

2005-03-10
CBS Control #3387
Ref #AUD05-062 HC127
HC File # C1892-100390

Ms. Sandra Decoste
Acting Operational Manager
Health Products & Food Branch Inspectorate
Atlantic Operational Centre
Suite 1625
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6

Dear Ms. Decoste:

Re: Responses to the Health Canada Audit of New Brunswick Centre
21-25 February 2005

The following are the actions undertaken by the New Brunswick Centre and Head Office in response to the observations contained in the Health Canada Exit Notice.

Raw material testing / Analyse des matières premières – C.02.009

- 1. During a health assessment of a donor, the screening nurse did not follow the directions “Check Cuff Placement” as indicated on the IVAC. She accepted the donor without repositioning the cuff and repeating the procedure.**

Resolved during inspection.

Raw material testing / Analyse des matières premières – C.02.009

- 2. Donors were instructed to read the consent during registration and not during screening.(SOP 01 043).**

Resolved during inspection.

Personnel / Personnel – C.02.006

- 3. No evidence in the training files of three staff members that they had received training on a COP that was listed on their training matrixes. (NSG 190D) A current training matrix was not dated and signed.**

Evidence of exposure training to COP NSG 190D has been placed in two of the three staff members' files. The third person has since left the employment of CBS. QIR 05 581 was initiated to document the non-conformance.

The matrix in question was dated and signed by the responsible Manager on 2005-02-25.

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

Sincerely,

Dr. Christian Choquet
Vice President, Quality Assurance
and Regulatory Affairs