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CANADIAN BIOSAFETY GUIDELINE

VETERINARY PRACTICES
Physical Design and Operational Practices for Diagnostic Activities

Canada

The *Canadian Biosafety Guideline – VETERINARY PRACTICES: Physical Design and Operational Practices for Diagnostic Activities* is available on the Internet at the following address: https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/guidance.html

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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.

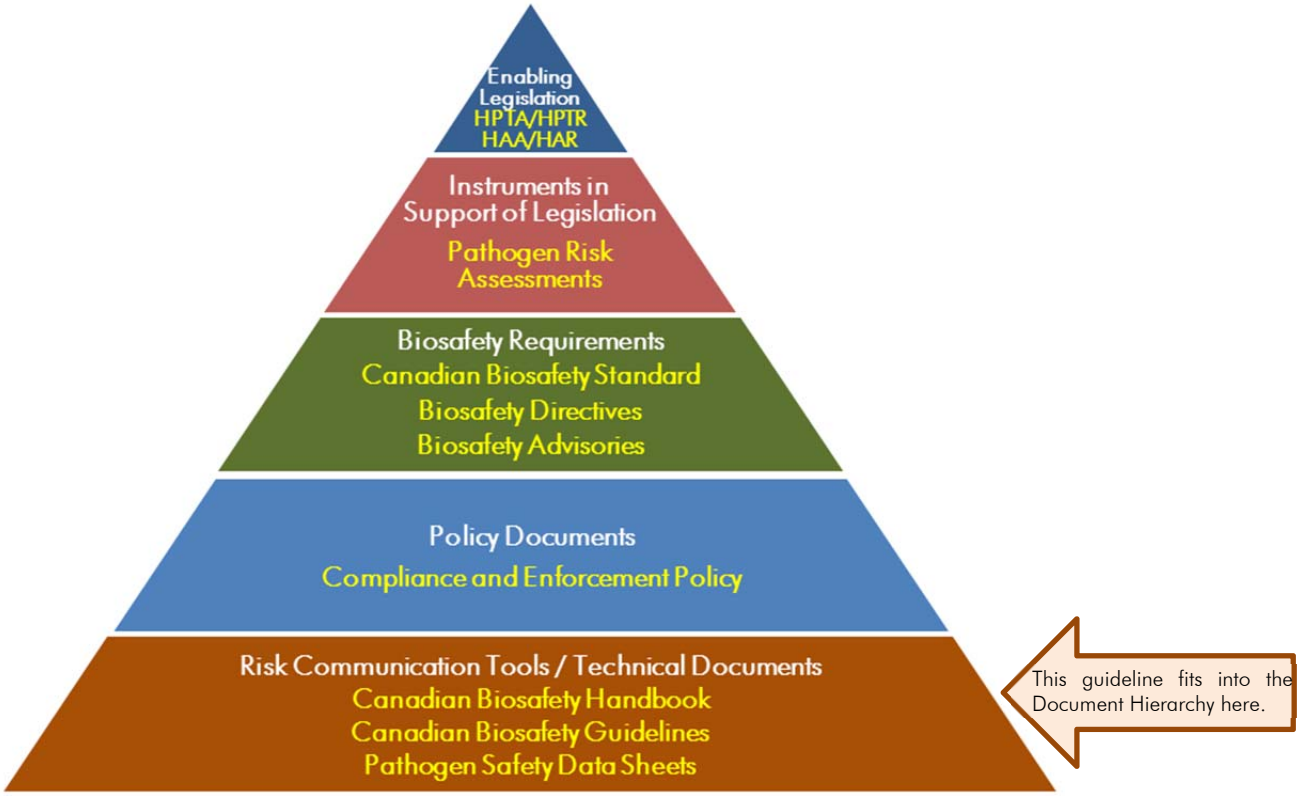

Figure 1: The Public Health Agency of Canada's Biosafety and Biosecurity Document Hierarchy

Veterinary Practices: Physical Design and Operational Practices for Diagnostic Activities 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 precautions and additional recommendations for veterinary facilities performing laboratory analyses and diagnostic testing with Risk Group 2 (RG2) human pathogens. The CBH and this guideline aim to provide guidance on how to mitigate risks when handling pathogens, toxins, or other infectious material within veterinary practices. As such, Chapters 2 and 3 of this guideline delineate physical design features and operational practices for veterinary facilities handling pathogens.

Veterinary Practices: Physical Design and Operational Practices for Diagnostic Activities is continuously evolving and subject to ongoing improvement. The PHAC and the CFIA welcome comments, clarifications, and suggestions for incorporation into the future versions. Please send this information (with references, where applicable) to:

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

ABBREVIATIONS AND ACRONYMS

ABBREVIATIONS AND ACRONYMS

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.

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
HAA	*Health of Animals Act*
HAR	*Health of Animals Regulations*
HPTA	*Human Pathogens and Toxins Act*
HPTR	*Human Pathogens and Toxins Regulations*
LRA	Local risk assessment
PHAC	Public Health Agency of Canada
PPE	Personal protective equipment
RG	Risk group (i.e., RG1, RG2, RG3, RG4)
SOP	Standard operating procedure

CHAPTER 1

1
2

INTRODUCTION

CHAPTER 1 - INTRODUCTION

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

In Canada, **facilities** that conduct controlled activities with human **pathogens**, including **zoonotic pathogens**, or **toxins** are regulated under the *Human Pathogens and Toxins Act* (HPTA) and *Human Pathogens and Toxins Regulations* (HPTR), unless they meet the exclusion criteria specified in the HPTA.[1,2] Facilities that are not excluded from the HPTA, or specifically exempted by the HPTR, require a licence to conduct controlled activities with human pathogens or toxins. Controlled activities include possessing, handling or using, producing, storing, permitting access to, transferring, importing or exporting, releasing or otherwise abandoning, and disposing of a human pathogen or toxin. Regardless of whether a material or activity is excluded or exempt from the HPTA, the importation of animal pathogens, infected animals, animal products (e.g., cream, milk, eggs) or by-products (e.g., blood, serum, tissues), or other organisms carrying an animal pathogen or part of one, and activities with the imported material are regulated under the *Health of Animals Act* (HAA) and the *Health of Animals Regulations* (HAR).[3,4]

1.1 Human Pathogens and Toxins Excluded from the HPTA

Section 4 of the HPTA outlines human pathogens and toxins that are excluded from the Act. The HPTA does not apply to a human pathogen or toxin that is in an environment in which it naturally occurs (e.g., **primary specimens**) provided it has not been cultivated (e.g., cultured) or intentionally collected or extracted so as to increase the concentration (e.g., centrifugation, chromatography) of the pathogen or toxin. Therefore, activities involving only human pathogens or toxins that are only present in primary specimens are considered excluded from the HPTA. As such, a facility conducting only these activities has no legal obligations under the HPTA and can use the information provided in this document as a reference for best **biosafety** practices.

Primary specimens (e.g., blood, plasma, urine, cerebrospinal fluid, tissue, and milk) collected from animals that may be naturally infected with a human pathogen are considered to be the natural environment of the pathogen and are excluded from the HPTA. Diagnostic assays, such as those designed to detect proteins, antibodies, or nucleic acids, that do not increase the quantity or concentration of the pathogen are also excluded. Primary specimens from symptomatic or asymptomatic animals may still pose a biosafety **risk** to personnel, the community, and the environment, and should be handled as though they contain, at a minimum, a **Risk Group** 2 (RG2) pathogen.[5] Where there is reason to believe that a primary specimen may contain a Risk Group 3 (RG3) or Risk Group 4 (RG4) human pathogen, it should be handled at a **containment level** appropriate to the risk group of the pathogen (i.e., Containment Level 3 [CL3] or Containment Level 4 [CL4], respectively).

1.2 Exemption from HPTA Licensing Requirements for Veterinary Practices

Under Section 27(2) of the HPTR, certain activities performed in a veterinary practice may be exempted from requiring a licence, and are further described below. In these cases, it remains a requirement under Section 6 of the HPTA to take all reasonable precautions to protect the health and safety of the public against the risks posed by the activity. This may be achieved by following the applicable **physical design features** and **operational practices** highlighted in this guideline; however, reasonable precautions may also be achieved by implementing features and practices outside of those discussed in this guideline, based on a **local risk assessment (LRA)**. Facilities exempt from licensing may still be subject to inspection by the Public Health Agency of Canada (PHAC) to confirm all reasonable precautions have been taken.

1.2.1 Performing Controlled Activities with RG2 Human Pathogens

Laboratory analyses or diagnostic testing of an RG2 human pathogen performed by a veterinarian who is registered under the laws of a province, or any persons under the supervision of a registered veterinarian, are exempt from the requirement for a Pathogen and Toxin Licence, on the condition that any controlled activities with the RG2 pathogen are conducted in the course of providing care to animals in a clinical practice in that province (HPTR 27[2]). This includes diagnostic activities such as the isolation, **culture**, cultivation, or concentration of the pathogen in order to identify an infection with an RG2 pathogen that may also infect humans (i.e., human or zoonotic pathogens).

The exemption does not apply to veterinary diagnostic facilities that provide diagnostic services to veterinary practices (i.e., they receive specimens from outside clinics and facilities), nor does it apply to diagnostic testing of specimens from animals intentionally or experimentally exposed to an RG2 human pathogen (i.e., veterinary research or *in vivo* studies involving pathogens or toxins). Facilities that are not exempted must obtain a Pathogen and Toxin Licence from the PHAC and comply with the minimum containment requirements specified in the *Canadian Biosafety Standard* (CBS), as per the conditions of the licence.[6]

1.2.2 Performing Controlled Activities with RG3 or RG4 Human Pathogens

The exemption from licensing does not apply to controlled activities (e.g., culturing, purifying) with a primary specimen identified to contain, or believed to contain, an RG3 or RG4 human pathogen. In such a case, activities involving the cultivation (e.g., culture), collection, or extraction of an RG3 or RG4 pathogen from the specimen will require a Pathogen and Toxin Licence. Otherwise, the activity must be stopped and

the sample disposed of in accordance with the regulations, or safely and securely transferred to a licensed facility with the appropriate containment level where further diagnostic or confirmatory testing can be conducted. Examples of RG3 and RG4 human pathogens can be found in HPTA Schedules 3 and 4.

Figure 2 serves to clarify when the HPTA and the HPTR are applicable to veterinary practices, depending on the type of activity conducted within the facility. Facilities conducting controlled activities with diagnostic samples from animals that have been intentionally exposed and/or infected with a RG2 pathogen are not covered by this schematic; experimental animal work with RG2 pathogens requires a Pathogen and Toxin Licence.

1.3 Scope

The *Veterinary Practices: Physical Design and Operational Practices for Diagnostic Activities* guideline provides risk-based biosafety precautions and recommendations for the safe handling of samples collected from animals that may contain RG2 human pathogens. Veterinary practices in which controlled activities conducted are exempt from licensing but not excluded from the HPTA must ensure that all reasonable precautions have been taken to protect the health and safety of the public against the risks associated with the materials in their possession (HPTA 6). This may be achieved by following the physical design features and operational practices highlighted in this guideline; however, reasonable precautions may also be achieved by implementing features and practices outside of those discussed in this document, based on an LRA. The features and practices presented in Chapters 3 and 4 have been modified from the minimum CBS requirements for CL2 facilities to make them more relevant to the veterinary community.

Veterinary facilities and diagnostic laboratories are required to immediately report to the Canadian Food Inspeciton Agency (CFIA) the presence of an animal that is contaminated or suspected of being contaminated with a reportable disease in accordance with the HAA, HAR, and the *Reportable Diseases Regulations*.[7] This includes the presence of a foreign animal disease (i.e., non-indigenous to Canada) or a new and emerging animal disease (e.g., a novel strain of highly pathogenic avian influenza). In the event that a veterinary facility detects a reportable, foreign, or new and emerging animal disease, the work is to be stopped and the CFIA notified immediately. In such a case, the CFIA and the PHAC will advise regarding transfer of the sample(s) to the National Centre for Foreign Animal Disease (NCFAD) or the National Microbiology Laboratory (NML) for confirmatory testing.

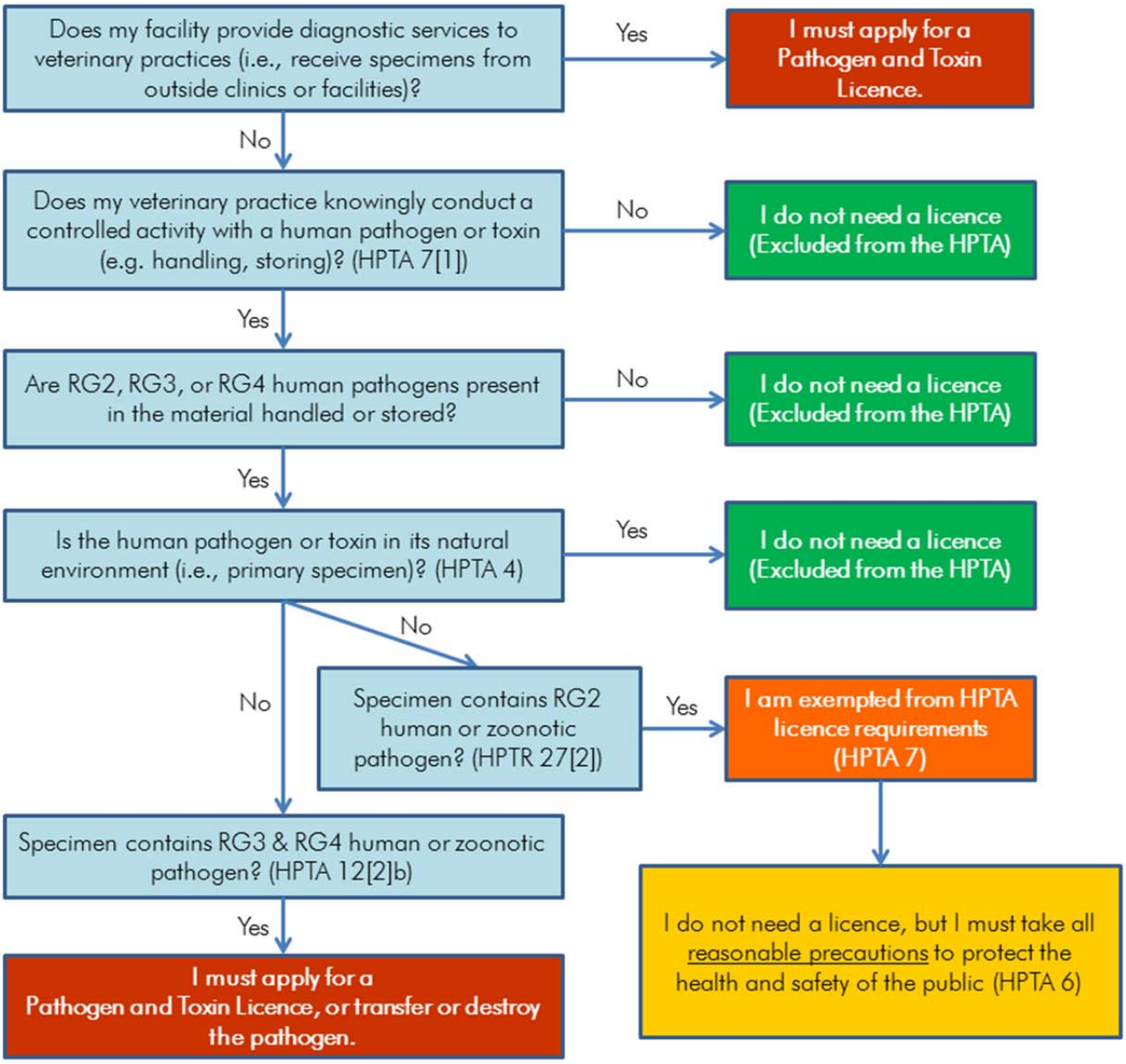

Figure 2: Oversight of veterinary practices under the *Human Pathogens and Toxins Act* and the *Human Pathogens and Toxins Regulations*

1.4 How to Use the *Veterinary Practices: Physical Design and Operational Practices for Diagnostic Activities* Guideline

Physical design features and operational practices are outlined in Chapters 2 and 3, respectively. The features and practices that demonstrate that all reasonable precautions have been taken are shown with a filled circle (●). Additional features and practices that are recommended, but not required, are shown with a hollow circle (o). Reference to the related CBS requirement appears in smaller font in brackets beneath the number of the precaution/recommendation. Facilities exempt from licensing may be subject to inspection to confirm that all reasonable precautions (●) have been taken.

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.[8]

References

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

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

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

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

5 Public Health Agency of Canada. (2012). *Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Healthcare Settings*. Ottawa, ON, Canada: Public Health Agency of Canada.

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

7 *Reportable Diseases Regulations (SOR/91-2)*. (2017).

8 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

Basic facility design and engineering controls are implemented to prevent personnel exposure to infectious material and limit the spread of pathogens. In some cases, these features may not be feasible for a given environment (e.g., in the field, in a barn). In such situations, an alternative approach may be implemented to meet the intent of the precaution. For example, it may be acceptable for a puncture-resistant bag that is only opened in the work area (e.g., a barn) to be used as the space provided for the storage of personal protective equipment (PPE) (best practice 2.1.4). The determination of alternative risk mitigation strategies should be based on an LRA.

2.1 General Physical Design Features

These physical design features are based on CBS requirements for CL2 laboratory work areas relating to structure and location, access, surface finish, air handling, and support areas.

Legend: ● Reasonable Precaution ○ Additional Recommendation

2.1	General Physical Design Features	
2.1.1 (CBS 3.1.1)	Diagnostic testing activities are conducted in a dedicated room or space that is separated from public, administrative, animal housing, and animal care areas, usually by a door.	○
2.1.2 (CBS 3.1.2)	Dedicated paper/computer work stations within areas where diagnostic activities are performed are segregated from work stations where biological material (e.g., samples, specimens) is handled.	○
2.1.3 (CBS 3.2.1)	Openable windows in the area where diagnostic activities are performed include effective pest control and security, such as window screens and locks.	○

2.1	General Physical Design Features	
2.1.4 (CBS 3.3.9)	Dedicated space is provided for the storage of PPE used in the work area (e.g., lab coat) in order to separate from personal clothing.	○
2.1.5 (CBS 3.4.5)	Floors are slip-resistant in accordance with function.	○
2.1.6 (CBS 3.4.1)	Floors, walls, benchtops, and furniture in the area where diagnostic activities are performed are constructed of or coated with a material that is non-absorbent, resistant to scratches, and able to withstand repeated cleaning and disinfection (e.g., sealed concrete, epoxy resin, vinyl or laminate covering). Benchtops and other work surfaces do not have open seams.	●
2.1.7 (CBS 3.7.11)	Equipment or procedures for the decontamination of materials is available.	●
2.1.8 (CBS 3.4.4)	Backsplashes in the area where diagnostic testing is performed are sealed at the wall-bench junction for ease of cleaning and decontamination.	●
2.1.9 (CBS 3.6.4)	Sinks are provided and located to facilitate handwashing upon exit from the area where diagnostic activities are performed. If sinks are not available, sanitizers are provided to decontaminate hands.	●
2.1.10 (CBS 3.7.14)	Decontamination technologies are equipped with monitoring and recording devices that capture operational parameters.	○
2.1.11 (CBS 3.3.2)	Signage that includes entry requirements is posted at point(s) of entry to the area where diagnostic activities are performed.	○

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 pathogens and potentially infectious material, and the release of pathogens into the environment. The following precautions are based on CBS requirements for the safe handling, use, storage, and disposal of RG2 pathogens and biological material that may contain RG2 pathogens. Reference to the related CBS requirement appears in smaller font in brackets beneath the number of the best practice.

In some cases, these practices may not be feasible for a given environment (e.g., in the field, in a barn). In such situations, an alternative approach may be implemented to meet the intent of the operational practice. For example, where the installation of a **biological safety cabinet** (BSC) is not possible (e.g., in the field), an alternative approach may be used to contain **aerosols**, or procedures may be adapted to reduce the risk of aerosol creation. The determination of alternative risk mitigation strategies should be based on an LRA.

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.[1] The application of these by personnel in any work area where laboratory-related activities involving biological material are performed helps to prevent exposure or injury and prevent **contamination** of samples and the environment. Good microbiological laboratory practices provide the foundation upon which all biosafety practices at higher containment levels are based.

When used appropriately, PPE, such as gloves, aprons, and safety glasses, protect workers from infectious material with which they may come into contact in the course of performing their work. It is best practice to have general cleaning and decontamination protocols in place for all areas of the facility to ensure that they are cleaned and decontaminated in accordance with their function and amount of use. Cleaning removes organic matter, and is performed prior to decontamination to improve the efficacy of the disinfecting agent. Decontamination protocols should be documented, available to personnel, and included in the personnel training program. Detailed information on decontamination is provided in section 3.4.

Legend: ● Reasonable Precaution ○ Additional Recommendation

3.1	Good Microbiological Laboratory Practices	
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 are strictly prohibited in the area where diagnostic activities are performed.	●
3.1.3 (CBS 4.6.2)	When working with infectious material, hair that may come in contact with the biological material is restrained (e.g., hair tied or clipped back) or covered.	●
3.1.4 (CBS 4.6.4)	Jewellery (e.g., rings or long necklaces) that may come in contact with material that may contain pathogens or damage protective gloves are not worn when handling samples.	○
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 (e.g., benchtop) and areas where diagnostic activities are performed (including floors) are kept clean and uncluttered to avoid cross-contamination and facilitate cleaning and disinfection.	●
3.1.7 (CBS 4.4.1, 4.4.4, 4.4.3, and 4.4.2)	While handling infectious material in the area where diagnostic activities are performed, all personnel, including visitors and trainees, wear appropriate PPE, including: • closed-toe and closed-heel shoes with no or low heels; • dedicated lab coats or aprons; • gloves; and • protective eyewear such as goggles when there is a risk of exposure to splashes.	●
3.1.8 (CBS 4.5.11)	Personal belongings (e.g., purses, backpacks, personal electronic devices) and street clothing (e.g., coats, scarves) are stored separately from dedicated PPE and away from work stations where infectious material is handled.	○

3.1	Good Microbiological Laboratory Practices	
3.1.9 (CBS 4.6.11)	Work surfaces (e.g., benchtop) are cleaned and disinfected before handling infectious material, after any spills, and after work with biological material is complete.	●
3.1.10 (CBS 4.6.27)	Hands are washed with soap and water for 15-20 seconds immediately after removing gloves, before leaving the area where diagnostic activities are performed, or before undertaking other tasks in the area. If sinks are not available, sanitizers are used to decontaminate hands.	●
3.1.11 (CBS 4.5.14)	Personnel doff (remove) PPE in a manner that minimizes contamination of the skin and hair.	○
3.1.12 (CBS 4.6.9, 4.6.10, and 4.8.3)	Safe practices for handling sharps are developed and strictly followed, and should include: • actively avoiding the use of needles, syringes, and other sharps; where possible, safe alternatives or sharps devices with built-in engineering controls to prevent injury should be used; • refraining from bending, shearing, breaking, or recapping needles, or removing needles from their syringes; • collecting and removing sharp objects (e.g., broken glassware or plastic) with a brush and dustpan, or tongs; and • discarding sharps in containers that are leakproof, puncture-resistant, and fitted with lids, or specially constructed for the disposal of sharps waste.	●

3.2 Work Practices

The use of safe work practices when handling infectious material helps protect personnel from exposure to pathogens, and helps prevent their release. In areas where infectious material is handled or stored, safe work practices include the proper use and maintenance of laboratory and biosafety equipment (e.g., centrifuges, BSCs), as well as aspects of general maintenance (e.g., tidiness, avoiding clutter) of the area where diagnostic activities are performed.

Legend: ● Reasonable Precaution ○ Additional Recommendation

3.2	Work Practices	
3.2.1	Samples (e.g., blood, tissues, feces, urine, vomitus, aspirates, swabs) collected for the purpose of diagnosing an infection are handled as though they were infectious.	○
3.2.2	Procedures are performed in a manner that minimizes the risk of producing splashes and aerosols.	○
3.2.3 (CBS 4.6.24)	A certified BSC is used for procedures that may produce infectious aerosols (e.g., pipetting, homogenization), when aerosol generation cannot be contained through other methods.	○
3.2.4 (CBS 4.1.15)	Protocols to don fresh PPE when entering the area where diagnostic activities are performed, and to doff and clean soiled re-usable PPE (e.g., lab coats) are available and followed.	○

3.3 Biosafety Program and Facility Management

The development of biosafety programs and policies is fundamental in implementing safe work practices and improving safety performance. A biosafety program may be created to mitigate the hazards identified by an **overarching risk assessment** of the veterinary practice or diagnostic 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 from exposure to infectious material, it is also important to establish a program to train and educate personnel (e.g., staff, students, volunteers), and an **emergency response plan (ERP)** to set out procedures for personnel to follow in various emergency situations. Policies on regular inspections of work areas 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 to infectious material.

Legend: ● Reasonable Precaution ○ Additional Recommendation

3.3	Biosafety Program and Facility Management	
3.3.1 (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).	●
3.3.2 (CBS 4.1.2)	A biosafety representative (or biological safety officer) is delegated the responsibility for the oversight of biosafety practices including: • arranging and documenting training for personnel; • conducting periodic inspections of the area where diagnostic activities are performed; • assisting with the development and maintenance of SOPs; and • documenting and assisting with internal investigations of **incidents** involving infectious material (e.g., exposures, spills).	○
3.3.3 (CBS 4.1.8)	An LRA is conducted and documented to examine each activity involving infectious material, identify risks, and develop safe work practices. LRAs are similar to a job hazard analysis, but are meant to identify risks specific to the handling and storing of pathogens and toxins.	●

3.3	Biosafety Program and Facility Management	
3.3.4 (CBS 4.1.10)	Written biosafety policies and procedures are developed and kept up to date, and include: • the facility's biosafety plans in response to the hazards and appropriate mitigation strategies identified by an LRA; and • safe work practices or SOPs for tasks involving pathogens and potentially infectious material (e.g., during diagnostic procedures), and other biosafety-related issues (e.g., PPE use, decontamination procedures), based on the hazards identified by LRAs.	●
3.3.5 (CBS 4.6.31)	Procedures are in place and include precautions, as determined by an LRA, to prevent a leak, drop, spill, or similar event during the movement of infectious material.	○
3.3.6 (CBS 4.6.7)	Traffic flow patterns from areas of lower contamination (i.e., clean) to areas of higher contamination (i.e., dirty) are established and followed, as determined by an LRA.	○
3.3.7 (CBS 4.9.1)	An ERP, based on LRAs, is 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 veterinary practice for: • accidents/incidents; • medical emergencies; • chemical/biological spills; • emergency evacuation; • reporting of incidents to the appropriate internal authority; and • incident follow-up and recommendations to mitigate future risks.	●
3.3.8 (CBS 4.3.10)	Personnel receive training on the ERP.	●

3.3	Biosafety Program and Facility Management	
3.3.9 (CBS 4.3.1 and 4.3.2)	A training program is developed for all personnel involved in the handling and storing of infectious material and should include: • the biosafety program; • potential hazards associated with handling infectious material in the area where diagnostic activities are performed; • SOPs; • correct use and operation of laboratory equipment; and • ERP.	●
3.3.10 (CBS 4.3.7 and 4.3.8)	Personnel (including volunteers and students) demonstrate knowledge of and proficiency in the SOPs on which they were trained prior to independently performing these duties. Trainees are supervised when conducting activities with infectious material until they have completed training.	●
3.3.11 (CBS 4.10.1)	Training is documented, and records kept on file.	●
3.3.12 (CBS 4.6.37)	An effective rodent and insect control program is maintained.	○
3.3.13 (CBS 4.5.1)	Doors separating public or administrative areas and the area where diagnostic activities are performed are kept closed.	○
3.3.14 (CBS 4.5.2)	Access to areas where infectious material is handled or stored is limited to authorized personnel and authorized visitors.	○
3.3.15 (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 are taken.	○
3.3.16 (CBS 4.10.5)	Records of regular inspections of the area where diagnostic activities are performed and corrective actions are kept on file.	●

3.4 Decontamination and Waste Management

Decontamination is the process by which materials and surfaces are rendered safe to handle and reasonably free of microorganisms, toxins, or prions. Depending on the situation, this may require disinfection, inactivation, or sterilization. Disinfection eliminates most forms of living microorganisms but is less lethal to infectious material than sterilization. Sterilization completely eliminates all living microorganisms, including bacterial spores. Inactivation refers to the destruction of biological activity of a microorganism (e.g., a virus or prion) through heat or chemical means.[2,3]

The effective decontamination of waste, materials, equipment, and surfaces that have come in contact with potentially infectious material is fundamental in limiting the spread of contamination beyond the work area and facility. Decontamination technologies are equipment used to render materials safe and reasonably free of microorganism (e.g., autoclaves and incinerators). Decontamination technologies may be provided on site, or contaminated waste can be transported to a designated facility for decontamination. Further guidance and information on decontamination technologies and waste management can be found in sections 3.4.1 and 3.4.2, respectively.

Legend: ● Reasonable Precaution ○ Additional Recommendation

3.4	Decontamination and Waste Management	
3.4.1 (CBS 4.8.2)	A disinfectant effective against a broad range of infectious material (e.g., bleach, commercial disinfectants) is readily available and in use in the area where diagnostic activities are performed. Written instructions for dilution and correct application of the product (e.g., contact time) are available.	●
3.4.2 (CBS 4.8.8)	Contaminated waste is placed in a labelled, leakproof container and decontaminated on site prior to disposal, or safely and securely transported to a designated decontamination facility in accordance with SOPs.	●
3.4.3 (CBS 4.8.7)	Contaminated liquids are decontaminated prior to release to sanitary sewers.	●
3.4.4 (CBS 4.8.4)	Equipment that has come in contact with infectious material is decontaminated prior to maintenance.	●

3.4	Decontamination and Waste Management	
3.4.5 (CBS 4.8.5 and 4.8.8)	All items, including clothing and PPE, that has come in contact with infectious material is decontaminated after use or prior to disposal.	●
3.4.6 (CBS 4.8.6)	Used PPE is decontaminated prior to disposal or laundering.	●
3.4.7 (CBS 4.8.10 and 4.8.11)	In facilities where decontamination of waste material is provided on site, decontamination technologies and processes (e.g., autoclaves) undergo a validation initially, as described in SOPs, and routine verification, based on an LRA.	●
3.4.8 (CBS 4.1.15)	A waste management program is established that includes detailed procedures to manage both hazardous and non-hazardous solid and liquid waste generated through routine handling of animals and animal specimens. The waste management program of any facility handling pathogens and toxins should include: • written waste management plans, procedures, or SOPs that address: o decontamination of waste and specimens; o segregation, packaging, and labelling of waste; o temporary storage or holding of waste; o decontamination and treatment of waste; o safe movement and transportation of potentially infectious material; • an overview of waste management regulations applicable to the facility; and • emphasize accurate documentation/record-keeping.	○
3.4.9 (CBS 4.8.3)	Sharps to be discarded in containers that are leakproof, puncture-resistant, and fitted with lids, or specially constructed for the disposal of sharps waste.	○
3.4.10 (CBS 4.3.2)	Personnel to be trained on the potential hazards associated with any work involving potentially infectious substances, including training on identification, handling, treatment, packaging, storage, and transport of infectious waste.	○

3.4.1 Additional Guidance on Decontamination

Decontamination processes and technologies can function by chemical (e.g., chlorine, iodine, alcohol), thermal (e.g., steam sterilization, incineration), or physical (e.g., irradiation) means. This section aims to provide some basic information and considerations when selecting the appropriate means or method(s) of decontamination to be used. Further information on decontamination and decontamination technologies can be found in Chapter 15 of CBH.

The effectiveness of the disinfection process is dependent on several factors, including:

- the nature and quantity of microorganism(s);
- the amount of organic matter present;
- the type and state of items being disinfected; and
- the temperature.

Chemical decontamination methods include the use of disinfectants for the decontamination of surfaces and equipment that cannot be autoclaved, specimen and sample containers, spills of infectious materials, rooms, and animal cubicles. The most commonly used chemical disinfectants are chlorine (e.g., bleach [sodium hypochlorite], chlorine dioxide [ClO_2]), alcohols (e.g., 70% ethyl or isopropyl alcohol in water), iodine (aqueous solutions, tinctures and iodophores), phenolics, quaternary ammonium compounds, and hydrogen peroxide; many of these are used alone or in combination in commercially available disinfectants. The selection of a chemical disinfectant should be based on its ability to effectively decontaminate the pathogen(s) being handled. Organic load, chemical concentration, contact time, temperature, relative humidity, pH, and stability are all parameters that can also impact the efficacy of a chemical disinfectant. A detailed description of chemical disinfectants, including considerations for their selection and use, can be found in Section 15.3 of the CBH.

Thermal decontamination methods include dry heat sterilization, composting, incineration, and steam sterilization (e.g., using an autoclave or hydroclave). Autoclaves are the most common decontamination technology used for routine decontamination of laboratory waste. An autoclave uses saturated, pressurized steam at high-temperature to decontaminate infectious waste. The effectiveness of the process depends on time, temperature, and direct steam contact with the infectious agents. Incineration is another heat-based decontamination technology that involves burning at high temperatures, resulting in an 85-95% reduction in volume.[2] Further information on autoclaves, including recommended procedures for use and routine monitoring, and information on incineration can be found in Sections 15.4 and 15.8 of the CBH, respectively.

Composting is the thermal biodegradation of organic material. Large scale composting can reach temperatures of 60-70°C, which is sufficient to effectively decontaminate some pathogens.[4] In some situations (e.g., barns, field testing),

composting may be an acceptable decontamination method, as long as it can be validated to be effective against the pathogen in question and routinely verified.

3.4.2 Additional Guidance on Waste Management in Veterinary Health Care Facilities

Even after contaminated or biohazardous waste has been thoroughly and effectively decontaminated, disposal of the waste may not be as simple as throwing it into the normal garbage collection stream for transfer to a local landfill. Depending on the type of waste material, additional waste management considerations or requirements specified by the provincial, territorial, or local (i.e., municipal) authorities may also apply and should be consulted and complied with when establishing and implementing a waste management program. The waste management program can be relatively simple in nature or complex, depending on the range of activities being performed by the organization.

The Canadian Council of Ministers of the Environment (CCME) *Guidelines for the Management of Biomedical Waste in Canada* describes the recommended minimum practices to follow in the management of biomedical waste, including animal waste, laboratory waste, and sharps waste, across Canada; however, the CCME guidelines are only enforced where they are adopted by provincial legislation or municipal by-laws.[5] Local by-laws may be more stringent than the guidelines recommended by CCME. Additional considerations for handling biomedical waste when developing and implementing a sound waste management program can be found in the Canadian Standards Association (CSA) standard CSA Z317.10, *Handling of health care waste materials*.[6,7] Further details on biomedical and laboratory waste management can also be found in Chapter 16 of CBH.

In the event that a waste container breaks or leaks, workers handling and disposing of infectious or potentially infectious biological waste may be at risk of exposure to pathogens and toxins. Sharps waste may pose a significant risk; sharps waste that are mixed in with other types of waste and not properly separated become hidden hazards and can lead to sharps-related incidents (e.g., needlestick injuries, inoculation). Sharps waste can be safely disposed of directly after use into a puncture-resistant container in accordance with National Standard of Canada (CAN)/CSA standard *CAN/CSA Z316.6, Sharps Injury Protection – Requirements and Test Method – Sharps Containers*.[8] Sharps containers should never be overfilled and the instructions for use closely followed, so that the lid is secure from opening during transport and disposal.

Infectious and biomedical wastes being transported for disposal are regulated in Canada under the *Transportation of Dangerous Goods Regulations* (TDGR).[9] In accordance with the TDGR, containers used for the transportation of infectious and biomedical waste must meet requirements of the National Standard of Canada (CAN)/Canadian General Standards Board (CGSB) standard *CAN/CGSB-43.125,*

Packaging of Category A and Category B infectious substances (Class 6.2) and clinical, (bio) medical or regulated medical waste.[10] Biological waste can be stored temporarily prior to disposal. Refrigeration or freezing will reduce the rate of microbial growth, putrefaction, and smell, especially when awaiting transfer to off-site disposal.

Under federal, provincial, and territorial legislation, including the *Canadian Environmental Protection Act, 1999*, the generator of hazardous waste remains responsible for their waste from "cradle-to-grave" (i.e., from generation until its final destination).[11] If an accident happens during transportation away from the facility for disposal, the generator of the waste is responsible; as such, the waste management program should include contingency planning in the event of an accident or spill. It remains the responsibility of the employer (i.e., the owner or manager of the veterinary practice) to provide the necessary training for individuals under their supervision to work safely with hazardous substances. It is the responsibility of all workers to practise due diligence at all times with respect to the appropriate handling, treatment, and disposal of any infectious waste generated.

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CHAPTER 4

GLOSSARY

CHAPTER 4 - GLOSSARY

It is important to note that the definitions provided in the glossary may differ from universally accepted definitions or those published in the CBS or 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

Administrative area *	Dedicated room or adjoining rooms that are used for activities that do not involve biological material, including infectious material. Examples of administrative areas include offices, photocopy areas, meeting/conference rooms, and waiting/reception areas.
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.
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 infectious material, or its 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).

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 infectious 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. In the context of this guideline, "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.
Decontamination technology	Equipment proven by validation to render materials safe to handle and reasonably free of microorganisms, toxins, or prions. Examples include autoclaves, incinerators, tissue digesters, and effluent decontamination systems.
Diagnostic activities	Activities (e.g., antibody assay, nucleic acid testing, histology, clinical chemistry) involving primary specimens for the purpose of identifying an infection, intoxication, or disease. These activities are regularly carried out in hospitals and clinical laboratories.
Disinfection	Process that eliminates most forms of living microorganisms; disinfection is much less lethal to infectious material than sterilization.
Doff	Action of removing an article of wear (e.g., personal protective equipment) from the body.
Don	Action of putting on an article of wear (e.g., personal protective equipment).

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, 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 infectious material or toxins are 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 practices	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, intoxication, disease, or damage. Incidents can involve infectious material, infected animals, or toxins, including a biological spill, exposure, inadvertent release of infectious material, 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.
Infectious material	Any isolate of a pathogen or any biological material that contains human or animal pathogens and, therefore, poses a risk to human or animal health.
Laboratory work area	A dedicated room or space inside a facility designed and equipped for *in vitro* work with biological material.
Local risk assessment (LRA)	Site-specific risk assessment used to identify hazards based on the infectious material or toxins 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 laboratory work area to protect personnel, the environment, and ultimately the community, from infectious material.
Overarching risk assessment	A broad risk assessment that supports the biosafety program as a whole and may encompass multiple laboratory 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 infectious 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 or 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 infectious material being handled, thereby minimizing the risk of exposure. PPE may include, but is not limited to, lab coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks, and respirators.
Physical design features *	Engineering controls and facility design characteristics in place to protect personnel, the environment, and ultimately the community, from infectious material.
Primary specimen	Samples derived directly from an animal (e.g., blood, urine, saliva, skin, hair).

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 infectious material and toxins 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.*
Validation	The act of confirming that a method achieves its objective by observing that specific parameters have been met (e.g., using biological indicators to confirm that a given autoclave cycle can decontaminate a representative load of waste). Validation infers that a method is suitable for its intended purpose.
Verification	The routine monitoring of equipment and processes to ensure continued efficacy between validations. This includes comparing the accuracy of a piece of equipment to an applicable standard or standard operating procedure (e.g., testing of a Class I biological safety cabinet in accordance with the manufacturer specifications).
Waste	Any solid or liquid material generated by a facility for disposal.
Zoonotic pathogen	A pathogen that causes disease in humans and animals, and that can be transmitted from animals to humans and vice versa (i.e., zoonoses). They are considered both human and animal pathogens.

CHAPTER 5

REFERENCES AND RESOURCES

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