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

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Form B-CL3 - Document Submission Requirements for the Certification Performance and Verification Testing of Containment Level (CL) 3 Laboratories in accordance with the *Containment Standards for Veterinary Facilities*, 1996, Canadian Food Inspection Agency (and where applicable, *Laboratory Biosafety Guidelines*, 2004, Public Health Agency of Canada)

Item		Required Information	Notes / Suggestions
A. Contacts		✓ Provide name, title, email address, fax and phone numbers of a key contact for inquiries regarding the submission contents. ✓ Provide current contact information for the institute director, principal investigator (lab supervisor), facilities manager, and biosafety officer.	
B. Program Intent		✓ Give a brief overview of the agents to be used and procedures to be followed in your facility, as well as the general goal/purpose of the work. ✓ Provide a list of pathogens manipulated and/or stored in the facility. ✓ Provide a list of animal species manipulated in the facility. ✓ A program change request must be submitted to this office before any new pathogen is introduced in the facility. ✓ At any time there is a significant change in procedures, you are required to inform this office immediately.	♦ Information to include: maximum volumes of infectious materials to be worked with, identification of any procedures that may produce aerosols, etc.
C. Drawings and Specifications		✓ All "as built" drawings for the facility including architectural, mechanical (HVAC, plumbing, piping, drainage), electrical, and control schematics. If "as built" drawings are not available, tender or construction drawings with change orders are acceptable. ✓ Specifications as listed above including controls sequence of operations.	♦ Drawings for associated structures/services are also required, for example: biowaste system, incinerator, etc. ♦ Indicate the laboratory containment barrier on all drawings.

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D. Verification & Performance Testing 1. Room Integrity		For each required test or verification, describe the test procedure, acceptance criteria, observations, results, pass/fail decision, names, dates, signatures, witnesses and corrective measures required. Testing must have been performed during the last 12 months.	
		✓ Visually and with a smoke pencil, or other visual aid, confirm the integrity of all penetrations and seals on the containment perimeter (include service penetrations and seals around doors, windows, autoclaves and dunk tanks). ✓ Visually inspect floors, walls, and ceiling for cracks, chips or wear, and verify integrity of wall/floor and wall/ceiling joints. ✓ List all defects, corrective measures and re-test results (if applicable).	♦List by room, either in a table or schematic or by elevation (floors, walls, ceiling) of the facility. ♦ All joints should be periodically checked by smoke pencil or other visual aid. ♦ Certain small and large animal facilities may require pressure decay of the room. Please contact the Office of Biohazard Containment and Safety, Canadian Food Inspection Agency (CFIA) for details.
2. Communication Devices		✓ Provide a list and a statement as to how they were verified as operational (phone, intercom, radio, video, etc.).	♦Communication should be maintained with minimum interruption during power outage.
3. Door Interlocks		✓ Indicate combination of doors which are interlocked (e.g. door A with door B, door B with door A and C). ✓ Verify the operation of interlocked doors to ensure that doors cannot be opened simultaneously. ✓ Verify that emergency egress overrides the interlocks. ✓ For facilities that do not have physically-interlocked doors, please confirm that procedures are in place to ensure that no critical combinations of doors can be opened simultaneously.	♦ Provide a plan of the facility and surroundings with clearly labelled doors (i.e. each individual door is uniquely identified).
4. Access Control and Security Devices		✓ List access control and security devices (e.g. key, proximity card, keypad, biometric reader) on all entry points to the CL3 (change rooms, anterooms, pass through, etc). ✓ Provide verification that they operate as intended. ✓ If there is a door on the containment perimeter (e.g. equipment door, emergency exit), please indicate if that door is sealed and how access is controlled.	♦ Verify that a correct code/card works and also that an incorrect code/card will not work.

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5. Demonstration of Inward Directional Airflow (during normal operation)		✓ Inward directional airflow to be visually demonstrated at all critical doors (e.g. by holding a smoke pencil, or other visual aid, at each door leading to adjacent area). ✓ Include a labeled floor plan (letter/legal sized format) with arrows indicating the directional airflow for each door tested.	♦ Air must flow towards areas of higher containment.
6. Autoclaves & Disinfection Systems		✓ Autoclaves to be verified for operation as specified and to be microbiologically tested using representative loads. ● Include the time/temperature criteria required for your specific agent/waste. ● Include a description of the different types of loads to be run and a short description of the load test procedure (e.g. laundry, solid waste, liquid waste, etc.). ● Include a time/temp chart and biological indicator test results for each load test performed. Positive control results must be included (from the same lot#). ✓ Provide verification that interlocking doors or visual/audible alarms are functioning as intended. ✓ All disinfection systems (e.g. dunk tanks, fumigation chambers, etc.) to be verified to operate as intended and microbiologically tested using representative loads.	♦ Generally, for technologies based on heat, *Geobacillus stearothermophilus* spores are adequate and, for technologies based on chemicals, *Bacillus subtilis* spores are used. ♦ Resistance of test organism must be representative of organisms likely to be encountered.
7. Backflow Preventers		✓ Provide a list of all backflow preventers associated with the lab (including type, general location, and purpose). ✓ Water supply backflow preventers must be tested in accordance with CAN/CSA - B64.10-07/B64.10.1-07: *Manual for the Selection and Installation of Backflow Prevention Devices/Manual for the Maintenance and Field Testing of Backflow Prevention Devices* (2007). ● Provide backflow preventers test certificates. ● Provide the name and certification number of the tester. ✓ Backflow prevention for other services (e.g. gases) to be verified to ensure that the system will operate as specified.	♦ This helps ensure all backflow preventers are accounted for.
8. Emergency Generator		✓ Provide a load test report. ✓ Verify that all critical systems are on emergency power (including, but not limited to, controls, fans, security, critical equipment, phones, effluent treatment, etc.). ✓ Previous monthly test report is acceptable.	♦ Load testing results should verify that the generator can pick up and carry the load if required. When live load testing is not possible, simulated load testing is acceptable.

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9. Effluent Treatment * * for laboratories handling non-indigenous animal pathogens and/or certain parasites; and * for animal housing rooms where the room is the primary containment barrier		✓ The system and run criteria are to be validated by microbiological challenge. Ideally, the methodology should be discussed with the Office of Biohazard Containment and Safety , CFIA. • Briefly describe the run criteria for the specific agent/waste in use. • Describe the microbiological challenge and verification procedures. • Provide trending charts, test reports, digital printouts and other data as pertinent. ✓ Drains and associated piping leading to effluent treatment systems (including associated vent lines) to be tested in accordance with *National Plumbing Code of Canada, section 3.6* (1995); Canadian Commission on Building and Fire Codes, National Research Council Canada. Pressure for air test on drainage system shall be a factor of safety beyond standard code requirements of 35kPa (e.g. 2 x code).	♦ Complete this section if facility has a biowaste system, even if not working with non-indigenous animal pathogens.
10. Biological Safety Cabinets		✓ Provide a list of all BSCs associated with the lab plus the test certificate for each. ✓ Each BSC test certificate must contain the following information: • type of cabinet and type of exhaust connection (hard, thimble); • standard to which the cabinet was tested and the qualifications of the tester; • statement as to whether the HEPA filter was scanned or probed, and the pass/fail criteria; • when a unit cannot be tested to NSF 49, it must be tested to manufacturer's specifications; the particle penetration given as a percentage of the upstream challenge must be provided; • indication of any repairs to HEPA filter(s) and subsequent retest results; • downflow and inflow (exhaust) measurements and acceptable ranges specific for the model; • alarm test results - airflow tests, failure alarm test; and • test of airflow patterns within the cabinet. ✓ Class III BSC to be tested in accordance with BS EN 12469:2000: *Biotechnology-Performance criteria for microbiological safety cabinets* (2000); British Standards Institute, and *Laboratory Safety Monograph: A Supplement to NIH Guidelines for Recombinant DNA Research* (1979); National Cancer Institute Office of Research Safety and the Special Committee of Safety and Health Experts. Acceptance criteria: measured leakage from any point in the cabinet shall not exceed a leak rate of 10 X 10^{-7} cc/sec at 750 Pa (3" w.g.). ✓ Provide the calibration certificates for the equipment used for the verification (must be valid on date of test).	♦ This helps ensure all BSCs are accounted for. ♦ 2B2 Puff back: the time from the moment of alarm detection of failure to the moment of air reflux from the cabinet should be known. If not carried out when installed, testing and adjustment of the cabinet alarm should be done as to give the earliest warning possible to the user and maximize the amount of time before the puff back occurs.

