Canadian Blood Services
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2017-11-15
CBS Control #: CBS6113
HPFB File #: C1892-100390
REF: H-1718-LON

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

Dear Ms. Rave:

Re: Responses to Health Canada Inspection of Licensed Activities at London 2017-09-27 to 2017-09-29

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-10-18.

Section 41 – Donor Suitability Assessment

1. **When assessing the donor's suitability, the establishment did not obtain sufficient information for determining the presence of risk factors for diseases transmissible by blood. On the donor medical questionnaires for donations C05561727278400X (Clinic L0001, clinic date 16/08/2017) and C05561719311300L (Clinic L0001, clinic date 12/05/2017), it was documented that the donor had travelled to Puerto Plata, Dominican Republic in the last 12 months. However, the city/resort in the province of Puerto Plata was not documented, thereby making it difficult to assess if the donor had travelled to a malaria risk city/resort, as listed in 01 200, Donor Selection Criteria Manual, Part 2, Section D (Version 8).**

   Quality Event Report # 56-17-112207 was initiated and reviewed with the RN involved on 2017-10-04. The RN was also reminded of the appropriate malaria documentation requirements as per SOP 01 200, Donor Selection Criteria Manual.

   In addition, feedback will be provided to screening staff through a Read and Sign Memo to be completed by 2017-11-30.

Section 41 – Donor Suitability Assessment

2. **The establishment did not accurately assess the donor's suitability. For donation C05561719311300L (Clinic L0001, clinic date 12/05/2017), documentation on the donor medical questionnaire for the physical examination was discrepant. For example, question A4 ("Do you have any allergies?") had a "Yes" answer whereas the follow-up question A5 ("allergies – identify") had a "NONE" answer.**

   Quality Event Report # 56-17-112207 was initiated and reviewed with the staff member involved on 2017-10-04 highlighting the need to ensure documentation accurately reflects the donor's suitability as per SOP 01 144, Screen Donor and SOP 01 059, Perform Physical Examination (Plasmapheresis).

In addition, this observation will be shared with screening staff via a Read and Sign Memo to be completed by 2017-11-30.

Section 75- Distribution

3. The establishment did not use shipping containers capable of resisting damage and maintaining the safety of the blood. The shipping containers used for transporting frozen blood components to the distribution and production centre were not qualified for their use.

Improved insulated shipping containers qualified for shipping frozen products will be implemented with the final phase of the shipping process project. The new processes will be in place in Q1 of FY 18/19. With the implementation of these new insulated shipping containers in the near future, and the long-standing use of the current shipping containers, which have demonstrated over that time their adequacy to maintain the safety of the blood, no interim measures are being proposed.

Please also note that all shipments of frozen components between CBS sites are visually inspected upon receipt to confirm that the products have not been damaged and that they are not thawing and were maintained frozen during the shipment.

Section 94 - Quality Management System

4. The document control or records management system was not sufficient. The Clinic Kitting Check Sheet Daily Red Carts and Packs used to record supplies sent to mobile clinics was not document controlled.

This Clinic Kitting Check Sheet is a tool to aid in work efficiencies and is used by the Kitting staff to help them in sending sufficient quantities of supplies to the clinic. The Material Master numbers are tracked in eProgesa to maintain traceability of the supplies used on clinic. As such, no corrective actions are deemed necessary.

Section 95 - Operating Procedures

5. Some operating procedures were not always followed. While observing the collection process for a plateletpheresis donor (Clinic L0001, clinic date 27/09/2017), step 1.8 of procedure 01 143, Collect Product- Plateletpheresis, (Revision Number 4) was not followed in the correct sequence. For example, the sample diversion pouch (SDP) was disconnected prior to the specimen tubes being inverted.

Quality Event Report # 56-17-112215 was initiated on 2017-10-04. It was verified in ePROGESA on 2017-10-04 that no issues were noted regarding the testing performed for this unit.

Feedback was provided to the individual involved during the inspection on 2017-09-27 highlighting the need to follow the steps in sequence as outlined in SOP 01 043, Collect Product-Plateletpheresis.

In addition, this observation will be shared with all plateletpheresis staff via a Read and Sign Memo to be completed by 2017-11-30.

Section 117 - Records

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

a) The MABAG Service Report KLF (V2.2) containing the preventative maintenance (2015-10-19) for the blast freezer (R000003495) did not list the serial number in the designated spot at the top of the record.

The Service Report was corrected on 2017-10-19. The Supervisor who performed review of the Service Report as per SOP 09 350, Management of Equipment by Owners Step 3.2 Review Service Documentation was made aware of the observation on 2017-10-11.

This observation and expectations of the supervisory review will also be shared at the Supervisors Meeting on 2017-11-28. If any Supervisors are not in attendance, they will be required to review the observation upon their return.

b) The PocH-i Maintenance and QC Log (R15286; 2017-05-01 to 2017-05-11) was not supervisory reviewed. During the inspection, a late entry review was completed.

This observation and expectations of the supervisory review will be shared at the Supervisors Meeting on 2017-11-28 to emphasize the importance of supervisory review. If any Supervisors are not in attendance, they will be required to review the observation upon their return.

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,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch