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CANADIAN BIOSAFETY GUIDELINE

CONTAINMENT LEVEL 1: Physical Design and Operational Practices

Canada

The *Canadian Biosafety Guideline – Containment Level 1: Physical Design and Operational Practices* is available on the Internet at the following address:
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PREFACE

PREFACE

In Canada, facilities where Risk Group 2, 3, and 4 human pathogens or toxins are handled and stored are regulated by the Public Health Agency of Canada (PHAC) under the *Human Pathogens and Toxins Act* (HPTA) and the *Human Pathogens and Toxins Regulations* (HPTR). The importation of animal pathogens, infected animals, animal products or by-products (e.g., tissue, serum), or other substances that may carry an animal pathogen or toxin or parts thereof are regulated by the PHAC or the Canadian Food Inspection Agency (CFIA) under the *Health of Animals Act* (HAA) and *Health of Animals Regulations* (HAR).

The following figure depicts the document hierarchy used by the PHAC to oversee biosafety and biosecurity operations. Each tier of the pyramid corresponds to a document type, with documents increasing in order of precedence moving upwards. Acts and regulations are the documents that convey the PHAC's legal authorities, and, therefore, are found at the top of the pyramid. Guidance material and technical pieces are found at the bottom of the pyramid, as they are intended to summarize recommendations and scientific information only.

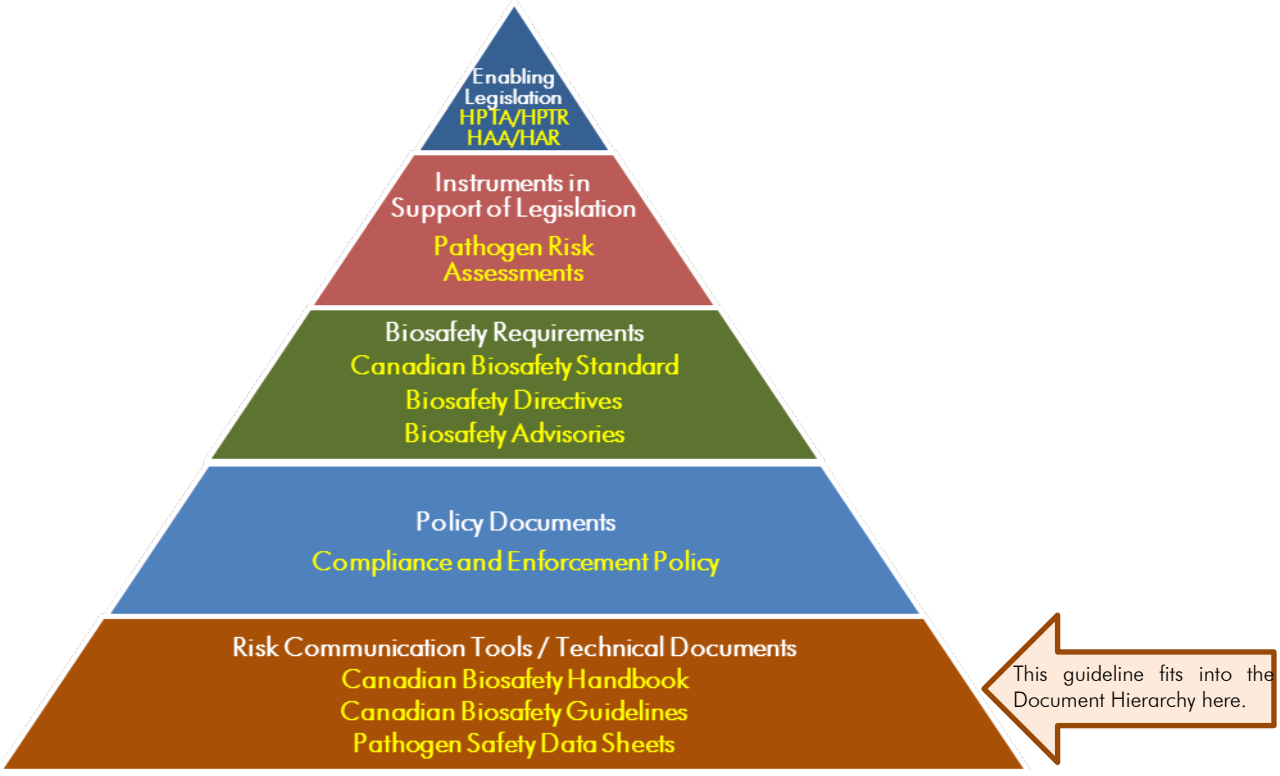

Figure 1: The Public Health Agency of Canada's Biosafety and Biosecurity Document Hierarchy

Containment Level 1: Physical Design and Operational Practices was developed by the PHAC and the CFIA as part of a series of electronic publications that expand upon the biosafety and biosecurity concepts discussed in the current edition of the *Canadian Biosafety Handbook* (CBH), the companion document to the *Canadian Biosafety Standard* (CBS). This guideline provides risk-based biosafety recommendations for facilities handling Risk Group 1 (RG1) biological material.

While the CBS does not specify requirements applicable to the handling and storing of RG1 biological material, it is recommended that RG1 material be handled safely using safe work practices, and be conducted in a laboratory or animal area that incorporates basic laboratory design. The CBH and this guideline aim to provide stakeholders with support and guidance on how to mitigate risks when working with RG1 biological material. At most, RG1 biological material can pose a low risk to the health of individual humans or animals, and a low risk to public health or animal populations; still, reasonable precautions should be taken 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 continuously evolving and subject to ongoing improvement. The PHAC and the CFIA welcome comments, clarifications, and suggestions for incorporation into future versions. Please send this information (with references, where applicable) to:

- PHAC e-mail: PHAC.pathogens-pathogenes.ASPC@canada.ca

ABBREVIATIONS AND ACRONYMS

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BSC	Biological safety cabinet
CBH	*Canadian Biosafety Handbook*
CBS	*Canadian Biosafety Standard*
CFIA	Canadian Food Inspection Agency
CL	Containment Level (i.e., CL1, CL2, CL3, CL4)
ERP	Emergency response plan
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

1
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INTRODUCTION

CHAPTER 1 - INTRODUCTION

The words in bold type are defined in the glossary found in Chapter 4.

Containment level 1 (CL1) describes a basic **laboratory** designed for the safe handling and storing of **Risk Group** 1 (RG1) **biological material**. CL1 design and practices provide the foundation for all containment laboratories to limit exposure of personnel and the environment to the 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: laboratory work areas, large scale production areas, and animal work areas. Due to the low public and animal health risks of RG1 biological material, the *Canadian Biosafety Standard* (CBS) does not specify requirements applicable to such facilities.[1] However, some RG1 organisms may be regulated under other legislation, such as the *Canadian Environmental Protection Act, 1999* and the *New Substances Notification Regulations (Organisms)*, administered by Environment and Climate Change Canada.[2,3]

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 required in higher containment levels and specified in the CBS. Elements provided in this document are presented as recommendations only and may be followed on a voluntary basis. As described in Section 1.2, 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).

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, or parts thereof, 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**; or b) capable of causing human disease or animal disease, but unlikely to do so.

RG1 pathogens pose a low risk to the health of individual humans and 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). The *Human Pathogens and Toxins Act* (HPTA) and *Human Pathogens and Toxins Regulations* (HPTR) do not cover RG1 organisms, due to their low risk; therefore, laboratories and other facilities conducting activities with RG1 biological material are not regulated by the Public Health Agency of Canada (PHAC).[4,5] Nevertheless, reasonable precautions should be taken (e.g., good microbiological laboratory practices) when handling these materials. If RG1 biological material is modified resulting in an increased risk to personnel or the environment (i.e., increased virulence or pathogenicity, communicability, resistance to a preventive or therapeutic treatment, or toxicity of a toxin), work with the material is to be stopped and the material must be transferred to a facility of an appropriate containment level that holds a valid Pathogen and Toxin Licence from the PHAC for such activities. Alternatively, the facility may choose to apply for a Pathogen and Toxin Licence from the PHAC to conduct controlled activities with a Risk Group 2, 3, or 4 pathogen.

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

This guideline describes the general recommendations and considerations for basic laboratory design and the safe handling of RG1 biological material; these recommended practices are risk-and evidence-based. The physical design features and operational practices for CL1 zones described in this document are considered best practices for work involving RG1 pathogens. A local risk assessment (LRA), based on the procedures to be performed and the organisms to be handled, may indicate that some of the recommendations be modified or not applicable, depending on the situation. Chapters 2 and 3 describe the recommended physical design features and operational practices, respectively. The format used in this document is similar to that used in the CBS to present the biosafety requirements for containment levels 2 to 4. Recommendations are grouped by topic into multiple matrices; reference to the related CBS requirement(s) appears in smaller font in brackets beneath the number of the recommendation. 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) 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.[6]

References

1 Government of Canada. (2015) *Canadian Biosafety Standard* (2nd ed.). Ottawa, ON, Canada: Government of Canada.

2 *Canadian Environmental Protection Act, 1999 (S.C. 1999, c. 33).* (2017).

3 *New Substances Notification Regulations (Organisms) (SOR/2005-248).* (2017).

4 *Human Pathogens and Toxins Act (S.C. 2009, c. 24).* (2017).

5 *Human Pathogens and Toxins Regulations (SOR/2015-44).* (2017).

6 Government of Canada. (2016). *Canadian Biosafety Handbook* (2nd ed.) . Ottawa, ON, Canada: Government of Canada.

CHAPTER 2

PHYSICAL DESIGN FEATURES

CHAPTER 2 - PHYSICAL DESIGN FEATURES

For all containment levels, design and engineering controls are established to limit the spread of biological material. In CL1 zones, this can be quite basic, and is largely achieved by segregating work areas from surrounding public and administrative areas, and establishing designated spaces within the work area where 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.

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. Design features specific to large scale production areas incorporate considerations to manage a spill or leak of large volumes of liquids.

2.1	General Physical Design Features
2.1.1 (CBS 3.1.1)	Laboratory work areas, large scale production areas, and animal work areas are separated from public and administrative areas by a door.
2.1.2 (CBS 3.1.2)	Dedicated paper/computer work stations are segregated from work stations where RG1 biological material (e.g., samples, specimens) and animals are handled.
2.1.3 (CBS 3.2.1)	Windows that open to the outside are equipped with basic pest control (e.g., installed with screens or kept closed at all times).
2.1.4 (CBS 3.3.9)	Space is provided for the storage of personal protective equipment (PPE) in use.
2.1.5 (CBS 3.4.1)	Floors, walls, benchtops, and furniture are non-absorbent and resistant to scratches, moisture, and impact, to allow decontamination and cleaning, in accordance with function.
2.1.6 (CBS 3.4.2)	Benchtops and other work surfaces do not have open seams, to allow cleaning and decontamination.

2.1	General Physical Design Features
2.1.7 (CBS 3.4.4)	Backsplashes that are installed tight to a wall are sealed at the wall-bench junction, to allow cleaning and decontamination.
2.1.8 (CBS 3.4.5)	Floors are slip-resistant in accordance with function.
2.1.9 (CBS 3.6.4)	Sinks are provided for handwashing. If sinks are not available, sanitizers are provided to decontaminate hands.
2.1.10 (CBS 3.6.6)	Emergency eyewash station or equipment is provided in accordance with work activities.
2.1.11 (CBS 3.6.7)	Large scale production areas prevent the release of large scale process fluids containing viable organisms into sanitary sewers or any other route of exit from the facility.
2.1.12 (CBS 3.7.4)	Process equipment, closed systems, and other containment devices used for large scale activities with RG1 organisms are 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 best practices build upon the general best practices for laboratory work areas as well as the basic design considerations established by the Canadian Council on Animal Care's *Guidelines on Laboratory Animal Facilities*.[1]

2.2	Additional Physical Design Features for Animal Work Areas
2.2.1 (CBS 3.1.4)	Laboratory work areas are located outside of rooms where animals are housed.
2.2.2 (CBS 3.7.10)	Animal cages and rooms where animals are housed are designed to prevent animal escape.

2.2.3 (CBS 3.1.5)	Cold storage area (e.g., cold room) or equipment (e.g., freezer) is provided in or adjacent to the PM room, where the design includes a dedicated PM room, to minimize the decay of animal carcasses during temporary storage.
2.2.4 (CBS 3.4.1)	Floors and walls are resistant to repeated decontamination and high pressure washing, in accordance with function.
2.2.5 (CBS 3.4.6)	Floors and walls in animal work areas, including PM rooms and corridors, are able to withstand anticipated loads (e.g., heavy animals and caging equipment), in accordance with function.

Reference

1 Canadian Council on Animal Care (CCAC). (2003). *CCAC Guidelines on: Laboratory Animal Facilities - Characteristics, Design and Development.* Ottawa, ON, Canada: Canadian Council on Animal Care.

CHAPTER 3

OPERATIONAL PRACTICES

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.

3.1 Good Microbiological Laboratory Practices

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 is to be avoided. Open flames inside a BSC disrupt airflow and can damage the BSC and its filters. The term "good microbiological laboratory practices" describes a basic set of safe practices and techniques established in microbiology laboratories.[1,2] 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.

3.1	Good Microbiological Laboratory Practice
3.1.1 (CBS 4.6.5)	Oral pipetting is strictly prohibited.
3.1.2 (CBS 4.6.1)	Eating, drinking, smoking, storing food and utensils, applying cosmetics, or handling contact lenses is strictly prohibited in work areas.
3.1.3 (CBS 4.6.2)	Hair that may become contaminated through contact with hands, specimens, containers, or equipment is restrained (e.g., hair tied or clipped back) or covered when working with RG1 biological material.
3.1.4 (CBS 4.6.4)	Jewellery that may come in contact with biological material being handled (e.g., rings or long necklaces) or that may puncture a protective glove are not to be worn while handling RG1 biological material.
3.1.5 (CBS 4.6.6)	Open wounds, cuts, scratches, and grazes are covered with waterproof dressings.
3.1.6 (CBS 4.6.35)	Work stations and work areas, including floors, are kept free of clutter and obstructions in order to facilitate cleaning and disinfection. Excess or extraneous materials are stored outside of the work area, and use of materials that are difficult to decontaminate is avoided.

3.1	Good Microbiological Laboratory Practice
3.1.7 (CBS 4.5.1)	Doors to laboratories and animal work areas (including PM rooms) are kept closed.
3.1.8 (CBS 4.5.2)	Access to work areas is limited to authorized personnel and authorized visitors.
3.1.9 (CBS 4.4.1, 4.4.2, 4.4.4, 4.6.3)	All personnel, including visitors, volunteers, and trainees, wear suitable footwear and PPE while inside the work area or while handling RG1 biological material. PPE should be exclusively worn and stored in the CL1 work area including: • shoes that cover the entire foot, with no or low heels; • PPE, such as lab coats, aprons, gloves, or coveralls; • protective eyewear, such as goggles, 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.
3.1.10 (CBS 4.5.10, 4.5.11)	Personal belongings (e.g., purses, backpacks, personal electronic devices) and street clothing (e.g., coats, scarves) are stored separately from PPE and away from work stations where RG1 biological material is handled.
3.1.11 (CBS 4.6.11, 4.6.36, 4.6.33)	The following practices are used to establish aseptic technique and provide basic personnel protection from exposure: • work surfaces are cleaned and disinfected before handling RG1 biological material and after any spills; and, • procedures are performed in a manner that minimizes the risk of producing splashes and aerosols.
3.1.12 (CBS 4.8.7, 4.8.8)	After work with RG1 biological material is complete, work surfaces are 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, are decontaminated after use or prior to disposal.
3.1.13 (CBS 4.5.15)	Hands are washed with soap and water for 15-20 seconds after handling RG1 biological material if gloves are not worn or immediately after removing gloves, and before leaving the work area. If sinks are not available, sanitizers are used to decontaminate hands.
3.1.14 (CBS 4.8.5)	All clothing and PPE (including gloves) are decontaminated when a known or suspected exposure has occurred.
3.1.15 (CBS 4.5.14)	Personnel doff PPE in a manner that minimizes contamination of the skin and hair.

3.1	Good Microbiological Laboratory Practice
3.1.16 (CBS 4.6.9, 4.6.10, 4.8.3)	Safe work practices for handling sharps are developed and strictly followed, and include: • actively avoiding the use of needles, syringes, and other sharps; wherever possible, safe alternatives or safety-engineered sharps devices are 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. A biosafety program is created to mitigate the hazards identified by an overarching risk assessment of the facility and its general activities. 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, 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 or cause a release into the environment.

The size and complexity of an organization will determine who is responsible for the development and implementation of the biosafety program, including the overarching and local risk assessments. For example, in a larger institution such as a university, the overarching risk assessment is often carried out by senior management in collaboration with the biological safety officer, while the local risk assessment may be conducted by laboratory workers and/or the principal investigator. In smaller organizations, biosafety program and facility management may be a shared responsibility between laboratory workers and administrative personnel.

3.2	Program and Facility Management
3.2.1 (CBS 4.1.1)	A biosafety program that meets the facility's specific biosafety needs is 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 (CBS 4.1.10)	Biosafety policies and procedures are developed, kept up to date, and incorporated into the facility's existing safety manual, and include: • institutional biosafety policies, programs, and plans, in response to the hazards and appropriate mitigation strategies identified by an overarching risk assessment; and, • SOPs for safe work practices for each task involving RG1 biological material, based on the hazards identified by LRAs.
3.2.3 (CBS 4.6.31)	Procedures are 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 or to other parts of the building.
3.2.5 (CBS 4.9.1)	An ERP, based on an overarching risk assessment and LRAs, is developed and kept up to date. The ERP 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 (CBS 4.1.14, 4.3.1, 4.3.2)	A training program is 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 fulfill all stipulated training requirements before working independently with RG1 biological material.
3.2.7 (CBS 4.6.37)	An effective rodent and insect control program is developed and maintained.

3.2	Program and Facility Management
3.2.8 (CBS 5.1.2)	Regular visual inspections of the work area are conducted and documented by personnel to identify faults and deterioration (e.g., cracked or chipped walls or floors, chipped or worn benchtops, faulty equipment and lighting); when found, corrective actions should be taken.
3.2.9 (CBS 4.10.5)	Records of regular inspections of the work area and corrective actions are kept on file.
3.2.10 (CBS 5.1.7)	Process equipment, closed systems, and other containment devices used for large scale activities are 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 microorganisms 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 RG1 biological material. A 10% dilution of bleach (i.e., 1 in 10 dilution, or 5,000 parts per million [ppm] sodium hypochlorite), prepared daily and applied for an appropriate contact time, 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, detergents, and alcohols may also be suitable alternative disinfectants for use, depending on the biological material and the work being performed. For example, alcohol (e.g., 70% ethanol or isopropanol, in water) is often used as an alternative to bleach as it is generally effective against vegetative bacteria, mycobacteria, and enveloped viruses; however, it is not effective against bacterial or fungal spores.[3,4] Contact time and concentration of an alcohol solution are critical factors for its effectivity as a disinfectant since it can quickly evaporate; therefore, procedural and storage conditions should be designed to account for this.[5]

3.3	Decontamination and Waste Management
3.3.1 (CBS 4.8.1)	Gross contamination is removed prior to decontamination of surfaces and equipment, and disposed of in accordance with SOPs. Organic material such as bedding, feed, excrement, blood, and tissues are examples of gross contamination that can be removed by physical methods, such as scraping, brushing, and wiping.

3.3	Decontamination and Waste Management
3.3.2 (CBS 4.8.2, 4.8.11)	Disinfectants or neutralizing chemicals effective against the RG1 biological material are available, used in the work area, and routinely verified.
3.3.3 (CBS 4.8.8)	Equipment that has come in contact with RG1 biological material is decontaminated prior to maintenance and repair.
3.3.4 (CBS 4.8.7, 4.8.8)	Solid and liquid waste, equipment, and other items that have come in contact with RG1 biological material is decontaminated prior to disposal or removal from the work area, or placed in closed, labelled, and leakproof containers that have been surface decontaminated for movement or transport to another area for decontamination.

3.4 Animal Work Considerations

Additional biosafety concerns exist for work involving animals. Animals may harbour microorganisms that are pathogenic to humans as part of their normal flora, creating additional risks to personnel that include exposure to RG1 pathogens from infected animals or animal products containing RG1 pathogens, and injury due to bites, scratches, or kicks. 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 (CBS 4.7.1)	Proper methods of restraint are used to minimize scratches, bites, kicks, crushing injuries, and accidental self-inoculation.
3.4.2 (CBS 4.7.2)	Caging that houses infected animals is identified with labels.
3.4.3	Surgical procedures and necropsies are conducted in an area that is separate from the area where animals are housed.
3.4.4 (CBS 4.7.7)	Inoculation, surgical, and necropsy procedures are designed and carried out to prevent injuries to personnel and minimize the creation of aerosols.
3.4.5 (CBS 4.7.5)	Infected animals and carcasses are securely moved into, out of, and within the animal work area.
3.4.6 (CBS 4.8.14)	Animal work areas, PM rooms, and associated corridors, when present, are decontaminated routinely and when grossly contaminated.

References

1 Occupational Safety and Health Administration and American Biological Safety Association Alliance. (date unknown). *Principles of Good Microbiological Practice*. Retrieved 06/24, 2017 from https://absa.org/wp-content/uploads/2017/01/PrinciplesGoodMicroPracticesFactSheet.pdf

2 Microbiology Society. (2017). *Good microbiological laboratory practice*. Retrieved 06/24, 2017 from http://microbiologyonline.org/teachers/safety-information/good-microbiological-laboratory-practice

3 Ali, Y., Dolan, M.J., Fendler, E.J., & Larson, E.L. (2001). *Alcohols*. In: Block, S.S. (Ed.), *Disinfection, Sterilization, and Preservation* (5th ed., pp. 229-253). Philadelphia, USA: Lippincott Williams & Wilkins.

4 Favero, M.S., and Arduino, M.J. (2006). *Decontamination and Disinfection*. In Fleming, D.O. & Hunt, D.L. (Eds.), *Biological Safety: Principles and Practices* (4th ed. pp.373-381). Washington D.C., USA: ASM Press.

5 McDonnell, G. (2007). *Antisepsis, Disinfection, and Sterilization*. Washington, DC, USA: ASM Press.

CHAPTER 4

GLOSSARY

CHAPTER 4 - GLOSSARY

It is important to note that the definitions provided in this glossary may differ from universally accepted definitions or those published in the CBS and the CBH. Terms identified with an asterisk (*) have been specifically adapted from the CBS and the CBH definitions for use within the context of this 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 material 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.
Biosecurity	Security measures designed to prevent the loss, theft, misuse, diversion, or intentional release of pathogens, toxins, and other related assets (e.g., personnel, equipment, non-infectious material, and animals).
Closed system	An apparatus or process system designed to contain biological material and prevent its release into the surrounding environment.
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).
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.
Doff	Action of removing an article of wear (e.g., personal protective equipment) from the body.
Emergency response plan (ERP)	A document outlining the actions to be taken and the parties responsible in emergency situations such as a spill, exposure, release of infectious material or toxins, animal escape, personnel injury or illness, power failure, fire, explosion, or other emergency situations (e.g., flood, earthquake, hurricane).
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	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, large scale production areas, 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	An area within a facility or the facility itself where biological material is handled for scientific or medical purposes.
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 work area to protect personnel from inadvertent exposure to, and the environment from the inadvertent release of, biological material.
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 Risk Group 2, Risk Group 3, and Risk Group 4 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).
Release	The discharge of infectious material or toxins, from a containment system.
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 animals and the animal population.
Standard operating procedure (SOP)	A document that standardizes safe work practices and procedures for activities with biological material in a containment zone, as determined by a local risk assessment.
(Microbial) Toxin	A poisonous substance that is produced or derived from a microorganism and can lead to adverse health effects in humans or animals. Human toxins are listed in Schedule 1 and Part 1 of Schedule 5 in the *Human Pathogens and Toxins Act.*
Waste	Any solid or liquid material generated by a facility for disposal.

CHAPTER 5

REFERENCES AND RESOURCES

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Ali, Y., Dolan, M.J., Fendler, E.J., & Larson, E.L. (2001). *Alcohols*. In: Block, S.S. (Ed.), *Disinfection, Sterilization, and Preservation* (5th ed., pp. 229-253). Philadelphia, USA: Lippincott Williams & Wilkins.

Canadian Council on Animal Care (CCAC). (2003). *CCAC Guidelines on: Laboratory Animal Facilities - Characteristics, Design and Development*. Ottawa, ON, Canada: Canadian Council on Animal Care.

Canadian Environmental Protection Act, 1999 (S.C. 1999, c. 33). (2017).

Chosewood, L. C. & Wilson, D. E. (Eds). (2007). *Biosafety in Microbiological and Biomedical Laboratories* (5th ed.). Washington. D.C., USA: U.S. Government Printing Office.

Cipriano, M. L. (2006). Large-Scale Production of Microorganisms. In Fleming, D.O. & Hunt, D.L. (Eds.), *Biological Safety: Principles and Practices* (4th ed., pp. 561-577). Washington D.C., USA: ASM Press.

Favero, M.S., and Arduino, M.J. (2006). *Decontamination and Disinfection*. In Fleming, D.O. & Hunt, D.L. (Eds.), *Biological Safety: Principles and Practices* (4th ed., pp. 373-381). Washington D.C., USA: ASM Press.

Fleming, D. O. (2006). Prudent Biosafety Practices. In Fleming, D.O. & Hunt, D.L. (Eds.). *Biological Safety: Principles and Practices* (4th ed., pp. 361-371). Washington D.C., USA: ASM Press.

Government of Canada. (2016). *Canadian Biosafety Handbook* (2nd ed.). Ottawa, ON, Canada: Government of Canada. Available from https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/handbook-second-edition.html

Government of Canada (2015). *Canadian Biosafety Standard* (2nd ed.). Ottawa, ON, Canada: Government of Canada. Available from https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/second-edition.

Health of Animals Act (S.C. 1990, c. 21). (2017).

Health of Animals Regulations (C.R.C., c. 296). (2017).

Human Pathogens and Toxins Act (S.C. 2009, c. 24). (2017).

Human Pathogens and Toxins Regulations (SOR/2015-44). (2017).

McDonnell, G. (2007). *Antisepsis, Disinfection, and Sterilization*. Washington, DC, USA: ASM Press.

Microbiology Society. (2017). *Good microbiological laboratory practice*. Retrieved 06/24, 2017 from http://microbiologyonline.org/teachers/safety-information/good-microbiological-laboratory-practice

New Substances Notification Regulations (Organisms) (SOR/2005-248). (2017).

Occupational Safety and Health Administration and American Biological Safety Association Alliance. (date unknown). *Principles of Good Microbiological Practice*. Retrieved 06/24, 2017 from https://absa.org/wp-content/uploads/2017/01/PrinciplesGoodMicroPracticesFactSheet.pdf

Pritt, S., Hankenson, F. C., Wagner, T., & Tate, M. (2007). The basics of animal biosafety and biocontainment training. *Lab Animal*, 36(6): 31-38.

Public Health Agency of Canada. (2004). *Laboratory Biosafety Guidelines* (3rd ed.). Ottawa, ON, Canada: Public Health Agency of Canada.

Public Health Agency of Canada. (2008). *Laboratory Biosafety 101* (video recording). Retrieved 06/22, 2017 from https://training-formation.phac-aspc.gc.ca

World Health Organization. (2004). *Laboratory Biosafety Manual* (3rd ed.). Geneva, Switzerland: World Health Organization.