



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-07-19
CBS Control #: CBS6331
HPFB File #: C1892-100390
REF: H-1920-WSO-L

Farah-Michelle Manigat-McLaughlin
Regional Compliance & Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada

Dear Ms. Manigat-McLaughlin:

**Re: Responses to Health Canada Inspection of Licensed Activities at Windsor
2019-06-05 to 2019-06-06**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-07-05.

Section 95 - Operating Procedures

1. Some operating procedures were not always followed.

According to step 1.2.1 of procedure number 01-56-003, revision 8, titled: Refrigerator/Freezer/Incubator Monitoring and Maintenance -Permanent Site, effective date 2017-11-20, the temperature readings for refrigerators/freezers (excluding Interim Storage Refrigerator) will be documented at the beginning of each clinic when operating and every 4 hours until clinic end. This was not performed when looking at the Refrigerator Temperature Log of December 13, 2017, where the 2nd reading was taken after 5 hrs (1st reading at 14:47. 2nd reading at 19:47) for R3591.

According to the refrigerator temperature log and the circle chart for 2017-12-13, the temperatures were always within specifications. A notation was added, as per good documentation practices, to the temperature log.

Staff was made aware of the missing documentation during the inspection and was reminded to follow procedure 01-56-003, Refrigerator/Freezer/Incubator Monitoring and Maintenance - Permanent Site.

Section 117 -Records

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

- 1- As per required on the Digital Touchscreen Recorder PM, form 800340, version 2017-08-02, Pass or Fail was to be documented in the section indicating: "Confirm that the Serial Number, unless positioned in the back of the equipment and not accessible, and the RAM asset ID are accurate, intact, legible and correspond to the RAM Work Record". This was not performed in MNT-100636 for R19589.

Note: During the inspection, it was confirmed that the serial number and asset ID were accessible and that pass or fail had been documented in other preventive maintenances.

The record was corrected as per good documentation practices.

A Digital Preventative Maintenance form – Work Plan Template for the Dickson digital touchscreen recorder was implemented on 2019-02-08 and replaced form F800340 Digital Touchscreen Recorder PM. The Work Plan Template requires an entry in all fields before it can be finalized.

2- An incorrect "next due date" was recorded in the RAM "schedule/results" tab, as well as on the work details, of MNT-095819 for equipment R12649. RAM and the work details showed a next due date of 2019-05-27. However the label affixed to the equipment showed a next due date of 2019-05-21.

QER 56-19-114597 was initiated 2019-07-12.

The next due date was corrected during the inspection in RAM on the work details report as per good documentation practices.

Equipment services staff was made aware of the error during the inspection and was reminded to follow SOP 09 356, Equipment Services Work Management Step 5.8.4 for accurate review of data entered in RAM.

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