Canadian Biosafety Guidelines

Containment Level 1:
Physical Design and Operational Practices

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PREFACE

This guidance document was developed by the Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) as part of an ongoing series of electronic publications that expands upon a variety of biosafety and biosecurity concepts discussed in the *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015. The CBH, itself, is a companion document to the *Canadian Biosafety Standard* (CBS), 2nd Edition, 2015. The CBH systematically addresses the concepts required for the development and maintenance of a comprehensive risk-based biosafety management program, and provides the core information and guidance necessary to meet the minimum biosafety and biosecurity requirements for Containment Level 2 to Containment Level 4 facilities outlined in the CBS. The *Containment Level 1 Physical Design and Operational Practices* guideline continues that approach by providing risk-based biosafety recommendations for facilities handling Risk Group 1 (RG1) biological material.

The legislation administered by the PHAC and the CFIA do not apply to RG1 pathogens; consequently, the CBS does not specify requirements for activities with RG1 biological material. It is important to note that *only* the requirements detailed in the CBS are legally enforced; the CBH and this Guideline aim to provide stakeholders with further support and guidance on how to mitigate risks when working with RG1 biological material. Since RG1 biological material can pose a low risk to the health of individual humans or animals, due care should be exercised and safe work practices should be followed when handling these materials. This Guideline describes the general recommendations and considerations for basic laboratory design and the safe handling of RG1 biological material.

Containment Level 1 Physical Design and Operational Practices is a continuously evolving document and subject to ongoing improvement. The PHAC and the CFIA welcome comments, clarifications, and suggestions for incorporation into the future versions of this guidance document. To this end, information and suggestions (with references, where applicable) for the continual improvement of this Guideline can be sent to:

- PHAC e-mail: standards.normes@phac-aspc.gc.ca
- CFIA e-mail: standardsnormes@inspection.gc.ca

ABBREVIATIONS AND ACRONYMS

BSC	Biological safety cabinet
CBH	*Canadian Biosafety Handbook*
CBS	*Canadian Biosafety Standard*
CCAC	Canadian Council on Animal Care
CFIA	Canadian Food Inspection Agency
CL	Containment level (i.e., CL1, CL2, CL3, CL4)
ERP	Emergency response plan
HAA	*Health of Animals Act*
HPTA	*Human Pathogens and Toxins Act*
LRA	Local risk assessment
PHAC	Public Health Agency of Canada
PM room	Post mortem room
PPE	Personal protective equipment
RG	Risk Group (i.e., RG1, RG2, RG3, RG4)
SOP	Standard operating procedure

CHAPTER 1 - INTRODUCTION

Risk Group 1 (RG1) **biological material** consists of **microorganisms**, nucleic acids, or proteins that are either unable or unlikely to cause human or animal **disease**. **Containment level** 1 (CL1) describes a basic laboratory designed for the safe handling and storing of RG1 biological material. CL1 design and practices provide the foundation for all **containment** laboratories to limit **exposure** of personnel and the environment to the RG1 biological material handled within a **facility**. **Biosafety** is primarily achieved through **physical design features** (e.g., a well-designed, functional laboratory), and a basic level of **operational practices** (e.g., **good microbiological laboratory practices**). A CL1 zone can include the following types of work areas where RG1 biological material is used: **laboratory work areas**, **large scale production areas**, and **animal work areas**.

In Canada, the handling, storing, and other activities involving Risk Group 2 (RG2), Risk Group 3 (RG3), and Risk Group 4 (RG4) human **pathogens** and toxins are regulated under the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations*. The importation of RG2, RG3, and RG4 animal pathogens and toxins is regulated under the *Health of Animals* Act (HAA) and the *Health of Animals Regulations*. These acts apply to facilities where activities with RG2, RG3, and/or RG4 are conducted, and are administered by the Public Health Agency of Canada (PHAC) or the Canadian Food Inspection Agency (CFIA), or both. Neither the HPTA nor the HAA apply to RG1 biological material, and by extension, do not apply to CL1 facilities that exclusively handle RG1 biological material.

1.1 Scope

The *Containment Level 1 Physical Design and Operational Practices* guideline provides comprehensive guidance on best practices for basic laboratory design and the safe handling of RG1 biological material. These practices encompass the basics of biosafety and serve as starting points for developing the mandatory practices that are required in higher containment levels, and that are set out in the *Canadian Biosafety Standard* (CBS), 2nd Edition. CL1 work areas are not subject to regulation by the PHAC or the CFIA; thus, the recommendations provided in this document are not to be interpreted as legally binding. Elements provided in this document are presented as recommendations only, and may be followed on a voluntary basis. While work with RG1 biological material does not pose significant biosafety **risks**, it is important to exercise prudent biosafety practices and use good microbiological laboratory practices while working with RG1 biological material. RG1 biological material is not devoid of risk, and has the potential to cause infection in some circumstances (e.g., individuals with compromised immune function).

Additional biosafety training tools, such as online courses and instructional videos, are available on the PHAC's e-learning portal: https://training-formation.phac-aspc.gc.ca. For more information about the biosafety work of the PHAC, an e-mail can be sent to biosafety_biosecurite@phac-aspc.gc.ca, or visit the PHAC website (www.publichealth.gc.ca/pathogens). For more information about the work of the CFIA, an

email can be sent to biocon@inspection.gc.ca, or visit the CFIA website (www.inspection.gc.ca/english/sci/bio/bioe.shtml).

1.2 Risk Group 1 Biological Material

Biological material refers to microorganisms, proteins, and nucleic acids, as well as other biological matter (e.g., cells, tissues, other specimens) that may contain microorganisms, proteins, and nucleic acids, regardless of whether or not they are infectious or toxic. RG1 biological material is defined as a microorganism, nucleic acid, or protein that is either a) not capable of causing human or animal disease (i.e. not a pathogen); or b) capable of causing human disease or animal disease, but unlikely to do so (i.e., a low risk pathogen). Biological agents that are capable but not likely to cause disease are considered to be RG1 **opportunistic pathogens** and pose a low risk to the health of individual humans and/or animals, and low or no risk to public health and animal populations. RG1 pathogens may pose harm to immunocompromised or immunosuppressed individuals (e.g., through medical therapy, pregnancy, diabetes, or other conditions). RG1 biological material is not regulated by the PHAC or the CFIA due to its low risk to public health and animal populations. Nevertheless, due care and safe practices (e.g., good microbiological laboratory practices) are encouraged when handling these materials. In the event that the RG1 biological material has been modified such that it poses a higher risk to personnel and/or the environment and no longer meets the risk profile of RG1 biological material, work with the material should be stopped and the material transferred to a facility of an appropriate containment level.

1.3 How to Use the *Containment Level 1 Physical Design and Operational Practices* Guideline

The *Containment Level 1 Physical Design and Operational Practices* guideline describes the general recommendations and considerations for basic laboratory design and the safe handling of RG1 biological material. The recommendations are risk- and evidence-based and, where possible, performance-based. The recommendations are grouped by topic into multiple matrices in Chapter 2 and Chapter 3 in a manner similar to the requirements outlined in the CBS. Chapters 2 and 3 describe recommended physical design features and recommended operational practices, respectively. Different types of work areas for handling biological material are described, including laboratory work areas, large scale production areas, and animal work areas. A detailed list of all abbreviations and acronyms used throughout this Guideline is located at the beginning of this document. Each abbreviation or acronym is spelled out upon first use in the Guideline, with the abbreviation immediately following in brackets; after its initial definition, the abbreviation is used exclusively throughout the remainder of the document. A comprehensive glossary of definitions for technical terms is located in Chapter 4 of this document; words defined in the glossary appear in **bold type** upon first use in the Guideline. A list of references and other resources is provided in Chapter 5. The *Canadian Biosafety Handbook* (CBH), 2nd Edition, 2015, may be consulted for further guidance and details on a variety of biosafety-related topics, including the development of a comprehensive risk-based biosafety management program.

