

2025-05-30

CBS Control #: CBS6900

HPFB File #: C1892-100390

REF: H-2526-DAR-W

Craig Turk
Regional Regulatory Compliance & Enforcement Officer
GMP Inspection Central
Regulatory Operations and Enforcement Branch (ROEB)
Health Canada
2301 Midland Avenue
Toronto, ON M1P 4R7

Dear Craig:

**Re: Responses to Health Canada Inspection of Wholesale Activities
at Dartmouth Operations from 2025-04-31 to 2025-05-01**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2025-05-16.

C.02.015 Quality Control Department

1. Change controls were not initiated when modifications were made to the shelving configurations in the ambient storage area (Room 1044), and as such, there was no assessment conducted to evaluate the impact of these changes on the existing temperature mapping that was performed in 2013. For example:

- 1) The shelving configuration during the 2013 mapping, did not include shelving on the North wall; however, shelving was subsequently installed along this wall at an undetermined time without evidence of formal change control.**
- 2) Shelving located in the center of the storage area had been removed approximately four months prior to the start of the inspection, without the initiation of a change control.**

DEV-25-004850 was initiated on 2025-05-22.

The ambient storage room has been continuously monitored for temperature using the central continuous monitoring system as per WI-00673, "Viewlinc Operation" with the probes in the previously identified high and low locations.

Following the completion of a validation assessment for the shelving configuration change on 2025-05-22, a change request was initiated on 2025-05-22, as the validation assessment

indicated that the area requires temperature mapping to the current configuration. The target to complete summer and winter temperature mapping is 2026-04-15.

Follow up has been performed at the time of inspection with distribution supervisor and manager to ensure that they are aware of the requirements of WI-01405 Standard Change – Initiator, to ensure all assessments and approvals are captured in a change request prior to executing any changes in a GMP environment such as a temperature mapped area. In addition, refresher training to WI-01405 will be completed by 2025-06-30.

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,

Steven Carswell

[Steven Carswell \(2025-05-30 12:14 EDT\)](#)

Steven Carswell

Vice-President

Quality & Regulatory Affairs