Biosafety Manual Requirements Checklist
Containment Level 3 Facilities

Standard Operating Procedures must be facility specific and provide detailed descriptions on how all aspects of biosafety will be maintained. This checklist was developed to assist in the preparation of the Biosafety Manual for CL3 facilities.

Items to consider include:

REQ: requirement as stated in the *Laboratory Biosafety Guidelines* and the *Containment Standards for Veterinary Facilities*;

A*:* denotes a requirement for CL3 facilities handling aerosol agents;

REC: recommendations to promote good biosafety laboratory practices.

The items in this checklist are presented as a guide and are not meant to be exhaustive. Items not addressed in the checklist may be included in the Biosafety Manual of certain facilities depending on their design and program while other items may require some adaptation.

1. Executive Summary

Items to Consider	REQ	REC
Program Overview and Facility Description		
1. Program intent and goals.	√	
2. Agents manipulated.	√	
3. Agents stored.	√	
4. CL3 lab area description and floor plan (including room numbers and door labels).	√	
5. Glossary of terms and abbreviations.		√

2. Standard Operating Procedures

Each procedure should include the following sections:

a. Purpose – short summary of the procedure objectives;
b. Glossary– list of acronyms, abbreviations and facility-specific terms with associated definition;
c. Personnel Responsibilities – overview of roles and responsibilities for personnel implicated in the procedure;
d. Safety – highlight important considerations to ensure the safety of personnel;
e. Equipment and Material Required
f. Detailed Instructions – step by step instructions on protocol to follow ;
g. References - list of information sources cited in the procedure.

Items to Consider	REQ	REC
Conditions of Access		
A) Medical Surveillance		
1. Confirmation that risk assessment was performed.	√	
2. Pre-employment and annual medical requirements.	√	
3. Immunizations requirements (if any).	√	
4. Respiratory protection program; must include:		
▪ Selection of respirator.	√A	
▪ Fit Testing (requirements and schedule).	√A	
▪ Training.	√A	
5. Symptoms to look for – reference to MSDS or provide list.	√	
6. Contact (i.e. Health Care Physician, OSH committee) in the event of an exposure.	√	
7. Special considerations for immuno-compromised and pregnant staff members.	√	
B) Training		
1. Training program must cover:		
▪ General knowledge of physical operation and design of facility.	√	
▪ General training requirements – see operational practices requirements in the *Laboratory Biosafety Guidelines* and/or *Containment Standards for Veterinary Facilities*.	√	
▪ Read SOP Manual, *Laboratory Biosafety Guidelines* and/or *Containment Standards for Veterinary Facilities.*	√	
▪ Other regulatory requirements (i.e. WHMIS, TDG, etc.).	√	
2. Training program must include:		
▪ Evidence that training is understood (includes supervision period and/or dry-runs).	√	
▪ Employee training records signed by trainer, trainee and CL3 supervisor.	√	
▪ Annual re-training requirements.	√	

Items to Consider	REQ	REC
Entry and Exit		
A) Personnel		
1. Verification of systems prior to entry:		
▪ Verification of HVAC system gauges.	√	
▪ Verification of indicator lights.		√
▪ Verification of communication system.		√
2. Entry/exit logs:		
▪ Sign in/sign out.		√
▪ HVAC system gauges reading.		√
3. Buddy system (normal and silent hours):		
▪ Enter lab accompanied with another staff member; or description of how safety of employee is assured if entering the CL3 alone (i.e. with frequent communication checks).	√	
4. Entry:		
▪ Remove jewelry and access card.	√	
▪ Remove contact lenses (if applicable).		√
▪ List dedicated lab clothing (i.e. scrubs, shoes, socks).	√**A**	√
▪ Remove street clothing and don dedicated lab clothing; or use full coverage protective clothing over street clothing.	√**A**	√
▪ Don additional layer of protective clothing (i.e. solid-front gowns with tight-fitting wrists, gloves, respiratory protection); must include where each item is donned.		√
▪ Respirator check.		√
▪ After entering CL3 ensure that doors are shut properly.	√	
▪ Specific procedure must be in place when critical doors are not interlocked (i.e. lights, time lapse) to ensure that 2 doors are not opened at the same time.	√	
5. Exit:		
▪ Decontaminate items that will be removed from CL3 (including respirator and eyeglasses, if applicable).	√	
▪ Remove additional layer of protective clothing (i.e. solid-front gowns with tight-fitting wrists, gloves, respiratory protection) in a manner that prevents contamination; must include where each item is doffed.		√
▪ Remove dedicated lab clothing (scrubs, shoes, socks).	√**A**	√
▪ Shower thoroughly (if applicable). Note: showering is required in the event of a known or suspected aerosol exposure (following risk assessment); when working with non-indigenous pathogens; when exiting a large animal/Post Mortem facility.	√	
▪ After exiting CL3 ensure that doors are shut properly.	√	
▪ Specific procedure must be in place when doors are not interlocked (i.e. lights, time lapse) to ensure that 2 doors are not opened at the same time.	√	

Items to Consider	REQ	REC
B) Materials		
1. Routine items and equipment (animals, cages, waste):		
▪ Remove excess packaging before bringing in CL3.		√
▪ Entry through autoclave conditional to autoclave previously cycled, and/or entry through pass-through conditional to pass-through previously decontaminated.	√	
▪ All materials taken out of the CL3 must be decontaminated at the containment barrier.	√	
▪ Exit conditional to autoclave cycled, pass-through decontaminated or dunk tank filled with appropriate disinfectant.	√	
2. Movement of large equipment through containment barrier.	√	
Infectious Material		
1. MSDS available inside and outside containment.	√	
2. Best practices must be emphasized and include the following (or a reference to *Laboratory Biosafety Guidelines* and/or *Containment Standards for Veterinary Facilities* is acceptable) :		
▪ SOP manual must be available to all staff (inside containment).	√	
▪ Eating, chewing gum, drinking, smoking, storing food, and applying cosmetics are prohibited.	√	
▪ Oral pipetting of any substance is prohibited in any laboratory.	√	
▪ Use of needles, syringes and other sharp objects should be strictly limited. Needles should not be bent, sheared recapped or removed from the syringe; they should be promptly placed in a puncture-resistant sharps container.		√
▪ Work surfaces must be cleaned and decontaminated with a suitable disinfectant at the end of the day and after any spill of potentially biohazardous material.	√	
▪ Hands should be washed frequently (after handling infectious materials, after removing gloves, and before leaving the laboratory).		√
▪ Open-toed and high-heeled shoes must not be worn in the laboratory.	√	
▪ Long hair should be tied back so that it cannot come into contact with hands, specimens, containers or equipment.		√
▪ Gloves must be worn when handling infectious materials.	√	
▪ BSC must be used for procedures with potential for producing infectious aerosols and with high concentrations or large volumes of zoonotic materials.	√	
▪ Centrifugation of infectious materials must be carried out in sealed safety cups of rotors that are loaded/unloaded in a BSC.	√	
3. Storage and Inventory:		
▪ Agents should be stored inside the CL3.		√
▪ If stored outside the CL3, agents must be in leakproof containers and kept locked with restricted access.	√	
▪ Regular inventory tracking.		√

Items to Consider	REQ	REC
4. Transportation within containment:		
▪ Use of closed container.	√	
▪ On a trolley/cart.		√
5. Shipping and Receiving:		
▪ Use of leakproof containers (as per *Transportation of Dangerous Goods)*.	√	
▪ Proper training requirements (as per *Transportation of Dangerous Goods)*.	√	
Decontamination		
1. List of disinfectants (effective against pathogens in use), and include:		
▪ Purpose.	√	
▪ Concentration.	√	
▪ Contact time.	√	
▪ Shelf life.	√	
2. Liquid waste treatment :		
▪ Biologicals, liquid cultures, etc.	√	
▪ Biologically-contaminated chemicals and radioisotopes (if applicable).	√	
3. Solid waste treatment:		
▪ Lab waste	√	
▪ PPE	√	
▪ Paper waste	√	
4. Sharps.	√	
5. Liquid effluent (if applicable).	√	
6. Full room decontamination:		
▪ Schedule.		√
▪ Procedure.	√	
▪ Validation method.	√	
7. Other methods of decontamination (if applicable).	√	
Emergency Procedures		
1. Response to Biological spills:		
▪ Small and large volumes inside BSC.	√	
▪ Small and large volumes outside BSC.	√	
▪ Inside centrifuge and inside sealed safety cups.	√	
▪ Outside containment area (if applicable).	√	
2. Response to medical emergency within containment.	√	
3. Response to BSC failure.	√	
4. Response to power failure.	√	
5. Response to fan (supply/exhaust) failure.	√	
6. Response to other alarms.	√	

7. Response to other situations (i.e. fire, earthquakes, floods, etc.).	√	

Items to Consider	REQ	REC
Incidents and Accident Reporting		
1. Must be reported to lab supervisor (or other).	√	
2. Forms/records to be completed	√	
3. Investigation and risk assessment.		√
4. Follow-up (communication of results to staff).		√
5. New recommendations to mitigate future risk.		√
Use and Maintenance of Equipment		
1. PPE and respirator.	√A	
2. Autoclave.	√	
3. Dunk tank (if applicable).	√	
4. Pass-through (if applicable).	√	
5. BSC.	√	
6. Spill kits.	√	
7. Other (if applicable).		√
Housekeeping and Facility Maintenance		
1. List of tasks (daily, weekly, monthly, and annually).		√
2. Drainage traps to be filled with liquid.	√	
3. Safety equipment (eyewash station, spill kits, etc.)	√	
4. Insect/rodent control.	√	
5. Verification and performance testing requirements (for annual re-certification)	√	
Animals (may be a separate manual and training program)		
1. For animal care, refer to Canadian Council for Animal Care (http://www.ccac.ca/).	√	
2. Use of cage dumping stations.	√	
3. Animal escape (prevention and response).	√	
4. Bites and scratches (prevention and treatment).	√	
5. Proper handling techniques (i.e. restraint mechanisms).		√
6. Specific protocols for large animals and post-mortem areas – refer to *Containment Standards for Veterinary Facilities* for requirements.	√	