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11. HEPA Filters* * Although this may not be a requirement for laboratories handling pathogens not transmitted via inhalation, if the system is in place, then testing should occur.		✓ Provide a list of all the HEPAs associated with the lab plus the test certificate for each. ✓ Each HEPA filter is to be tested *in situ* by particle challenge testing using the scanning method according to IEST-RP-CC001.5: *HEPA and ULPA Filters* (2009); Institute of Environmental Sciences and Testing. ✓ Each HEPA filter test certificate must contain the following information: ● statement confirming scan testing; ● particle penetration for scan testing, given as a percentage of the upstream challenge concentration, not to exceed 0.01%; or particle penetration for probe testing, given as a percentage of the upstream challenge concentration, not to exceed 0.005%; and ● indication of any repairs and retest results. ✓ Provide the calibration certificates for the equipment used for the verification (must be valid on date of test). ✓ Provide results of verification for small in-line filters (e.g. installed in mag gauge lines) or confirmation of scheduled maintenance/replacement.	♦ This helps ensure all HEPAs are accounted for. ♦ Small in-line filters do not need to be in-situ scan tested - a maintenance program to include visual inspection and regular replacement is adequate. ♦ When scan testing is not possible provide reason for probe testing.
12. HEPA Filter Housings* * Although this may not be a requirement for laboratories handling pathogens not transmitted via inhalation, if the system is in place, then testing should occur.		✓ The integrity of HEPA filter housings, with inlet and outlet bubble tight dampers installed into supply and exhaust ductwork, to be tested *in-situ* by pressure decay in accordance with ASME N510: *Testing of Nuclear Air-Treatment Systems* (1989-reaffirmed 1995). Acceptance criteria: rate of leakage not to exceed 0.1% of vol/min at 1000 Pa (4"wg) minimum test pressure.	♦ The engineer shall provide the test pressure to be used (which is the system's maximum operating pressure) in accordance with ASME N509-2002: *Nuclear Power Plant Air-Cleaning Units and Components* (2002) - minimum test pressure 1000Pa (4"wg).
13. Supply and Exhaust Air Ductwork* * Although this may not be a requirement for laboratories handling pathogens not transmitted via inhalation, if the system is in place, then testing should occur.		✓ Supply duct work, where backdraft protection is required on supply, and exhaust air ductwork located between containment perimeter and HEPA filter or bubble tight backdraft damper to be constructed in accordance with *HVAC Air Duct Leakage Test Manual* (1985); Sheet Metal and Air Conditioning Contractors National Association, Inc., ✓ To be tested *in-situ* by pressure decay method in accordance with ASME N510: *Testing of Nuclear Air-Treatment Systems* (1989- reaffirmed 1995). Acceptance criteria: rate of leakage not to exceed 0.1% of vol/min at 1000 Pa (4"wg) minimum test pressure.	♦ Damper to damper testing required. ♦ The engineer shall provide the test pressure to be used (which is the system's maximum operating pressure) in accordance with ASME N509-2002: *Nuclear Power Plant Air-Cleaning Units and Components* (2002) - minimum test pressure 1000Pa (4"wg).

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14. Control Systems/Fail-Safe Operation		✓ Submit a report for each failure scenario performed. ✓ Failures to be simulated include: ● exhaust fan failure; ● supply fan failure; ● power failure (if not possible, provide reason why); and ● additional failures (as appropriate) for the particular facility (e.g. class II B2 BSC exhaust failure, control panel failure, etc.). ✓ For each failure, verify that: ● room/cubicle positive pressurization is prevented; ● inward directional airflow is maintained at all critical doors (verify the airflow by smoke pencil, or other visual aid); and ● audible and visual alarms function correctly. ✓ Each report to contain: ● description of the failure protocol and the control/HVAC systems' expected response; ● indication as to whether or not the system responded as expected; ● results of verification and maintenance of inward directional airflow; and ● alarm results. ✓ Report and describe the investigation of any system failures (e.g. reversed airflow, fan interlock failure) as well as corrective measures taken. ✓ Submit control sequence of operation.	♦ In some circumstances brief airflow reversals (of a few seconds) may be acceptable - consult with this office. ♦ Audible alarms should also to be tested for the capability to detect positive pressurization. ♦ A simple way to depict airflow results is with a labelled plan using arrows to indicate the directional airflow at each critical door tested. ♦ Graphs and trend logs for failure scenarios are helpful and desirable.

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E. Biosafety Manual **Note:** the Biosafety Manual, which may consist of a collection of Standard Operating Procedures (SOPs) is a critical part of the certification documentation. Please realize that fulfilling the requirements of this section entails a substantial amount of work and detail. Do not leave this section until project completion. An example of items to be addressed in each SOP are: ● Purpose ● References ● Personnel/Responsibility ● Glossary/Definitions ● Equipment and Material Required ● Safety ● Policy ● Detailed Instructions Refer to the *Biosafety Manual Requirements Checklist for Containment Level 3 Laboratories* available on the CFIA website for more details on the requirements to be included in the facility's Biosafety Manual.		✓ Roles and responsibilities ✓ Conditions of access ● Orientation, security clearance, working alone/silent hours, medical. ✓ Training ● Supervision period, demonstrated capability, regulatory (WHMIS, etc.). ✓ Employee health and medical surveillance ✓ Entry/exit ● Personnel (include non-routine scenarios such as emergencies and alarms), materials, equipment, animals, and waste. ✓ Personal protective equipment ● Use, maintenance, decontamination. ● Respiratory protection program if applicable. ✓ Transportation, handling and storage of pathogens ● Movement within the containment suite, inventory and access, receiving and shipping. ✓ Decontamination and disinfection ● Disinfectant selection, use, shelf life daily procedures, special considerations. ● Use of vaporized hydrogen peroxide, pass-through or decontamination chamber. ● Full room decontamination. ✓ Infection control practices ● Control of aerosols, prevention of injuries. ● Use of BSC/centrifuge/other. ✓ Hazardous waste management ● Segregation, storage and package. ● Autoclave procedures, incinerate, renderer. ✓ Housekeeping ✓ Animal care and safety ● Animal caging systems, use of cage dumping stations. ● Animal allergens, restraint mechanisms, proper handling techniques. ● Protocols for post-mortem areas, animal carcass movement and transport. ✓ Emergency response ● Failures (HVAC, effluent treatment system, power, BSC). ● Spills (biological – inside BSC, outside BSC, outside facility). ● Animal escape. ● Medical emergency within containment. ● Specific… earthquakes, flood, etc. ✓ Incident reporting ● Requirements/definitions.	♦ This section should be submitted in a separate binder. ♦ The list is not exhaustive and will change depending on the facility and program. ♦ Please feel free to contact this office for more information on the required components of an institutional biosafety program or for specific procedure requirements.