

2017-06-07
CBS Control #: CBS6061
HPFB File #: C1892-100390
REF: H-1718-DAR

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
Dartmouth Production and Distribution Site
2017-05-01 to 2017-05-05**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-05-19.

Section 95 - Operating Procedures

- 1. Section 2 Retrieving Paper Records, step 2.6 of 08 092 Rev 7 Transferring and Retrieving Paper Records To/From Offsite Storage (effective 2016-01-11) is not performed as prescribed by this procedure. For example, boxes received from the Service Provider are taken directly to the requester by ITFS/Shipper-receivers and not stored in the secure storage room. In addition, when the shipper-receivers deliver the boxes steps 2.6.4 to 2.6.6 which includes the verification steps performed by ITFS, occurs after the requester has received the boxes (step 2.8). There is no statement in the procedure allowing steps to be performed in an alternate order.**

All IT Field Support (ITFS) staff and shipper/receivers will be retrained to SOP 08 092, Transferring and Retrieving Paper Records To/From Offsite Storage by 2017-07-31.

SOP 08 092 will be revised to clarify the work instructions to ensure that the chain of custody of records is followed and all verification steps are completed in order. This will be completed no later than 2017-10-15.

Section 117 - Records

- 2. Records were not always accurate, complete, legible, indelible and/or readily retrievable.
a) Form F800354 (20 15-09-02) Driver File Checklist did not document "Hiring Qualification Documents" for a CBS driver.**

Form F800354, Driver File Checklist was corrected at the time of the inspection on 2017-05-04.

Feedback was provided to the supervisor responsible for the completion of the forms. The supervisor will undertake a review of all records for existing drivers by 2017-06-30 to ensure F800354, Driver File Checklist is completed as required.

b) The height and weight of first time donors under the age of 23 was not documented for donations C057 116494598009 and C057 11712161000F.

Non-conformance Reports 71-17-325088 and 71-17-325090 were initiated on 2017-05-19.

The Clinic Supervisor reviewed the weight and height criteria as per SOP 01 200 Donor Selection Criteria Manual with staff involved on 2017-05-24 and 2017-05-30.

In addition, all staff will be reminded of the appropriate DSCM criteria at a clinic huddle on 2017-06-05.

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