

2018-12-17
CBS Control #: CBS6260
HPFB File #: C1892-100390
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Ms. Victoria Hurlbut
Biologic Products 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 St. John's Operations
2018-11-19 to 2018-11-23**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-11-30.

Section 95 • Operating Procedures

1. Some operating procedures were not always followed.

a) Contrary to SOP 01 144 Rev 09 (effective 2018-07-09) Screen Donor, the height and weight was not obtained for first time Donor 6262983 on October 17, 2018 and Donor 6241006 on August 21, 2018 although the donors were < 23 years of age.

QER # 90-18-114773 was initiated on 2018-11-22.

On 2018-11-22, individual feedback was provided to the involved staff and the procedural requirements for donor height and weight were reviewed.

The observation was discussed with all clinic staff on 2018-11-29.

SOP 01 144 Screen Donor will be revised to clarify work instructions on when height and weight must be obtained for first time Donors. Implementation is targeted for 2019-09-30.

b) Contrary to SOP 13 036 Rev 02 (effective 2018-04-30) ViewLinc Operation, initials were not documented on the ViewLinc Daily System Checks (F800968 (2017-07-18) for September and October 2018 for the system check, threshold check and alarm check. In addition, the comment section was not completed as prescribed by the procedure.

Review of the logistics records generated since the implementation of viewLinc confirmed that all checks were completed as required.

Warehouse staff and logistics supervisor reviewed the requirements of SOP 13 036 v2 viewLinc Operation on 2018-11-22 and 2018-11-23 respectively.

Section 117 - Records

2. Records were not always accurate, complete, legible, indelible and/or readily retrievable.

a) The Daily Vehicle Inspection Record dated 2018-03-06 for the BTS van (asset number 130862) did not have the "BTS Equipped, indicate" box checked and did not document whether the BTS unit was utilized during the vehicle use.

Based on the destinations indicated on the Daily Vehicle Inspection Record, the vehicle was not used to transport products and the BTS was not utilized.

The record was corrected on 2018-11-22 as per SOP 08 851, Manual of Good Documentation Practices.

The requirements of the Daily Vehicle Inspection Record were reviewed with the involved staff on 2018-11-22.

b) The ViewLinc Daily System Checks forms completed by Production/Distribution had the following issues:

i) The September 2018 form did not document the Site.

ii) The October 2018 form did not document the Site and the comments added to the form to explain why readings were not taken were not representative of the actual circumstances that occurred.

Corrections of the records were completed on 2018-11-23 as indicated in viewLinc alarm reports. The records for viewLinc daily system checks and associated viewLinc alarm reports since the implementation in August 2018 were reviewed and no further issues were identified.

All staff responsible for completing and reviewing the viewLinc Daily System Checks forms were reminded of the importance of completeness and accuracy during the inspection.

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