# Canadian Biosafety Standards and Guidelines Implementation Guide

The CBSG was released on June 20th 2013 and will replace the existing standards and guidelines on July 5th 2013.

## Background on the *Canadian Biosafety Standards and Guidelines* (CBSG)

The Public Health Agency of Canada (PHAC) and the Canadian Food Inspection Agency (CFIA) developed the *Canadian Biosafety Standards and Guidelines* (CBSG) pertaining to human and terrestrial animal pathogens, toxins and prions. These Standards and Guidelines combine and update the following documents:

- *Laboratory Biosafety Guidelines 3rd Edition*, 2004 (PHAC)
- *Containment Standards for Veterinary Facilities 1st Edition*, 1996 (CFIA)
- *Containment Standards for Laboratories, Animal Facilities and Post Mortem Rooms Handling Prion Disease Agents,* 2005 (CFIA)

An Expert Working Group (EWG) was established to provide technical input into the development of the CBSG. The EWG included 21 members with expertise in the field of biosafety or biocontainment, representing a wide range of sectors (i.e. industry, academia, and public health) and various levels of government.

The handling or storing of infectious material or toxins necessitates an awareness and application of biosafety and biosecurity practices among laboratory personnel and those who work with pathogens, toxins, or infected animals in containment zones. The release of human and animal pathogens and toxins from laboratories or other containment zones may pose a risk to public health, animal health, or both. Personnel can reduce the risks associated with infectious material or toxins through the application of appropriate biosafety and biocontainment principles and practices.

The second edition of the CBSG is scheduled for release in December 2015, and will be coordinated with, and correspond to, the full implementation of the *Human Pathogens and Toxins Act* (HPTA). It will also incorporate new information in the field of biocontainment engineering.

The HPTA received Royal Assent on June 23, 2009. The purpose of the Act is to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins. The HPTA applies to persons conducting specified activities with human pathogens and toxins. "Person" includes a corporation, individual, organization, partnership or public body.

For further information on the HPTA, please visit: publichealth.gc.ca/pathogens

## Purpose, Audience and Objectives of the Implementation Guide

The purpose of this resource is to provide guidance on the implementation of the CBSG as a national harmonized standard for the handling and storing of human and terrestrial animal pathogens and toxins in Canada. The CBSG is intended to facilitate compliance with the regulatory framework by incorporating risk-based, evidence-based and where possible, performance-based biosafety and biosecurity requirements. The CBSG also streamlines the requirements for handling or storing human or terrestrial animal pathogens and toxins into a single national reference document.

This guide is for any person carrying on activities with human or terrestrial animal pathogens or toxins, including:

- importers of human and terrestrial animal pathogens, toxins, including prions;
- professional organizations;
- academia, researchers and workers in facilities possessing, handling, storing or using human and terrestrial animal pathogens, toxins and/or prions;
- industrial associations(e.g., pharmaceutical, cosmetic, food and other industries that use pathogens and toxins for quality control);
- public health institutions; and
- provincial and territorial governments, other federal departments/agencies

Users will be informed regarding the:

- importance of appropriate biosafety for the handling and storing of human and terrestrial animal pathogens and toxins;
- scope and components of the *Canadian Biosafety Standards and Guidelines*; and
- Agencies' approach to compliance and enforcement.

## Scope of the *Canadian Biosafety Standards and Guidelines* (CBSG)

In the context of the CBSG, biological material that contains human and/or animal pathogens is referred to as "infectious material" and the word "toxin" refers only to microbial toxins regulated by the PHAC. Part I (The Standards) of the CBSG applies specifically to facilities in Canada that are governed under the *Human Pathogens Importation Regulations*, the HPTA, and the *Health of Animals Act* or the *Health of Animals Regulations* (see the following section on Regulatory Authorities). This includes facilities with imported human or terrestrial animal pathogens or toxins, and facilities with imported animals, animal products, by-products, or other substances that may carry a pathogen or toxin or parts thereof. Under the HPTA, the CBSG also applies to facilities where domestically acquired human pathogens and toxins are handled or stored. Toxins governed by the PHAC are listed in Schedule 1 and Part 1 of Schedule 5 of the HPTA.

Animal pathogens referred to in the CBSG consist solely of pathogens that cause disease in terrestrial animals, including avian and amphibian animals, but exclude aquatic animals and invertebrates. Facilities where imported aquatic animal pathogens are handled or stored must comply with the CFIA's *Containment Standards for Facilities Handling Aquatic Animal Pathogens*, 1st edition, 2010. Facilities where both aquatic and terrestrial animal pathogens are handled or stored will be required to adhere to the aquatic standards as well as Part I of the CBSG.

For further details on the Scope, please refer to the CBSG Chapter 1(Section 1.1).

## Regulatory Authorities

Human pathogens and toxins are governed under the authority of the *Human Pathogens and Toxins Act* (HPTA), and under the *Human Pathogens Importation Regulations* (HPIR). Imported animal pathogens are regulated under the *Health of Animals Act* (HAA) and *Health of Animals Regulations* (HAR). The PHAC is responsible for issuing importation permits and certifications for facilities where human pathogens or toxins are handled or stored, in accordance with the HPIR and sections of the HPTA currently in force. As of April 1, 2013, PHAC is also responsible for issuing importation permits and certifications under the HAA and HAR for facilities importing or transferring terrestrial animal pathogens, with the exception of non-indigenous animal pathogens and pathogens causing emerging animal diseases.

For further details on Regulatory Authorities, please refer to the CBSG Chapter 1(Section 1.2).

## How to Use the *Canadian Biosafety Standards and Guidelines* (CBSG)

The CBSG is divided into two distinct parts: Part I (The Standards) and Part II (The Guidelines). These two parts are linked together by a Transition Index.

Part I (The Standards) provides the physical containment and operational practice requirements for facilities where infectious material or toxins are handled or stored. The requirements provided in Part I are risk-based and evidence-based, and, where possible, more performance-based than prescriptive. It is important to note that the overall number of requirements has not increased from the previous standards, and that some requirements have actually been removed or have become less stringent due to the risk-based approach that was used during development. In some cases, there is a higher or unique level of risk associated with handling certain pathogens or with certain types of work (e.g., large scale volumes of pure or concentrated cultures of pathogens, handling of non-indigenous animal pathogens, or work involving prions). Special considerations related to these cases are outlined in Part I. In general, the risk group (RG) and containment level (CL) bear the same number for a particular type of work with a pathogen; however, where they differ, the specific requirements are stipulated in the importation permit or specified by the PHAC and the CFIA.

The Transition Index, located between Parts I and II, provides additional information as to why a requirement exists in Part I, provides examples of how the requirement can be achieved, and indicates where to find further guidance on the subject in Part II. This index is organized in such a way that each requirement in the matrices in Part I, Chapters 3 and 4, has a corresponding entry in the Transition Index, following the same numbering convention. The Transition Index does not include additional requirements but rather provides information and recommendations only.

Part II (The Guidelines) provide information on how to achieve the biosafety requirements outlined in Part I. They are structured to systematically address the concepts required for the development of a comprehensive risk-based biosafety management program. Part II provides general guidance for containment zone personnel rather than specific guidance or SOPs for individual pathogens.

For further details on How to Use the CBSG can be found in the CBSG Chapter 2 and in the Quick User Guide.

## Implementation Tools

The following tools are available to support organizations in the implementation of the CBSG:

- *CBSG website*: Further background information, electronic copies of the CBSG in both official languages, FAQs as well as other resources including the CBSG Team contact information can be found on this site.

- *Quick User Guide:* This brochure provides a quick reference on how to interpret the CBSG (symbols, headers, etc.) and can be used as a training tool within organizations to facilitate understanding of and compliance with the CBSG.

- *Containment Level 2 Compliance Letter application forms*: These checklists are used by the Agencies' to verify compliance with the physical containment and operational practice requirements. Upon satisfactory review of this application a *Compliance Letter* is issued. Please see Compliance Verification section for further details.

- *Containment Level 3 (CL3) and Containment Level 4 (CL4) and Prions:* All certification letters issued prior to June 20, 2013 will continue to be valid as of July 5th, 2013. These include letters issued by the PHAC (for high containment facilities handling human and/or zoonotic pathogens) and by the CFIA (for high containment facilities handling indigenous terrestrial animal pathogens). Please see Compliance Verification Section for further details.

- *Comparison Documents*: These documents are available upon request and provide a side by side comparison of each requirement in the CBSG to the previous corresponding requirements in the LBGs, CSVF and Prion standard. They will help orientate and facilitate the understanding of the reasoning and origination of the requirements within the CBSG. It is important to note that the overall number of requirements has not increased from the previous standards, and that some requirements have actually been removed or have become less stringent due to the risk-based approach that was used during development.

- *Biosafety E-Learning and Training Resources Portal*: This free portal is a joint PHAC and CFIA initiative to provide an integrated approach to the online delivery of biosafety training and resources for Canadian stakeholders. The portal offers training and tools to promote the inclusion and practice of biosafety principles and practices amongst stakeholders and raise the level of awareness to promote compliance and reduce the level of non-compliance.

## Implementation Recommendation

Organizations are strongly encouraged to familiarize themselves with the structure and contents of the CBSG and determine an implementation path that is appropriate to their particular situation. It is also recommended that the organization's compliance expectations are communicated to all appropriate personnel.

## Compliance Verification

- **Containment Level 2 facilities:** As the requirements within the CBSG do not differ significantly from the previous standards and guideline, and for the purposes of administrative efficiency, as of July 5, 2013, all existing CL2 Compliance Letters (to the LBG) will remain valid until their original expiration date. The existing CL2 Compliance Letters will continue to be recognized (until their current expiry) to obtain a Permit to Import Human and/or Terrestrial Animal Pathogen(s) or to acquire pathogens from a Canadian distributor.

  Facilities importing human pathogens and toxins will be expected to comply with physical and operational requirements set out in the CBSG. It is important to also remember that certain sections of the HPTA came into effect in 2009, including section 6 (duty of care) which requires persons conducting any activity with human pathogens and toxins, including domestically acquired agents, to take all reasonable precautions to protect the health and safety of the public against the risks posed by that activity. Compliance with the CBSG will be a key consideration in determining whether a facility is fulfilling its obligations under section 6, since it is considered national best practice.

  Although the existing CL2 Compliance Letters will remain valid until their original expiry, we will promote and encourage early conversion to the CBSG CL2 Compliance Letter. *Containment Level 2 Compliance Letters* indicating compliance with the CBSG 1st edition can be acquired in one of the following two ways:

  - Submission of an *Application for Containment Level 2 Compliance Letter* (the resulting document will be valid for a period of 2 years). This application must be completed upon expiry of an existing Compliance Letter.

  - Submission of a *Supplemental Application for a Containment Level 2 Compliance Letter* (the resulting document will be valid for a period of 2 years). This application can be completed only prior to the expiry of an existing Compliance letter.

    ***Note:*** Information on these processes and links to the both applications will be available on our website after June 20, 2013.

- *Containment Level 3 (CL3) and Containment Level 4 (CL4) and Prions*: All certification letters issued prior to June 20, 2013 will continue to be valid as of July 5th, 2013. These include letters issued by the PHAC (for high containment facilities handling human and/or zoonotic pathogens) and by the CFIA (for high containment facilities handling indigenous terrestrial animal pathogens).

    - As of June 20, 2013, facility certification letters indicating compliance of CL3, CL4, or Prion facilities with the CBSG 1st edition can be acquired by the Agency upon submission, review, and approval of documents in support of Certification or Recertification as described in Chapter 4.10 of the CBSG 1st edition.

    - The Agencies ask that CL3, CL4, or Prion facilities that are unable to meet the physical and/or operation requirements as listed in the CBSG 1st. edition to please contact the High Biocontainment Inspection (HBI) division so that HBI may provide guidance in an effort to assist the facility in achieving compliance with the CBSG 1st edition.

      *Note:* A template to facilitate the submission of documents in support of the Certification or Recertification of CL3, CL4, or Prion facilities in compliance with the CBSG 1st edition is currently in development and will be made available by the Centre for Biosecurity upon completion. A guidance document to assist regulated parties with this process is also under development.

## Approach to Compliance and Enforcement

Key activities of the compliance and enforcement approach include working with regulated parties to promote, monitor and verify compliance with CBSG requirements, and responding to situations of non-compliance in an appropriate fashion. Other activities include the development of resources and tools to promote and facilitate compliance, information sharing and informed decision-making.

The Agencies actively implement a risk-based approach to compliance and enforcement interventions. Interventions are managed primarily through compliance promotion activities with the support of compliance monitoring activities and incremental enforcement actions.

Actions taken are proportionate to the seriousness of the incident, and appropriate to the situation. The degree of intervention takes into consideration various factors, including the:

- level of risk or potential risk;
- degree of potential harm caused by the infraction;
- compliance history of the regulated party;
- whether the regulated party acted with indifference or premeditation;
- likelihood that the problem will recur; and
- anticipated outcome of each enforcement action.

The Agencies are committed to proactively identifying and minimizing, or eliminating, potential hazards to public health and safety while taking actions to promote and monitor compliance.

Key activities to promote and facilitate compliance with CBSG requirements include the:

- development and delivery of training courses;
- participation at national symposia;
- sharing of information on biosafety and biosecurity practices and principles;
- development and web posting of Pathogen Safety Data Sheets; and
- issuance of biosafety advisories or notifications concerning emerging human and animal pathogens.

These activities are supported through compliance monitoring and verification activities, including requests for information, inspections, and the verification of information submitted to the Agency. Monitoring activities may be supported by complaints of non-compliance or referrals from other provincial and federal regulatory agencies.

Enforcement activities may also be necessary, if warranted, and may include one or a combination of the following:

- issuing a notice of non-compliance;
- refusal to issue or renew a licence, or suspension or variation of a licence (when the requirement to have a licence becomes mandatory under the HPTA);
- issuing an inspector order;
- undertaking activities related to seizure, detention or forfeiture;
- conducting an investigation; and
- prosecution.

Activities may be undertaken in a progressive or iterative manner moving through the continuum of compliance promotion and monitoring to enforcement.

The CBSG will be used by the PHAC and the CFIA to verify the ongoing compliance of facilities where infectious material or toxins are handled or stored, and for the certification or recertification of containment zones.

The Agencies encourage regulated parties to share information and build networks amongst themselves to disseminate best practices and lessons learned. The development of internal responsibility systems within organizations also serve as an extension to the Agencies' compliance promotion activities by increasing the understanding of CBSG requirements.

For additional information, interested and regulated parties are encouraged to consult the PHAC's compliance and enforcement policy.

## Feedback Mechanism

The PHAC and the CFIA welcome comments, clarifications, and/or suggestions for incorporation into the future editions of the CBSG. To this end, please send information with references (where applicable) for the CBSG to:

**Canadian Biosafety Standards and Guidelines Team**
PHAC email: standards.normes@phac-aspc.gc.ca
CFIA email: standardsnormes@inspection.gc.ca

*For more information please visit our website: http://canadianbiosafetystandards.collaboration.gc.ca*