Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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2021-05-20
CBS Control #: CBS6508
HPFB File #: C1892-100390
REF: H-2021-HO

Mr. Kevin Donato
Regional 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 Mr. Donato:

**Re: Responses to Health Canada Inspection of Licensed Activities at Head Office 2021-03-22 to 2021-03-30**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-04-23.

**Section 94 - Quality Management System - Repeat Observation**

1. **Stemming from the observation during the previous inspection in July 2018, events categorized as low overall risk were still not being assessed regarding whether or not a CAPA is warranted.**

   *As per 09 233 "Deviation/Minor Quality Event Management - Quality Assurance Review" v. 4.0, a CAPA may be initiated for low risk deviations when deemed necessary by Quality Assurance.*

   *A process is also being finalized to further assess the need for CAPA initiation of low risk quality event. To that end, MPP 08 03 "Quality Event Management" v. 1.1 will be updated by 2021-12-31 to require data associated with low risk deviations to be reviewed at Quality Management System Review meetings, and CAPAs will be initiated for those events that have the highest product impact.*

**Section 95 - Operating Procedures**

2. **Some operating procedures were not always followed:**
   **a) The timeframes were not always met for reviewing facilities documentation as indicated in Attachment 2 of Facilities Maintenance Program, WI 13 032 rev 4.1, effective 2017-09-11. For example, the Security Access Card Log, F800363, completed on 2020-11-04 was reviewed on 2020-12-30, contrary to the SOP requirement of within 10 department business days.**

   *MQE-21-000966 was initiated on 2021-03-24.*

   *The Facilities Manager has developed a calendar alert tool with the facilities team to routinely*

*review required documents every 8 days for sign off. Eight days was selected to ensure the reviews are completed within the 10 business days requirement.*

*The Temporary Card Log forms (F800363) have been corrected in accordance with the Manual of Good Documentation Practices and the Quality Event Management system.*

*In addition, staff were reminded to adhere to timelines as per 13 032 Facilities Maintenance Program on 2021-04-29 during a staff meeting followed up by an email on 2021-05-12.*

**b) Section 1.2.2 of Temporary Building Access Control, WI 13 006 rev 9, effective 2020-03-31, was not followed for performing access card reconciliation using the Temporary Card Audit Log, F800086, from November 14 to 29, 2020.**

*DEV-21-002370 was initiated on 2021-03-24.*

*A full review of temporary card log forms F800086 from January 2020 to present will be completed by 2021-05-31. Any deviations and corrections will be made in accordance with Good Documentation Practices and the Quality Event Management System.*

*In addition, the card reconciliation will become a shared responsibility ( security guard the receptionist), rather than the responsibility of a single individual as is currently the case. This will ensure that the process is completed regardless of who is staffing the reception desk.*

**c) Section 3.1.1 of Manual of Good Documentation Practices, MAN 08 851 ver 8, effective 2020-12-28, was not always followed. For example, "End of Record" was not recorded following the last entry on Security Access Card Logs, F800363, completed on 2020-08-23, 2020-10-03, 2020-10-10, and 2020-10-25.**

*DEV-21-002370 was initiated on 2021-03-24.*

*The individuals who completed and reviewed the documents were reminded of the importance of good documentation practices during a staff meeting on 2021-04-29 and by email on 2021-05-12..*

3. **Some operating procedures were not always followed.**
   **The timeframes from the point of the "discovery of the event" as indicated in WI 09 230 ver 3, effective 2021-02-14, Deviation/Minor Quality Event Management [e.g. Operational Review (identification/containment); Closure] were not always being met. Several examples included, but were not limited to, the following files:**

   **DEV 20-003819, QER 55-19-140178 (QA Product Supply Chain)**

   **DEV 20-002670 (Laboratory and Enabling Services)**

   **DEV 20-001443 (IT deviation)**
   **DEV 20-006202 (BacT laboratory)**

   *Staff will be reminded by 2021-06-25 to adhere to timelines as per WI 09 230 for Deviations and Minor Quality Events and to provide an explanation for the delay as described in Attachment 5.*

   *09 230 v3 will also be revised and the recommendation will become a requirement for providing an explanation for the delay in meeting the timing requirements and the impact to products or services will be moved from Attachment 5 to Attachment 6 – Deviation/Minor Quality Event Timeframes. This update is targeted for completion by the end of December 2021.*

**<u>Section 96 - Operating Procedures</u>**

4. **The operation procedure did not meet some requirements.**
   **Regarding work instruction 08 530 Reporting to Regulatory Authorities, rev 15, effective 2020-10-30, the instruction in step 9, "Establish a timeframe for submission of the**

**Individual Report, as required," namely,**

> ***"Serious Donor Event: Fatality – 24 hours, hospitalization – 15 days if the reaction could impose a risk to the safety of blood product(s) Regulations."***

**does not fully meet the requirements of s. 109(1) of the Blood Regulations which sets the timeframe as "[…] within 24 hours after it learns of the death of the donor or within 15 days after it learns of the adverse reaction in any other case." [For further information, s. 109(1) also further defines the requirement to report these serious adverse reactions if they occur "during a donation or within 72 hours after a donation."]**

**In addition,**

> *"**Adverse reaction: Fatality – 24 hours following the determination within the investigation by Medical that the fatality could be attributed to the safety of the blood product(s)***
>
> ***Adverse Reaction: Others – 15 days if the reaction could impose a risk to human safety or to the safety of the blood product(s)."***

**does not fully meet the requirements of s. 113(1) of the Blood Regulations which sets the timeframe as "[…] within 24 hours after it learns of the death of the recipient or within 15 days after it learns of any other unexpected adverse reaction of serious adverse reaction."**

*This interpretation for the reporting of adverse transfusion events is not consistent with a decision taken at a Bilateral meeting with Health Canada on June 12, 2018. This was further discussed at the most recent bilateral meeting of May 18, 20221, and the Director General, BRDD will have internal discussion at Health Canada regarding this issue. It is also our understanding that the blood operators will then be consulted before any decisions are made.*

*In the case of the donor, as described in the Guidance Document for the Blood Regulations, section 109 (1) reactions are reported within the specific timeframe if it poses a risk to the safety of the blood, meaning it is associated with the safety of blood processed and distributed.*

*Therefore, at this time, work instructions in 08 530 are aligned to the requirements for both situations cited and no actions are deemed necessary.*

5. **Some operating procedures were not kept up-to-date. Section 1.3.5 of Security Access Control, WI 13 025 rev 7 effective 2018-06-04, does not describe the current process. Section 1.3.5 of the WI includes the requirement "Facilities Operations: Review documentation, sign and date the list…" referring to the semi-annual cardholder access levels lists generated from the card access system described in Section 1.3.1 of the WI. Multiple semi-annual lists were not signed/dated by Facilities Operations as email approvals are accepted. While Section 1.3.2 of the WI includes the note "Communication and responses may be completed via email", it is not clear how Sections 1.3.2 and 1.3.5 of the WI relate to each other or to the current process.**

   *MQE-21-001497 was initiated on 2021-05-06.*

   *It has been clarified that as per step 1.3.5 of WI 13 025 Security Access Control v7, Facilities Operations is responsible for the review of the semi-annual lists generated and to sign and date the documentation.*

   *A review of all semi-annual lists from January 2020 to present will be reviewed by 2021-05-31. Any deviations and corrections will be made in accordance with Good Documentation Practices and the Quality Event Management System.*

   *The reviewing manager will be retrained to WI 13 025 Security Access Control v7 by 2021-05-31.*

**Section 117 – Records**

6. **Records related to security access were deficient. For example:**
   **a) Multiple (at least 15) Security Access Card Logs, F800363, were incomplete, including,**
   **i. "Returned Initials" columns were left blank on multiple dates, including but not limited to: 2020-12-27, 2020-08-17, and 2020-05-27;**
   **ii. "Facilities Operations" signature sections were left blank on multiple dates, including but not limited to: 2020-12-10, 2020-11-08, and 2020-11-03;**
   **iii. The record of use of access card E119 was missing on 2020-10-28; a note was found on the 2020-11-04 log stating "…badge E119 was returned from 2020-10-28, badge is now reactivated"; however, the 2020-10-28 log did not include the issuance of access card E119. The October 2020 Temporary Card Audit Log, F800086, included a note dated October 28, 2020 explaining that badge E119 report by employee was missing and that the badge was deactivated.**

   **b) "Facilities Operations" signature and date sections were left blank on both pages of the November 2020 Temporary Card Audit Log, F800086.**

   *Combined response for a) and b):*

   *DEV-21-002370 was initiated on 2021-03-24.*

   *A review of Temporary Access Card Logs (F800363) and Temporary Card audit log forms (F800086) from January 2020 to present will be completed by 2021-05-31. Any deviations and corrections will be made in accordance with Good Documentation Practices and the Quality Event Management System.*

   *Staff were reminded on 2021-05-12 to follow SOP 13 006, Temporary Building Access Control when filling in the card forms.*

   *The following corrective actions will be implemented by 2021-05-31. The card reconciliation will become a routine shared task for those who staff the reception desk rather than the current state where one person completes the task. Records will be sent to the Facilities Manager daily to verify SOP compliance.*

   *In addition, the Facilities Manager has developed a calendar alert tool with the facilities team to routinely review required documents every 8 days for sign off. Eight days was selected to ensure the reviews are completed within the 10 business days requirement.*

7. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**
   **a) The Biological Safety Cabinet Maintenance log, F8000953, was incomplete. For example, unit R000018528 was not recorded as being cleaned for the shut down on Nov 30, 2020, and unit R000021316 did not have the "certification cleaning" entry noted for October 1, 2020, when it had its preventative maintenance. Upon the inspector identifying the issues, Minor Quality Events MQE-21-000-940 and MQE-21-000-942, respectively, were completed during the inspection.**

   **b) Section 3 of the Proficiency Testing Checklist, 1000105652, was not recorded as reviewed under "Reviewed by (Supervisor/Associate Director/Designate)" for the January 14, 2021 IQMH Proficiency Survey BACT-2101. Upon the inspector identifying the issue MQE-21-000-953 was completed during the inspection.**

**c) The Confirmation of Training, F800329, was not accurate for the initial performance training of a Microlab employee on Wis 02 304 rev 10, 02 305 rev 18.1 and 02 306 rev 6, in January 2020; the entry "2018-0" was crossed out and corrected to "2018-11-15" on 2019-01-14; the trainer's signature was dated January 10, 2019. It is acknowledged the employee was on sick leave between November 2018 and January 2019 and that the performance training took place on January 10, 2019. Upon this observation by the inspector MQE-21-001-025 was initiated during the inspection and completed on 2021-03-29.**

**Combined responses for a), b) and c)**

*As indicated MQE-21-00940, MQE-21-000-942, MQE-21-00953, MQE-21-000955, and MQE-21-001025 were initiated and completed during the inspection. Details of the observations and MQEs were discussed during a Micro Lab staff meeting on 2021-05-06. In addition, staff were reminded of the importance for good documentation practices.*

**d) PM/calibration/inspection records were not retrievable at the time of this inspection for the months between March 2020 and March 2021 for generator Cummins, performed as per Generator Operation and Maintenance, WI 13 021 rev 5, effective 2019-04-29.**

*DEV-21-003511 was initiated on 2021-05-06*

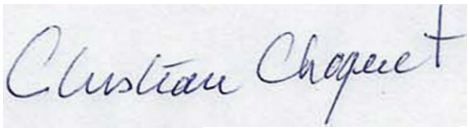
*Although the generator maintenance records were not provided at the time of the inspection, they are all available, with the exception of the semi-annual inspection (form F800120) for 2020-09-16.*

*When the annual test was completed on 2020-09-16, staff did not ensure the semi-annual inspection was completed as instructed on F801245.*

*Head Office staff* was *retrained to WI 13 021 Generator Operation and Maintenance by 2021-05-10 to ensure they follow the instructions on the forms.*

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,



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