Canadian Blood Services

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2023-05-25
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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 Calgary Operations 2023-03-20 to 2023-03-31

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-04-26.

Section 95 - Operating Procedures

1. **Some operating procedures were not always followed. For example:**
   a) Several Bacterial Testing (BacT) record packages were incomplete post review, contrary to the relevant work instructions and as a result, the information in the packages that were cleared for bacterial testing were not sufficient. For example:
   (i) For Test Date August 29, 2022 (reference donation no. C055202201909 8), the second page of the corresponding package was missing from the unload report.
   (ii) For Test Date August 29, 2022 (reference donation no. C052022165382); the test results page was missing from the corresponding unload report.

   The missing bacterial testing result pages were located and attached to the correct packages during the inspection.

   Staff will be reminded by 2023-06-30 to ensure that the Bacterial Testing record packages are complete.

   b) An Out of Service (OOS) Tag was placed on a Helmer Work in Progress (WIP) Incubator (RAM Asset ID#R22362) without indicating the OOS date and OOS Time. However, it was indicated during the inspection that the incorrect label was used, as the equipment was still in use. These actions were contrary to the relevant sections of 09 240: Out of Service / Service In-Progress Tags/ Labels Application and Removal, Revision 1.

   The correct "Service in Progress" label was applied to the incubator at the time of discovery during the inspection as per WI-00526 (legacy 09 240) Out of Service / Service In-Progress

Tags/ Labels Application and Removal. There was no risk to product as the storage conditions inside the incubator were within operating range and all alarms were investigated.

Staff will be reminded via a memo to appropriately label equipment requiring maintenance as per WI-00526 (legacy 09 240) Out of Service / Service In-Progress Tags/ Labels Application and Removal and a supply of "Service in Progress" labels will be kept in the department. These actions will be completed by 2023-06-30.

c) MQE-22-003942 was not created or operationally reviewed within 2 days of discovery, contrary to WI 09 230: Deviation/MQE Management, Revision 4.1. Specifically, the MQE was discovered on November 16, 2022, but not created or operationally reviewed until November 28, 2022.

DEV-23-003661 was initiated on 2023-05-02.

Feedback regarding following the timelines for quality events as described in WI-00518 (legacy 09 230) Deviation/Minor Quality Event Management was provided to all individuals involved by 2023-05-03.

d) For the re-write of a bacterial detection testing record due to a blood spill, clinic date 2023-02-07, not all the instructions were followed in the Rewriting Damaged Records section of the 08 851: Manual of Good Documentation Practices, Version 9.

MQE-23-001519 was initiated on 2023-05-02.

Staff will complete refresher training to the Rewriting Damaged Records section of CO-00066 (legacy 08 851) Manual of Good Documentation Practices by 2023-07-31.

e) On the cobas8000 Test System Calibration Form (Form# F802014), completed on 2022-09-26 for the TD-2022-0001, Anti-HBc v2 Reagent Study, it was noted that the staff who completed the form, also completed the initial review and final review section, contrary to the relevant section of Manual 08 851 (referenced above).

DEV-23-003648 was initiated on 2023-05-02.

A memo reminding the team to follow CO-00066 (legacy 08 851) Manual of Good Documentation Practices with particular attention to Section 7.1 will be developed and signed by the Transmissible Diseases Process Group by 2023-05-30.

Section 96 - Operating Procedures

2. Some operating procedures were not kept up-to-date. For example:
a) The Power Outage Generator Monitoring form (Form # F800121) completed and reviewed on March 28, 2023, did not include the date of the power outage start time and the date of the power outage end time, as there was no section in the form for this information to be noted.

Form F800121 Power Outage Generator Monitoring will be revised by 2023-12-31 to include the power outage start date and the power outage end date on page one of the form.

b) The following were noted for some forms related to production batch records:
(i) The Batching Record - B1 (Form#F800909) did not include a section to indicate who completed the "Earliest Bleed Time". It was confirmed that the staff completing

this section could be different from the staff completing the remaining activities indicated on the form.

Form F800909 Batching Record - B1 will be updated by 2024-01-30 to include a section to indicate who completed The Earliest Bleed Time.

(ii) The "Reviewed By" section at the bottom did not have a section to indicate the corresponding date of the final review for the following forms: Form#F800909 (referenced above); Batching Record - Platelets, Pooled (Form#F800916); and Buffy Coat Record (Form#F800979).

During the final Review of Production Records, as per WI-00327 (legacy 02 739.004) Review of Production Records Final Review, each form listed in Attachment 1 is reviewed and initialled. The date of completion is captured in ePROGESA as part of test result entry and on the Testing Pending Report. Test result entry is not completed unless all forms have been reviewed.

c) WI-00059: End Labelling, Revision 1 did not include instructions to document that frozen plasma did not show signs of thawing when it was outside of storage.

WI-00059 (legacy 04 729) End Labelling, Attachment 2 provides examples of evidence of unsuitable components, including apparent thawing of frozen plasma. When the end labeller initials in Section II of the End Labelling record, their initials indicate they performed the end labelling session as outlined in WI-00059, which includes the completion of the visual inspection, ensuring only suitable components are end-labelled for release.

d) There were no documented instructions in 05 071: Packing Blood Components, Revision 12.1 to document that the Tamper Indication Device was secured on the shipment, when required.

WI-001134 (legacy 05 071) Packing Blood Components will be updated to include instructions on documenting that the Tamper Indication Device was secured on the shipment when required. The planned closure date for this change is 2024-02-12.

e) There were no instructions in 05 060: Facility Distribution of Blood Components, Revision 31.3 or corresponding forms, to document that some steps were completed before distribution of product. Examples include, steps 3, 4 and 5 under section 4, which appeared as such in the work instruction:
Step 3 "Examine components as outlined in Attachment 2 - Inspection of Blood Components for Distribution..."
Step 4 "...Confirm correct Facility Information populates Order Number input."
Step 5 "Confirm Donation/Pool Number and component code of each component distributed."

eProgesa is the test of record. Each user is assigned a specific individual code and has a unique password. This information is used to generate the 'distributed by' name on the packing slip. The 'distributed by' name is the confirmation that steps 3, 4 and 5 have been completed.

WI-00066 (legacy 05 060) Facility Distribution of Blood Components will be updated to include a note stating the name that populates on the packing slip for "distributed by" is the

person who completes the inspection and confirms the information in Steps 3, 4 and 5 is correct. The planned closure date for this change is 2024-02-12.

f) The Shipping Transfer Record Form did not always reflect the appropriate temperature ranges shipped from certain sites. In addition, the time of receipt was not indicated on the form.

F800127 Shipment Transfer Record will be updated by 2023-11-06 to reflect the appropriate temperatures and include an area to document the receipt time.

g) The instructions in the corresponding Work Instructions (09 350; 09 351; 09 356) were not clear with respect to documentation of the following:
(i) when equipment is placed back into service after in house demand maintenance;
(ii) when equipment is placed out of service and returned to service after maintenance by external service providers.

WI 09 240 Out of Service In Progress Tags/Labels Application and Removal details the requirements to place an "Out of Service" label when equipment is placed out of service and the removal of the label once the equipment is restored to a validated state. The label must include the reason and the date when the equipment is taken out of operation. Once the equipment is ready to be placed back into service, the "Out of Service label" is removed. The return to service date occurs when the "Out of Service" label is removed.

h) The shelves and the agitator RAM Asset ID#s did not aways match inside some incubators, even though the agitators were indicated as non-portable in RAM. For example, for a WIP Incubator (RAM Asset ID# R22357):
(i) An agitator with RAM Asset ID# R22364 was on a shelf labelled for an agitator with RAM Asset ID# R22363;
(ii) An agitator with RAM Asset ID# R20656 was on a shelf labelled for an agitator with RAM Asset ID# R22364.

MQE-23-001595 was initiated on 2023-05-08.

For clarification, agitators are considered non-portable as Equipment Services only removes the agitators to perform the maintenance. Portable equipment is when the asset owner is required to send the equipment to Equipment Services for maintenance.

The labelling on the shelves do not serve a purpose and have been removed. The incubators are to include the agitators that were used as part of their validation. Each agitator is labelled with a unique ID corresponding to the unique ID on the incubator.

On 2023-05-03, Equipment Services confirmed that all of the agitators within the incubators were correct, in that they were used as part of their validation.

Section 98 - Personnel

3. **The records of staff qualifications, training or evaluation of their competency were not always sufficient. For example:**
a) For a Distribution Lab Attendant, the date of training to WI 05 060: Facility Distribution of Blood components could not be confirmed.

It was confirmed that the distribution lab attendant completed training to WI-00066 (legacy

05 060) Facility Distribution of Blood Components on 2020-07-03 and the competency assessment for rare blood component distribution was successfully completed on 2020-08-26.

b) For a Production Lab Attendant, the confirmation of Employee training record for WI 02 184: Preparation of Buffy Coat, did not correspond to the type of training required in the corresponding Training Matrix requirement for this staff. The training record indicated a requirement for "performance measurement" training, whereas only "awareness" training was needed.

The Learning Level documentation on the Confirmation of Employee Training form is selected from a drop-down menu. The incorrect selection was made in error. There is no impact to the training provided to the staff member, as there was no performance measurement component required for this training. The staff member received the required training to meet the awareness level training requirement.

Implementation of the new training platform SuccessFactors Learning Management System (LMS) will eliminate the use of manual records for documentation of training and competency assessments. LMS implementation in Supply Chain departments is targeted for September 2023. Verbal feedback was provided to the trainer during the audit.

Section 100 – Equipment

4. **The validation, calibration, cleaning, or maintenance of critical equipment were not always sufficient.**
   There was no documented process for cases where critical equipment for donor testing may be used before their validation approval and implementation dates. For example, actual test runs were conducted on February 28, 2023 with the Cobas p680 and Cobas 8800, before the corresponding validation, IOQ-COB-008-2023-02-15-151505, was approved on March 1, 2023, with an implementation date of March 1, 2023. It is acknowledged that test runs were only released post validation approvals.

   DEV-23-003652 was initiated on 2023-05-02.

   It is acknowledged that the validation protocol should have had final sign-off of the protocol certification by the Quality Assurance representative prior to initiating the testing process. There was no impact to the validated state of the cobas p 680 and cobas® 8800 system and to the sample testing performed between release of the system and final approval of the protocol. The protocol had been completed, all test sections reviewed by all signatories, all deficiencies closed, and all system specifications met.

   The Quality Team will issue a memo to the TD Process Group by 2023-05-30 reminding the Group that WI-00481 (legacy 08 413) Executing Qualification Protocols and WI-00526 (legacy 09 240) Out of Service/Service in Progress Tags/Labels Application and Removal need to be followed.

Section 117 – Records

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

a) The corresponding Form number at the bottom of the form did not print out in a legible manner for several Bacterial Detection Testing (BacT) records. Specifically, for records reviewed with respect to Clinic Date 2022-08-22/Test Date 2022-08-24.

The impacted form identification information was reviewed by Quality Assurance and determined to be legible for traceability. The issue with the printer had been identified by Canadian Blood Services staff prior to the inspection and was corrected on 2023-03-06.

b) A Building Access log showed a post-dated review date of March 29, 2023, for a record that was presented for review during the inspection on March 23, 2023.

MQE-23-001541 was initiated on 2023-05-03.

The Temporary Card Access Log was reviewed a second time and documentation of the review was completed with the correct date on 2023-05-17.

c) Not all visitors were documented on some access logs reviewed, specifically on March 22, 2023, supervisory reviewed on March 23, 2023.

MQE-23-001541 was initiated on 2023-05-03.

The guard was informed of the incident and will be re-trained to the WI-00661 (legacy 13 006) Temporary Building Access Control by no later than 2023-06-15.

In addition, Facilities will remind all security guards of the temporary access card logging process through a memo to ensure all staff are aware of the requirements. This will be completed by 2023-08-31.

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

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