Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Canada

2019-09-26
CBS Control #: CBS6356
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REF: H-1920-NB

Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
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Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Licensed Activities at Saint John Operations
2019-08-19 to 2019-08-22

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-08-30.

Section 94 - Quality Management System

1. **Procedures 08 810 Ver 7 (effective 2019-04-02) Quality Event Management-Identification and Containment and 08 811 Quality Event Management-Deviation Disposition Ver 4.1 (effective 2019-03-25) do not provide adequate instructions to ensure that the investigation of errors or accidents are thoroughly investigated and appropriately documented on the Quality Event Report (QER). For example, the following QERs did not adequately document the event including what happened, what was involved (e.g. equipment, personnel, etc.), what caused the event, what actions were taken by all staff and departments and how to prevent the issue from recurring.**

   a) QER# 71-19-126872 involved the over-collection of whole blood (weight 880 g) using docon R0998 on May 20, 2019. Procedure 01 141 Ver 4.1 Collect Product-Whole Blood Attachment 5 describes actions to be taken when a whole blood unit is over collected (refers to procedure 20 100-01 Ver 5 .1 Docon Trouble Shooting Guide "Overcollection"). Problem 15 Overcollection (Docon Trouble Shooting Guide) lists the potential reasons for an overcollection to occur and actions to be taken to prevent recurrence. The QER documented that the docon was assessed with the standard 585 g weight and determined ok. The other potential reasons for overcollection listed in the trouble shooting guide were not documented as assessed. It was verbally indicated that this type of issue is usually related to user error or docon error. There was no documentation to indicate whether user error was investigated, determined to be the cause or how to prevent reoccurrence of the issue.

b) QER# 71-19-127105 involved the over-collection of whole blood (weight 877 g) using a docon (no identification number documented) on June 24, 2019. There was no documentation to indicate how this event was investigated to identify the reasons for the overcollection or how to prevent reoccurrence.

c) QER# 71-19-127113 involved the incorrect labeling of samples for whole blood collection C05711964207820X where the samples were mislabelled with DNL 057119642081006. There was no documentation that described how this event was investigated to identify the reasons for its occurrence or how to prevent reoccurrence.

All three quality event reports identified in this document were reviewed and the risk assessments were found to have been performed correctly, and all three events were deemed to be low risk.

In an ongoing effort to continually improve our Quality Management System, an automated Quality Event Management process will be implemented on 2019-10-28, at which time the initiator will be prompted to enter specific information related to the description of the quality event. This will further provide information to enable thorough investigations and accurate risk assessments to be completed.

Section 95 – Operating Procedures

2. **Some operating procedures were not always followed:**
   a) Contrary to procedure 01 144 Ver 13 (effective 2019-06-02) Screen Donor, the following first time donors did not have their height and weight documented.
   Donor 6071835 donation Feb. 19, 2018
   Donor 6005676 donation Feb. 21, 2018
   Donor 5798996 donation Feb. 21, 2018
   Donor 6274205 donation Mar. 12, 2019
   Donor 6310012 donation Mar. 12, 2019
   Donor 63I0013 donation Mar. 12, 2019

   QER # 71-19-121977 was initiated on 2019-08-21.

   ePROGESA will be updated to make the entry of the height and weight of new donors between the ages of 17 and 23 a mandatory entry no later than 2020-06-30. Once ePROGESA is updated, staff will not be able to proceed to the next step without entering the information.

   In the interim, all Collections staff will be reminded to document the height and weight of new donors between the ages of 17 and 23 as per SOP 01 144 v15.1, Screen Donor Step 6 no later than 2019-10-31.

   b) Contrary to procedure 02 301 Ver 30 (effective 2018-07-18) Bacterial Detection Testing for Release of Platelet Components step 3.5.5, the Lab Assistant did not allow the septum of the BPA bottle to air dry prior to inoculating the culture bottle. In addition, the procedure does not specify the exact time required to allow the septum to dry.

   The staff member involved will be re-trained to ensure that there is a clear pause to allow for air drying as per 02 301, Bacterial Detection Testing for Release of Platelet Components.

Section 117 – Records

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

   a) The lot numbers for the normal and high quality controls for the Hematostat II were not documented correctly on the Hematostat II Verification and Maintenance Record. QC testing was performed from Aug. 6 to 14, 2019 before this error was discovered.

   QER # 71-19-121976 was initiated on 2019-08-20.

   The correct lot number for the normal and high controls were documented in the comments section of the Hematastat II Verification and Maintenance Record during the inspection. Feedback was provided to staff involved to ensure they are confirming the correct lot number is recorded on the form.

   b) The Daily Vehicle Inspection Record for vehicle 127086 performed on 2018/08/07 did not have the BTS utilized checked when the BTS unit was used for transport of blood components. It was noted that the temperature monitoring records for the BTS unit was part of the record.

   The Daily Vehicle Inspection Record was corrected. Daily Vehicle Inspection Records from 2019-01-01 to 2019-08-31 were reviewed and two additional records needed a similar correction. In addition, staff were reminded of the importance of good documentation practices during a staff meeting.

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: Shelley Smyth
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch