Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments

Biohazard, Containment and Safety Unit
Science Strategies
159 Cleopatra Dr.
Nepean, ON K1A 0Y9
Tel. (613) 221-7069
Fax (613)228-6129

Unité de confinement des biorisques et la sécurité
Stratégies Scientifiques
159 Promenade Cleopatra
Nepean, ON K1A 0Y9
Tel: (613) 221-7069
Fax: (613) 228-6129

Animal Pathogen Containment Level 3 Laboratory Certification Checklist

This checklist is provided to you as a tool to be used in conjunction with the *Containment Standards for Veterinary Facilities* (CSVF), *1st edition 1996.*

Institution:	***Institutional Biosafety Officer:***
Address:	***Address:***
Phone : ***Fax :***	***Phone :*** ***Fax :***
Building / Laboratory / Room #:	

Containment Level 3 laboratories handling imported animal pathogens require a physical inspection by CFIA before they will be certified. This checklist is intended to assist laboratories in determining their compliance with the *Containment Standards for*

Veterinary Facilities (CSVF).

Please provide YES, NO, N/A (not applicable) to indicate the answer to each of the criteria listed. For "NO" or "N/A" answers please contact the Biohazard Containment and Safety Unit immediately to discuss and provide a brief clarification/justification. For "YES" please provide any additional relevant information (i.e. type of coating for surfaces, type of biological safety cabinet, etc.). When responding to questions pertaining to the Drawings and Specifications please indicate the drawing number to which the information may be found and likewise for the specifications.

This checklist is subject to change by the Biohazard Containment and Safety (BCS) Unit at CFIA. The BCS Unit will make any changes or updates available to the regulated parties via our website, email, mail or other.

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
PHYSICAL REQUIREMENTS			
1 - Location & Access:			
Is access to the laboratory dedicated and controlled?			●
Is access to the laboratory limited to authorized personnel?			●
Do laboratory doors have appropriate signage (i.e. hazard identification, name and phone number of contact person, entry requirements)?			●
Is entry to the laboratory done via ventilated airlock with interlocks, warning light or audible alarm?			●
Is entry to laboratory provided with clothing change area to separate personal clothing from lab clothing dedicated to that zone? (ie. clean and dirty change areas)			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Is entry to laboratory provided with a shower on the containment barrier, separating clean and dirty change areas?			●
Do controlled entrance/exit doors have emergency manual overrides?			●
Are containment barrier support systems (e.g. HEPA filters, effluent sterilization system) located as close as possible to the laboratory?			❍
Are office areas located outside of laboratory?			●
If clerical work stations exist within the laboratory, then are they dedicated and segregated from hazardous material?			●
Is the laboratory located away from exterior envelope walls? Recommended for new level 3 constructions.			❍
Sign off by responsible authority (print name, title, date and signature):			
2 - Surface Finishes:			
Are interior coatings gas and chemical resistant in accordance with laboratory function?			●
Are interior surfaces continuous?			●
Do interior surfaces minimize movement of gases and liquids through perimeter membrane?			●
Are interior surfaces impact resistant in accordance with laboratory function?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are interior surfaces compatible with adjacent and overlapping materials (continuous perimeter)?			●
Is continuity of seal maintained between the floor and wall?			●
Are floors slip-resistant?			●
Are doors and frames non-absorptive with solid finishes?			●
Are hollow doors sealed?			●
Sign off by responsible authority (print name, title, date and signature):			
3 - Furnishings:			
Are surfaces scratch, stain, moisture, chemical and heat resistant in accordance with function?			●
Are solid-core materials (not wood) used?			●
Are floor contact surfaces rust resistant (except where stainless steel is used)?			●
Are bench tops continuous?			●
Can bench tops contain spillage of materials (marine edges and drip stops)?			❍
Do benches, doors, drawers, door handles, etc. have rounded rims and corners?			❍
Are backsplashes continuous with work surfaces?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are backsplashes installed tight to wall and sealed at wall-bench junction?			●
Are service raceway channels and upper cabinets sealed at junction to bench?			●
Sign off by responsible authority (print name, title, date and signature):			
4 - Laboratory services:			
Are exposed lab services piping installed with stand-offs for maintenance and cleaning?			●
Is the water supply control located outside laboratory?			●
Are supply water services provided with backflow prevention at the perimeter of laboratory?			●
Are water supply backflow prevention devices selected and tested in accordance with the Canadian Standards Association CAN/CS - B64.10-01/B64.10.1-01, *Manual for the Selection and Installation of Backflow Prevention Devices/Manual for the Maintenance, and Field Testing of Backflow Prevention Devices* (2001)?			●
Are compressed gas cylinders (with the exception of fire extinguishers) located outside of the laboratory?			●
Are supply gas services provided with backflow prevention at the perimeter of laboratory?			●
Are vacuum services provided from within the laboratory?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Is the internal contamination of the vaccum pump minimized by using HEPA filtration of vaccum line or use of disinfectant traps?			❍
Is the dedicated hand washing sink provided with "hands-free" capability?			●
Are emergency eyewash facilities in accordance with lab activities and applicable regulations (i.e.ANSI Z358.1 Emergency Eyewash and Shower Equipment (1998)?			●
Are quantities of hazardous materials limited in the laboratory?			❍
Where not possible to limit the quantity of hazardous materials, is an emergency shower equipment provided in accordance with lab activities and applicable regulations (i.e. ANSI Z358.1 Emergency Eyewash and Shower Equipment)?			●
Are drainage traps provided with required depth in accordance with air pressure differentials?			●
Are drains and associated piping (including autoclave chamber condensate) separated from other laboratories (go directly to main collector for sanitary sewer or liquid effluent treatment system as appropriate)?			●
For non-indigenous agents, are drains (including autoclave chamber condensate) and associated piping connected to an effluent sterilization system?			●
For indigenous agents, are drains (including autoclave chamber condensate) and associated piping connected to an effluent sterilization system consistent with laboratory activity and local regulations?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are drains connected to effluent sterilization sloped towards sterilization system/ installation of valves to isolate sections for decontamination?			●
Are piping heat and chemical resistant/ joints by thermo/chemical fusible means or welding to ensure integrity (i.e. in accordance with pressure decay testing specified in Section 7)?			●
Are drains and associated piping leading to liquid effluent treatment systems (including associated vent lines) tested in accordance with section 3.6 of the *National Plumbing Code of Canada, Canadian Commission on Building and Fire Codes, National Research Council Canada. Testing of Drainage and Venting Systems (1995):* pressure for air test on drainage system shall be at a factor of safety beyond standard code requirements of 35 kPa (e.g. 2 X code)?			●
For non-indigenous agents, are plumbing vent lines (including effluent sterilization system) provided with filter of efficiency equivalent to HEPA?			●
For indigenous agents, are plumbing vent lines (including effluent sterilization system) provided with filter of efficiency equivalent to HEPA consistent with requirement for any effluent sterilization system?			●
Are plumbing vent lines heat-resistant consistent with application?			●
Are plumbing vent lines combined with areas of lower containment only when provided with a filter of efficiency equivalent to HEPA before the connection (i.e. upstream from the connection)?			●
Are all sterilization systems (e.g. autoclaves, liquid effluent treatment systems) verified for operation as specified and microbiologically tested using representative loads (for technologies based on heat - using *Bacillus stearothermophilus* spores; for technologies based on chemicals - using *Bacillus subtilis* spores)?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are all disinfection systems (e.g. dunk tanks, fumigation chambers) verified for operation as specified and microbiologically tested using representative loads? Resistance of test organism representative of organisms likely to be encountered.			●
Are supply conduit and wiring sealed at the containment barrier?			●
Are power system circuit breakers located outside containment perimeter?			●
Are life-safety systems, lighting, biological safety cabinets, HVAC systems and other essential equipment supported by normal emergency power?			●
Is the emergency electrical generator tested under appropriate load conditions to ensure system will operate as specified?			●
Are security systems (e.g. controlled access, closed circuit TV) verified to ensure system will operate as specified?			●
Is a communication system (e.g. intercom, telephone, fax) provided between laboratory area and outside laboratory?			●
Are communication and electronic paper transfer systems verified to ensure system will operate as specified?			●
Sign off by responsible authority (print name, title, date and signature):			
5 - Containment Perimeter:			
Are all mechanical, electrical and service piping penetrations sealed at containment perimeter?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Do windows provide the required level of security?			●
Do door openings allow passage of required equipment?			●
Is a dedicated double-door barrier autoclave located and sealed on containment barrier?			●
Is the body of the autoclave located for ease of maintenance outside containment zone?			❍
Is the barrier autoclave equipped with interlocking doors, or warning light or audible alarms?			●
Is the autoclave equipped with a cycle log recorder (time, temperature, and pressure)?			●
Are other proven technologies for sterilization for non autoclavable materials provided at containment barrier (dunk tank, decontamination chamber)?			●
Is the laboratory proofed against entry or exit of vermin or insects?			●
Is the containment perimeter kept closed?			●
Sign off by responsible authority (print name, title, date and signature):			
6 - Air Handling System:			
Is there a minimum of 10 air changes per hour under normal operations?			●
Is the HVAC air distribution designed to minimize dead air spaces within the laboratory?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are supply & exhaust diffusers located to provide convection patterns that ensure airflow away from lab entrance?			●
Does the diffuser selection provide minimal throw velocities (i.e. < 15 m/m @ 1 m)?			●
Are supply and exhaust diffusers, biological safety cabinets and fume hood locations taken into consideration?			●
Is inward directional airflow maintained across the containment barrier (generally achieved by minimum of 25 Pa difference or 10% offset between zones)?			●
Are pressure monitoring devices at the lab entrance monitoring pressure between containment zones?			●
Are room static pressure monitoring lines provided with filters of at least equal efficiency to HEPA filter?			●
Are alarms (audible or visual) provided in and outside the lab to detect pressurization and air handling systems failure?			●
Is air supply HVAC system independent from adjacent laboratory zones (supply combined with areas of lower containment if provided with a bubble tight damper or HEPA filter after the connection)?			●
Is air exhaust HVAC system independent from adjacent laboratory zones (can be combined with areas of lower containment if provided with a HEPA filter before the connection)?			●
Is backdraft of contaminated air through air supply duct prevented?			●
Is air exhaust HEPA filtered?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are air supply and exhaust equipped with bubble tight dampers to permit gaseous decontamination (can be same bubble tight damper as required for backdraft protection and for isolation of the HEPA filters)?			●
Are air supply and exhaust HVAC systems linked to prevent lab positive pressurization?			●
Are airflow control devices and duct sensors located downstream of the exhaust HEPA filter and upstream of the supply bubble tight damper or HEPA filter?			●
Are bubble tight dampers and HEPA filters located as close as possible to the containment perimeter?			●
Are all air supply and exhaust ductworks located outside the containment laboratory accessible?			●
Are all air supply and exhaust ductworks sealed airtight between the room perimeter and bubble tight damper (pressure decay test)?			●
Sign off by responsible authority (print name, title, date and signature):			
7 - HEPA filters:			
Are filters provided with a minimum efficiency of 99.97% at 0.3um in accordance with the Institute of Envirionmental Sciences IES-RP-CC-001-86 *Recommended Practices for HEPA Filters* (1986)?			●
Is integrity of HEPA filters verified by in-situ particle challenge testing using the scanning method according to IEST-RP-CC-006.2 (section 6.2) (particle penetration not to exceed 0.01%)?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Is static pressure of HEPA filters monitored by pressure monitoring devices (eg. magnehelic gauges)?			●
Is integrity of other in-line filters (e.g. plumbing vent lines, gas supply lines, autoclave exhaust ducts) verified by particle challenge tests (filter efficiency to be equal to that of HEPA filter)?			●
Sign off by responsible authority (print name, title, date and signature):			
8 - HEPA Filter Housings:			
Are HEPA filter housings provided with bubble-tight dampers on air inlets and outlets for shut-off and isolation of the filter?			●
Are HEPA filter housings provided with upstream and downstream fumigation ports for *in situ* decontamination?			●
Are HEPA filter housings provided with upstream injection and downstream access ports to allow for *in situ* particle challenge tests by the scanning method?			●
Are HEPA filter housings leak tight in accordance with pressure decay testing specified in ASME N510 *Testing of Nuclear Air Treatment Systems* (1989- Reaffirmed 1995), rate of leakage not to exceed 0.1% of vol/min at 1000 Pa (4"wg) minimum test pressure?			●
Sign off by responsible authority (print name, title, date and signature):			
9 - Biological Safety Cabinets (BSC):			

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Is certification of biological safety cabinets by NSF accredited certifier in accordance with CSA Z316.3-95, *Biological Containment Cabinets: Installation and Field Testing* (1995) or *NSF 49-2002 Class II (Laminar Flow) Biohazard Cabinetry*?			●
Are valid calibration and verification certificates for the testing equipment used available?			●
Are BSCs located away from high traffic areas, doors and air supply/ exhaust ducts that may interrupt air flow patterns?			●
Do BSCs have minimum clearance of 30 cm between exhaust outlet on top cabinet and overhead obstructions?			●
Is a 30 cm clearance provided on each side of the cabinet to allow for access?			❍
Are propane gas outlets avoided in BSCs?			❍
For ducted cabinets, are blowers on the exhaust located at the terminal end of the ductwork?			❍
Does an exhaust flow failure signal an alarm to the user?			❍
Is an interlock system installed to prevent pressurization of the cabinet?			❍
Is an anti-backflow device installed to prevent reverse airflow through the HEPA filter?			❍
Sign off by responsible authority (print name, title, date and signature):			
OPERATIONAL PRACTICES:			

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
1. Safety Manual / Training			
Is laboratory reference material kept in the laboratory?			❍
Do employees working in the containment area have general knowledge of the physical operation and design of the facility (e.g. air pressure gradients between zones, directional air flow patterns, alarm signals for air pressure failure, containment perimeter)?			●
Is a protocol specific to the operation of the lab developed and read by personnel?			●
Are entry/exit protocols for persons, animals, equipment, samples, waste, etc. written, posted and followed?			●
Are general protocols supplemented with protocols specific for each project in progress?			●
Are employees certifying in writing that they have understood the material in the protocol?			●
Are emergency procedures for entry/exit, spill clean-up, air handling/biosafety cabinet failure, fire, animal escape and other emergencies written, posted and followed in the event of life-threatening emergencies? (Personal health and safety are a priority).			●
Are exit protocols established whereby routine procedures can be bypassed?			●
Is a reporting area identified where further steps must be taken (e.g. disinfecting footwear, changing, showering) prior to leaving?			●
Is personnel receiving training on the potential hazards associated with the work involved and the necessary precautions to prevent exposures to zoonotic agents and release of non-indigenous agents?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Is personnel showing evidence that they understood the training provided?			●
Is training documented and signed by both the employee and supervisor?			●
Are all persons (including visitors, maintenance staff, etc.) entering the containment area trained and follow all relevant protocols for the project in process?			●
Is laboratory personnel trained in and follow the safe use of laboratory equipment, biological safety cabinets, procedures to minimize the production of aerosols, decontamination and emergency response?			●
Do personnel demonstrate proficiency in microbiological practices and techniques (e.g. experience in handling infectious organisms or cell cultures)?			●
Are trainees accompanied by a trained staff member?			●
Is a health and medical surveillance program provided as recommended by Health Canada?			●
2. Entry Requirements			
Is entry restricted to laboratory staff, animal handlers, maintenance staff and other persons on official business?			●
Are only persons meeting specific entry requirements (e.g. immunization, serum screening) allowed to enter containment laboratories unless the facility has been appropriately decontaminated?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are persons entering the containment facility well prepared and bring all materials they will need with them? If something has been forgotten, traffic patterns must still be adhered to (ie. do not go back to get it; either phone for someone to bring it or exit via proper protocols).			●
Are open-toed and high-heeled shoes forbidden in the laboratory?			●
Is long hair tied back so that it cannot come into contact with hands, specimens, containers, or equipment?			❍
Are traffic flow patterns from clean to dirty areas established and adhered to (i.e. move from least to most contaminated areas)?			●
Are personal items such as purses and outdoor clothing kept outside the laboratory?			●
Is a containment check performed prior to entering the laboratory zone (ie. verify negative lab pressurization as designed)?			●
Is smoke testing (i.e. with a smoke pencil) done periodically by laboratory staff to verify correct airflow?			❍
Is personnel entering the laboratory zone removing street clothing and jewellery, and change into dedicated laboratory clothing and shoes?			●
3. Practices in Containment			
Is a second layer of protective clothing (ie. solid-front gowns with tight-fitting wrists, gloves) worn over laboratory clothing when directly handling infectious materials (e.g. dedicated for use at the biological safety cabinet)?			❍
Are gloves (e.g. intact vinyl or latex) worn when handling infectious materials?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are metal mesh gloves worn underneath the latex or vinyl glove to provide protection from sharps and needles?			❍
Is eye and face protection worn when it is necessary to guard against splashing hazardous materials, flying particles, and harmful light or other rays?			●
Are hands washed frequently (after handling infectious materials, after removing gloves, and before leaving the laboratory)?			❍
Are open wounds, cuts, scratches and grazes covered with waterproof dressings?			❍
Are eating, chewing gum, drinking, smoking, storing food, and applying cosmetics prohibited?			●
Are laboratory samples and supplies carried into the laboratory or passed through a ventilated pass-box?			❍
Where the barrier autoclave is used to pass materials into the laboratory, has the autoclave been cycled prior to opening the outer "clean side" door?			●
Are all activities with infectious materials are conducted in a biological safety cabinet?			●
Is work with open vessels containing infectious materials conducted on the open bench unauthorized?			●
Where it is not possible to conduct all activities with infectious materials in a biological safety cabinet, are other physical containment devices in combination with personal protective clothing and equipment used?			●
Is centrifugation of infectious materials carried out in sealed safety cups or rotors that are loaded and unloaded in a biological safety cabinet?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are all spills, accidents, overt or potential exposures to infectious materials, and losses of containment (e.g. lab positive pressurization) reported immediately to the laboratory supervisor?			●
Are written records of such incidents maintained?			●
Are work areas containing hazardous materials kept free from materials not pertinent to the work and that cannot be easily decontaminated (e.g. journals, books, correspondence)?			❍
Are paperwork and report writing kept separate from such work areas?			❍
Are infectious agents stored inside the laboratory?			❍
Are agents stored outside the laboratory kept locked in leakproof containers?			●
Are water seals maintained in drainage traps (i.e. through regular sink/shower usage and/or by filling traps in areas that are not being used)?			●
Is the laboratory zone kept locked?			●
Are laboratory doors kept closed as required by the facility design?			●
Is an effective rodent and insect control program maintained?			●
4. Decontamination / Exit			
Are contaminated work surfaces decontaminated?			●
Is contaminated equipment leaving the laboratory for servicing or disposal appropriately decontaminated?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are all waste materials leaving the laboratory zone decontaminated through a double-door autoclave at the barrier before disposal?			●
Is only one door of the double-door autoclave open at any time?			●
Are heat sensitive materials that cannot be autoclaved out of the laboratory zone decontaminated at the containment barrier (e.g. fumigated with formaldehyde or vaporized hydrogen peroxide, disinfected using liquid chemicals, or other technology proven to be effective)?			●
Are all contaminated materials decontaminated before cleaning for reuse?			●
Is contaminated clothing decontaminated prior to laundering (unless laundering facilities are within the laboratory zone and have been proven to be effective in decontamination of the microorganisms likely to be encountered)?			●
Is efficacy monitoring of autoclaves using biological indicators done at least weekly, depending on the frequency of use of the autoclave, and records of the results kept on file?			●
Are cycle log records (i.e. time, temperature and pressure) kept on file?			●
Where full body protective clothing is not worn, is a shower taken on exit from the laboratory?			●
Where a known or suspected aerosol exposure has occurred, (e.g. dropping infectious materials) is a shower taken on exit from the laboratory?			●
Is a shower (including washing hair, beards) taken on exit from a laboratory handling non-indigenous animal pathogens?			●

	YES / NO / NA (see above if NO or NA)	Comments	● Mandatory ❍ Recommended
Are eye glasses disinfected at the containment barrier?			●
Sign off by responsible authority (print name, date and signature):			

Signatures:

_____ _____ _____

Laboratory Representative Name (please print) Signature Date
(Responsible for accuracy of the checklist)

_____ _____ _____

Biosafety Officer Name (please print) Signature Date
(Responsible for accuracy of the checklist)