



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
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Canada

2019-04-11

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REF: H-1819-ANC-L

Mr. Kevin Donato
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions 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 Hamilton
2019-03-04 to 2019-03-06**

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

Section 95 – Operating Procedures

1. **Some operating procedures were not always followed. For example,**
 - a) **During the drive set-up of the clinic on March 4, 2019 the authorized user entered a start time of 15:48 and a stop time of 15:49. This was contrary to SOP 01 371, rev 3, step 1.1.1. which indicates to enter an end time of 23:59. After the inspector notified the clinic of the deviation the correct end time (23:59) was then entered.**

The supervisor reminded the staff member involved of the importance of entering 23:59 as the end time as described in SOP 01 137, Interim Storage at Clinic Site.

- b) **In the Digital Touchscreen Recorder Daily Temperature Log – Supply Chain (non-donor testing areas) the log for the recorder for the critical supplies room “Depot” (R000016171), week beginning January 21, 2019, was incorrectly filled with an “acceptable range” of 18°C to 25°C. The correct temperature range for this room is 15°C to 25°C as per Weekly Digital Touchscreen Recorder Review, Supply Chain Equipment (non-donor testing areas), Form F800788 (2018-04-12). The same log was error-corrected (incorrectly) to read 18°C to 24°C and this temperature range was then written on subsequent logs from January 29, 2019 through February 14, 2019.**

The Digital Touchscreen Recorder Daily Temperature Logs from the week of January 21, 2019 to February 14, 2019 were corrected as per good documentation practices to read an “acceptable range” of 15°C to 25°C. In addition, a memo reminding staff of the importance of ensuring to document the correct temperature range will be distributed by 2019-04-22.

- c) **Contrary to SOP 01-56-003, rev 8, Refrigerator/Freezer/Incubator Monitoring and Maintenance-Permanent Site,**
- i. **the temperature reading was not always documented every 4 hours (refer to Freezer Temperature Log, equipment # R000003503, the entries including 2018.11.01, 2018.12.22 and 2019.02.11; refer to Refrigerator Temperature log, equipment # R000002705, entries including 2018.11.01, 2018.12.22 and 2019.01.29); and**
 - ii. **some gaps were not explained for some circle charts (R000019542, including, but not limited to, charts for the weeks of 2018.10.18 and 2019.02.21).**

By verifying both the temperature logs and the circle charts for each freezer and refrigerator in question, it was determined that the temperatures were always within specifications. Notations were added, as per good documentation practices, to temperature logs and circle charts explaining each gap.

A memo will be distributed by 2019-04-22 reminding staff of the importance of ensuring that the temperature is recorded on temperature logs every four hours as per COP 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance-Permanent Site and that an explanation of any gaps that appear on circle charts is documented on the log as per good documentation practices.

Section 98 – Personnel

2. **The Confirmation of Employee Training (CET) (Form F800329, 2016-11-18), employee signed 2017-11-09, Event/Process Name “DCA Initial Training – Classroom training”, did not agree with the Initial Training Requirements Matrix (effective date 2017-11-02). For example, in the CET, the learning level for SOP 01 091 (Collect Samples Only) and SOP 01 716 (Management of Duplicate Donor at Clinic) was “Awareness” but the matrix specifies the requirement for “Performance Measurement”.**

The staff member completed initial training to 01 091 and 01 716 on 2015-08-15 and 2015-11-26, respectively. The Confirmation of Employee Training (CET) on those dates show a learning level of “performance measurement” which matches the requirements on the Initial Training Requirements Matrices dated 2015-08-04 and 2015-11-02. The awareness training noted during the inspection consisted of refresher training as part of the DCA level 2 (DCA2) training. It was recorded as “awareness” as the staff had already completed performance measurements for both procedures during initial training.

Section 117 – Records

3. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example,**
- a) **During the review of the medical questionnaire (ePROGESA entry) for donor 4015931, during the whole blood clinic of June 12, 2018, the donor answered they had received the Zostavax shingles vaccine on May 1, 2018. The “apply deferral” field (BW) was answered “no”. This was inconsistent with the deferral code which was ultimately applied (V090). It is noted that the donor did not donate blood**

The donor deferral code was applied correctly in eProgesa at the time of donation however the “apply deferral” field was incorrectly marked “No”. A comment has been entered into eProgesa noting the error and the correct response.

The event was reviewed with the staff and the staff was reminded of the importance of accurate documentation.

- b) **The Confirmation of Employee Training for a phlebotomist with Event/Process Name: Quality Education and Training Program contained dates that did not agree with each**

other. Namely, the record was signed and dated by the trainer by hand, 2017-03-01, but according to the record the training was noted, electronically, as being provided in 2015-10-14.

After review of the staff training file, it was determined that the individual completed "Accessibility for Individuals with Disabilities" on 2017-03-01 but that the CET for "What it means to be a Manufacturer" for which training had been completed on 2015-10-14 was printed in error and signed on 2017-03-01. This had been corrected at the time and the correct CET for "Accessibility for Individuals with Disabilities" completed and signed by the trainer on 2017-03-01 was located in the staff training file along with the erroneous record. The latter has been removed from the employee's training file.

- c) For a DCA's training records,**
- i. the entry of clinic hours and location of training for 2017-11-15 was missing from their corresponding weekly log sheet (page 9 of 9) and**
 - ii. according to their weekly log sheet, 4.5 hours were completed on 2017-12-08, however, this does not agree with their daily training log which read 4.0 hours.**

The DCA's clinic hours identified that all required training hours were achieved.

Staff in the training department were reminded of the importance of 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,



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Vice-President
Quality & Regulatory Affairs
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cc: Anita Mahadeo
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