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when completed

Blood Error or Accident Investigation Preliminary Report Form (FRM-0337)

This form is primarily designed to facilitate the submission of a preliminary error or accident (E/A) investigation report to Health Canada as required by section 107 of the Blood Regulations.

Establishments conducting an investigation must file a preliminary error or accident report with Health Canada within 24 hours after the start of the investigation, if **all** of the following criteria are met:

- The error or accident is thought to have occurred during an activity they conducted;
- The error or accident is identified after the blood is distributed or transfused; and
- There is a reasonable probability that the error or accident could lead to a serious adverse reaction.

It is acknowledged that all information may not be available at the time of initial reporting. For further information, please refer to the Guidance Document: Blood Regulations.

Important: Please complete all applicable sections of the form, then print, date and sign the form. Once completed, please fax or scan the form and submit it to the Regulatory Operations and Regions Branch (RORB) of Health Canada.

Section A: Information related to the establishment reporting the suspected E/A to Health Canada

Name of the Reporting Establishment:

Name/Title of person reporting the E/A to Health Canada:

Establishment Licence #:	Registration Number:	☐ Not applicable

Address (street, city, province/state, postal code):

Phone number:	Fax number:

Contact person, if different from above:

Email address:

Section B: Is this investigation the result of a notification received by the reporting establishment from another establishment?

◯ Yes. Complete section B with information on the establishment that sent the notice regarding the suspected E/A.

◯ No. The suspected E/A was discovered by the Reporting Establishment. Proceed to section C.

Name of Establishment that sent the notice regarding the suspected E/A:

Name/Title of person who communicated the suspected E/A to the Reporting Establishment :

Establishment Licence #:	Registration Number:	☐ Unknown	☐ Not applicable

Address (street, city, province/state, postal code):

Phone number :	Fax number :

Contact person, if different from above :

Email address :

Section C: Error or accident summary

☐ Summary provided in attached documentation

Date E/A was discovered: ☐ (yyyy/mm/dd)

☐ E/A discovered by Reporting Establishment
Date E/A was discovered: ☐ (yyyy/mm/dd)

☐ E/A discovered as a result of notification from another establishment
Date of notification: ☐ (yyyy/mm/dd)

Date the investigation was initiated by the Reporting Establishment: ☐ (yyyy/mm/dd)

E/A description :

Immediate and planned corrective actions (e.g.: risk assessment, quarantine, dates of notifications sent to other establishments, etc.):

Was Health Canada verbally notified of the E/A?

◯ Yes; indicate when verbal notification was given: ☐ (yyyy/mm/dd)

◯ No

Section D: Signature

Signature of person submitting the preliminary report: ----------	Date (yyyy /mm /dd):

Note:

An update describing any new information on the progress made in the investigation and on steps taken to mitigate further risk is required to be submitted within 15 days after the start of the investigation and on request by Health Canada. A final report containing the results of the investigation, final disposition of implicated blood including the reasons for that disposition, and any corrective actions taken, must be submitted upon completion of the investigation. The form should not be used for the ongoing or the final investigation reports where more details and comprehensive information are to be reported.

Submit report to:

Regulatory Operations and Regions Branch (RORB):
Email: BPCP-PCPB@hc-sc.gc.ca
Facsimile: 613-960-2156

Privacy notice

The personal information you provide to Health Canada is governed in accordance with the Privacy Act. We only collect the information we need to administer the Blood Regulations authorized under the Food and Drugs Act. The information you provide will help you meet the investigations and reporting requirements of the Blood Regulations.

In limited and specific situations, your personal information may be disclosed without your consent in accordance with subsection 8(2) of the Privacy Act.

This personal information collection is described in Info Source, available online at www.infosource.gc.ca. Refer to the personal information bank HC PPU 408.

In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Coordinator, Privacy Management Division, at 613-946-3179 or privacy-vie.privee@hc-sc.gc.ca.

You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.