Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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2019-07-09
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Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Licensed Activities at Dartmouth Operations 2019-05-13 to 2019-05-17

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-06-12.

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:**

   An unsure response was given to the question Have you ever had malaria? by donor 6294983 for donation C05711960882600P and the Donor Care Associate who screened the donor did not address this response in the screening room and update the record of donation. The donor was documented as acceptable to donate and the whole blood unit was collected. The unit was automatically rejected by Progesa at receipt at the production centre and was discarded. As a consequence of identifying this error, the donor deferral code M002 was placed on this donor during the inspection.

   QER 71-19-126843 was initiated on 2019-05-17.

   Feedback in the form of a memo was provided to clinic staff on 2019-05-17 emphasizing the importance of following SOP 01 144 Screen Donor to address all exceptional and unsure responses.

Section 94 - Quality Management System

2. **The process of using a Problem Solving Worksheet to identify corrective actions and preventative actions does not ensure that processes involved in the original Quality**

Event Report are accurately articulated so appropriate corrective and preventative actions are identified and proposed.

For example, CAPA 19-000016 was initiated as a result of QER 71-19-121229 where red blood cells were transported using series 22 plates instead of series 4 plates. CAPA 19-000016 indicated in step 4: Root Cause Analysis, that the series 22 plates and series 4 plates are stored in the same fridge. This is not correct, as series 22 plates are stored at 22-24 degrees C and series 4 plates are stored at 4 degrees C in separate maintain incubators set specifically to these temperature requirements. This was confirmed with the site where the incident occurred. Corrective Actions and Preventative Actions was identified and proposed based on this misinformation and ultimately no Corrective Actions or Preventative Actions were implemented to correct the issues identified and prevent their reoccurrence.

CAPA-19-000016 and QER 71-19-121229 were reviewed by the CAPA team. The initial investigation indicates a discrepancy in information provided to the CAPA Root Cause investigator. Examination of the process to ensure that it is not a systemic issue will be carried out by randomly sampling a subset of completed CAPAs. A further review and assessment to allow for appropriate corrective actions will be completed by 2019-08-31.

<u>Section 94 – Quality Management System</u>

3. **There is no process to ensure that the labeled volume of all blood components processed meet the specifications documented in the circular of information. For example, red blood cell unit C0511864878300F was released for distribution even though the labeled volume was 418 ml. The circular of information indicates the volume should be 293 +/- 26 ml. Additionally, procedures for performing end labeling and distribution do not require the labeled volume of blood components to be verified.**

The mean volume of a red cell unit for the time periods of July 2017 to June 2018 and July 2018 to May 2019 are 290 ± 24 ml (n = 7,749) and 289 ± 24 ml (n= 7,046), respectively. The unit noted in the observation is simply an outlier.

An upper volume limit of less than 390 ml verified during component production was implemented on 2018-10-22 (SOP 02 256.001, Preparation of Initial Components – Whole Blood Filter System and SOP 02 739.001, Review of Production Records). Any red cell unit above this volume is rejected. The unit noted above was collected on 2018-05-31, before the upper volume limit was introduced.

<u>Section 95 - Operating Procedures</u>

4. **Some operating procedures were not always followed:**
   a) Contrary to procedure 01 144 Rev 10 (effective 2019-01-07) Screen Donor, the following donors were not screened as required:
   i) Height and weight was not obtained for first time donors 6294992 donation C05711960886300F and 9295980 donation C05711960790300A

   QER# 71-19-111665 was initiated on 2019-05-17.

   SOP 01 144 Screen Donor v 12 was revised and implemented on 2019-04-29 to clarify work instructions on when height and weight must be obtained for first time donors. The collections that were reviewed took place on 2019-01-22 and 2019-01-2, respectively, prior to implementation of the revised process. All staff completed the training to the revision prior to implementation.

   b) Contrary to Job Aide J800066 Venepuncture not attempted-Whole blood, the phlebotomist did not enter the reason donation C0571 I 863916400B was not drawn.

QER# 71-19-111664 was initiated on 2019-05-17.

Job Aid J800066, Venipuncture Not Attempted – Whole blood, PDA entry and J800058 Scenarios at Bedside: Whole Blood were reviewed with the staff member directly involved in the omission. In addition, a read and sign memo indicating the observation and work instructions to be followed has been sent to and completed by all staff.

c) Contrary to Job Aide J800065 Restart venepuncture-Whole blood, the phlebotomist did not complete part 2-Assign the new DNL properly for donor 3004329 donations C05711865301700S and C05711865302200Y.

The process as described in J800065 was followed correctly, in that a new DNL is to be assigned to restart a venipuncture. Our collection process is designed in such a way that if initial venipuncture is not successful, and if staff is going to proceed with the second venipuncture, then the new collection pack with the new set of labels will be used. Both donation numbers will appear for the donor in the eProgesa for this date, with initial donation status as "not drawn".

The discrepancy was in the information provided to the inspector, i.e. that a new DNL should not be assigned. This was incorrect. The staff was made aware of the error, and there was no further misunderstanding on the process.

Section 117 - Records

5. Records were not always accurate, complete, legible, indelible and/or readily retrievable:
a) QER 71-18-127090 did not document how the event was discovered as required by the Quality Event Report 1000107140 (2017-02-21)

Feedback was provided to all production and distribution staff to emphasize the importance of accurately and completely documenting the description of event as per SOP 08 810 Quality Event Management – Identification and Containment, Attachment 7.

b) The Generator Preventive Maintenance dated 2019-02-27 did not document the Work Order number issued for performing the replacement of the outlet ventilation actuator.

The Generator Preventive Maintenance record was updated with the Work Order number generated at the time of the maintenance. All other records were reviewed to ensure that there were no further documentation errors.

The documentation error was discussed during the inspection with the staff involved. No further corrective actions were necessary as the staff involved completed training on the new version of 13 021 Generator Operation and Maintenance on 2019-03-22 which provides work instruction for documentation of the work order number for the purpose of tracking maintenance.

c) The following Confirmation of Employee Training records for a shipper/receiver documented the job title as Donor Care Associate:
i) Equipment Services 09 351 Create RAM Request
ii) Equipment Services 09 350 Management of Equipment by Owners
iii) Construction & Facilities Operations 13 036 viewLinc Operations

The Confirmation of Employee Training (CET) records referenced were generated within one week of the employee transferring from a DCA role into the shipper/receiver role. All CETs records for the shipper/receiver have been reviewed and no other errors were identified. The CETs in question have been corrected as per Good Documentation Practices. As of

2019-05-22, trainers have been reminded to verify the accuracy of job titles.

d) The Confirmation of Employee Training CET#LOG2A for a shipper/receiver did not document the employee name of pages 3 and 4 of the record.

The Confirmation of Employee Training was corrected upon discovery as per good documentation practices. Trainers were reminded to check this area for completion.

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

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Vice-President
Quality & Regulatory Affairs
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cc: Anita Mahadeo
A/Supervisor – Blood, Tissues, Organs and Xenografts
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