

2023-08-18

CBS Control #: CBS6760

HPFB File #: C1892-100390

REF: H-2223-CAL-L

Wei Zhang

Regulatory Compliance & Enforcement Specialist

Biological Product Compliance Program

Regulatory Operations and Enforcement Branch

Health Canada

180 Queen Street West, 10th Floor

Toronto, ON M5V 3L7

Dear Wei:

**Re: Responses to Health Canada Inspection of Ottawa Plasma Donor Centre
2023-07-19 to 2023-07-21**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-08-09.

Section 117 - Records

1. Records were not always accurate, complete, legible, indelible and/or readily retrievable.

a) The Premises Monthly Inspection Form (1000106185) for Oct 2022 was completed by Facilities Operations/Site Contact on Oct 28, 2022, but it was not reviewed and signed by Facilities Operations until July 20, 2023. A MQE-23-002493 was created by CBS during the inspection for further investigation.

Work instruction 13 022 Premises Cleaning has been revised to include timelines for forwarding and completing review of completed forms. The implementation date is 2023-09-05.

b) The box containing 7389 ml plasma (biomedical waste) was picked up by Stericycle Inc. Toronto on April 18, 2023 for destruction, but the field "received by" on the CBS's packing slip (0000003501903) kept blank.

The signature from the biomedical waste service provider for accepting the chain of custody of the biomedical waste is documented on the biomedical waste manifest. The packing slip that is generated from eProgesa includes the manifest number for traceability. Therefore, N/A was required in the received by section on the packing slip.

A huddle note will be sent out as a read and sign by 2023-08-25 reminding staff to follow good documentation practices as it relates to blank spaces and to document N/A as applicable.



**Canadian
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If you require clarification or further information, please do not hesitate to contact the undersigned.
Please reference the above CBS control number in any correspondence.

Sincerely,

for Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

c.c.: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch