Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2024-02-02
CBS Control #: CBS6785
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REF: H-2324-WIN-R

Jodie Leiman
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba R3C 4W1

Dear Jodie:

Re: Responses to Health Canada Inspection of Registered Activities at Winnipeg Operations 2023-11-06 to 2023-11-10

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-11-24.

Section 94 - Quality Management System

1. The establishment did not thoroughly investigate errors and accidents and determine corrective and preventive actions.

MQE-22-002571 was entered as a minor quality event (MQE) as a result of the quality event assessment by Canadian Blood Services (CBS) in QE-22-009492 that indicated "No" to some of the questions regarding product impact and regulatory compliance. The preventive maintenance (PM) for the [redacted] R00027451 was conducted on 2022-08-03 and was subsequently used the same day; four (4) irradiated RBC units and two (2) pooled platelet units were released prior to review of the PM records. Further, corrective actions were not considered in the MQE assessment.

DEV-23-009715 was initiated on 2023-11-15.

A review of the preventive maintenance (PM) records from 2022-08-03 was performed to verify that documentation was complete and PM passed. [redacted] *process was successful at time of event. It was determined there was no risk to patient and no need for retrieval of units.*

As stated in the observation, the PM for the [redacted] *was completed on 2022-08-03. Since the time of this event, the Quality Management System (QMS) group developed a Quality Event Management (QEM) Refresher and Clarification presentation to enhance process alignment/ understanding. The Winnipeg QA team delivered this*

presentation to Integrated Supply Chain (ISC) Managers/ Supervisors and Production/ Distribution staff beginning in February 2023 and completed on 2023-03-31. Production and QA staff were also made aware of this observation at the time of Health Canada Inspection.

Section 100 - Equipment

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

a) The PM of some biosafety cabinets (BSC) were not completed by their due date. For example, the BSC in the red cell serology laboratory R00003938 was due for PM on 2023-11-03 and was observed to be in use on 2023-11-06.

DEV-23-009428 was initiated on 2023-11-07.

Out of Service tags were affixed to the affected equipment on 2023-11-06 and the vendor was called in to complete the preventive maintenance (PM) on 2023-11-07. The PM passed without any deficiencies. A review of the work instruction WI-00534 Management of Equipment by Owners was done on 2023-11-22 with applicable Facilities staff and clarity provided that the responsibility of monitoring for PM for the biosafety cabinets resides with Facilities staff.

b) PM records for the [redacted] R00003984 were not reviewed prior to the due date of PM as per WI-00534 - Management of Equipment by Owners (rev 7). PM was due on 2023-07-31 but the review was completed significantly later on 2023-10-20.

DEV-23-009521 was initiated on 2023-11-09.

An investigation as part of the deviation was undertaken. Discussion on the timelines for the review of [redacted] results occurred on 2023-11-16 with those receiving results, emphasizing that they must be reviewed upon receipt per requirement of WI-00753 [redacted] Preventative Maintenance.

Contact information of additional staff to whom the results should be sent was also communicated to the service provider to ensure the results were received and acted upon immediately in the case where the primary contact was absent from work.

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,

C Christian Choquet

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs