Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2020-01-28
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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 Licensed Activities at Vancouver Operations 2019-12-09 to 2019-12-13

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-01-02.

Section 94 – Quality Management System

1. **Freezer R5994 was labelled as "Released Inventory" however the freezer contained WIP plasma components which were not end labelled for release and which had been stored in the freezer on Dec 3, 2019. In addition the Viewlinc Alternate Storage Location form posted on this freezer indicated the contents of the freezer were B19 specimens.**

   DEV-20-000253 was initiated on 2020-01-10.

   The intended use of freezer R5994 is to store quarantined product and as such the "Released Inventory" sign was replaced with a "General Quarantine" sign on 2019-12-10.

   B19 Specimens are not to be stored in the R5994 freezer and the freezer has never been used for that purpose. The inclusion of B19 specimens on the form was an error and the form has been corrected.

   In addition, a memo was distributed on 2020-01-07 reminding production staff to verify and comply with the signage on equipment.

Section 95 -Operating Procedures

2. **Some operating procedures were not always followed: For example:**
   a) **Contrary to SOP 12 308 v.8 Physical SAP inventory, the 2019 records of inventory counts and clearance of discrepancies were incomplete in that records were not available between 2019-05-24 and 2019-11-28. (Repeat Observation)**

   MQE-19-000599 was initiated on 2019-12-11.

   Logistics staff was retrained to SOP 12 308, Physical SAP Inventory by 2020-01-24.

   The completion of cycle counts, as per SOP 12 308, will be monitored by quality assurance for 6 months to ensure compliance.

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b) Contrary to SOP 12 302 v.8 Management of Internal Transfers and Goods Issues, the transfer orders for issuance of critical supplies were not always initialled and dated when processing an internal movement.

MQE-19-000599 was initiated on 2019-12-11.

The transfer orders were reviewed and corrected on 2019-12-17.

SOP 12 302, Management of Internal Transfers and Goods Issues step 1.5 will be reviewed with warehouse staff and supervisors by 2020-03-10.

c) Contrary to SOP 01 202 v2.1 Manage/Close Donor Reaction and Incident Reports, the following was found –

i. Two Reaction/Incident Reports from dated 2019-08-21 (#6354218) and 2019-10-28 (#6276885) were missing the documentation in Section 4 to confirm whether Medical Review consultation was required.

MQE 19-000644 was initiated on 2019-12-13.

The reaction incident reports noted above were reviewed by the Clinic Supervisor on 2019-12-19, and it was determined that the medical review was not required, and N/A should have been recorded. The records were corrected accordingly.

The process as described in SOP 01 202 Manage/ Close Donor Reaction and Incident Reports was reviewed with the clinic supervisor and the staff member to ensure the form is completed as required including the correct review at closure is completed.

ii. One Reaction/Incident Report dated 2019-11-09 (#6353480) required Medical Review and although it was signed off by a physician on 2019-11-21 the report was not subsequently reviewed and closed by the originator.

MQE-19-000641 was initiated on 2019-12-17.

The reaction incident report was reviewed and closed on 2019-12-13.

The staff member that filed the report before it had been properly closed has been retrained to WI 01 202, Manage/ Close Donor Reaction and Incident Reports.

Section 98 - Personnel

3. The records of staff qualifications, training or evaluation of their competency were not always sufficient. For example:

a) While observing the preparation of RBC as per SOP 02 256.001 v.2 Preparation of Initial Components – Whole Blood Filter System, it was noted that the lab assistant was not aware of the volume (>390 ml) referenced in Section 4 of the SOP over which RBC were to be manually rejected and there was no job aide or other tool available for reference.

The staff member involved has been retrained to SOP 02 256.001, Preparation of Initial Components – Whole Blood Filter System. The observation was also discussed during the daily huddle on 2019-12-16 and all production staff will be retrained by 2020-01-31.

In addition, a posting page of the work instruction with the information on the red cell volume was created and posted at the workstation on 2019-12-11.

b) Review of current Confirmation of Employee Training records (CETs) available in both Production and Distribution found that there were numerous CETs which were not signed off by all staff prior to the implementation date of the SOP. Furthermore, the process and responsibility to follow up on outstanding training records for staff before they complete the activity was not clear.

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DEV-20-000313 was initiated on 2020-01-13.

Staff have completed all outstanding training. In addition, the production and distribution records during the period in question were reviewed and there were no errors.

Production and Distribution supervisors have completed refresher training to SOP 08 552, Manage Training Gaps regarding the monitoring of the completion of training for staff and the periodic review of training records to identify gaps.

c) Review of completed training records in Component Production found one lab assistant was missing the Confirmation of Employee Training record for SOP 02 301 v.31 which was implemented 2019-09-30.

DEV-20-000319 was initiated on 2020-01-13.

Staff completed training to SOP 02 301, Bacterial Detection Testing for Release of Platelet Components v.31 on 2020-01-09. The investigation has identified that v31 of SOP 02 301, Bacterial Detection Testing for Release of Platelet Components incorporated the work instructions from 02 305, Handling of Positive Culture Bottle. It was confirmed that staff had completed training to 02 305.

Production and Distribution supervisors have completed refresher training to SOP 08 552, Manage Training Gaps regarding the monitoring of the completion of training for staff and the periodic review of training records to identify gaps

Section 100 – Equipment

4. The Preventive Maintenance for the ESPEC conditioning freezer (R18213) which was done on 2019-08-20 was incomplete in that the document provided by the external service provider did not include details on the work completed yet this work was signed off by the equipment owner (Logistics). The incomplete document was uploaded to RAM by Equipment Services and although the Supervisor of Equipment Services identified the inadequacy of the paperwork on Sept 6, 2019 and placed the RAM "on hold" and sent it back to the equipment owner, as of Dec 9, 2019 there had been no follow up with the external service provider and the PM remained incomplete.

DEV-20-000057 was initiated on 2020-01-03.

The preventive maintenance on the unit was repeated on 2019-12-11 and found to be within specifications. The record was reviewed and was then uploaded to RAM.

As of December 2019, the preventative maintenance of ESPEC equipment is performed by Canadian Blood Services staff using a work plan template form F801769, Freezer, EPZ-3H, PM, 6mth which was implemented on 2019-11-29. The work plan template requires an entry in all fields before it can be finalized and saved in RAM.

Supervisors in equipment services will monitor, identify and follow up on a weekly basis to ensure that asset managers are dealing, in accordance with SOP 09 350, Management of Equipment by Owners with work in RAM that is flagged as missing documentation or having discrepancies, such as 'Hold', resulting in a timely identification and follow-up of incomplete work. The associated work instructions will be updated with this requirement by 2020-08-01.

Section 117 – Records

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

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a) **The expiry date from the original bottle was not added to the spray bottle into which the 70% isopropyl alcohol is transferred for spraying gloved hands during inoculation of BacT bottles.**

A label with the expiry date was created on 2019-12-12. In addition, a review of the WHMIS labelling was completed at the daily huddle on 2019-12-12.

b) **While observing B1 production on 2019-12-10 it was noted that the Target Processing Completion Time for the 2019-12-09 orange batch was documented as 12:35 but based on the processing start time of 0535 it should have been calculated to be 11:35. The second in-process review of the record had been completed but the final review was still pending.**

The record was corrected during the inspection and comments were added to the batching record with the correct target processing completion time.

The observation was also discussed at the daily huddle meeting on 2019-12-12 to bring awareness to staff on the importance of proper documentation, as well as a reminder to staff on the requirement as a reviewer. This reminder was also included on a memo for staff to read that was distributed on 2020-01-07.

c) **The 2019-09-03 Preventive Maintenance for WIC 4578 (R21334) included a comment that the condenser for system #2 had a lot of vibration and immediate action was required but the external service provider service report indicated that the repair work was done on condenser #1 and this work was signed off by Facilities.**

MQE-20-000120 was initiated on 2020-01-10.

It was verified that the repair was completed on system #2. The record was corrected with the reference to the MQE.

d) **Review of completed Quarantine Logs (FV05024) found two records from April 2019 for which Section III: Supply Disposition and the Final Supervisor review had not been completed. In both situations the critical supplies were not released from quarantine but were returned to the supplier.**

MQE-19-000555 was initiated on 2019-12-09.

The quarantine logs were corrected and reviewed.

COP 5003 v.7 Quarantine of Non-Conforming and Critical Supplies regarding the completion of the quarantine logs will be reviewed with warehouse staff and Supervisors by 2020-03-10.

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,

Christian Choquet

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

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