

2023-01-11

CBS Control #: CBS6700

HPFB File #: C1892-100390

REF: H-2223-BRP-L

Kevin Donato
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Kevin:

**Re: Responses to Health Canada Inspection of Licensed Activities
at Brampton Operations
2022-12-21 to 2022 12-25**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-12-22.

Section 95 - Operating Procedures

- 1. Contrary to WI 20 180 Component Scale Verification & Operation (Revision 7; effective 2021-03-08), the “displayed weight” values of the standard weights being used to verify the component scales were not being recorded on the associated Scale Verification Logs (Form F801943; version 2020-06-04); instead, a checkmark was being written for all of the daily verification checks conducted for the months reviewed of October - December 2021 and March - May 2022 (R000002258 and R000015446).**

MQE-22-003871 was generated during the inspection.

Refresher training to steps 5, 6 and 7 of WI 20 180 v7 Component Scale Verification & Operation will be completed by all Production staff by the end of January 2023.

Section 117 - Records

- 2. Two Macopress Maintenance Log Forms F800932 (version 2019-11-01) for R000021484 were generated and filled in for the month of April 2022. In one of the completed forms (signed off as reviewed on 2022-05-03), the press was indicated to be out of service the entire month, whereas the other completed form (signed off as reviewed on 2022-05-01) indicated the press had been returned to service as of 2022-04-17.**

MQE-22-003863 was generated during the inspection (closed).

As discussed at the closing meeting, a response is not required for those issues where an



**Canadian
Blood
Services** BLOOD
PLASMA
STEM CELLS
ORGANS
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MQE-file is noted in this Exit Notice as "closed".

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

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