

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