

2021-11-25

CBS Control #: CBS6554

Registration #: 2-000182-J

REF: H-2122-CAR-R

Urbee Shome-Pal  
Regulatory Compliance & Enforcement Specialist  
Biological Product Compliance Program  
Regulatory Operations and Enforcement Branch  
Health Canada  
180 Queen Street West, 10th Floor  
Toronto, ON M5V 3L7

Dear Urbee:

**Re: Responses to Health Canada Inspection of Registered Activities at Carling  
2021-10-05 to 2021-10-08**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-11-01.

**Section 95 – Operating Procedures**

- 1 a) **WI 01 170 Autologous Programme Acceptance, Rev No. 5.1, effective no later than 2019-04-01, was due for a review in March 2021, however, it has not yet been reviewed.**
- b) **WI 01 046 Maintain Autologous Donor File, Rev no. 4.1, effective no later than 2019-04-01, was due for a review in June 2021, however, it has not yet been reviewed.**

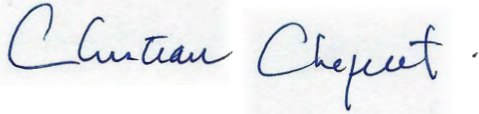
**It was indicated that due to the pandemic, there was a business disruption suspension of all periodic reviews, which was lifted in September 2020. However, even though the above due dates were new review due dates reflected in the CDI for the documents, they were still not completed without any deviations noted.**

*MQE-21-003876 was initiated on 2021-11-24.*

*The periodic reviews of work instructions 01 170 Autologous Programme Acceptance, Rev No 5.1 and 01 046 Maintain Autologous Donor File, Rev No 4.1 were completed on 2021-11-23. Both documents were found to be current and no changes were required.*

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

c.c.: Naima Bendahmane  
Supervisor – Biological Product Compliance  
Regulatory Operations and Regions Branch