agents. In addition, monitoring and documenting laboratory-associated infections should be included as part of the programme to prevent subsequent infections in the community.	▪ How and when should medical evaluations and clearances be conducted? ▪ How are medical records stored and who can access them? ▪ What is the best way to communicate to personnel regarding the laboratory-associated hazards? ▪ Should personnel be trained in first aid, and are first-aid procedures documented? ▪ What vaccinations are available and required? ▪ What post-exposure prophylaxis is available? ▪ What support is available for at-risk personnel? ▪ In what circumstances should personnel carry emergency contact cards? ▪ What information should be included on emergency contact cards? ▪ Is it necessary to liaise with the local hospital or health clinic?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Personnel management and training	Personnel management includes the training, capability, reliability and integrity of employees. It is crucial to ensure that the organization's overarching biosafety policies and operational working practices and procedures are being followed by appropriate personnel. A training programme identifies current and future training needs for the institution, and ensures that personnel demonstrate competency before working independently. Training needs will vary throughout an institution and should consider the biosafety and biosecurity risks identified in the biosafety and biosecurity risk assessments.	▪ What are the job descriptions of personnel within the laboratory or organization? ▪ Are job descriptions well defined and documented? ▪ What are the recruitment and hiring procedures? ▪ When and how is competence assessed? ▪ What is the required type and frequency of biosafety training (including needs assessments and evaluations)? ▪ What are the visitor training and access/escorting procedures? ▪ What are the disciplinary and termination procedures? Are these documented? ▪ Are there succession planning procedures in place? ▪ How will training programmes be developed and delivered?
Operational working practices and procedures	Operational working practices and procedures documented in the SOPs provide personnel with ready access to the procedures required to protect laboratory personnel from the risks posed by the biological agents in use.	▪ Are SOPs written in clear and simple language that is easily understood by all personnel? ▪ Are the following SOPs documented and available to personnel? – entry and exit procedures, – personal protective equipment, including procedures for putting on and removing the equipment, – good microbiological practice and procedure, – equipment maintenance, – Transfer and movement of biological material, and – decontamination and waste management. ▪ When and how are existing SOPs reviewed and additional SOPs developed? ▪ What is the approval process for new or revised SOPs?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Facility design and laboratory equipment	Facility design and appropriate safety equipment are crucial to the safe handling of hazardous biological agents and are an integral component of most biosafety programmes.	▪ Are the facility planning, design and verification processes commensurate with the programme of work? ▪ What are the procedures for commissioning and decommissioning facilities? Are they documented? ▪ What are the systems for maintenance, control, calibration, certification and validation of the facility and infrastructure support? ▪ Is there a current inventory of laboratory equipment, including equipment used for specimen storage? ▪ Are equipment log books and records kept up to date? ▪ Who reviews and approves purchase requests? ▪ Does the organization's budget support long-term maintenance and operation of equipment? ▪ Who is responsible for ensuring proper selection, installation, calibration, validation, certification, operation and maintenance of equipment and support systems? ▪ What are the procedures for unscheduled maintenance/shut-down of containment areas?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Decontamination and waste management	Effective decontamination and waste management is crucial in laboratory areas to ensure that contaminated materials are properly treated and safely disposed of. The principles of decontamination are essential to reduce the risk of personnel exposure or release of contaminants to the environment or community.	▪ How are disinfectants selected, purchased, prepared and labelled? ▪ How is efficacy of decontamination evaluated? ▪ Are there any special procedures for room and equipment decontamination (that is surface versus vapour and gas decontamination)? ▪ Are personnel trained on proper use of disinfectants and decontamination technologies, including their hazards? ▪ Where and how is laboratory waste collected? ▪ How is waste identified and segregated? ▪ How is waste packaged and labelled? ▪ How is waste transported and stored? ▪ How is waste decontaminated? ▪ How is waste transported to its final destination? ▪ Is decontamination performed on site or by a third party? ▪ If using a third-party company, are their methods verified, are they licensed and are they compliant with legislation/regulations?
Emergency/incident response	Emergency/incident response planning prepares an organization to take appropriate actions in the event of a spill, exposure, power failure, fire or other emergency. An emergency response plan enables an organization to protect the health and safety of the individual, the community and the environment.	▪ Who is responsible for emergency response? ▪ What are the local emergency response organizations and/or hospitals that should be consulted when developing a plan? ▪ How will an emergency and associated response be communicated throughout the facility? ▪ What are the emergency exits and ways out that avoid evacuation through contaminated areas? ▪ Are there protocols for the safe removal or exit of contaminated personnel? ▪ What emergency equipment is available in containment areas (for example, eyewash station, first-aid kits, spill kits)? ▪ Is there training on the components of the emergency response? ▪ When and how often will practice drills be performed?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Records and documentation	Records provide evidence that a specific laboratory activity was performed and document the results of the laboratory activity. They can also be used for ongoing improvement of the biosafety programme as a whole.	▪ Is there a scheduled/regular review cycle of documents, and what is the approval process for updates? ▪ Who is responsible for record-keeping and management? ▪ Are records digital, hard copy or both? ▪ What security features are necessary to safeguard records? ▪ Is there a central secure facility/area for storing records? ▪ Who has access to records, and how accessible are they when needed? ▪ Are the following kept on file; if so, what is the retention time? – training records, – records of audits and inspections, including corrective actions, – records of incidents (for example, exposures), – equipment and facility records, – laboratory access requests and security logs, and – inventories of biological agents, including their transfer or movement. ▪ What are the procedures for unscheduled maintenance/shut-down of containment areas?
Inventory control	Inventory control allows an organization to monitor its stock of biological agents to allow ready access to and rapid identification of missing materials. Facilities that work with biological agents should develop a system to manage and oversee their inventory of these materials to have complete and timely knowledge of what exists, where they are located and who is accountable for them.	▪ Who is responsible for creating and maintaining the inventory? ▪ What items and information are recorded in the inventory? ▪ Do records identify a responsible person for the material? ▪ Do records identify transfers (incoming and outgoing) and destruction? ▪ Is there training on how to maintain inventory records? ▪ What are the inventory reconciliation processes (for example, auditing, reporting, and resolving discrepancies)? ▪ What information is required when labelling materials?

Table 5.1 Foundational elements of a biosafety programme (continued)

ELEMENT	DESCRIPTION	KEY CONSIDERATIONS
STEP 3: IMPLEMENTATION		
Communication plan	Communication is a vital part of the biosafety programme. Its goal is to help all stakeholders, including laboratory personnel, understand the risk assessment methods, results and risk-management decisions.	▪ Who is responsible for internal (for example, laboratory personnel, senior management) and external (for example, the general public, regulatory authorities) communications? ▪ In what format will communications be sent and received (for example, email, newsletter, forum). ▪ What type of information and level of detail will be communicated? ▪ What will be the frequency of communication updates to personnel? ▪ Is there an open system for personnel to communicate biosafety concerns?
STEP 4: REVIEW AND IMPROVEMENT		
Incident reporting and investigations	Incidents are occurrences that have the potential to result in (that is a near miss) or actually result in (that is an accident) the release of and/or exposure to a biological agent or harm to personnel, the community or the environment. Reporting and investigating an incident are essential to determine the cause in order to prevent a recurrence; they are not intended to assign blame. Reports, investigations and corrective actions are indicators of a biosafety programme's effectiveness as they identify deficiencies and gaps and the actions taken to correct them.	▪ Who should incidents be reported to (within the organization, external authorities)? ▪ When should incidents be reported (immediately, or as soon as they become known, for example, in the case of a laboratory-associated infection)? ▪ What are the procedures for reporting an incident? ▪ What are the procedures for determining the cause of an incident? ▪ How are corrective actions implemented? ▪ Who documents the outcomes of the incident investigation? ▪ How is the effectiveness of implemented risk control measures assessed? ▪ Are there legislative requirements that need to be met?
Internal and external audits and inspections	Internal and external audits and inspections serve to actively identify hazards, deficiencies or areas in need of improvement in an organization's biosafety programme. They contribute to the prevention of incidents with and exposures to biological agents.	▪ Who is responsible for internal and external audits and inspections? ▪ What is the frequency of audits and inspections (that is the frequency proportional to the risk of the laboratory work)? ▪ What are the objectives and expected outcomes? ▪ What are the procedures for audits and inspections? ▪ How are corrective actions implemented?

5.2 Biosafety programme management in different types of facilities

Facilities working with biological agents range in size and complexity. For example, a simple facility could be a small, one-room, diagnostic laboratory with a small number of personnel (up to 10) testing a single specimen type for low-consequence pathogens. A medium-sized facility may have multiple laboratories contained within the same building, with up to 100 personnel. A combination of research and diagnostic activities may be performed using low- to high-consequence pathogens. A large and complex facility could be a multicampus university where a combination of research and animal work is conducted across different laboratories, buildings and campuses, using low- to high-consequence pathogens.

Table 5.2 outlines different facility types (based on size and complexity of work) and provides a brief example of what the biosafety programme elements may include for that facility type. These examples are not meant to be prescriptive; rather, they are intended to demonstrate how a biosafety programme can be created or adapted depending on the complexity of an institution.

Table 5.2 Biosafety programme elements in facilities of different complexity

	COMPLEXITY OF ORGANIZATION		
ELEMENT	**LOW COMPLEXITY EXAMPLE** SINGLE LABORATORY	**MEDIUM COMPLEXITY EXAMPLE** MULTIPLE LABORATORIES IN A SINGLE FACILITY	**HIGH COMPLEXITY EXAMPLE** MULTIPLE FACILITIES
Biosafety policy	Part of a broader health and safety policy	Separate, specific policy	Separate, specific policy + code of practice
Biosafety officer	Laboratory personnel/ overarching safety officer/ quality manager	Experienced employee; may be an additional duty, full or part time	Dedicated full-time employee(s) or team
Biosafety committee	Subgroup of an existing safety or laboratory committee; meets periodically	Established committee; meets periodically	Established committee; meets frequently
Biosafety risk assessment	Established assessment, review and approval processes; performed by individuals with practical and theoretical expertise in biosafety		
Biosecurity risk assessment	Established assessment, review and approval processes; performed by individuals with practical and theoretical expertise in biosecurity		
Biosafety manual	Part of a general safety manual	Separate, specific manual	Separate, specific manuals may be required for different laboratories

Table 5.2 Biosafety programme elements in facilities of different complexity (continued)

	COMPLEXITY OF ORGANIZATION		
ELEMENT	**LOW COMPLEXITY EXAMPLE** SINGLE LABORATORY	**MEDIUM COMPLEXITY EXAMPLE** MULTIPLE LABORATORIES IN A SINGLE FACILITY	**HIGH COMPLEXITY EXAMPLE** MULTIPLE FACILITIES
Biosecurity plan	General laboratory security + additional risk control measures as determined by biosecurity risk assessment	+ laboratory-specific measures as determined by biosecurity risk assessment	+ facility-specific measures as determined by biosecurity risk assessment
Occupational health programme	Part of an overarching worker health programme + consider vaccinations; system to report, document and monitor infections	+ consider personnel evaluations (for example, awareness for at-risk employees)	+ consider coordination with local hospital or health clinics for occupational health services
Personnel management and training	Laboratory- and/or facility-level coordination and delivery; scope, frequency and evaluation based on needs assessment	+ multiple training streams for different pathogens and laboratory procedures	+ more laboratory-specific training
Operational working practices and SOPs	Included in the general safety manual	Included in the biosafety manual	+ stand-alone laboratory-specific components
Facility design and laboratory equipment	Routine and preventive maintenance and equipment operation performed by contractors or laboratory personnel, as needed; scheduling based on a risk assessment		
Decontamination and waste management	SOPs for segregation, decontamination, packaging and transport meet regulatory requirements	+ centralized system (for example, to coordinate facility-wide services)	+ organization-wide system (for example, to coordinate services across multiple locations)
Emergency/incident response	Alarm and life safety systems (for example, emergency shower, device to detect chemicals in air); SOPs for efficient personnel response; regular system testing	+ coordination with emergency response services	
Records and documentation	Stand-alone electronic and/or hard-copy records maintained by laboratory personnel	Facility-wide information management system (for example, electronic spreadsheets and/or databases)	+ tracking of records and documents from multiple electronic and/or hard-copy sources throughout multiple facilities

SOPs = standard operating procedures.

Table 5.2 Biosafety programme elements in facilities of different complexity (continued)

	COMPLEXITY OF ORGANIZATION		
ELEMENT	**LOW COMPLEXITY EXAMPLE** SINGLE LABORATORY	**MEDIUM COMPLEXITY EXAMPLE** MULTIPLE LABORATORIES IN A SINGLE FACILITY	**HIGH COMPLEXITY EXAMPLE** MULTIPLE FACILITIES
Inventory control	Hard-copy system (for example, notebook) with minimum essential inventory details	Electronic system with additional level of detail as determined by a risk assessment (for example, spreadsheet or database)	+ method (for example, laboratory information management system) for real-time tracking and analysis and periodic inventory check
Communication plan	Format(s) and frequency based on need (periodic or ad hoc); responsibility of the laboratory director or manager	Multiple formats; may include a dedicated individual who coordinates with an institutional team	
Incident reporting and investigation	System to report, review and implement corrective actions for incidents and near misses	+ coordination and information-sharing between laboratories	
Audits and inspections	Regular review of requirements; a system to review findings and implement corrective actions; coordinated by the laboratory manager	+ greater frequency and depth; may be conducted by the biosafety officer	+ high frequency and depth; may be conducted by a member of the safety team

References

1. Laboratory biosafety manual, fourth edition. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

2. Risk assessment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

3. Laboratory design and maintenance. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

4. Biological safety cabinets and other primary containment devices. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

5. Personal protective equipment. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

6. Decontamination and waste management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

7. Outbreak preparedness and resilience. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

Further information

Laboratory quality management system: handbook. Geneva: World Health Organization; 2011 (https://www.who.int/ihr/publications/lqms/en/, accessed 30 April 2020)

ANNEX 1. PATHOGEN SAFETY DATA SHEET TEMPLATE

The following template can be used to develop pathogen safety data sheets. It can help gather information about the biological agents being handled in order to perform a comprehensive risk assessment. It can also help develop targeted emergency/ incident response in the event of breaches in biosecurity or biosafety with a specific biological agent. The sections and the amount of information in the sheets can be modified and adapted to fit your organization's needs.

Pathogen safety data sheet template
SECTION 1 Biological agent

Pathogen		
Pathogen *(Official taxonomic naming convention)*		
Other names *(for example, former taxonomic name, common name)*		
Agent type	☐ Bacterium ☐ Fungus ☐ Parasite	☐ Virus ☐ Prion ☐ Other (describe)
Taxonomy	Family	
	Genus	
	Species	
	Subspecies/strain/clonal strain	
Characteristics	Appearance	
	Size	
	Shape	
	Genome structure *(for example, RNA/DNA virus, sense/antisense)*	
	Other (describe)	
Properties contributing to risk	Modifications from parental strain	
	Sporulation	
	Toxin production	
	Oxygen requirements	
	Enzymatic activity	
	Life cycle	
	Reproduction	

Pathogen safety data sheet template
SECTION 2 Hazard identification

Pathogenicity / toxicity	
Duration of associated illness/disease in humans	
Duration of associated illness/disease in animals	
Mortality rate (human)	
Mortality rate (animal)	
Symptoms of illness/disease (human)	Description
	Severity
	Prevalence
	Variations
	Clinical presentation
Symptoms of illness/disease (animal)	Description
	Severity
	Prevalence
	Variations
	Clinical presentation
Other ailments associated with the illness/disease	
Potential acute and chronic effects	
Predisposing factors *(List of conditions or cofactors that may predispose to infection, disease, or more severe disease, for example, pregnancy, immune status)*	

Pathogen safety data sheet template
SECTION 2 Hazard identification (continued)

Pathogen		
Transmission routes	☐ Ingestion ☐ Injection ☐ Mucous membrane ☐ Skin contact	☐ Genitourinary ☐ Inhalation ☐ Other (describe)
Preferred mode of transmission		
Likelihood of transmission by direct contact *(that is intimate, casual contact)*	☐ Low ☐ Medium	☐ High ☐ Unknown
Likelihood of transmission by indirect contact *(that is fomites, vectors)*	☐ Low ☐ Medium	☐ High ☐ Unknown
Epidemiology		
Is the disease maintained in human populations?	☐ No	☐ Yes (indicate geographic range)
Is the disease maintained in animal populations?	☐ No	☐ Yes (indicate geographic range)
Have there been outbreaks?	☐ No	☐ Yes Where: When: Magnitude:
Host range		
Natural host(s) *(If possible indicate primary [definitive], secondary [intermediate] and dead-end hosts)*		
Other hosts *(Include experimentally infected hosts)*		
Infectious dose (ID)		
The number of organisms or concentration of organisms required to cause disease in the natural host(s)	☐ ID_{50} (specify) ☐ $TCID_{50}$ (specify)	☐ Unknown
Incubation period		
The duration between contact with the biological agent and presentation of the earliest clinical signs of the disease in the natural host(s) (usually measured in days)		

Pathogen safety data sheet template
SECTION 3 Dissemination

Reservoir		
Organisms (often a species of small mammal or bird) in which the biological agent is maintained without causing any obvious clinical symptoms		
Zoonosis/reverse zoonosis		
Is the disease spread between animals and humans?	☐ No ☐ Unknown	☐ Yes Human to animal (list species) ☐ Animal to human (list species)
Vectors		
Invertebrate species that can carry and transmit the pathogen to humans or animals *(Typically this refers to an arthropod that transmits by biting or laying eggs, but could refer to a mechanical vector, for example, flies)*	☐ No ☐ Unknown	☐ Yes, arthropod (list species) ☐ Yes, mechanical vector (list species)

Pathogen safety data sheet template
SECTION 4 Stability and viability

Pharmaceutical susceptibility		
List drugs/pharmaceutical agents that are effective and available for treating infection/disease Known drug resistance or multidrug resistance		
Disinfection and inactivation		
Disinfectants capable of destroying the pathogen and applicable toxins or spores *(or class of pathogens, and any known conditions that are necessary for disinfection and inactivation – concentration, contact time, temperature)*		
Physical inactivation *(Include the type [for example, ultraviolet or gamma irradiation, dry or moist heat, pH] and parameters [method, duration, environmental condition] for inactivation of the pathogen or class of pathogens)*		
Is there documentation of survival times for the infectious agent outside of its host environment? *(for example, is the infectious agent still viable in collected blood, semen, or other fluids? Is it viable in dried blood, on surfaces or in aerosol form?)*	☐ No ☐ Unknown	☐ Yes (indicate survival time)

Pathogen safety data sheet template
SECTION 5 First aid and medical treatment

Surveillance		
Symptoms of disease/illness		
Detection/diagnosis methods		
Recommendations for surveillance *(based on the occupational health programme)*		
For epidemiological tracing, should an individual's history of contact with animals be established as a requirement of an occupational health programme?	☐ No ☐ Unknown	☐ Yes (indicate applicable animals to note interactions with)
For epidemiological tracing, should international travel of an individual be established as a requirement of an occupational health programme?	☐ No ☐ Unknown	☐ Yes (indicate applicable countries/areas to note travel to/from)
First aid/treatment		
Typical treatment options		
Is treatment typically undertaken for infected animals?	☐ No ☐ Unknown	☐ Yes (describe)
Specific first aid/treatment recommended (*based on the occupational health programme and emergency/incident response*)		
Immunization		
Recommended preventative and/or post-exposure immunizations for those working with the pathogen (*based on the available and effective vaccines and the occupational health programme*)		
Are these recommendations universal or based on the activities being performed or other factors?	☐ Universal ☐ Activity-specific	☐ Other factors (describe)
Are there specific cofactors (for example, pregnancy) that would change the recommendations?	☐ No ☐ Unknown	☐ Yes (describe)
Are animals typically vaccinated against the pathogen?	☐ No ☐ Unknown	☐ Yes (describe)
Prophylaxis		
Recommended pre- or post-exposure prophylaxis (*based on the occupational health programme*)		
Are these recommendations universal or based on the activities being performed or other factors?	☐ Universal ☐ Activity-specific	☐ Yes (describe)
Are there specific cofactors (for example, pregnancy) that would change the recommendations?	☐ No ☐ Unknown	☐ Yes (describe)

Pathogen safety data sheet template
SECTION 6 Laboratory hazards

Laboratory-associated infections		
Are there known exposure incidents within the organization?	☐ No ☐ Unknown	☐ Yes (describe incidents and circumstances)
Are there known exposures external to the organization? *(Evidence from the literature [research, diagnostic, health care] of laboratory-associated infections with the biological agent, including the circumstances)*	☐ No ☐ Unknown	☐ Yes (describe)
Sources/specimens		
List primary biological specimens likely to contain the biological agent *(for example, blood, urine, semen, mucous, faeces, necropsy tissues)*		
Primary hazards		
Indicate primary hazards	☐ Ingestion ☐ Exposure ☐ Auto-inoculation ☐ Inhalation ☐ Fomites	☐ Bites/scratches (from infected animal) ☐ Exposure to animal waste or carcasses ☐ Other (describe)
Special hazards		
Indicate special hazards *(for example, in diagnostic laboratories that receive potentially contaminated testing request forms shipped in the same box as the specimens)*		

Pathogen safety data sheet template

SECTION 7 Risk control measures and personal protective equipment (PPE)

Risk		
Risk classification (human)		
Risk classification (animal)		
Risk control measures		
Are risk control measures needed for work with the pathogen? *(for example, core requirements, heightened control measures, maximum containment measures)*	☐ No ☐ Unknown	☐ Yes (describe)
Is this the same for all activities? *(for example, in vitro and in vivo)*	☐ No ☐ Unknown	☐ Yes (describe)
Are there specific requirements for certain activities? *(for example, using a biological safety cabinet)*	☐ No ☐ Unknown	☐ Yes (describe)
PPE		
List specific PPE to be used when working with this pathogen		
Other precautions		
List any other precautions to be used when working with this pathogen		

Pathogen safety data sheet template
SECTION 8 Handling and storage

Spills
Detail the procedure to follow in response to a spill involving the pathogen
Indicate the type and quantity of disinfectant to be used
Disposal
Indicate specific decontamination procedures for liquid and solid waste *(for example, physical inactivation versus effluent treatment)*
Storage conditions
Indicate storage conditions for the pathogen

Pathogen safety data sheet template
SECTION 9 Regulatory and other information

Regulatory information
List all applicable regulatory authorities for the use, storage, import, export, transport, transfer, disposal, or other activities involving the pathogen in the country in which this pathogen safety data sheet is being used.
Other information
Date this pathogen safety data sheet was last updated
Pathogen safety data sheet prepared by
References cited in this pathogen safety data sheet

ANNEX 2. BIOSAFETY RISK ASSESSMENT TEMPLATE

The following template can be used to help complete a biosafety risk assessment. It provides an overview of the steps required as part of a biosafety risk assessment, the information that should be gathered and the outcomes that should be recorded. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

For more information and more comprehensive templates for the risk assessment, please refer to the *Monograph: risk assessment (2)*.

Biosafety risk assessment template

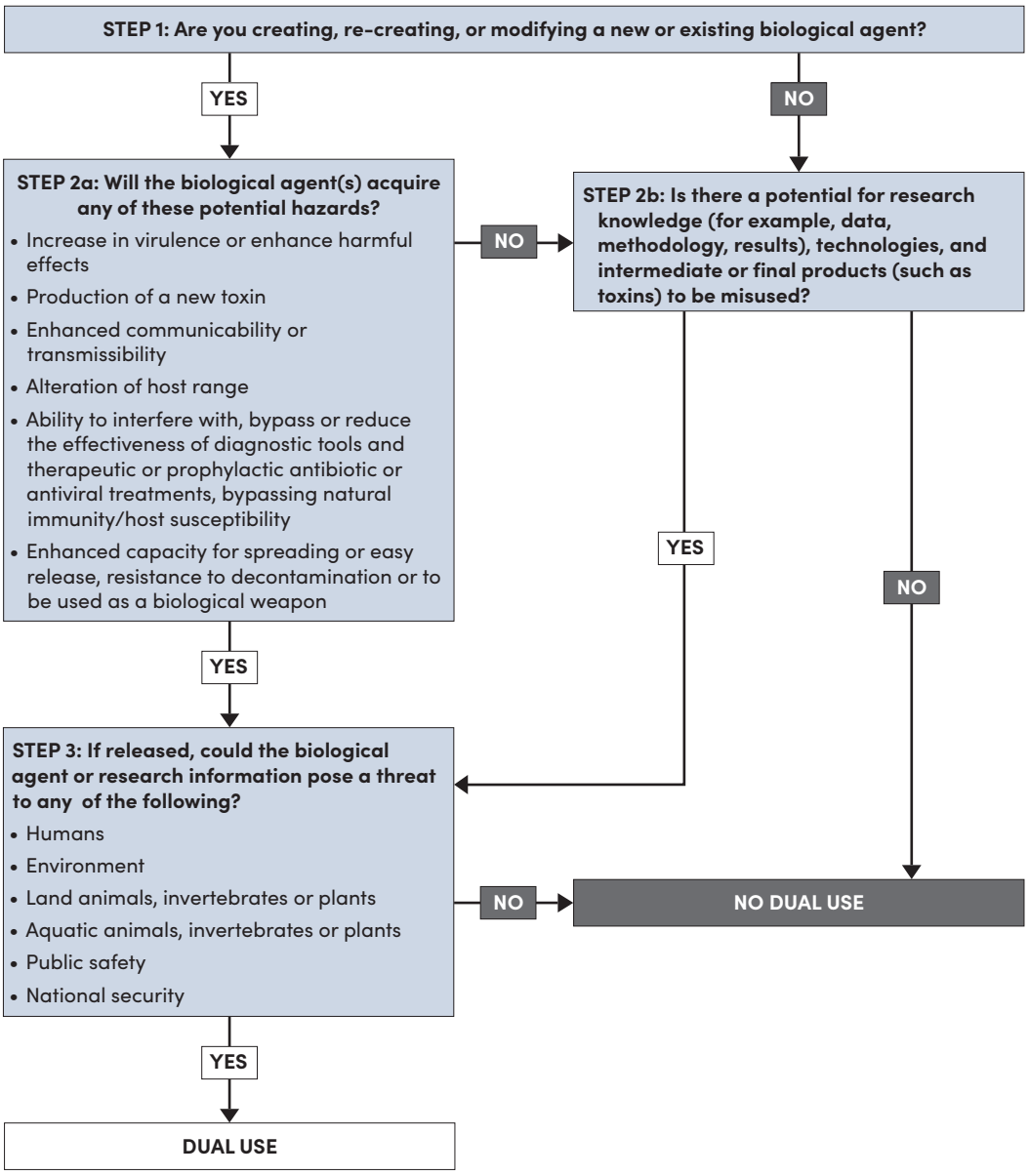
Step 1: Gather information	**Step 2: Evaluate the risks**	**Step 3: Develop a risk control strategy**	**Step 4: Select and implement risk control measures**	**Step 5: Review risks and risk control measures**
For example, biological agents, other potential hazards, laboratory procedures, types of equipment, type and condition of the facility and human factors	For example, potential situations in which exposure or release could occur, likelihood of exposure/release and severity of consequences of exposure/release and the initial risk of the laboratory activity	For example, national legislation, guidelines, policies, available resources and their applicability and sustainability	For example, suitable, advisable or mandatory risk control measures and their availability, effectiveness and sustainability and the residual risk of the laboratory activity	For example, establishment of review cycles for the identification of changes in laboratory activity, biological agent, personnel and changes in knowledge of the biological agent

ANNEX 3. BIOSECURITY RISK ASSESSMENT TEMPLATE

The following template can be used to help complete a biosecurity risk assessment. It provides an overview of the steps required as part of a biosecurity risk assessment, the information that should be gathered and the outcomes that should be recorded. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

	Step 1: Asset identification	Step 2: Risk identification and assessment			Step 3: Risk control		Step 4: Risk acceptance and review
	Asset inventory	**Risk scenarios**	**Likelihood**	**Consequences**	**Risk control measures**	**Vulnerability assessment**	**Strategy review**
Description	Inventory of all tangible and intangible assets.	Description of what could happen as a result of an incident occurring with the asset as listed below.	General indication of the possibility of the risk if a risk control measure is not in place. Consider including: • potential adversary (for example, internal personnel, external individuals), • their motivation and capability to act, and • predicted or known frequency of the scenario.	Indication of the consequences to relevant populations and the extent of the effects.	Description of the applicable risk control strategies to be implemented. Consideration should be given to prevention and response actions.	Assessment of the effectiveness of the risk control strategy on the identified weaknesses in relation to the impact of the likelihood and consequences	Based on the risk assessment and risk control measure, determine the overall risk associated with the asset. Review whether the risk is acceptable. Where the risk is unacceptable, a cost–benefit analysis may help determine if additional risk control measures are necessary. The biosecurity risk assessment should be routinely reviewed and updated when changes affect the risk.
Examples	• information or organisms with dual-use potential • animals • floor plans • equipment • software • documented information • personnel • contractors	• deliberate or accidental loss • unauthorized release • diversion • sabotage • theft • espionage • misuse • terrorism • extortion	• very low • low • moderate • high • very high	• harm, disease or death of animals • harm, disease or death of humans • financial losses • negative effect on the reputation of the organization	Personnel suitability: • security screening • insider threat training Access controls: • security barriers • access control systems • entry and exit records Emergency response: • release recovery procedure • incident reporting	• very low • low • moderate • high • very high	• acceptable • not acceptable

Decision tree to evaluate dual-use potential



ANNEX 4. BIOSAFETY MANUAL TEMPLATE

Table of Contents

Figure A4.1 Example of the table of contents of a biosafety manual

The following template can be used to develop an organizational biosafety manual. It provides suggestions for the information that should be documented and made readily accessible to all personnel as a reference for developing, implementing and reviewing their biosafety obligations and practices. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

1 Overview and purpose

Give a brief description of the institutional or programme overview and the purpose of the biosafety manual. This may include an outline of the intended activities that will be conducted (such as diagnostic, research, production).

2 Scope

The scope of the biosafety manual should identify any areas and individuals that will use this manual, and in which facility locations it will be used.

3 Definition of terms

Complete this section as needed.

4 Institutional policies

4.1 Occupational health policy

Provide a statement that defines the organization's overarching policy and procedures on occupational health, and the associated objectives and targets. The policy may include a statement indicating the commitment of management to occupational health and safety, and may outline the roles and responsibilities that reflect the needs of the organization. The policy may also outline terms of reference, including applicable legislation.

4.2 Biosafety policy

Provide a statement that defines the organization's biosafety intentions, and the associated objectives and targets. The policy may include a statement indicating the commitment of management to biosafety, and outline the roles and responsibilities for safety and security. The policy may also outline terms of reference, including applicable legislation.

5 Roles and responsibilities

Clearly define the roles and responsibilities of all parties involved in the implementation of the biosafety programme, including effective communication and accountability systems. This may include definitions of membership, roles on subcommittees, and the expected frequency and structure of meetings. A code of practice may also be helpful to reinforce a biosafety culture. The parties include:

5.1 Senior management

5.2 Biosafety committee

5.3 Biosafety officer

5.4 Laboratory personnel

6 Operational working practices

Provide a description of the types of operational risk control measures to be implemented and when in order to reduce risk to an acceptable risk.

6.1 Safe work practices and standard operating procedures (SOPs)

6.1.1 Good microbiological practice and procedure (GMPP)

6.1.2 Minimizing aerosols

6.1.3 Working with sharps

6.1.4 Pathogen safety data sheets

6.2 Personal protective equipment

6.3 Working with laboratory animals

6.4 Principles of decontamination

7 Records and documentation

List the types of records that should be retained, who is responsible for maintaining these records, retention periods, legislative or regulatory requirements to keep records, and any associated considerations for the record-management system.

7.1 Inventory control

7.2 Laboratory access

7.3 Licences and authorizations

7.4 Inspection and audit reports

8 Personnel competence and training

Provide a framework that outlines the requirements for personnel training, and how it is developed, implemented and monitored. This may outline mandatory training for all personnel, as well as any job-specific training. Trainings that can be considered include safety (GMPP, SOPs), security, emergency preparedness and response, and legislative obligations. Mechanisms to identify training needs (for example, training needs assessment), and assess knowledge and competence should be considered, as well as frequency of retraining.

8.1 Training programme

9 Risk control measures

Provide a description of the engineering measures and physical controls that were incorporated in the laboratory design in order to reduce risks to an acceptable risk. Consider also equipment maintenance, certification, validation and verification.

9.1 Facility design

9.2 Laboratory equipment

9.3 Biological safety cabinets

9.4 Fume hoods

9.5 Autoclaves and steam sterilizers (safe procedures; verification)

10 Waste management

Provide a description of how waste is to be managed within the organization, including relevant segregation procedures. This section may also outline terms of reference, applicable legislation and the role of third-party waste disposal companies.

11 Biosecurity plan

A comprehensive biosecurity plan will address physical security, personnel suitability and reliability, accountability for pathogens and toxins, inventory control, incident and emergency response, and information management and security. Consideration may be given to the internal oversight mechanisms in place for controlling biosecurity risks (for example, role of the biosafety committee in reviewing projects of dual-use potential).

11.1 Dual-use research of concern

12 Emergency/incident response

Provide details of the organization's emergency response. This includes the actions that will be taken in the event of a spill, release, exposure, power failure, fire or other emergency situations. The contact information of the appropriate personnel can also be included. Incident response and investigation should also be addressed, including internal and external notification requirements.

12.1 Biological spill kit

12.2 General spill procedures

12.3 Incident response

12.4 Incident investigation

13 Occupational health programme

Provide details of the organization's occupational health programme, including measures that are in place to minimize exposure and laboratory-associated infections. Consider the need for medical evaluation and clearances, follow-ups after an incident, available vaccines and post-exposure prophylaxis.

13.1 First aid

13.2 Medical evaluations

13.3 Post-incident follow-up

13.4 Vaccines and preventive medicines

14 Transport and shipment of biological materials

Provide details of the organization's policies and procedures on the transport and shipment of biological materials, including legislative requirements. Consider personnel training or certification before transport, permit or licensing requirements, labelling and packaging, and inventory factors.

14.1 Specimen receipt and storage

14.2 Training and certification

14.3 Packaging and handling

15 Internal and external audits and inspections

Provide details and considerations for conducting internal and external audits and inspections, including legislative requirements, scope, frequency and roles and responsibilities.

16 Laboratory decommissioning

Indicate the considerations for decommissioning a laboratory, including liaison with applicable regulatory authorities, safe waste disposal, transfer of materials and decontamination.

ANNEX 5. BIOSECURITY PLAN TEMPLATE

The following template can be used to develop an organizational biosecurity plan. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

Location information

Facility:

Individual	Phone number	Email address
Biosafety officer Name:		
Security personnel Name:		
Local law enforcement Name:		
Facility manager *(for example, director, senior scientist)* Name:		
Other, as applicable Name:		

Room number:

Date biosecurity plan created:

Date biosecurity plan updated:

Personnel information

Scope

The scope of the biosecurity plan should identify all people and areas to which this plan applies.

Definition of terms

Complete this section as needed.

Roles and responsibilities

Define the roles and responsibilities of all parties involved in the development and implementation of the biosecurity plan. This includes the biosafety officer, senior management, biosafety committee and all other relevant personnel.

Inventory of pathogens and toxins

An inventory is always required for the biological agents handled and stored within a facility. Duplicating the inventory in the biosecurity plan is not necessary; the location of the inventory can be referred to (for example, in the quality management handbook or a designated file in the laboratory office). Referring to an inventory, rather than duplicating it, may support record management and information security, and may also facilitate timely updating (for example, if a laboratory information system is used to manage the inventory).

Biosecurity risk assessment

Complete and include a site-specific assessment of the biosecurity risks. Include descriptions of the risks associated with the assets (for example, pathogens and toxins, animals, knowledge, information, personnel) present and/or procedures conducted in the facility.

Dual-use potential

Detail how and when to assess research with dual-use potential, and how to identify whether more security requirements are necessary should potential dual use be identified.

Risk control measures

Describe risk control measures to be implemented, as identified through the biosecurity risk assessment process. These may include the following paragraphs.

Physical security

List and describe the physical barriers or measures to prevent unauthorized access to

the facility, part of the facility or to assets within the facility, and to protect assets from the identified security risks (for example, theft, diversion, intentional release or misuse). The complexity of the physical security measures should be proportional to the risk.

Personnel suitability and reliability

List and describe the policies and procedures on personnel suitability and reliability, and document the training, experience, competency and suitability requirements for personnel who have access to pathogens, toxins or other assets within the facility.

Pathogen and toxin accountability and inventory control

List and describe the procedures implemented to protect and secure biological assets against theft, misuse, diversion or intentional release. Material control also includes procedures to account for and safely move a pathogen or toxin within the facility, or to transport it to a different building (on site or off site). The level of accountability and risk control measures are identified through the biosecurity risk assessment.

Incident and emergency response

List and describe measures to control biosecurity risks related to incident and emergency response. Relevant procedures from the emergency response can be included here.

Information management and security

List and describe how information on biosecurity assets are protected and secured.

Implementation, evaluation and improvement

Detail the procedures for implementing the biosecurity plan. This can include the installation and testing of physical security components, the initial training of personnel on security policies and procedures, ongoing biosecurity awareness and periodic retraining.

This section should also include procedures for evaluating the effectiveness of the biosecurity plan and how any vulnerabilities will be identified and corrected.

ANNEX 6. OCCUPATIONAL HEALTH AND SAFETY PROGRAMME TEMPLATE

The template below can be used to help develop an occupational health programme. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

Facility information

Facility name:

Facility address:

Date occupational health programme created:

Date occupational health programme updated:

Individual	Phone number	Email address
Biosafety officer Name:		
Employing authority Name:		
Health and safety officer Name:		
Health and safety committee representative Name:		
Other, as applicable Name:		

Scope

Indicate the scope of this document (for example, applicable personnel and locations).

Definition of terms

Complete this section as needed.

Policy

List and describe the facility's occupational health policy. A facility's health policy is a statement of principles and general rules that serve as guides for action.

Roles and responsibilities

Define the roles and responsibilities of the biosafety officer, the health and safety officer or the designated individual (if applicable), the health and safety committee (if applicable) and personnel, as they relate to the occupational health programme.

Occupational health and safety assessment

Complete and include a site-specific assessment of the occupational health and safety risks to personnel, including descriptions of these risks (for example, pathogen or toxin, routes of exposure).

Hazard communication

Describe the procedures that will be used to communicate to personnel the hazards associated with working in the laboratory.

Training programme

Outline occupational health training for all personnel. This may include organization-wide mandatory training, as well as job-specific training when needed.

First-aid training

Indicate whether personnel, and if so how many in a facility, will be trained in first-aid procedures. Procedures to maintain a minimum number of trained first-aid responders on site may be included.

Medical evaluations and clearances

Describe the policies and procedures in place for medical evaluations and clearances. Consider the following components.

Preplacement medical evaluations

Describe procedures for preplacement medical evaluation of personnel. Consider previous and ongoing medical problems, current medications, allergies (for example, to medicines, animals and environmental proteins), and previous immunizations. Patient confidentiality should be considered if pre-existing medical records are reviewed.

Medical evaluations following occupational illness or injury

Describe the facility's procedure for conducting medical evaluations following an occupational illness or injury. Personnel should be encouraged to seek medical evaluation for any emerging symptoms that may be related to the infectious agents in their work area.

Medical records

Describe how the medical records of personnel will be stored and define who will have access to them.

Vaccination

Commercial vaccines can be made available to personnel to provide protection against infectious agents to which they may be exposed. Describe the facility's policy and procedure for vaccinating personnel.

Post-exposure prophylaxis

Describe policy and procedure for post-exposure prophylaxis. Consider whether post-exposure prophylaxis is available following an exposure, where to obtain this, who to contact, timing of administration, and the consequences of exposure compared with the potential harm of treatment.

Monitoring and documentation of laboratory-associated infections

Describe the policies and procedures in place to monitor and document suspected and confirmed laboratory-associated infections, including any legislative or regulatory obligations.

Medical contact card

Consider having a medical contact card for personnel working with high-risk agents or biological agents not commonly encountered in local hospitals. The example below can be modified as needed.

EMERGENCY MEDICAL CONTACT CARD

NAME: _____

DATE ISSUED: _____

I WORK WITH, OR MAY BE EXPOSED TO

Biological agent: _____

Biological agent: _____

Biological agent: _____

Biological agent: _____

This card is to be kept in the possession of the laboratory employee and presented to a physician if an illness occurs that may be associated with a pathogen used within the laboratory (see reverse).

TO THE PHYSICIAN

This employee works in an environment where pathogenic microorganisms are present. Please contact the individuals listed below for information on the agents to which this individual may have been exposed.

FACILITY NAME: _____

ADDRESS: _____

_____

CONTACT 1

Name: _____

Phone number: _____

CONTACT 2

Name: _____

Phone number: _____

ANNEX 7. EMERGENCY RESPONSE TEMPLATE

The following template can be used to help develop an emergency response. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

Facility information

Facility name:

Facility address:

Date emergency response created:

Date emergency response updated:

Scope

Indicate the scope of this document (for example, applicable personnel and locations).

Definition of terms

Complete this section as needed.

Emergency contact information

Add or remove emergency contacts as relevant to your organization

Emergency scenario	Phone number	Email address
Emergency services		
Organizational		
Fire department		
Ambulance		
Police		
Paramedics		
Hospital		
Security		
Environmental health and safety		
Biosafety officer Name:		
Emergency coordinator Name:		
Health and safety officer Name:		
Environmental programmes Name:		
Hazardous waste disposal Name:		
Facility/utility services		
Building manager Name:		
Facilities office Name:		
Electric		
Gas		
Water		
Telephone services		
Internet services		
Medical services		
Medical centre		
Shipping/receiving		
Shipping supply		

Roles and responsibilities

Define who is responsible for emergency response, including training, and the role of the biosafety officer and personnel.

Medical emergencies

MEDICAL EMERGENCY – QUICK REFERENCE SHEET

CALL MEDICAL EMERGENCY PHONE NUMBERS

Paramedics:

Ambulance:

Fire department:

Other *(indicate):*

Tell them what happened

Nature of the emergency

Location *(for example, room number, building, street)*

Your name and phone number

Help the victim

Do not move the victim unless absolutely necessary.

Call the following personnel trained in cardiopulmonary resuscitation/first aid:

- Local first-aid responder *(name and phone number)*
- Personnel *(name and phone number)*

If personnel trained in cardiopulmonary resuscitation/first aid are NOT available:

- Stop bleeding with firm pressure on the wounds *(note: avoid contact with blood or other bodily fluids).*
- Clear the air passages using the Heimlich manoeuvre in case of choking.

In case of needing to give assistance to personnel exposed to hazardous materials, consult the material safety data sheet and wear the appropriate personal protective equipment. Attempt first aid ONLY if trained and qualified.

Describe the procedures that must be followed when a medical emergency occurs. In an emergency situation, an easy-to-follow reference sheet (see example below) or poster may help personnel in their response and may support subsequent incident investigation procedures.

Safety equipment procedures

Describe the procedures in place for using the facility's safety equipment. Safety equipment can include fire extinguishers, emergency eyewash stations and emergency showers.

Evacuation procedures

Describe the facility's evacuation procedures, including avoiding areas of contamination.

Power failure

Describe the procedures to follow in the event of a power failure.

Failure of primary containment devices

Describe the procedures to follow if any of the facility's primary containment devices fail. Consider including information on requirements and procedures for back-up power, full-room decontamination and personnel decontamination.

Emergency planning

Describe the type and level of emergency planning needed for each possible emergency. The course of action may be specific for each emergency (for example, medical, fire and explosions, spills, release of aerosols, injuries, severe weather, natural

Emergency response template

Fire and explosions	
Scenario	**Response/action**
1. ALERT (if fire alarm is not automatically activated)	Notify the local fire department **Phone number:** Notify additional relevant personnel **Phone number:**
	• Describe the procedure personnel must follow if they are working with hazardous biological materials when the fire alarm rings or an explosion occurs • Define the responsibilities of the biosafety officer, emergency coordinator or designated official during a fire/explosions • Describe any additional actions before exiting the laboratory
2. RESCUE	• Detail the emergency exits and routes • Describe the facility's evacuation procedure • Describe additional actions after exiting the laboratory
3. FIRE FIGHTING	• Define when it is safe, if at all, to attempt to extinguish the fire

Severe weather and natural disasters	
Scenario	**Response/action**
1. ALERT	Notify the biosafety officer **Phone number:** Notify additional relevant personnel **Phone number:**
2. SECURE	• Describe the procedure for securing the laboratory in the event of severe weather/natural disaster • Define the responsibilities of the biosafety officer and applicable personnel during a severe weather/natural disaster event • Describe any additional actions required
3. EVACUATE	• Detail the emergency exits and routes • Describe the laboratory evacuation procedure

Emergency response template (continued)

Injuries	
Scenario	**Response/action**
1. ALERT	Notify the biosafety officer **Phone number:** Notify emergency contacts **Phone numbers:**
	• Alert the appropriate people. Consider the level of detail required (for example, What happened? How many people were affected? Where did the incident occur?) • Define the responsibilities of the biosafety officer and relevant personnel during an incident that results in injury
2. ACT	• Describe the procedure for responding to an incident or accident that results in injury • Describe the procedure for the safe removal of contaminated personnel (if applicable) • Describe the procedure for preparing an incident report • Be prepared to provide the biosafety officer with sufficient details for the incident report • Describe any additional actions required

Infectious material spill (without release of aerosols)	
Scenario	**Response/action**
1. ALERT	Notify the biosafety officer **Phone number:** Notify additional relevant personnel **Phone numbers:**
	• Describe the procedure for alerting personnel that a spill has occurred. Consider the level of detail required (for example, Where did the spill occur? What was spilled? How many people were affected?) • Define the responsibilities of the biosafety officer and relevant personnel during a spill • Indicate what emergency equipment is available in the containment area
2. SECURE	• Secure the area, evacuate the area if necessary • Describe the procedure for spill clean-up • Handle the spill in accordance with instructions described in the pathogen safety data sheet • Describe how the incident will be documented • Describe any additional actions required
3. ACT	• Define how injuries will be handled and reported

Emergency response template (continued)

Infectious material spill (with release of aerosols)	
Scenario	**Response/action**
1. CLEAR THE DANGER AREA	• Immediately evacuate all personnel from the area
2. ALERT	Notify the biosafety officer **Phone number:** Notify additional relevant personnel **Phone number:**
	• Describe the procedure for alerting personnel that a spill has occurred. Consider the level of detail required (for example, Where did the spill occur? What was spilled? How many people were affected?) • Define the responsibilities of the biosafety officer and relevant personnel during a spill • Indicate what emergency equipment is available in the containment area
3. SECURE	• Secure the area • Describe the procedure for the safe removal of contaminated personnel (if applicable) • Describe the procedure for cleaning up spills that result in aerosol production • Handle the spill in accordance with instructions described in the pathogen safety data sheet • List and describe how the area and contaminated equipment will be decontaminated • Describe how the incident will be documented • Describe any additional actions required
4. ACT	• List and describe how injuries will be handled and reported

disasters and bomb threats).

The following tables are intended to facilitate emergency response for different emergency scenarios. They do not represent comprehensive emergency response and should be adapted and further developed to meet the needs of your organization.

Incident review and response improvement

Following an incident that results in an emergency response, a review of the facility's response can be conducted to determine if any improvements to the emergency response can be made.

Drills and exercises

Preparation is vital for an effective response in the event of an emergency. Describe the drills and exercises that will be performed to prepare personnel to respond appropriately in the event of an emergency, including how often these will occur and whether or not personnel will be forewarned.

ANNEX 8. INCIDENT REPORTING FORM AND INVESTIGATION REPORT

The following templates (incident reporting form, and investigation reporting form and corrective action plan) can be used to collect information on incidents that have occurred with biological agents. They may help collect information about the occurrence of an incident (including a near miss) that can be used to inform risk assessment reviews and justify corrective actions. They can be modified and adapted to fit your organization's needs.

Definition of terms

Incident: An occurrence that has the potential to, or results in, the exposure of laboratory personnel to biological agents and/or their release into the environment that may or may not lead to actual harm.

Accident: An inadvertent occurrence that results in actual harm such as infection, illness, injury in humans or contamination of the environment.

Primary individual: Person who was directly involved in the incident (for example, injured, first to observe a near miss).

Incident reporting form and investigation report template

SECTION 1 Incident reporting form

To be completed by the primary individual (that is the person who was directly involved in or affected by the incident).

Primary individual		
Name		
Phone number	Home number:	Work number:
Job title		
Job/duties at time of the incident		
Length of time in current position		
Employment status	☐ Full time ☐ Part time ☐ Temporary	☐ Student ☐ Visitor/other
Did injury occur?	☐ No	☐ Yes (describe):
Response to injury	☐ None ☐ No first aid administered; returned to work ☐ First aid administered; returned to work ☐ Saw a physician; returned to work without time lost from work ☐ Saw a physician; returned to light work ☐ Saw a physician; time lost from work ☐ Refused medical treatment ☐ Other (describe):	

Incident reporting form and investigation report template

SECTION 1 Incident reporting form (continued)

To be completed by the primary individual (that is the person who was directly involved in or affected by the incident).

Incident details		
Date and time of incident	Date:	Time:
Date and time that the incident was reported	Date:	Time:
Location of the incident	Building:	Room number:
Description of the incident: *(Include: relevant events leading up to, during and after the incident; any equipment involved; and any personal protective equipment used. Attach additional pages as needed).*		
Date and time of description:		

Incident reporting form and investigation report template

SECTION 2 Investigation reporting form

To be completed by the incident investigator.
Immediate investigation is required in any of the following cases: fatalities, critical injuries, lost time, occupational illness, property damage, fire, or environmental release.

Incident investigation			
Investigator	Name:	Title:	Phone number:
Supervisor	Name:	Title:	Phone number:
Primary individual	Name:	Title:	Phone number:
Witness (1) *(Include additional sections as needed)*	Name:	Title:	Phone number:
Witness account of incident			
Contributing factors *(Check all that apply)*	☐ Hazardous method/procedure ☐ Deviation from/not following procedure ☐ Improper position/posture (ergonomics) ☐ Inadequate personal protective equipment ☐ Incorrect/defective tools ☐ Substandard housekeeping arrangements	☐ Unsafe design/construction ☐ Inexperience ☐ Inadequate training ☐ Inadequate oversight ☐ Inadequate lighting/ventilation ☐ Other (describe):	
Details of contributing factors *(for example, If safety procedures were not followed, why not? If a machine was faulty, why did it fail? Consider: equipment/machinery, tools, procedures, training and work environment. If any of these factors are identified, determine why they were not addressed before the incident.)*			
Recommended corrective actions to prevent a reoccurrence *(Check all that apply)*	☐ Improve design/procedures ☐ Correct congested area ☐ Repair/replace defective tool/equipment ☐ Install guards or safety devices	☐ Retrain person(s) involved ☐ Request ergonomic assessment ☐ Update training ☐ Other (describe):	

Incident reporting form and investigation report template

SECTION 3 Detailed action plan

To be completed by the supervisor, with contributions from a biosafety officer. Action items should be based on the outcome of the incident investigation.

<table>
<tr><th colspan="2">Corrective action plan</th></tr>
<tr><td colspan="2">Plan
(Describe the recommendations, why they are necessary and how they will be implemented)</td></tr>
<tr><td rowspan="4">Action item 1
(Add more items, as necessary)</td><td>Description:</td></tr>
<tr><td>Individual responsible for implementation:</td></tr>
<tr><td>Target implementation date:</td></tr>
<tr><td>Status:</td></tr>
<tr><td colspan="2">Follow-up
(Describe follow-up action observed or needed to prevent subsequent incidents)</td></tr>
</table>

Incident reporting form and investigation report template

Section 4 Information collection checklist

The questions below should be asked (as needed) during an incident investigation and can be included in the templates above.

Who?	
• Who was injured? • Were there any witnesses? • Was anyone working with the employee?	• Who had instructed/assigned the employee? • Who else was involved in the incident? • Who else can help prevent recurrence?
Where?	
• Where did the incident occur? • Where was the employee at the time? • Where was the supervisor at the time?	• Where were coworkers at the time? • Where were other people who were involved at the time? • Where were witnesses when the incident occurred?
When?	
• When did the incident occur? • When did the employee start the task associated with the incident? • When was the employee assigned to the task associated with the incident?	• When was the employee made aware of the hazards associated with the work? • When did a supervisor last check on the employee's overall progress in the job?
Why?	
• Why did the employee continue working under the circumstances? • Why was the supervisor not there at the time? • Why was the employee injured? • Why was the employee doing that task? • Why was protective equipment not available or used?	• Why were specific instructions not given to the employee? • Why was the employee in a particular physical position (ergonomic consideration)? • Why was the employee using the tools or machine? • Why did the employee not check with their supervisor?
How?	
• How did the employee get injured? • How could the incident have been avoided? • How could the employee have avoided injury?	• How could coworkers have avoided the incident? • How could a supervisor have prevented the incident?
What?	
• What was the incident? • What was the injury? • What was the employee doing? • What had the employee been told to do? • What tools was the employee using? • What machine/equipment was involved? • What instructions had the employee been given? • What specific precautions were necessary? • What specific precautions was the employee given? • What personal protective equipment should have been used? • What personal protective equipment was the employee using?	• What had other persons done that contributed to the incident? • What problem or questions did the employee encounter? • What did the employee or witnesses do when the incident occurred? • What extenuating circumstances were there? • What did the employee or witnesses see? • What will be done to prevent recurrence? • What safety rules were violated? • What new rules are needed?

ANNEX 9. INVENTORY TEMPLATE

The following template can be used to help develop a pathogen inventory. It outlines the information that should be recorded and monitored in order to maintain an inventory of biological agents. The sections and the amount of information in them can be modified and adapted to fit your organization's needs.

Inventory template

Principal investigator Name:	
Users with inventory access (add additional names as required) 1. Name: 2. Name: 3. Name: 4. Name:	
Biological agent	For example, bacterium, virus, fungus, toxin
Agent details	Genus, species, strain (as much detail as is known)
Source	Source of the original biological agent, or description of the genetically modified organism
Units (mg/mL, no. of tubes or vials)	Amount of material present
Physical state **Storage location**	State of the stored material (for example, frozen as liquid, lyophilized powder) Building, room no., freezer no., box no. (as detailed as possible)
Acquisition date	Date on which the specimen was received or propagated (and added to inventory)
Use or disposal date	Date that part or all of the material was removed from the inventory
Signatory (upon use or disposal)	Name or signature of the individual that used or disposed of the material

ANNEX 10. SELF-INSPECTION CHECKLIST TEMPLATE

The following template can be used to help complete a biosafety and biosecurity self-audit within your facility. It may be useful for organizations or institutions to internally evaluate their competencies in biosafety and identify any weaknesses that may need to be addressed. It may also be useful to prepare an organization for participation in external inspection or auditing processes. The sections and the amount of information in them should be modified and adapted to fit your organization's needs.

Self-inspection checklist template

Location information			
Facility:			
Department:			
Room number(s):			
Date of audit:			
Personnel information			
Individual´s name	**Phone number**	**Email address**	
Laboratory director Name:			
Biosafety officer Name:			
Lead auditor Name:			
Additional auditor(s) Name(s):			
Other observer(s)/participant(s) Name(s):			
Self-audit checklist (N/A = not applicable)			
Biosafety manual		**Yes**	**No**	**N/A**
The biosafety manual, or relevant components, is accessible to all personnel		☐	☐	☐
The biosafety manual includes all necessary components *(as detailed in Monograph: biosafety programme management)*		☐	☐	☐
Comments *(Description of concerns to be addressed):*				
Biosecurity: laboratory access and physical security		**Yes**	**No**	**N/A**
Access to the laboratory is limited/restricted to authorized personnel		☐	☐	☐
The laboratory is locked when unoccupied		☐	☐	☐
Pathogens are secured (for example, in lockable freezers) and only accessible to authorized personnel		☐	☐	☐
Comments *(Description of concerns to be addressed)*				

Self-inspection checklist template (continued)

Self-audit checklist (N/A = not applicable)			
Occupational health programme	**Yes**	**No**	**N/A**
Appropriate vaccination is considered/provided to personnel	☐	☐	☐
Personnel carry emergency contact cards with up-to-date information	☐	☐	☐
Comments *(Description of concerns to be addressed):*			
Personnel management and training	**Yes**	**No**	**N/A**
Applicable trainings have been successfully completed by all personnel *(Add additional lines for specific training programmes such as equipment, waste management)*	☐	☐	☐
Training records are available and up to date	☐	☐	☐
Proficiency is demonstrated before handling specified pathogens or performing specified activities	☐	☐	☐
Comments *(Description of concerns to be addressed)*			

Self-inspection checklist template (continued)

Self-audit checklist (N/A = not applicable)			
Operational working practices and procedures	**Yes**	**No**	**N/A**
Good microbiological practice and procedure are implemented	☐	☐	☐
Personal protective equipment is available and appropriately used	☐	☐	☐
Appropriate biosafety equipment is available *(for example, biological safety cabinet)*	☐	☐	☐
Equipment is properly maintained	☐	☐	☐
Biosafety manual is readily available	☐	☐	☐
Documented standard operating procedures are readily available	☐	☐	☐
Appropriate warning signs are posted	☐	☐	☐
Appropriate waste containers are available and clearly labelled *(for example, for biohazards, sharps)*	☐	☐	☐
Vaccinations are given and/or medical surveillance is done	☐	☐	☐
Movement and transport procedures are in place and followed	☐	☐	☐
All incidents, including near misses, are reported	☐	☐	☐
All personal protective equipment is removed before leaving the laboratory	☐	☐	☐
Comments *(Description of concerns to be addressed)*			

Self-inspection checklist template (continued)

Self-audit checklist (N/A = not applicable)			
Facility design and safety equipment	**Yes**	**No**	**N/A**
Biohazard signs are posted *(for example, on doors)*	☐	☐	☐
A sink is available for hand washing	☐	☐	☐
The laboratory is designed to be easily cleaned *(for example, it does not have carpets; bench tops and furniture surfaces are made of impervious materials that can be easily disinfected)*	☐	☐	☐
The laboratory is maintained in a clean, orderly and sanitary condition	☐	☐	☐
Separate areas outside of the laboratory are available for storage of personal items, consumption of food and drink	☐	☐	☐
There are no apparent structural defects *(for example, in floors, ceilings)*	☐	☐	☐
Storage units are secure and designed to bear the loaded weight	☐	☐	☐
Storage units are free of accumulated waste, unwanted materials and hazards	☐	☐	☐
Appropriate ventilation systems are present and in working order	☐	☐	☐
Equipment is properly installed	☐	☐	☐
Equipment is certified safe for use	☐	☐	☐
Equipment calibration and/or preventive maintenance schedules are established and followed	☐	☐	☐
Equipment is routinely decontaminated as well as after spills, splashes or other potential contamination	☐	☐	☐
Equipment is decontaminated before repair, maintenance or removal from the laboratory	☐	☐	☐
Comments *(Description of concerns to be addressed)*			

Self-inspection checklist template (continued)

Self-audit checklist (N/A = not applicable)			
Decontamination and waste management	**Yes**	**No**	**N/A**
Processes are in place for the identification and segregation of contaminated materials	☐	☐	☐
Methods for decontamination of waste are available and close to the laboratory *(for example, disinfectants, autoclaves)*	☐	☐	☐
Decontamination methods are verified	☐	☐	☐
Decontamination methods are routinely validated	☐	☐	☐
Comments *(Description of concerns to be addressed)*			
Emergency/incident response	**Yes**	**No**	**N/A**
Emergency contact information is posted	☐	☐	☐
An eyewash station is accessible and maintained	☐	☐	☐
Emergency shower exit is accessible and maintained	☐	☐	☐
Alarm systems are installed and in working order	☐	☐	☐
Emergency response drills are conducted annually	☐	☐	☐
First-aid materials are accessible	☐	☐	☐
Contact information for first-aid personnel and emergency services is clearly posted	☐	☐	☐
Independent power support units are available	☐	☐	☐
Emergency exits are clearly marked	☐	☐	☐
Passageways and exit routes are unobstructed *(for example, clear of furniture)*	☐	☐	☐
Spill clean-up kits are readily available	☐	☐	☐
Comments *(Description of concerns to be addressed)*			

Self-inspection checklist template (continued)

Self-audit checklist (N/A = not applicable)			
Records and documentation	**Yes**	**No**	**N/A**
Standard operating procedures (SOPs) are documented *(Add additional rows for specific types of documents: for example, SOPs for decontamination, for verification of decontamination technology)*	☐	☐	☐
Documents are regularly reviewed, updated and dated *(for example, annual review of SOPs)*	☐	☐	☐
Equipment calibration, maintenance and verification records are maintained	☐	☐	☐
An inventory system is in place and maintained *(for example, for pathogens, for equipment)*	☐	☐	☐
Incident reports are completed and stored, as appropriate	☐	☐	☐
Medical evaluation, vaccination, surveillance and treatment records are maintained	☐	☐	☐
Comments (Description of concerns to be addressed):			
Pathogen list			
(List of pathogens that are handled or stored in the laboratory)			
Additional comments			
(Any additional comments/concerns that are not addressed elsewhere in the checklist)			

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