



Canadian Blood Services
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2018-07-11
CBS Control #: CBS6208
HPFB File #: C1892-100390
REF: H-1819-DAR

Ms. Victoria Hurlbut
Compliance Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
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Dear Ms. Hurlbut:

**Re: Responses to Health Canada Inspection of Licensed Activities at Dartmouth Operations
2018-05-28 to 2018-06-01**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-06-18.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed.**
 - a) **Contrary to 02 304 Load/Unload Negative Culture Bottles (Version 5 effective 2017-10-23) step 1.3, the Bacterial Detection Testing record for test date 2018-01-06 did not have initials indicating greater than or equal to 6 hours had elapsed since the last bottle load time on the audit trail and test result (6995) was complete.**
 - b) **Contrary to 02 040 Identifying Units/Components Requiring Special Handling (Version 12 effective 2018-04-23), the Production Exception Record dated 2018-04-23 lavender batch did not have an NA checked for red cell unit C05711860960720B to indicate the red cell unit had been determined to meet production and storage timeframes and did not require to be rejected.**

Combined responses a) and b)

The records were corrected at the time of the inspection as per SOP 08 851 Manual of Good Documentation Practices using verifiable sources. Feedback was provided to staff emphasizing the importance of good documentation practices.

- c) Contrary to the Donor Selection Criteria Manual, the donation deferral code L001 was not applied to donor 3015665 on July 24, 2017 when the donor's systolic blood pressure was too high to allow donation of whole blood.**

QER# 71-18-106816 was initiated at the time of the inspection on 2018-06-01.

SOP 01 144 Screen Donor and Donor Selection Criteria Manual guidelines for blood pressure were reviewed with the staff member involved on 2018-06-11.

Section 117 - Records

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable.**
a) **The PCM Conditioning Cycles for R000018103 Series 4 (Stage 2) Percival performed on April 27, 2018 was documented as April 26, 2018.**

The date on the PCM Conditioning Cycles was corrected at the time of the inspection on 2018-06-01 using the temperature chart from the Digital Touchscreen Recorder chart as a verifiable source. All PCM Conditioning Cycles records from the last 3 months were reviewed and no deficiencies were identified. The observation has been reviewed with all Logistics staff.

- b) **The T05128-Observation Checklist for one employee (IL) did not have the employee's job title and location documented.**

The record was corrected on 2018-06-20.

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