Canadian Blood Services
Société canadienne du sang

1800 Alta Vista
Ottawa, ON K1G 4J5
T 613.739.2300 F 613.731.1411
www.blood.ca www.sang.ca

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Ms. Anita Mahadeo
Regulatory Compliance & Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Mahadeo:

Re: Responses to Health Canada Inspection of Licensed Activities at Ottawa Sub-Centre 2017-07-12 to 2017-07-14

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-08-14.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example:**
   a) **Job Aid "Scenarios at Bedside: Whole Blood" (J800058) was not followed for a whole blood donation (C055516695490000). The fifth specimen sample field was blank on the technical questionnaire in ePROGESA. The Job Aid indicated that, when all specimens, are not obtained, additional specimen information is to be selected (e.g., Incomplete Specimen Set). However, this additional information was not entered into ePROGESA since the response to the question "WB – Is there any Specimen Information?" was "No" on the technical questionnaire.**

   Upon investigation, it was identified that donation C055516695490000 was a Directed Donation. As such SOP 01 141, Collect Product –Whole Blood was followed correctly as a B19 specimen sample is not required for a Directed Donation. Therefore, all specimens had been collected and there was no additional specimen information to enter in eProgesa.

   b) **Operating procedure CO 061 "Temperature Monitoring of Critical Supplies", version 2.0, effective June 30, 2015 was not followed on January 22, 2017 and March 21, 2017 for monitoring room temperature using the chart recorder R15908. Operating procedure CO 061 states to document daily monitoring on the Critical Supplies Temperature Monitoring Log. However, there were no entries on the log for January 22, 2017 and March 21, 2017. It was confirmed that the clinic was open on these dates.**

   Records from the Temperature Chart recorder in this clinic area were reviewed for the 2 dates in question and the temperature was within specifications.

   The observation will be reviewed with the Clinic Services staff in a memo format outlining the importance of following procedure CO 061 and ensuring daily documentation of the temperature is completed. This memo will be circulated for read and sign with completion by 2017-10-31.

c) Operating procedure 13 022, "Premises Cleaning", Revision 2, was not followed for performing a monthly inspection in April 2017. For example, a completed Premises Monthly Inspection Form for April 2017 was not provided during the inspection when requested.

A review of the Premises Monthly Inspection Forms was completed and it was determined that April 2017 was the only missing record. The completion of the Premises Monthly Inspection Form for 1575 Carling was added to the computerized maintenance management system to prevent missing tasks effective 2017-05-01.

Section 117 – Records

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

a) On the April 2017 Incubator/Depot Refrigerator Temperature Monitoring Log for the platelet incubator (R1453), the temperature reading documented for April 14, 2017 was not complete (i.e., only one digit was recorded and legible, and it could not be verified whether the temperature was within the acceptable range of 20-24 degrees Celsius).

A review of the Interim Storage Record (F020009) for this date showed that the incubator was within specifications when Apheresis platelets were placed into the incubator. There is no overnight storage in this incubator.

The observation will be reviewed with the Clinic Services staff in a memo format outlining the importance of following proper Good Documentation Practices and ensuring any documentation of the temperature is complete and legible. This memo will be circulated for read and sign with completion by 2017-10-31.

b) The next Preventive Maintenance (PM) due date recorded on the PM label for the Trima apheresis equipment (R1387) was not accurate (i.e., March 14, 2018). During the inspection, it was confirmed, in RAM, that the next PM due date is September 14, 2017.

The PM Interval is identified as Semi Annual maintenance activity on the RAM Schedule. The PM label was corrected, scanned and uploaded in RAM.

c) The calibration due date for a temperature reference equipment (R1925) was not recorded on the Independent Chart Recorder Maintenance Inspection form completed January 5, 2017. During the inspection, the calibration report for the reference equipment was attached in RAM and it was confirmed that the calibration had not expired during the maintenance of the chart recorder performed on January 5, 2017.

The due date was recorded on the form and the incomplete form in RAM was replaced with the corrected one and reviewed.

d) There were two records for the maintenances performed on CompoLab TM Hemoglobinometers on May 10, 2017 (i.e., for CompoLabs R12701, R12718, R12727, R12732, R12747, R16849, R17458, R17459, R17465 and R17462). These maintenances were recorded on the CompoLab TM Hemoglobinometer Verification Log. For the same maintenances performed:

- **The log attached in RAM indicated that it was reviewed by the Department Manager / Designate on May 10, 2017; and**
- **The copy of the log provided to the Inspector indicated that the log was reviewed on May 11, 2017 by the same person.**

The scanned document signed on May 10th, 2017 was kept as the original record for these 10 CompoLab devices as per SOP 08 113, Scanning Documents. The document dated May 11, 2017, which consisted of the original scanned document that had also been forwarded to and signed upon receipt by the Department Manager was destroyed.

A review of SOP 08 113 was completed by 2017-07-17 with the staff member involved providing clarification of the scanning process.

e) The reviewed by and date fields were blank on page four of the Critical Supplies Temperature Monitoring Log for April 2017. This review related to the temperature monitored on April 29, 2017 only.

The document was reviewed and temperatures were within specifications.

Supervisor involved was made aware of this omission during the audit process. All Supervisors were advised of this error by email by 2017-08-31 and instructed to be attentive to ensure all documents are reviewed.

f) On the Helmer Platelet Incubator Maintenance Inspection for R1453, completed June 13, 2017, the "Last Done" and "Next Due" date fields for the section referring to replace all batteries annually was not completed.

The record was corrected based on the dates on the previous quarterly maintenance record, uploaded in RAM and reviewed. The battery is still within date and is due to be changed at the next PM interval.

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: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch