

2017-11-02
CBS Control #: CBS6103
HPFB File #: C1892-100390
REF: H-1718-EAU

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

**Re: Responses to Health Canada Inspection of Licensed Activities at Eau Claire Market
2017-09-11 to 2017-09-22**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-10-11.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example:**
 - a) **Donor #3500191 was deferred for a high systolic blood pressure on 10/07/2017 but the 1 day deferral code L001 was not assigned in eProgesa as is required according to Part B of the DSCM.**

eProgesa was updated on 2017-10-17 to reflect the deferral history and the associated quality event.

A direct entry CAPA was initiated on 2017-10-17 to investigate potential root causes and corrective/preventative actions. Individual feedback was provided at the time of the observation and the process reviewed by the Clinic Services trainer. Further follow-up with the individual has demonstrated compliance to the process.

Feedback was provided in the minutes of the Clinic Services staff meeting on 2017-10-25 that all staff are expected to read and sign off no later than 2017-12-31 as some staff may not be scheduled for work for several weeks.

- b) **Contrary to required procedures as stated by the Clinic Manager, during donor screening a screener did not turn the computer screen to have the donor confirm that his demographic information already entered into eProgesa was correct (donation C052017316827207). Instead, the screener compared the information in eProgesa with what was written on the donor's driver's licence.**

Individual feedback was provided at the time of the observation and the process reviewed by the Clinic Services trainer. Further follow-up with the individual has demonstrated compliance to the process.

As indicated above, feedback was provided in the minutes of the Clinic Services staff meeting on 2017-10-25 that all staff are expected to read and sign off no later than 2017-12-31 as some staff may not be scheduled for work for several weeks.

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