

Office of Biohazard Containment and Safety Bureau du confinement des biorisques et de la sécurité

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**Inspection Checklist for Level 2 *In Vitro* Facilities**

This Inspection Checklist may be used for the verification of compliance with the physical and operational requirements and recommendations of containment level 2 aquatic laboratories in accordance with the *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, 1st Edition, 2010 and containment level 2 terrestrial animal laboratories in accordance with the *Canadian Biosafety Standards*, 2nd Edition, 2015.

|  |  |
| --- | --- |
| **Company/Organization Name:**  |   |
| **Applicant's name:** [ ]  Mr. [ ]  Ms. [ ]  Dr. | **Biological Safety Officer’s name:** [ ]  Mr. [ ]  Ms. [ ]  Dr. |
|   |   |
| Phone: |   | Phone: |   |
| Email:  |   | Email:  |  |
| Physical Address of Containment Zone: (including building information) |  |
| Room(s) # where material will be handled for ***in vitro*** work:  |

The expression «Containment zone» is used merely to simplify the text; it refers to laboratory room(s) where terrestrial and/or aquatic animal pathogen(s) will be handled and stored.

| ***No*** | ***Facility and Program Information*** |
| --- | --- |
| 1 | Type of Facility: | [ ]  Government (Federal) | [ ]  Hospital | [ ]  Private |  |
|  | [ ]  Government (Provincial) | [ ]  Academic | [ ]  Other, specify:  |
| 2 | Program Intent: | [ ]  Research & Development | [ ]  Environmental Microbiology | [ ]  Other, specify:  |
|  | [ ]  Diagnostic / Proficiency Testing | [ ]  Food Microbiology |
| 3 | Material(s) handled: | [ ]  Bacteria | [ ]  Fungi | [ ]  Tissues or body fluids (animal) | [ ]  Cells (culture, monkey) |
| [ ]  Viruses | [ ]  Parasites | [ ]  Tissues or body fluids (human) | [ ]  Other, specify:  |
| 4 | Provide a brief description of the program intent(s) for the containment zone:   |

| ***No*** | ***Questions*** | ***Answers / Comments*** |
| --- | --- | --- |
| **Biological Safety** |
| 5 | Is there a Biological Safety Officer (BSO) designated to oversee biosafety and biosecurity for the containment facility*?* *(A biological safety committee may be used to assist with the safety program. The BSO is to be present during the inspection)* | [ ]  Yes [ ]  No |   |
| 6a | Is there a copy of the Canadian Biosafety Standards (CBS), 2nd Edition (2015) available to containment zone staff and have staff read this document?  | [ ]  Yes [ ]  No |   |
| 6b | Is there a copy of the *Containment Standards for Facilities Handling Aquatic Animal Pathogens* available to containment zone staff and have staff read this document?  | [ ]  Yes [ ]  No |
| 7 | Is there a Biosafety Manual and is it available to all staff?(*Review the manual. It needs to include a description of the containment zones, how they operate, biosafety program, training, emergency response procedures and decontamination, waste management, etc.)* | [ ]  Yes [ ]  No |   |
| 8 | Is the Biosafety Manual reviewed and updated regularly? | [ ]  Yes [ ]  No |   |
| 9 | Are there written emergency procedures for biological spill clean-up, BSC failure, power failure, fire, and other emergencies?*(Review these procedures. Spill procedures must include a section regarding the prevention of release of contaminated materials into drainage systems unless linked to a decontamination system).* | [ ]  Yes [ ]  No |   |
| **Training** |
| 10a | Has a training needs assessment been conducted?  | [ ]  Yes [ ]  No |   |
| 10b | Is a review of the training needs assessment conducted, at minimum, annually? | [ ]  Yes [ ]  No |
| 11 | Do employees working in the containment zone have general knowledge of the physical operation and design of the facility?*(e.g. inward directional airflow, decontamination system, primary containment systems)* | [ ]  Yes [ ]  No |   |
| 12 | Have containment zone staff read, received training in, and understood the Biosafety Manual and associated operational protocols (SOPs)?*(Ask a staff member if they have read the manual, ask questions)* | [ ]  Yes [ ]  No |   |
| 13 | Do all persons in the containment zone know, demonstrate competence, and follow the Biosafety Manual and associated operational protocols (SOPs) for the projects in process? | [ ]  Yes [ ]  No |   |
| 14 | Are employees trained on the potential hazards associated with the work involved and the precautions required to prevent exposure to infectious substances and potential zoonotic agents? | [ ]  Yes [ ]  No |   |
| 15 | Does employee training include the review of Pathogen Safety Data Sheets (PSDS) for the pathogen(s) handled in the laboratory?*(Verify if they are available and used during training. If not publicly available, the applicant or trainer must prepare their own)* | [ ]  Yes [ ]  No |   |
| 16 | Are refresher and retraining programs implemented as appropriate? | [ ]  Yes [ ]  No |   |
| 17 | Is refresher training on emergency response procedures provided annually? | [ ]  Yes [ ]  No |   |
| 18 | Is there written documentation of the training provided?*(Review this documentation. It must describe the training provided and be signed by both the employee and the supervisor)* | [ ]  Yes [ ]  No |   |
| 19 | Are documented records of training and refresher training kept on file? | [ ]  Yes [ ]  No |   |
| 20 | Are the employees (researchers, technicians, etc.) working in the containment zone responsible for housekeeping? | [ ]  Yes [ ]  No |   |
| 21 | Are non-laboratory staff (e.g. janitors, maintenance workers, contractors) entering the containment zone trained in the operational procedures for entry and exit and the hazards associated with the biohazardous material?*(Review the training module(s) and visitor policy. Visitors and trainees to be accompanied by a trained staff member)* | [ ]  Yes [ ]  No |   |
| **Containment Structure, Location and Access** |
| 22 | Is the containment zone separated from public and administrative areas by a door? | [ ]  Yes [ ]  No |   |
| 23a | Is access to the containment zone restricted to persons on official business? | [ ]  Yes [ ]  No |   |
| 23b | Indicate how the containment zone is restricted to authorized personnel: |  |  |
| [ ]  Lockable (key) doors | [ ]  PIN/Access card | [ ]  Signage | [ ]  Other, specify:  |
| 24 | Are doors to the containment zone kept closed?*(Verify that they are all closed. Doorstops should not be present)* | [ ]  Yes [ ]  No |   |
| 25a | Are windows installed on the containment barrier of the containment zone? | [ ]  Yes [ ]  No |   |
| 25b | If yes, are the windows,  | [ ]  openable | [ ]  non-openable | [ ]  sealed |
| If not sealed, indicate the mechanism(s) in place to maintain effective security and pest control:  |
| 26 | Is appropriate biohazard signage posted on each entry door to the containment zone? | [ ]  Yes [ ]  No |   |
| If yes, indicate which elements are present on the signage: |
| [ ]  international biohazard symbol[ ]  name(s) and phone number(s) to contact  in case of emergency | [ ]  Containment Level 2 (CL2)[ ]  Aquatic Level 2 (AQC2)[ ]  entry requirements (e.g. PPE) |
