Canadian Blood Services

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

2023-07-31
CBS Control #: CBS6755
HPFB File #: C1892-100390
REF: H-2324-HAM

Urbee Shome-Pal
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 Urbee:

Re: Responses to Health Canada Inspection of Licensed Activities at Hamilton 2023-06-08 to 2023-06-09

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-07-04.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example:**
   a) Contrary to CO-00066: Manual of Good Documentation Practices, Revision 1 (section 7.1, p.11), the following deficiencies were noted for Form F801368 (2020-08-15): Digital Touchscreen Recorder Daily Temperature Log - Supply Chain (Non-Donor Testing Areas), completed on a weekly basis for RAM Asset ID# R19585, which monitors the shipping area and clinic temperature:
   (i) On the form for the week beginning on 2022/01/01, the same staff who completed the operational section 2 on Jan 1 and Jan 7, also reviewed the form on 2022/01/07, under section 3.
   (ii) On the form for the week beginning on 2022/01/08, the same staff who completed the operational section 2 on Jan 8 and Jan 14, also reviewed the form on 2022/02/18, under section 3.

   MQE-23-002037 was initiated 2023-06-15.

   The forms were reviewed again and the clinic supervisor discussed the observation with staff members to bring awareness of the quality event and the requirements of CO-00066 (08 851) Manual of Good Documentation Practices regarding step 7.1 where the reviewer must be a different person than the originator performing the entry.

   b) Contrary to section 10 of WI 00538: Equipment Services Work Management, Revision 1, some equipment maintenance logs did not always indicate the person who transcribed the corresponding MNT number (i.e. RAM Work order #) onto the PM

record, prior to scanning the document into RAM for the relevant equipment. Specifically, on the CompoLab TM Hemoglobinometer Verification Log completed on 2022-08-11 for a CompoLab (RAM Asset ID# R28130 / MNT-196933), the initials and date of the person transcribing the MNT number was not indicated.

DEV-23-004793 was initiation 2023-06-09.

The impacted document has been corrected with the initials and date and the deviation number was added to the comment field.

The supervisor discussed this issue with staff and in addition an email was sent on 2023-06-09 to raise awareness of the error and to remind them of the requirements of CO-00066 (08 851) Manual of Good Documentation Practices to include the initials and date.

Section 96 - Operating Procedures

2. **Some operating procedures were not kept up-to-date. For example:**
   a) WI-00250: Collect Product - Trima Accel, Revision 2, Attachment 5 - HLA/HPA and Selected Patient Units, states the following: "Second authorized user will verify tagging information and initial and date on the F800898 (F801079): HLA/HPA Selected Platelet Tag/Untag Form." However, it was noted that the referenced form only tracks the initials and not the corresponding date of verification by the second authorized user.

   F800898 (F801079) HLA/HPA Selected Platelet Tag/Untag Form will be revised and implemented by 2023-09-25, to include a date field to align with WI-00250: Collect Product – Trima Accel, Revision 2, Attachment 5 requirements whereby the second authorized user will initial and date once tagging information is verified.

   b) The current Revision Number for WI-00251 (Effective Date 2022-11-28): Screen Donor, is indicated as "2 Reissue #1" on the header of each page of the document. However, the corresponding "Revision History" section and the "Summary Page" section for this work instruction do not note the same Revision # as the header. It is acknowledged that WI-00229: Create/Revise Controlled Document - Document Developer, Revision 2, effective date 2023-05-29, was revised to clarify that the reissue # should also be added to the revision history table. However, this revision is not yet reflected in all WIs, such as, WI-00251.

   As discussed during the inspection, staff followed the version of WI-00229 (08 324) Create/Revise Controlled Document – Document Developer, Revision #6, which was current at time of the implementation of WI-00251 (01 144) Screen Donor Revision #2 (implemented 2022-11-28).

   Subsequently, WI-00251(01 144) Screen Donor has been revised to Revision #3 and implemented on 2023-06-26. Both the header and revision history table now indicate Revision #3 as per the current version of WI-00229 (08 324) Create/Revise Controlled Document – Document Developer.

   WI-00229 (08 324) Create/Revise Controlled Document – Document Developer, was revised and was implemented on 2023-05-29 bringing clarity in formatting of re-issued documents. In a review of all approved documents that were reissued since May 2022, only

one additional work instruction was identified to contain formatting concerns in conflict with the revised instruction.

The impacted work instruction will be revised during their next revision planned for 2024-03-25.

c) Form 1000106028 (2019-06-21): CompoLab TM Hemoglobinometer Verification Log does not track all relevant test equipment. Specifically, there is no place on the form to track the lot numbers and expiry dates of the DiaSpect Cuvettes, used during the verification of the relevant equipment. As a result, this information was not being documented on these forms.

DiaSpect cuvette lot numbers and expiry dates are entered in ePROGESA upon receipt as it is a critical supply, as per WI-00599 (12 111) Entering Supplies in PROGESA, Section 1 Step 2. At every donor event the DiaSpect cuvette lot number is again entered in ePROGESA during drive set-up as per WI-00260 (01 371.001) Drive Set-Up. ePROGESA verifies the entry matches a lot number previously entered and released for use. The DiaSpect Cuvette lot number and expiry date are not documented on F1000106028 (2019-06-21) CompoLab TM Hemoglobin Maintenance Log, as the lot number can be traced by date in ePROGESA.

d) The training level to WI 01 371.001: Drive Set-Up, Rev 4, indicated for the role of Screener (RN and DCA2) on the corresponding training matrix, was inadequate. Specifically, for a Screener RN, who was observed as performing clinic drive set-up, as per this work instruction, during the inspection, was described as receiving and needing performance measurement level training to this work instruction.

The training level of "Awareness" for WI-00260 (01 371.001) Drive Set-Up, Rev 4 for the role of Screener (RN and DCA2) as indicated in the training matrix was reviewed with the process owner and found to be appropriate and compliant to CO-00321 Training Management – User Manual.

As per CO-00321 Training Management - User Manual, Awareness level of training is defined as training without requirement for evaluation and Performance level of training is defined as training with requirement for evaluation. Both these levels require applicable training activities.

Other considerations by the process owner in determining training as "Awareness" included the following: Drive set-up is completed frequently (one or more times per collection day); during drive set-up staff can only enter critical supply lot numbers that have been released by the warehouse to be used for collection therefore if supplies are entered incorrectly eProgesa will flag the supply as not available; and when staff perform drive set-up and need assistance they are to refer to and follow WI-00260 (01 371.001) Drive Set-Up.

Selection of either Awareness or Performance Measurement level is determined by the process owner following an assessment using a decision flow in Section 4.3.4 "Determining Assessments" of CO-00321.

Canadian Blood Services

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

Section 117 – Records

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

a) The following equipment records related deficiencies were noted on some maintenance service reports of a Trima Accel & Sealer, RAM Asset ID# R2369, used for plasma/platelet collection:

(i) For PM conducted on Sept 28, 2022, the incorrect calibration due date of 12/31/2023, was indicated for the Torque Wrench - Serial # 104501014, one of the test equipment used to conduct the maintenance. However, the correct calibration due date for the Torque Wrench was confirmed as May 31, 2023, from its corresponding Certificate of Calibration.

(ii) For PM conducted on March 22, 2023, the "Grounding Straps" cell was left blank under the "Electrical Safety and Power" section.

(i) MQE-23-002127 was initiated 2023-06-22.
(ii) MQE-23-002367 was initiated 2023-07-10.

Corrections were made on the PM documents, following confirmation with the vendor Service Technician for: (i) the correct calibration due date, and (ii) the "grounding straps" cell was left blank in error. The vendor now has a process to mitigate these calibration date errors on future service reports.

Follow up was completed at the time of the inspection with staff to ensure that they follow the requirements of WI-00534 (09 350) Management of Equipment by Owners, specifically emphasizing the importance of reviewing third party documents for accuracy and completeness.

b) The following facility records related deficiencies were noted:

(i) Form F800086 (2016-12-02): Temporary Card Audit Log, completed for December 2021, was not reviewed.

(ii) The 2022 Card Audit Log and Access Logs were not available for review during the inspection. However, it is acknowledged that post-inspection, an attestation of locating the 2022 logs was sent internally by Facility Management and this attestation was reviewed and accepted by the establishment's Quality Assurance.

DEV-23-005739 was initiated 2023-07-07.

The logs have now been reviewed by facilities with the deviation number documented on the records. All documents were found to be satisfactory, and all cards were reconciled.

Facilities has assigned a specific team member to the process. The assigned team member will be retrained to WI-00661 (13 006) Temporary Building Access Control by 2023-07-21. The remainder of the team has been made aware of this observation and applicable requirements on 2023-07-11.

Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

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

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