



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-11-08
CBS Control #: CBS6363
HPFB File #: C1892-100390
REF: H-1920-CAL-R

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 Registered Activities at Calgary Operations
2019-09-16 to 2019-09-27**

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 100 – Equipment

1. **The establishment did not ensure that critical equipment was validated, calibrated, cleaned or maintained properly. According to the Calculation of Irradiation Setting (F040449), the calculation to determine the irradiation setting for the irradiator that was done on 2019-04-02, which is to be performed every 6 months, was not done until two days after the previous Calibration Expiry Date of 2019-03-31.**

QER# 20-19-107557 was initiated on 2019-10-23.

The 2 day delay in the calculation of the irradiator setting had no impact on the irradiator setting as the difference in the setting since the last calibration, i.e. 6 months prior to this one, was 3 seconds.

The schedule for the timer check on the irradiator has been added in RAM.

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