

2022-04-25

CBS Control #: CBS6629

HPFB File #: C1892-100390

REF: H-2122-PDCSUD

Kevin Donato

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 Kevin:

**Re: Responses to Health Canada Inspection of Licensed Activities  
at Plasma Donor Centre Sudbury  
2022-03-15 to 2022-03-17**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-03-29.

**Section 95 - Operating Procedures**

- 1. Contrary to WI 13 022 Premises Cleaning, rev 3, eff 2017-05-23, section 2, the cleaning communication binder had not been reviewed to the specified biweekly frequency for review and initialling, as well as filing the book in the designated area. The book had not been reviewed between October 18, 2021, and December 9, 2021. The book that captured dates prior to this period was lost.**

**The file DEV-22-001975 is currently in progress.**

*DEV-22-001975 was initiated on 2022-03-07.*

*We have had coaching sessions with staff on 2022-03-21 to emphasize the importance of following work instructions.*

*With the exception of the Cleaning Communication Logbook prior to 2021-10-18 that could not be located, all entries prior to 2022-03-21 have been reviewed by the Facilities staff.*

*WI 13 022 Premises Cleaning was revised to clarify the requirements for the review of the Cleaning Communication Logbook, including its frequency and documentation.*

*The new paginated Cleaning Communication Logbook has been delivered to the Sudbury Plasma Donor Centre for implementation on the 2022-04-25 and has been placed in a designated area. The first page has been re-formatted to provide a more structured data entry process to align with the work instructions and the pagination will ensure traceability.*

*Staff responsible for reviewing the Logbook have completed training to the new version.*



**Canadian  
Blood  
Services** BLOOD  
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& TISSUES

1800 Alta Vista Drive  
Ottawa ON K1G 4J5

[blood.ca](http://blood.ca)

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,

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