Canadian Blood Services

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2025-04-03
CBS Control #: CBS6877
HPFB File #: C1892-100390
REF: H-2425-Regina-Albert Street

Jodie Leiman
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
391 York Ave,
Winnipeg, Manitoba
R3C 0P4

Dear Jodie:

**Re: Responses to the Health Canada Inspection of Regina-Albert Street 2025-02-26 to 2025-02-27**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2025-03-10.

**Section 117 – Records**

**1. The establishment's records were not always accurate or complete. For example:**

**a) The Cell Separator Incident Log (F800412; Revision 1) was not reviewed and signed off in a timely manner. The form was initiated and completed by staff on 2024-09-04 and it was reviewed on 2025-01-09.**

*MQE-25-000749 was initiated on 2025-02-28.*

*A read and sign memo will be sent to staff to remind them to submit F800412 Cell Separator Incident Log to supervisors for review as per WI-00246 Machine Alarms (Automated Apheresis), Section 2 Step 3 on the day of completion so that it can be reviewed and filed in a timely manner*

*This will be completed by 2025-03-31.*

**b) Staff that completed the Docon Shaker Verification and Maintenance Log (F800366; Revision 1) for Asset #R000004391 on January 19, 2024 did not add their initials to their entry. Further, the manager that completed the monthly review of the form on 2024-02-05 did not identify the staff's initials were missing. As a result, an MQE was not initiated as per written procedures.**

*MQE-25-000752 was initiated on 2025-02-28.*

*A read and sign memo will be distributed to staff to remind them to ensure all entries are complete and accurate as per CO-00066 Manual of Good Documentation Practices. This will also include a reminder that if an error is identified a quality event should be initiated immediately as per WI-00518 Deviation/Minor Quality Event Management and the number identified on the corresponding record.*

*This will be completed by 2025-03-31.*

c) **Interim Storage Record F020009.001 (2021-08-26) for the Helmer Incubator (R000027573) and associated Dickson Recorder (R000027690) was not signed/dated by the reviewer for 2023-01-20.**

*MQE-25-000756 was initiated on 2025-02-28. The form was reviewed on 2025-02-28 and no issues were identified.*

*A read and sign memo will be sent to staff reminding them that F020009.001 Interim Storage Record and any associated documents should be reviewed by the supervisors for complete and accurate documentation as per CO-00066 Manual of Good Documentation Practices and in a timely manner.*

*This will be completed 2025-03-31.*

d) **The Quality Inspection of Critical Supplies form 1000105559 (2021-06-09), Section 1 was incomplete for the supply Trima Plt Smplr Auto PAS, lot #: 1000108426. Specifically, the date of receipt was not documented for the shipment December 2024 shipment.**

*MQE-25-000796 was initiated 2025-03-03.*

*A read and memo will be sent to staff reminding them to complete F1000105559 Quality Inspection of Critical Supplies as per WI-00773 Inspection of Critical Supplies, step 2.*

*This will be completed by 2025-04-30.*

e) **The Quality Inspection of Critical Supplies form 1000105559 (2021-06-09) was incomplete for two (2) shipments of BD Vacutainers received on 2025-01-28 (red top – lot #: 4123394 and lavender top – lot #: 4198218). Specifically, the "Canadian Blood Services Shipment Assessment Stamp" and the subsequent assessment/inspection of the shipment was not documented on the receiving forms as required by WI-00597.**

*DEV-25-002042 was initiated 2025-03-03. Both impacted supply shipments were re-inspected upon discovery of this event and found to be acceptable.*

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*A read and sign memo will be sent to logistics staff reminding them to follow WI-00597 Processing Material: Inventory Requiring Quality Inspection (QI) Step 1 which instructs them to use the Shipment Assessment Stamp.*

*A read and sign memo will be sent to quality assurance staff to remind them that they are to ensure all quality inspection documents are complete and accurate as per WI-00221 Quality Assurance Shipment Assessment.*

*These will be completed by 2025-04-30.*

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,

Steven Carswell
Steven Carswell (2025-04-03 13:50 EDT)

Steven Carswell
Vice-President
Quality & Regulatory Affairs