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

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Form D-TSE -Document Submission Requirements for the Certification and Re-certification Performance and Verification Testing of Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents in Accordance with the *Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents*, 2005, and the *Containment Standards for Veterinary Facilities*, 1996, Canadian Food Inspection Agency (and where applicable, *Laboratory Biosafety Guidelines*, 2004, Public Health Agency of Canada)

Door interlocks, demonstration of directional airflow, emergency generator, HEPA filters, HEPA filter housings, supply/exhaust ductwork and control systems are all items that are not required in facilities handling prion disease agents. However, if these systems are functional, a verification that these systems operate as intended should also be performed. Test results should be included in the initial certification submission and all subsequent re-certification submissions. Please refer to Form B for the performance and verification testing requirements for these items.

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. Certification Requirements		***Required for new facility certifications. It is not necessary to submit this information during the re-certification process.*** ✓ Provide description and/or specifications of all surface materials (e.g. walls, floors, benches, casework, etc). ✓ Provide a floor plan of facility with the containment barrier outlined and appropriate; include room numbers.	

Item		Required Information	Notes / Suggestions
D. Verification & Performance Testing		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.	
1. Room Integrity		✓ Provide confirmation that the integrity of all penetrations and seals (**at or below the work surface**) on the containment perimeter were confirmed visually – including all service penetrations (e.g. gas lines) and seals around doors, windows, autoclaves, pass-through, dunk tanks, etc. ✓ Visually inspect floors, walls, and ceiling for cracks, chips or wear, and verify integrity of wall/floor joints. ✓ List all defects, corrective measures and re-test results (if applicable).	
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. 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 TSE laboratory (change rooms, anterooms, pass through, etc). ✓ Provide verification that they operate as intended.	♦ Verify that a correct code/card works and also that an incorrect code/card will not work.
4. Autoclaves & Disinfection Systems* *** If autoclave is used as a method of decontamination, it should be verified.**		**Autoclave present at, within, or outside containment:** ✓ Autoclaves to be verified for operation as specified using representative loads and to be tested microbiologically (121ºC) or with thermocouples / temperature probes (134ºC). ● Include the time/temperature criteria required for your specific agent/waste and a description of the different types of loads to be run (description of contents) and a description of the load test procedure (e.g. laundry, solid waste, liquid waste, etc.). ● Include an autoclave print out (time/temp log) and biological indicator or thermocouple / temperature probe test results for each load test performed. ● Confirmation that positive control results included and from the same lot#. ● Confirmation that the autoclave is capable of achieving 134ºC (or 121ºC if a two-step process is used). ✓ If it is not possible to locate the autoclave at or within the containment perimeter, provide waste control procedures for the transport of waste and equipment in leak proof and impact resistant containers to a suitable autoclave within the facility. ✓ Confirmation that all disinfection systems (e.g. dunk tanks, fumigation chambers, etc.) operate as intended and the system was verified using representative loads tested microbiologically or with thermocouples / temperature probes.	

5. Backflow Preventers *† *** Although this may not be a requirement for facilities handling prion disease agents, if the system is in place, then testing should occur.** † **Only required in large animal facilities and in post mortem rooms.**		**Only if water backflow preventers are installed:** ✓ 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 (or that other municipal/provincial standards meet the 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.
6. Effluent Treatment*† *** Although this may not be a requirement for facilities handling prion disease agents, if the system is in place, then testing should occur.** † **Only required in animal housing rooms where the room is the primary containment barrier.** (Consult *the Containment Standards for Veterinary Facilities*)		**Only if effluent treatment is installed:** ✓ The system and run criteria are to be validated. 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 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.
7. Biological Safety Cabinets * *** Required in laboratories and small animal facilities.**		✓ 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 – airflowtests, failure alarm test. ✓ 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.

Item		Required Information	Notes / Suggestions
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. *** In re-certification submissions: a statement is required that there have been no changes to the program. If there are new agents or procedures in use, please submit the appropriate safety and operational procedures for review.** Refer to the *Biosafety Manual Requirements Checklist for Facilities Handling Prion Disease Agents* 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 ✓ Training ● Supervision period, demonstrated capability, training records. ✓ Employee health and medical surveillance ✓ Entry/exit ● Personnel, 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. ● Waste segregation, storage and package. ● Procedure for the safe removal of BSC HEPA filters. ✓ Housekeeping ✓ Animal care and safety if applicable ● 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 (power, BSC, effluent treatment system). ● 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.