



Canadian Blood Services
Société canadienne du sang

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2018-11-09
CBS Control #: CBS6250
HPFB File #: C1892-100390
REF: H-1819-EDM-L

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

**Re: Responses to Health Canada Inspection of Licensed Activities at Edmonton Operations
2018-10-22 to 2018-10-26**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-10-30.

Section 95 - Operating Procedures

1. Some operating procedures were not always followed.

- a) **Contrary to Attachment 8 of SOP 08 810 Quality Event Management - Identification and Containment, Rev. 3, closure of QER #21-18-118737 was not done within 15 days of discovery of the event. Specifically, the event was discovered 2018-01-06 and the QER was not closed by QA until 2018-02-12.**

A read and sign memo was distributed to staff on 2018-11-05 to remind them of the timelines as stated in Attachment 8 of SOP 08 810 v.3, Quality Event Management - Identification and Containment. Quality Assurance staff, Production Supervisor and Product Distribution Supervisor have read and signed the memo on 2018-11-06.

- b) **Contrary to Section 1.2.4 of SOP 08 132 Retrieval - Departmental Review, Rev. 3, the Component Retrieval Record associated with QER #21-18-107229, was not signed and dated by the Supervisor to demonstrate their review of the document.**

The initial and final reviews by Quality Assurance documented on QER 21-18-107229 confirmed that the retrieval was completed appropriately.

The Component Retrieval Record was rescinded with the revisions to SOP 08 132v4 Retrieval - Departmental Review, effective 2018-10-15. The process includes ePROGESA printouts that capture information previously documented on the Component Retrieval Record. The review of the retrieval file is documented on the Lookback Event Details Report. No further corrective actions are deemed necessary.

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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

cc: Shelley Smyth
A/Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch

