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

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Form E-PPC3 - Document Submission Requirements for the Certification Performance and Verification Testing of Plant Pest Containment Level 3 Facilities (PPC-3) in Accordance with the *Containment Standards for Facilities Handling Plant Pests*, 2007, Canadian Food Inspection Agency

Item		Required Information	Notes / Suggestions
A. Contacts		✓ Provide name, title, fax and phone numbers of a key contact for enquiries 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 the facility, as well as the general goal/purpose of the work. ✓ Provide a list of pathogens and/or arthropods manipulated and/or stored in the facility. ✓ A program change request must be sent to this office before any new pathogen or arthropod is introduced in the facility, and anytime changes related to the nature of the work or the procedures employed increase the risk of pest escape from the facility. ✓ Please inform this office immediately before any significant change to the procedures.	♦ 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) 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 sequence of operations.	♦ Drawings for associate structures/services are also required (i.e. autoclave) ♦ Indicate the containment barrier on all drawings. Dirty change room and shower are included inside the containment zone.

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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 two years.	
		✓ 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, and autoclaves). ✓ 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.	♦List by room, either in a table or schematic or by elevation of the facility. ♦ All seals and joints should be periodically checked by smoke pencil or other visual aid.
2. Communication Devices		✓ Provide a list and a statement as to how they were verified as operational (phone, fax, radio, etc.).	
3. Self closing doors		✓ List doors equipped with self-closing mechanism. ✓ Provide verification that devices operate as intended. ✓ Provide verification that lights automatically switch on/off with opening/closing of doors (for facilities handling arthropods only).	♦ For facilities handling arthropods, lights in anteroom must automatically switch off when either door is opened, and switch on only when both doors are closed.
4. Door Interlocks		✓ Indicate combination of doors which are interlocked (e.g. door A with door B, door B with door A and C). ✓ Verify operation of doors and applicable interlocks 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).
5. Access Control and Security Devices		✓ List access control and security devices on all entry points to the PPC-3 facility (including anterooms and emergency exits). ✓ Provide verification that devices operate as intended. ✓ If there is a door on the containment perimeter (e.g. equipment door, emergency exit), please indicate of 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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6. Ventilation and Inward Directional Airflow		✓ If installed, provide verification of forced-air curtain installed at inner anteroom door. ✓ Inward directional airflow to be visually demonstrated at all doors on the containment perimeter (e.g. by holding a smoke pencil, or other visual aid, at each door leading to adjacent area).	♦ Air must flow towards areas of higher containment. ♦ Provide a labeled plan with arrows indicating the directional airflow for each door tested.
7. Waste Treatment		✓ Provide results of validation for each waste treatment system (using representative loads). ● Provide the time and temperature/concentration criteria required for the specific agent/waste and references to supporting literature. ● Provide 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.). ✓ Autoclave must be verified for operation as specified and must be microbiologically tested using representative loads. ● Provide the time/temperature criteria required for the specific agent/waste. ● Provide 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.). ● Submit 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.	♦ 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.
8. Emergency Power System		✓ Provide a load test report (previous monthly test report is acceptable). ✓ Provide confirmation that all critical systems are on emergency power (including, but not limited to, HVAC, lighting, BSCs, essential equipment and other safety system, etc.).	♦ Load testing results should verify that the emergency power system 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. Biological Safety Cabinets		✓ Provide a list of all BSCs associated with the PPC-3 facility plus the test certificate for each. ✓ Each BSC test certificate must contain the following information: ● type of cabinet and type of exhaust connection; ● 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 NSF 49 is not applicable, the particle penetration given as a percentage of the upstream challenge must be provided; ● indication of any repairs and 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. ✓ Provide the calibration certificates for the equipment used for the verification.	♦ This helps ensure all BSCs are accounted for.
10. HEPA Filters		✓ Provide a list of all the HEPAs (including in line filters) 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-CC-001.5, 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%; and ● indication of any repairs and retest results. ✓ Provide the calibration certificates for the equipment used for the verification.	♦ 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. ♦ Particle penetration for probe testing, given as a percentage of the up stream challenge concentration, not to exceed 0.005%.
11. HEPA Filter Housings		✓ 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 1000Pa (4"w.g.) 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"w.g.).

12. Supply and Exhaust Air Ductwork		✓ 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 1000Pa (4"w.g.) 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"w.g.).
13. Control Systems		✓ Provide verification that supply and exhaust air systems are interlocked to prevent sustained laboratory positive pressurization. ✓ 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 positive pressurization is prevented; ● inward directional airflow is maintained at all critical doors (verify the airflow by smoke pencil, or other visual aid); and ● alarms function correctly to detect loss of containment. ✓ Control system performance verification should include speed of response, accuracy, and repeatability. ✓ Each report to contain: ● description of the failure protocol and the control/HVAC system's 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.	♦ In some circumstances brief airflow reversals (of a few seconds) may be acceptable - consult with this office. ♦ 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 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 address 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 Plant Pest Containment Level 3 Facilities* available on our website for more details on the requirements to be included in the facility's Biosafety Manual.		✓ Roles and responsibilities ✓ Requirements/definitions ✓ Conditions of access ● Orientation, security clearance. ✓ Training ● Supervision period, demonstrated capability, regulatory (WHMIS, etc.). ✓ Entry/exit ● Personnel (include non-routine scenarios such as emergencies and alarms), materials, equipment and waste. ✓ Personal protective equipment ● Use, maintenance, decontamination. ✓ Transportation, handling and storage of plant pests and arthropods ● Movement within the containment suite, inventory and access, receiving and shipping. ✓ Decontamination and disinfection ● Disinfectant selection, use, shelf life daily procedures, special considerations. ✓ Hazardous waste management ● Segregation, storage and package. ● Autoclave procedures, other methods. ✓ Housekeeping ✓ Emergency response ● Failures (HVAC, decontamination systems, power, BSC). ● Spills (biological – inside BSC, outside BSC, soil, outside facility). ● Arthropod escape. ● Medical emergency within containment. ● Other… earthquakes, flood, etc. ✓ Incident reporting	♦ 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.