

2004-12-09
CBS Control #3191
Ref #AUD04-413 HC122
HC File # C1892-100390

Mr. Jean-Marc Charron
Operational Manager
Health Products and Food Branch Inspectorate
Ontario Operational Centre
2301 Midland Avenue
Toronto, ON M1P 4R7

Dear Mr. Charron:

Re: Responses to the Health Canada Audit of Hamilton Centre
25-29 October 2004

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

Manufacturing control / Contrôle de la fabrication – C.02.011

- 1. There was no process in place to ensure that duplicate donors who had been previously deferred by another centre were always identified by Progesa at donor registration.**

Due to the creation of a national donor database with the implementation of PROGESA, a large pool of duplicate donors has been created. With BLIS 2000 each Centre managed their own individual donor database including duplicate donors identified on their database. With PROGESA, a national donor database was created with duplicate donor records being identified between sites and across the country. The number and complexity associated with many of the duplicate records identified requires more intensive inter-site coordination and additional resources to manage the potential duplicates identified. Although the SOPs to direct the work have been submitted to and approved by Health Canada, a plan must be developed to ensure the proper identification, assessment and resolution of the duplicate donors identified. To do this, the support structure for the management of duplicate donors within CBS will have to shift from being local at each site to national. CBS will develop the plan by January 31st to identify the required resources, as well as the new support structure to manage the routine program of duplicate donor management.

Manufacturing control / Contrôle de la fabrication – C.02.011

2. **The following deficiencies were noted regarding the handling practices for quarantined components;**
- a) **There were no documented specified timeframes for the application of the appropriate code(s) in Progesa in order to place components into electronic quarantine.**
 - b) **There was no requirement for the physical segregation of rejected components from other blood components.**
 - c) **There was no mechanism for documenting the physical location (eg. movement of a component from one area to another) of a rejected component or other component that may require temporary quarantine.**
- a) *Electronic quarantine of components takes effect at the time a Lookback Event is created. Guidelines for the creation of Lookback Events and the resulting electronic quarantine of components in inventory are captured in processes/procedures for the following:*
- *Non-Conformances - control of components whose suitability has been called into question are acted on as part of the immediate actions taken to address the non-conformance, including creation of a Lookback Event OR applying a manual quarantine in PROGESA, to electronically quarantine the components;*
 - *Positive Transmissible Disease (TD) test results – upon entry of positive TD test results, a Lookback Event is automatically created and therefore electronic quarantine is placed on any components in inventory from the donor;*
 - *Recalls (any retrieval not related to TD test results) - due to the variability associated with Recalls (for example, a single donor with one donation versus many donors and/or many donations), the time required to assess the information received and create a Lookback Event varies. Creation of a Lookback Event to place the associated components into electronic quarantine occurs as described in SOP 01 764, Information Received Post Donation.*
- b) *SOP 04 729, End Labelling and SOP 04 731, Re-label Released Units/Components will be updated to indicate that components rejected during the end labelling process will be placed in the designated storage area within quarantine or forwarded for boxing. CR #4229 has been submitted to request the revisions to these documents.*
- c) *It should be noted that with PROGESA there is no status of temporary quarantine. When a component is placed into quarantine in PROGESA, the quarantine status remains in effect and can only be updated through user intervention in PROGESA to either release or reject the component. It should also be noted that components cannot be distributed to a transfusion facility once an electronic quarantine has been applied to the component, or once the component has been rejected or has expired. With regards to documenting the physical location of these components to track their location, directive D2004-026, Review Status of Rejected/Expired Components, which was implemented on November 22, 2004, requires that sites generate a rejected and expired component report a minimum of once per week. Every component listed on either of these reports must be accounted for.*

Premises / Locaux – C.02.004

3. **The window coverings on the donor screening rooms at the Hamilton Permanent Clinic were sheer and had gaps and therefore did not adequately provide an area which would maintain confidentiality for the donor during donor suitability assessment or the confidential unit exclusion process.**

Temporary window coverings were installed during the inspection. Permanent window coverings will be installed by 2004-12-31.

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

4. **The following documentation errors were noted during record review;**
- a) **During review of the Record of Donation (Rd) for the Burlington Permanent Clinic on September 2, 2004 (unit #0552 3 849283), the screening nurse provided clarification in the collections staff comment box under 8b) (Have you ever had epilepsy, coma, stroke, convulsions or fainting?), instead of under 9b) (In the last three years, have you been outside Canada, other than the U.S.?). NCDR #52-04-02768 was initiated during the inspection.**
 - b) **During review of the Record of Donation (Rd) for the Burlington Permanent Clinic on September 2, 2004, an NCDR was not initiated on unit #3-849325 when the screening nurse identified that a hemoglobin result was not documented on the Rd for a donor deferred for an unacceptable hemoglobin result. NCDR # 52-04-02767 was initiated during the inspection.**
 - c) **During review of plateletpheresis charts, in one instance there was no indication that the donor had been found acceptable by the Physician. NCDR #52-04-02718 was initiated during the inspection.**
- a) *SOP 01 043, Perform Health Interview, was reviewed with the screening nurse by the clinic supervisor on 2004-10-28. A non-conformance report was initiated during the inspection and immediate corrective action was taken. The response provided for 8b was appropriate for 9b therefore the error was in the transcription of the corresponding health assessment question number. There was no risk to the product because the response to the travel indicated no malarial risk. The following update is further to CBS' response to the Health Canada audit of Ottawa Centre, 4-8 October 2004; Head Office response to observation #1a and 1b. BGTD has provided CBS with permission to proceed with the pilot of a new submission process allowing the review of multiple versions of the same procedure under review with BGTD. One of the pilot projects of this new submission process will be Phase 1 of the Reduce RD Errors project. CBS has completed the user acceptance of the Phase 1 revisions and is targeting submission of Phase 1 of the Reduce RD Errors Project on 2005-01-31.*
 - b) *In order to ensure that nonconformance reports are initiated once an error/omission has been identified as required at the next critical control point, COP H7500 "Required Actions When a Nonconformance Deviation is Identified", was reviewed with the staff involved on 2004-11-29.*
 - c) *A memo was forwarded to all physicians on 2004-10-28 reminding them to complete the appropriate checkbox (accept/defer) when reviewing plateletpheresis charts. As well, Registered Nurses were reminded to ensure that all fields are complete during the review of the donor files.*

Equipment / Equipement – C.02.005

5. **It was not clear which requirements for the daily back-up of the BacT/Alert bacterial detection system should be followed in that three applicable procedures (SOP 25-301, BacT/Alert Maintenance, SOP 07-112, Managing Magnetic Media and SOP 07-220, System Back-up) contained different specifications for the storage location, conditions and the frequency that information should be backed up.**

SOP 25 301 "BacT/ALERT Maintenance" has been revised to remove reference to SOP 07 112 "Managing Magnetic Media" and SOP 07 220 "System Back-up". Specific work instructions have been added to SOP 25 301 "BacT/ALERT Maintenance" for labelling, storing and handling back-up disks as well as frequency of running back-up. Submission of SOP 25 301 to Health Canada is planned for February 2005.

Equipment / Equipement – C.02.005

6. **The BacT/Alert Bacterial Detection System Installation Checklist performed by the external service provider on 2004-04-13 did not provide a link between the test equipment used to perform the service and the calibration certificates. Further, there were no acceptable parameters specified. Efforts to address this issue with the external service provider were initiated prior to the inspection and are on going.**

Discussions are ongoing with the external service provider to ensure that the installation checklist provides a link between test equipment used to perform service and the calibration certificates provided. Acceptable parameters will also be addressed. Resolution to these items is expected by February 2005.

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