



2017-07-13  
CBS Control #: CBS6072  
HPFB File #: C1892-100390  
REF: H-1718-VIC

Ms. Lesley Beaton  
Regional Regulatory Compliance and Enforcement Specialist  
Regulatory Operations & Regions Branch  
Health Products and Food Branch Inspectorate  
#400-4595 Canada Way, 4<sup>th</sup> Floor  
Burnaby, British Columbia  
V5G 4P2

Dear Ms. Beaton:

**Re: Responses to Health Canada Inspection of Licensed Activities at Victoria Collection Site  
2017-06-06 and 2017-06-07**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-06-16.

**Section 39 -Donor Suitability Assessment**

1. The eProgesa record for donation C051017148636000 from the Nanaimo mobile clinic (V0032) dated 03/05/2017 stated that the date of shingles vaccine was April 15, 2017 but the required shingles vaccine 90 day deferral (V090) was input with a vaccination date of 08/04/2017 resulting in an assigned deferral time shorter than required. The deferral was to 07/07/2017 rather than the required 14/07/2017. No units have been collected from this donor since the date of the shingles vaccine.

NCR # 10-17-316982 was initiated during inspection and donor was contacted and confirmed the date of vaccination was April 15, 2017 and deferral date was updated in eProgesa.

*The staff member involved completed refresher training to SOP 01 373, Manage Deferrals, Version 3 and J800093, PROGESA Entry Manage Deferrals Version 2016-08-05 on 2017-06-30.*

**Section 98 – Personnel**

2. The records of staff qualifications, training or evaluation of their competency were not sufficient.
  - a. The following Logistics staff Confirmation of Employee Training Records were not available:
    - i. Training of two Logistics Attendants on v.12 of SOP 07 791, Progesa Mobile Kit Preparation, which was implemented 2017-02-13.

*Nonconformance Report # 10-17-332708 was initiated on 2017-06-08.*

*Logistics staff completed change update training to SOP 07 791, Progesa Mobile Kit Preparation, Version 12 on 2017-07-12. Logistics will also complete a self-audit of training records by 2017-09-08 to ensure completeness and accuracy.*

**ii. Training of a Driver III on v.9 of SOP 01 016, Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log, which was implemented 2017-01-16.**

*Nonconformance Report # 10-17-332711 was initiated on 2017-06-08.*

*The driver will complete training to SOP 01 016, v.9, Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log by 2017-07-31. Logistics will also complete a self-audit of training records by 2017-09-08 to ensure completeness and accuracy.*

**b. The Victoria clinic staff responsible for completion of the monthly premises inspection were not able to present a copy of the Sanitation Program Document during the on-site inspection yet the May Premises Monthly Inspection record had been completed, including checking of the "Review of the Sanitation Program Completed". SOP 13 022 v.3 was implemented May 27, 2017 and the training record for this SOP had been signed off by the Manager and Supervisor in May 2017.**

*An explanation as to what the Sanitation Program document was and the role of the site contact in terms of the sanitation program was provided in writing to the Manager and Supervisor by Facilities on 2017-06-27. A copy of this written communication and the Sanitation Program document has been placed in the cleaning binder at the Victoria site.*

**Section 117 – Records**

**3. Review of SOP 01 016 v.9, Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log, and the April/May 2017 Daily Vehicle Inspection Records and Daily Blood Transportation System Inspection Records for BTS Vehicle #124350 identified the following examples of incomplete records:**

**i. No Supervisory review of the Daily Vehicle Inspection Records and associated Daily Blood Transportation System Inspection Records on April 18, 2017 and between May 2-31, 2017. Furthermore it was noted that two of these records included comments under "Comments (document alarms/excursions)" and a few others had incomplete entries on both Section B (Vehicle Log) of the Daily Vehicle Inspection Record and Section A of the Daily Blood Transportation System Inspection Record.**

**ii. The April 25, 2017 Daily Blood Transportation System Inspection Record was signed off by the Supervisor although the document included no identifying information.**

**iii. The April 18 and 26, 2017 Daily Blood Transportation System Inspection Records had been supervisory reviewed but were missing a selection for "Remote alarm device with vehicle Y or N"**

*Combined Response for 3i, 3ii and 3iii:*

*The importance of complete and accurate documentation and of its review was provided to the staff responsible for completing and reviewing the Daily Vehicle Inspection Records (DVIRs) and associated Daily Blood Transportation System Inspection Records on 2017-06-09.*

*The DVIRs and Daily Blood Transportation System inspection records noted in the observation have been reviewed for accuracy and completeness*

*In addition, all DVIRs and associated documentation from January 2017 to present will be reviewed by 2017-09-08 to ensure completeness and accuracy.*

*The process flow has also been modified to ensure the timeliness of completion and review of the DVIRs and associated documentation.*

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