Canadian Blood Services
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2018-10-19
CBS Control #: CBS6233
HPFB File #: C1892-100390
REF: H-1819-CAL

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

Re: Responses to Health Canada Inspection of Licensed Activities at Calgary Operations from 2018-09-10 to 2018-09-14

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-09-28.

Section 95 - Operating Procedures

1. Some operating procedures were not always followed.

a) Contrary to Standard Operating Procedures, a review of the following equipment records for the identified months revealed that, although the records were complete, they had not been reviewed and signed by the Supervisor or a designate.

i) GSE Scale Daily Calibration for scale with RAM ID 5139, from May to August 2018

ii) Compodock Maintenance Log - Daily & Weekly for Compodock with RAM ID 4858, from May to August 2018

iii) Compomat Maintenance Log - Daily & Weekly for Compomat G4s with RAM IDs 4863 and 5318, for August 2018

iv) Daily Buffy Coat Volume Logs and Monitoring Charts for Compomat G4s with RAM IDs 4863 and 5318, for August 2018

v) General Equipment Maintenance - Weekly and General Equipment Maintenance - Monthly, which includes the weekly and monthly maintenance of refrigerator RFG-001 and Centrifuges with RAM IDs 4845, 4849, 4843 and 16281, for August 2018.

It was acknowledged by the Production Manager that none of the records for any of the calibration/maintenance routinely performed by laboratory staff, for any of the Scales, Compodocks, Compomat G4s or Centrifuges in use had been reviewed and signed by the Supervisor or a designate from May to August 2018. He also acknowledged that none of the Daily Buffy Coat Volume Logs/Monitoring Charts had been reviewed and signed for any of the Compomat G4s in use during the same date range.

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QER # 20-18-138528 was initiated on 2018-10-09.

All impacted records were supervisory reviewed upon discovery by the Distribution Supervisor.

The training plan for the Production Supervisor will be updated by 2018-11-30 to ensure it properly reflects the requirements of the position, including the review of equipment records per their corresponding Standard Operating Procedures to the role and duties.

The Production Supervisor will complete all required training by 2018-11-30. In the interim, the Distribution Supervisor will continue to review the equipment maintenance records.

Designates to perform the supervisory review of equipment records will also be put in place. They will be trained by 2018-12-31.

b) Contrary to Section 4.1 of SOP 13 002 Pest Control, a revised Trap Location Map had not been created since 2015-09-18, even though traps had been removed and trap locations had been changed since that time. Instead undated and unsigned hand written notations had been added to the existing map. In addition, the existing maps for the Basement and 2nd Floor had not been signed and dated as "Verified" as had the maps for the other floors.

The pest control trap map was revised and version controlled as per SOP 13 002 Pest Control at the inspection on 2018-09-12.

Review of the monthly inspection reports from September 2015 to September 2018 indicated that monthly inspections were completed as required and all the traps were inspected to the schedule.

Finally, the pest control requirements described in SOP 13 002 Pest Control were reviewed by the facilities 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

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

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