

2023-01-16

CBS Control #: CBS6700

HPFB File #: C1892-100390

REF: H-2223-BRP-R

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 Registered Activities
at Brampton Operations
2022-11-21 to 2022-12-02**

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 117 – Records

1. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example,**
 - a. **The Haemonetics Cell Processor ACP-215 Maintenance Records (Form 1000105514) and associated sterile docker, Compodock Maintenance Log - Daily & Weekly Forms (Form 1000103296) were not consistently completed for the daily and weekly maintenance activities for the months of March and April 2022 as follows:**
 - i. **For ACP-215 units R000002372, R000002373 and R000002374, the March 2022 maintenance records were missing the March 1 daily maintenance checks and the weekly "Grease 'O' ring" step was not checked off as completed during the weekly maintenance checks for "week 1" of the month.**
 - ii. **For ACP-215 unit R000002373, the April 2022 maintenance record was missing the employee's initials that conducted the "week 2" and "week 3" (weekly) maintenance steps and the "Reviewed by" section for the record was left blank.**
 - iii. **For ACP-215 R000002372, the April 2022 maintenance record was missing the date the week 1 maintenance steps were conducted, as well as the date the record review was conducted.**
 - iv. **For Compodocks R00002329 and R000002337, the March 2022 maintenance records were missing the March 1 daily maintenance checks and the records also did not indicate that a weekly maintenance check was performed for the first week of the month.**
 - v. **For Compodock R000002337, two weekly maintenance checks were recorded for**



the week of April 7, 2022.

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-22-003889 was generated to address these discrepancies during the inspection (closed).

As discussed at the closing meeting, a response is not required for those issues where an MQE-file is noted in this Exit Notice as “closed”.

b. Additionally, although the daily maintenance for Cell processor ACP 215 (R000002373) and Sterile Docker, Compodock R000002337, was indicated with “N/A” (to signify that the equipment was not in use) on the respective maintenance forms (Form 1000105514 and 1000103296) for April 2, 2022, both machines were listed as used during cell washing of RBC unit C0556 22 261183 20Y on the associated ACP-215 Saline Washed Red Blood Cell Production Record (Form 1000105513).

MQE-22-003899 was initiated on 2022-11-24.

All staff were reminded via email on 2022-12-04 to ensure that daily maintenance has been performed on the ACP-215 as per Section 1 of WI 01153 Haemonetics ACP-215 Maintenance and on the Compodock as per Section 1 of WI 00739 Compodock Maintenance before a unit is washed.

In addition, a follow up memo was shared with staff on 2023-01-11 instructing them to perform maintenance daily as per WI 01153 and WI 00739 including weekends. All staff shall review and sign the memo by 2023-01-31.

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