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Inspection approach for blood establishments



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Canada 

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Disclaimer

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

Ce document est aussi disponible en français.

Table of contents

1. Introduction	4
2. Purpose.....	4
3. Background	5
4. Scope.....	5
5. Inspection process and duration	6
5.1 Inspection Process Overview	6
5.2 Inspection Duration.....	7
6. Inspection frequency.....	7
6.1 Inspection of licensed blood establishments.....	7
6.2 Inspection of registered blood establishments	9
6.3 Inspection of establishments that do not require an establishment licence or registration.	9
Appendix A – Glossary.....	10
Acronyms	10
Terms.....	10
Appendix B – References	12

The following icon is used in this document:



Supplementary information

1. Introduction

In November 1997, the Government of Canada released the final report of the Commission of Inquiry on the Blood System in Canada (Krever Commission Report). Guided by the report's recommendations, Health Canada's role in protecting blood safety has significantly evolved. Extensive improvements to the Canadian blood system are evident through advances in blood safety technology, legislative changes and higher industry standards. Canada's blood system is now recognized as one of the safest blood systems in the world.

Prior to the Krever Commission, source plasma was regulated as a drug and subject to the requirements of the Food and Drug Regulations. Health Canada's regulatory oversight was limited to submissions from manufacturers of drugs derived from blood, inspections of blood product manufacturing plants, and plasmapheresis collection centres operated by the Red Cross and private corporations. In 1989, regulatory oversight was expanded to include all "blood" further encompassing most of the operations of national blood transfusion services.

On October 23, 2014, the stand-alone Blood Regulations came into force, consolidating pre-existing regulations that applied to blood. Currently, before an establishment is allowed to start their operations or make any significant changes to the screening of donors and processing of blood for transfusion or plasma for manufacture into a human drug, Health Canada conducts an extensive scientific review of the proposed processes. Sufficient evidence is required to demonstrate proposed processes will not compromise human safety and will result in blood that is safe for distribution. Following the release of the Krever Commission report, licensed facilities have been inspected on an annual basis and inspections cover plasmapheresis centres and any center processing blood for transfusion.

Regulatory compliance among Canadian licensed blood establishments has remained consistently high. This high rate of compliance supports Health Canada's introduction of a modernized approach to inspections. This updated policy demonstrates Health Canada's commitment to compliance and enforcement transformation by considering potential risk factors for a more active risk-based approach in determining when licensed establishment sites should be inspected.

2. Purpose

The purpose of this document is to describe Health Canada's approach for inspecting blood establishments in order to assess their compliance with the [*Food and Drugs Act*](#) (the Act) and the [Blood Regulations](#).

3. Background

The Blood Regulations, under the *Food and Drugs Act* (Act), came into force on October 23, 2014. Prior to the Blood Regulations coming into force, blood and blood components were regulated under the [Food and Drug Regulations](#).

The Blood Regulations are intended to promote the safety of blood for transfusion or for further manufacture into a drug for human use. Establishments are regulated based on the degree of risk their activities pose.

The Blood Regulations contain requirements for human safety and the safety of blood with respect to the following activities related to human blood components for transfusion: processing (donor suitability assessment, collection, testing, and blood component preparation); transforming (washing, pooling and irradiating); labelling; storing importing and distributing.

The [Guidance Document: Blood Regulations](#) provides information to blood establishments on how to comply with the requirements of the Blood Regulations.

Health Canada is the federal authority responsible for the regulation of the safety of blood in Canada. Health Canada inspectors derive their statutory authority to conduct inspections from section 23 of the Act. This applies to all establishments regulated under the Blood Regulations, including establishments that do not require a licence or a registration. Inspections are conducted to assess the compliance of establishments with the Act and the Blood Regulations.

4. Scope

This inspection approach applies to all establishments in Canada that perform any of the following activities regulated under the Blood Regulations:

- processing
 - donor suitability assessment
 - collection
 - testing
 - blood component preparation
- transformation
- labelling
- storage
- distribution
- importation

Establishments that process allogeneic blood must be both authorized and licensed by Health Canada. This process involves an extensive scientific review prior to authorization. Establishments that collect autologous blood, transform blood or have a pre-assessed donor program must be registered with Health Canada. Other establishments that conduct regulated activities such as hospitals that store or distribute blood, do not require an establishment licence or registration however, must still comply with applicable sections of the Blood Regulations.

5. Inspection process and duration

5.1 Inspection Process Overview

An inspection is an assessment of an establishment's activities, procedures and ability to comply with the applicable requirements of the Act and the Blood Regulations.

An inspection may be announced or unannounced. In most cases, establishments are given notice before the inspection. The inspector contacts the establishment to confirm the information on the Establishment Licence or Registration (if applicable) and to schedule the inspection. The establishment may also be requested to provide information or documents in preparation for the upcoming inspection. Unannounced inspections may be conducted in situations where an immediate risk to health and safety has been identified or when it is anticipated that this approach will provide a more accurate compliance assessment.

During the inspection, the inspector will make observations if they note areas where the establishment is not adequately meeting its regulatory requirements.

After completing the inspection, the inspector issues an Exit Notice to the establishment. The Exit Notice summarizes the deficiencies (observations), if any, found during the inspection and provides an overall rating of compliant or non-compliant. Individual observations are also assigned a rating of critical, major or minor.



For more information on the rating of observations and the overall inspection rating, please refer to the [*Risk Classification of Observations made during Inspections of Blood Establishments \(GUI-0061\)*](#).

Following the issuance of the Exit Notice, the establishment will be given 20 business days to provide a written response to the observations, which must include corrective actions to address the observed deficiencies and prevent their reoccurrence.

When an establishment is given a non-compliant rating, it must address the deficiencies by creating and implementing a detailed corrective and preventative action plan. The plan must

include target dates for completion. Where necessary, Health Canada will consider enforcement action in accordance with the [Compliance and Enforcement Policy \(POL-0001\)](#).

Drug and health product inspections database

Shortly after the inspection and before the Exit Notice is issued to the establishment, Health Canada posts online an Initial inspection deficiencies (IID) report, which provides a preliminary overview of any initial deficiencies found during the inspection. After the Exit Notice is issued to the establishment, Health Canada will post the Inspection Report Card (IRC) to summarize the inspection observations and rating. These reports can be found on the [Drug and Health Product Inspections Database](#).

5.2 Inspection Duration

In general, inspectors determine the length of each inspection on a case-by-case basis. The average time for an inspection will vary depending on the:

- complexity and number of activities conducted at the establishment
- number of inspectors conducting the inspection
- size of the establishment

6. Inspection frequency

Health Canada applies a risk-based approach to the frequency of inspections.

The frequencies set out in this policy are for regular inspections. Re-assessments and re-inspections may be conducted sooner, as required.

Despite the routine inspection frequencies listed below, any establishment regulated under the Blood Regulations may be inspected at any reasonable time, whether on a routine or random basis or for cause.

6.1 Inspection of licensed blood establishments

Establishments that process allogeneic blood must be licensed by Health Canada.

6.1.1 Newly licensed establishments or sites

Establishments applying for a new establishment licence or to amend a licence to add a new site may be inspected prior to the issuance of an establishment licence or amended licence. A

regular inspection will be conducted within 12 months after the commencement of licensable activities at the new establishment or site.

6.1.2 Regular inspections of licensed establishments

At the conclusion of a site's second inspection, and each subsequent inspection by Health Canada, a Site Risk (SR) rating will be assigned which will determine its inspection frequency, although more frequent or random inspections may still be conducted.

The SR rating will be assigned after the completion of each inspection based on the following SR rating criteria:

1. The previous inspection and the current inspection were both assigned “Compliant” ratings, and
2. Corrective actions implemented by the establishment for any critical (risk 1) or major (risk 2) observations assigned at the last inspection, were assessed and deemed satisfactory during the current inspection.

Sites that demonstrate a high level of compliance by meeting both of the SR rating criteria noted above are assigned a lower SR rating and will ordinarily be inspected in accordance with the inspection frequency outlined in Table 1 below.

Table 1: Inspection frequency for sites assigned a lower SR rating

Type of site	Lower SR rating inspection frequency
Production Site	2 years
Collection Site (whole blood and apheresis)*	3 years
Contact Centres	

*Mobile collection sites and mobile blood collection vehicles may be selected for inspection during the inspection of their associated production or collection site.

However, if after an inspection, a site does not meet **both** of the above SR rating criteria (i.e. was assigned a “Non-Compliant” rating for at least one of the 2 most recent inspections and/or have unsatisfactory corrective actions), the site is assigned a higher SR rating and the following inspection will be scheduled sooner in accordance with Table 2 below.

Table 2: Inspection frequency for sites that are assigned a higher SR rating

Type of site	Higher SR rating inspection frequency
Production Site	1 year
Collection Site (whole blood and apheresis)*	2 years
Contact Centres	

*Mobile collection sites and mobile blood collection vehicles may be selected for inspection during the inspection of their associated production or collection site.

During any inspection, all regulated activities may be inspected.

The site of an establishment that has oversight of the organizational Quality Management System (e.g. head office) may also be regularly inspected to assess the establishment's compliance with applicable sections of the Blood Regulations.

6.2 Inspection of registered blood establishments

Establishments that collect autologous blood, transform blood or have a pre-assessed donor program must be registered with Health Canada. Registered establishments are required to annually re-certify their continued compliance with the Blood Regulations in order to retain their registration.

Generally, an establishment will not be subject to an inspection prior to being registered.

Health Canada is developing a standard frequency for inspecting registered blood establishments. In the interim, all registered establishments were inspected between 2015 and 2018 and will continue to be subject to regular inspections by Health Canada.

Health Canada will consult stakeholders and update this document during the development of the inspection approach for registered establishments.

6.3 Inspection of establishments that do not require an establishment licence or registration

Establishments that conduct regulated activities but do not require an establishment licence or registration, such as hospitals that store, distribute, aliquot blood or pool cryoprecipitate, etc., must still comply with applicable sections of the Blood Regulations and may be subject to inspections.

Appendix A – Glossary

Acronyms

IID: Initial Inspection Deficiency

IRC: Inspection Report Card

SR rating: Site Risk rating

Terms



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or associated regulations, the definition in the Act or regulations prevails.

Allogeneic - Blood that is collected from an individual for transfusion into another individual or for use in the manufacture of a drug for human use.

Apheresis - The process of withdrawing blood from a donor, separating specific components from the blood, and returning the remaining blood components to the donor.

Autologous - Blood that is collected from an individual for transfusion into the same individual at a later time.

Blood - Human blood that is collected either for transfusion or for use in the manufacture of a drug for human use, and for greater certainty, it includes whole blood and blood components (e.g. red blood cells, platelets, plasma, granulocytes).

Collection site - Permanent site where blood is collected (whole blood or by apheresis).

Compliance – When a regulated party (including a corporation, institution, individual, or other legal entity) conforms to a legislative or regulatory requirement, or a recognized standard.

Contact centre - A site where calls and/or inquiries from donors are received and decisions regarding donor suitability are made.

Enforcement - Actions that may be taken to induce, encourage or compel compliance with the Act and its associated regulations.

Mobile blood collection vehicle - A self-contained donor clinic held in a vehicle that can move from one location to another.

Mobile collection site - A blood collection site that is held at a non-permanent location.

Production site - Permanent site where blood component preparation and/or any testing on blood that is required under the Blood Regulations is carried out. This includes independent testing laboratories located in Canada that are licensed under the Blood Regulations.

In addition, other regulated activities may also be conducted at a production site such as donor suitability assessment and blood collection.

Note: A licensed site that does not conduct any component preparation or testing on site can still be considered a Production site if another establishment conducts testing on its behalf, since the licensed site is responsible for the testing activity. The testing activity is listed on the “Other Establishments Annex” of that specific site’s licence.

Regular Inspection: An inspection during which all of the applicable requirements of the Act and its associated regulations are assessed.

Re-Inspection: A follow-up inspection carried out in response to the assignment of a Non-Compliant (NC) rating. The inspection is focused on, but not restricted to, those sections of the Act and its associated regulations where observations were made.

Re-Assessment: A follow-up inspection carried out in situations where, although the establishment was assigned a Compliant (C) rating on the previous inspection, the number or type of observations contained in the previous inspection Exit Notice require corrective action in a timely manner. The inspection is focused on, but not restricted to, those sections of the Act and its associated regulations where observations were made.

Site Risk (SR) rating— Concept of rating a site by estimating the level of risk that the establishment’s products, activities and compliance history may pose to users based on identified criteria.

SR Ratings:

- **Lower risk rating**- identifies sites that have a lower likelihood of having significant deficiencies (high level of compliance)
- **Higher risk rating**- identifies sites that may have a higher likelihood of having significant deficiencies (poor compliance)

Appendix B – References

Blood Regulations

<http://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/page-1.html>

Compliance and Enforcement Policy (POL-0001)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html>

Drug and Health Product Inspections Database

<https://www.canada.ca/en/health-canada/services/inspecting-monitoring-drug-health-products/drug-health-product-inspections.html>

Food and Drug Regulations

http://laws.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html

Food and Drugs Act

<http://laws-lois.justice.gc.ca/eng/acts/f-27/>

Guidance Document: Blood Regulations

<https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/blood-regulations/guidance-document-blood-regulations-1.html>

Risk Classification of Observations made during Inspections of Blood Establishments (GUI-0061)

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor/risk-classification-observations-made-inspections-blood-establishments-0061.html>