

2022-12-12

CBS Control #: CBS6688

HPFB File #: C1892-100390

REF: H-2223-LETPDC

Supriya Rave

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 Supriya:

**Re: Responses to Health Canada Inspection of Licensed Activities at  
Lethbridge Plasma Donor Centre  
2022-10-31 to 2022-11-03**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2022-11-18.

**Section 95 - Operating Procedures**

1. **Contrary to WI 01 010, Evaluate Donor Centre Locations, Revision Number 9.1, The Donor Centre Evaluation Checklist for the initial inspection conducted on 2020-11-04 was marked off as the site being accepted, even though one of the mandatory donor centre requirements was unacceptable. For example, for 'fire exits and fire extinguishers clearly identified' a 'NO' was indicated, yet the supervisory acceptance review and managerial final review indicated that the site was accepted. Note that a re-evaluation was completed on 2020-11-18 which indicated that extinguishers were installed at the centre.**

*As noted in the observation, a re-evaluation was successfully completed on 2020-11-18, prior to the opening of this site on 2020-12-22.*

*As of 2021-09-13, WI 01 010 Evaluation Donor Centre Locations was revised and retitled to Evaluate Mobile Donor Centre Locations as site evaluations are no longer applicable for permanent sites and only applicable to mobile sites.*

**Section 117 - Records**

2. **The following were observed during record review:**
  - i) **The review of the Premises Monthly Inspection indicated the following:**
    - a) **The inspection record for 03/2022 was not available.**
    - b) **Not all inspections were reviewed (e.g., 06/2022, 08/2022 and 09/2022).**



**c) Areas of concern were documented, however, there were no additional comments to indicate follow up actions. For example, for 08/22, it was identified that 'Front doors continue to be problematic when raining. Sensors do not work.' and for 09/22, 'Foul odour noted from Biohazard bins (large yellow tubs)' was stated on the record, however, there was no documentation to indicate follow up actions.**

*MQE-22-003629 and MQE-22-003630 were initiated on 2022-11-03.*

*The Centre Manager will ensure inspections are being performed, documented, and submitted for review monthly as per WI 13 022 Premises Cleaning.*

*In addition, the Centre Manager and Team Leads were reminded that the inspection form is for cleaning deficiencies only, as per 13 022 Premises Cleaning and a work order should be placed for other Facilities related matters.*

*The problem with the front doors was addressed through Facilities work order 866701 which was closed on 2022-09-03. The vendor was notified on 2022-09-16 regarding the foul odour and the bins were replaced at their next pick up on 2022-09-28.*

**ii) Contrary to work instruction 17 015, Distribute and Ship Source Plasma Units and B19 Samples - Plasma Program, Revision 3, the time of the post load vehicle temperature on Packing Slip 0000003293540 was not recorded.**

*MQE-22-003605 was initiated on 2022-11-02.*

*Work instruction 17 015, Distribute and Ship Source Plasma Units and B19 Samples - Plasma Program, Revision 3 were reviewed with team members on 2022-11-07.*

**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