Health Canada Santé Canada

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Investigating and reporting errors and accidents under the *Blood Regulations*

Frequently Asked Questions

June 2022

Canada

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Introduction

Health Canada is pleased to provide you with this information package to help hospital blood banks understand the requirements for the investigation and reporting of errors and accidents under the *Blood Regulations*.

The *Blood Regulations* contain requirements for human safety and the safety of human blood components for transfusion with respect to the following activities: processing (donor suitability assessment, collection, testing, and blood component preparation), labelling, storage, distribution, transformation, record keeping, importation, and error, accident and adverse reaction investigation and reporting.

Although error and accident investigation and reporting requirements apply to all blood establishments, this package was developed specifically to provide information and guidance to blood establishments that only store, transfuse or transport blood (such as hospital blood banks that do not require a registration, also referred to as non-registered blood banks) on meeting the error and accident requirements outlined in the *Blood Regulations*.

For additional information on the requirements you must meet under the *Blood Regulations*, you should also review the *Guidance Document: Blood Regulations*.

Any questions regarding the information in this document can be sent to the Biological Product Compliance Program at bpcp-pcpb@hc-sc.gc.ca

Disclaimer

This document does not constitute legislation. In the event of any inconsistency or conflict between the legislation and this document, the legislation takes precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the legislation and the applicable administrative policies.

Ce document est aussi disponible en français.

Questions and answers

General

1. What are errors and accidents?

The *Blood Regulations* define errors and accidents as follows:

An **error** is a deviation from the operating procedures or applicable laws that could compromise human safety or the safety of blood.

An **accident** is an unexpected event that is not attributable to a deviation from the operating procedures or applicable laws and that could compromise human safety or the safety of blood.

Errors and accidents are collectively referred to as **E/A**s. The terms "E/A" and "suspected E/A" are used interchangeably throughout this document due to the variation in types of E/As. It is understood that some E/As are more immediately apparent than others without requiring confirmation through an extensive assessment.

As defined in the *Blood Regulations*, "**human safety**" means the safety of donors and recipients of blood, in so far as it relates to the safety of the blood.

2. What are examples of incidents not considered errors or accidents under the *Blood Regulations*?

Two key factors in determining whether or not an incident falls under the scope of the *Blood Regulations* is assessing whether:

1. activities regulated under the *Blood Regulations* are involved, and
2. the safety of the blood is compromised.

Even though some incidents may result in transfusion reactions, they would not be considered adverse reactions under the *Blood Regulations*, since they do not involve a regulated activity or they are not associated with the safety of the transfused blood.

Therefore, the following are not considered E/As under the *Blood Regulations*:

- Any incident involving drugs manufactured from blood (e.g., blood products such as albumin, immunoglobulins or coagulation factors). Refer to the *Food and Drug Regulations* for blood product reporting requirements.
- Any incident related to recipient sample testing, for example:
    - blood sample collection and mix-up in the blood samples
    - incidents during the pre-transfusion recipient testing (group and screen) and cross-matching
- ABO/Rh retesting errors conducted at hospitals.
- Blood bank sending the wrong blood to the ward (blood type or component).
- Service delivery time standards were not met but the safety of the blood was not impacted (e.g., blood arrives 10 minutes late).
- Incidents related to the practice of transfusion medicine, for example:
    - transfusing the unit of blood in the wrong patient
    - transfusing the blood too slowly or too quickly
    - unit of blood left unattended by a nurse for a few hours, later picked up and transfused
    - transfusing blood that expired after distribution by the blood bank. Note: if the blood was already expired and unknowingly distributed by the blood bank, it would be an error subject to the *Blood Regulations*

These are examples of scenarios that would not be considered E/As under the *Blood Regulations* even though these incidents may result in transfusion reactions:

- A unit of plasma is distributed using the pneumatic tube system to the intensive care unit at 6:00 a.m. At 6:30 a.m., the ward calls the blood bank to tell them that the plasma is yet to arrive. After following up, the blood bank realizes that the plasma was sent to the wrong ward. **Sending the blood to the wrong ward does not compromise the safety of the blood itself.**
- The blood bank sent the wrong unit of blood to the patient floor (e.g., different component or wrong blood type). **Selecting and sending the wrong unit of blood to the patient floor does not compromise the safety of the blood itself.**
- A unit intended for one patient was sent to a different patient. The blood unit was appropriately labelled. **Sending the unit of blood to the wrong patient does not compromise the safety of the blood itself.**
- A nurse left the blood at room temperature for a few hours and then proceeded to transfuse the unit. **This is considered practice of transfusion medicine.**
- The transfusion of platelets occurred later than anticipated and consequently were expired at the time of the transfusion. The platelets were not expired when the blood bank distributed the unit. **However, if the blood was already expired and unknowingly distributed by the blood bank, it would be an error subject to the *Blood Regulations*.**

- During an emergency, a patient in the ER was transferred to another hospital with blood that was not appropriately packaged for transportation. Upon arriving to the other hospital, the unused blood is returned to the blood bank and discarded. **This is considered practice of transfusion medicine. However, if the blood bank accepted it back into inventory without assessing the safety of the blood, then it would be an error subject to the *Blood Regulations***.
- A blood bank issues a unit of expired blood on the request of a physician who makes a medical decision to transfuse the specific unit of expired blood to a patient under their care. **This is considered practice of transfusion medicine.**
- Irradiated blood was ordered, but non-irradiated blood was sent (blood correctly labelled as non-irradiated). **However, if the blood was not irradiated but labelled incorrectly as irradiated, this would be an error under the *Blood Regulations***.

Investigation and reporting may be necessary according to provincial or hospital requirements.

3. Do we need to follow the error and accident requirements if our establishment is not required to register with Health Canada?

YES. Any blood establishment, including those that distribute, store or transfuse blood must assess, investigate, document and report all known or suspected E/As, as required in the *Blood Regulations*. This includes licensed and registered establishments, as well as establishments that are not licensed or registered with Health Canada.

As defined in the *Blood Regulations*, "**establishment**" means a person that conducts any of the following activities in respect of blood:

(a) importation;

(b) processing;

(c) distribution;

(d) transformation; or

(e) transfusion.

4. a) What are some of the regulated activities that are commonly conducted by non-registered blood banks?

Any activity that may impact the safety of blood is regulated under the *Blood Regulations.* Some examples include, but are not limited to:

- storage of blood, including during transportation
- appropriate quarantining of blood, when required
- distribution of blood within the hospital or to another hospital
- labelling

- pooling of cryoprecipitate
- aliquoting blood
- thawing of blood
- plasma extraction/reduction
- preservative depletion
- supernatant reduction

4. b) What do we need to know about incidents involving blood stored in the operating room or on a patient floor?

Storage of blood in satellite locations is also subject to the *Blood Regulations*. Any incident involving the storage of blood, including storage in satellite locations, would be considered an E/A under the *Blood Regulations* if the safety of the blood is believed to have been compromised.

5. Do we need operating procedures outlining all the error and accident requirements of the *Blood Regulations*?

Yes, all establishments are required to have processes in place to identify, investigate and report E/As as outlined in sections 103 to 108 of the *Blood Regulations*. The processes must be documented in an operating procedure with clear instructions on how to meet the requirements. Procedures for E/A identification should refer to the procedures for adverse reaction identification, investigation and reporting, and vice-versa, to ensure E/As associated with adverse reactions are handled appropriately.

Incident Identification, Notice, Assessment and Investigation (Sections 103-106)

6. We discovered an issue with a blood unit. What should we do?

First you must determine if the issue is considered an E/A under the *Blood Regulations*:

1. Is it an unexpected event or a deviation from an operating procedure?
2. Do you have reason to believe that the safety of the blood unit has or could have been impacted?
3. Could it have occurred during a regulated activity?

If the three criteria are met, it is an E/A under the *Blood Regulations*.

Next, you need to determine whether that regulated activity was conducted at your establishment or at another establishment from which you received the blood. Refer to question 4 for examples of regulated activities under the *Blood Regulations*.

- If the potential cause of the E/A is suspected to have occurred during a regulated activity conducted at your establishment, refer to question 8 for next steps.
- If the potential cause of the E/A is likely due to a regulated activity conducted at another establishment, refer to question 7 for next steps.

7. We believe an error or accident occurred during a regulated activity conducted at another establishment. What should we do?

Section 103 of the *Blood Regulations* outlines the actions to take when your establishment suspects an E/A occurred at another establishment.

Your establishment must immediately:

- Determine the donation codes of any blood known or suspected to be implicated.
- Identify and quarantine any blood known or suspected to be implicated in your possession.
- Notify all the following establishments:
    - the establishment that collected the implicated blood
    - the establishment from which you received the implicated blood, if different than the establishment that collected the implicated blood
    - any establishment to which you distributed implicated blood

In this case, you are not responsible for conducting the investigation or for reporting to Health Canada. However, under section 105 of the *Blood Regulations*, you must provide the establishment that is conducting the investigation with any relevant information about the blood you distributed or transfused. For example, this information could include an inventory list of implicated blood with their disposition (e.g., distributed, transfused, quarantined) and the names of establishments to which you distributed the implicated blood.

8. If we suspect or are notified by another establishment that an error or accident occurred at our establishment, what actions do we have to take?

Section 104 of the *Blood Regulations* outlines the actions to take when your establishment suspects an E/A occurred at your establishment.

Your establishment must immediately:

- Determine the donation codes of any blood known or suspected to be implicated.

- Identify and quarantine any blood known or suspected to be implicated in your possession.
- Determine whether there is sufficient evidence to warrant proceeding to an investigation in the suspected E/A.

9. How do we determine whether there is sufficient evidence to warrant proceeding to an investigation?

If you discover or were notified of a suspected E/A, you must conduct an assessment to determine if the regulated activities were conducted at **your** establishment and if the safety of the blood was or could be compromised.

After the assessment, if there is sufficient evidence that the E/A occurred at your establishment and the safety of the blood could be compromised, then you must conduct an investigation. If you determined that an investigation is not warranted, you must document the decision with a detailed rationale and retain these in your records.

10. The assessment determined there is sufficient evidence to warrant proceeding to an investigation. What actions do we now have to take?

Investigation

You must conduct an investigation and notify every establishment to which you distributed implicated blood of the following:

- that you are conducting an investigation
- the donation codes of the blood known or suspected to be implicated
- a description of the suspected E/A
- an explanation of how the safety of the implicated blood may have been compromised

An investigation involves an examination of the facts to determine what factors contributed to the occurrence of the E/A. It also involves identifying the root cause so appropriate corrective actions can be implemented to effectively mitigate the risk and prevent a reoccurrence. An investigation may be simple or complex depending on the nature and severity of the incident, and size and complexity of the establishment and/or its activities. This may require discussions with staff involved, and review of records and documents. This may also involve a review of the following areas to identify the full extent of what happened, including:

- relevant processes/procedures
- what regulated activities were involved
- potential impact to safety of the blood

- root cause analysis

Corrective Actions

Immediate corrective actions to mitigate risk and prevent reoccurrence must be determined.

You must document details of all actions taken during the investigation, including the date and the name of the person conducting the action.

Your determination of the corrective actions will depend on, but may not be limited to:

- the nature and severity of the E/A
- the personnel, processes, equipment, and materials involved
- the potential/inherent risks and impacts
- the identified causes that allowed the E/A to occur

Some examples of corrective and preventive actions include, but are not limited to, the following:

- quarantining or recall of the blood units
- retraining of staff
- revisions to procedures
- adding verification steps
- changes to one or more system(s)

Reporting to Health Canada (Section 107)

11. We are conducting an investigation. How do we know if we need to report to Health Canada within 24 hours?

You are required to submit a preliminary report of the E/A to Health Canada within 24 hours of the start of the investigation if your establishment is conducting an investigation into an E/A that meets the following three criteria:

1. The E/A is thought to have occurred during a regulated activity your establishment conducted.

2. The E/A was identified after the blood was distributed (either within your facility or to another establishment).

3. There is a reasonable probability that the E/A could lead to a serious adverse reaction.

As defined in the *Blood Regulations*, "**serious adverse reaction**" means an adverse reaction that results in any of the following consequences for the donor or recipient:

(a) their in-patient hospitalization or its prolongation;

(b) persistent or significant disability or incapacity;

(c) medical or surgical intervention to preclude a persistent or significant disability or incapacity;

(d) a life-threatening condition; or

(e) death.

You must report an E/A (known or suspected) that meet these criteria to Health Canada within 24 hours after beginning the investigation. You should not delay reporting until the results of the investigation confirm that an E/A occurred or that safety was indeed affected. The preliminary report must include all relevant information, recognizing that not all information may be available at that time. The final report could state that this incident was not an E/A (since safety of the blood was not affected).

12. a) How do we know if the error or accident meets the 2nd reporting criteria described in question 11 of the blood being distributed?

The blood is considered distributed if the blood has left the blood bank, regardless of whether the units were transfused. For example, the blood was sent to a ward or operating room or to another hospital.

12. b) The error or accident meets the first two reporting criteria, but an adverse reaction did not actually occur. Do we still need to report it to Health Canada?

Yes, you would still need to report the E/A to Health Canada if there is a reasonable probability that a serious adverse reaction **could have** occurred. The third reporting criteria is to assess the potential impact of the E/A on the recipient. You may still be required to report to Health Canada regardless of whether the blood was actually transfused or not, or whether the transfused blood resulted in a serious adverse reaction or not.

For example, the E/A would still need to be reported to Health Canada in the following scenarios:

- If the blood was transfused and

- an adverse reaction did not occur, but there is a reasonable probability that the E/A could have led to a serious adverse reaction, or
- a serious adverse reaction did occur.

- If the blood was not transfused, but there is a reasonable probability that the E/A could have led to a serious adverse reaction had it been transfused.

In order to make this determination, you may need to consult with the medical director or a designated specialist. It is important to document the rationale for the decision of whether or not the 3rd reporting criteria was met.

13. What are some examples of errors and accidents that would be reportable to Health Canada?

The following are examples of E/As that meet the three criteria presented in question 11 and therefore, you would need to report them to Health Canada within 24 hours. These examples are applicable to blood banks.

1. A unit of red blood cells (RBC) was left outside of its storage refrigerator for 120 minutes in the blood bank. The blood bank's procedure states the maximum time allowed outside of a temperature controlled environment is 60 minutes. The unit was subsequently distributed.

2. Two RBC units were dispensed to the operating room. At the end of each day, a blood bank employee is responsible for retrieving all blood from the operating room fridge and bringing it back to the blood bank. However, three days later, the two units were found in the operating room fridge with no records to demonstrate where they were stored in the last three days. The two RBC units were brought back to the blood bank, but not quarantined as required. Instead, they were put back into inventory and redistributed.

3. A blood bank packed blood using the incorrect ice packs. Specifically, the ice packs used were stored at the incorrect temperature and resulted in the blood arriving below acceptable temperature limits. The blood was deemed not safe for transfusion by the receiving site. The receiving blood bank must notify the blood bank that sent them the blood. The blood bank that shipped the blood is responsible for investigating and reporting this error to Health Canada as they are responsible for packaging the blood in a way to ensure that it remains within the required temperature range during transport.

4. Hospital B received 4 RBC units from Hospital A and noticed upon receipt that some segments on the RBC units were haemolysed. It was suspected that the units had frozen during transportation. Hospital A shipped the units to Hospital B by taxi during the winter. Although Hospital A was using the same packaging configuration as the collecting establishment, their ice packs and container were different, and they had not validated this

specific packaging. Upon receipt of the blood, Hospital B notified Hospital A of the issue. Hospital A is responsible for investigating and reporting this error to Health Canada.

5. A blood bank was informed by the device manufacturer that the bags from lot number 1234, which were used by the blood bank during pooling of cryoprecipitate, had a manufacturing defect (pinholes not visible to the naked eye). Upon investigation of this accident, the blood bank learned that three units of the pooled cryoprecipitate made with the defective bags had been transfused.

6. The collecting establishment sent a notice of component recall and withdrawal to a blood bank requesting that 2 RBC units be quarantined because the corresponding units of platelets associated with the RBC units tested positive for bacterial growth using the BacT system. The hospital retrieved the 2 RBC units and placed them in the quarantine section of the fridge but misread one of the unit numbers on the recall notice and quarantined the incorrect RBC unit. It was later found that the recalled unit was instead transfused after the recall notice was processed by the hospital.

7. Five units of cryoprecipitate were thawed and immediately placed in the refrigerator (4°C) for two hours, then pooled, distributed and transfused. However, the collecting establishment's circular of information requires thawed cryoprecipitate to be stored between 20 and 24°C.

8. After aliquoting a unit of RBC, the parent bag was not put back into the fridge. A few hours later, more aliquots were prepared from the same parent bag and distributed to the ward for transfusion.

9. An aliquot of RBC was labelled with an incorrect expiry date/time which resulted in the distribution and transfusion of an expired aliquot.

10. A fridge in the blood bank was affected by a power outage overnight and the temperature exceeded the acceptable range, reaching a temperature that impacts the safety of the blood. Three units from this fridge were sent to the operating room the next morning before the temperature deviation was noticed.

NOTE: As per the criteria indicated above, the E/As in these examples were identified **after** the blood was distributed (from or within the facility) and not necessarily transfused. If the E/As in these examples were discovered **before** distribution, they would not be reportable to Health Canada but would be investigated and included in the annual report.

14. What are examples of errors and accidents not required to be reported to Health Canada?

If any of the E/A described in question 12 were discovered before the blood was distributed (from or within the facility), they would not be reportable to Health Canada but still need to be investigated by the appropriate establishment.

In addition, all E/As that do not have a reasonable probability of causing a serious adverse reaction are not reportable to Health Canada. For example:

Situation 1: A box of RBC was distributed from site A to site B. Upon receiving the blood, site B notices the tamper proof seal is missing; however, the box does not appear to have been opened or tampered with, and the packaging configuration is compliant.

As per section 103, site B must report the incident to site A because shipping is a regulated activity that was conducted by site A. Based on the details site B provided to site A and other relevant information gathered during the assessment, site A determined that it is unlikely that the incident could have resulted in a serious adverse reaction. Therefore, they are not required to report to Health Canada. However, site A must investigate to determine why the seal was absent and if any measures are required (e.g., retraining the employee and/or relocating the tamper-proof seals to ensure their regular use during packing).

Situation 2: The lot number for the saline solution used in the reconstitution process for two units of cryoprecipitate was not documented. The establishment was able to confirm that the expiry and storage conditions were respected.

Although it is very important to document this information in case of a recall or if a safety issue is identified with the supplies used, not documenting the lot number of one supply used does not have a reasonable probability of causing a serious adverse reaction. Therefore, this error does not have to be reported to Health Canada.

Situation 3: The documentation for the daily temperature check of the fridge used to store blood in the operating room was missing for a specific day. The continuous temperature recording chart on the fridge indicates the temperature always remained within range.

Since it can be confirmed the temperature inside the fridge stayed within range, this error does not have a reasonable probability of causing a serious adverse reaction. Therefore, this error does not have to be reported to Health Canada as the third criteria would not be met (see question 11).

E/As that are not reportable still require investigation, and must be included in an annual report (see question 17).

15. How do we report an error or accident to Health Canada?

You can report an E/A to Health Canada by completing and submitting the Error or Accident Investigation Preliminary Report Form (FRM-0337).

Although it is recommended that you use FRM-0337 for your preliminary report, other formats are accepted as long as all of the required information stated in section 107 of the *Blood Regulations* is provided. Health Canada acknowledges that all of the information about an E/A may not be available upon submission of the preliminary report.

FRM-0337 should be used only when filing your preliminary report to Health Canada as the ongoing and final investigation reports require more detailed and comprehensive information.

E/A reports must be submitted to the Biological Product Compliance Program (BPCP) of the Regulatory Operations and Enforcement Branch (ROEB). The preferred method of submission is by email: bpcp-pcpb@hc-sc.gc.ca

Health Canada will notify you when your report has been received. After reviewing the report, you may be asked to provide additional information.

16. After the preliminary report is submitted to Health Canada, do we need to submit updates or a final report?

Yes, you need to submit a 15-day update and a final report.

Within 15 days after the start of the investigation, you must submit a written update on any new information about the E/A to Health Canada. The written update must include any available information on the following:

- status of all implicated blood units (within your facility or sent to another hospital), if known
- number of implicated establishments contacted
- progress made in the investigation since the preliminary report
- immediate corrective actions and steps taken to mitigate further risks, such as conducting a recall and changes made to relevant processes

Health Canada may also request an update at any time after the preliminary report and/or order a recall based on the information received.

Upon completion of the investigation, you must submit a final report to Health Canada. The final report must include:

- results of the investigation, including the root cause analysis and, if applicable, the name of any infectious agent(s) involved and results of any tests performed
- details of the final disposition of the blood (e.g., number of units distributed, transfused, quarantined, returned to inventory and discarded), and the reasons for that disposition
- follow-up and corrective actions taken (including actions taken to mitigate further risks and prevent reoccurrence)
- any changes recommended to be made to relevant processes, and
- any additional relevant information not previously shared with Health Canada.

17. Is there a form we can use to submit our final report?

Since the amount of information in the final report may vary depending on the scope and complexity of the investigation, this information may be provided in a format of your choice. The report should clearly indicate that it is a final report and be linked to the preliminary report.

18. If during the investigation of a serious adverse reaction, we discover an error or accident, do we need to also report the error or accident to Health Canada?

Yes, if an E/A related to an activity regulated under the *Blood Regulations* is discovered, which is suspected to have caused a serious adverse reaction, you must report it to Health Canada separately in addition to the adverse reaction report already submitted. These reports are sent to separate groups within Health Canada.

The same applies if, during an investigation of an E/A, it is discovered that a serious or unexpected adverse reaction has occurred. They must each be reported separately as described above.

The E/A must be reported to the **Biological Product Compliance Program** by **email** at bpcp-pcpb@hc-sc.gc.ca

We suggest including in your E/A report that you submitted an adverse reaction report to the Canada Vigilance Program.

Serious or unexpected adverse reactions must be reported to the **Canada Vigilance Program.** The preferred method of securely submitting adverse reaction reports is by secure File Transfer Protocol (sFTP). For enquiries on how to register for submission using sFTP, please contact tpmo-bgpc@hc-sc.gc.ca

Fax is an alternate secure method to submit adverse reaction reports:

Fax number: 613-957-0335

For more information or questions on adverse reaction reporting, email the Canada Vigilance Program at: canada.vigilance.blood-sang@hc-sc.gc.ca

Annual Report (Section 108)

19. a) What is the annual report referenced in section 108?

