Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-10-28
CBS Control #: CBS6367
HPFB File #: C1892-100390
REF: H-1920-BRM

Ms. Urbee Shome-Pal
Compliance Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Shome-Pal:

Re: Further to the Responses to the Health Canada Inspection of the Licensed Activities at Brampton Operations from 2019-04-29 to 2019-05-03 and from 2019-05-28 to 2019-05-31

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2019-10-01, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of licensed activities at Brampton Operations.

Section 94 - Quality Management System

1. **The system for identifying and investigating errors and accidents was not sufficient. For example:**
   a) There was no documented process in place to consider all factors (i.e. processes, equipment, supplies, personnel, etc.) that could have contributed to the errors or accidents documented as Quality Event Reports (QERs). Furthermore, there is a lack of instructions around how to conduct risk assessments consistently and there is no requirement to assess if a CAPA would be required if a QER is given a low risk assessment. Specifically,
   (i) For QER 56-18-136411, Hospital received four units that were damaged. One leaked upon thawing. Risk assessment was indicated as low.
   (ii) For QER 56-18-122125, Hospital reported receiving a shipment of 13 RBC units in which one bag leaked and contaminated the rest of the bags with red cells. Units were discarded. Risk assessment was indicated as low.
   (iii) For QER 56-18-117249; Hospital reported 2 RBC units with suspected hemolysis. Hemolysis confirmed. The units were returned and discarded. Risk assessment was indicated as low.
   For all of the above examples and for all the QERs reviewed, if the risk was assessed as low, there was no root cause analysis conducted or an assessment of whether any further actions or CAPA would be required for the incidents.

   Canadian Blood Services Response:

   Instructions on how to conduct risk assessments are provided in SOP 08 812 "Quality Event Management – Quality Assurance Assessment and Review" and in section 9 of the quality event

report itself. The risk assessment performed by quality assurance 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, which includes processes, equipment, supplies, personnel, etc., as required by the use of tools such as 5 Whys, MEEpP or fish bone analysis.

Based upon the review of the quality event reports, it was found all risk assessments were completed appropriately and correctly classified as "Low" risk.

By their definition, low risk quality events are those which present no or minimal risk to patient, donors or staff based on worst case scenario. 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). At a later point in time (to be determined), Canadian Blood Services will implement a strategy for the management of low risk quality events.

Health Canada Follow-up letter dated 2019-10-01:

The CBS response does not address the portion of this observation where it speaks to the lack of a documented process to consider all factors that could have led to an error or accident. It was stated during the September 19, 2019 meeting with CBS and HC that a new process for electronic documentation of QERs will be implemented in Oct 2019. Please confirm whether or not this new process will address this gap and how it will do so. The response also indicates that CBS will implement a strategy for low risk quality events at a later point in time. Health Canada would like a firmer commitment by CBS on this matter and is therefore requesting a timeline for the implementation of this strategy. Additionally, please also provide a copy of SOP 08 812 highlighting the sections that provide instructions on how to conduct a risk assessment.

Canadian Blood Services Response:

The automated Quality Event Management process will be implemented on 2019-10-28, at which time the initiator will be prompted to enter specific information related to the description of the quality event. The mandatory information will include: a general description; the location or department where the event was discovered; how the event was discovered; the specific requirement or result that was not met; and the procedure associated with the process. This will further provide information to consider all factors that could have led to an error or accident and enable thorough investigations and accurate risk assessments to be completed.
Previous reviews of quality event reports randomly sampled were performed on two separate occasions, and 157 reports were reviewed each time. Each review has shown that in all cases product containment and disposition and the risk assessment levels were appropriate and CAPAs were correctly initiated where required.

As mentioned previously, we have chosen to focus our limited resources on corrective and preventive action on events that are more potentially impactful (i.e. medium and high risk). Other than to share our intent to conduct by 2020-01-31 a review of low risk QER that are reportable, nothing more definitive has yet been determined with regard to a strategy for the management of low risk quality events through the CAPA process. We fully intend to define such a strategy but as we have to balance the need to advance with our limited resources more pressing and higher priority corporate initiatives, this has yet to be determined.

Please refer to Section 2 of the attached SOP 08 812, Quality Event Management – Quality Assurance Assessment and Review version 6 for instructions on performing a risk assessment and Section 9 of the attached Quality Event Report.

b) The following deficiencies were also noted for QERs reviewed:
ii) Some time frames for the completion of QERs were not always met contrary to SOP 08 810: Quality Event Management, Identification and Containment, Revision 7. For instance, QER 130-18-117287 was discovered on 2018-12-19 and closed on 2019-01-30. This does not meet the instructions indicated in the table to Attachment 8 of SOP 08 810, where it instructs the closure of the QER to be within 15 calendar days of discovery of the event.

Every effort is made to close QERs within the required timeframe however there are some instances where closure is delayed due to unusual circumstances such as in this case where additional information was required from the hospital, i.e., there was missing information on the Notification of Component Recall/Withdrawal form that had to be requested from the hospital. Canadian Blood Services contacted the hospital for the missing information on 2018-12-21 and again 2018-12-24. The hospital provided the requested information on 2019-01-23.

Health Canada Follow-up letter dated 2019-10-01:

Is there a process in place to make a note if established timelines will not be met for QERs?

Canadian Blood Services Response:

With the implementation of the automated Quality Event Management system on 2019-10-28, an explanation when timing requirements are not met and why it is acceptable (i.e. no impact to products or services) will be required.

2. **The system that identifies, documents and tracks all critical equipment or supplies was not sufficient. For example:**
b) In the Donor Testing TD lab, it was noted that a P100 volume pipette was labelled with two different Equipment RAM numbers, R13853 (white label) and R13852 (yellow label). QER 56-19-120164 was initiated on May 9, 2019 and the relevant pipette along with another one that was discovered to have the same issue were taken out of service.

QER 56-19-120164 initiated 2019-05-09.

The white labels representing the preventive maintenance were corrected during the inspection on the 2 pipettes to correspond to their appropriate yellow RAM asset ID labels.

Refresher training to SOP 09 356, Equipment Services Work Management will be completed by 2019-08-16.

Health Canada Follow-up letter dated 2019-10-01:

Was an assessment done to ensure that other equipment did not have the same issue? To whom will this refresher training be given?

Canadian Blood Services Response:

This error occurred as a result of batching the pipettes for maintenance. The pipettes were the only equipment being batched and this practice has been discontinued.

Refresher training was provided to all FSRs in August 2019.

c) For April 9, 2019 production records, the equipment IDs for some equipment were not tracked. For example, Macopresses (Extractors), GSE Scales and Sealers. This would also apply to all production records after the implementation of the new production process flow and related production batch forms.

Canadian Blood Services is able to identify GSE Scales, Macopress (Extractors) and Compodocks utilized each day through the daily maintenance records. Sealers are not documented on the production records as tubing seals are inspected as they are made. In the event that a piece equipment is taken out of service, an "out of service" tag is attached to prevent further use of the equipment. In addition, a Quality Event is initiated and, as part of the process, an assessment of the impact on components produced is conducted.

Health Canada Follow-up letter dated 2019-10-01:

Please confirm whether or not compodocks are being tracked on production records. Additionally, would the centrifuges, which are being tracked on production records also have associated daily maintenance records? If so, then why are some critical equipment being tracked and not others? Please provide a rationale.

Canadian Blood Services Response:

Compodocks are being tracked on the production records. The centrifuges do not have a daily maintenance record as the maintenance is performed weekly. The decision to track specific equipment on the production records and not others is based on the potential impact to the products being produced.

3. **The document control or records management system was not sufficient. For example:**
a) The condition of pre-printed or photocopies of some forms reviewed were poor with faded cells, pre-printed strikethroughs and some missing tombstone information. Specifically, Form F800382 (2016-07-15): PCM Conditioning Cycles and Form F800716 (2016-05-20): PCM Conditioning Cycles - Transport to Clinic.

All forms that were pre-printed or photocopied were removed and discarded at the time of the inspection. Staff were reminded to only print the required amount of printable forms as per SOP 08 042 Use of On-Line Controlled Documents. Logistics Attendants staff were also reminded of the importance of legible, accurate and complete records.

Health Canada Follow-up letter dated 2019-10-01:

How was this communicated to staff and what was the date of this staff reminder?

Canadian Blood Services Response:

This was verbally communicated to on-site Logistics Attendants at the time of the inspection on 2019-05-06 and to the remaining Logistics Attendants during morning and afternoon shift huddles on 2019-05-07.

b) The following were noted for equipment maintenance records reviewed in RAM contrary to the relevant sections of SOP 09 356: Equipment Services Work Management, Revision 5:
(i) PM records of R 19221 (Espec Chamber), were missing Pages 2 and 3 for MNT-099848.
(ii) PM records of R 14168 (Fridge storing SPE reagents), were not fully uploaded and verified for MNTs 104556, 104557, 104558, and 104559.

QER 56-19-137746 was initiated on 2019-07-04.

The missing preventative maintenance records were re-scanned and uploaded into RAM.

Staff were reminded to verify all uploaded preventative maintenance forms into RAM as per 09 356 Equipment Services Work Management.

Work plan templates (automated Preventive Maintenance (PM) forms generated and tracked through the RAM system) will be implemented for the refrigerators and freezers by end of March 2020. This will eliminate the requirement to upload maintenance records into the system.

Health Canada Follow-up letter dated 2019-10-01:

How was this communicated to staff and what was the date of this staff reminder?

Canadian Blood Services Response:

All Field Services Representatives completed refresher training to SOP 09 356. This was completed by 2019-08-08.

Section 95 - Operating Procedures

4. **Some operating procedures were not always followed. For example:**
b) On a Prism Next Assay Kit Shipment Acceptance form for HCV assay kit for shipment received on Feb 6, 2019, the incorrect expiry date of 2019-10-15 was recorded for Master Lot Number 95022M500. The correct expiry date for this Master Lot Number was 2019-10-16. This is contrary to step 1.2.1 in SOP 30 620: Prism Next Shipment Acceptance, Revision 4.

c) On a Prism nEXT HBsAg Confirmatory Assay Worksheet for Prism nEXT S/N 1518, Test Date 2019-05-26, Batch ID 1409, the Additional Dilution Required section was not completed for Sample ID# C055519425720. This is contrary to Step 4.1.2 of SOP 03 656: Prism Next HBsAg Confirmatory Assay, Revision 4.

Combine b and c:

The records were corrected as per good documentation practices

Health Canada Follow-up letter dated 2019-10-01:

Please provide the date(s) by which these records were corrected. Were any other records of the same nature reviewed to ensure that these errors were not systemic to rule out a requirement for re-training of relevant staff to the cited SOPs?

Canadian Blood Services Response:

The records were corrected on 2019-07-04. The documentation corrections were verifiable by the expiry date on the on the Lot Release memo and Abbott Prism Assay Kit Card and by the test results and interpretation of the sample tested on the Prism report "Abbott Prism (tm) Confirmatory Report" which did not necessitate further testing on a dilution. No further records were reviewed as it was deemed that the records audited during the inspection represented a sufficient sampling size and since no other evidence of GDP errors were detected, re-training was not deemed necessary.

d) The following deficiencies were noted for production records reviewed. Specifically,
(i) On Form F800914 (2017-03-05): Plasma Record, dated April 9, 2019, the batch colour sticker was placed incorrectly covering the component type and not in the cell which stated, "Place Coloured Dot Here";
(ii) On Form 1000105505 (2014-04-14): Whole Blood Component Assessment/Production Record - B2, dated Dec 8, 2018, a check mark was not recorded to indicate the component type (RP) for each donation number listed on the records for Index Bleed

Times 08:21, 09:08, 10:15, 13:30. This is contrary to section 1.5.2 of SOP 02 723: Perform Electronic Separation, Revision 26. It is acknowledged that downtime procedures were being followed during this time, but it was confirmed that the check marks should still have been indicated under the corresponding component type for each donation number.

Random production days' worth of plasma records were reviewed and no further errors regarding the placement of the stickers were identified.

Records were corrected on 2019-05-21 as per good documentation practices.

Health Canada Follow-up letter dated 2019-10-01:

How many production days' worth of plasma records were reviewed?

Canadian Blood Services Response:

Five days of production records were reviewed.

g) The Validation assessment, VAL2019-051 for equipment changes related to production equipment, signed by the process owner on 2019-02-11 and on 2019-02-13 by QA, indicated "no validation required" for 3 new Zebra Labelers. This is contrary to SOP 20 091: Management and Installation of Zebra Label Printers, Revision 1. It is acknowledged that despite this statement, the validation of the Zebra label printers was conducted.

All validation activities for Zebra Label Printers are completed by the IT department as per SOP 20 091 Management of Installation of Zebra Label Printers. The intent of the validation assessment; "No validation required", is to indicate that there are no additional qualification activities required by the validation department. We acknowledge that the statement "No validation required" is misleading and as such, more accurate validation assessment responses have been developed.

Health Canada Follow-up letter dated 2019-10-01:

For instances where no additional qualification activities are required by the validation department, what will the statement now be instead?

Canadian Blood Services Response:

For situations where there are no additional qualification activities required by the Validation department as the qualification activities are already established in approved work instructions, the guidance has been given to Validation department personnel to include reference of those instructions in the assessment response. An example of the assessment response would be: "Please perform the qualification activities described in <department> work instructions ###."

h) The system, Threshold and Alarm Checks were not recorded on the Viewlinc Daily System Checks Form F800968 (2017-07-18) in Production for January 31, 2019, as per required on the form and steps 5, 10 and 13 of section 3 daily systems checks of SOP 13 036: Viewlinc Operation Revision 2.

The record has been corrected as per good documentation practices. There was no impact to product as checks were performed without incident the day before and day after.

Health Canada Follow-up letter dated 2019-10-01:

Please provide a date by which these records were corrected.

Canadian Blood Services Response:

The record was corrected on 2019-07-10.

j) The following deficiencies were noted on Form F800968 (2017-07-18): Viewlinc Daily System Checks, for records completed by Distribution:
(i) ITSM # 665544 was generated for an issue related to Viewlinc probe BRM 5012 for R2457 (Platelet Incubator). Although, the issue lasted from Dec 29, 2018 to Jan 7, 2019, the corresponding ITSM # was not noted between Jan 2 - 6, 2019. Additionally, the Squipp impact was not indicated for this equipment on the forms.
(ii) ITSM # 669862 was generated for an issue related to Viewlinc probe BRM 1500 for R2466 (Platelet Incubator). Although the issue lasted from Jan 26 to March 11, 2019, the corresponding ITSM# was not noted consistently. For instance, it was not noted between Jan 27 - 31, 2019. Additionally, the Squipp impact was not indicated for this equipment on the forms.

QER 56-19-140453 was initiated on 2019-07-11.

Procedure 13 036, Viewlinc Operation was revised and implemented on 2019-06-11. The revision included clarification to the instructions regarding adding comments pertaining to SQuIPP and recording the ISTM# in the comment section of the Viewlinc Daily System Check form. The QER and the observation were reviewed with Technical Specialists to ensure that documentation is consistent with instructions outlined in the procedure.

Health Canada Follow-up letter dated 2019-10-01:

Please provide a date of review with the technical specialists.

Canadian Blood Services Response:

The review of the observation, QER, as well as the refresher training to SOP 13 036 Viewlinc Operation was completed in July 2019 with all technical specialists.

(iii) For the October 2018 form completed for Oct 29-31, 2018, the reviewed by section was not completed until 2019-04-18.
This was contrary to relevant sections of SOP 13 036: Viewlinc Operation, Revision 2.

QER 56-19-140453 was initiated on 2019-07-11.

Procedure 13 036, Viewlinc Operation was revised and implemented on 2019-06-11. The revision included clarification to the instructions regarding adding comments pertaining to SQuIPP and recording the ISTM# in the comment section of the Viewlinc Daily System Check form. The QER and the observation were reviewed with Technical Specialists to ensure that documentation is consistent with instructions outlined in the procedure.

Health Canada Follow-up letter dated 2019-10-01:

Were reviewers of this form reminded to complete the forms as per the SOP? Please confirm.

Canadian Blood Services Response:

The reviewers (Manager or designates) were reminded of the SOP and completed refresher training in July 2019.

k) The following deficiencies were noted for the completion of Form F800874

(2018-06-01): COBAS(R) 8800 - Maintenance records:
(i) For COBAS 8800 Serial Number 5087, March 2019, under the section titled "Review of Reagent Storage Temperature", the Reviewed by Section was indicated as N/A for Week 5 even though it would have been applicable.
(ii) For COBAS 8800 Serial Number 5087, under the Instrument Maintenance section, Check Status of Hard Drives was completed for Week 1 and Week 3 on the March 2019 record, but indicated as N/A for April 2019 record for Week 1, 2, 3, 4 and 5.
This was contrary to relevant sections of WI 25 074: COBAS 8800 Maintenance, Revision 4.

The Cobas 8800 – Maintenance forms have been corrected as per good documentation practices and supervisory reviewed.

Health Canada Follow-up letter dated 2019-10-01:

By which date were the records corrected? Was there any refresher training done for staff to address the inconsistencies?

Canadian Blood Services Response:

The records were corrected on 2019-07-04. The observations, maintenance logs and work instructions were reviewed with all NAT trained staff by 2019-07-19.

I) On Form F060003 (2016-09-16): Clinic Shipping Record ISC, the ISC ID was indicated as N/A for several forms reviewed. Specifically, for Clinic Codes T0128, Clinic Date 2018/12/08 and L000I, Clinic Date 2018/12/08.

SOP 01 151, Prepare Blood Specimens and Documents for Transport - ISC indicates to complete Section II of F060003 Clinic Shipping Record - ISC. As only one shipping box was used for samples, the ID of the box was not required and therefore N/A was recorded. No corrective actions are deemed necessary.

Health Canada Follow-up letter dated 2019-10-01:

During the inspection it was discussed that this practice of indicating ISC IDs would not be applicable for Brampton. Therefore, has consideration been given to update the form to reflect current practice?

Canadian Blood Services Response:

The current practice at all sites will be reviewed and F060003, Clinic Shipping Record ISC will be revised accordingly. The expected completion and implementation date of changes is 2020-04-30.

Section 96 - Operating Procedures

5. **Some operating procedures were not kept up-to-date. For example:**
a) Form F800271 (2019-09-30): Prism nEXT Batch Start-Up and Acceptance Form and the relevant SOP 20 146: Prism Next Operation, Revision 5 do not provide instructions on the documentation of whether or not unplanned re-test samples were re-centrifuged. For instance, for Testing Date, Nov 28, 2018 the Plan Work Load section indicated the number of re-tests as 0 and the Re-test Samples Re-centrifuged section was indicated as N/A However, the unplanned HBcore re-test samples were run without any indication of whether or not they were re-centrifuged.

Procedure 20 146, Prism Next Operation will be revised by 2020-03-02 to include work instructions for documenting whether re-centrifugation is required for unplanned retesting of

samples.

Health Canada Follow-up letter dated 2019-10-01:

Would Form F800271 also need to be revised to reflect this? Please confirm.

Canadian Blood Services Response:

SOP 20 146 was updated with the required instruction. It was not necessary to revise F800271. The revised SOP 20 146 will be implemented by 2020-03-02 with our Chagas project.

d) For the three Blast Freezers in production (FRZ 3002, FRZ 3003, FRZ 3101), there was no process in place to document that plasma was loaded into the freezer when the temperature reached the range indicated in Step 2.2.1 of SOP 25-56-002: Operation and Maintenance of the Blast Freezers, Revision 4. The three blast freezers are not on the continuous monitoring system (ViewLinc).

Procedure 25-56-002 Operation and Maintenance of the Blast Freezers step 2.2.1 directs staff to ensure the temperature is verified and acceptable prior to loading. Blast freezers are not monitored by ViewLinc as they are used for interim storage of products. Each blast freezer has been validated for its use in quick freezing of plasma.

Health Canada Follow-up letter dated 2019-10-01:

What is the corrective action that was implemented to address this observation? Where is it being documented that the plasma was in the freezers for the required amount of time?

Canadian Blood Services Response:

Each site that is using a Blast freezer does have a local work instruction to ensure the freezer is at the proper temperature prior to loading.

Step 5 in Section 3 of 02 251.001 instructs staff to document the start time in and stop time on the Blast Freezer Record F800915.

Moving forward, a national work instruction for the operation of the blast freezer will be developed as part of the document restructure project and the expected implementation is November 2020. This will include instructions regarding temperature requirements prior to loading.

e) For PCM Conditioning Cycles records, there were no instructions in place to indicate the time frame of the temperature graphs that need to be generated for the weekly review to demonstrate the acceptability of the temperatures during the conditioning cycles. The weekly review of the acceptability of PCM conditioning graphs entails the review of the PCM Conditioning Cycles Forms in terms of the appropriate start and end cycles of the conditioning plates and the corresponding graphs generated to show temperatures during the conditioning. However, since there were no instructions around the required timeframe of the generated graphs, some of the graphs for the PCM conditioning records reviewed did not always span the conditioning cycle time period. Examples of relevant SOPs that are silent on these instructions are SOP 12 502: Condition Phase Change Material - Series 4, Revision 4 and WI 12 011: Digital Touchscreen Recorder Operation - Supply Chain Equipment (Non-Donor Testing Areas), Revision 3.

When downloading the graphs, staff must ensure that the duration is set to 7 days as per Attachment 1 in 12 011 Digital Touchscreen Recorder Operation – Supply Chain Equipment

(Non -Donor Testing Areas). The process was reviewed with the staff to ensure that the time period covered for the verification of the dates on PCM Conditioning Forms is correct. All staff have been retrained.

Health Canada Follow-up letter dated 2019-10-01:

Please indicate what is meant by "all staff' in the last statement of the response. What was the date of re-training for the staff?

Canadian Blood Services Response:

All staff was in reference to the two staff who are responsible for collecting the information and downloading the graphs. They were re-trained in August 2019 regarding the information required for the graphs and the dates that need to be captured.

Section 100 – Equipment

7. **The validation, calibration, cleaning, or maintenance of critical equipment were not sufficient. For example:**
   c) While reviewing several non-QC related Bacterial Detection Maintenance Log (BDML) records, it was noted that for data recorded on October 1, 8, 13, 15, 2018 and December 1, 7, 10, 23, 2018, the review occurred on the following day. However, the (BDML) "reviewed by" column is to be initialed and dated on a daily basis according to step 4.1, in particular 4.1.3, of SOP 02 302: Management of Sample Containment Unit, Bacterial Detection, Revision 5.

   The review is intended to be conducted as soon as operationally possible but not necessarily on the same day. Training material to that effect indicates that "It is important to review each day's documentation to ensure any errors or omissions are found in a timely manner. This review does not have to be performed the same day as the activities, but it should be reviewed as soon as operationally feasible". We acknowledge that on its own the SOP as currently designed may be misleading. We will take this under consideration at the next periodic review of the procedure.

   Health Canada Follow-up letter dated 2019-10-01:

   When is SOP 02 302 due for periodic review?

   Canadian Blood Services Response:

   SOP 02 302 is due for periodic review in June 2021, however the SOP is planned to be updated to the new work instruction format by November 2020 and will include any necessary revisions at that time.

Section 117 – Records

8. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For examples:**
   c) The following were noted for PCM Conditioning Cycles and related weekly review records:
   (i) For RAM Asset ID# R-17792 - R-18860, in Section 2A: Start Cycle, the dates between 2019-03-07 to 2019-03-11 were not legible.
   (ii) For RAM Asset ID # R-18910 - R-18083, Section 1: Conditioning Equipment was left blank for conditioning that occurred between March 7, 2019 to March 13, 2019. However, based on the attached graph it was confirmed that the Series 4 (Stage 2) PCM Plates were being conditioned.

(iii) For Weekly Digital Touchscreen Recorder Review. Supply Chain Equipment (Non-Donor Testing Areas) records, the incorrect RAM ID #s were indicated. Specifically, R-8877 was recorded instead of R-18877 and R-9626 was recorded instead of R-19626 for Week reviewed: 2019-03-07 to 2019-03-14.

As indicated in the statement at the beginning of the response letter all staff in Brampton will be required to attend an educational session which will focus on the importance and requirements of clear, accurate and complete record keeping.

Health Canada Follow-up letter dated 2019-10-01:

What is the planned date for this session?

Canadian Blood Services Response:

The sessions with Logistics staff were completed in July 2019. Other sessions are still being held with other groups. Due to scheduling challenges, we intend to have all staff attend a session by the end of March 2020.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

Christian Choquet

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affair
Fax Number: 613-739-2505

cc: Shelley Smyth
A/Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch