Inspection strategy for blood establishments

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Draft for consultation

Canada

Inspection strategy for blood establishments

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Ce document est aussi disponible en français.

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1. Purpose

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

2. 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 protection of the safety of Canadian blood donors and recipients in connection with the safety of blood for transfusion or for further manufacture into a drug for human use.

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; record keeping; importing; distributing; and error, accident and adverse reaction investigation and reporting.

The *Guidance Document: Blood Regulations* provides the necessary information for blood establishments 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 and derives its statutory authority to conduct inspections from section 23 of the Act. Health Canada conducts inspections to assess the compliance of establishments with the Act and the Blood Regulations.

3. Scope

This inspection strategy 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

4. Inspection process and duration

4.1 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 working 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 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, 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, Heath 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.

4.2 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.

5. Inspection frequency

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

Health Canada may inspect any establishment regulated under the Blood Regulations, whether routine or for cause.

5.1 Inspection of licensed blood establishments

5.1.1 Newly licensed establishments or buildings

Establishments applying for a new establishment licence or to amend a licence to add a new building should be ready for inspection at the time of filing, since the new building may be inspected prior to the issuance of a licence or amended licence. A regular inspection will be conducted within 12 months after the commencement of licensable activities at the new establishment or building.

5.1.2 Regular inspections of licensed establishments

At the conclusion of a building's second inspection, and each subsequent inspection by Health Canada, a Site Risk (SR) rating will be assigned to the building which will determine its inspection frequency.

The SR rating of the building will be assessed 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 risk 1 or risk 2 observations assigned at the last inspection, were assessed and deemed satisfactory during the current inspection.

Buildings that demonstrate a high level of compliance by meeting both of the SR rating criteria above are assigned a lower SR rating and 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	

However, if after an inspection, a building does not meet **both** of the above 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 building is assigned a higher SR rating and the next 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	

During the inspection, all regulated activities, including other licensed activities may be inspected.

The building 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 Regulations.

Mobile clinic sites and mobile blood collection vehicles may be randomly selected for inspection.

5.2 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 regulations in order to retain their registration.

Generally, an establishment will not be subject to an inspection prior to being registered. However, registered establishments will continue to be subject to regular inspections by Health Canada.

A standard frequency for inspecting registered blood establishments has not yet been established. Once determined, Health Canada will consult stakeholders and update this inspection strategy.

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

Establishments that conduct regulated activities but do not require a 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.

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.

Inspection - Assessment of compliance against any of the applicable requirements of the Food and Drugs Act and its associated regulations by a designated inspector. Inspections are conducted at predetermined intervals or on a risk basis.

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

Mobile clinic site - A blood collection site that is held at a non-permanent location. Critical supplies and equipment are generally not retained on site at a mobile clinic.

Production site - Permanent site that conducts blood component preparation and/or any test on blood that is required under the Blood Regulations. This includes independent testing laboratories located in Canada that are licensed under the Blood Regulations.
In addition, some production sites may also conduct donor suitability assessment and blood collection.

Note: A licensed building 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 building is responsible for the testing activity. The testing activity is listed on the "Other Establishments Annex" of that specific building's licence.

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