

# Certification of Containment Facilities

PUBLIC HEALTH AGENCY of CANADA  
AGENCE DE SANTÉ PUBLIQUE du CANADA

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## Containment Level 2

- How are CL2 facilities Assessed?
  - Self-assessed against LBG requirements
    - CL2 checklist
    - [http://www.phac-aspc.gc.ca/ols-bsl/containment/pdf/cl2-checklist\\_e.doc](http://www.phac-aspc.gc.ca/ols-bsl/containment/pdf/cl2-checklist_e.doc)
  - There are recommended and mandatory requirements.
    - » All mandatory requirements must be met, cannot have a N/A.

## Let's go through the checklist...

- Health and Medical surveillance program:
  - Facility wide SOP indicating that risk assessments must be performed by a multidisciplinary group to assess the needs of the program
  - Program may include: medical examination, immunizations
  - Program should indicate any special precautions to be taken for pregnant or immuno-compromised individuals.

- Biosecurity Plan:
  - is a plan that aims to prevent the deliberate theft or diversion of high-risk biological agents for malicious use (bioterrorism, bio-weapons)
- The plan should include:
  - Facility/lab mission and statement
  - Risk definitions
    - Essential to develop threat potential vs consequences chart
  - Risk assessment (define threats, vulnerabilities, countermeasures)
  - Physical security measures
  - Personnel management
  - Material control and accountability
  - Material transfer/transport security
  - Information security
  - Incident response plans and reporting

- SOP Manual:
  - This is a manual that details biosafety practices, not the research that is occurring.
  - For example in a CL2 research lab:
    - How to work safely in a BSC
    - How to properly decontaminate contaminated equipment
    - Emergency procedures for spill clean-up, BSC failure, fire etc...
    - Basic practices such as: hand-washing, no eating, drinking etc...
    - What to do if exposure occurs.
    - How to fill an autoclave bag
  - **Q.9-Q.30 are basic practices questions.**

- Physical requirements:
  - Is the lab:
    - Separated from public areas by a door?
    - Access limited?
    - **Door kept closed at all times?**
    - bench non-absorptive
  - Are street clothes and lab coats physically separated?
  - Is a BSC available in the lab?

- Are BSCs used for procedures that involve high concentrations, large volumes or that may produce aerosols?

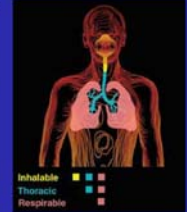


## What are aerosols?

- Particles less than 5  $\mu\text{m}$  diameter and small droplets 5-100  $\mu\text{m}$
- Not visible to the naked eye

### Particle in the air is:

- Inhalable  $\leq 10 \mu\text{m}$
- Thoracic  $\leq 5 \mu\text{m}$
- Respirable  $\leq 3 \mu\text{m}$



## How are aerosols created?

•Aerosol particles are created by any activity that imparts energy into a liquid or semiliquid material:

- Shaking, pouring, string, dropping
- Streaking agar plates, inoculation cell culture flasks with pipette
- Multichannel pipetting
- Homogenizing, Vortexing, centrifugation
- Working with animals



- Biological Safety Cabinets:

- Are you annually certifying your BSCs? (NSF49 standard)
- Are BSCs kept away from areas that may interrupt airflow patterns?
- Are you following the LBGs regarding safe working in a BSC?



- Are BSCs kept away from areas that may interrupt airflow patterns?



- Decontamination and Disposal of Waste:

- Are all contaminated materials decontaminated before disposal, reuse or removal?
- Are contaminated materials contained to prevent release if removed from the lab?
- Are products effective against the pathogen used for decontamination?
- Are all bench tops decontaminated at the end of the day?
- Are biological indicators used to verify load decontamination?

## Loading an autoclave

- Fill bags only to 2/3
- Do not overload autoclave
- Do not compact autoclave bag
- Leave bags open in autoclave
- Verify steam penetration regularly using **Biological Indicators** or in each load if standard loads do not exist.



## •Spills, Incidents and Emergencies:

- Are procedures written and accessible and FOLLOWED?
- Is a record made of first responders entering the facility during emergency?
- Are spills reported immediately to supervisor?



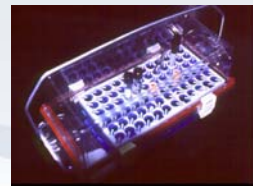
## • Training:

- On hazards and precautions
- Have all people working in the CL been trained in and follow the protocols for the project in process?
- Are records of training kept?
- Training on BSC use?

What about supervisory period or dry-runs?

## •Regulatory Aspects for Handling Infectious Substances:

- Import permits?
- Transportation of Dangerous Goods
- Are leak-proof containers used for the transport of materials within facilities?



## •Recombinants and Genetic Manipulations:

- Has a risk assessment been performed?
  - Does the new organism have higher risk than the parent?
  - CL of recipient, CL of donor, replication competency, properties of the donor protein
- Are recombinants handled at the required CL determined in RA?



*Variola major*

## •Cell Culture:

- Was a detailed RA performed?
- Are cell lines handled at the CL determined in RA?
- Cell lines containing known/potential viral contaminants handled at CL of higher risk contaminant?
- Special considerations for macaca and bovine cell culture.
  - Cynomologous
- Are self-self experiments prohibited?



## Containment Level 3

- How are CL3 facilities certified?
  - Starts with commissioning
    - PHAC or CFIA receives:
      - A full set of drawings and specifications
      - Performance and Verification Testing
        - » Critical containment components
      - Standard Operating Procedures
      - Facility Inspection
        - » Inward directional airflow
        - » Finishes
        - » Penetrations
        - » Failure testing

## What is required for CL3 operational?

- CL2 physical with CL3 operational:
  - Sometimes a requirement of importation permit
- In your CL2 facility, you use CL3 operational practices (see p. 23-26 LBG)
- Examples of organisms requiring this:
  - HIV diagnostic
  - Adenovirus vector containing oncogene
  - Avian Flu diagnostics
  - E.coli O157:H7 work

- Before entering the CL2 / CL3 operational facility, personnel must remove street clothing and shoes and don dedicated laboratory clothing. Use of full coverage protective clothing over street clothing is acceptable.



- Centrifugation of infectious material must be carried out in sealed safety cups or rotors and are loaded and unloaded in a BSC.



- All activities with infectious material are conducted in a BSC.
- All materials are decontaminated prior to exit from lab.
- Emergency protocols are written and accessible.



- Infectious agents should be access controlled to only those trained to handle them.
- Stored locked in leakproof containers



## To contact us...

- <http://www.phac-aspc.gc.ca/ols-bsl/index.html>
  - Laboratory Biosafety Guidelines
- email: [biosafety\\_biosecurité@phac-aspc.gc.ca](mailto:biosafety_biosecurité@phac-aspc.gc.ca)
- My email: [lise\\_murphy@phac-aspc.gc.ca](mailto:lise_murphy@phac-aspc.gc.ca)
- Telephone: 613-957-1779