Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Biological Product Compliance Program
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Health Canada
180 Queen Street West, 10th Floor
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Dear Farah-Michelle:

**Re: Responses to Health Canada Inspection of Licensed Activities at Peterborough 2021-09-07 to 2021-09-13**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-10-14.

**Section 95 – Operating Procedures**

**1. A) According to section 1, step 3 of work instruction 09 239, titled Alternate Approval for Quality Management System Related Documents and Records, revision number 2., effective date 2020-04-21, employees are instructed to "In all signature blocks/areas for which e-mail approval has been received, enter "see attached e-mail approval"". This instruction was not followed on the CompoLab TM Hemoglobinometer Verification Log, for the preventative maintenance of R12530, on 2020-07-27, as the "Reviewed by" and "date" sections were left blank without that note.**

*The CompoLab TM Hemoglobinometer Verification Log was corrected on 2021-09-09.*

*The approval email requirements as per work instruction 09 239 Alternate Approval for Quality Management System Related Documents and Records were reviewed with the employee on 2021-09-09.*

**B) According to the requirement 4.2 c) of Management Process Procedure 08 01, titled Document Management, revision 1.6, effective date 2020-08-25, "Only current versions are distributed, available and accessed at points of use". Those instructions were not followed, when version 2018-08-22 was used to record data on the Digital Touchscreen Recorder Daily Temperature Log-Supply Chain (non-Donor Testing Areas) form F801368, instead of using version 2020-08-15, on the weeks beginning with the following dates:**

**- 2020-09-29 (page 1 of 10 of DTR 16097 Oct 2020 (CSRoom))**
**- 2020-10-06 (page 3 of 10 of DTR 16097 Oct 2020 (CSRoom))**
**- 2020-10-13 (page 5 of 10 of DTR 16097 Oct 2020 (CSRoom))**
**- 2020-10-20 (page 7 of 10 of DTR 16097 Oct 2020 (CSRoom))**
**- 2020-10-27 (page 9 of 10 of DTR 16097 Oct 2020 (CSRoom))**

*The version date on the form is not the date the version became effective it is the date the form was created or revised. Version 2018-08-22 of form F801368 was effective on 2018-11-30 and rescinded on 2020-12-30 when version 2020-08-15 became effective. All five records identified used the correct version 2018-08-22 of form F801368.*

*The Controlled Document Index (CDI) ensures only current documents and forms are made available to staff. The CDI also indicates dates when documents and forms become effective or rescinded.*

**Section 117 - Records**

**2. A) In work order: MNT-102872, for asset ID# R16097, pass or fail was not recorded/indicated in section G: Alarm verification, as required for the Digital Touchscreen Recorder PM for the following:**
**i) Verify that alarm sounds, visual alarm notice displays and alarm indicator flashes red**
**ii) Verify that "Alarm Mute" button silences the recorder alarm when pressed**
**iii) Verify that alarm indicator stops flashing when set point is returned to normal.**

*DEV-21-007758 was initiated 2021-10-15.*

*All alarms were shown to work on its next scheduled preventive maintenance (2019-10-31).*

*As of 2019-02-08, the PM for the Digital Touchscreen Recorder is documented electronically in RAM. The work plan template requires an entry in all fields before it can be finalized and saved in RAM.*

**B) For work order: MNT-081667, for asset ID# R2622, the date was left blank in the section where the technician was to have indicated when he/she completed/conducted the PM.**

*DEV-21-007757 was initiated 2021-10-15.*

*Work order MNT-081667 using form F1000103873 was completed 2018-05-15 which was verified by the audit trail in RAM.*

*As of 2021-04-30, the Preventive Maintenance on this model is documented electronically in RAM. The work plan template requires an entry in all fields before it can be finalized and saved in RAM.*

*The following further actions are applicable to 2C, 2F, 2G, 2H, 2I, 2J and 2K. Further details as required are included under each observation.*

- *All staff have completed Good Manufacturing Practices (Refresher) training.*
- *A summary of the audit findings and reminder to follow good documentation practices was sent to staff and clinic supervisors on 2021-10-21.*
- *All documentation errors will be reviewed with all staff at the December team meeting.*

**C) The date of July 22nd was entered instead of July 23rd on the Non-Contact Infrared Thermometer Verification and Maintenance Log for the month/year 07/21, for equipment # R27158. (Page 2 of document Irt-R27157-R27158)**

*MQE 21-002961 was initiated 2021-09-15.*

*Review of This error was reviewed with staff upon discovery. The Non-Contact Infrared Thermometer Verification and Maintenance Log has been corrected as per good documentation practices.*

*See above for further actions.*

**D) The date was missing on the Transfer order: 0000254270 during the release of Vacutainer tubes pink plastic, batch 0044171. (Page 7 of 18 of Document title Pink top tubes – 0044171).**

*This section of the Transfer order is where a second verification would be documented with initials and date. Work instruction 12 109 Processing Material: Inventory Requiring Quality Inspection (QI) v1.1 section 4.2 does not require a second verification on the transfer order. Per good documentation practices, "N/A" should have been added to the date field, as it was added to the "Verified by" field. This was reviewed with staff during a staff meeting on 2021-10-22.*

**E) Yes or No was left unchecked for the questions: "Is inspection satisfactory?" on form 1000103233 (2016-05-26) for Blood Packs batch #11431078bn (page 2 of 25 of document QICS-BI-11431078BM).**

*The error was reviewed with staff during the audit. The form was corrected on 2021-09-13 as per good documentation practices.*

*A communication was sent to all quality assurance staff on 2021-10-22 to ensure this field is marked yes or no prior to release.*

**F) The reviewed by and date were missing on the Daily Room Temperature Monitoring Log-Informer, for Informer Location CSR Cupboard #3, of the year/month 2019/09 (page 5 of document SEPT2019Dailyroomtemplog-InformerII).**

*MQE 21-002934 was initiated 2021-09-15.*

*See above for further actions.*

**G) The acceptance review section was left blank on page 6 of the Donor Centre Evaluation Checklist form F020925 (20201-01-09). (Page 6 of document T0006Siteevaluation 2021-04-13). The following were therefore left unchecked or missing:**

**- Site accepted: Yes, No or N/A**
**- Signature**
**- Date**

*The Donor Centre Evaluation Checklist form was reviewed with the supervisor on 2021-09-15. The supervisor also reviewed work instruction 01 010 Evaluate Mobile Donor Centre Locations to review how the form is to be completed according to good documentation practices.*

*For this evaluation, this section does not apply. The final reviewer has added the comment "this section does not apply" to the document.*

*See above for further actions.*

**H) The following inaccuracies were noted while reviewing the Clinic Temperature Monitoring Log-Buffy Coat for the month of October 2020 form #1000104195 2006-09-22 (document CTMLOctober2020T0006)**
**- The clinic date was documented as 2010-10-09. However the date was 2020-10-09 (page 6 of 19)**
**- On October 22nd, the thermometer ID was recorded as R0001957. However the correct ID is R000019571 (page 13 of 19).**
**- On October 29th, the thermometer ID was recorded as R1957, rather than R19571, as per equipment list supplied (page 18 of 19).**

*The Clinic Temperature Monitoring logs has been corrected as per good documentation practices.*

*See above for further actions.*

**I) The Daily Room Temperature Monitoring Log-Informer form 56F:015 were reviewed for the month of July 2018. Each of the three cupboards had their own monthly record consisting of two pages. In all three scenarios, page one indicated a hand written note "1 of 2" at the top of the record. However, no signature or date applied to indicate who added the note. The same issue was found at the top of page 2, which indicated "2 of 2". It was also noted that the top of some pages indicated "2 of 2", while the bottom of those pages continued to state "Page 1 of 1". The same error was noted in each of the three sets of records reviewed (applicable to all pages of document 2018 Daily temp monitoring for CS cupboards #1, 2, 3).**

*The Daily Room Temperature Monitoring Log-Informer forms has been corrected as per good documentation practices.*

*See above for further actions.*

**J) The initials to indicate who had "printed and reviewed" the temperature chart recorder for the time period started 10/14/2020 were missing (page 8 of DTR16097Oct2020(CSroom)).**

*MQE 21-002933 was initiated on 2021-09-15.*

*The printout has been reviewed and corrected as per good documentation practices.*

*See above for further actions.*

**K) The "Ram asset ID(s) of equipment being monitored" was not documented. Nor was the N/A checkbox selected. The two options were left blank on the Digital Touchscreen Recorder Daily temperature Log Supply Chain (Non-Donor Testing Areas), form F801368, for the week beginning 2021-0504 (page 3 of DTRR19571CScupboardMay2021).**

*MQE 21-002917 was initiated on 2021-09-16.*

*The Digital Touchscreen Recorder Daily Temperature Log has been corrected as per good documentation practices.*

*See above for further actions.*

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: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch