Containment Level 2 Checklist – Mandatory Requirements

Required for **all containment zones**

Introduction

Laboratories or containment zones which handle or store biological agents or toxins are regulated by the Public Health Agency Canada (PHAC) and the Canadian Food Inspection Agency (CFIA). These laboratories or zones must ensure that appropriate biosafety and biocontainment principles and practices are rigorously applied, to minimize the risk of spreading disease or contaminating users and equipment.

This document outlines the minimum requirement for the containment level 2 (CL2) laboratories, including the **physical containment requirements**, **operational practice requirements** as well as **performance and verification testing requirements** which are outlined in the *Canadian Biosafety Standard (CBS), 3rd Edition, 2022*.

Reference

The *Canadian Biosafety Standard (CBS),3rd Edition, 2022*:

Canadian Biosafety Standard, Third Edition - Canada.ca

Checklist

Principal Investigator		**Lab Location**	
Tel #		**Email**	
Faculty		**Department**	

Physical Containment Requirements

Ref.	Items	Yes	No	Comments
Containment Barrier				
3.1.1	Openable windows positioned on the containment barrier to include effective pest control.			
3.1.4	Windows to provide security as determined by a biosecurity risk assessment.			
Access				
3.2.1	Biohazard warning signage to be posted at points of entry to the containment zone, animal room, animal cubicle, PM room and areas where unique hazards exist.			
3.2.2	Biohazard warning signage to include: a) international biohazard warning symbol;			

	b) containment level; c) required PPE; d) entry requirements, if applicable; and e) emergency contact information.			
3.2.3	In areas where regulated materials are stored outside the containment zone, biohazard warning signage to: a) be posted at points of entry to these areas or on equipment in which regulated materials are stored; b) include the international biohazard warning symbol; c) include the risk group of the regulated materials; and d) include emergency contact information.			
3.2.4	Containment zones to be separated from public and administrative areas by a lockable door.			
3.2.9	Space to be provided inside the containment zone for dedicated PPE that has been worn and may be reused.			
Surface finishes and casework				
3.3.1	In accordance with function, surfaces and coatings, including floors, ceilings, walls, doors, frames, casework, benchtops, and furniture, to be: a) cleanable; b) non-absorbent; c) resistant to physical damage; and d) resistant to damage caused by decontamination procedures and products.			
3.3.2	Surfaces that may come in contact with regulated materials to be continuous with adjacent and overlapping materials.			
Facility and services				
3.5.4	Sinks to be provided to facilitate handwashing.			
Essential biosafety equipment				
3.6.1	BSCs or other primary containment devices to be provided, based on an LRA. [Not required for areas where the room serves as primary containment.]			
3.6.5	Decontamination technologies to be provided within the containment zone, or procedures to be in place to safely and securely move or transport waste for decontamination outside			

	the containment zone**.**			
3.6.7	Decontamination technologies to be equipped with monitoring devices and recording mechanisms that capture operating parameters.			
3.6.8	Mechanisms to be provided to prevent contamination of vacuum systems and the release of regulated materials.			

Operational Practice Requirements

Items		Yes	No	Comments
Biosafety program management				
4.1.1	A biosafety program to be developed, documented, implemented, kept up to date, and evaluated and improved as necessary.			
4.1.2	A biosafety representative (i.e., BSO) with the knowledge appropriate for the containment levels and regulated materials handled, to be designated for the oversight of biosafety and biosecurity practices including: a) verifying the accuracy and completeness of applications for legislative documents, as applicable; b) communicating with the PHAC and the CFIA, as applicable; c) promoting and monitoring compliance with applicable legislation (including the HPTA, HPTR, HAA, and HAR), conditions of licence and terrestrial animal pathogen import permits, the biosafety manual, and SOPs, which includes, but is not limited to: i. arranging and documenting appropriate biosafety and biosecurity training for personnel, as applicable; ii. conducting periodic inspections and biosafety audits and reporting the findings, as applicable; and iii. informing the licence holder and/or terrestrial animal pathogen import permit holder, as applicable, in writing of any non-compliance by a person working with regulated materials that is not being corrected by that person after they have been made aware of it; d) assisting in the development and maintenance of SOPs and the biosafety manual; and			

	e) assisting with internal investigations of incidents.			
4.1.4	An overarching risk assessment to be conducted, documented, and kept up to date.			
4.1.5	A biosecurity risk assessment to be conducted, documented, and kept up to date.			
4.1.6	An LRA to be conducted, documented, and kept up to date for activities involving regulated materials.			
4.1.7	A biosafety manual to be developed, documented, implemented, followed, kept up to date, and communicated and made available to authorized personnel. A biosafety manual includes a description of the: • institutional biosafety policies, programs, and plans; • physical design and operation of the containment zone and systems; • overarching, biosecurity, and local risk assessments; • biosecurity plan; • medical surveillance program; • training program; • ERP and incident reporting procedures; • housekeeping program; • facility and equipment maintenance program for components of the containment zone, including integrity testing of primary containment devices; and • SOPs for safe work practices specific to the containment zone.			
4.1.8	A biosecurity plan to be developed, documented, implemented, followed, evaluated, kept up to date, and communicated and made available to authorized personnel. A biosecurity plan describes: • risks associated with activities and assets with dual-use potential; • physical security; • personnel security; • accountability and defined accountability measures for regulated materials; • inventory control; • incident and emergency response; • information management; and • biosecurity training and awareness.			
4.1.9	A medical surveillance program based on an overarching risk assessment and LRAs to be developed, documented, implemented, followed, and kept up to date.			
4.1.10	SOPs for operational practices and performance and verification			

	testing to be developed, documented, implemented, followed, kept up to date, and communicated and made available to authorized personnel.			
Training program				
4.2.1	A training needs assessment to be conducted, documented, kept up to date, and reviewed annually.			
4.2.2	A training program, based on a training needs assessment, to be developed, documented, implemented, kept up to date, and evaluated and improved as necessary. A training program includes training on: • SOPs and relevant elements of the biosafety manual; • potential hazards associated with the regulated materials handled; • signs and symptoms of diseases associated with the regulated materials handled; • necessary precautions to prevent exposure to, or the release of, regulated materials handled; • necessary precautions to prevent biosecurity incidents involving regulated materials or related assets (e.g., sensitive information); • relevant physical design and operation of the containment zone and containment systems; • correct use and operation of laboratory equipment, including primary containment devices; • restraint and handling techniques for work involving animals; and • emergency response procedures (including annual refresher training).			
4.2.3	Visitors, maintenance and janitorial staff, contractors, and others who require temporary access to the containment zone to be trained and/or accompanied by authorized personnel, in accordance with their anticipated activities in the containment zone.			
4.2.4	Personnel to demonstrate knowledge of the relevant elements of the biosafety manual and proficiency in the procedures on which they were trained before engaging in unsupervised activities with regulated materials and regulated animals.			
Personal protective equipment				
4.3.1	PPE selection to be determined by an LRA.			
4.3.2	Gloves to be worn when handling regulated materials or regulated animals, as determined by an LRA.			
Entry and exit				
4.4.1	Doors and other openings to the containment zone, animal room, animal cubicle, and PM room to be kept closed.			
4.4.2	Only authorized individuals to be granted access to the			

	containment zone, animal room, animal cubicle, PM room, room housing an effluent decontamination system, and to areas where other services supporting the containment zone are located.			
4.4.8	Personal clothing and belongings to be stored separately from dedicated PPE that has been worn in the containment zone.			
4.4.9	Personal belongings and items for personal use not required for work to be kept separate from areas where regulated materials are handled or stored.			
4.4.11	Open wounds, cuts, and scratches to be covered in a manner that prevents exposure prior to entering the containment zone.			
4.4.12	Jewellery that may become contaminated or compromise PPE to be removed or covered prior to entering the containment zone.			
4.4.13	Personnel to don dedicated PPE prior to entering the containment zone in accordance with entry procedures.			
4.4.16	Activity-specific PPE or an additional layer of PPE to be donned prior to beginning the activity in the containment zone.			
4.4.18	Dedicated and activity-specific PPE to be doffed in a manner that minimizes contamination of the skin, hair, and personal clothing (where worn), and stored or disposed of within the containment zone or containment barrier.			
4.4.19	Personnel to wash hands when exiting the containment zone, containment barrier, animal room, animal cubicle, or PM room.			
Work practices				
4.5.1	Procedures to be followed to prevent personnel exposure to regulated materials and the spread of contamination during tasks.			
4.5.2	Traffic and work flow patterns to be established and followed to prevent the spread of contamination.			
4.5.3	Containment zone to be kept clean and the presence of the following to be minimized:			

	a) obstructions; b) materials that are in excess or not required; and c) items that cannot be easily decontaminated.			
4.5.4	Contact of the face or mucous membranes with items contaminated or potentially contaminated with regulated materials to be prevented.			
4.5.5	Hair that may become contaminated when working in the containment zone to be restrained or covered.			
4.5.6	Use of sharp and glass objects to be strictly limited and avoided when suitable alternatives can be used.			
4.5.7	Use of needles and syringes to be strictly limited. Bending, shearing, re-capping, or removing needles from syringes to be avoided, and if necessary, performed only as specified in SOPs.			
4.5.8	Verification of small in-line filter assemblies associated with vacuum pump systems to be performed at a frequency based on use.			
4.5.9	Verification of primary containment devices to be performed at a frequency based on use.			
4.5.12	Personnel to doff activity-specific PPE in a manner that minimizes contamination of the skin, hair, and personal clothing (where worn) after completing work activities and when PPE may have become contaminated.			
4.5.13	Primary containers of regulated materials to be opened only at the containment level to which the material and activities have been assigned by the regulators..			
4.5.14	Primary containers of regulated materials removed from the containment zone to be stored in a labelled, leak-proof, impact-resistant secondary container, and kept either in locked storage equipment or within an area with limited access**.**			
4.5.19	Procedures to be in place to prevent a leak, drop, spill, or similar event during storage or the movement of regulated materials.			
4.5.20	A BSC or other primary containment device to be used for activities with open vessels, based on the risks associated with: a) the inherent characteristics of the regulated material; b) the potential to produce infectious aerosols or			

	aerosolized toxins; c) the handling of high concentrations of regulated materials; and d) the handling of large volumes of regulated materials. [Not required when inoculating or collecting samples from regulated animals housed in an animal cubicle.]			
4.5.22	BSCs and other primary containment devices to be located and operated in a manner that minimizes airflow disruption of the devices.			
4.5.23	Centrifugation of regulated materials that are primarily infectious or transmitted by inhalation to be carried out in sealed safety cups or rotors that are unloaded using a mechanism that prevents their release.			
4.5.27	A mechanism to be in place to prevent, detect, and respond to pest control issues.			
Decontamination and waste management				
4.7.1	Gross contamination to be removed from surfaces and equipment prior to their decontamination.			
4.7.2	Surfaces that may become contaminated to be cleaned and decontaminated at a frequency determined by an LRA.			
4.7.3	Disinfectants and neutralizing chemicals effective against the regulated materials handled or stored to be available and used in the containment zone.			
4.7.4	Sharps to be discarded in containers that are leak-proof, puncture-resistant, and fitted with lids, or constructed for the purpose of sharps disposal.			
4.7.5	HEPA and high efficiency filters to be: a) decontaminated *in situ* prior to removal; or b) contained using an alternative mechanism during removal and subsequent decontamination.			
4.7.6	Contaminated liquids to be decontaminated prior to release into sanitary sewers. Note: don't release decontaminated liquids in to the sewers at uOttawa. Get rid of them through the chemical waste stream.			
4.7.7	Regulated materials, contaminated items, and waste to be: a) decontaminated prior to disposal or removal from			

	the containment zone, animal room, animal cubicle, or PM room, or prior to testing or repair of equipment; or b) placed in closed, labelled, and leak-proof secondary containers that have been surface decontaminated prior to removal from the containment zone, animal room, animal cubicle, or PM room.			
4.7.10	Performance of decontamination technologies to be routinely verified at a frequency determined by an LRA.			
4.7.12	Contaminated bedding to be: a) removed within a primary containment device or ventilated cage changing station prior to decontamination; or b) decontaminated within containment cages.			
Emergency response				
4.8.1	An ERP, based on overarching and local risk assessments, to be developed, documented, implemented, reviewed, and kept up to date.			
4.8.3	Emergency medical contact card to be issued to containment zone personnel handling non-human primates or regulated materials that cause uncommon diseases or illnesses in Canada, as determined by an LRA.			
4.8.4	ERP to describe emergency procedures for incidents within and outside the containment zone that may lead to personnel exposure to regulated materials, or their release from containment.			
4.8.5	ERP to include procedures for: a) the notification of key internal personnel and relevant regulatory authorities (e.g., PHAC, CFIA); b) biosafety or biosecurity incident investigation and follow-up; and c) the implementation of measures to mitigate future risks.			
4.8.8	Suitable PPE and materials needed to respond to biological spills to be available.			
4.8.9	Biosafety and biosecurity incidents to be reported immediately to the appropriate internal authority.			
4.8.10	Investigation of biosafety and biosecurity incidents to be conducted and documented to determine root causes and			

	measures to mitigate future risks.			
4.8.11	The PHAC to be informed without delay via the submission of a notification report following: a) an exposure to a human pathogen or toxin; b) recognition of a disease that has or may have been caused by an exposure to a human pathogen or toxin; or c) non-exposure biosafety and biosecurity incidents.			
4.8.12	An exposure follow-up report documenting the completed investigation to be submitted to the PHAC within: a) 15 days of the submission of an exposure notification report involving an SSBA; or b) 30 days of the submission of an exposure notification report involving a human pathogen or toxin other than an SSBA.			
4.8.13	Where non-indigenous terrestrial animal pathogens are handled or stored, or in accordance with conditions of the terrestrial animal pathogen import permit, the CFIA to be informed without delay of incidents involving: a) regulated materials or regulated animals, including a possible release or animal escape; and b) failure of containment systems or control systems.			
Records and documentation				
4.9.1	Records and documentation to be kept on file for a minimum of: a) 5 years for licence activities with human pathogens and toxins; b) 2 years following the date of disposal, complete transfer, or inactivation of the imported material in accordance with terrestrial animal pathogen import permit requirements for terrestrial animal pathogens or part of one (e.g., toxin); and c) 5 years for performance and verification test records or until repeat testing is conducted, whichever is longer.			
4.9.2	Records of biosafety and biosecurity incidents to be kept on			

	file for a minimum of 10 years.			
4.9.4	All biosafety and biosecurity training to be documented; records to be kept on file.			
4.9.5	An inventory of regulated materials in long-term storage to be maintained and to include locations and risk groups.			
4.9.8	Records of containment zone (including support areas) and equipment maintenance, repair, inspections, deficiencies, corrective measures, testing, and certification (including performance and verification testing records) to be kept on file.			
4.9.10	Documents (e.g., certificates) demonstrating calibration was valid at the time of testing to be kept on file for equipment used for performance and verification testing of containment systems and essential biosafety equipment.			
4.9.12	Records of validation and routine verification of decontamination technologies and processes to be kept on file.			

Performance and Verification Testing Requirements

Items		Yes	No	Comments
Performance and Verification Tests for All Containment Levels				
5.1.1	Performance and verification tests described in 5.1.2-5.1.8 to be conducted and documented prior to initial use, and at minimum annually thereafter, or more frequently as necessitated by: a) a change, repair, or modification that may affect biocontainment; b) a condition of licence; c) a condition of terrestrial animal pathogen import permit; or d) a request from the PHAC or the CFIA.			
5.1.2	Inspections of the containment zone (e.g., surfaces, equipment, procedures) to be conducted; when deficiencies are identified, implementation of corrective measures to be verified.			
5.1.3	Visual inspection of small in-line filter assemblies to be conducted and filters to be replaced or tested in accordance with manufacturer's specifications.			
5.1.4	Performance of decontamination technologies to be validated under in-use conditions using representative loads in conjunction with application-specific biological indicators, chemical integrators, and/or parametric monitoring devices consistent with the technology.			

5.1.5	Monitoring devices that visually indicate inward airflow to be verified to function as intended.			
5.1.6	Class II BSCs to be certified under typical conditions of use in accordance with NSF/ANSI 49, if such certification is possible.			
5.1.7	If the design of a BSC or other ventilated device does not allow certification in accordance with NSF/ANSI 49, verification of the following manufacturer's specifications under typical conditions of use to be performed: a) integrity of the HEPA filters to be tested in accordance with the HEPA filter test method IEST-RP-CC034.3 or equivalent; b) maintenance of containment during normal operation and failure conditions to be verified; c) integrity of devices designed with positive-pressure plenums to be demonstrated by determining that exterior surfaces of all plenums, welds, gaskets, and plenum penetrations or seals are free of leaks; and d) alarms to be demonstrated to function as intended.			
5.1.8	Integrity of primary containment devices other than BSCs and ventilated devices to be tested in accordance with testing procedures and acceptance criteria appropriate for the equipment and design**.**			
Performance and verification tests to be conducted during commissioning and at specified intervals for all containment zones				
5.3.1	Performance and verification tests described in 5.3.2-5.3.9 to be conducted and documented during commissioning, and as specified, or more frequently as necessitated by: a) a change, repair, or modification that may impact the implicated system; b) a condition of licence; c) a condition of terrestrial animal pathogen import permit; or d) a request from the PHAC or the CFIA.			
5.3.7	During commissioning and every 10 years, HVAC systems and controls to be verified during scenarios simulating failure of system components related to Class II B2 BSC exhaust fans (where present). Acceptance criteria include the demonstration that Class II B2 BSC puff-back is minimized and associated system alarms and interlocks operate as intended.			

Abbreviations and Acronyms

ANSI	American National Standards Institute
BSC	Biological safety cabinet
BSO	Biological Safety Officer
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
HEPA	High efficiency particulate air
HPTA	Human Pathogens and Toxins Act
HPTR	Human Pathogens and Toxins Regulations
HVAC	Heating, ventilation, and air conditioning
IDA	Inward directional airflow
IEST	Institute of Environmental Sciences and Technology
LRA	Local risk assessment
NSF	National Sanitation Foundation
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
SSBA	Security sensitive biological agent