| 27 | Are hooks or lockers provided at the entry/exit point(s) of the containment zone to allow the separate storage of street clothing and personal protective equipment (e.g. lab coats)? | [ ]  Yes [ ]  No |   |
| 28 | Is access to supporting mechanical and electrical services for the containment zone limited to authorized personnel? | [ ]  Yes [ ]  No |   |
| 29 | Are office areas located outside of laboratory working areas? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 30 | Describe the mechanism(s) in place to minimize the risk of contaminating paperwork, workstation computers, and reference material, etc. within the containment zone:  |
| **Surfaces, Finishes and Casework** |
| 31 | Are the floors slip-resistant?If no, describe how the risk of slippage is mitigated:  | [ ]  Yes [ ]  No |   |
| 32 | Are surfaces and interior coatings, including, but not limited to, floors, ceilings, walls, doors, frames, casework, benchtops, and furniture, cleanable, non-absorbent, and resistant to scratches, stains, moisture, chemicals, heat, impact, repeated decontamination, and high pressure washing, in accordance with function? (*Are surfaces and coatings in good condition?)* | [ ]  Yes [ ]  No |   |
| 33 | Is unfinished wood present in the containment zone? | [ ]  Yes [ ]  No |   |
| 34 | Are surfaces continuous with adjacent and overlapping material? | [ ]  Yes [ ]  No |   |
| 35 | Is there a continuity of seal maintained between the floor and wall? | [ ]  Yes [ ]  No |   |
| 36 | Describe the frequency of visual inspections conducted of the containment zone in order to identify faults and/or deterioration and provide a brief outline of the corrective action procedure(s) to be taken when faults and/or deterioration are found:  |
| **Facility Services** |
| 37 | Does the containment zone have inward directional airflow (IDA)? | [ ]  Yes [ ]  No |   |
| 38 | Are emergency eyewash facilities and emergency shower equipment provided in the containment zone in accordance with activities performed and applicable regulations (i.e. ANSI Z358.1 Standard)? | [ ]  Yes [ ]  No |   |
| 39 | Does the containment zone have a system to control the release of large scale process fluids to the sanitary sewer? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 40 | Indicate which containment zone services and equipment critical to maintaining containment and biosecurity are supported by emergency power:  |
| 41 | Sink(s) are to be provided for hand washing. Indicate which of the following apply to the containment zone sink(s):  |
| [ ]  hands-free operation | [ ]  dedicated to handwashing | [ ]  located to facilitate handwashing upon exit  from containment zone |
| Additional Information:  |
| 42 | Is the facility proofed against vermin and insects?*(Check for dead flies and mouse droppings)* | [ ]  Yes [ ]  No |   |
| **Biological Safety Cabinets (BSCs) and other Primary Containment Devices** |
| 43 | Are certified biological safety cabinets (BSCs) provided within the containment zone? | [ ]  Yes [ ]  No |   |
| 44 | Are other primary containment devices (e.g. custom enclosures, isolators, centrifuges with sealable cups, process equipment, fermenters) provided? | [ ]  Yes [ ]  No |   |
| 45 | Are BSCs certified in accordance with *NSF/ANSI 49, Biosafety Cabinetry: Design, Construction, Performance, and Field Certification* at least annually?*(Check for certification sticker - some BSCs need to be certified according to manufacturer specifications)* | [ ]  Yes [ ]  No[ ]  N/A |   |
| 46 | Is a copy of the certification report(s) readily available and/or certification sticker indicating the certification date, date of next certification, to what standards the tests were performed and the name of the certifier? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 47 | For the certification of BSCs and custom ventilated enclosures which cannot be certified in accordance with NSF/ANSI 49, provide a description of the frequency and procedure used, including testing criteria for certification:[ ]  N/A (no BSCs and/or custom ventilated enclosures are present in the containment zone)[ ]  N/A (all BSCs are tested in accordance with NSF/ANSI 49)  |
| 48 | Does the HVAC system (Heating, Ventilation and Air Conditioning) interfere with the airflow of biological safety cabinets?*(Check to make sure BSCs are not located directly under a supply/exhaust diffuser)* | [ ]  Yes [ ]  No[ ]  N/A |   |
| 49a | Are Class II B2 BSCs provided within containment zone for work with infectious, or potentially infectious, material? | [ ]  Yes [ ]  No |   |
| 49b | Class II Type B2 BSC(s) are to be installed, set up and tested to demonstrate that airflow from the face of the BSC is maintained during a failure of the HVAC system, control system or BSC exhaust fan. **Note** that this testing is supplemental to the interlock testing conducted as part of annual NSF-49 certification.Indicate the date of testing (approximate) and procedure used to demonstrate that the risk of release of infectious aerosols is mitigated at the face of Class II B2 BSCs:  |
| 50 | When are procedures with infectious, or potentially infectious, material conducted within a certified BSC?: |
| [ ]  N/A (no BSC) | [ ]  activities may produce aerosols | [ ]  working with high concentrations |
| [ ]  always | [ ]  working with large volumes | [ ]  when aerosol generation cannot be contained through other methods |
| Additional Information:  |
| 51 | If procedures with infectious or potentially infectious material are not conducted within a certified BSC or other primary containment device, describe why and/or how the risk(s) of personnel exposure, contamination of the containment zone and/or release from the containment zone are mitigated.[ ]  N/A All procedures with infectious or potentially infectious material are conducted within a certified BSC or other primary containment device. |
| 52 | Are employees using BSCs trained in their correct use and care and have a good understanding of their operation?*(Verify training records; ask a staff member to describe the procedure; ask staff to identify the air split)* | [ ]  Yes [ ]  No[ ]  N/A |   |
| **General Operational Practices** |
| 53 | Are the containment zone rooms kept neat, orderly and clean?*(Check for boxes stored on the floor, cluttered benchtops which cannot be routinely decontaminated; cleanliness of sink used for handwashing)* | [ ]  Yes [ ]  No |   |
| 54 | Describe how containment personnel use traffic patterns from clean to dirty areas within containment*(Observe personnel to see if patterns are established and adhered to)*:  |
| 55 | Are uniforms (lab coats, gowns, coveralls) worn and properly fastened when working in the containment zone?*(Also applies to visitors and trainees; were you asked to wear a lab coat?)* | [ ]  Yes [ ]  No |   |
| 56 | Is personal protective equipment worn only in the containment zone?*(All dedicated clothing must be removed before exiting each containment zone. Check to see if anyone is wearing lab coats or gloves in hallway, offices, cafeteria, etc.)* | [ ]  Yes [ ]  No |   |
| 57 | Is appropriate footwear (i.e. closed toe, closed heel and low heel) worn in the containment zone?  | [ ]  Yes [ ]  No |   |
| 58 | Are gloves worn when in direct contact with infectious materials? | [ ]  Yes [ ]  No |   |
| 59 | Handwashing is one of the most effective ways to prevent the spread of contamination. Specify when personnel wash their hands: |
| [ ]  after handling infectious materials | [ ]  exiting the BSC | [ ]  after completing tasks that involve the handling of infectious material and before undertaking other tasks in the containment zone |
| [ ]  after removing gloves | [ ]  exiting the containment zone |
| [ ]  other, specify:  |
| 60 | Is long hair tied back so that it cannot come into contact with hands, infectious material or equipment?*(Check employee’s hair)* | [ ]  Yes [ ]  No |   |
| 61 | In the containment zone, are personnel allowed to bring in personal belongings (such as cell phones, iPods, coats, purses, etc.), eat, store food, chew gum, smoke or apply cosmetics? | [ ]  Yes [ ]  No |   |
| 62 | Are Good Microbiological Laboratory Practices employed to protect personnel and prevent the contamination of the containment zone and environment?  | [ ]  Yes [ ]  No |   |
| 63 | Is oral pipetting of any substance permitted? | [ ]  Yes [ ]  No |   |
| 64 | Is the use of needles, syringes and other sharp objects limited where possible? | [ ]  Yes [ ]  No |   |
| 65 | Are open wounds, cuts, scratches and grazes covered with waterproof dressings? | [ ]  Yes [ ]  No |   |
| 66 | When working with infectious material where inhalation is a primary route of infection, is centrifugation carried out in sealed safety cups (or rotors) that are unloaded in a certified BSC? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 67 | For large scale culture work within a closed system, describe the procedure(s) used to prevent the release of aerosols or the contamination of exposed surfaces during sample collection, the addition of materials or the transfer of culture fluid from one closed system to another:[ ]  N/A  |
| **Decontamination and Waste Management** |
| 68 | All contaminated or potentially contaminated materials are to be decontaminated prior to disposal, reuse or removal from service. For each type of material, specify means of decontamination: |
| *Type of Material* | *N/A* | *Autoclave* | *3rd Party* | *Chemical* | *Other, specify:* |
| Solid waste | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Gloves | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Sharps (e.g. needles, syringes, glass slides, broken glass/plastic)  | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Liquid waste | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Reusable items (e.g. labware, glassware) | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Reusable PPE (e.g. lab coats prior to laundering) | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Carcasses and tissues | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Equipment prior to service or removal from containment | [ ]  | [ ]  | [ ]  | [ ]  |   |
| Other, specify:  | [ ]  | [ ]  | [ ]  | [ ]  |   |
| 69 | Are written procedures available for each type of decontamination method used? Are the procedures up to date?*(Ask to review a copy of these documents)* | [ ]  Yes [ ]  No |   |
| 70 | Is an on-site autoclave or other decontamination technology, within the containment zone or in a centralized decontamination area, used for decontamination purposes? **If no, skip to Q74** | [ ]  Yes [ ]  No |   |
| 71 | Are the autoclave(s) and other decontamination technologies equipped with monitoring and recording devices (e.g. cycle log recorder) that capture operational parameters? (*Examine print out and verify that the parameters, e.g. time and temperature, were met for decontamination)* | [ ]  Yes [ ]  No |   |
| 72 | Were the autoclave cycle(s) and other decontamination processes **validated** using standardized representative loads with appropriate biological indicators and/or thermocouples to ensure the parameters are effective? | [ ]  Yes [ ]  No |   |
| 73 | Provide a brief description and specify to the frequency of routine verification (i.e. ongoing efficacy monitoring) and validation of autoclaves and other decontamination systems: |
| Verification:  |   |
| Validation:  |   |
| 74 | Are sharps discarded into containers that are specifically designed for sharps waste? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 75 | Are work surfaces decontaminated regularly and at the end of each day? *(Ask to review the procedure; check to see if disinfects are readily available; verify concentration and contact time are respected)* | [ ]  Yes [ ]  No | Click here to enter comments. |
| 76 | Disinfectants used for decontamination are to be effective against the infectious material in use. Specify the disinfectant(s), concentration(s), contact time and shelf-life:  |
| 77 | Describe the procedures in place for the safe movement of waste from the containment zone to a centralized decontamination area and/or 3rd party certified waste disposal company:[ ]  N/A – do not use centralized decontamination area [ ]  N/A – do not use 3rd party certified waste disposal company  |
| 78 | Records are to be maintained for decontamination technologies and processes: For each type of records, indicate if they are maintained and specify how long the records are retained. |
| *Records* | *Yes* | *No* | *N/A* | *Specify Retention Period* | *Comments* |
| Validation of standardized cycles | [ ]  | [ ]  | [ ]  |   |   |
| Routine verification/efficacy monitoring | [ ]  | [ ]  | [ ]  |   |   |
| Specific parameters (cycle log printout) for *each* decontamination cycle run using a decontamination technology (e.g. autoclave)  | [ ]  | [ ]  | [ ]  |   |   |
| Waste sent to 3rd party certified waste disposal companies | [ ]  | [ ]  | [ ]  |   |   |
| Decontamination of equipment prior to service or removal from containment | [ ]  | [ ]  | [ ]  |   |   |
| Other, specify:  | [ ]  | [ ]  | [ ]  |   |   |
| **Storage and Transport** |
| 79 | Is infectious material stored only within the containment zone? If infectious material is stored outside of the containment zone, specify if it is | [ ]  Yes [ ]  No |   |
| [ ]  appropriately labelled | [ ]  in leak-proof, impact resistant containers |
| and kept in [ ]  locked storage equipment or [ ]  within an area with limited access |
| 80 | Is an inventory of infectious material maintained and kept up-to-date?Specify what the inventory includes:[ ]  infectious material stored inside and outside of the containment zone[ ]  identification of the infectious material[ ]  location [ ]  risk group [ ]  source (e.g. importation information) | [ ]  Yes [ ]  No[ ]  N/A |   |
| 81 | Are leak proof and impact-resistant containers used for the transport of infectious agents within facilities (e.g., between laboratories in the same facility)? | [ ]  Yes [ ]  No[ ]  N/A |   |
| 82 | Is the transportation of infectious agents from the facility done in accordance and compliance with the appropriate regulatory authority (e.g. Transport Canada’s Transportation of Dangerous Goods Regulations)? | [ ]  Yes [ ]  No[ ]  N/A |   |
| **Records and Reporting** |
| 83 | Are records kept on file of incidents involving pathogens, toxins, other regulated infectious material, or losses of containment? | [ ]  Yes [ ]  No | Specify how long records are maintained:   |
| 84 | Are records kept on file of incident investigation for any incident involving infectious material, or failure of containment systems or control systems, in order to determine the root cause(s)? | [ ]  Yes [ ]  No | Specify how long records are maintained:   |
| 85 | Are records kept on file of regular inspections of the containment zone and corrective actions? | [ ]  Yes [ ]  No | Specify how long records are maintained:   |
| 86 | Are records kept on file of building and equipment maintenance, repair, inspection, testing, or certification, including performance verification and testing records, in accordance with containment zone function? | [ ]  Yes [ ]  No | Specify how long records are maintained:   |
| 87 | Does the equipment used for the testing of containment systems and essential biosafety equipment (e.g. BSC) have a valid calibration certificate at the time of testing? | [ ]  Yes [ ]  No |   |
| 88 | Records are to be maintained for imported infectious material. 1. Indicate which components are included as part of the records maintained:

