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Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

2019-09-27
CBS Control #: CBS6334
HPFB File #: C1892-100390
REF: H-1920-KIT

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

Dear Ms. Shome-Pal:

Re: Further to the Responses to the Health Canada Inspection of Kitchener-Waterloo 2019-06-27 and 2019-06-28

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2019-08-21, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of Kitchener-Waterloo.

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.**

   Canadian Blood Services Response:

   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.

Health Canada Follow-up letter dated 2019-08-21:

What is the verification step to ensure that the original expiries that are entered by supply chain are accurate?

Canadian Blood Services Response:

Upon receipt of donor number labels (DNLs) at the site, every lot of DNL is released by quality assurance following procedure 30 011, Acceptance of Critical Supplies, Section 1 for the assessment of shipments. Quality assurance staff also verifies the lot number and the expiry date of the DNL entered into SAP before they can be issued to the clinics. The supplies are then entered into eProgesa to ensure traceability of which DNL are used at the time of collection.

A new work instruction 01 460, Issue Supplies to Donor Centre has been created to further implement controls when preparing supplies for the clinic. Step 1 will instruct staff to confirm all expiry dates are acceptable and to discard any expired supplies. Procedure 01 460 will be implemented in November 2019.

In addition, considerations will be given to adding a verification step for the information entered into eProgesa as part of future opportunities to improve this process.

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.

Health Canada Follow-up letter dated 2019-08-21:

Please provide copies of SOP 01 030 and SOP 01 459 for review and indicate the relevant sections.

Canadian Blood Services Response:

Attached are procedures 01 030 and 01 459 (see Attachment 1 and Attachment 2). The relevant sections are as follows: SOP 01 030 v13.1 step 9 and the associated attachment 4; SOP 01 459 v1 steps 1 and 2.

Section 96 - Operating Procedures

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.**

   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.

   Health Canada Follow-up letter dated 2019-08-21:

   Upon completion of review, how are these records maintained, especially since multiple sites are sending these records to CBS Hamilton, Ancaster ON for review? Based on the response to this observation, does the reviewer look up the clinic sites based on the RAM ASSET IDs of the digital touchscreen recorders identified or do they rely on the clinic site code identified in the Comments section of the form? Please clarify.

   Canadian Blood Services Response:

   In the event where the clinic site identification is not included on the Digital Touchscreen Recorder Temperature Monitoring Log, including the comments section, the reviewer will search the RAM ID# for the permanent donor centre location and subsequently file the monthly documents under the permanent donor centre location.

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.

Health Canada Follow-up letter dated 2019-08-21:

The observation identified that there was documented evidence of training to version 2 of SOP 08 810 although version 7 is the current version for this SOP. The response indicated that training would not be required to version 7 for this staff. Please confirm which versions of SOP 08 810, the staff was trained to prior to the implementation of version 7 for this SOP.

Canadian Blood Services Response:

The Donor Services Representative staff is trained only to the Identifier role for 08 810. The staff was trained to version 2 only. Versions 3, 4, 5 (not implemented), 6 and 7 had no changes in the process that would be applicable to the Identifier role, therefore no training was required.

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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