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Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Head Office
2018-07-09 to 2018-07-13

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-08-08.

Section 52 – Testing

1. **During the review of records associated with the subculture of BacT/ ALERT Positive Bottles (BPA-BT-18015) for apheresis platelet unit C055618271200201, it was noted that the subculture QC plates and Test plates (BA, ChA, CDC) were only incubated for 3 days and then reported as no growth. Procedure 11 012 TCC00110 Follow-up of Positive Bacterial Cultures and/or Blood Components, steps 4.1.1 to 4.1.3 require subculture plates to be incubated for at least 5 days before reporting as no growth. As a consequence of this testing, an apheresis plasma unit collected concurrently with the apheresis platelet unit was removed from quarantine, released, and distributed as safe for transfusion.**

   QER # 135-18-103017 and CAPA # 135-18-103017 were initiated on 2018-07-19.

   Repeat testing of bottle BPA-BT-18015 was performed showing negative growth on the plates after 5 days of incubation. Staff will re-train to procedure 11 012 TCC00110 Follow-up of Positive Bacterial Cultures and/or Blood Components by 2018-09-30.

Section 94 – Quality Management System

2. **The processes for performing bacteriological culturing and identification testing did not ensure procedure 11 012 TCC00110 Follow-up of Positive Bacterial Cultures and/or Blood Components is performed consistently and as it was intended to be performed in order to produce predictable outputs. For example,**
   a) **Numerous records of Identification of Gram Positive Cocci from BPA Bottles (F800947) did not document the results for the positive and negative control organisms for catalase and coagulase testing.**

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b) Numerous records of Identification of Gram Positive Cocci from BPA Bottles (F800947) did not document the coagulase and lyostaphin results for the test organism to be identified.

c) The positive control result (Staphylococcus aureus) for catalase testing was documented as negative instead of the expected positive result. This documentation invalids the testing performed on the bacterial isolate from BPN-BT-18091.

d) The coagulase test result for the BPN-BT -18091 bacterial isolate was not documented.

e) The Bacterial Identification-BacT/ALERT Positive Bottles (F800946) did not document growth for the BA agar plate for BPN-BT-18027.

f) The Bacterial Identification-BacT/ALERT Positive Bottles did not document the expiry date check for the gram stain reagents for testing performed 2018-03-13.

g) A number of records for the Identification of Gram Positive Cocci from BPA Bottles (F800947) did not document the performed by section for Catalase control strain testing.

h) Records were reviewed and signed off as complete and accurate even though numerous documentation errors and omissions were noted.

Combined response for 2a to 2h:

QER 135-18-103020 was initiated on 2018-08-10.

Staff will re-train to procedure 11 012 TCC00110 Follow-up of Positive Bacterial Cultures and/or Blood Components by 2018-09-30. Also, a re-training session on Good Documentation Practices will be delivered to Micro Lab staff by Quality Assurance the week of September 10th, 2018.

3. The Quality Event Management system is not followed consistently by staff to ensure errors and accidents are thoroughly investigated. For example,

a) The defined criteria for determining the scope of an investigation are not consistently followed:

i. To ensure all processes, equipment, supplies, personnel, etc. are identified, assessed and evaluated.

ii. To evaluate whether the issue applies locally or nationally.

iii. To ascertain whether the point of discovery (i.e. prior to release or after distribution) signifies potential risk to control of processes.

b) The criteria for assessing the categories used to perform the Risk Assessment of an issue were not sufficiently defined to ensure consistent assessment.

Combined Response for 3a and 3b:

An evaluation of quality event reports will be conducted to assess the extent of the inconsistency. Based upon the assessment, appropriate corrective actions will be identified by 2018-12-07.

In the interim, consistent application of the Quality Event Management (QEM) process will be reinforced by 2018-09-28 with the quality assurance management team as all quality events are reviewed by quality assurance for appropriateness of actions and completeness of documentation.

c) Low risk Quality Event Reports are not assessed for Corrective Action Preventative Action (CAPA).

SOP 08 812, Quality Event Management – Quality Assurance Assessment and Review requires the quality assurance reviewer to perform a risk assessment for every quality event. The risk

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assessment includes an evaluation of the probability of occurrence, detectability, and severity of impact of product and patient/donor. The outcome of the risk assessment is documented on the quality event report.

Every quality event classified as medium or high risk results in the initiation of a CAPA. The CAPA, managed per SOP 08 175, CAPA Management, will investigate the event to identify the root cause(s) and address them with appropriate corrective/preventive actions.

Low risk quality events are defined as those which do not present a risk to patient, donors or staff. At this time, Canadian Blood Services has chosen to focus its corrective and preventive action resources on events that are more potentially impactful (i.e. medium and high risk).

Section 95 – Operating Procedures

4. **Although review of NDAS temperature trend logs were performed, they did not always occur weekly as required by 13 009 Rev 9 NDAS Site Operation (eff. 2017-03-13) for example AVL 2016 Upright Freezer and LAN 1001 Space Temp.**

Staff have been reminded of the importance of performing weekly review of NDAS reports as per SOP 13 009 Rev 9, NDAS Site Operation.

A review of weekly NDAS temperature trend logs records from August 2017 to August 2018 was completed by 2018-08-31 to identify and correct any late reviewed reports according to the QEM process. It should be noted that with the implementation of Viewlink in August 2018, the review of NDAS temperature trend logs is no longer a requirement.

Section 117 – Records

5. **Records were not always accurate, complete, legible, indelible and/or readily retrievable.**
   a) **The records for temporary access cards were deficient, for example:**
      i. **The information documented on the Temporary Access Card Log (F800363) did not match information documented on the Temporary Card Audit Log (F800086) on a number of records e.g. the dates when cards were returned did not match.**
      ii. **The site was not recorded on the Temporary Access Card Log (F800363) covering dates Apr 4, 2018 to May 1, 2018.**
      iii. **The notations in the Comments section documented on the Temporary Access Card Log (F800363) were not referenced to the area of the log e.g. *2 explained the documentation for card E120 but there was no *2 linked to the line for this card.**
      iv. **The returned initials were not documented for card ID 1913053407 issues 2018-03-02 and for Card ID C154 issued 2018-05-02 on the Temporary Access Card Logs (F800363).**
      v. **The company was not documented for card ID C-152 issued on 2018-05-29.**

Combined Response for 5ai to 5av:

QERs 120-18-106492, 120-18-106491, 120-18-106490, 120-18-106489, 120-18-106488 were each initiated on 2018-08-17, respectively.

*Regarding the missing site name error on the Temporary Access Card Log, it can be verified that the document in question is for 1800 Alta Vista using the authorized facility agent list. This list can also be used to verify the company name for a repeat facilities agent that was missing. Regarding the missing *2 for one record, the entry was verified and will be corrected using verifiable data and good documentation practices. Regarding the two instances of missing returned initials, it was confirmed that management review did occur on the following business day and no cards were missing.*

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The temporary access process has changed with the elimination in 2017 of exterior door access on temporary cards and therefore those who fail to return temporary cards cannot gain access to the site.

A review of completed forms F800363 from January 2018 to June 2018 has been completed and there were no further discrepancies or missing information. Also staff will re-train to SOP 13 006, Temporary Building Access Control by 2018-09-11.

b) The Training Plan and Initial Training Requirements Matrix for 07 291 IT Incident Management for a Telecommunications Cost Analyst indicated P (performance measurement) training was required. However an email from Corporate Training dated July 10, 2017 indicated awareness training was required. The training plan and matrix had not been revised. Training provided to a Telecommunications Cost Analyst on June 13, 2018 for this SOP was awareness.

The training provided for 07 291 v14, IT Incident Management and associated confirmation of employee training records were correct as awareness training and all staff were trained appropriately. The training plan for 07 291 v14 was revised on 2018-07-25 to indicate awareness training. The training matrices for all relevant IT departments will be updated by 2018-09-21 to reflect the required awareness level of training for 07 291 v14.

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: Shelley Smyth
A/Supervisor – Blood Tissues, Organs and Xenografts
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