

2024-05-10
CBS Control #: CBS6807
HPFB File #: C1892-100390
REF: H-2324-OTTCBB

Lydia Papanastotelis
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
2301 Midland Ave
Scarborough, ON M1P 4R7

Dear Lydia:

**Re: Further to the Responses to the Health Canada Inspection of the Ottawa Cord Blood Bank
2024-02-13 to 2024-02-20**

The following are the responses from Canadian Blood Services to the Health Canada letter dated 2024-05-08, requesting clarification for an observation to the Exit Notice for Health Canada's inspection of licensed activities in the Ottawa Cord Blood Bank.

Section 64.02 - Personnel

2. Personnel training records were not always complete.

There was no documentation to demonstrate that a back-up medical director was trained on the curriculum training matrix for Cord Blood Manufacturing: Release to Inventory and Distribution – Awareness- Director (curriculum ID 1256), even though he was granted access in the system (SCNSS) to perform the release to inventory and distribution functions.

It was determined after the inspection that access had been granted to the Stem Cells National Systems Solution (SCNSS) for a back-up medical director on 2023-02-28, with a training date of 2023-03-03. In order for process training to be completed in full, access to the system must be granted, which is the reason that the access date precedes the training date. As per Canadian Blood Services policy and practice, staff are not to perform tasks until they are fully trained to the applicable process/work instructions. Review of the situation confirmed that the back-up medical director had never performed any related tasks.

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

It is acknowledged that training was conducted for a back-up medical director on March 3, 2023 (2023-03-03). However, it was noted during the inspection that a back-up medical director was not yet trained to-date (February 15, 2024) on the curriculum training matrix for cord blood manufacturing (ID 1256), although they were previously granted SCNSS access. As such, please (re)clarify if after the inspection, it was



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

1800 Alta Vista Drive
Ottawa ON K1G 4J5

blood.ca

determined that this back-up medical director was appropriately trained on March 3, 2023, and provide a copy/screenshot of their training confirmation.

Canadian Blood Services Response:

Following the inspection, stem cell training support identified that the backup medical director had trained to curriculum ID 1256 on 2023-03-01. Please see attached confirmation of training.

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