CHAPTER 2 - PHYSICAL DESIGN FEATURES

In CL1 zones, basic facility design and engineering controls are established to limit the spread of biological material. This is largely achieved by segregating work areas from surrounding administrative and public areas, and establishing designated spaces within the work area where RG1 biological material may be handled. The work areas themselves should be designed to be easy to clean and decontaminate. Basic safety, emergency, and security features are integrated to protect personnel, to prevent animal escape, and to provide a basic level of access and pest control. The following recommendations for physical design features in CL1 zones provided in the matrices are not to be interpreted as requirements; rather, they are provided as best practices for work involving RG1 pathogens. For work involving non-pathogenic RG1 biological material, some of these recommendations may be modified based on a risk assessment.

2.1 General Physical Design Features

The basic physical design features outlined below are applicable to any CL1 work area. This includes laboratory work areas, large scale production areas, and animal work areas. Recommendations specific to large scale production areas incorporate considerations to manage a spill or leak of the large volumes of liquids associated with large scale work.

2.1	General Physical Design Features
2.1.1	Laboratory work areas, large scale production areas, and animal work areas should be separated from public and **administrative areas** by a door.
2.1.2	Dedicated paper/computer work stations should be segregated from work stations where RG1 biological material (e.g., samples, specimens) and animals are handled.
2.1.3	Windows that open to the outside should be equipped with basic pest control (e.g., installed with screens or kept closed at all times).
2.1.4	Space should be provided for the storage of **personal protective equipment** (PPE) in use.
2.1.5	Floors, walls, benchtops, and furniture should be designed to be non-absorbent and resistant to scratches, moisture, and impact for ease of cleaning and **decontamination**, in accordance with function.
2.1.6	Benchtops and other work surfaces should not have open seams.
2.1.7	Backsplashes should be sealed at the wall-bench junction for ease of cleaning and decontamination.
2.1.8	Floors should be slip-resistant in accordance with function.

2.1	General Physical Design Features
2.1.9	Sinks should be provided for handwashing.
2.1.10	Emergency eyewash system should be provided in accordance with work activities.
2.1.11	Large scale production areas should be designed to control the release of large scale process fluids containing viable organisms into sanitary sewers.
2.1.12	**Process equipment**, **closed systems**, and other containment devices used for large scale activities with RG1 organisms should be designed to prevent the release of viable organisms and minimize the generation of **aerosols**.

2.2 Additional Physical Design Features for Animal Work Areas

The following physical design features are applicable to CL1 animal work areas, which include rooms where animals are housed, **post mortem rooms** (PM rooms), and may also include associated corridors. These recommendations build upon the general recommendations for laboratory work areas as well as the basic design considerations established by the Canadian Council on Animal Care's (CCAC's) *Guidelines on Laboratory Animal Facilities*.

2.2	Additional Physical Design Features for Animal Work Areas
2.2.1	Laboratory work areas should be located outside of rooms where animals are housed.
2.2.2	Animal cages and rooms where animals are housed should be designed to prevent animal escape.
2.2.3	Cold storage area (e.g., cold room) or equipment (e.g., freezer) should be provided. Where the design includes a dedicated PM room, cold storage should be located inside or adjacent to the PM room.
2.2.4	Floors and walls should be resistant to repeated decontamination and high pressure washing, in accordance with function.
2.2.5	Floors and walls in animal work areas, including PM rooms and corridors, should be able to withstand anticipated loads (e.g., heavy animals and caging equipment), in accordance with function.

CHAPTER 3 - OPERATIONAL PRACTICES

Operational practices refer to the administrative and procedural controls in place to prevent the inadvertent exposure of personnel to biological material and the release of biological material into the environment. The following recommendations for operational practices in CL1 zones provided in the matrices below are not to be interpreted as requirements; rather, they are provided as best practices for work involving RG1 pathogens. For work involving non-pathogenic RG1 biological material, some of these recommendations may be modified based on a risk assessment.

3.1 Good Microbiological Laboratory Practices

The term "good microbiological laboratory practices" describes a basic set of safe practices and techniques established in microbiology laboratories. Personnel can apply these in any work area where similar laboratory-related activities are performed involving RG1 biological material to prevent the exposure or injury of personnel and to prevent the **contamination** of samples and the environment. Good microbiological laboratory practices provide the foundation upon which all biosafety practices at higher containment levels are based. Due to the low level of risk associated with RG1 biological material, it is generally considered safe to conduct most procedures on a benchtop. In the event that work with RG1 biological material is performed inside a **biological safety cabinet** (BSC), the use of open flames inside the BSC should be avoided so that the protective airflow patterns of the BSC are not disrupted, or the BSC and its filters are not damaged by the flames.

