

2024-04-08

CBS Control #: CBS6811

HPFB File #: C1892-100390

REF: H-2324-SASK

Danny Phan

Regulatory Compliance & Enforcement Specialist

Regulatory Operations and Enforcement Branch, Health Canada

Biological Product Compliance Program

400-4595 Canada Way

Burnaby, BC V5G 1J9

Dear Danny:

**Re: Responses to Health Canada Inspection of Saskatoon
2024-02-28 to 2024-02-29**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2024-03-19.

Section 96 - Operating Procedures

- WI-00534 RAM Management of Equipment by Owners (Revision 2; Effective 2024-02-12) did not clearly differentiate the processes for managing the relocation of portable and non-portable equipment within the RAM system. While the work instruction required a change request to be completed for equipment relocations, it did not specify that this requirement applied exclusively to non-portable equipment. Consequently, there were no specific instructions regarding the relocation of portable equipment, such as Docon Shakers, which are frequently moved between CBS sites (e.g., Saskatoon and Regina).**

DEV-24-003071 was initiated on 2024-03-25.

RAM change requests were initiated on 2024-03-28 to correct the locations of the impacted portable equipment.

A CAPA will be initiated to identify the root cause(s) pertaining to portable equipment movement and traceability and identify corrective/preventive actions to maintain traceability. Target completion date of the investigation is 2024-06-30.

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