



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, 4th 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