Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-08-02
CBS Control #: CBS6334
HPFB File #: C1892-100390
REF: H-1920-KIT

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 Kitchener & Waterloo
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 observation of Clinic Drive Set-up for clinic date June 27, 2019, it was noted that the back of the Donation number Label (DNL) pad was not verified contrary to WI 01 371: Drive Set-Up, Revision 3.1, Section 4. Instructions, Step 2. The back of the DNL pad contains the Adhesive Expiration Date for the DNL pad in use. A training power point presentation for relevant staff provides direction to relevant staff regarding the verification of expiry dates of critical supplies during clinic drive set-up. It was further noted that WI 01 371: Drive Set Up, Revision 3.1 is silent on the verification of expiries during this activity.**

There is no requirement to verify the expiry date of DNLs during the drive set-up.

As per SOP 01 371, Drive Set-Up, Section 4, step 2, user is to enter the JOB number, which could be found on the front or back of the DNL's pad to associate clinic supplies. If an expired supply is entered during drive set-up at the donor centre, an error message will be received and will prevent the clinic from starting. All product expiry dates are entered into eProgesa before they are issued to donor centres by supply chain in Brampton Operations.

The training material provides awareness that expiry dates are important however are not entered during drive set-up as they are entered before being issued and explains that a warning message is received when an expired supply is scanned.

The observation and response were discussed with the staff during the huddle on 2019-08-02. No additional corrective action is deemed necessary.

b) **For Form 1000104195: Clinic Temperature Monitoring Log - Buffy Coat, temperatures were documented for 1110, 1509 and 1944 from the end processing digital recorder (R19587). The instructions in SOP 20 251: Cooling Trays, Operation and Maintenance, Rev 4, Step 2.2.6 instructs to document this temperature at start of clinic and at the end of clinic. It was noted that if additional temperatures were recorded then there should have been a comment associated with it, which was not done. Furthermore, written instructions around the current practice of moving product to the critical supplies room while awaiting pick up and recording the critical supply room temperature are not clearly indicated.**

The Clinic Temperature Monitoring Log – Buffy Coat was corrected as per good documentation practices.

The supervisor reviewed the steps describing the temperature recording requirements in SOP 20 251, Cooling Trays, Operation and Maintenance with the employee.

Instructions for product storage and pick up are described in SOP 01 030, Donor Centre Management and SOP 01 459, Logistics Pick-up After Donor Centre Has Closed respectively. This includes moving the product to a locked/ secured temperature monitored storage room and recording the critical supply room temperature. Staff have been reminded of the work instructions regarding product storage and product distribution from donor centres.

c) **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.

As stated, the 2018 Annual Key Audit was completed with no issues identified. The 2019 Annual Key Audit will be completed by 2019-09-30. No further actions are deemed necessary.

Section 96 –Requirements

2. **Some operating procedures were not kept up-to-date.**

   The following were noted during review of Form: F800503: Digital Touchscreen Recorder Temperature Monitoring Log:

   a) **For the form completed on the week beginning 2018/06/14, Digital Touchscreen Recorder RAM Asset ID # R19587, End Processing there was no clinic site identification recorded.**

   b) **While completing this form, it was noted that staff were recording the Clinic Site code under the comments section, to identify the clinic. However, the form itself does not have a section in which to identify the clinic site completing the log. Additionally, it was also noted that multiple sites, including this site are sending these logs to CBS Hamilton, Ancaster ON for review in which case, clinic identification on the forms becomes even more relevant.**

   The Digital Touchscreen Recorder Temperature Monitoring form captures the RAM Asset identification number of the equipment. All RAM Asset identification numbers are located in RAM and are traceable to the equipment location. No further actions are deemed necessary.

Section 98 –Personnel

3. **For training records reviewed for a Donor Services Representative (DSR), the following deficiencies were noted contrary to the relevant requirements listed on Form F800304: Initial**

Training Requirements Matrix, signed on 2019-06-05 by the Donor Centre Manager, Clinic Services:

a) **There was no documented evidence of training to version 7 of SOP 08 810: Quality Event Management – Identification and Containment. It is acknowledged that the initial training to version 2 of this SOP was done on Dec 6, 2017. Furthermore, there was no documented evidence of Performance Measurement training type to this SOP, contrary to what is required for DSRs on the training matrix for this document.**

Upon investigation, it was identified that Donor Services Representatives are only trained to the identifier role for SOP 08 810, Quality Event Management – Identification and Containment which only requires awareness training. Training to version 7 of SOP 08 810 was not required as the work instructions for the identifier role had not changed from the previous version.

The training matrix was corrected on 2019-07-18 to reflect that SOP 08 810 is awareness only for the Donor Services Representative.

b) **There was no documented evidence of Performance Measurement training to SOP 01 716: Management of Duplicate Donor at Donor Centre contrary to what is required for DSRs on the training matrix for this document. It is acknowledged that Awareness training was done to version 6 of this SOP on April 16, 2019.**

Upon investigation, it was identified that only awareness level training is required for a Donor Services Representative for SOP 01 716, Management of Duplicate Donor at Donor Centre. The training matrix was corrected on 2019-07-18 to reflect that.

Section 117 – Records

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

For example:
Form 1000106165 (2017-02-28): Premises Monthly Inspection was not always fully completed. Specifically, the "Review of Sanitation Program Completed" section was left blank on 2018-09-29 and 2019-02-28.

QER#56-19-137738 was initiated on 2019-06-28.

Facilities staff responsible for the review of the Premises Monthly Inspection form have completed refresher training for Good Documentation Practices on 2019-07-22 and were reminded of the importance of complete and accurate documentation.

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