Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Urbee Shome-Pal
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Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Urbee:

Re: Further to the Responses to the Health Canada Inspection of Licensed Activities at Carling 2021-10-05 to 2021-10-08

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2021-12-22, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of licensed activities at Carling.

Section 95 – Operating Procedures

1b) The Clinic Site Evaluation of K0191 (NDHQ Cartier Square Drill Hall) conducted on 2015-06-03, did not complete all the relevant instructions under Step 1.3 of SOP 01 010, Evaluate Clinic Site, Revision Number 8. Specifically, although there were notes in the "Follow Up (If Required)" section, the corresponding sections were not completed - Completed by, Department, Accepted / Rejected, Date. In addition, the document was reviewed and signed off by a Manager/Designate on 2016-10-08 without the completion of the appropriate follow-up, contrary to step 1.4.1 of the same SOP.

Canadian Blood Services Response:

MQE-21-003693 was initiated on 2021-11-09.

Work Instruction 01 010 Evaluate Mobile Donor Centre Locations was revised as of 2021-09-13. The supervisor is no longer required to review the form F020925 Mobile Donor Evaluation Checklist, only the manager needs to accept or reject the location.

Health Canada Follow-up letter dated 2021-12-22:

This observation spoke to applicable sections not being completed to acknowledge the information in the "Follow Up (If Required)" section. Please confirm if the appropriate follow up was conducted. In the new version of the WI 01 010, is there a corresponding signature/date to the manager accepting/rejecting a location?

Canadian Blood Services Response:

The record was reviewed and there were no follow up activities requiring further evaluation. The comment in the follow up section was regarding the use of extension cords that would be required in order to hold a clinic in that location. A mobile clinic was successfully held on 2015-10-02. This clinic location is no longer being used for mobiles. The last clinic held there was 2017-02-04.

In the revised work instruction 01 010 Evaluate Mobile Donor Centre Locations v12 the signature and date for the manager are required to accept/reject the location. The manager is to complete the documentation on F020925 Mobile Donor Centre Evaluation Checklist version 2021-09-07, section 6.

Section 96 – Operating Procedures

2a) There were no documented instructions on how to transfer B1 and plasma units directly on the trays in the transport vehicles, as per the current practice of the site. The relevant WIs provided for review were: WI 01 151.001: Prepare and Transfer Units, Samples and Documents - Insulated Shipping Container, Revision Number 1; and WI 157.001: Transfer and Deliver Units Shipped Warm in a Blood Transportation System, Revision Number 1. However, these WIs do not provide instructions on when the units are placed into the blood transport vehicles directly on the trays.

Canadian Blood Services Response:

Because instructions on how to maintain and monitor the temperature of collected units are provided, it is not deemed necessary to provide additional instructions as to how and when to transfer units. Temperature monitoring follows work instruction 01 106 v3, Monitor Ambient Temperature at the Donor Centre – Warm B1 Collection Set. Temperature monitoring on the Blood Transportation System (BTS) follows work instruction 01 157.001 v1, Transfer and Deliver Units Shipped Warm in a Blood Transportation System (BTS) or work instruction 01 203.001 v2, Transfer and Deliver Units Shipped Cold in a Blood Transportation System (BTS).

Health Canada Follow-up letter dated 2021-12-22:

Based on the response provided, it is unclear as to why instructions related to the transfer of blood prior to transport are not deemed as necessary. The response speaks to instructions on temperature monitoring. However, is there a link between temperature monitoring and the transfer of B1 units / plasma units into the transport trucks for transportation? Please elaborate.

Canadian Blood Services Response:

Yes, the temperature is monitored in the clinic and the units are transferred from the clinic into a blood transportation system which has been conditioned to the appropriate temperature, as described in 01 157.001 v1, Transfer and Deliver Units Shipped Warm in a Blood Transportation System (BTS) and work instruction 01 203.001 v2, Transfer and Deliver Units Shipped Cold in a Blood Transportation System (BTS). The importance of the transfer of blood is included in the staff training material, T01157 B1 2021-01-21 – Transfer & Deliver Units Shipped Warm in a Blood Transportation System (BTS). The training material states "It is very important when transferring whole blood units into the blood transportation system it is completed with undue delay" and "It is very important

upon arrival to the production site, after units are removed from the blood transportation system, they are transferred to production with undue delay".

2c) Although typically, all units are picked up from the Carling site and transported to the Concourse site by the end of the day, there were no documented instructions on what actions to take in the interim if there is a delay.

Canadian Blood Services Response:

Documented instructions on what actions to take in the interim if there is a delay in picking up whole blood collections from a donor event for transport to a production site is not required as temperature monitoring occurs regardless of any delay in pickup.

Temperature monitoring at donor centre follows work instruction 01 106 v3, Monitor Ambient Temperature at the Donor Centre – Warm B1 Collection Set. Temperature monitoring on the Blood Transportation (BTS) follows work instruction 01 157.001 v1, Transfer and Deliver Units Shipped Warm in a Blood Transportation System (BTS) or work instruction 01 203.011 v2, Transfer and Deliver Units Shipped Cold in a Blood Transportation System (BTS).

Health Canada Follow-up letter dated 2021-12-22:

Do the referenced WIs in the response to this observation indicate to continue the temperature monitoring until pick up? If not, then where are these instructions noted? If this is not noted anywhere, then it should be included. Please clarify.

