Canadian Blood Services
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Ms. Lesley Beaton
Compliance Specialist
Regulatory Operations & Regions Branch
Health Products and Food Branch Inspectorate
#400-4595 Canada Way, 4th Floor
Burnaby, British Columbia
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Dear Ms. Beaton:

Re: Responses to Health Canada Inspection of Licensed Activities at Vancouver Operations 2018-01-22 to 2018-01-26

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated **2018-02-06.**

Section 94 - Quality Management System

1. **All required documentation was not available for six fridges/freezers/incubators used for the maintenance of the Phase Change Material (PCM). Neither the NDAS Alarm and Trend Logs nor the Digital Touchscreen Recorder Graphs had been printed and reviewed since the installation and initial use of these six storage devices in April 2017. The six PCM storage devices were located in Distribution however the equipment owner was Logistics.**

   Review of the preventive maintenance records found that required preventive maintenance had been completed by Equipment Services and that the alarm notification process was active for this equipment.

   QER-10-18-116258 was initiated on 2018-02-16.

   Roles and responsibilities for monitoring activities such as printing and review of alarms and trend logs have been clarified with staff. NDAS monitoring data for the period in question have been reviewed and found to be within specifications.

Section 95 – Standard Operating Procedures

2. **Some operating procedures were not always followed:**
   a) **Contrary to the SOPs regarding the conditioning of the Phase Change Material (SOPs 12 502, 12 503, 12 504, and 12 011) all required information was not always documented on the PCM Conditioning Cycles form (F800382) nor the Weekly digital Touchscreen Recorder Review – PCM Equipment (F800788). Examples included**

missing identification of the Conditioning Equipment, missing End Cycle information and missing Supervisory Review.

QER-10-18-116259 was initiated on 2018-02-16.

A staff meeting was held on 2018-02-27 to ensure everyone is clear on the proper completion of form F800382.

In addition, refresher training on SOPs 12 502, Condition Phase Change Material - Series 4; 12 503, Condition Phase Change Material - Series 22; 12 504, Condition Phase Change Material - Series 20M; 12 011, Digital Touchscreen Recorder Operation - PCM Equipment and SOP 08 851, Manual of Good Documentation Practice will be conducted with the warehouse staff by 2018-03-29.

b) Contrary to COP 5003 v. 7, Quarantine of Non-Conforming and Critical Supplies, there was no "Hold" tag on two boxes of Sodium Chloride Solution 0.9% (Lot #W7L04MOA) for which the Lot Acceptance documentation had yet been received by Logistics.

The room will be re-organized to ensure that a clear separation exists between quarantined items pending quality inspection and release versus those that have been released. Additionally, warehouse staff will complete refresher training on COP 5003 v.7 Quarantine of Non-Conforming and Critical Supplies by 2018-05-01.

c) Contrary to SOP 01 144 v. 7, Screen donor, the height and weight was not obtained for first time Donor 3C05101718604900G at clinic V0057 dated 2017-07-21 although the donor was < 23 years of age.

QER 10-18-116248 was initiated on 2018-01-26.
The Clinic Supervisor has reviewed with staff involved the weight and height assessment as per SOP 01 144, Screen Donor v.7.

In addition, the Clinic Supervisor has observed the staff screen first time donors and the staff has demonstrated the necessary competence.

Section 96 – Standard Operating Procedures

3. With regard to SOP 12 011 v. 1, Digital Touchscreen Recorder Operators – PCM Equipment:

a) The SOP did not clearly indicate the expectations with regard to downloading, printing and reviewing of the Digital Touchscreen Recorder temperature data in situations where the equipment was monitored through both NDAS in addition to the TSB Digital Touchscreen Chart Recorder.

SOP 12 011 Digital Touchscreen Recorder Operators – PCM Equipment was revised to clarify requirements, i.e., Section 1 of the SOP 12 011 should be followed for PCM Equipment used for conditioning plates and references SOP 13 009 NDAS Operation for PCM Equipment monitored through both NDAS and the TSB Touchscreen Chart Recorder. In addition, the SOP clarifies the management of Digital Touchscreen Recorder Temperature data in situations where the equipment is monitored through both NDAS and the TSB Digital Touchscreen Chart Recorder. This has been in effect since 2018-02-26.

b) The completed Dickson TSB DTR Settings – PCM Equipment Form (F800787) were not filed in the local Equipment History Files (RAM) as stated in section 2 of the SOP, rather these forms had been retained by CBS Head Office.

Copies of the completed Dickson TSB DTR Settings – PCM Equipment Form (F800787) for the PCM equipment in Vancouver will be uploaded in RAM by 2018-03-31 as required by SOP 12 011, Digital Touchscreen Recorder Operators – PCM Equipment. Staff who were responsible for executing the IOQ have been reminded to ensure the completed forms are kept with the equipment history file in future.

Section 100 – Equipment

4. The validation, calibration, cleaning, or maintenance of critical equipment were not sufficient.

a) The system to track the required annual replacement of batteries in the Helmer Platelet Incubator was inadequate. Specifically the Helmer Platelet Incubator Maintenance Inspection for incubator R18224 dated 2017-12-06 and incubator R6755 dated 2017-12-15 noted that the replacements of batteries were due 2018-01-06 and 2018-01-13 yet as of 2018-01-24 these batteries had not been replaced.

QER 10-18-11646 was initiated on 2018-01-24.

All batteries were replaced and the old batteries were confirmed to be functional. All Equipment Services Supervisors and Managers have been made aware of the observation. All Equipment Services staff at Vancouver are being reminded to review the due date for battery replacement during each preventive maintenance (PM). All Equipment Services staff nationally will be made aware of the observation by 2018-03-31.

In addition, an annual Battery Change event for any applicable incubator, freezer and fridge equipment with battery backup monitoring will be added in RAM in order for this activity to have an individual schedule and work order. This will allow for independent tracking and documentation of the annualized battery change event independent of the primary PM. This will also be in place no later than 2018-03-31.

b) A number of the Walk-in Cooler/Freezer Maintenance Inspection quarterly PM records for WIC 4578, WIC 4900 and WIC 4976 dated 2017-03-09 included values outside of the documented acceptable values for Suction and Discharge Pressures however no follow up actions were noted.

QER 10-18-116245 was initiated on 2018-01-22.

A review of subsequent preventive maintenance records demonstrated that the criteria for suction and discharge pressures were within acceptable range. The process and the importance of a thorough review of vendor documentation were emphasized with the staff member involved.

c) The completed preventive maintenance records for the WIF 2700 Anteroom did not include consistent acceptable temperature and pressure ranges for the Anteroom nor was the maintenance of the anteroom referenced in SOP 13 028, Walk-In and Blast Freezer Refrigeration Inspection and Maintenance.

The anteroom was designed to provide a buffer zone between the freezer and the outside air at room temperature and thus reduce frost build up in the freezer. Because of its function as a buffer zone, no requirements for temperature and pressure ranges have been specified and it is sufficient to only monitor the freezer where products are actually stored. As such no corrective actions are deemed necessary.

Section 117 – Records

5. Records were not always accurate, complete, legible, indelible and/or readily retrievable.

a) The Generator Preventive Maintenance Record (form F800120) dated 2017-10-23 for the semi-annual and annual maintenance of the generator (GEN-001) did not include the required checks for completion of the semi-annual maintenance. In addition the Monthly Generator Test Form dated 2017-01-31 included an incomplete result for the Coolant Temperature Reading.

QER 10-18-116243 was initiated on 2018-01-22. The vendor annual preventive maintenance report confirmed that checks pertaining to the semi-annual preventive maintenance were completed. The process and the importance of a thorough review of vendor documentation were emphasized with staff involved in this activity.

b) The Reach-In Refrigerator/Freezer Maintenance Inspection form (1000105249) completed 2017-09-01 for the preventive maintenance of PCM conditioning freezer unit R17736 referenced the use of Reference Thermometer Probe R6325 with a past calibration due date of 2017-05-08. It was confirmed that this reference thermometer was actually calibrated 2017-05-08; however the supervisor had signed off on the completion of this preventive maintenance.

QER 10-18-114800 was initiated 2018-01-25 and closed 2018-01-30.

A calibrated thermometer was used for the preventive maintenance. The record will be corrected as per 08 851 Manual of Good Documentation Practices using the Report of Calibration as the verifiable source.

c) Four Whole Blood Component Assessment/Production Records B1 forms (1000105504) and one Review of Clinic Checklist form (FV03330) from the 2017-12-28 clinic date production records were missing processing completion dates and the final records received date, respectively.

QER 10-18-107795 was initiated on 2018-01-30.

All Production staff including those who perform supervisory review were reminded to follow good documentation practices, emphasizing the importance of completeness of documentation.

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
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cc: Hugo Tremblay
Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch