Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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Canada

2019-08-02
CBS Control #: CBS6335
HPFB File #: C1892-100390
REF: H-1920-GUE

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

Dear Ms. Shome-Pal:

Re: Responses to Health Canada Inspection of Guelph from 2019-06-27 to 2019-06-28

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-07-16.

Section 95 –Operating Procedures

1. Some operating procedures were not always followed. For example:

a) During the observation of whole blood collection, it was noted that Step 8, "Apply Clamp approximately 5cm from collection container" was done before Step 7, "Stop Shaker", contrary to WI 01 141: Collect Product Whole Blood, Revision 4.1.

The staff was made aware of the error during the inspection.

The Supervisor reviewed procedure 01 141, Collect Product - Whole Blood, with the employee and subsequently observed the staff to ensure that the process is completed in the correct order.

b) The 2017 Annual Key Audit for the site was not completed contrary to the requirements in section 5.2, "Perform Audit - Sites without Card Access" of SOP 13 025, Revision 6 (version applicable in 2017). The current version of SOP 13 025, Revision 7 still has the same requirements under section 5.2 and it is acknowledged that the 2018 Annual Key Audit was completed for the site with no issues identified.

A review of the 2017 key log was performed and no issues were identified. The 2019 annual key audit will be completed by 2019-09-30.

c) A completed Form F020925: Clinic Site Evaluation Checklist of the establishment was not available for review for 2015. This is contrary to SOP 01 010: Evaluate Clinic Site, Revision 8 (version applicable at the time), Section 1.1.1, "Inspection must be performed

every two years as long as the venue is being used for a clinic site." The two last clinic site evaluations that were available for review were conducted on 2017-03-02 and 2013-08-01. It is acknowledged that WI 01 010, Revision 9.1, no longer requires that active clinic sites be evaluated every 2 years without cause.

We have determined that the record was lost following an audit by a third-party audit in 2017.

Staff involved in managing records during audits will receive refresher training to SOP 08 096, Request and Original or Copy of a Record which provides instructions for records keeping during audits and inspections.

Section 117 – Records

2. Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:

a) Form 1000104195: Clinic Temperature Monitoring Log - Buffy Coat, was not always being completed consistently. Specifically, for Time noted as 2001, the Current Temperature, Acceptable Y/N, Initials, Comments/Action sections were not completed for clinic date 2019-02-20. It was also confirmed, that when there are additional temperatures other than the temperatures at the start and end of clinic, there should be corresponding notes to this.

Records were corrected on 2019-07-23 as per good documentation practices.

Clinic services and logistics personnel have been reminded to follow good documentation practices when completing and/or reviewing documents.

b) The following deficiencies were noted for equipment maintenance related records:

(i) For Docon R2090, MNT-071974, the out of service date was incorrectly recorded as 2017-01-08 instead of 2018-01-08 on the Docon Maintenance Inspection Form for PM conducted on 2018-01-09.

QER 56-19-140606 was initiated on 2019-07-22.

The out of services date was corrected on the Docon Maintenance Inspection form and uploaded into RAM on 2019-07-22.

A Digital Preventative Maintenance form – Work Plan Template for the Docon maintenance was implemented on 2018-05-07. With this change, the date is automatically inserted on the work request.

As indicated above, logistics personnel have also been reminded to follow good documentation practices when completing and/or reviewing documents.

(ii) For the Sanyo Fridge for B1 unit Elements, R2704, MNT-108855, the lower set point was incorrectly recorded as 2.6°C instead of 2.5°C on the Reach-In Refrigerator Maintenance Inspection form for PM conducted on 2019-05-03.

QER 56-19-140610 was initiated on 2019-07-22.

A preventative maintenance of the Sanyo Fridge has been performed and the alarm set point is the correct one.

Refrigerators will be transitioned to work plan templates by 2020-03-20 where the alarm setpoints will be automatically inserted in the template which will prevent this type of error.

As indicated above, logistics personnel have also been reminded to follow good documentation practices when completing and/ or reviewing documents.

(iii) For the Digital Temperature recorder in End Processing, R19812, MNT- 102119, the MNT number was recorded, incorrectly as 1022119 on the Digital Touchscreen Recorder PM form dated 2019-01-11.

QER 56-19-140607 was initiated on 2019-07-22.

The MNT number was corrected on the Digital Touchscreen Recorder PM form and uploaded into RAM on 2019-07-22.

A Digital Preventative Maintenance form – Work Plan Template for the Digital Touchscreen Record was implemented on 2019-02-08. With this change, the MNT number is automatically inserted on the work request.

As mentioned above, logistics personnel have also been reminded to follow good documentation practices when completing and/or reviewing documents.

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

cc: Anita Mahadeo
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch