Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-09-23
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Ms. Farah-Michelle Manigat
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Manigat:

Re: Responses to Health Canada Inspection of Licensed Activities at Oshawa 2019-07-22 to 2019-07-24

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-08-22.

As many of the observations relate to records keeping and good documentation practices, all staff at Oshawa will be required to attend an educational session on "Documentation and chain of custody" in addition to the actions described below. This session will focus on the importance and requirements of clear, accurate and complete record keeping.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example,**
   a) **While observing collection on July 22, 2019, it was noticed that the specimens (tubes) were collected prior to entering the shaker ID and accepting the Donation time. This is contrary to Work Instruction 01 141, titled: Collect Product-Whole Blood, revision number 4.1, effective date: 2019-06-24, where employees are to complete all the steps related to step 8 (initiate collection), prior to moving on to step 9 (Collect Specimens).**

   QER#56-19-125369 was initiated on 2019-07-22.

   The steps in Work Instruction 01 141 Collect Product-Whole Blood were reviewed with the staff involved at the time of the inspection.

b) The reviewed by and date were left blank on the Compolab TM Hemoglobinometer Verification Log for MNT-079654. This is contrary to step 1.9.2 of procedure number 27 036, titled: Compolab TM Hemoglobinometer Verification, revision 5, effective date 2015-06-22, where employees are instructed to "Sign and date for review on CHVL".

The uploaded log was reviewed and signed off on 2019-07-24 and uploaded into RAM as required by SOP 09 356, Equipment Services Work Management during the inspection.

c) Initials were missing on the circle chart initiated on 2018-12-29 for equipment R2710. This is contrary to step 1.1.2 of procedure number 01-56-003, revision 8, effective date 2017-11-20, which states: "document the start date, asset ID, location and initials on the back of the new chart".

d) According to step 1.2.1 of procedure number 01-56-003, revisions 6 and 7, titled: Refrigerator/Freezer/Incubator Monitoring and Maintenance - Permanent Site, effective dates 2016-09-19 and 2017-03-06, the "temperature readings for refrigerators/freezers (excluding Interim Storage Refrigerator) will be documented at the beginning of each clinic when operating and every 4 hours until clinic end". This was not performed when looking at the Refrigerator Temperature Logs of November 21, 2016, (1st reading at 08:45. 2nd reading at 13:45. 10 minutes past due) and December 10, 2017 where the 2nd reading was taken after 5 hrs (1st reading at 09:35. 2nd reading at 13:45) for R 2710. That equipment is currently used to store the elements and it was confirmed that it was not an interim storage refrigerator.

Combined response for 1c and 1d:

The circle chart initiated on 2018-12-29 was reviewed and no issued were identified.

The temperature logs and the circle charts were verified for each freezer and refrigerator in question, it was determined that the temperatures were always within specifications. Notations were added to the temperature logs and circle charts explaining each gap as per good documentation practices.

A memo will be distributed by 2019-09-13 reminding staff of the importance of ensuring that the temperature is recorded on temperature logs every four hours as per COP 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance-Permanent Site.

Section 98 - Personnel

2. The records of staff qualifications, training, or evaluation of their competency were not sufficient. For example,

a) The Pathophysiology-Written Competency Exam for a Donor Care Associate (DCA) was not reviewed. The assessor name, initials/signature and date were missing (i.e. left blank). There is therefore no indication as to whether the DCA passed or failed this exam, as there was also no grading of the answers.

On review of the Pathophysiology-Written Competency Exam, the Donor Care Associate was found to have passed, however it was documented on the first page instead of the final page. A comment regarding the missing documentation was placed on the exam. Trainers were reminded to complete all required documentation.

b) According to step 2.3.2 of procedure number 08 553, revision 3, effective date: 2017-03-31, employees were instructed to "Ensure employees complete section 2 of Confirmation of Employee Training forms upon completion of training". Employees were further instructed in step 2.4.1 to "Review Confirmation of Employee Training forms for completeness and accuracy. Complete section 4 of the form." Those instructions were not followed in these instances:
A) A PHL signed off for his/her training on 2017-07-12. While the reviewer confirmed that training on 2017-06-05. (i.e. a month and a few days prior to training)
B) An employee signed 6 Confirmations of Employee Training on 2017-06-28, while the reviewer signed all of those documents on 2017-06-27. (i.e. the day before training for those 6 occasions).

Site Trainers were reminded on 2019-08-27 to follow 08 553, Deliver Training when signing and reviewing Confirmation of Employee Training forms.

Section 117 - Records

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

a) According to the guidelines and responsibilities listed in the DCA Precepting Guidance Document, version 2016-06-11, nurses are to ... "Scan the DNL" ... "Following this review, initial beside the applicable DNL". Those instructions were not followed during the 4 occasions listed here, when reviewing the DCA Training-Precepting Document, version 2017-03-16:

i. C0556 17 409614 (collected 2017-10-18)
ii. C0556 17 430968 (collected 2017-11-09)
iii. C0556 17 430972 (collected 2017-11-09)
iv. C0556 17 430976 (collected 2017-11-09)

b) Yes or No was not check marked to indicate whether a nurse had to take over for the review of a question for Donor ID 6138556 on the Record of Consultation dated 2017-11-01.

c) An employee start date was listed as 2016-03-03 on the Health and Safety Awareness Checklist, while the employee and reviewer signed the form on 2015-03-03. It was confirmed that the accurate start date for that employee was 2015-03-03 and that the year 2016 was inaccurate.

d) The dates entered by an employee on the Confirmation of Employee Training, form F800329, version 2015-02-02, were not legible in that one year appears to be 2006 on one page and 206 on another page for the same type of form for that same employee. The year was 2016.

e) The Hemoglobin Analyzer Daily Maintenance Log, form F801369, version 2018-12-04, was not reviewed for the Month of June 2019. The reviewed by Supervisor/Designate and date were left blank.

f) The Calibration Due Date recorded on the Freezer Temperature Log, form F800001, version 2011-08-15, was 2017-05-10 for verifications performed on 2017-04-13 and 2017-04-14. The Calibration Due Date on those dates was in fact 2017-10-12.

Combined response for 3a, 3b, 3c, 3d, 3e and 3f

As stated above, all staff will attend an educational session on "Documentation and chain of custody". This session will focus on the importance and requirements of clear, accurate and complete record keeping within the Supply Chain before the end of the fiscal year.

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