Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
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Canada

2021-07-23
CBS Control #: CBS6559
HPFB File #: C1892-100390
REF: H-2122-RED

Jodie Leiman
Regional Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Enforcement Branch
Health Canada / Government of Canada
391 York Avenue, Winnipeg, MB

Dear Jodie:

Re: Responses to Health Canada Inspection of Licensed Activities at Red Deer 2021-05-31 to 2021-06-11

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-07-08.

Section 95 - Operating Procedures

1. **Contrary to the operating procedure Manual of Good Documentation Practices 08 851 version 8, the reviewer did not initial and date entries they made in the Comments section for Premises Monthly Inspection records dated 2018-07-03, 2019-04-02, 2019-05-14, 2019-08-08 and 2019-09-05.**

   MQE-21-001891 was initiated on 2021-06-07.

   The staff was notified of the error on 2021-06-07 and will be retrained on 08 851 Manual of Good Documentation Practices (GDP) V8 by 2021-07-27.

Section 117 - Records

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable.**

   Please note, that for the responses 2a, 2b,2c, 2d and 2e, all staff attended GDP refresher training on 2021-06-23. For responses 2a, 2c, and 2e, records were updated with the reference to the applicable MQE.

   For example:
   a) In the CompoLab TM hemoglobinometer verification log, for R000012452, R000012453, R000012454, R000012668 and R000012759, the Acceptable Range field was not filled out with a checkbox for Yes or No during the verification performed on 2021-01-15.

   MQE-21-001904 was initiated on 2021-06-09.

   The records in question were reviewed and found that the Compolab readings were within acceptable ranges.

   b) In the Docon Shaker Verification and Maintenance Log for unit R000005202 the entry for 2021-03-25 was not fully populated, including the serial number of the 585 g weight, acceptability, initials. The unit was used during clinic held that day.

DEV-21-004432 was initiated on 2021-06-09.

Verification of the Docon maintenance logs prior and post to the 2021-03-25 entry were performed and confirmed that there were no over or under weight units collected with this equipment.

c) In the Digital Touchscreen Recorder Daily Temperature Log for the clinic area (R000023124, range 18-24°C), for the weekly logs of beginning January 19, February 2 and February 9, 2021, the acceptable range was incorrectly noted as 15-25°C. Furthermore, in the logs of January 9 and 12, 2021 the thermometer ID was incorrectly recorded as R2312.

MQE-21-001904 was initiated on 2021-06-09.

It was confirmed that the thermometer ID was R000023124, and it is the only thermometer available in the clinic.

The temperature range was incorrectly documented as 15-25C. Review of the actual Digital Touchscreen Recorder alarm settings confirmed that the equipment was operating to the correct alarm setting of 18-24°C. Also, the alarm was not triggered as per review of the Digital Touchscreen Recorder electronic logs.

d) The Range of Use entries in RAM for the Digital Touchscreen Recorders (R000023122 and R000023124) reflect incorrect temperatures (18-24°C and 15-25°C, respectively). It is noted that the alarm settings for the units are set correctly.

MQE-21-001904 was initiated on 2021-06-09.

It was confirmed that this was a documentation error on form F800787 Dickson Digital Touchscreen Recorder Settings – Supply Chain Equipment that was submitted for the RAM entry. The Digital Touchscreen Recorder units had the correct alarm settings.

The "Range of Use" entries in RAM were updated for R23124 and R23122 on 2021-07-21 to indicate proper temperature ranges.

Follow up with the supervisors who complete form F800787 was done on 2021-07-12 with the review of the temperature requirements for clinic operations.

e) The Premises Monthly Inspection record identified as 02/2019 is entered incorrectly as Completed By on 2019-01-07.

MQE-21-001891 was initiated on 2021-06-07.

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