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
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Dear Ms. Hurlbut:

Re: Further to the Responses to the Health Canada Inspection of St. John's Operations 2017-10-23 to 2017-10-27

The following are the actions taken by Canadian Blood Services in response to the Health Canada email dated 2017-12-14, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of St. John's Operations.

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.

   Canadian Blood Services 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.

Health Canada Follow-up email dated 2017-12-14:

During the inspection, the Manager involved performed an investigation into these issues. It was determined the training matrix did not match the requirements of the training plan. The training plan indicated the training expected for procedures 036 659, 12 920 and 12 921 was awareness training. It was explained by the Manager that a regional decision was made to enhance the training to performance measurement so the training matrix was changed to performance measurement. However it was also indicated that this process for making these changes has not been defined in approved processes and likely contributed to the issues identified in the observation. The Inspector and Manager discussed these issues and there was an expectation that the response to this observation would include any corrective actions taken to define the process for enhancing training requirements that did not align with the training plan and training matrix.

Please provide further information about any corrective actions that have been taken or are intended to be taken to address the issues identified above.

Canadian Blood Services Response:

There is a process defined in SOP 08 551 'Identify Training Requirements' that includes work instructions for the review of the training plan against the training matrix and includes work instructions for entering individual exceptions with respect to learning levels in the comments fields of the training matrix.

It has been determined that the process was followed regarding the training enhancements as per SOP 08 551. However, there were deficiencies in the documentation to support this training. These were corrected on the training matrix as per SOP 08 551 Attachment 2 to clarify the training requirements.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affair
Fax Number: 613-739-2505

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