

2023-08-31

CBS Control #: CBS6762

HPFB File #: C1892-100390

REF: H-2324-OTT

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 Operations
2023-07-17 to 2023-07-18

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 95 - Operating Procedures

Some operating procedures were not always followed.

- 1. Records CBS's Temporary Card Audit Log (F800604) requires Temporary Access Cards must be returned daily. However, the access card ID E405 was issued at 07:10 am on Feb 1, 2023, returned at 07:00 am. The access card ID E412 was issued at 14:29 on Feb 1, 2023, returned at 09:09 am. CBS confirmed during the inspection that both access cards were returned in the morning of the following day. In addition, Security Guard notified Facilities Operations of an unaccounted access card C457 by email at 15:30 on Feb 24, 2023 and completed the section B of Temporary Card Audit log. However, no associated entry in the section C of the log was completed by Facilities Operations/ Site Contact.**

MQE-23-002854 was initiated on 2023-08-18.

It was confirmed that Temporary card C457 was returned, and the time was documented by the security guard on the Temporary Access Card Log (F800604). Currently there is no requirement to document the date when returned as the cards are to be returned daily.

Facilities personnel at the Ottawa Concourse Gate location responsible for completing the Temporary Card Audit Log will be re-trained to the process by 2023-09-08 to ensure that the log is completed and cards are deactivated as per WI-00661 Temporary Building Access Control.

Facilities will also undertake a complete review of the process of managing temporary access cards and implement revisions to clarify the instructions to include a requirement to capture the date that the temporary cards are returned. This will be completed by 2024-02-28.

Section 117- Records

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

2. (1) No records indicated a scheduled follow-up check of cockroach traps was performed on Jan 5, 2023 by Orkin Canada, a pest control service provider. The missing record was not identified by CBS Facilities Operations during record quality review.

DEV-23-006277 was initiated on 2023-07-26.

Communication with the service provider confirmed that the insect traps were verified during the inspection, and it was confirmed by e-mail that the traps were clear. Work instruction WI-00659 Pest Control will be updated by 2024-02-28 to include follow-up for demand maintenance and documentation of the follow-up.

(2) The Regulatory Assets Management (RAM) indicated the next due of Preventative Maintenance for TSD-II Sterile Tubing Welder (R000026812) is 2026-04-20, but the due date on the sticker of the device is 2024-04-20. It was confirmed by CBS during the inspection the due date on RAM is correct. A work request (WR-057555) was created on July 18, 2023 to print new PM due label and replace current one on the device.

DEV-23-006026 was initiated 2023-07-26.

A work request was completed on 2023-07-19 to address the discrepancy. All other TSCD-II tube welders at the site were checked and corrected as necessary to ensure all devices displayed an accurate and consistent PM label.

The TSCD-II at other locations across the organization were also verified by their respective equipment services staff and confirmed to have no issue with their label or next PM due date.

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

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