Canadian Blood Services Response:

Yes, work instruction 01 106 v3 Monitor Ambient Temperature at Donor Centre – Warm B2 Collection Set provides instructions to monitor the ambient temperature of the location where collected B1s are stored on crates at for the duration of the donor centre operations. The work instructions state to document the temperature every hour the donor centre is operating or at the end of donor centre operations when a thermometer with an audible alarm is used.

Section 100 – Equipment

3a) Asset ID# R1383 (Trima Accel), the weekly maintenance was not completed for the week of June 8, 2020 on the Trima Accel Maintenance Log for June 2020; reviewed on 2020-07-02. This is contrary to WI 25 026: Trima Accel Maintenance, Revision Number 5.1, Section 2.

Canadian Blood Services Response:

MQE-21-003669 was initiated on 2021-11-10.

The work instruction 25 026 Trima Accel Maintenance was reviewed with supervisors and staff.

Health Canada Follow-up letter dated 2021-12-22:

What was the date of the review that was conducted?

Canadian Blood Services Response:

The review was conducted on 2021-11-08.

Section 117 - Records

4b) The following deficiencies were noted while reviewing Clinic Site Evaluation (CSE) records:

i. K0001 (Carling), CSE conducted on 2017-12-01 inaccurately indicated N/A for the Site Contact.

ii. K0191 (Shaw Center), CSE conducted on 2015-04-02, the first floor lobby review was missing completion of the following checkboxes under Clinic Site Evaluation Checklist: "Safe and Easy Access to Clinic by General Public" and "Ability to Secure Collections/Equipment/Documents/Supplies if Staff are not on the Premises."

iii. K0199 (Greely Community Center), CSE conducted on 2015-04-29, were missing the electrical and emergency contacts details.

Canadian Blood Services Response:

MQE-21-003683 was initiated on 2021-11-09.

Staff have been reminded on 2021-11-15 of the importance of following good documentation practices when completing all records.

The Clinic Site Evaluation form (F020925) has been revised and implemented on 2021-09-13. All staff were trained prior to implementation.

Health Canada Follow-up letter dated 2021-12-22:

What were the changes made to Form F020925: Clinic Site Evaluation Form?

Canadian Blood Services Response:

Form F020925: Clinic Site Evaluation Form has gone through many changes since 2015. The changes include the following:

- *The current form is broken down into sections for clarity of information.*
- *Section 1: Mobile Donor Center Site Information. Additional details; document if this is an initial evaluation or re-evaluation and include primary and secondary site contact information.*
- *Section 2: Mandatory Mobile Donor Center Requirements. Clarifies the mandatory requirements for a donor event. Additional information captured: parameters for adequate square footage to operate bed models, electrical capacity required by bed model, elevator requirements, safe access for loading/off-loading activities, parking available for CBS vehicles, public access and parking available, Site Connectivity/Site Survey Test Results.*
- *Section 3: Non-Mandatory Mobile Donor Center Requirements. Additional information captured; separate breakroom for staff, site provides waste removal, site provides table and chairs, any other equipment provided, site provides snow removal/salting.*
- *Section 4: Pandemic Mobile Donor Center Requirements. Additional information to accommodate physical distancing, enhanced cleaning provisions and separate break room for staff if in a pandemic period.*
- *Section 5: Event Scheduling System Site Comments. Additional information captured; muster point, local hospital name, on site contact, floor plan map, inspector name, department, signature and date.*

- *Section 6: Mobile Donor Center Acceptability. Clarified signature and date for mobile donor acceptance by initial evaluation or re-evaluation. Document name and date of entry into the Event Scheduling System – ESS.*

4d) For Asset ID# R12557 (Compolab), although it was located at the Carling site, it was allocated to the Concourse site in RAM. All other Compolabs reviewed that were located at the Carling site, indicated Carling in RAM.

Canadian Blood Services Response:

CompoLabs are listed as portables in RAM and may be relocated temporarily to replace an out of service device. Once the device is repaired the spare unit is sent back to its original location, with its location in RAM used for tracking purposes.

Health Canada Follow-up letter dated 2021-12-22:

Was the location of Asset ID# R12557 inaccurately reflected in RAM? If it was inaccurately reflected, then has that error been resolved along with the appropriate re-training/review, as needed?

Canadian Blood Services Response:

The location of Asset ID #R12557 was updated to Carling on 2021-11-09.

Staff were re-trained to the work instruction 09 350 Management of Equipment by Owners on 2021-11-22 to ensure that the location of assets are accurate in RAM.

4e) For Asset ID# R1703 (timer), the person that conducted the PM on January 8, 2020 was not the same as the person that appeared in the RAM audit trail as having conducted the PM on January 8, 2020.

Canadian Blood Services Response:

Newly hired Field Service Representatives (FSR) are not granted edit access to RAM until they complete their training, as was the case in this situation. As a part of their training, new FSRs complete PMs under the supervision of a senior FSR. The senior FSRs upload the PM form and close the work order in RAM. No impact on documentation, accuracy, and traceability.

Health Canada Follow-up letter dated 2021-12-22:

Are there documented instructions to reflect this practice? If not, then relevant document(s) should be updated to reflect this. Please confirm.

Canadian Blood Services Response:

The Onboarding Checklist – FSR, a document used during training, was updated 2022-01-07 to include this information.

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

Sincerely,

Christian Choquet

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