All establishments that are regulated under the *Blood Regulations*, including establishments that do not conduct activities requiring a licence or a registration, are required to prepare an annual E/A report.

This annual report must include all E/A investigations conducted in the previous 12 months, whether they were reported to Health Canada or not. The 12-month period for the annual report is defined by the establishment.

This annual report summarizes all E/A investigations conducted in the previous 12 months related to a regulated activity and were identified prior and after distribution of blood, including those that have been reported to Health Canada. The annual report must include a summary of each E/A, as well as an analysis of the investigations to identify possible trends.

19. b) What format should we use to prepare this annual report?

There is no prescribed format for the annual report, as long as all the required information is included.

If your site already generates a report for all blood related incidents, this report may be used for the annual report as long as all E/As related to a regulated activity are identified and it includes the required analysis of recurring issues and trends.

19. c) When do we need to submit the annual report to Health Canada?

Unless requested by Health Canada, you are not required to submit the annual report, but Health Canada may request these reports at any time. Annual reports are typically reviewed during inspections.

If during your analysis of the investigations, you discover any E/A with a previously unidentified risk that should have been reported, you must immediately report this to Health Canada.

Records Retention (Sections 119-122)

20. How long must we keep information and records about an error or accident?

Under sections 119 to 122 of the *Blood Regulations*, all records related to E/A investigations and reports must be kept for 10 years from the date the record was created. Record retention requirements must be documented in a policy or procedure.

In addition, records related to the E/As must sufficiently demonstrate that all pertinent steps of the procedures were followed.

If an establishment determines that an investigation is not warranted, it must document the decision with a detailed rationale and retain these in its records.

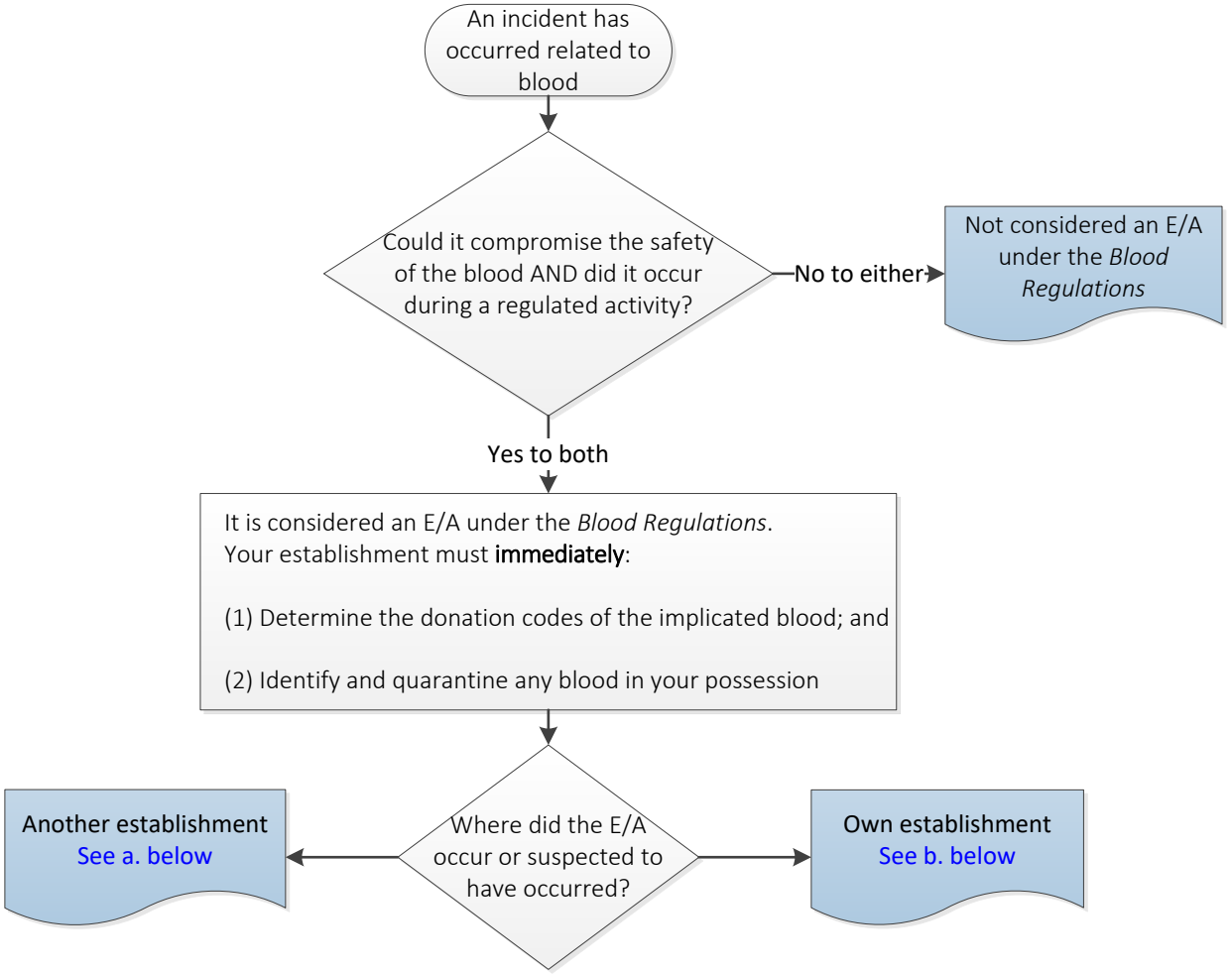
Error and Accident Investigation and Reporting Flow Chart

In all cases (E/A at own establishment or another establishment), if a notification is provided verbally, a confirmatory written notice must be sent as soon as possible afterwards.

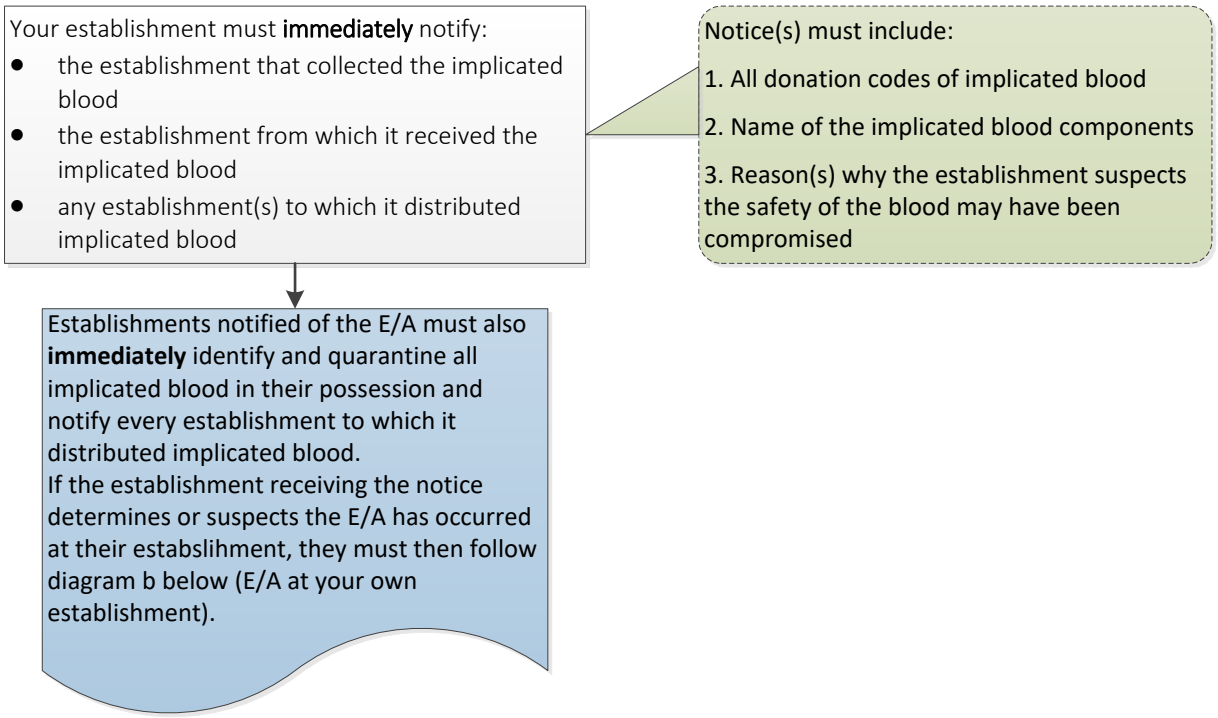
All affected establishments must cooperate during an investigation

Establishments **must**, on request, provide any establishment that is conducting an investigation with any relevant information in its possession in respect of blood that is distributed or transfused.

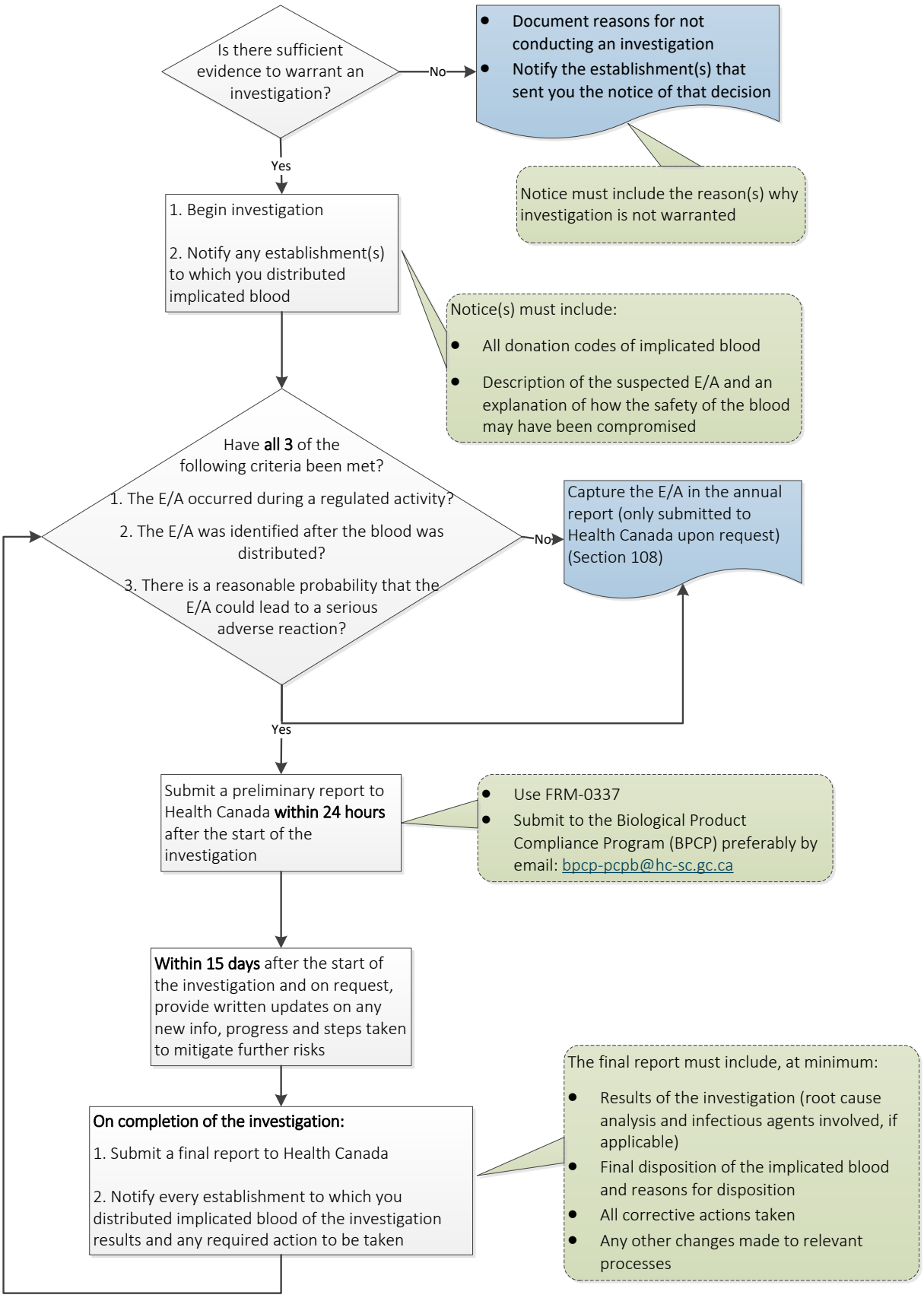
If the investigation of an E/A affects more than one establishment, then each establishment must ensure that every other affected establishment is informed of all relevant information and of all developments and issues that arise during the investigation.



a. E/A of another establishment (Section 103)



b. E/A at your own establishment (Section 104)



Useful guides and documents

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

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

CSA Group National Standards: CAN/CSA-Z902 Blood and Blood Components
https://community.csagroup.org/community/health-care-safety-and-accessibility/blood-and-transplants-standards-view-access
View Access to the CSA Standards Blood and Blood Components is available by registering with the CSA Communities website.

All blood establishments must meet **all relevant sections** of the *Blood Regulations*. In addition, the *Blood Regulations* reference **some sections** of the CSA's National Standards for Blood and Blood Components. Only the referenced sections of the National Standards are mandatory requirements. Because the National Standards may be updated from time to time, all blood establishments must have access to the latest version to know their regulatory requirements.

Health Canada webpage "Blood for transfusion or for use in the manufacture of a drug"
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/blood-donor.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