Canadian Blood Services
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Ms. Victoria Hurlbut
Compliance Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia
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Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Licensed Activities at Ottawa Operations 2018-06-11 to 2018-06-15

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-06-26.

Section 61 – Labelling

1. **There is no process in place to ensure the labelled volume of apheresed platelets is accurate. For example, during review of EA 55-18-135185 it was noted that a unit of apheresed platelets was distributed to a hospital with an incorrect volume on the end label. Although the root cause was determined to be associated with an error by the operator performing separation in eProgesa on the platelet unit, there are no other processes or controls in place to verify the volume on the "Work in Process" or final end label is accurate.**

   A review of the the volumes of all apheresis platelets produced in the last six months indicate that this is the only occurrence of a platelet unit labelled with a default weight of 495 mL. An assessment will be performed by 2018-11-30 to determine if ePROGESA can be configured to prevent any apheresis platelet with a default volume from being end labelled.

Section 95 – Operating Procedures

2. **Contrary to 09 350 Management of Equipment Rev 4 (eff. 2017-09-25) step 3.5.2, the equipment maintenance label for R000018296 did not have the initials of the service personnel who performed the maintenance.**

   A review of records confirmed that the preventative maintenance performed on 2018-03-14 was completed as required.

   Coincidentally, the vendor was on site at the time of inspection to perform a scheduled preventative maintenance on the equipment in question. Management reviewed the documentation requirements with the vendor and prior to the technician's departure ensured that all documentation including labels was accurate.

Section 98 - Personnel

3. **The records of staff qualifications, training or evaluation of their competency were not sufficient.**

a) The Initial Training Requirements Matrix F800304 (2015-02-02) for Concourse Gate Supply Chain indicated that procedures 12 502 Condition Phase Change Material-Series 4; 12 503 Condition Phase Change Material-Series 22; and 12 504 Condition Phase Change Material-Series 20M required awareness training for production, distribution, Managers/Supervisors and trainers. However all staff were expected to receive performance measurement training. Performance measurement training was provided to all staff.

The incorrect level of training was documented on the Initial Training Requirements Matrix F800304 for the relevant roles for SOPs 12 502, 12 503 and 12 504. The form has been corrected.

According to the correct training requirements, Lab Assistants and Technologists in Distribution, the Distribution and the Production Supervisor require performance measurement training whereas the Lab Technologists in Production require awareness training.

b) 08 553 Deliver Training Rev 4 (eff. 2017-11-27) was not followed. For example,
i) The Confirmation of Employee Training for the Production Supervisor did not have Section 4-Reviewer Confirmation documented.
ii) The Confirmation of Employee Training for the two Laboratory Technologists did not have Section 3-Trainer Confirmation documented to verify competency had been assessed.

It was confirmed that training was completed as required and the records were corrected accordingly. Trainer confirmation was not required as the learning level was awareness and not performance measurement.

Expectations for training documentation in accordance with SOP 08 553 'Deliver Training' was also reviewed with the Trainer for Supply Chain Operations involved in these deficiencies.

Section 117 – Records

4. **The Maintenance of Informer Thermometers F800268 (2014-06-03) completed 2017-12-06 did not document the Pass/Fail assessment for Section D: Reference/Test Equipment for the Reference ECN R000018793.**

QER# 55-18-134982 was initiated on 2018-06-15.

It was confirmed that the associated Informer Thermometers were not in use between 2017-12-06 and 2018-06-15 at which time they were taken out of service permanently.

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,

Christian Choquet

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cc: Hugo Tremblay
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