Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
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Canada

2019-01-22
CBS Control #: CBS6263
HPFB File #: C1892-100390
REF: H-1819-BCY-L

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 Vancouver Operations 2018-12-03 to 2018-12-07

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-01-03.

Section 39 – Door Suitability

1. **The establishment did not accurately assess the donor's suitability:**

   Donor C05101857166400V at mobile clinic V0045 dated 2018-06-14 was not screened as required in that the donor indicated they had taken ASA in the last 3 days yet the "Medications contain ASA" option was not selected resulting in this unit incorrectly being used for B1 Buffy Coat platelet production.

   QER# 10-18-132414 initiated on 2018-12-07.

   SOP 01 200 Donor Selection Criteria Manual, Part 1, Section A regarding medication containing ASA was reviewed with staff involved on 2018-12-28.

   In addition, the Clinic Supervisor has observed the staff perform assessment and documentation of medications and the staff has demonstrated the necessary competence.

Section 95 – Operating Procedures

2. **Some operating procedures were not always followed:**

   a) Contrary to SOP 12 308 v.8, Physical SAP Inventory, the 2018 records of inventory counts and clearance of discrepancies were incomplete for the year in that only records for May - July 2018 were available. Furthermore, the June and July inventory records included numerous changes to the counts and there were no initials nor dates to indicate who had completed these count changes.

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QER 10-18-123172 was initiated on 2018-12-04.

The managers and warehouse staff reviewed SOP 12 308 Physical SAP Inventory. In addition, schedules were developed for the weekly inventory counts for Oak street, Victoria, and Kelowna warehouses.

In addition, staff will be retrained to SOP 08 851 Manual of Good Documentation Practices by 2019-01-18 to ensure compliance to good documentation practices.

b) Contrary to SOP 01 144 v.10, Screen Donor, the height and weight was not obtained for first time donor C05101855571100C at clinic V0001 dated 2018-05-02 although the donor was < 23 years of age.

QER# 10-18-132411 was initiated on 2018-12-05.

SOP 01 144 Screen Donor and SOP 01 200 Donor Selection Criteria Manual Part 1, Section W, X, Y & Z weight criteria were reviewed with staff involved on 2018-12-19.

Clinic Supervisor has observed the staff perform assessment and documentation of this step and the staff has demonstrated the necessary competence.

SOP 01 144 Screen Donor will be revised to clarify work instructions on when height and weight must be obtained for first time Donors. Implementation is targeted for 2019-09-30.

c) Contrary to CBS procedures on controlled documents, three uncontrolled versions of documents were found in logistics. Specifically, an uncontrolled copy of SOP 27 036 (Compolab TM Hemoglobinometer Verification) and Directive D30483 (CompoLab TM Use of Cuvettes and Controls) were found as well as a copy of rescinded Directive D30540 (CompoLab TM - Verification Prior to Implementation).

QER 10-18-132408 was initiated on 2018-12-04.

Uncontrolled documents were removed from the area.

Staff was reminded of the importance of document control and to either utilize the Controlled Document Index or request controlled copies from Document Control to ensure work tasks and activities are completed using only current approved procedures.

Section 98 - Personnel

3. The records of staff qualifications, training or evaluation of their competency were not sufficient:

Review of Logistics training records found two logistics attendants with incomplete training records. Specifically training on the current version of SOPs 12 304 (v.9), 12 308 (v.8) and 12 809 (v.4) were missing for both logistics attendants. In addition, records of training on SOPs 12 012 (v.1), 12 920 (v.4) and 12 921 (v.4) were missing for one of the logistics attendants.

QER# 10-19-124628 was initiated on 2019-01-09.

The trainer attested to the presence of the individuals at the training sessions and CETs were generated for those procedures they were trained to. One staff member did not have the training for SOP 12 809 Managing Temperature Excursions for Plasma Protein Products - Canadian Blood Services Sites, however that employee does not perform the associated duties.

Section 100 - Equipment

4. Following a repair or change, critical equipment was not revalidated or recalibrated:

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There was a preventive maintenance failure for walk in cooler, WIC 4976, on 2018-09-12 and although brazing and welding work was undertaken to fix Compressor 1 on 2018-09-18 and the compressor 1 function was confirmed, the complete preventive maintenance was not repeated on this walk in cooler following the repair work.

QER# 10-19-104908 was initiated on 2019-01-03.

The staff involved was retrained to the procedure to ensure that preventive maintenance is repeated upon completion of repairs.

The preventive maintenance on walk-in unit WIC 4976 was done on 2018-12-07 and met all requirements.

Section 117 – Records

5. Records were not always accurate, complete, legible and/or readily retrievable:

a) Both the viewLinc and RAM records for two continuous monitoring devices (VAN 3403/R19508 and VAN 3402/R19506) listed the incorrect warehouse location for the devices. Specifically, VAN 3403 was listed as being in Warehouse B and VAN 3402 was listed as being in Warehouse A, however the locations were reversed. Review of the viewLinc records since May 1, 2018 found no alarms or temperature deviations for either sensor.

QER# 10-18-132412 was initiated on 2018-12-06.

Loggers R19506 and R19508 were corrected on 2018-12-20 to read 'VAN 3402 Warehouse B Room Temperature' and 'VAN 3403 Warehouse A Room Temperature' in viewLinc and in the description sections of the RAM Asset record accordingly.

b) A couple of Daily Vehicle Inspection Records for BTS #127099 (RAM R6080) were missing entries on the Daily Blood Transportation System Inspection records and although these errors had been identified the follow up notes did not include any comments on the risk assessment of this missing data.

QER 10-18-132413 was initiated on 2018-12-07.

BTS printouts confirmed that the temperature was within the specified range at the time collections were loaded as well as during transit.

SOP 01 016 'Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log', and its associated job aid J800031 'Blood Transportation System: Driver's Operating Manual' was reviewed with staff.

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: Hugo Tremblay
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