



2021-01-22
CBS Control #: CBS6470
HPFB File #: C1892-100390
REF: H-2021-VIC

Ms. Lesley Beaton
Regional Regulatory Compliance and Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
#400-4595 Canada Way, 4th Floor
Burnaby, British Columbia
V5G 4P2

Dear Ms. Beaton:

**Re: Responses to Health Canada Inspection of Victoria
2020-12-15 to 2020-12-17**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2020-12-30.

Section 95 – Operating Procedures

1. Contrary to SOP 01 144 v.25, Screen Donor, the height and weight were not documented in eProgesa for the following collections from first time donors:

i. C051020567459005 (age 20) from clinic V0035 (Port Alberni) dated 2020-07-02

ii. C05102058490700A (age 22) from clinic V0006 (Victoria) dated 2020-08-11

MQE 20-004204 and MQE 20-0004218 were initiated on 2020-12-15 and 2020-12-16 respectively.

eProgesa is being updated to make the entries of height and weight of new donors between the ages of 17 and 23 mandatory. This is targeted for implementation on 2021-02-15.

In the interim, collections staff present at the North Island Mobile (V0035) and all Victoria Staff (V0006) were reminded to document the height and weight of new donors between the ages of 17 and 23 as per SOP 01 144 V25 Screen Donor Step 6.

Section 98 – Personnel

2. Review of Logistics training records and the Logistics training matrix found no records of training (CETs) for the Logistics Manager on the following two SOPs:

- i. SOP 01 016 v.9.1 (Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log) effective 2020-02-03
- ii. SOP 01 462 v.2 (Manage Temperature Excursions) effective 2020-07-13

MQE-20-004373 was initiated on 2020-12-31.

Logistics Manager completed the training to WI 01 016 Vehicle and Auxiliary Equipment Inspection Record and Vehicle Log and to WI 01 462 Manage Temperature Excursions on 2021-01-20.

Section 117 – Records

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

a) Review of the equipment service preventive maintenance records in Blue Mountain RAM for Carescape R6709 found that although the record had been signed off by the Supervisor as complete the actual record uploaded to RAM was an unrelated confirmation of employee training form. The completed PM record for R6709 dated 2020-08-14 was subsequently located during the inspection.

Minor Quality Event (MQE) 20-004211 was initiated.

The comment section of the work order was updated with the following: "PM work order MNT-143748 was reviewed and closed by the supervisor after checking the uploaded PM document and other information".

A Digital Work Plan Template for the Carescape will be implemented by 2021-06-30. The Work Plan Template requires an entry in all fields before it can be finalized and it will eliminate the requirement to upload maintenance records into the system.

b) The RAM number documented on the completed and reviewed Temperature Verification Record (Chart Recorder) - Refrigerator Form (FV02025) for Oct and Nov 2020 for the Cooling Element Fridge in the Victoria lower warehouse was incorrectly documented as R6449 rather than R6149.

MQE-21-000027 was initiated on 2021-01-04.

Temperature Verification Record (Chart Recorder) – Refrigerator forms for October 2020 and November 2020 were corrected on 2020-12-17.

All warehouse staff reminded the importance of Good Documentation Practices during the staff meetings and followed by email on 2020-12-16.

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
Christian.Choquet@blood.ca