



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-09-26
CBS Control #: CBS6360
HPFB File #: C1892-100390
REF: H-1920-SUR

Ms. Lesley Beaton
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
#400-4595 Canada Way, 4th Floor
Burnaby, British Columbia
V5G 4P2

Dear Ms. Beaton:

**Re: Responses to Health Canada Inspection of Licensed Activities at Surrey
2019-08-28 to 2019-08-29**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-09-04.

Section 95 - Operating Procedures

1. Contrary to SOP 01 144 v.13, Screen Donor, the following were noted while reviewing completed eProgesa records-

i. First time donor C051019585801006 (age 20) at Burnaby mobile clinic (V0008) on Aug 11, 2019 did not have the height and weight documented.

QER-10-19-139525 was initiated on 2019-08-29.

ePROGESA is already 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 planned to be implemented no later than 2020-06-30. Once ePROGESA is updated, staff will not be able to proceed to the next step without entering the required information.

In the interim, all Collections staff will be 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 no later than 2019-10-31.

ii. Donor C051018660195004 at Surrey clinic (V0003) on Dec 20, 2018 was deferred after consent due to height/weight requirements but before venipuncture however the phlebotomy type was not changed to "*" not drawn".

Feedback was provided on 2019-09-05 to the staff member, followed with a review of WI 01 144, Screen Donor Step 6. In addition, the Clinic Supervisor observed the staff complete an assessment and documentation of this step to ensure necessary competence as part of their performance assessment.

Section 117 - Records

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable.**
a) **The annual Maintenance of Informer Thermometers (F800268) for Informer R15461 was completed 2018-11-19 but the PM date on the record was documented as 2019-11-19 and the "as found PM due date" and "out of service date" were missing on the form which had been supervisory reviewed.**

QER# 10-19-145178 was initiated on 2019-08-29.

The records were reviewed and corrected as per the date in the RAM system that was associated with the event. The RAM record was updated with the reference to the QER. In addition, staff involved were reminded of the importance of Good Documentation Practices.

- b) **The current (August 2019) critical supply room Temperature Monitoring Record (FV05009) for Surrey clinic (V0003) listed the Asset ID of the Informer 2 as R15641 but it was actually R15461.**

The record was corrected by the Clinic Supervisor utilizing the RAM number on the Informer 2 as a valid source on 2019-08-28. A contributing factor to the error was the positioning of the Informer which made the reading of the RAM number difficult, the Informer 2 was relocated for easier access/ better visualization of the Asset ID number.

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