3.1	Good Microbiological Laboratory Practice
3.1.1	Oral pipetting should be strictly prohibited.
3.1.2	Eating, drinking, smoking, storing food and utensils, applying cosmetics, or handling contact lenses should be strictly prohibited in work areas.
3.1.3	Hair (including beards) should be restrained (e.g., hair tied or clipped back) or covered to prevent contact with specimens, containers, or equipment when working with RG1 biological material.
3.1.4	Jewellery that may come in contact with biological material being handled (e.g., rings or long necklaces) or puncture protective gloves should not be worn while handling RG1 biological material.
3.1.5	Open wounds, cuts, scratches, and grazes should be covered with waterproof dressings.
3.1.6	Work stations (e.g., benchtops) should be kept clean and uncluttered to avoid cross-contamination and facilitate cleaning and **disinfection**.

3.1	Good Microbiological Laboratory Practice
3.1.7	All personnel, including visitors and trainees, should wear suitable footwear and PPE while inside the work area or while handling RG1 biological material, which may include: • closed-toe and closed-heel shoes with no or low heels; • dedicated PPE, such as lab coats, aprons, or coveralls worn and stored inside the work area; • gloves when handling RG1 pathogens, animals infected with RG1 pathogens, and materials suspected of containing RG1 pathogens; • protective eyewear, such as googles, when there is a risk of exposure to splashes; and • full face protection (e.g., face shield) when there is a risk of flying objects.
3.1.8	Personal belongings (e.g., purses, backpacks, personal electronic devices) and street clothing (e.g., coats, scarves) should be stored separately from dedicated PPE and away from work stations where RG1 biological material is handled.
3.1.9)	The following practices should be used to establish **aseptic technique**: • clean and disinfect work surfaces before handling RG1 biological material and after any spills; • perform work close to a flame (e.g., Bunsen burner) while vessels of RG1 biological material are opened on a benchtop; • flame the neck of bottles or tubes to create an airflow that is outwards from the vessel upon opening; and • procedures should be performed in a manner that minimizes the risk of producing splashes and aerosols.
3.1.10)	After work with RG1 biological material is complete, work surfaces should be cleaned and disinfected using an appropriate disinfectant and contact time. All items that have come in contact with biological material, including liquid and solid **waste**, should be decontaminated after use or prior to disposal.
3.1.11	Hands should be washed with soap and water for 30-45 seconds after handling RG1 biological material (if gloves are not worn), immediately after removing gloves, and before leaving the work area.
3.1.12	Disposable gloves used when handling RG1 biological material should be discarded after use.
3.1.13	All clothing and PPE should be decontaminated when a known or suspected exposure has occurred.
3.1.14	Personnel should doff PPE in a manner that minimizes contamination of the skin and hair.

3.1	Good Microbiological Laboratory Practice
3.1.15	Safe work practices for handling sharps should be developed and strictly followed, and should include: • actively avoiding the use of needles, syringes, and other sharps; wherever possible, safe alternatives or safety-engineered sharps devices should be used to prevent injury; • refraining from bending, shearing, breaking, or recapping needles, or removing needles from their syringes; • collecting and removing sharp objects (e.g., broken glassware) with a brush and dustpan, or tongs; and • discarding used sharps (e.g., scalpel blades, syringes) and other sharp objects (e.g., broken glassware, pipette tips, broken pipettes) in appropriate puncture-resistant sharps containers.

3.2 Program and Facility Management

The development of facility-wide biosafety programs and policies is crucial in implementing safe work practices and improving safety performance when personnel engage in activities involving RG1biological material. A biosafety program may be created to mitigate the hazards identified by an **overarching risk assessment** of the facility and its general activities. **Local risk assessments** (LRAs), on the other hand, are conducted to identify risks associated with site-specific activities, for which safe work practices are developed and incorporated into standard operating procedures (SOPs). To foster a safe work environment and protect workers from exposure to RG1 pathogens, it is equally important to establish a program to train and educate staff, and an emergency response plan (ERP) to set out procedures for staff to follow in various emergency situations. Policies on regular inspections of the work area by personnel are important for the timely identification of faults and deterioration of surfaces, installations, and equipment that may put personnel at risk of exposure.

3.2	Program and Facility Management
3.2.1	A biosafety program that meets the facility's specific biosafety needs should be in place to oversee safety practices. This may be included with, or incorporated into, other safety programs (e.g., occupational health and safety, chemical safety, radiation safety).
3.2.2	Biosafety policies and procedures should be developed, kept up to date, and incorporated into the facility's existing safety manual, and should include: • institutional biosafety policies, programs, and plans, in response to the hazards and appropriate mitigation strategies identified by an overarching risk assessment; • safe work practices for each task involving RG1 biological material, based on the hazards identified by LRAs; and • SOPs for safe work practices.

3.2	Program and Facility Management
3.2.3	Procedures should be in place and include precautions (e.g., use of cart, closed containers), as determined by an LRA, to prevent a leak, drop, spill, or similar event during the **movement** of biological material within the work area, to other parts of the building, or between buildings.
3.2.4	Traffic flow patterns from areas of lower contamination (i.e., clean) to areas of higher contamination (i.e., dirty) should be established and followed, as determined by an LRA.
3.2.5	An ERP, based on an overarching risk assessment and LRAs, should be developed and kept up to date. The ERP should include the name and telephone number of the emergency contact person and describe emergency procedures in the work area for: • **accidents/incidents**; • medical emergencies; • chemical/biological spills; • animal escape (if applicable); • reporting of incidents to the appropriate internal authority; and • incident follow-up and recommendations to mitigate future risks.
3.2.6	A training program should be developed to educate personnel on all aspects relevant to the safe handling of RG1 biological materials (e.g., SOPs, potential hazards associated with the work involved, necessary precautions, and the correct use of laboratory equipment). Based on this program, personnel should fulfill all stipulated training requirements before working independently with RG1 biological material.
3.2.7	An effective rodent and insect control program should be maintained.
3.2.8	Work areas, including floors, should be kept free of clutter and obstructions in order to facilitate cleaning and disinfection. Excess or extraneous materials should be stored outside of the work area, and use of materials that are difficult to decontaminate should be avoided.
3.2.9	Doors to laboratories and animal work areas (including PM rooms) should be kept closed.
3.2.10	Access to work areas should be limited to **authorized personnel** and authorized visitors.
3.2.11	Personnel should conduct and document regular visual inspections of the work area to identify faults and/or deterioration (e.g., cracked or chipped walls or floors, chipped or worn benchtops, faulty equipment and lighting); when found, corrective actions should be taken.
3.2.12	Records of regular inspections of the work area and corrective actions should be kept on file.

3.2	Program and Facility Management
3.2.13	Large scale **cultures** of RG1 biological material should be contained within a closed system or other containment device (e.g., fermenters, processing vessels) designed to prevent the release of viable organisms.
3.2.14	Process equipment, closed systems, and other containment devices used for large scale activities should be visually inspected for leaks on a regular basis.

3.3 Decontamination and Waste Management

The effective decontamination of waste, materials, equipment, and surfaces that have come in contact with RG1 microorganisms or pathogens is fundamental in limiting the spread of contamination beyond the work area and facility. Bleach is an example of a broad spectrum disinfectant that is generally effective against the majority of concentrated samples of RG1 biological material. A 1:10 dilution of bleach, prepared daily, is sufficient for surface decontamination of most RG1 microorganisms. Rinsing work surfaces with water after the application of bleach will reduce the occurrence of pitting in some surface materials (e.g., stainless steel). Solvents and detergents may also be suitable alternative disinfectants for use, depending on the work being performed.

3.3	Decontamination and Waste Management
3.3.1	Gross contamination should be removed prior to decontamination of surfaces and equipment, and disposed of in accordance with SOPs.
3.3.2	Disinfectants or neutralizing chemicals effective against the RG1 biological material in use should be available and used in the work area.
3.3.3	Equipment that has come in contact with RG1 biological material should be decontaminated prior to maintenance.
3.3.4	Solid and liquid waste, equipment, and other items that have come in contact with RG1 biological material should be decontaminated before disposal or removal from the work area.

3.4 Animal Work Considerations

Additional biosafety concerns exist for work involving animals. Additional risks to personnel include exposure to RG1 pathogens from infected animals or animal products containing RG1 pathogens, and injury due to bites, scratches, or kicks. Animals may harbour microorganisms that are pathogenic to humans as part of their normal flora. Thus, it is important to develop safe work practices to minimize animal stress and protect personnel from exposure or injury.

3.4	Animal Work Considerations
3.4.1	Proper methods of restraint should be used to minimize scratches, bites, kicks, crushing injuries, and accidental self-inoculation.
3.4.2	Caging housing infected animals should be identified with labels.
3.4.3)	Surgical procedures and necropsies should be conducted in an area that is separate from the area where animals are housed, as determined by an LRA.
3.4.4	Inoculation, surgical, and necropsy procedures should be designed and carried out to prevent injuries to personnel and minimize the creation of aerosols.
3.4.5	Infected animals and carcasses should be securely moved into, out of, and within the animal work area.
3.4.6	Animal work areas, PM rooms, and associated corridors, when present, should be decontaminated routinely and when grossly contaminated.

CHAPTER 4 - GLOSSARY

It is important to note that while some of the definitions provided in the glossary are universally accepted, many of them were developed specifically for the CBS or the CBH, and some have been modified to be applicable in the context of the *Containment Level 1 Physical Design and Operational Practices* guideline.

Accident	An unplanned event that results in injury, harm, or damage.
Administrative area	Dedicated room or adjoining rooms that are used for activities that do not involve biological material, including infectious material and toxins. Examples of administrative areas include offices, photocopy areas, and meeting/conference rooms.
Aerosol	A suspension of fine solid particles or liquid droplets in a gaseous medium (e.g., air) that can be created by any activity that imparts energy into a liquid/semi-liquid material.
Animal work area	A room or space dedicated to housing or conducting activities with animals.
Aseptic technique	A set of techniques and practices used in microbiological work when handling microorganisms or other biological samples to prevent sample contamination by microorganisms in the environment. These practices may also provide basic personnel protection from exposure while handling biological material.
Authorized personnel	Individuals who have been granted access to the work area. This should be dependent on completing training requirements and demonstrating proficiency in the standard operating procedures, as determined to be necessary by the facility.
Biological material	Pathogenic and non-pathogenic microorganisms, proteins, and nucleic acids, as well as any biological matter that may contain microorganisms, proteins, nucleic acids, or parts thereof. Examples include, but are not limited to, bacteria, viruses, fungi, prions, toxins, genetically modified organisms, nucleic acids, tissue samples, diagnostic specimens, live vaccines, and isolates of a pathogen (e.g., pure culture, suspension, purified spores).
Biological safety cabinet (BSC)	A primary containment device that provides protection for personnel, the environment, and the product (depending on BSC class) when working with biological material.
Biosafety	Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to biological material, or their accidental release.
Closed system	An apparatus or process system designed to contain biological material and prevent its release into the surrounding environment.

Community	Encompasses both human (i.e., the public) and animal populations.
Containment	The combination of physical design parameters and operational practices that protect personnel, the immediate work environment, and the community from exposure to biological material. The term "biocontainment" is also used in this context.
Containment level (CL)	Minimum physical containment and operational practice requirements for handling infectious material or toxins safely in laboratory, large scale production, and animal work environments. There are four containment levels ranging from a basic laboratory (containment level 1; CL1) to the highest level of containment (containment level 4; CL4).
Contamination	The undesired presence of biological material on a surface (e.g., benchtop, hands, gloves) or within other materials (e.g., laboratory samples, cell cultures).
Culture	The *in vitro* propagation of microorganisms, tissue cells, or other living matter under controlled conditions (e.g., temperature, humidity, nutrients) to generate greater numbers or a higher concentration of the organisms/cells. "Cell culture" refers to cells derived from a human or animal source.
Decontamination	The process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions; this may be accomplished through disinfection, inactivation, or **sterilization**.
Disease	A disorder of structure or function in a living human or animal, or one of its parts, resulting from infection or intoxication. It is typically manifested by distinguishing signs and symptoms.
Disinfection	Process that eliminates most forms of living microorganisms; disinfection is much less lethal to microorganisms than sterilization.
Exposure	Contact with, or close proximity to, infectious material or toxins that may result in infection or intoxication, respectively. Routes of exposure include inhalation, ingestion, inoculation, and absorption.
Facility (plural: facilities)	Structures or buildings, or defined areas within structures or buildings, where biological material is handled or stored. This could include individual research and diagnostic laboratories, or animal housing zones. A facility could also be a suite or building containing more than one of these areas.
Good microbiological laboratory practice	A basic laboratory code of practice applicable to all types of activities with biological material. These practices serve to protect workers and prevent contamination of the environment and the samples in use.

Incident	An event or occurrence with the potential of causing injury, harm, infection, disease, or damage. Incidents may include a biological spill, exposure, inadvertent release of biological material, animal escape, personnel injury or illness, missing samples or specimens, unauthorized entry, power failure, fire, explosion, flood, or other crisis situations (e.g., earthquake, hurricane). Incidents include accidents and near misses.
Laboratory work area	A room or space inside a facility designed and equipped for *in vitro* work with biological material.
Large scale production area	A room or space where activities involving the production of toxins or the *in vitro* culture of biological material on a scale of 10 litres or greater are conducted. This could be a single vessel with a volume of 10 litres or greater, or based on the processes and the microorganism used, could be multiple vessels with a total volume of 10 litres or greater.
Local risk assessment (LRA)	Site-specific risk assessment used to identify hazards based on the biological material in use and the activities being performed. This analysis provides risk mitigation and risk management strategies to be incorporated into the physical design and operational practices of the facility.
Microorganism	A cellular or non-cellular microbiological entity, capable of replication or transferring genetic material and that cannot be reasonably detected by the naked human eye. Microorganisms include bacteria, fungi, viruses, and parasites, and may be pathogenic or non-pathogenic in nature.
Movement	The action of moving (e.g., bringing, carrying, leading, relocating) people, material, or animals from one physical location to another physical location in the same building.
Operational practices	Administrative controls and procedures followed in a containment zone to protect personnel from inadvertent exposure to, and the environment from the inadvertent release of, biological material.
Opportunistic pathogen	A pathogen that does not usually cause disease in a healthy host but can cause disease when the host's resistance is low (e.g., compromised immune system).
Overarching risk assessment	A broad risk assessment that supports the biosafety program as a whole and may encompass multiple work areas within an institution or organization. Mitigation and management strategies reflect the type of biosafety program needed to protect personnel from exposure and to prevent the release of biological material.

Pathogen	A microorganism, nucleic acid, or protein capable of causing disease or infection in humans or animals. Examples of human pathogens are listed in Schedules 2 to 4 and in Part 2 of Schedule 5 of the *Human Pathogens and Toxins Act,* but these are not exhaustive lists. Examples of animal pathogens can be found by visiting the Canadian Food Inspection Agency website.
Personal protective equipment (PPE)	Equipment and/or clothing worn by personnel to provide a barrier against biological material being handled, thereby minimizing the risk of exposure. PPE may include, but is not limited to, lab coats, gowns, gloves, protective footwear, safety glasses, and safety goggles.
Physical design features	Engineering controls and facility design characteristics in place to protect personnel from inadvertent exposure to, and the environment from the inadvertent release of, biological material.
Post mortem (PM) room	A room within an animal work area where animal necropsies and dissections are conducted.
Process equipment	Specific equipment used to carry out a manufacturing procedure involving biological material. This term is generally used to describe equipment used in large scale processes (e.g., industrial fermentation equipment).
Risk	The probability of an undesirable event (e.g., accident, incident, inadvertent release) occurring and the consequences of that event.
Risk group (RG)	The classification of biological material based on its inherent characteristics, including pathogenicity, virulence, risk of spread, and availability of effective prophylactic or therapeutic treatments, that describes the risk to the health of individuals and the public, as well as the health of individual animals and the animal population.
Sterilization	Process that completely eliminates all living microorganisms, including bacterial spores.
Waste	Any solid or liquid material generated by a facility for disposal.

CHAPTER 5 - REFERENCES AND RESOURCES

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