Canadian Blood Services
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Ms. Victoria Hurlbut
Biologic Products Specialist
Regulatory Operations and Regions Branch
Health Canada
Suite 1625, 16th Floor
1505 Barrington Street
Halifax, Nova Scotia B3J 3Y6

Dear Ms. Hurlbut:

Re: Responses to Health Canada Inspection of Licensed Activities at St. John's Operations on 2017-10-23 to 2017-10-27

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-11-24.

Section 98 - Personnel

1. **The records of staff qualifications, training or evaluation of their competency were not sufficient. The training records for Donor Testing Shipping Box Changes of shippers/receivers were not complete or accurate. For example,**

   a) For procedure 036 659 Shipping Samples to Donor Testing, the training matrix indicated the shipper/receiver trainer was to receive performance measurement training. The training record indicated awareness training was given to the trainer.

   b) Performance measurement training was provided for procedures 12 920 Preparing Phase Changer Materials for Transport to Clinics (Ver 3.0) and 12 921 Condition Series 4 and Series 0 PCM Plates-Transport to Clinic (Ver 3.0) but Section 3 Trainer Confirmation was not documented on the CET.

   c) Section 4 Reviewer Confirmation was completed by the trainer who performed the performance measurement training.

   Combined response for 1a, 1b and 1c:

   It was confirmed that training was completed as required and the records were corrected accordingly.

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

Section 100 - Equipment

2. **The establishment did not ensure that critical equipment was validated, calibrated, cleaned or maintained properly.**

   The Espec 3H Ram ID# R18295 was qualified including temperature mapping at -65 degrees Celcius only. However the Espec 3H has been programmed for six different conditioning cycles so it can be used as a back-up for conditioning and maintaining phase change plates used in the

new insulated shipping containers. The Espec 3H has not been temperature mapped for the other temperatures required for conditioning/maintaining phase change plates.

A qualification will be performed by 2018-03-31, as part of the Shipping Process project, to ensure that the ESPEC 3H can condition and maintain the PCM plates for all 6 different conditioning cycles.

Section 117 - Records

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

a) The Weekly Digital Touchscreen Recorder Review-PCM Equipment was not accurate.
i. The RAM asset ID number for the Dickson graph was documented as R18114 and should have been R18885.
ii. The RAM asset ID number for the Dickson graph was documented as R00195 and should have been R19325.

Combined response for 3ai and 3aii:

The RAM asset ID numbers were verified and the forms were corrected on 2017-11-30.

Group feedback which included the importance of accurate documentation was provided to staff on 2017-10-30.

b) The PCM Conditioning Cycles-Transport to Clinic for R17774/ R18882 was not accurate. The PCM Plates (Conditioning Stage) was checked off for Series 4 (stage 2) which does not occur in R17774/ R18882.

The record was corrected on 2017-12-01.

Staff were notified of the discrepancy and were reminded to follow SOP 12 921 'Condition Series 4 and Series 0 PCM Plates – Transport to Clinic' for the documentation requirements of form F800716 'PCM Conditioning Cycles – Transport to Clinic'.

c) The Certificate of Training (CET) printed from the LMS for procedure 09 350 Management of Equipment by Owners (Vers. 4) indicated the training completed was awareness. However the training provided to the field service representative was actually performance measurement.

It was confirmed that the expected training for SOP 09 350 is awareness training. The Equipment Services Training Matrix noted above indicated performance measurement in error.

The Training Matrix was revised on 2017-11-15.

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
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cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch