



2005-04-22
CBS Control #3392
Ref #AUD05-098 HC129
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 PEI Sub-Centre
29 March – 01 April 2005

The following are the actions undertaken by the PEI Sub-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. The following documentation errors were noted on reviewed Records of Donations (RD's):

On one RD, the phlebotomy type was entered as “plasma” although blood was not drawn.

On one RD, the phlebotomy status was not entered.

On two RD's, the pack types were entered, although the donors were deferred.

Incidents INC800504007, INC800504008, and INC800504009 were initiated to address the above RD documentation errors. These incident reports were reviewed with staff to ensure they are aware that distractions during routine documentation on records of donation may result in documentation errors. Staff were reminded that if interrupted, to ensure the sequence of documentation requirements are performed correctly. In addition, they were reminded to review their own work as well as documentation from previous steps. The requirement to review previous steps is also outlined in CBS SOPs, such as 01 043 “Perform Health Interview”, 01 101 Phlebotomy (Whole Blood), 01 130 “Complete Collection (Whole Blood/Autologous), and 01 703 “Data Entry of Donation Information”, for the activities cited above. These events were entered into the Centre's non conformance database. This data is monitored on a monthly basis for unacceptable trends.

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

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