



Canadian Blood Services  
Soci t  canadienne du sang

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2018-06-21  
CBS Control #: CBS6203  
HPFB File #: C1892-100390  
REF: H-1819-SASK-R

Ms. Shelley Smyth  
Regulatory Compliance and Enforcement Specialist  
Regulatory Operations and Regions Branch  
Health Canada  
300-391 York Avenue  
Winnipeg, Manitoba  
R3C 4W1

Dear Ms. Smyth:

**Re: Responses to Health Canada Inspection of Registered Activities at Saskatoon  
2018-05-16 to 2018-05-17**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-06-11.

**Section 95 - Operating Procedures**

- 1. Contrary to SOP 08 169 "Periodic Review of Controlled Documents" (effective 2016-09-06), there was no evidence of periodic review to confirm that the following documents were up to date and accurately reflect the current practices and regulatory requirements: SOP 01 046 "Maintain Autologous Donor File" Version 4 Site Effective Date 2007-06-11 and SOP 01 170 "Autologous Programme Acceptance" Version 5 Site Effective Date 2007-06-11.**

*A process to identify and follow up on late periodic reviews is being developed and will be implemented by end of September 2018.*

*In the interim, an assessment of the periodic review activities within the Supply Chain will be conducted and any late periodic reviews will be completed by the end of August 2018.*

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