



**Canadian  
Blood  
Services**

BLOOD  
PLASMA  
STEM CELLS  
ORGANS  
& TISSUES

1800 Alta Vista Drive  
Ottawa ON  
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Canada

2020-02-04

CBS Control #: CBS6389

HPFB File #: C1892-100390

REF: H-1920-MON

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

Dear Ms. Hurlbut:

**Re: Responses to Health Canada Inspection of Licensed Activities at Moncton  
2020-01-07 and 2020-01-09**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-01-15.

**Section 95 - Operating Procedures**

**1. Contrary to procedure 01 144 Rev 16 (effective 2019-12-02) Screen Donor the following was identified:**

- a. While observing the repeat hemoglobin testing of a donor during screening, it was noted that the screener entered the first repeated hemoglobin result in eProgesa to accept the donor for screening. Procedure 01 144 Screen Donor requires the screener collect two cuvettes from the donor and test both samples using the compolab but only enter the second hemoglobin result in eProgesa to accept the donor for donation.**

*Deviation # DEV-20-000626 was initiated on 2020-01-23.*

*Feedback was provided to the staff involved on 2020-01-09 to clarify the procedure and ensure that the correct hemoglobin value is entered as per WI 01 144 Screen Donor. Staff were made aware of the observation during the clinic huddle. A read and sign memo indicating the observation and work instructions to be followed was distributed to staff to be completed by 2020-01-31.*

- b. The height and weight was not obtained for the following first time donors who were less than or equal to 23 years of age:**

- i. Donor 6191307 (C057118624739003) on March 26, 2018. In addition, the deferral question was answered yes but there was no reason for this donor to be deferred.**  
**ii. Donor 6116219 (C057 II 715005500V) on August 25, 2017.**

*Deviation # DEV 20-000647 was initiated on 2020-01-24.*

All collections staff have been reminded to document the height and weight of new donors between the ages of 17 and 23 as per SOP 01 144 v15.1, Screen Donor Step 6.

ePROGESA is also scheduled to be updated to make the entry of the height and weight of new donors between the ages of 17 and 23 a mandatory entry. This is currently scheduled for implementation by 2020-09-30. Once ePROGESA is updated, staff will not be able to proceed to the next step without entering the required information.

## **Section 117 - Records**

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

**a. The following temperature monitoring records were not accurate or complete:**

**i. For the Sanyo Refrigerator (R0626) on June 5, 2019, the decisions for temperatures acceptable and whether there were graph excursions were not documented.**

**ii. For the critical supplies storage area:**

**a) On October 28, 2019, the decision for the temperature acceptable had both yes and no documented.**

**b) On June 13, 2019, the digital display (degrees C) was not documented.**

*Minor Quality Event # MQE-20-000255 was initiated on 2020-01-23.*

*All temperature monitoring records from January 2019 to present were reviewed for both fridges and the storage area and there were no temperature excursions or documentation errors noted.*

*Staff were made aware of the observation during the clinic huddle. A read and sign memo indicating the observation and work instructions to be followed was distributed to staff to be completed by 2020-01-31.*

**b. The training matrix for the Clinic Supervisor indicated that performance measurement was required for initial training of procedure 01 376 Manage Post Donation Information. It was confirmed that a Clinic Supervisor requires awareness training for this procedure. The new Clinic Supervisor received awareness training for this procedure.**

*MQE# 20-000247 was initiated on 2020-01-23.*

*The training matrix has been corrected to indicate that awareness training is required. It will be reviewed by 2020-02-14 to ensure there are no additional errors.*

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