Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2021-06-08
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Ms. Inessa Belyavsky
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Belyavsky:

Re: Responses to Health Canada Inspection of Licensed Activities at Barrie 2021-05-12 and 2021-05-13

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-05-25.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example:**
   a) An operating procedure did not clearly describe a process: Work Instruction (WI) 27 036, rev 6 effective 2019-12-16, CompoLab TM Hemoglobinometer Verification, did not indicate that the opened expiry date must not exceed the manufacturer's expiry date of the DiaSpect control solution used for the 6 month verification of hemoglobinometers. The WI requirement related to expiry dates read: "Confirm acceptable manufacturer's expiry date on the control solution; Document date opened on vial [...] Control has a 60-day opened expiry. Day opened + 60 days stored at +2 to +35 deg C." The WI does not clearly describe whether the manufacturer's expiry date must be confirmed at the time of initial opening only or every time the control solution is used. It is acknowledged that, in practice, the manufacturer's expiry date was being confirmed prior to each use.

   Work instruction 27 036 v6, Compolab TM Hemoglobinometer Verification, will be revised to clarify that the Compolab control manufacturer's expiry date and the open vial expiry date is to be verified before each use. This revision will ensure that the control vial open expiry date (date opened + 60 days) does not exceed the manufacturer's expiry date.

   b) Furthermore, an equipment verification record had an inaccurate entry: form 1000106028 CompoLab TM Hemoglobinometer Verification Log completed on May 3, 2021 had an incorrect entry for the opened expiry date of the control. "2021-07-03" was entered, which is 61 days after the control was opened on May 3, 2021; the requirement stated on the form and in the above WI is "Date opened + 60 days". Upon the inspector's observation during

this inspection, MQE-21-001642 was initiated.

MQE 21-001642 was initiated on 2021-05-18.

Refresher training for the calculation of the opened expiry date, as described in WI 27 036 Compolab TM Hemoglobinometer Verification, was completed by the staff member on 2021-05-18.

Section 117 – Records

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**
   a) A donation record was incomplete: there was no successful collection from donor ID 6428969 on Feb 26, 2021, but no reason for "not drawn" was noted in the donation record and no deferral was applied in eProgesa. DEV-21-003647 was initiated upon the inspector's observation during this inspection.

   Deviation 21-003647 was initiated on 2021-05-12.

   The staff member has been reminded of the requirement to select "Vein Related" for missed venepuncture which results in an automatic same day deferral. In addition, the staff member completed refresher training on Attachment 3 - Restart Venepuncture - Whole Blood in WI 01 141.003 v1 Collect Product – Whole Blood.

   b) A Reaction/Incident Report (RIR) was incomplete: form F030001 RIR filled out on Feb 23, 2021 for donor ID 6386103 was sent to Head Office, but the date sent stated "2021-0" in Section 3 of the RIR.

   The staff member was able to locate the email that was sent to Head Office as objective evidence and corrected the date sent as a Late Entry on the Reaction/Incident Report form.

   The staff member has been reminded on 2021-05-13 of the importance of complete and accurate documentation as per good documentation practices.

   c) A Minor Quality Event (MQE) had an inaccurate entry: "2021-01-16" was entered in eTQ under event date discovered for MQE-21-001344, but the event was discovered and created on Apr 24, 2021 during an external audit. Upon the inspector's observation during this inspection, the issue was resolved during the inspection by adding a comment in eTQ to clarify the date discrepancy.

   A comment clarifying the date of discovery was added to MQE-21-001344 on 2021-05-13.

   The MQE was reviewed at the time of the inspection and the staff member was made aware of the difference between a date discovered and a date occurred when completing an MQE.

   d) A Confirmation of Employee Training (CET) was not accurate: form F800304 Initial Training Requirements Matrix indicated "P" for Performance Measurement under Donor Care Associate (DCA) for the initial training on SOP 20 050 Vital Signs Monitors, Operation; however, form F800329 CET for the initial training of DCA LE on SOP 20 050 conducted on Dec 4, 2017 indicated "A" for Awareness under Learning Level.

   The staff member creating the Confirmation of Employee (CET) was made aware of the documentation error at the time of the audit on 2021-05-13.

   The CET was corrected as per good documentation practices on 2021-05-13 to indicate Performance Measurement training as per the Matrix and Training Plan.

   e) A Temperature Monitoring Log was not accurate: comments indicating that blood

products were secured in the Critical Supply Room on Feb 20 and Feb 26, 2021, were added to form 1000104195.001 Donor Centre Temperature Monitoring Log - Warm B1 Collection Set for Temperature Monitoring Device (TMD) R19573, which monitors the temperature in the shipping area; however, these comments were not added to the log for TMD R19574, which monitors the temperature in the Critical Supply Room. Upon the inspector's observation during this inspection, MQE-21-001592 was initiated.

MQE 21-001592 was initiated on 2021-05-13.

Refresher training to WI 01 030.002 v2 Donor Centre Management was completed by the staff member on 2021-05-13 to ensure that a separate Temperature Monitoring Log for the secured storage location is initiated when storing products after hours.

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: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch