Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-09-05
CBS Control #: CBS6310
HPFB File #: C1892-100390
REF: H-1920-BRP

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

Dear Ms. Shome-Pal:

**Re: Responses to Health Canada Inspection of Licensed Activities at Brampton Operations 2019-04-29 to 2019-05-10 and 2019-05-28 to 2019-05-31**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-07-03.

*As many of the observations relate to records keeping and good documentation practices, all staff at Brampton will be required to attend an educational session on "Documentation and chain of custody" in addition to the actions described below. This session will focus on the importance and requirements of clear, accurate and complete record keeping*

**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.**

   *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.*

**b) The following deficiencies were also noted for QERs reviewed:**
**(i) QER 56-18-116003, where a BacT positive FFPA unit culture bottle found at QC, was sent for further confirmatory testing and came back as indeterminate due to lack of sample was risk rated as low. Section 9: Review & Risk Assessment assigned this incidence a low risk under Severity of Impact. The rationale provided under the Risk to Patient/Donor section did not account for the fact that the confirmatory test came back as indeterminate and could potentially still be a positive. It is acknowledged that management deemed that a CAPA would be needed for this and CAPA # 56-18-116801 had been conducted. However, the overall risk assessment rating of Low had not been changed on the QER and section 10 indicated N/A for CAPA#.**

*As correctly pointed out, the severity of the event was improperly assessed. The risk assessment was changed to medium and the CAPA number was included in section 10 of the QER. SOP 08 812, Quality Event Management - Quality Assurance Assessment and Review was reviewed with the staff and Confirmation of Employee Training record completed. QERs from 2018-08-01 to 2019-07-12 relating to positive culture bottles were reviewed and no other anomalies were noted.*

**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.*

**2. The system that identifies, documents and tracks all critical equipment or supplies was not sufficient. For example:**
**a) There were no instructions in place to link the letters that are used to identify the Compodocks and Blast Freezers on relevant production records to the corresponding Equipment IDs listed on the Equipment, systems and the relevant SOPs.**

*Letter designations were removed from the Compodocks and Blast Freezers on 2019-05-12. Staff have since been documenting the RAM ID number as the equipment ID on the production records. Work request #029443 was initiated on 2019-06-26 to add the letter designation in the RAM (Regulatory Asset Manager) system for traceability to past production records.*

**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.*

**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.*

**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.*

**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.*

**c) For PM conducted on 2019-01-09 for the temperature probes in RFG-2006 (1-6°C WIP Fridge) - R2639, R2640, R2643 and R2644, their labels all showed a next due date of 2019-01-18.**

*The PM labels were corrected for each of the solution bottles during the inspection. Field Services Representatives (FSRs) were reminded during the weekly team meeting on 2019-07-10 to verify the calculated Next Due Date as per 09 356 Equipment Services Work Management.*

**Section 95 - Operating Procedures**

**4. Some operating procedures were not always followed. For example:**
**a) SOP 03 038, "Management of Donor For Transmissible Diseases Re-Entry - Testing" Revision 8, Section 4, was not followed regarding the deletion of the current 4050 Deferral Code. For example, the following donors were deemed "Ineligible After Successful Re-Entry", yet the current code 4050 was not removed:**
**(i) Donor 3080371 after a whole blood donation on March 21, 2019 (repeat reactive for anti-HCV);**
**(ii) Donor 6I58801 after a whole blood donation on March 23, 2019 (repeat reactive for anti-HIV-112).**
**During the inspection, the establishment initiated Quality Event Report 56-19-120170 and removed**

**the current 4050 deferral codes for these donors.**

*QER 56-19-120170 was initiated on 2019-05-28.*

*A review of previous records has been completed to ensure the 4050 deferral code was deleted when required as per SOP 03 038 Management of Donor for Transmissible Diseases Re-Entry – Testing Revision 8, Section 4. All records did include the appropriate permanent deferral.*

*In addition, the Technical Supervisors will retrain to WI 03 038 Management of Donor for Transmissible Diseases Re-Entry – Testing by 2019-07-08.*

*SOP 03 038 was revised and implemented on 2019-07-08 to ensure that the donation has been archived in ePROGESA before the deletion of the 4050 occurs.*

**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-I5 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.*

**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.*

**e) The following deficiencies were noted for non-QC Bacterial Detection Testing (BDT) records contrary to the relevant sections of SOP 02 304: Load/Unload Negative Culture Bottles, Revision 10:**
**(i) For BDT test date 2019-02-16, Initials were left blank next to the section indicated as, "6 hours has elapsed since the last bottle load time on the Audit Trail and test result (6995) entry is complete, (not applicable for re-culture)." Therefore, it could not be confirmed whether or not Step 1.3.1 of SOP 02 304: "Ensure 6 hour hold has elapsed and document initials on the BDT" was completed.**
**(ii) On several BDT and associated records, for test date Feb 13, 2019, the review date stamp was indicated as Jan 13, 2019.**

*It was confirmed through eProgesa that the platelets associated to the missing initials were end labelled over 6hrs from the last bottle load time. This record was corrected to reflect the missing initials and the confirmation that the end labelling time requirement was met. All records associated to the wrong review date stamp were also corrected. All actions and corrections were completed on 2019-05-25.*

**f) Form 1000103465 (2017-1-02): Special Request Order Form, Section 2: "For CBS Use Only" of**

**the form was not always being completed as required. For instance,**
**(i) For the form completed by CBS on April 2, 2019, the Amount; ABO/Rh; Progesa Order# sections were left blank.**
**(ii) For the form completed by CBS on April 7, 2019, the Progesa Order # section was left blank.**

*QER 56-19-140452 was initiated on 2019-07-11 and the records were corrected.*

*Staff were retrained to SOP 05 732, Assess & Enter Facility Order of Blood Components by 2019-08-01. Random weekly reviews of these records will be performed by a Supervisor/Technical Specialist or designate beginning in August 2019 until February 2020 to ensure the procedure is followed and records are accurate.*

**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.*

**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.*

**i) The temperature monitoring circle chart R2306 for a walk in fridge for the week of 2018-09-03 to 2018-09-10 was missing the "reviewed by" signature. According to step 3. 7.4 of SOP 13 009: NDAS Site Operation, Revision 10, the circle chart should have been discarded after having been reviewed and signed.**

*We acknowledge that the review of these charts was missed. Since then procedure13 036, viewLinc Operation version 3.1 has been implemented and no longer requires a review unless notified by the System Administrators. Charts are kept for a minimum of 1 week then discarded unless otherwise notified by the System Administrator. SOP 13 009 NDAS Site Operation was rescinded in Brampton on 2018-11-02 with the implementation of viewLinc.*

**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.**
**(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.*

**k) The following deficiencies were noted for the completion of Form F800874**
**(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. (2018-06-01): COBAS(R) 8800 - Maintenance records:**

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

**l) 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 L000l, 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.*

**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.*

**b) For SOP 03 019, "Bio-Rad Geenius HIV-1/2 Confirmatory Assay, Test Method", version 4, step 1.33 states to verify QC testing is acceptable as per step 1.21. However, the reference to step 1.21 is not accurate because step 1.31 explains how to interpret the results on the QC reports.**

*The correct step reference will be included in the next revision of SOP 03 019, Geenius HIV-1/2 Confirmatory Assay, Test Method to be implemented by 2020-01-31.*

**c) SOP 03 348: PK 7300 Test Run Acceptance, Revision 9 does not have instructions to identify the relevant equipment for the print screen when there are no reject samples for PK7300 Batch runs and reagent shipment acceptance records.**

*SOP 03 348, PK7300 Test Run Acceptance version 9 is currently under revision. Work Instructions have been added to record the PK S/N and initials and date on the Sample Reject List or print screen. The revised procedure will be implemented by 2019-12-09.*

**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.*

**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.*

**Section 98 - Personnel**

**6. The records of staff qualifications, training or evaluation of their competency were not sufficient. For example:**

**a) Some corrective actions listed for some observations from the previous inspection were not completed satisfactorily. Specifically,**

**(i) For Observation I(i), staff training dated 2018-01-30 of SOP 02 255: Receipt of Units from Clinic, did not indicate the version number of the SOP on the Confirmation of Employee Training (CET) records.**

**(ii) Evidence of corrective actions to some observations, which included staff training to SOP 08 851: Manual of Good Documentation Practices, Version 6, was demonstrated with the CET record, reviewed on 2018-12-18. This CET indicated that two staff members were on sick leave when the training was provided. It was confirmed on April 29, 2019 that although the staff had returned from sick leave, they had not received this training. It is acknowledged that the staff were trained to this SOP during the inspection.**

*It was a Validation of Skills Record dated 2018-01-30 for SOP 02 255: Receipt of Units from Clinic, that did not indicate the version number of the SOP and not a Confirmation of Employee Training record. At that time, there was no requirement to include the version number of the SOP on the Validation of Skills Record. This record has now been replaced by the Continued Competency Record which does include a field for documenting the version of procedures.*

*The Manager will ensure that employees returning from extended leaves have completed all required training.*

**b) Both training matrices for Production (approved by the production manager on 2019-04-25) and Distribution (approved by the distribution manager on 2019-04-26) indicated "Validation of skills" in the Comments section. However, it was confirmed that this term was no longer used.**

*The term "Validation of Skills" has been revised to "Continued Competency" and it is not required on the training matrix as per SOP 08 551, Identify Training Requirements. Both training matrices were updated and the term was removed.*

**c) The following were noted for Distribution training matrix and records:**

**(i) SOP 05 272: Delete Site Transfer Packing Slip Return of Blood Components from Site Transfer was not listed on the training matrix for distribution staff although it was applicable.**

**(ii) The entire Manual 02 700, was listed as applicable to distribution staff. However, according to the training plan and training records, it was confirmed that only relevant sections would be applicable.**

*QER# 56-19-140454 was initiated on 2019-07-16.*

*The training matrix was updated to add SOP 05 272, Delete Site Transfer Packing Slip Return of Blood Components and to include only the relevant sections of the Manual 02 700, Component Production and Transformation Reference Manual that staff have to be and are trained to.*

**d) The confirmation of employee training (CET). records for a Logistics Attendant did not contain SOP 12 301 Inspect/Maintain Shipping supplies, contrary to the Initial Training Requirements Matrix where it was specified that this position requires Performance Measurement level of training to this SOP. It is noted that the employee's manager did observe the completion of the tasks outlined in the SOP above but the manager did not list this SOP on their CET records.**

*The Logistics attendant completed training to SOP 12 301 Inspect/Maintain Shipping Supplies on 2019-05-09 and a Confirmation of Employee Training record was completed. It was confirmed that Performance Measurement level training was not required and the Training Matrix was updated to add "Awareness".*

**Section 100 - Equipment**

**7. The validation, calibration, cleaning, or maintenance of critical equipment were not sufficient. For example:**

**a) On Form 56F:079 2017-01-16: Production Cleaning Log reviewed for December 2018, the weekly maintenance form indicated "Centrifuges" for all Sorval Centrifuges in use at the time. Therefore the Equipment IDs of which Centrifuged were being referenced could not be confirmed. It is acknowledged that the site no longer uses this form since the implementation of the new Hettich centrifuges.**

*In December 2018, instructions did not require documentation of each centrifuge ID number. Once all centrifuges in use in the production area were cleaned, staff would initial the form.*

*The current form F800931 Hettich Centrifuge Maintenance Log implemented 2018-04-23 requires the centrifuge ID to be recorded.*

**b) For the March 2019 Macopress Maintenance Log, Extractor ID: R2I499, the document was not reviewed until April 26, 2019. This is contrary to section 1.3.1 of SOP 25 029: Macopress Maintenance, Revision 2 which states, "At the end of each month, review maintenance log for completeness."**

*On 2019-07-26, staff responsible for reviewing records have been reminded of the importance of meeting timelines as per SOP 25 029 Macopress Maintenance.*

**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.*

**d) According to the PM label of MNT-067201 performed for RI5380 (Biological Safety Cabinet in production for BacT inoculations) on Dec 01, 2017, the "next test date" was due Dec 1, 2018. However that test was performed 17 days after this due date on Dec 18, 2018 (MNT-095936).**

*QER 56-19-147953 was initiated on 2019-07-10.*

*The preventive maintenance performed 2018-12-18 was reviewed and no deficiencies were identified.*

*Staff have been reminded of the importance of monitoring the Scheduled Events Due report as per step 2.1.2 of 09 350 Management of Equipment by Owners to ensure that equipment maintenance is done on time.*

**e) On Form F800445 (2016-03-10): Percival Step Rate Incubator Series 4PM, MNT-09071, for asset R18086, Pass or Fail was not recorded in section titled, D:UUT Mode. This is contrary to step 1.4.1 of SOP 25 141, Step Rate Incubator PM and Calibration, Revision 5.**

*QER 56-19-149325 was initiated on 2019-07-04.*
*The form was corrected as per good documentation practices and re-uploaded into RAM. In addition, the incubators will be transitioning to Work Plan Templates by December 2019. The Work Plan Template requires an entry in all fields before it can be finalized.*

**f) On Form 1000103428 (2008-02-26): BacT/Alert 3D Preventive Maintenance Record, MNT-063940 for R2023, Pass or Fail was not selected in the "Performed Post PM/Service Validation (4.11.0)" section.**

*The next service request MNT-088297 for R2023 performed on 2018-08-14 shows a Pass for Performed Post PM/Service Validation (4.11.0) on the BacT/Alert 3D Preventive Maintenance Record – showing that the system was not out of tolerance. Vendor has been reminded to complete all documentation as required.*

**Section 117 – Records**

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

**a) The final result on the certificate of calibration for T/RH indicator w/Probe, ID R3301, was incorrectly indicated as fail, when it was confirmed to have passed based on MNT-092233 in RAM. This certificate was used for the validation of all the Hettich Roto Silenta centrifuges with the following protocol numbers:**

**A) IOQ-CFG-028-2018-11-02-100226**
**B) IOQ-CFG-028-2018-11-02-101043**
**C) IOQ-CFG-028-2018-11-02-101417**
**D) IOQ-CFG-028-2018-11-02-101518**
**E) IOQ-CFG-028-2018-11-02-101805**
**F) IOQ-CFG-028-2018-11-02-101903**
**G) IOQ-CFG-028-2018-11-02-102003**
**H) IOQ-CFG-028-2018-11-02-102134**
**I) IOQ-CFG-028-2018-11-02-102400**

*QER 56-19-140601 was initiated on 2019-07-09.*

*Vendor certificates for each of the probes were reviewed and found that all had passed all calibration.*

*The qualified states of the Hettich Roto Silenta centrifuges, that were qualified using this probe, are not impacted. The in-date calibration status of the test probe during the qualification period is confirmed as part of the validation process.*

*The error in the handwritten statement on the Calibration Certificate for the T/RH indicator w/Probe (asset ID R3301) was corrected on 2019-05-03 by Equipment Services representatives. The RAM maintenance record; MNT-092233, with the corrected Calibration Certificate was reviewed and closed on 2019-05-03.*

**b) In the evidence provided for corrective actions to Observation 1d) from the previous inspection, the test equipment attached (yes/no) section was not completed for several equipment maintenance records.**

*QER 56-18-108400 was initiated on 2018-01-19.*

*The service provider uses Canadian Blood Services test equipment, and all certificates are on file in RAM. The record was corrected on 2019-07-29 as per good documentation practices.*

**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.*

**d) The following were noted for QC related BacT Maintenance Logs:**
**(i) The "BacT ALERT Preventative Maintenance Performed Date" was not documented as required on the Bacterial Detection Maintenance Log of 10/2018.**
**(ii) The "reviewed by" column of the Bacterial Detection Maintenance Log of 10/2018 shows a date of 2018/10/06 for data which was recorded on 2018/10/07.**
**(iii) Week 5 information was not completed in the "Weekly Maintenance Biological Safety Cabinet Only" section of the Bacterial Detection Maintenance Log for Dec 2018.**
**(iv) The "record Control Module Display Temperature Set Point" was not entered as per the BacT/Alert 3D Preventive Maintenance Record form 1000103428 2008-02-26, on MNT-088297 for R2023.**

i. *Preventative Maintenance Performed Date was confirmed in the RAM system and the record was updated accordingly.*
ii. *It was confirmed that the data was within specifications.*
iii. *Staff have been reminded of the importance to conduct preventive maintenance according to schedule.*
iv. *The Temp reading on the screen was documented on page 3 of the record and was within specifications. In addition, the comment section indicates that there were no unacceptable findings. Daily maintenance is performed as per SOP 25 301: BacT/ALERT Maintenance to ensure the temperature is within 36°C +or- 0.5°C.*

*Records have been corrected as per good documentation practices.*

**e) The following documentation deficiencies were noted while reviewing maintenance records in RAM:**
**(i) When reviewing Form F800264 (2017-02-09): Blast Freezer Preventive Maintenance Inspection for MNT-091599 performed on 2018-08-29, the following deficiencies were noted:**
**(ii) The Next PM Completion date was marked as 2018-12-16. However, the PM label shows the next maintenance being due on 2019-02-28.**
**(iii) The completed by date was recorded as 2019-08-29, when it was in fact 2018-08-29.**

*QER # 56-19-140602, initiated 2019-07-10.*

*The preventive maintenance form completed on 2018-08-29 was corrected and uploaded into RAM on 2019-07-10.*

*The Service Technician completed refresher training to T08851 Recording Information on Canadian Blood Services Forms, Facilities Contractors, v 2017-07-26 on 2019-07-10.*

**(iv) Yes or No was not checked on the Espec Chamber Preventive Maintenance Checklist - Quarterly EPZ 3H and EPZ 4H on MNT-091209 and MNT-099848 for R19221.**

*The service provider uses Canadian Blood Services test equipment, and all certificates are on file in RAM. The record was corrected on 2019-07-19 as per good documentation practices.*

**(v) The RAM "schedule/results" tab for MNT-084372 for equipment R2373 showed a next due date of2019-06-26. However the label affixed to the equipment showed a next due date of June-22, 2019.**

**The yearly maintenance for this equipment was performed on June 22, 2018, therefore the correct next due date is confirmed as June 22, 2019**

*QER# 56-19-140604 Initiated on 2019-07-19.*

*This has been corrected in RAM on 2019-07-19 as per good documentation practices.*

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,

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

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