Building for the Future

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PROTECTING CANADIANS FROM ILLNESS

Public Health Agency of Canada | Agence de la santé publique du Canada

Canada

Presentation outline

- PHAC Regulatory authorities
- *Canadian Biosafety Standards and Guidelines*
- Costs and facility design considerations
- Process for certification and compliance verification
- PHAC International work
- HPTA Process Moving Forward

Public Health Agency of Canada's Centre for Biosecurity

- Formerly the Pathogen Regulation Directorate
- National authority on biosafety and biosecurity for human pathogens and toxins
- Strives to protect the health and safety of the public by promoting a minimum standard of practice for all persons conducting activities with human pathogens and toxins, as well as cultures of terrestrial animal pathogens in Canada

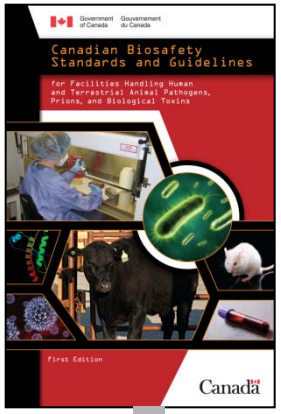
PHAC Regulatory Roles

- *Human Pathogen Importation Regulations, 1994,* and the *Human Pathogens and Toxins Act, 2009*
  - » give the Public Health Agency of Canada (PHAC) the authority to govern activities with **human** pathogens and toxins.
- *Health of Animals Act, 1990, & Regulations*
  - » give the Canadian Food Inspection Agency (CFIA) the authority to govern the importation of **animal** pathogens into Canada.
- As of April 1, 2013 the Agencies consolidated the importation processes and laboratory compliance monitoring and certification for human and terrestrial animal pathogens.
- The *Canadian Biosafety Standards and Guidelines* is the tool for assessing compliance

Canadian Biosafety Standards and Guidelines (CBSG) Concept

- ***Joint project between the PHAC and the CFIA***
  - » began in June 2010.
- ***Harmonized Initiative*** to combine 3 existing biosafety documents
  - » Standards and guidelines for human and terrestrial animal pathogens and toxins (including prions).
- ***Clear update*** with a ***NEW*** approach:
  - » a more risk-, performance-, and evidence-based lens.

Structure of the CBSG



Part I: The Standards

Sets out the requirements

Transition Index

Explains requirements in Part I and provides examples of how to achieve and link to relevant sections of Part II

Part II: The Guidelines

Guidance on how to achieve compliance with requirements in Part I

Biocontainment Engineering Science Working Group (BESWG)

- Established to:
  - identify, challenge, and re-define requirements based on outdated biocontainment engineering principles
  - redefine requirements to increase biocontainment safety, properly manage risk, maximize energy conservation, and bring forward modern engineering technologies;
- Engaged participation: members are from PHAC, CFIA, PHAC-NML, and Industry (canadian and international);
- BESWG challenged many requirements during the development of the CBSG 1st Edition;
- BESWG is still active and continues to provide feedback in the development of future editions of the CBSG.

Biocontainment Engineering Science Working Group

- Working group assembled to discuss and develop methods to investigate and/or test various biocontainment engineering issues and knowledge gaps within the biocontainment industry in order to validate compliance requirements or establish new ones;

- The working group will also link to the IFBA Biocontainment working group and the *Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities* (DRM 2012).

Benefits to Regulated Parties

- Nationally streamline biosafety requirements and practices;
- Single reference document for facilities handling animal **and** human pathogens;
- Ease burden for regulatory compliance; and,
- Continued collaboration between PHAC and CFIA to harmonize regulatory processes.

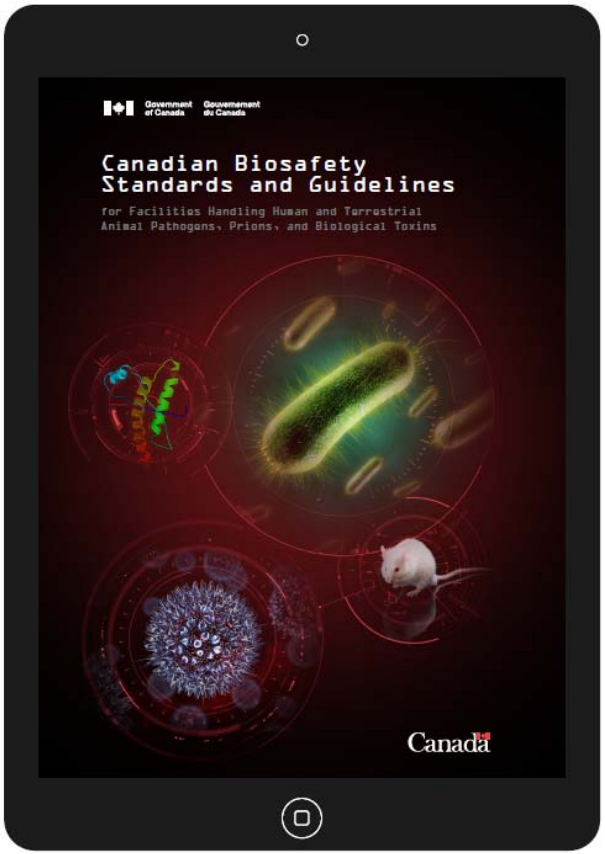
Final CBSG Overview

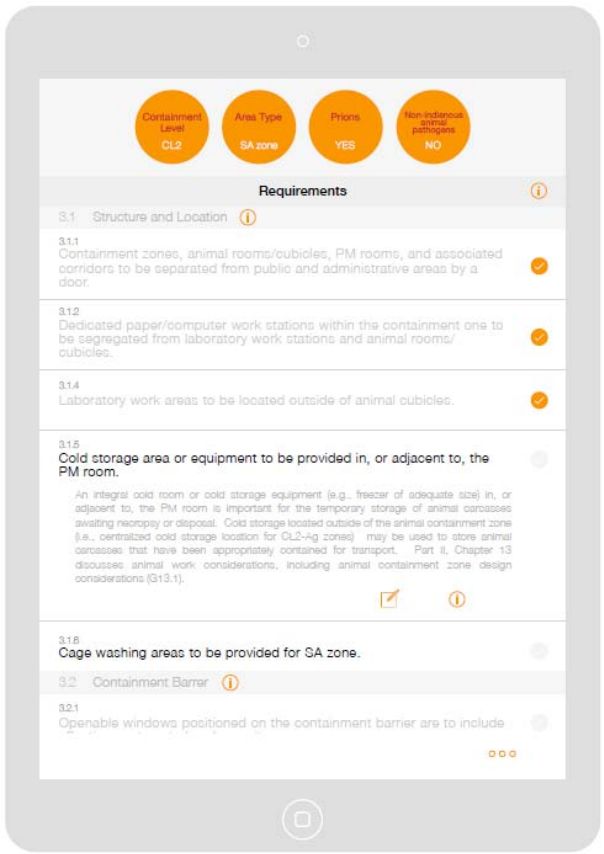
- The number of requirements did not increase and are not significantly different from the previous standards and guideline—performance- and risk-based wording changes;
- There were some ‘new’ requirements added that were based on input throughout development; also some are ‘new’ to certain work areas due to harmonization;
- Some requirements were removed or have become less stringent due to the risk-and evidence-based approach that was used during development.

Future Editions

- The 2nd Edition being developed and scheduled for release in February 2015
  - » will correspond to the full implementation of the *Human Pathogens and Toxins Act* (HPTA);
- 2nd Edition will be split into 2 volumes:
  - » *Canadian Biosafety Standards* (CBS) – an update of Part I of the CBSG;
  - » *Canadian Biosafety Handbook* (CBH) – an update of Part II of the CBSG;
- 2nd Edition incorporating information from the HPTA consultations and changes as a result of completed BESWG reviews;
- New series of additional guidelines documents are being developed to further complement the CBS, CBH, and to further support the HPTA;
- Comments, clarifications, and suggestions for the 2nd Edition are welcomed
  - » comment period on draft to begin soon through the CBSG website.

CBSG App – In Development



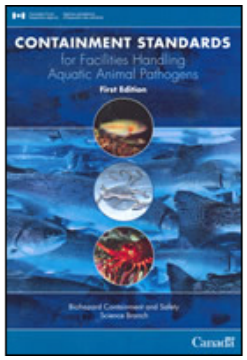


- Sorts requirements based on CL and work type;
- Creates checklists;
- Links requirements to Transition Index entries and related Guidelines;
- Animated diagrams.

Standards

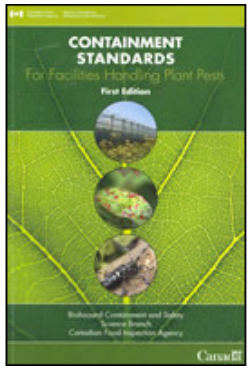
Terrestrial human/animal (Canadian Biosafety Standard and Guidelines)

- CL2 / CL2-Ag (including large scale and TSE facilities)
- CL3 / CL3-Ag (including large scale and TSE facilities)
- CL4



Containment Standards for Facilities Handling Aquatic Animal Pathogens

- AQC2 and AQC3 (in collaboration with CFIA)



Containment Standards for Facilities Handling Plant Pests

- PPC1, PPC2 and PPC3 (in collaboration with CFIA)

CBSG requirements for : Handwashing Sink

- R 3.6.4 Handwashing sinks to be provided and located as close as possible to the point(s) of exist of the containment zone, animal room/ cubicle and PM rooms (All areas)
- R 3.6.5 Handwahing sinks to be provided with hands-free capability (All areas except CL2 LWA)

Hands-free

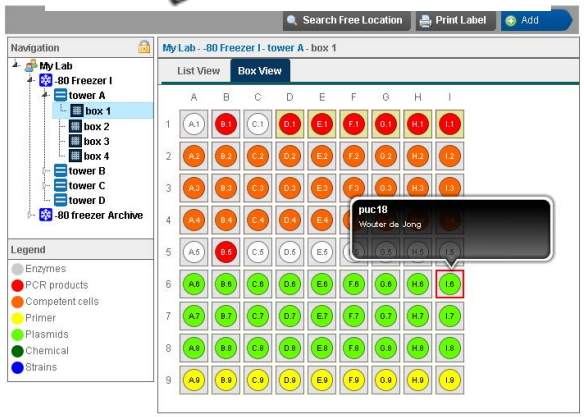
$1000
-1,500

CBSG requirement for : Inventory

- R 4.1.12 Inventory of infectious material and toxins handled or stored in the containment zone to be maintained, and kept up to date. Infectious material or toxins stored outside the CL2 and/or CL3 zones to be included in the inventory.

$150

$3,000 to $50,000



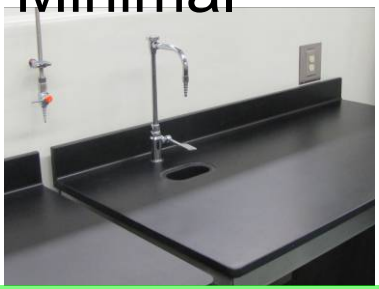
Minimal

Other Methods

CBSG requirement for : Surface Finishes

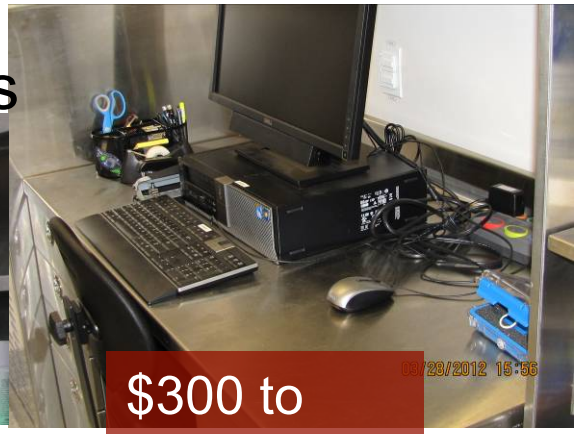
- R 3.4.1 Doors, frames, casework, bench-top and laboratory furniture(e.g., stools, chairs) to be constructed from non-absorbent materials. Wood surfaces are permitted in CL2 laboratory work areas if sealed to be non-absorbent.
- R 3.4.2 Surfaces and interior coatings to be cleanable and resistant to scratches, stains, moisture, chemicals, hear, impact , repeat decontamination, and high pressure washing, in accordance with function.
- R. 3.4.6 Floors to be slip-resistant in accordance with function.

Minimal



Sealant $5/m^2

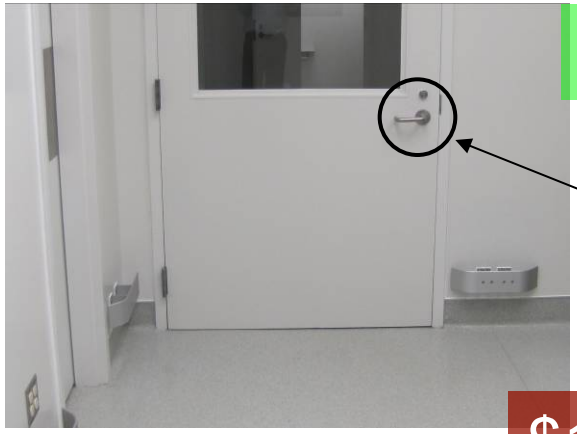
Other Methods



$300 to $1,000/m^2

CBSG requirement for : Access control

- R.3.3.1 Doors to the containment zone to be lockable.



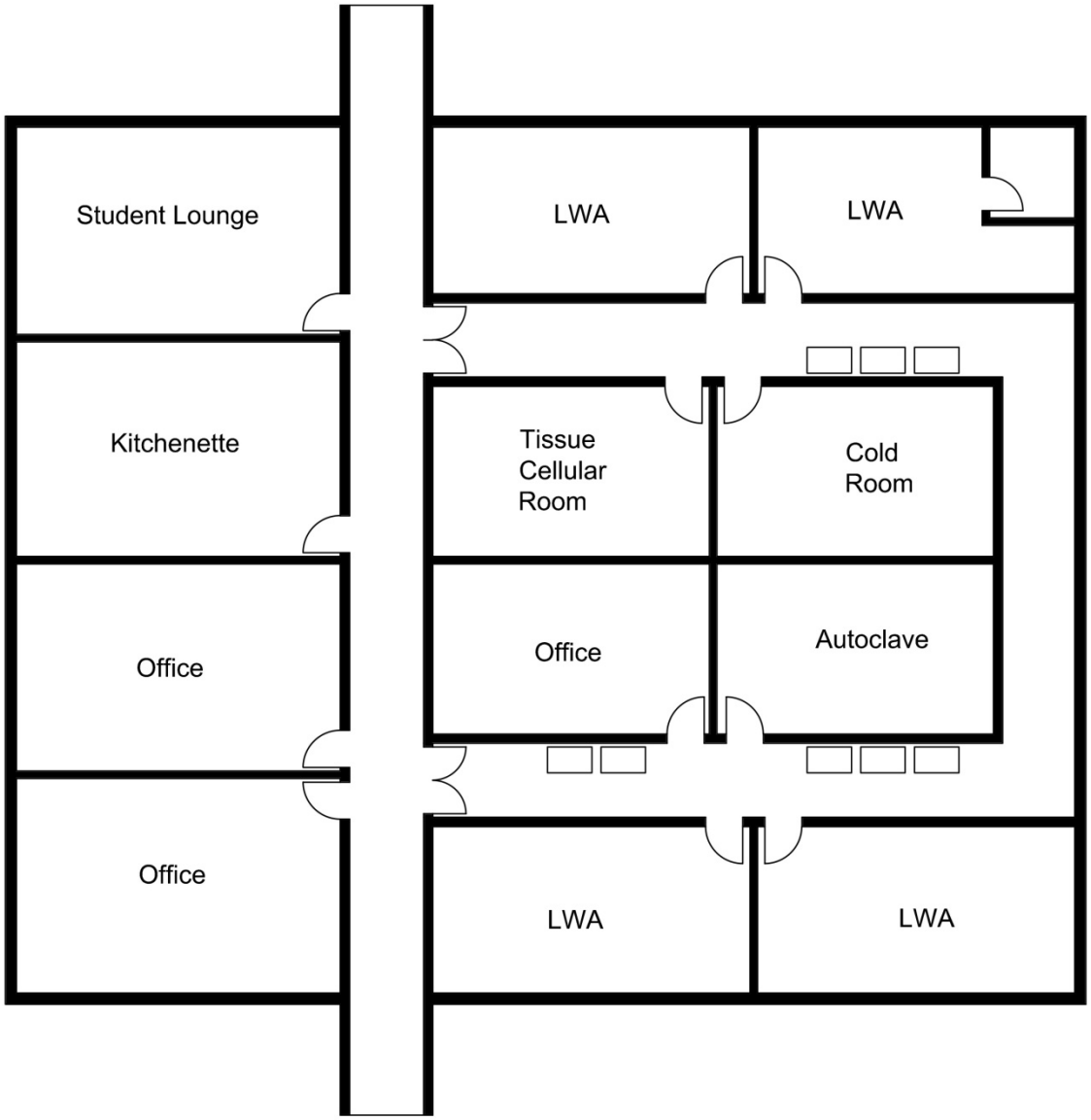
$100

Minimal

- Restricted access into the containment zone to be provided through a controlled access system (All areas except CL2 LWA).

$1,000 to $2,500

Other Methods



Containment Zone Definition

What are the options?

Containment Zone Option 1

Legend:

= Containment zone

= Administrative area

= Public area

= Access point

= Biohazard signage

= Freezer

Containment Zone Option 2

Legend:

= Containment zone

= Administrative area

= Public area

= Access point

= Biohazard signage

= Freezer

CBSG requirement for : Interlocking doors

- Anteroom(s) to be provided with mechanically or electronically interlocked doors (equipped with manual overrides for emergency exist), or visual/ audible alarms, or other acceptable means to ensure that no critical combination of doors can be opened simultaneously (CL2Ag, CL3).

$50

Visual

$1,000 to $1,500

Electronic

Minimal

Other Methods

CBSG requirement for : Monitoring

- R 3.7.19 Observation windows and/or video equipment to be installed in a manner that allows activities to be visually monitored from outside the containment barrier (CL4 only).

$1,000

Minimal

$15,000

Other Methods

CBSG requirements: Air Changes Per Hour (AC/hr)

- R. 3.5.1 HVAC system to provide sufficient air changes per hour (AC/hr) under normal operation to maintain airflow, bases on facility function.

- Frequently Asked Questions
  - » How many AC/hr do I need for my lab ?

    ACH is based on facility function and typically determined by the facilities management.
  - » Where can I find information about AC/hr ?

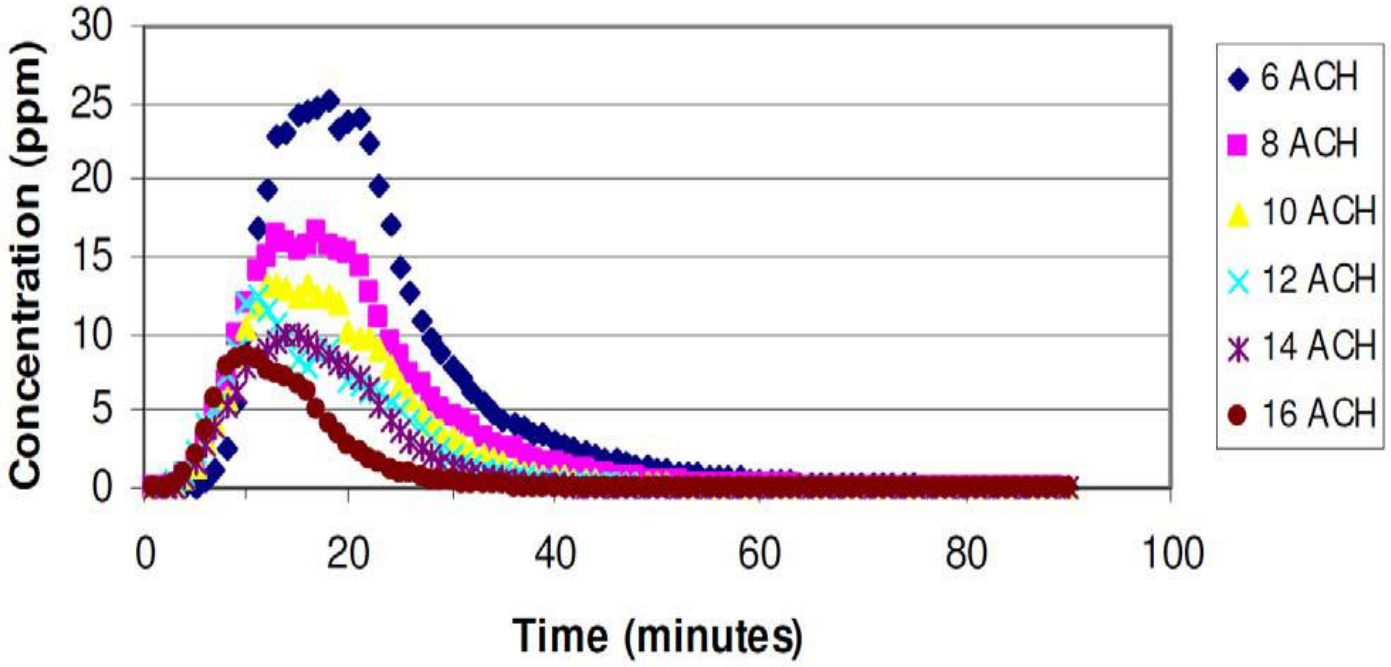
    There are a couple of good sources to reference; ASHRAE 62.1, Canadian Council on Animal Care.
  - » What contributes to determining AC/hr ?

    Occupancy, heat load (equipment, lighting, etc.), work activities (e.g. working with chemicals).

CBSG requirements: Air Changes Per Hour (AC/hr)

- How does ACH contribute to biosafety and biocontainment ?

  The following table can provide a theoretical understanding of how AC/hr can contribute to good biosafety and biocontainment practices.



CBSG requirement: Containment barrier integrity

- R. 4.10.4 Integrity of containment barrier to be tested by pressure decay testing by pressure decay testing. Acceptance criteria include two consecutive tests with a maximum of 250 Pa loss of pressure from an initial 500 PA over a 20 minutes period (CL3-Ag non indigenous and CL4 areas).
  - » Consider design to accommodate pressure decay testing if required;
  - » Consider structural design of containment barrier based on maximum operating pressure.

Items Investigated by the Biocontainment Engineering Science Working Group

- 100% Outside Supplied Air;
- 10 Air Changes Per Hour;
- Structural stability to withstand 1.25 times maximum design pressure
- inward directional airflow necessary;
- “airtight”/”sealed”/”sealable” labs;
- Prevention of positive pressurization: Acceptable mechanisms ?

Previous requirement on Air Changes per Hour

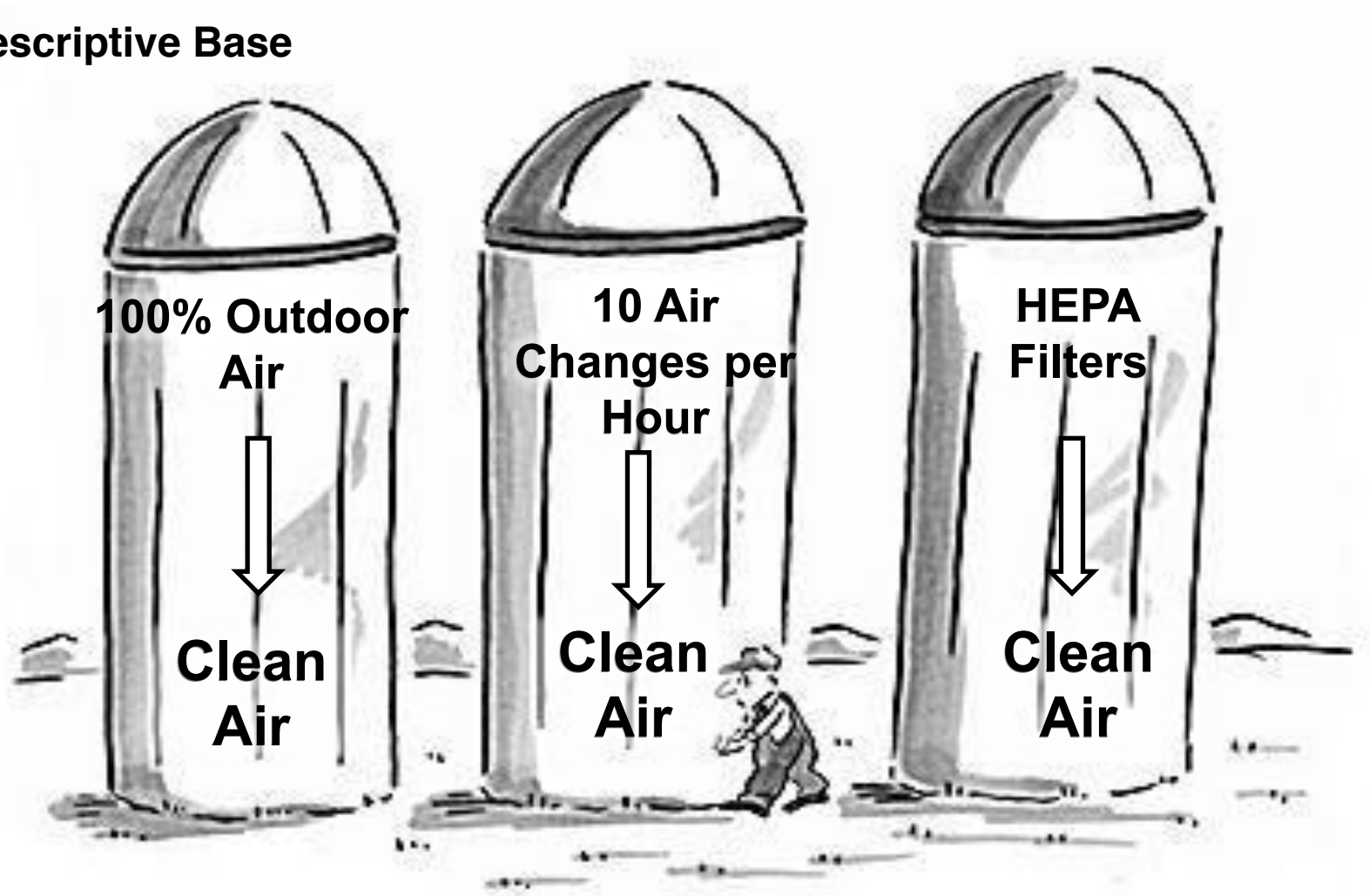
- **<u>Air systems are required to provide a minimum of 10 airchanges per hour under normal operations</u>**

Item #	Matrix 3.5: Heating, Ventilation, and Air Conditioning (HVAC)	CL1	CL2	ACL2	CL3	ACL3	CL4
3.5.1	Exhaust air system to provide a minimum of 10 air changes per hour under normal operations.	❍	●	●	●	●	●
3.5.2	Exhaust air system from animal rooms/cubicles to provide 15-20 air changes per hour as per the Canadian Council on Animal Care (CCAC) *guidelines on: laboratory animal facilities*.	❍	●	●	●	●	●

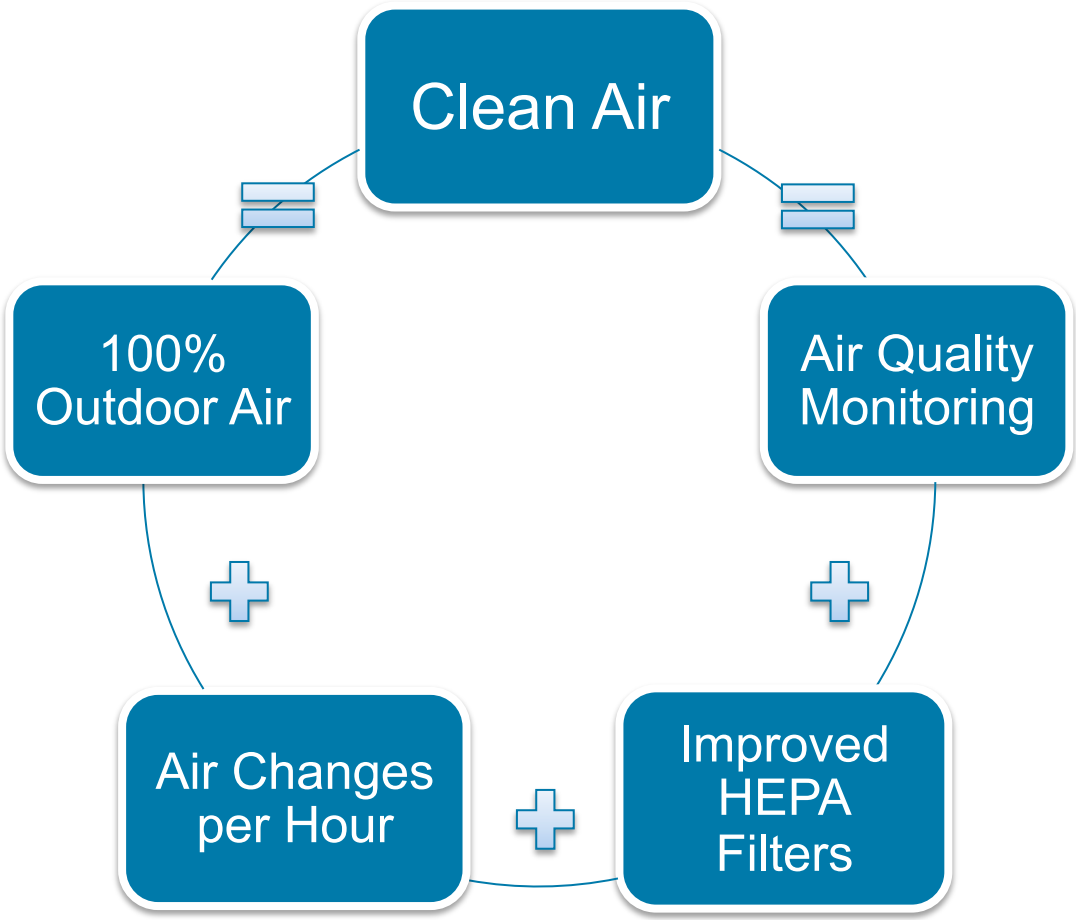
Q1: Under what conditions would it be necessary to have a minimum number of air changes per hour for biocontainment laboratories ?
Q2: How should this be established ?

Biocontainment Engineering Science Working Group (BESWG)

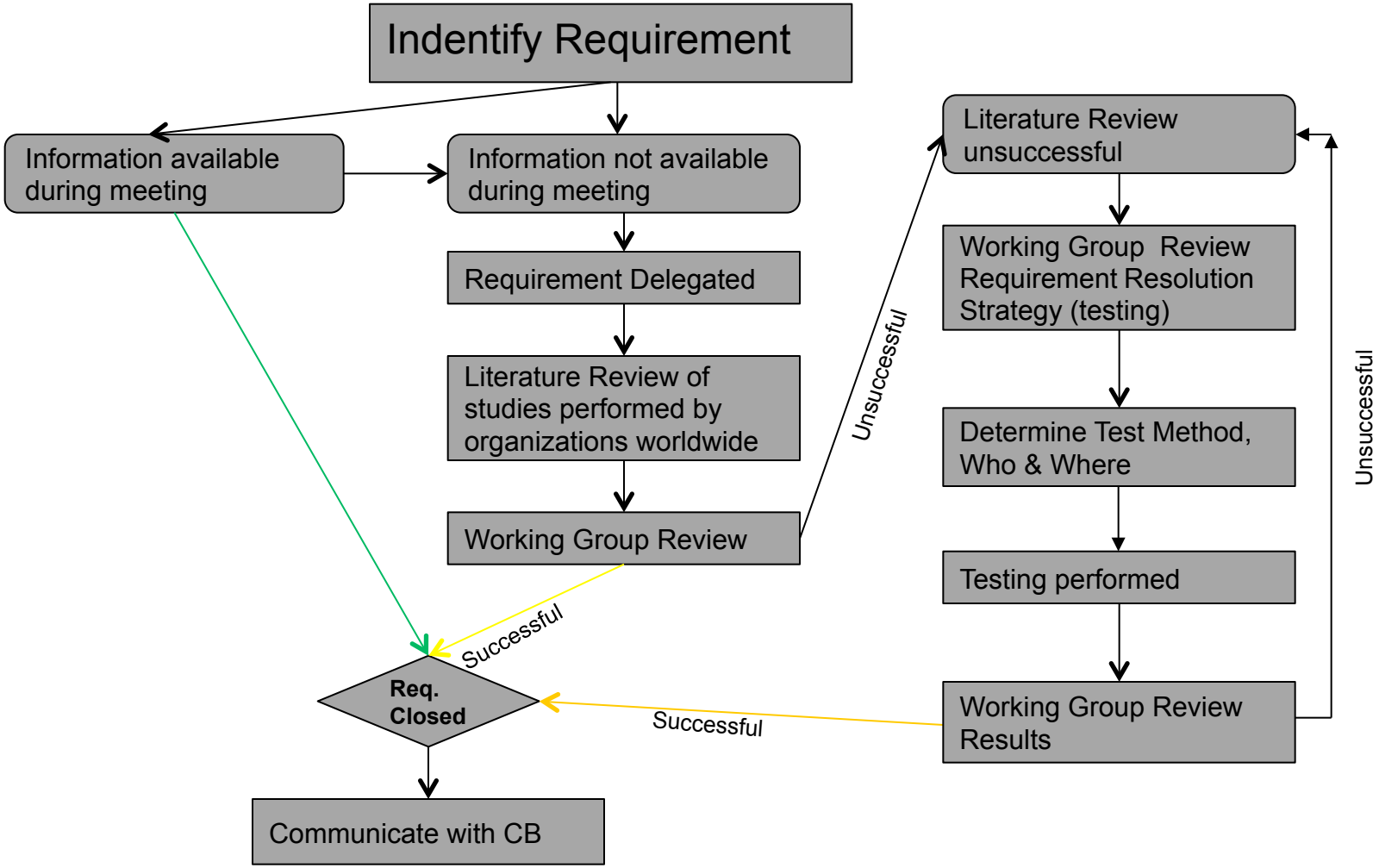
Prescriptive Base



Performance Based



Working Group Requirement Solution Approach



Resolved Item

- Method to determine an acceptable quantifiable airflow reversal;
- Removal of In-Line HEPA filters as a requirement for CL3 if air tightness of pressure differential devices can be proven;
- Slip Resistant for Floors performance based requirement;
- Ventilation System Interlocks defined for performance based;
- 100% Outdoor Supply Air, no longer required;
- Air changes per hour to be performance based for;
- Inward Directional airflow requirements for CL2 and CL3 reviewed & defined;
- Guidelines to be provided on how laboratories are to treat fire suppression water in the vent of a release.

Unresolved Item

- In what instances can the air in a Plumbing Vent Line be contaminated and how would it impact any other part of the building ?
- For what reason does the supply air to a CL4 need to be HEPA filtered ?
- Provide design and operational issues that can occur with the removal of the "100% fresh outside air" requirement?
- Provide guidance to the relationship between CSA and local plumbing code requirements for backflow preventers;
- In what instances would Autoclave condensate be considered contaminated ?
- In what instances would Autoclave exhaust air be considered contaminated ?

Over Engineering

- **Benefits**
  - Increases perceived quality;
  - Promotes development of emerging technology;
  - Can produce a safer work environment through redundancies;
  - Reduced reliance on operational practices.

- **Drawbacks**
  - **Very Costly;**
  - Higher risk for complications;
  - Numerous procedures, SOP Required;
  - Precedent;
  - Often difficult and costly to maintain and test.

Approach to Compliance

- Key compliance and enforcement activities for the Agency include:
  - » Compliance promotion (e.g., education, tools and dialogue);
  - » Compliance monitoring (e.g., inspections, audits);
  - » Enforcement (orders, investigation or prosecution, if warranted).

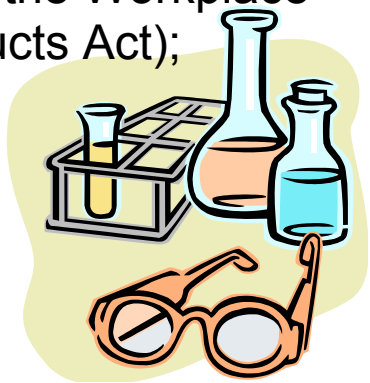
- The Agency has traditionally focussed on compliance promotion.
  - » Evidence demonstrates that compliance is higher for regulated parties who understand why it is important to comply and how to comply.

Pathogen Safety Data Sheets (PSDSs)

- Technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting;

- Produced by the PHAC as educational and informational resources for laboratory personnel working with these infectious substances;

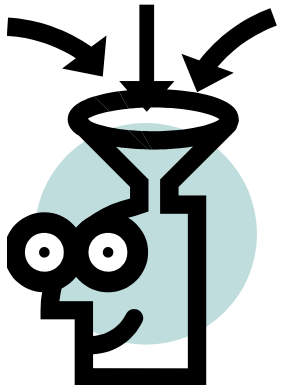
- Can be adapted to meet legal obligations to produce or provide a safety data sheet for infectious substances (i.e., as obligation under the Workplace Hazardous Materials Information System or Hazardous Products Act);



PHAC e-Learning Portal

- Several online biosafety courses and videos are offered for free

- New online courses coming soon:
  - Toxins
  - Working with Small Animals in Containment
  - Working with Large Animals in Containment
  - Dual Use
  - And More!



Compliance Promotion

- In preparation for the implementation of the *Human Pathogens and Toxins Regulations* (HPTR) at the end of 2015, the PHAC has a proactive approach to help regulated parties achieve compliance through:
  - » Education
    - Assisting regulated parties in understanding their obligations;
  - » Information sharing and dialogue
    - Providing guidance, advice, training, and support.

Compliance Monitoring & Verification

- Ensuring that regulated activities are carried out in accordance with the provisions of the HPTR
  - Reviewing Applications received for the issuance of Containment Level 2 Compliance Letters or CL3 re-certification;
  - Performing audits;
  - Evaluation of biosafety programs.

- Validation that regulated activities are carried out in accordance with the provisions of the relevant Acts and regulations
  - Conducting on-site inspections;
  - Verifying shipping and customs declarations.

Compliance Promotion - Containment Level 3 Certification

- Verify that applicants meet the applicable requirements under CBSG, 1st Edition
  - » SOP reviews, drawing reviews, performance verification test report reviews;
  - » Facility inspections.
- Compliance may be verified at a later time by the PHAC or the CFIA.
- Will support an application to import human and animal pathogens and toxins.

➢ PHAC reviews most CL3 certifications

- » PHAC verifies compliance for: human and terrestrial animal pathogen labs;
- » CFIA verifies compliance for: FADs and emerging animal pathogen labs.

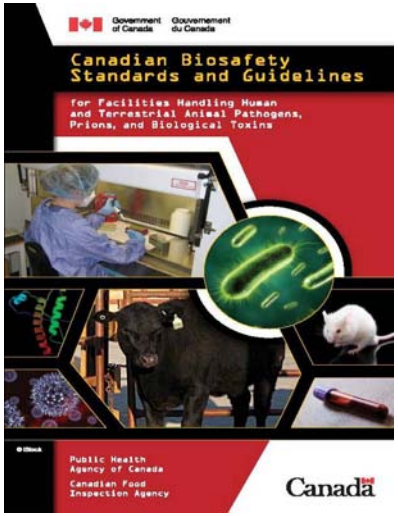
ESS Involvement

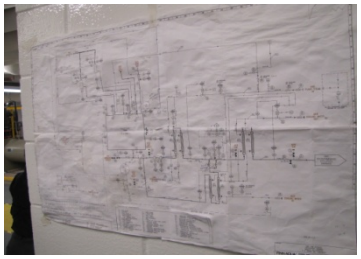
Drawing / Specification Review

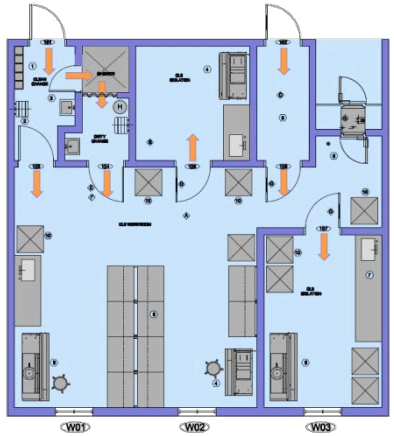
- Understanding overall system and layout
- Compliance verification

Technical Guidance

- General inquiries
- Performance and verification testing







ESS Inspections

Pre-inspection / Site Visit

- Opportunity for discussion with regulated party

On-Site Inspection

- Certification
- Follow-up

Recertification Inspection

- Aligned with licencing every 3 years (proposed)

Frequent issues for CL3 facilities

- Incomplete commissioning
- Mechanical failure
- Equipment issues
- Equipment knowledge
- Equipment issues

A) Incomplete Commissioning

Building Commissioning vs. Lab Certification

- Two different activities;
- Ensure both activities are covered in contract documents.

Building Commissioning Issues

- Ductwork layout (no unknown cross-connections);
- Piping layout (no unknown cross-connections);
- Correct positioning of dampers.

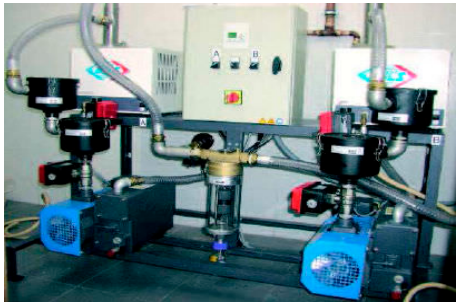
Lab Certification Issues

- Understanding CBSG testing requirements (Chapter 4).

B) Equipment Knowledge

Effluent Decontamination System

- Is it required for your lab ?
- Understanding all functions and intent.



Microbiological Vacuum System

- Portable vs. Permanent;
- Understanding intent of system.

Municipal / Provincial Requirements for use

- System selection should consider municipal and provincial requirements (ie. temperature and pH levels).

C) Mechanical Failure

<u>Supply and Exhaust Fan System</u>

- Loose or broken fan belt;
- Motor failure;
- Fan key break.

<u>Considerations</u>

- Preventative maintenance program;
- Replacement parts in stock;
- Impact on operational modes;
- Fan redundancy.

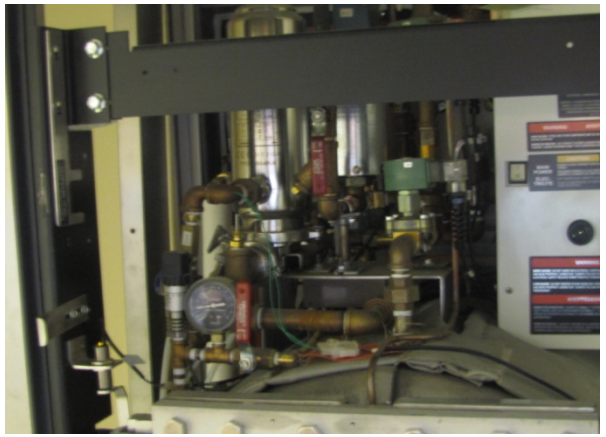
D) Equipment Issues

Autoclave Air Filters

- High probability of clogging;
- Replacement not tracked on all autoclaves.

Considerations

- Consider tracking for next autoclave purchase;
- Incorporate into preventative maintenance;
- Verify replacement frequency with manufacturer.



D) Equipment Issues (cont'd)

Biological Safety Cabinets

- BSC selection;
- Class II/B2 BSC "puffback";
- Inflow issues combined with airtight spaces.

Considerations

- Understand differences for each BSC selection;
- "Puffback" or airflow reversal issues:
  a) Mechanical breaking mechanism;
  b) Adjust flow setpoints;
  c) Implement procedures;
  d) Perform biological work in a different cabinet;
- Modify control sequences serving airtight room to eliminate inflow issues.

Containment Level 2 Compliance Monitoring

- Compliance Letter
  - » Self-attestation from the applicant that the facility meets the applicable requirements under the CBSG, 1st Edition published in July 2013;
  - » Compliance may be verified at a later time by the PHAC or the CFIA;
  - » Will support an application to import human and animal pathogens and toxins;
  - » Will allow purchase of human and animal pathogens and toxins at Canadian distributor companies;
- PHAC reviews all CL2 compliance letter applications. Compliance letter application to the CFIA is no longer needed.

Inspection of CL2 Facilities

- Selection of sites
  - » Inherent risk
    - Nature of work
      - – Diagnostic; *in vitro*; *in vivo*; storage; large scale production
    - Complexity of the work
  - » Compliance history (e.g., previous inspections, import issues)
  - » Current issues arising
  - » Request for assistance
  - » Random selection of facilities that do not meet above criteria

For announced inspections, selected sites will be contacted at least 10 days before the on-site visit

Enforcement

- The correction of non-conformities can often be achieved through the development of appropriate corrective measures.

- Further enforcement actions may be used when:
  - The cooperative approach does not lead to compliance;
  - The regulated party is incapable of correcting the non-compliance.

- In some cases, enforcement actions may be the appropriate initial tool to correct or prevent non-compliance.

Beyond our Borders

- Canada is involved in international collaborative groups and initiatives both as part of ensuring we share and benefit from global best practices and as a result of formal obligations and a common goal of prohibiting the proliferation and development of biological weapons.

- CB also provides expertise to other countries to help build expertise in biosafety, biosecurity and biocontainment.

HPTA Process Moving Forward

- Pre-publication of proposed regulations in Canada Gazette, *Part I* for public comment ;
- Web-based consultations on draft regulations;
- CBS 2nd Edition open for public comments;
- Parliament's review of the regulations;
- Approved regulations published in Canada Gazette*, Part II*;
- CBSG 2nd Edition final;
- Up to December 2015 the Agency will work with stakeholders to support implementation.

December 2015

- Remaining sections of the HPTA to come into force, along with regulations.

Information and Engagement

- New monthly newsletter distributed via e-blast (Are you in our database?)
  - Key program updates;
  - Quick hits;
  - Stay connected – share your stories;
  - Suggestions/comments.

- Revamped website
  - User friendly;
  - Timely/updated content;
  - www.publichealth.gc.ca/pathogens.

- Advisory Committee-HPT Call for membership – June 30th deadline.

- Information sessions concurrent with Canada Gazette. I

- Exposure reporting tool: touch-base.

Contact Information

- CBSG
  - » http://www.publichealth.gc.ca/pathogens
  - » standards.normes@phac-aspc.gc.ca
- E-Learning portal
  - » www.publichealth.gc.ca/training
- PSDS
  - » http://www.phac-aspc.gc.ca/lab-bio/res/psds-ftss/index-eng.php
- BESWG
  - » Joe Tanelli joe.tanelli@phac-aspc.gc.ca
- Compliance letters (CL2)
  - » biosafety_biosecurite@phac-aspc.gc.ca
- Certification (CL3)
  - » biocon@phac-aspc.gc.ca
- HPTA consultation/Newsletter
  - » HPTA.LAPHT.consultations@phac-aspc.gc.ca