FRM-0414: Pre-inspection package for blood establishments (version 2)

Introduction

This information package is intended to help your blood establishment prepare for an inspection. The primary responsibility of a regulated party is to understand its obligations under the *Food and Drugs Act* (the Act) and its associated regulations and to comply with these requirements. Regulated parties who fail to comply will be subject to compliance and enforcement actions as per the Compliance and enforcement policy for health products (POL-0001).

Under the authority of the Act, Health Canada is responsible for verifying that blood establishments comply with the *Blood Regulations*. The *Blood Regulations* address the safety of blood and human safety, as it relates to the safety of the blood, with requirements related to processing (donor suitability assessment, collection, testing and blood component preparation), labelling, storage, distribution, transformation and importation, for all establishments performing these activities.

This package also contains general questions regarding the *Blood Regulations* and questions on the Registration and Establishment Licence requirements.

You should review the *Guidance Document: Blood Regulations*, as it provides more details on how to comply with the requirements of the *Blood Regulations*. It will also help you determine whether the activities you conduct with blood and blood components fall under the *Blood Regulations*. Policies, guidance documents and forms related to blood and blood components can be found on Health Canada's website at:

https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor.html

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.

Frequently asked questions

1. Blood Regulations

1. How is blood regulated in Canada?

Human blood collected for transfusion or for further manufacturing into a drug for human use is regulated under the *Food and Drugs Act* (the Act) and the *Blood Regulations*, which came into force on October 23, 2014.

The *Blood Regulations* directly reference specific sections of the National Standard of Canada, CAN/CSA Z902 - *Blood and blood components* (CSA Blood Standard) published by the CSA Group. For this reason, the referenced sections of the CSA Blood Standard are also law in Canada and are therefore mandatory.

The sections of the CSA Blood Standard that are not referenced in the *Blood Regulations*, but are referenced in the Guidance *Document: Blood Regulations* are not regulatory requirements, however they should be considered as recommended best practices.

In the case of a discrepancy between the *Blood Regulations* and sections of CSA Blood Standards, the requirements outlined in the *Blood Regulations* take legal precedence. The CSA Blood Standard may be updated from time to time, therefore all blood establishments must have access to the latest version to know their regulatory requirements. The CSA Blood Standard is available by ordering it through the Canadian Standards Association website. The CSA Blood Standard is also available for view access by registering to the CSA's community website.

2. To whom do the *Blood Regulations* apply?

The *Blood Regulations* apply to all persons or establishments that process, label, store, import, distribute or transform human blood for transfusion or further manufacturing into a drug for human use.

Depending on the regulated activities conducted, establishments must obtain an Authorization, Blood Establishment Licence (BEL) and/or Blood Establishment Registration (BER) from Health Canada.

Regardless of whether an Authorization, BEL or BER is needed, all establishments that store and transfuse blood need to meet specific requirements described in the *Blood Regulations*. This includes meeting all requirements related to areas such as:

- storage
- distribution
- record keeping
- error, accident and adverse reaction investigation and reporting.

3. Is a guidance document available on the *Blood Regulations*?

Yes. The *Guidance Document: Blood Regulations* can be found on the Health Canada website. It interprets the requirements of the *Blood Regulations* to provide necessary information for establishments to comply with the requirements of the *Blood Regulations*.

4. Which requirements are applicable to my establishment?

The requirements applicable to each type of establishment can be found in Chart 1 of the *Guidance Document: Blood Regulations*. Chart 2 outlines the sections applicable to establishments that do not require a Licence nor a Registration, but still conduct regulated activities under the *Blood Regulations*, such as establishments that only store and transfuse blood (for example: hospitals). These establishments may still be inspected. Sections of the *Blood Regulations* that apply to all establishments conducting regulated activities include requirements related to areas such as storage; distribution, record keeping; and error, accident and adverse reaction investigation and reporting.

5. Do the *Blood Regulations* apply to drug products manufactured using blood or blood components?

No. The manufacturing of drug products using blood or blood components falls outside the scope of the *Blood Regulations* and is instead regulated under the *Food and Drug Regulations*.

In addition, the *Blood Regulations* do not apply to the following therapeutic products:

- cord blood and peripheral blood for use in lymphohematopoietic cell transplantation that are regulated under the *Safety of Human Cells, Tissues and Organs for Transplantation Regulations*
- blood and blood components that are the subject of clinical trials as described in Division 5, Part C of the *Food and Drug Regulations*
- blood and blood components that are imported for use in the manufacturing of a drug for human use

- autologous blood for further manufacture of a human drug
- autologous platelet rich plasma (PRP) (see Health Canada's Information Update on PRP)
- blood that is of a rare phenotype — not available in Canada — and that is imported in accordance with a prescription.

If you have any questions about the scope and application of the *Blood Regulations*, please contact the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) at brdd-cppic brdd-cppci@hc-sc.gc.ca

2. Registration

1. What is a Blood Establishment Registration (BER) and who needs to apply for one?

A BER is a registration number (issued as a certificate) that allows an establishment in Canada to conduct certain blood-related activities that require a Registration.

An establishment must obtain a BER before performing any of the following activities:

- conducting collection or component preparation of autologous blood
- pre-assessed donor program
- transforming blood (i.e. pooling, washing or irradiation)

Note: Establishments that only test autologous blood samples and/or pool cryoprecipitate do not need a BER.

For more information about applying for a Registration, see the *Blood Regulations: Guidance Document*, sections 30 to 37.

2. Is there a fee to apply for a BER?

No, there is no fee associated with obtaining a Registration issued under the *Blood Regulations*.

3. What are my responsibilities after obtaining a BER?

To maintain a BER, establishments must:

- submit a Statement of Compliance (Part A and B of FRM-0353) by April 1st each year
- submit a Notice of Change within 30 days after any change is made to the information provided in the establishment's application for the Registration
- continue to comply with all applicable sections of the *Blood Regulations*.

4. Who does not need to apply for a BER?

Establishments conducting only the following activities do not require a BER:

- transfusion of blood
- plasma extraction
- supernatant reduction
- super-concentrating of platelets
- pooling of cryoprecipitate (This is a transformation activity that is regulated under the *Blood Regulations*. However, if an establishment is only pooling cryoprecipitate then they are not required to register with Health Canada.)
- aliquoting blood
- storage of blood
- transportation of blood between establishments or between buildings within an establishment.

5. Does Health Canada have a tool that I can use to check if the practices at my establishment are meeting the requirements of the *Blood Regulations*?

Yes. A pre-registration self-assessment tool can be found in *Appendix C of the Guidance Document: Blood Regulations*. In addition, another self-assessment tool has been developed to enable establishments to assess their compliance with the *Blood Regulations* and was distributed to establishments in December 2024. These tools will help you identify any areas that your establishment may need to address to comply with the *Blood Regulations*. These tools are intended for your own use and not to be submitted to Health Canada.

These tools do not replace the requirements of the *Blood Regulations*. Also, the completion of this form alone is not considered to be a record of compliance for the internal audit requirements under paragraph 94(1)(j) of the *Blood Regulations*.

Each section of these documents should be read in conjunction with the relevant sections of the *Blood Regulations*.

In addition, Health Canada developed a compliance promotion document titled “Investigating and reporting errors and accidents under the *Blood Regulations*” which was distributed to all establishments in June 2022. The document contains frequently asked questions (FAQ) to assist hospital blood banks in understanding the requirements for the investigation and reporting of errors and accidents under the *Blood Regulations*.

If you have not received a copy of the FAQ or the self-assessment tools, one can be requested by writing to bpcp-pcpb@hc-sc.gc.ca.

3. Establishment Licence

1. What is a Blood Establishment Licence (BEL) and who needs to apply for one?

A BEL allows an establishment in Canada to conduct certain blood-related activities that require an Establishment Licence. The Establishment Licence, issued as a certificate, includes all the buildings where licensable activities are being conducted.

An establishment must submit an application and obtain a BEL before conducting any of the following activities:

- Processing allogeneic blood
    - Donor suitability assessment
    - Collection
    - Testing
    - Component preparation
- Importing

In addition, an establishment located in Canada must obtain their own BEL if they intend to conduct any processing activity on behalf of another establishment.

The establishment must also submit an application to amend an existing BEL (e.g. adding a new building to an existing BEL). For more information on how to apply for a Blood Establishment Licence, see the *Blood Regulations: Guidance Document* sections 17-29.

2. What is an Authorization and who needs to apply for one?

An Authorization is permission from Health Canada for an establishment to process allogeneic blood: i.e. conduct donor suitability assessment, collect blood from donors, test blood, and prepare blood components. Therefore, all establishments that process allogeneic blood must have an Authorization to do so, in addition to a Blood Establishment Licence (BEL).

A new establishment obtains an Authorization by applying to the Biologic and Radiopharmaceutical Drugs Directorate (BRDD) of Health Canada and submitting the required information for review. Establishments that already hold an Authorization and a BEL must apply for an amendment to their Authorization whenever they intend to make a significant change to

their processing activities. In certain cases, an amendment to the authorization may also require establishments to apply to amend their BEL.

A new or amended BEL cannot be issued unless an Authorization has been issued with respect to the activities and blood components that are to be processed or imported under the BEL.

For more information about applying for an authorization, see the *Blood Regulations: Guidance Document* sections 5 to 16.

3. What if I want to contract out testing to a foreign establishment?

If testing will be conducted by a foreign establishment on behalf of an establishment in Canada, the testing establishment must be listed on the Blood Establishment Licence (BEL) of the Canadian establishment. Further details on what information and evidence must be submitted to add a foreign testing laboratory to your BEL can be found in section 18 of the *Blood Regulations: Guidance Document*.

An Authorization amendment is also required and the information listed in section 52 of the *Blood Regulations: Guidance Document*, under the heading “When testing is performed by a laboratory outside of Canada”, must be submitted for review.

This is different from a contracted establishment located in Canada who must obtain their own BEL if they intend to conduct any processing activity on behalf of another establishment.

4. Will my establishment be inspected before receiving a new or amended Establishment Licence?

Establishments applying for a new Blood Establishment Licence (BEL) or to amend an existing BEL (e.g. to add a new site, new licensable activity) may be inspected prior to the issuance of the BEL. Therefore, establishments must be prepared for the possibility of a pre-licensing inspection when submitting their application. The decision of whether or not an inspection will be conducted depends on various factors and is made on a case-by-case basis upon receipt of the application.

5. What could the inspector assess during a pre-licensing inspection?

The inspector will cover at a minimum the following items during the pre-licensing inspection, therefore being ready for inspection means these activities have started (with an implementation plan for completion) or have already taken place:

- Training of new staff
- Receipt of critical supplies
- Validation and calibration of critical equipment
- Qualification of storage equipment
- Qualification and alarms enabled for environmental monitoring systems
- Facility cleaning and sanitation
- Access restricted only to designated staff
- Implementation of the quality management system

Please note this is not a comprehensive list and any regulated activity can be subject to inspection.

Lack of readiness during the pre-licensing inspection may result in a Non-Compliant (NC) rating which would prevent the issuance of the BEL. In addition, if a Compliant (C) rating is given but there are one or more significant observations that need to be addressed before the new or amended BEL is issued, the inspector may request to receive proposed corrective actions for those observations and review them before recommending the issuance of the new or amended BEL. Consequently, a C rating may not always mean an immediate recommendation for issuance of the BEL.

6. What are my responsibilities after obtaining a BEL?

To maintain a BEL, establishments must:

- continue to comply with all applicable sections of the *Blood Regulations*
- submit an application to amend your Licence before making any changes to the following:
    - list of activities
    - list of blood components
    - adding a new building or moving an existing building
    - other establishments conducting activities on your behalf
- submit a notice of change as soon as possible after a change is made to the following:
    - the establishment's name and head office address
    - the civic address of buildings where records will be stored
    - contact information
- submit a notice of change within 30 days after the cessation of any licensed activity.

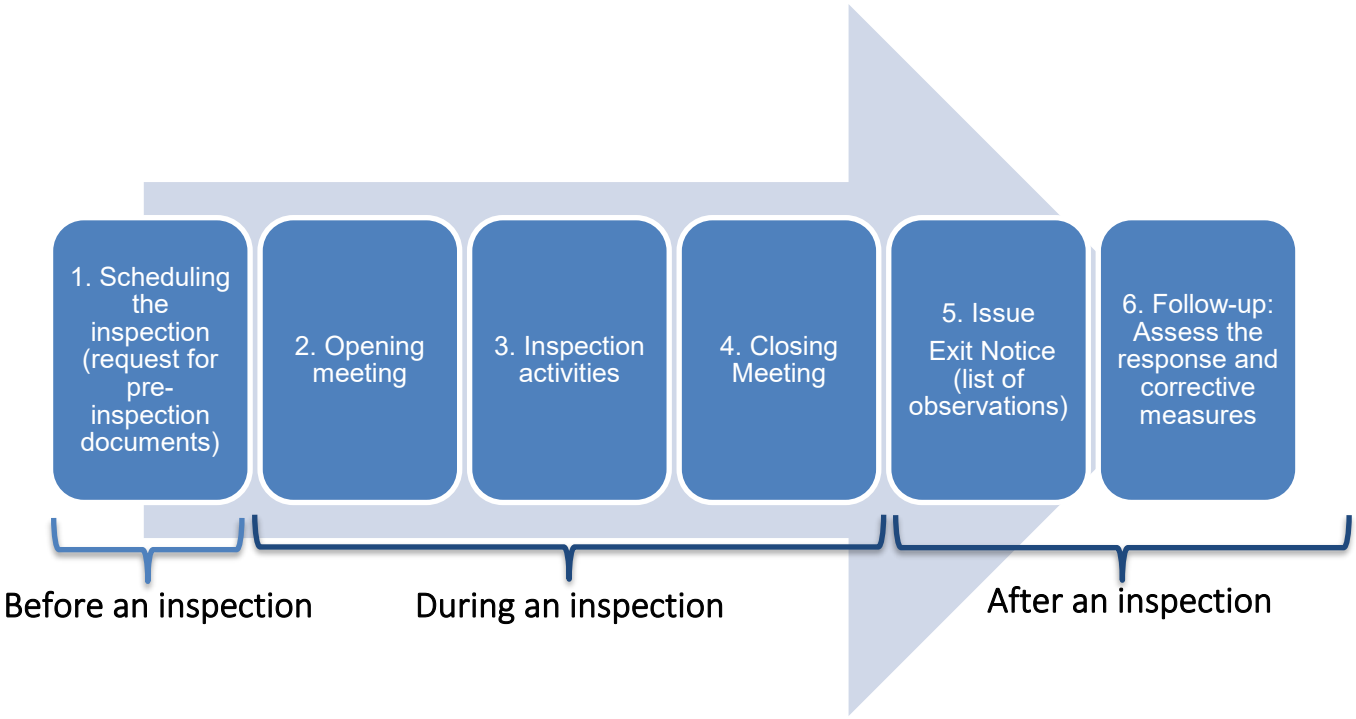
If you have any questions about the requirements regarding Blood Establishment Licences, including whether a change requires an application or a notification, contact roeb.blood-sang.dgoral@hc-sc.gc.ca.

Any changes to your establishment may also require an application to amend your Authorization. Contact BRDD at brdd.ora@hc-sc.gc.ca should you have any questions.

4. Inspections

4.1 General

An inspection generally consists of the following steps:



1. What are Health Canada's inspection authorities?

Under section 22(1) of the Act, Health Canada designates inspectors to enforce the Act and ensure compliance.

Section 23 of the Act outlines the powers given to inspectors so they can perform their role. Section 23 gives them the power to enter establishments, either in person, or remotely by a

means of telecommunication, where regulated activities are believed to be performed. This section also provides inspectors the authority to examine products, equipment and other articles related to those activities, and take action when non-compliance with the Act and Regulations is found. Inspectors decide on the course of action to take based on the risk of the deviation, deficiency or failure poses to health and safety.

All establishments regulated under the *Blood Regulations* may be subject to an inspection, whether routine or for cause.

Health Canada's approach to inspecting blood establishments is outlined in *Inspection Strategy for Blood Establishments* (POL-0039). The following policies also contain information regarding inspections conducted by Health Canada:

- The *Compliance and enforcement policy for health products* (POL-0001) describes Health Canada's national compliance and enforcement approach for all health products regulated under the *Food and Drugs Act* and its regulations.
- *Policy on accessing the premises of a regulated party remotely to verify compliance* (POL-0138) describes the remote access of places by means of telecommunication for health products as provided for under section 23(3) of the *Food and Drugs Act* (the Act).

2. How long does an inspection take?

In general, inspectors determine the length of each inspection on a case-by-case basis. The average time for an inspection varies depending on the following, but not limited to:

- regulated activities conducted at the establishment
- number of inspectors that will be conducting the inspection
- size of the establishment

4.2 Before an inspection

1. Will I be given notice before my inspection?

Inspections may be announced or unannounced. However, you will usually be given some notice before an inspection is to be conducted. The inspector will contact you in advance to schedule the inspection. Health Canada may also conduct unannounced inspections if deemed appropriate.

2. Will I need to provide information or documents before my inspection?

The inspector may request information and/or documents to be provided before the inspection. This may include, but is not limited to, the following:

- an organizational chart and list of key personnel
- a list of critical equipment and critical supplies used for conducting regulated activities
- a list and/or copies of procedures or records
- any changes since the last inspection, if applicable (i.e. personnel, critical equipment, critical supplies, processes, etc.)
- a list of errors and accidents

4.3 During an inspection

1. What happens during an inspection?

An inspection consists of a review of the establishment's documents, records and procedures and observation of its practices, premises, equipment, and supplies. Personnel may also be interviewed. This may be conducted either onsite and/or by means of telecommunications. During an inspection, a regulated party is required to provide all reasonable assistance and information necessary for the inspector to perform their inspection, including the provision of documentation and records that are requested to verify regulatory requirements are being met.

Health Canada inspectors use an open and transparent process while assessing the compliance of the establishment's regulated activities against the requirements of the *Blood Regulations*. If the inspector has any findings during the inspection, you will be informed of them so that you can begin work to clarify or resolve any issues.

2. What will be discussed during the opening meeting?

Generally, during the opening meeting, the inspector will:

- describe the objectives of the inspection program
- outline the scope of the inspection (e.g. purpose, schedule)
- confirm company information such as contact person and contact information
- provide any relevant Health Canada updates, as applicable.

3. What will be looked at during the inspection?

During the inspection, the inspector will observe regulated activities being performed, interview staff who are conducting the activities and review records and procedures related to the

activities performed at your establishment. This list provides examples of records and activities that an inspector may look at during an inspection. It is not all-inclusive and is not provided in any order of priority:

- processing of allogeneic and autologous blood (i.e. donor suitability assessment, collection, testing, blood component preparation)
- accuracy of the information on your establishment's current Registration or Licence (if applicable)
- qualification and acceptance records for critical supplies (e.g. specifications, certificate of analysis)
- implementation of the corrective actions for the observations from the last inspection.
- records of final disposition (e.g. transfused, returned, recalled)
- processes in place to ensure the blood is transported under appropriate environmental conditions (e.g. temperature monitoring, time records, validation of coolers, packaging configuration, conditioning of gel packs)
- measures in place to prevent contamination of the blood when doing manipulation activities in an open system
- records of cleaning, maintenance and environmental monitoring of the facilities.
- records of calibration, maintenance, cleaning and qualification/re-qualification for equipment associated with regulated activities
- records to demonstrate blood has been stored in accordance with the required temperature (including temperature logs and monitoring procedures)
- a list of suppliers for supplies and services and relevant agreements
- labelling
- aliquoting
- distribution
- transformation activities and records (irradiation, pooling and washing)
- procedure and records related to exceptional distribution
- quality management system in place for the regulated activities
- operating procedures for all regulated activities
- staff qualification records (e.g. training, experience, education, competency assessment)
- establishment's organizational chart
- internal audit records and associated corrective actions
- investigations of errors, accidents and adverse reactions (including corrective and preventive actions, trending, reporting to Health Canada, as applicable).

4. What happens if the inspector observes a non-conformity?

Regulated parties are expected to understand the relevant regulations and their obligations, and ensure their products, activities, and processes comply with the applicable regulations. The inspector will note a deviation, deficiency or failure to comply with the *Blood Regulations* as an observation. Observations are rated as one of the following:

- Risk 1 (Critical)
- Risk 2 (Major)
- Risk 3 (Minor)

Throughout the inspection, the inspector will keep you informed of any observations. If an observation poses a high risk, the inspector will bring it to your immediate attention, so that timely corrective actions can be initiated.

For more information about observation risk ratings, see the *Guidance Document: Risk Classification of Observations made during inspection of a blood establishments* (GUI-0061).

5. What will be discussed at the closing meeting?

The closing meeting will be held on-site at the establishment or teleconference. At the closing meeting, the inspector will:

- discuss any outstanding items or questions
- provide you with a verbal summary of the deficiencies noted
- verify that you understand the deficiencies (to be issued in a final Exit Notice)
- confirm the status of any blood placed under quarantine and/or voluntary detention, if applicable
- describe response timelines and next steps.

4.4 After an inspection

1. What happens after an inspection?

Following an inspection, the inspector will send you an Exit Notice usually within 20 working days. The Exit Notice is an official report listing each observation with the corresponding section

of the regulations and its risk classification. It will also include an overall inspection rating for your establishment: compliant (C) or non-compliant (NC).

Within 20 working days of receiving the Exit Notice, you must provide a written response which includes a written corrective action plan for any observations identified and target dates for completion. Health Canada will assess your response to the observations and may seek further clarification/information. Once satisfied with your response, the inspector will send you an inspection completion letter.

The implementation of corrective and preventive actions is usually verified at the subsequent inspection of your establishment. In some cases, Health Canada may conduct a re-assessment, a re-inspection and/or compliance verification to ensure that the proposed corrective actions have been implemented. Regulated parties who fail to comply may be subject to compliance and enforcement actions as described in the *Compliance and enforcement policy for health products* (POL-0001).

2. What does it mean if my establishment is assigned a compliant rating?

An establishment is rated as compliant if, at the time of inspection, the establishment has demonstrated an overall compliance with the Food and Drugs Act and *Blood Regulations*. An establishment may receive a compliant rating even if observations have been identified.

3. What happens if my establishment receives a non-compliant (NC) rating?

An establishment is rated as non-compliant if, at the time of the inspection, it has not demonstrated control over its regulated activities and an overall lack of compliance with the *Blood Regulations*.

If your establishment receives an NC rating, it is your responsibility to take timely and appropriate corrective actions to come into compliance with the *Blood Regulations*. If there is an immediate or potential health risk to blood recipients, the blood must be placed under quarantine until the end of an investigation. Health Canada will explain what is necessary to achieve compliance but will not dictate how compliance is to be achieved.

An NC rating may have serious consequences for your establishment and can result in the suspension and/or cancellation of your establishment's Licence or Registration.

Health Canada may also take additional enforcement actions as described in the *Compliance and Enforcement Policy for Health Products* (POL-0001).

5. Transparency

1. Will information about the inspection be posted online?

The results of all Health Canada blood inspections conducted since January 1, 2012 are posted online on the Drugs and Health Products Inspection Database (DHPID).The DHPID shows a summary of the observations noted at each establishment with the inspection outcome and measures taken.

2. What information about the inspection will be posted online?

For each inspection posted online, the following information is available:

- establishment name and address
- licence number or registration number, if applicable
- date of the inspection
- inspection type
- initial inspection deficiencies
- inspection report card
- inspection rating
- inspection outcome
- measures taken by Health Canada

An Initial Inspection Deficiencies (IID) report is posted 3 days after the inspection, which provides a preliminary overview of any initial observations found during the inspection. A more detailed Inspection Report Card (IRC) is posted after the Exit Notice is issued using standard lines. The risk rating of each observation is not posted online.

Appendix A – Glossary

Acronyms and abbreviations

BEL: Blood establishment licence

BER: Blood establishment registration

C: Compliant

CSA: Canadian Standards Association

DHPID: Drugs and Health Products Inspection Database

FAQ: Frequently asked questions

NC: Non-compliant

PRP: Platelet rich plasma

Terms

Exit Notice: A report listing the observations and/or violations of the *Food and Drugs Act* and Regulations found during an inspection. *(avis de fin d'inspection)*

Inspection: An examination and assessment of a regulated party's facilities, products, packaging, documents, records and any other thing deemed relevant by an inspector to determine compliance with legislative, regulatory and authorization requirements. *(inspection)*

Observation: A deviation from or deficiency in compliance with the legislative, regulatory or authorization requirements noted during the inspection of a regulated party, product or activity. *(observation)*

Appendix B – References

Legislation

Food and Drugs Act
http://laws-lois.justice.gc.ca/eng/acts/f-27/

Blood Regulations
http://laws-lois.justice.gc.ca/eng/regulations/SOR-2013-178/index.html

Z902 National Standards for Blood and Blood Components
https://www.csagroup.org/store/product/CAN-CSA-Z902%3A20/

Guides, Policies and Forms

Blood Establishment Licensing Application Form and Instructions - (FRM-0354)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/blood-establishment-licensing-application-form-instructions-0354.html
Establishments can request a copy of FRM-0354 from Health Canada by emailing: roeb.blood-sang.dgoral@hc-sc.gc.ca

Blood Establishment Registration Application: Form and Instructions (FRM-0353)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/forms/blood-establishment-registration-application-form-instructions-0353.html
Establishments can request a copy of FRM-0353 from Health Canada by emailing: roeb.blood-sang.dgoral@hc-sc.gc.ca

Blood Regulations self-assessment tool for non-registered hospital blood banks (FRM-0586)
Establishments can request a copy of this document from Health Canada by emailing: bpcp-pcpb@hc-sc.gc.ca

Blood Regulations self-assessment tool for registered hospital blood banks (FRM-0558)
Establishments can request a copy of this document from Health Canada by emailing: bpcp-pcpb@hc-sc.gc.ca

Compliance and enforcement policy for health products (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

Error or Accident Investigation Preliminary Reporting Form (FRM-0337)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor/blood-regulations-error-accident-investigation-preliminary-report-form-0337.html

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

Guidance on 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

Inspection approach for blood establishments (POL-0039)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor/inspection-strategy-blood-establishments-0039-summary.html

Policy on accessing the premises of a regulated party remotely to verify compliance (POL-0138)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-accessing-premises-regulated-party-remotely-verify-compliance.html

Policy on collection and retention of records related to health product compliance and enforcement (POL-0140)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-collection-retention-records-health-product-compliance-enforcement.html

Policy on Individual(s) accompanying a health products inspector (POL-0141)
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-individual-accompanying-health-products-inspector.html

Web pages/other documents

A Guide to Health Canada Inspections
https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/guide-inspections.html

Compliance and enforcement policy framework
https://www.canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html

Drugs and Health Products Inspection Database
http://healthycanadians.gc.ca/apps/blood-sang/index-en.html

Investigating and Reporting Errors & Accidents under the Blood Regulations – Frequently Asked Questions (June 2022)
Establishments can request a copy of this document from Health Canada by emailing: bpcp-pcpb@hc-sc.gc.ca