Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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2019-07-12
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REF: H-1920-KEL

Ms. Lesley Beaton
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
#400-4595 Canada Way, 4th Floor
Burnaby, British Columbia V5G 4P2

Dear Ms. Beaton:

Re: Responses to Health Canada Inspection of Licensed Activities at Kelowna 2019-05-27 to 2019-05-29

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-06-17.

Section 95 – Standard Operating Procedures

1. **Some SOPs were not always followed:**
   a) **Contrary to SOP 01 144 v.12, Screen Donor, during donor screening of Donor C051019552553002 at the Kelowna fixed site on 2019-05-28, the DCA did not get the donor to state his full name, rather the donor only stated his first name before starting screening. The donor did however confirm the accuracy of the information in eProgesa.**

   QER10-19-139554 was initiated on 2019-05-29.

   The observation was immediately discussed with the staff member and was asked to review SOP 01 144, Screen Donor. The staff member was then observed performing two donor screening on that day and the procedure was performed correctly.

   b) **Contrary to the DSCM requirements the following were noted while reviewing completed eProgesa records –**

      I. **For eProgesa record C05101952335200Q from Vernon mobile clinic V0055 dated 2019-03-05 the eProgesa records indicated yes for ASA yet neither of the two medications listed on the donor record (Metformin and Synthroid) contained ASA. Buffy coat was rejected at production based on ASA response.**
      II. **For eProgesa record C05101951338900W from Kelowna permanent clinic V0005 dated 2019-02-12 the donor answered yes to having a sore throat and the one day deferral code C001 was applied rather than the L001 one day deferral code.**

   QER #s 10-19-139388 and 10-19-139387 were initiated on 2019-05-30.

The observations were reviewed with both staff members involved who were then observed by a trainer to ensure that the correct process is followed when using the DSCM.

Section 98 – Personnel

2. **The records of staff qualifications, training or evaluation of their competency were not sufficient:**
   a) **A number of Confirmation of Employee Training records at the Vernon Mobile Clinic had not yet been completed by all required staff and the implementation dates had passed. Specific examples included:**
      I. **08 810 and 08 193 effective 2019-04-02**
      II. **T08599 v.15 effective 2019-05-13**

      QER # 10-19-139745 was initiated on 2019-05-29.

      Staff have now completed all training that were incomplete at the time of the audit. The Supervisor/charge will verify on a regular basis that training has been completed by staff prior to implementation supported by completed Confirmation of Employee Training (CET) forms.

   b) **Review of Logistics training records and the Logistics training matrix found no records of training for two warehouse attendants and two drivers from Kelowna on version 3 of SOP 12 011, Digital Touchscreen Recorder Operation, which was effective 2019-01-21.**

      QER # 10-19-139393 was initiated on 2019-05-31. Training has been completed and training files for the respective employees updated accordingly.

      Until the learning management system is implemented, a training binder for logistic staffs will be created and management will follow up regularly to ensure all training is completed in a timely manner and supported by confirmation of employee training records.

Section 117 – Records

3. **Records were not always accurate, complete, legible, indelible and/or retrievable:**
   a) **Review of the completed Temperature Monitoring Records for 2018 and 2019 for the cooling element refrigerators, J82 ice pack freezer, NIT ice pack freezer and critical supply warehouse at the Kelowna permanent site found numerous examples of missing or out of range data with no additional comments from either the person that completed the record or the Manager that completed the review.**

      QER # 10-19-139392 was initiated on 2019-05-31.

      Kelowna Logistics staff were reminded to ensure any anomalies, whether they be omissions or temperature excursions, are to be documented on the Temperature Monitoring Record, and a QER initiated by the individual who discovers the anomaly as per COP 2556, Verification and Cleaning of Refrigerators and Freezers. Refresher training to COP 2556 and COP 5012, Supply Temperature Monitoring and Segregation has been completed by Kelowna Logistics staff.

   b) **The Dec 2018 Kelowna Temperature Monitoring (Chart Recorder) – Freezer had the initial Asset ID as R6137 (-8 to -14 range) but the Asset ID was error corrected to R6566 (< -30 degrees) on 2019-01-07 with no confirmation of accuracy as the temperature readings for the month were between -8 and -14 which was the R6137 range.**

      QER # 10-19-139391 was initiated on 2019-05-30.

      All charts and corresponding circular graphs for all assets at the Kelowna facility for the entire months from the dates selected during the inspection were examined and all records were found to be accurate indicating that this is an isolated incident. Refresher training on SOP 08

851, Manual of Good Documentation Practices and COP 3093, Manual Room Temperature Records has been completed by the individual involved.

c) **The Clinic Temperature Monitoring Log – Buffy Coat dated 2019-02-08 for Kelowna clinic (V0055) was missing the Thermometer ID of the Informer.**

QER # 10-19-139386 was initiated on 2019-05-30.

Feedback was provided to the staff who will also complete refresher training to 08 851 Manual of Good Documentation Practices by 2019-07-14.

d) **The Blood Transportation System Inspection Record for BTS #134305 dated 2019-03-14 was identified prior to the inspection as missing the Transcan Receipt which confirms maintenance of BTS temperatures however no QER or follow up was documented.**

QER 10-19-139390 was initiated on 2019-05-30.

Refresher training to SOP 08 810, Quality Event Management – Identification and Containment will be completed by staff responsible for the review of the Blood Transportation System Inspection Records to ensure that any missing information is evaluated and investigated in accordance to the Quality Event Management process. Refresher training will be completed by 2019-09-30.

e) **The incorrect version (2016-08-25) of The Weekly Digital Touchscreen Record Review – PCM Equipment forms (F800788) were used on 2019-02-04 and 2019-02-12. The version dated 2018-04-12 was effective 2019-01-21.**

QER # 10-19-139389 was initiated on 2019-05-30.

Both staff members trained to warehouse responsibilities completed training to SOP 12 011, Version 3, Digital Touchscreen Recorder Operation on 2019-06-19. All copies of the prior version of form F800788 (2016-08-25) were removed from the Kelowna warehouse. Staff were immediately made aware to only print the amount of forms required from the Controlled Document Index as per 08 042 Use of On-Line Controlled Documents.

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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A/Supervisor – Blood, Tissues, Organs and Xenografts
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