



2019-01-21  
CBS Control #: CBS6263  
HPFB File #: C1892-100390  
REF: H-1819-BCY-R

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

Dear Ms. Beaton:

**Re: Responses to Health Canada Inspection of Registered Activities at Vancouver Operations  
2018-12-03 to 2018-12-07**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-01-03.

**Section 95 – Operating Procedures**

1. **Contrary to COP 3916 v2.0, Production Equipment Operation and Maintenance, the speed and temperature for centrifuge R14973, located in the washing/freezing production room, was not recorded on each day of centrifuge use. It was indicated that staff were directed during a training session that this was no longer required however the COP had not been updated to reflect this change.**

*QER#10-18-132409 was initiated on 2018-12-04.*

*COP 3916 Production Equipment Operation & Maintenance was updated to remove the requirement to record the speed and temperature of the centrifuge while performing daily maintenance. The revised procedure was implemented on 2019-01-14.*

**Section 100 – Equipment**

2. **There was no documentation available to demonstrate that the Jan and Feb 2018 preventive maintenance of the ACP-215, Automated Cell Processor, had been completed.**

*QER#10-18-132230 was initiated on 2018-12-04.*

*It was confirmed that all preventive maintenance records for the ACP-215 from December 2017 and from March 2018 to present were completed without any issues and are available.*

*Feedback was provided to staff regarding good documentation practices and retention requirements for weekly and monthly maintenance records.*

**Section 117 – Records**

3. **The Irradiator Setting results were not accurately recorded on the Irradiator Maintenance Log for Feb - May 2018 in that the irradiator setting was calculated to be 3 minutes 36 seconds in Dec 2017, however the setting was recorded on the form as 3 minutes 35 seconds.**

*QER#10-18-132235 was initiated on 2018-12-07.*

*Feedback was provided to staff and the supervisor emphasizing the importance of good documentation practices. Retraining on SOP 25 055 Irradiator Maintenance will be completed by 2019-02-28.*

*In addition, it was confirmed that there was no risk to patients.*

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