

2004-12-21  
CBS Control #3247  
Ref #AUD04-441 HC124  
HC File # C1892-100390

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

Dear Ms. Decoste :

**Re: Responses to the Health Canada Audit of Newfoundland Centre  
29 November – 03 December 2004**

The following are the actions undertaken by the Newfoundland 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 the health interview of a donor, the nurse did not verbally instruct the donor to contact the blood centre should he develop any illness after the donation.**

*Following the health interview in question it was confirmed that the donor had been verbally instructed to contact the blood centre should he develop any illness after the donation. Since that time, all staff nurses have completed a review of SOP 01 043, "Perform Health Interview." In addition, on 2005-01-07 a training session will be held and a review of the SOP will be completed with the nursing staff clarifying the requirements related to this issue.*

**Manufacturing control / Contrôle de la fabrication – C.02.011**

- 2. In one autologous file, the "Eligibility for Autologous Program" section was not completed on the "Physicians Request for Consideration for Autologous Transfusion" form.**

*Resolved during inspection.  
A non-conformance was initiated and the error addressed. The observation was considered resolved during inspection.*

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

- 3. On two records of donations (RD) the nurse dated a corrected response to two questions on each RD. SOP 01 043 Version 13 stipulates that corrections are to be initialled and dated by the donor.**

*Resolved during inspection.*

*A memo was circulated by the Collections Manager reminding Nursing staff to follow SOP 01 043 "Perform Health Interview" when making corrections to errors on the RD. The observation was considered resolved during inspection.*

**Personnel / Personnel – C.02.006**

**4. The training received by two medical officers was not reflective of the training matrix on their files.**

*As of 2004-12-08 an updated training matrix reflecting the current training for the medical consultants was printed and signed by the Medical Director and placed in the appropriate training binders.*

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

Sincerely,

Christian Choquet, Ph.D.  
Vice-President, Quality Assurance  
and Regulatory Affairs