Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2024-03-14
CBS Control #: CBS6801
HPFB File #: C1892-100390
REF: H-2324-NB

Shawn MacEachern
Regulatory Compliance & Enforcement Specialist
Regulatory Operations and Enforcement Branch
Biological Product Compliance Program
191 Great George Street
Charlottetown, PE
C1A 4L2

Dear Shawn:

Re: Responses to Health Canada Inspection of Licensed Activities at Saint John Operations
2024-01-30 to 2024-02-02

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2024-02-19.

Section 94 - Quality Management System

1. **The establishment did not always ensure that the investigation of errors or accidents were thorough and complete. For example, the following DEVs did not adequately document the reason for occurrence or how recurrence was going to be prevented:**
   a. DEV23-000480 involved a plasmapheresis device (R1027) whose preventive maintenance (PM) was due on January 11, 2023, however the device was not taken out of service until January 13, 2023. While the DEV documented that the PM was missed, there was no indication as to the cause of the omission; the impact, if any, to other plasmapheresis devices at the centre or the actions to be implemented to prevent recurrence.

   b. DEV22-007481 involved the potential contamination of blood collection disposables where a trainee informed the trainer, after donation, of the possible contamination. While the unit was located and rejected, there was no documentation indicating how this event was investigated to identify the cause of the issue or the preventive actions required or taken to prevent recurrence.

   Combined response to 1a and 1b:

   These 2 events were considered low risk.

   As per MPP 08 32, Corrective Action and Preventive Action (CAPA), "Data associated with low-risk deviations will be reviewed regularly at quality management system review and CAPAs will be initiated based upon product impact".

Data on low-risk deviations are brought to the relevant quality management system review team by Quality Assurance and the team decides which CAPAs to launch based on the data.

Section 95 - Operating Procedures

2. Some operating procedures were not always followed:

a. Contrary to WI 01 070 - Perform Venepuncture - Rev 6 Effective Date 2022-03-23, during the preparation of the arm for venepuncture for donation C057124604240207, the ChloraPrep Swabstick Applicator was not turned at least once during the scrub. It is acknowledged that during the inspection DEV-24-001137 was initiated.

The trainer reviewed the work instruction in WI 01 070 Perform Venepuncture relating to the arm scrub with the apheresis staff and Clinic Supervisor on 2024-01-31 and 2024-02-01.

b. The deferral information identified after donor screening for donation C057124604242203 was recorded in the Medical Screening section of eprogesa which is contrary to the WI-00262 - Manage Deferrals - Rev 1 Reissue#1, Effective Date 2023-09-25, which states deferrals noted outside of the screening booth must be applied, along with an explanation of the code assigned, in the Donor Record Management section of eprogesa. It is acknowledged that during the inspection DEV-24-001146 was initiated.

The deferral information was entered in the Donor Management section in eProgesa upon discovery of the error during the inspection.

Staff completed refresher training to WI-00262 Manage Deferrals regarding managing deferrals outside of medical screening by 2024-02-20.

c. The Series 20M Phase Change Material Plates (Condition Stage) were not conditioned for the minimum time required of 12 hours at ≤ -60.0 degrees Celsius as stipulated in F800382 (2020-07-22), Phase Change Material - Conditioning Cycles. On 2023-11-16 the conditioning cycle began at 20:00 and on 2023-11-17 the conditioning cycle ended at 07:17 totaling only 11 hours and 17 minutes.

MQE-24-000522 was initiated on 2024-02-02.

Upon investigation of the conditioning cycle time, it was identified from a magnified view that the start cycle time on the ESPEC R19012 digital chart recorder on 2023-11-16 was 19h00 and the end cycle was after 07h00 on 2023-11-17, which meets the required 12-hour cycle time.

The Supply Technicians and Supervisor, Logistics completed refresher training to WI-00623 Condition Phase Change Material-Series 20 on 2024-02-22 including completion of the form F800382 Phase Change Material – Conditioning Cycles.

Section 98 - Personnel

3. The training of responsible staff was not completed for WI-00092 - Management of Blood Components Received From External Supplier - Rev 2 Effective Date

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2022-11-07. It is acknowledged that during the inspection MQE-24-000496 was initiated.

Lab Assistants were issued training material for WI-00092 Management of Blood Components Received from External Supplier - Rev 2 at time of discovery by the inspector. This training was completed by 2024-02-07.

Note: This site has never imported blood components from an external supplier to date.

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 and Regulatory Affairs