Canadian Blood Services
Société canadienne du sang

1800 Alta Vista Drive
Ottawa ON K1G 4J5
T 613-739-2300 F 613-731-1411
www.blood.ca www.sang.ca

2017-11-27
CBS Control #: 6115
HPFB File #: C1892-100390
REF: H-1718-WIN

Ms. Shelley Smyth
Compliance Specialist
Biological Products Compliance Program
Regulatory Operations and Regions Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba
R3C 4W1

Dear Ms. Smyth:

Re: Responses to Health Canada Inspection of Licensed Activities at Winnipeg 2017-10-16 to 2017-10-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-11-02.

Section 44 - Donor Suitability Assessment

1. **It was observed at the clinic held on October 16, 2017 that an Apheresis donor was not verbally instructed to contact CBS should he develop any illness noted in the pamphlet within time frames identified as per the instructions in SOP 01 144 "Screen Donor" Revision 5.**

   Individual feedback was provided to the employee during the inspection on 2017-10-16 and this employee reviewed the missed steps with the donor prior to their departure from the clinic.

Section 95 - Operating Procedures

2. **Some operating procedures were not always followed. For example:**
   a) For the ESPEC freezer R000018292 the Quarterly Preventative Maintenance Checklist completed by an external provider was not signed and dated as reviewed by a CBS employee (Equipment Owner/Operator) for Preventative Maintenance inspections completed on June 26, 2017 and September 18, 2017, which is contrary to SOP 09 350 "Management of Equipment by Owners" Revision 4.

   In both cases, the Quarterly Preventative Maintenance Checklist had been reviewed as required by the Supervisor as part of processing the service documentation and forwarding it to the Equipment Services staff for entry into RAM. All results were within specifications.

   The record was reviewed at the time of the inspection and a notation to address the missing entries was made on the records in accordance with SOP 08 851 V.5 Manual of Good Documentation Practice.

   The observation was brought to the attention of the Logistics Supervisor to emphasize the importance of the completeness of his review. Additionally, the Logistics Supervisor completed

retraining to SOP 09 350, Management Equipment by Owners V.04 on 2017-10-24.

b) The NDAS Alarm History Review Log (form# 1000104971) initiated by the Logistics department for July 2017 was not completed in a manner to record each daily review throughout the month, which is contrary to SOP 13009 "NDAS Site Operation" Revision 9.

This deficiency was identified in a previous audit. The QER that was initiated at the time, QER 40-17-111134, which included corrective actions was reviewed during the inspection. The Health Canada inspector was presented with evidence that since then documentation has been performed in accordance with the SOP. No further corrective actions are deemed necessary.

Section 107 - Investigation and Reporting

3. **There was no Error/ Accident reported to Health Canada relating to the Adverse Transfusion Reactions #40-17-800001AR and #40-17-800002AR that were caused by a transfused double platelet unit that had false negative BacT test results. These adverse transfusion reactions were reported to Canada Vigilance on August 28, 2017.**

   40-17-800001AR and 40-17-800002AR were reported on 2017-08-30 as Adverse Transfusion Reactions to the Health Canada Marketed Health Products Safety and Effectiveness Information Bureau, as required by section 110 of the Health Canada, Blood Regulations.

   The request to also report this issue as an Error/Accident creates unnecessary duplicate reporting.

   This item will be brought forward for discussion at the Bilateral Meeting between Health Canada and Blood Operators in December 2017.

Section 117 – Records

4. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**
   a) The Clinic Site Evaluation Checklist for Site W0121 (University of Manitoba) evaluated on 2017-09-11 was documented as signed by the department Manager on 2016-09-20 when the correct date was 2017-09-20.

   The record was corrected at time of the inspection in accordance with SOP 08 851 V.5, Manual of Good Documentation Practices.

   b) The record for the Reach in Refrigerator/Freezer Maintenance Inspection for the Freezer R000017761 completed on 2017-09-01 did not have an entry of PASS or FAIL indicated under section B - "Check Audible and Visual annunciations of alarms" and "Check renunciation of alarms when muted or placed in standby".

   Since the inspection, a preventive maintenance has been completed on the Reach-In Freezer R000017761 and all results were within specifications.

   Additionally, the importance of completion and verification of documents prior to upload and acceptance into RAM will be emphasized to staff at a meeting to be held no later than 2017-11-30.

   c) The record for "The Percival Step Rate Incubator Series 4 PM" for R000018068 completed on 2017-10-13 did not have an entry of PASS or FAIL indicated under Section E: Probe Verification and section F: Functional Checks and Maintenance.

   Since the inspection, a preventive maintenance has been completed on the Percival Step Rate

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Incubator R000018068 and all results were within specifications.

Additionally, the importance of completion and verification of documents prior to upload and acceptance into RAM will be emphasized to staff at a meeting to be held no later than 2017-11-30.

d) The record for the Walk-in Cooler/Freezer Maintenance Inspection for RFG 0023 completed on 2016-11-08 did not have an entry of PASS or FAIL indicated for the first part of the section relating to the Evaporator Cabinet under System #2.

A review of the quarterly Walk-in Cooler/Freezer Maintenance Inspection records for RFG-0023 dated 2016-08-11 and 2017-02-09 indicated that all criteria were within specifications. The NDAS trend logs for RFG-0023 for the period 2016-08-07 to 2017-02-13 were also reviewed and there were no temperature excursions identified. This documentation error was discussed with the Refrigeration Service Provider on 2017-11-07 and the Service Technician completed the Self-Study Module T08851-SS-FAC, Recording Information on Canadian Blood Services forms – FACILITIES CONTRACTORS on 2017-11-08 prior to performing the next scheduled quarterly inspection and maintenance.

e) The record for the Weekly Generator Inspection for WIN-GEN-077 that was completed on 2017-08-23 under Section 2: DC System Batteries and Charging Equipment under 2.1 was marked as N/A when this should have been checked during the inspection and under 2.3 there was no check mark or indication of N/A.

This documentation error was discussed with the Facilities staff member involved during the inspection on 2017-10-20. Additionally, Facilities staff were re-trained to SOP 08 851 V5, Manual of Good Documentation Practices on 2017-11-07.

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