[ ]  date(s) of importation / receipt of transferred imported material / shipment received (e.g. from Canadian Distributor)[ ]  Date(s) of transfer (i.e. shipment) of imported material, information regarding the material transferred, and recipient information[ ]  CFIA Permit to Import or Transfer Approval Permit[ ]  Conditions of importation/transfer[ ]  when and where the infectious material was used[ ]  storage location[ ]  date of disposal / complete transfer / inactivation[ ]  other, specify: 1. Provide additional information for item(s) above which are deemed non-applicable:
2. Specify how long records are maintained:
 |
| 89 | All spills, accidents and overt or potential exposures to infectious materials, as well as containment failures, are to be reported immediately. Specify who reporting is made to:  |
| [ ]  laboratory supervisor and/or director  | [ ]  BSO | [ ]  CFIA | [ ]  other regulatory authorities, as appropriate |
| [ ]  other, specify:  |   |

***DECLARATION***

[ ]  I hereby declare that the information provided is complete, true and accurate to the best of my knowledge and belief.

[ ]  I agree to abide by the requirements outlined in the *Canadian Biosafety Standards,* 2nd Edition (2015)as well as any additional guidelines or conditions provided to me by the Office of Biohazard Containment and Safety (OBCS), CFIA.

[ ]  I agree to abide by the requirements outlined in the *Containment Standards for Facilities Handling Aquatic Animal Pathogens,* 1st Edition (2010) as well as any additional guidelines or conditions provided to me by the Office of Biohazard Containment and Safety (OBCS), CFIA.

[ ]  I will comply with all conditions specified on CFIA Importation Permit issued to our facility and to the conditions of use and limitations provided to me by Canadian Distributors of material regulated by OBCS, CFIA.

|  |  |  |
| --- | --- | --- |
| **Applicant**. |  |  |
| Name (Please print)  | Signature | Inspection Date  |
| **Biological Safety Officer** |  |  |
| Name (Please print)  | Signature | Inspection Date  |

**ONCE COMPLETED, PLEASE FORWARD (EMAIL, FAX OR MAIL) TO:**

**Animal Pathogen Importation Program**

**Office of Biohazard Containment & Safety**

Canadian Food Inspection Agency

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