

2024-05-09
CBS Control #: CBS6811
HPFB File #: C1892-100390
REF: H-2324-SASK

Danny Phan
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
400-4595 Canada Way
Burnaby, BC V5G 1J9

Dear Danny:

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

The following are the responses from Canadian Blood Services to the Health Canada letter dated 2024-04-29, requesting clarification for an observation to the Exit Notice for Health Canada's Inspection of licensed activities at Saskatoon.

- 1. 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).**

Canadian Blood Services Response:

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.

Health Canada Follow-up letter dated 2024-04-29:

The response does not explicitly address the lack of differentiation between the management processes for portable and non-portable equipment in WI-00534. Please specify how WI-00534 (and/or other work instructions) will be revised to clearly differentiate between the processes for managing portable and non-portable equipment.



**Canadian
Blood
Services**
BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

Canadian Blood Services Follow-up Response:

Work instruction WI-00534 RAM Management of Equipment by Owners will be updated and the words Portable and Non-portable will be added to Section 3 Step 1 to clarify that equipment relocation updates apply to both types of equipment. The revisions to the work instruction will be implemented 2024-05-13.

If you require clarification or further information, please do not hesitate to contact the undersigned.
Please refer to the above control number in all correspondence.

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505