

2017-06-26
CBS Control #: CBS6062
HPFB File #: C1892-100390
REF: H-1718-STC

Ms. Supriya Rave
Regulatory Compliance & Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Rave:

**Re: Responses to Health Canada Inspection of Licensed Activities at
St Catharines Donor Clinic
2017-05-08, 2017-05-09 and 2017-05-12**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-06-05.

Section 94 - Quality Management System

1. **The establishment did not carry out corrective and preventive actions when required. The Clinic Site Evaluation Checklist for clinic H0003 conducted on 2015-06-23 and supervisory reviewed on 2015-06-25 was contradictory in that both "Unsatisfactory" and "No impact (Satisfactory)" were check marked for the wireless impacts evaluation.**

The Clinic Site Evaluation Checklist was corrected on 2017-05-26 to indicate that the wireless impacts were satisfactory.

The staff that performs the evaluation received feedback on 2017-05-10 of the importance of accuracy when completing forms and reviewing work for accuracy.

Section 94 - Quality Management System

2. **The establishment did not evaluate the effectiveness of corrective or preventive actions after they were carried out. The RAM entry for a pressure meter (R000003278) that was out of tolerance was closed without a proper supervisory review. For example, the incorrect NCR# 56-16-201559 was recorded. During the inspection, it was confirmed that the correct associated NCR was 56-16-201566.**

Correction was made at the time of the inspection on 2017-05-09. SOP 09 356, Equipment Services Work Management, will be updated by November 2017 to include the verification of information into RAM as part of the supervisory review.

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Section 95 - Operating Procedures

3. The freezer chart recorder chart (serial number R2431) had a reviewed date of 2017-05-09, which is two months after the stop day (2017-03-09) when the completed chart was removed. This is contrary to procedure 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance- Permanent Site. During the inspection, a notation was made on the chart and it was re-reviewed.

The temperature chart was reviewed at the time of the inspection on 2017-05-09 and all temperatures were within range. The staff received feedback on 2017-05-10 emphasizing the importance of Good Documentation Practices and documentation review.

Section 117 - Records

4. There was a discrepancy in the serial numbers recorded for the electrical safety analyzer (R000003300) in RAM. The Certificate of Calibration (September 06, 2016) stated a serial number of 9050036 whereas the corresponding RAM entry stated 530742. During the inspection, it was indicated that the serial number on the Certificate of Calibration was the accurate one.

The Asset serial number was re-verified and corrected in RAM on 2017-05-10. A memo was sent to staff on 2017-06-20 emphasizing the importance of accurate data entry and verification of data entry.

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

