Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

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Urbee Shome-Pal
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 Urbee:

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

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-11-01.

Section 95 – Operating Procedures

1 a) During the observation of the Clinic drive set up on Oct 6, 2021, instructions in Attachment 1 of WI 01 371.001: Drive Set-Up, Revision Number 2 were not fully followed with respect to verifying expiry dates. Specifically, Step 1 instructed to refer to Attachment 1 if warning messages are present. The reason for the warning message was confirmed as being due to the lot# for the specific critical supply being omitted prior to arriving at the site. Although the corresponding work instructions in Attachment 1 require that the expiry date be checked prior to proceeding to the next step, "Enter generic lot# "ZZ", this was not done. The inspector also confirmed this with both staff completing the task.

Before continuing to the next step, the expiry date of the material being entered was verified during the inspection. Staff completed refresher training to work instruction 01 371.001 Drive Set-Up on 2021-11-15.

1 b) 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.

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.

1 c) Form (020925, 2016-04-20) completed for the Clinic Site Evaluation of K0001 (Carling) on 2017-11-23 was missing pages 3 of 4 and 4 of 4. Therefore, it could not be verified whether the missing pages were completed for the corresponding evaluation.

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

The missing pages of the clinic site evaluation for K0001 were not located. A subsequent clinic site evaluation for K0001 was completed on 2017-12-01 and approved.

Section 96 – Operating Procedures

2 a) 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.

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).

2 b) WI 01 151.001 (as referenced above), incorrectly referenced 01 108.001: Donor Centre - Packing Configurations, as 01 108

With multiple sites and staggered implementations (i.e., changes that start at one site and implement gradually at the rest of the sites over a predetermined period of time), a process was required to allow for variations of a document to be effective at different sites until all sites have implemented. To facilitate this, when revising a document that falls into this scenario, a three digit suffix is added to the base document number (e.g., base document 01 151 v24 becomes variation document 01 151.001 v1).
Since one document may be referenced in multiple other documents that may or may not change, it would be very difficult to manage and potentially cause a great deal of confusion for staff to change the document number completely. By using variation documents, we

ensure the links to other documents are not broken and staff are trained to reference the base number (e.g., 01 151 or 01 108) when looking for a document on the Controlled Document Index or a hard copy at the site. The Controlled Document Index controls accessibility to documents by having staff access the site where they work. This ensures only documents that are current and implemented at the employee's site are accessible to them. Likewise for hard copies, only the implemented version is distributed at the site thereby preventing access to other versions.

2 c) 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.

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).

2 d) For SOP 30 353: Incoming Inspection of Hematology Analyzer Reagents, Revision Number 10, the Revision History page at the end of the SOP was for Revision Number 9 instead of Revision Number 10 of the SOP.

Work instruction 30 353 Incoming Inspection of Hematology Analyzer Reagents v11 revision history page has been corrected to indicate version 11 and will be implemented by 2021-12-13.

<u>Section 100 – Equipment</u>

3 a) 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.

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

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

3 b) For Asset ID# R16459 (apheresis scale), the PM records did not include the calibration due dates for the test equipment used, nor were the test equipment Calibration Certificates a part of the PM records for PM conducted on April 7, 2020 and April 9, 2021. Additionally, the list of test equipment provided on the April 7, 2020 PM record, were not consistent with the list provided on the April 9, 2021 PM

record.

MQE-21-003878 was initiated on 2021-11-24.

Staff completed refresher training on work instruction 09 350 Management of Equipment by Owners on 2021-11-18. The test equipment calibration certificates have been uploaded into RAM.

3 c) Asset ID# R15976 (Docon calibration weight), for PM conducted in January 2020, the dates of when the tasks were completed did not match the final PM conducted date. Specifically, some tasks appeared to have been conducted on January 13, 2020 and some on January 14, 2020 in the RAM Work Details for this equipment. In the electronic signatures section, it appeared that the PM was completed on January 14, 2021. However, the PM conducted date was indicated as January 13, 2021 in RAM and the corresponding equipment sticker. It was indicated that this type of PM would typically take one day only. Therefore, it could not be confirmed when it was actually completed.

DEV-21-007572 was initiated on 2021-10-08.

The audit trail in RAM confirms the PM was started and finished on 2021-01-14. No impact to maintenance as all steps of the work plan template were completed and subsequent PMs were completed successfully.

<u>Section 117 - Records</u>

4 a) For Donor# 4108905, Donation # C05551946530100U (Sept 16, 2019), the Medical Questionnaire completed on September 16, 2019, a travel location was incorrectly documented as being a malaria risk and the corresponding date of departure was not appropriately documented. Specifically, Question 6F asked, "In the last 6 months have you travelled outside of Canada and the U.S.?" In the relevant follow up questions to this, the specific area of travel, Cozumel in the State of Quintana Roo, was documented as "Yes" to malaria risk. However, this was contrary to the DSCM, Malaria Version 8, Amendment 12 (relevant at the time of the donation), which indicated that it was not a malaria risk area. Furthermore, the subsequent question, which asked for the date of departure to Cozumel in the State of Quintana Roo, indicated "Grand Caymen(sic)", instead of the date of departure.

MQE-21-003672 was initiated on 2021-11-08.

The staff member who completed the questionnaire completed refresher training on work instruction 01 144 Screen Donor on 2021-11-13.

4 b) 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.

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.

4 c) For Asset ID# R1329, the Docon Shaker Verification and Maintenance Log, completed on 2021-10-01, the Donor Centre Clinic Code was indicated as K0002 instead of K0001.

MQE-21-003667 was initiated on 2021-11-08.

The staff member was made aware on 2021-11-10 of the error and the importance of following good documentation practices.

4 d) 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.

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.

4 e) 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.

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.

4 f) For Asset ID# R12747 (Compolab), although the PM was conducted on 2021-01-19, the record reviewed date was entered as 2020-01-19.

MQE-21-003709 was initiated on 2021-11-10.

The error was reviewed with the staff member on 2021-11-10 to remind them of the

importance of complete and accurate documentation as per good documentation practices.

4 g) The following were noted for Asset ID# R20418 (refrigerator):

i. The Daily Temperature Monitoring Log, completed for December 2020 was missing the Temperature Monitoring Device (R15883) PM due date and the PM due date for the refrigerator (R20418) was incorrectly indicated as 2021-10-23, instead of 2021-10-29.

ii. On the Incubator/Refrigerator Temperature Monitoring Log, completed for February 2020, the acceptable temperature range for the refrigerator was indicated as 2-9°C in Section 1 and Section 2. However, the acceptable temperature range for the refrigerator was confirmed as 2-8°C.

iii. The power failure alarm section was not completed on the April 29, 2021 PM record.

i) MQE-21-003894 was initiated on 2021-11-25

The Daily Temperature Monitoring Log form was corrected on 2021-11-25.

Staff were reminded of the importance of complete and accurate documentation as per good documentation practices. The form Daily Temperature Monitoring Log F801280 has been rescinded as a Digital Temperature Recorder is now used to monitor the temperature of the refrigerator.

ii) The Incubator/Refrigerator Temperature Monitoring Log for February 2020 was reviewed and there were no temperature deviations identified. The Incubator/Refrigerator Temperature Monitoring Log CS 059-B version 2019-02-12 was a locally developed form that was rescinded 2020-07-13 and was replaced with form F801280 Daily Temperature Monitoring Log, which lists the range of 2°C to 8°C for acceptable temperature range for a refrigerator.

iii) DEV-21-007753 was initiated on 2021-10-15.

The Power failure alarm check was missed on the form while completing the PM A subsequent PM has been completed on 2021-10-13 successfully, including the power failure test. The PM on this model is documented electronically in RAM.

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Ottawa ON K1G 4J5

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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,

Christian Choquet

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