



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-12-17

CBS Control #: CBS6384

HPFB File #: C1892-100390

REF: H-1920-WIN-L

Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

**Re: Responses to Health Canada Inspection of Licensed Activities at Winnipeg Operations
2019-11-18 to 2019-11-22**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-12-02.

Section 98 - Personnel

1. **The training records for a new driver had the following deficiencies:**
 - a) **The CET for Living Our Brand did not have Section 4-Reviewer Confirmation completed.**
 - b) **Various records requiring performance measurement did not have Section 3-Trainer Confirmation completed.**

DEV# 19-001043 was initiated on 2019-11-27.

Records were corrected as per 08 851 Manual of Good Documentation Practices.

A review of all current employee training records in Logistics was performed. Thirty-four (34) documentation deficiencies were identified that will be corrected by 2020-01-31.

A review of SOP 08 553 Deliver Training and associated documentation was completed by the Logistics Manager on 2019-12-11 and will be completed by the Supervisor by 2020-01-31.

Section 117 – Records

2. **Whole Blood Component Assessment/Production Record B 1 (clinic 2018-10-15), processing completion 2018-10-16, was not supervisory reviewed and dated.**

MQE-19-000286 initiated on 2019-11-19.

The staff member responsible for the review was made aware of the importance of reviews and documentation of such. The Whole Blood Component Assessment/Production Record-B1 was corrected as per 08 851 Manual of Good Documentation Practices on 2019-11-19.

The Whole Blood Component Assessment/Production Record-B1 is no longer required with the

implementation of the new production methods.

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: Shelley Smyth
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch