



**Canadian  
Blood  
Services**

BLOOD  
PLASMA  
STEM CELLS  
ORGANS  
& TISSUES

1800 Alta Vista Drive  
Ottawa ON  
K1G 4J5  
Canada

2019-11-28  
CBS Control #: CBS6364  
HPFB File #: C1892-100390  
REF: H-1920-LET

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 Lethbridge**  
**2019-09-26**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-10-10.

**Section 95 - Operating Procedures**

- 1. Contrary to Section 2 of SOP 25 050 Vital Signs Monitors, Verification and Maintenance, Rev. 6, monthly maintenance was not performed on the Carescape monitor with RAM ID #R000013235 for the month of June, 2019.**

*The review of records from May 2019 and July 2019 demonstrated monthly maintenance had been completed and there were no observed deficiencies. In addition, according to the daily verification records conducted in June, the equipment was operating within acceptable limits. Feedback was provided to the staff member involved at the time of 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