

2023-11-15  
CBS Control #: CBS6776  
HPFB File #: C1892-100390  
REF: H-2324-DAR

Melanie Mercier  
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 Melanie:

**Re: Responses to Health Canada Inspection of Licensed Activities  
at Dartmouth Operations**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-10-10.

**Section 94 - Quality Management System**

1. The form F801517(Legacy F802002) "CAD transfer & split of illuminated pooled platelets" did not require the recording of the time and date that the platelets were drained from the Compound Adsorption Device (CAD) container, which did not allow for the confirmation and verification of the complete process, ie. that the platelets rest for 6 to 16 hours on the flatbed agitator as required by "WI-00347 Transfer illuminated platelets to compound absorption device".

*As stated in the observation the time of CAD Transfer & Split of Illuminated Platelets (F802002) form does not have a field to indicate the time of transfer out of Compound Absorption Device (CAD).*

*Canadian Blood Services is using a check mark as an alternative approach to provide evidence that staff have verified that the time of transfer out of CAD meets the requirement of 6-16 hrs.*

**Section 95 - Operating Procedures**

2. Contrary to "WI-00059 rev. 2 End Labelling" there was no form "F800228 End Labelling Record" in the production records for the platelets tested on August 11th, 2023 (Clinic date August 9th, 2023) to document that the end-labelling was done at least 6h after the bottle load into the BacT/ALERT 3D as per "WI #02 304 rev. 10.1 Load/unload negative culture bottles".

*Form F800228 End Labelling record for platelets tested on 2023-08-11, from clinic date*

2023-08-09, was located and was added to the records for clinic date 2023-08-09.

### **Section 100 - Equipment**

3. The rationale for granting all BacT/ALERT users the "Administrator" access level to the system was inadequate, as this allowed all users to modify some of the parameters in the system. There was no process in place to evaluate and verify the impact of the user abilities under the Administrator level, such as deletion and modification of data that could potentially impact the results.

*Canadian Blood Services will assess the access levels for Bac-T/Alert users at all sites and provide guidance as to who should have administrator level.*

*If required, the training material will be updated with the information that defines the differences between the access levels.*

*The completion date for the above is 2023-12-31.*

### **Section 117 – Records**

4. Records were not always accurate, complete, legible, indelible and/or readily retrievable:
- a) There was no form "F800120 (2018-06-12) Generator Semi-Annual Inspection, and Maintenance", as well as "F801245 (2018-06-12) Generator Annual Inspection, Test and Maintenance" for the semi-annual maintenances done by Cummins on August 14, 2023 for all four (4) generators, as well as for the Annual maintenance done by Cummins on January 24th to 27th, 2023 for all four (4) generators.

*F800120 and F801245 were not completed for the dates identified in the observation as technicians assumed service provider reports could be used. There was no impact to generator operation as there is documented evidence of service from the vendor which meets the requirements as outlined on the forms.*

*Technicians were informed as to the proper work instruction for completing the inspection of the generator and maintenance forms on 2023-09-26. Refresher training to WI-00664 Generator Maintenance has been completed.*

- b) The records for the Annual Maintenance done by Cummins on January 24th, 2023 (WO#1129144) for Generator C9E02609 were incomplete as pictures which were referenced in the report were never received by CBS.

*Missing pictures from the service report were not identified during documentation review. No other occurrences were identified during review of previously completed maintenance. Pictures capturing repairs completed during the maintenance were received following the inspection and added to the report.*

*Refresher training to WI-00664 Generator Maintenance has been completed.*

- c) The "Quinquennial Test Log C282" (WO#129147) done on January 27th, 2023 was incomplete as it had an incomplete field for "Perform Megger".

*The test was completed, and the result was listed on the log but not in the required field. A complete report was received from the vendor following the inspection.*



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1800 Alta Vista Drive  
Ottawa ON K1G 4J5

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*Building technicians have completed refresher training to WI-00664 Generator Maintenance.*

**d) The forms "F800604 (revision 2) Temporary Access Card Log" were incomplete for entries on February 8th, 2023, April 4th, 2023 and May 16th, 2023.**

*It was confirmed that all cards had been returned.*

*Security Guards have completed refresher training to WI-00661 Temporary Building Access.*

**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**