

2004-12-21
CBS Control #3222
Ref #AUD04-421 HC123
HC File # C1892-100390

Ms. Alexis Grolla
Acting Operational Manager
Health Products and Food Branch Inspectorate
Manitoba and Saskatchewan Operational Centre
510 Lagimodière Boulevard
Winnipeg, Manitoba. R2J 3Y1

Dear Ms. Grolla:

**Re: Responses to the Health Canada Audit of Winnipeg Centre
22-26 November 2004**

The following are the actions undertaken by the Winnipeg 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. REPEAT OBSERVATION : At the time of the inspection there was no evidence that the duplicate donor extract process had been completed since May 2003. Additionally, there is no current process in place such as the duplicate donor extract, even though a Health Canada "No Objection Letter" was received by CBS Head Office on October 6, 2004 regarding the MAK Implementation Project, Duplicate Donor SOPs.**

The Duplicate Donor Extract was performed by Centre DRBS staff using the BLIS 2000 database on 2003-12-12. Assessment for potential duplicate donors was completed for these extract lists. However, contact and resolution of all potential duplicate donors was not completed prior to MAK conversion on 2004-02-06. 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 2005-01-31 to identify the required resources, as well as the new support structure to manage the routine program of duplicate donor management.

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

- 2. During review of record of donations (RDs) for Steinbach mobile clinic from August 19, 2004 the following deficiency was noted, for Question 2 b) "Do you have**

a cold, sore throat, fever, infection or allergy problem today?". The answer was recorded as yes but there was no explanation documented on the RD donation number 0540 6 747588. Recall was initiated during the inspection, recall #CO 04-100.

Please note that there is an error in the Health Canada citation in that this citation should reference question 1b rather than question 2b. Quality Improvement report CO-04-0878 and recall CO-04-100 were initiated in response to this observation during the inspection. Feedback to the individuals involved was provided on 2004-11-29. The second phase of the Reduce RD Errors Project will target these type of errors (i.e. omissions on the Health Interview portion of the RD). In addition, the documentation requirements for comments to Health Interview questions will also be reviewed with Phase 2. Phase 2 is targeted for initiation once the Phase 1 portion of the project has been submitted to Health Canada, currently targeted for 2005-01-31.

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

3. **Screening nurse at Stonewall Mobile did not ask donor to read/review CUE (Confidential Unit Exclusion) instruction sheet as per SOP 01 084 (Explain and Have Donor Perform CUE).**

The screening nurse was retrained to the steps outlined in SOP 01 084 on 2004-12-14. A review of this SOP was performed during the staff meeting which was held on 2004-12-17.

Manufacturing control / Contrôle de la fabrication – C.02.011

4. **Contrary to correspondence from CBS head office to Health Canada on April 19, 2004 regarding E/A 125-04-00001 Network Connection Interruption (Winnipeg Centre), SOP 02 797, Manual Contingency Plan (PROGESA Site) Labelling Transformed Components outside of PROGESA and associated forms and labels have not been submitted to Health Canada.**

Subsequent to our correspondence of 2004-04-19, CBS provided a "Simulation Summary Report" to Health Canada (reference CBS Control #CBS1848, 2004-07-22) outlining the results of the simulation exercise which we conducted in our Halifax site on 2004-06-12. With respect to SOP 02 797, "Manual Contingency Plan (Progesa Site) – Labelling Transformed Components Outside of PROGESA", we advised that the SOP would be revised to clarify the "note" in step 4.1. Although we have not had a response back from Health Canada regarding this 2004-07-22 submission, we will proceed to make the revision and submit the SOP to Health Canada by mid January 2005. Implementation in all CBS sites will follow Health Canada approval.

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

5. **SOP 01 795 Manual Contingency Plan (PROGESA Site) - Collections does not address the use of mobile laptops in the Centre Clinic contrary to the error description provided to Health Canada regarding E/A #125-04-00001 Network Connection Interruption (Winnipeg Centre).**

The internal CBS communication protocol around a PROGESA service interruption is addressed in CBS' MAK PROGESA System Recovery Guide, version 1.0, submitted to Health Canada on 2004-04-30 (reference: CBS Control #CBS1848). Section 4.3 of this document indicates that "regardless of the type/nature of service interruption being experienced, the MAK Support Team will be involved in the assessment process and together with Centre Management and Head Office staff will determine the most appropriate course of action". Additionally, section 4.5.1, scenario #2 specifically provides for the option of setting up a mobile kit at the permanent site and then operating the clinic as if it were a mobile. The decision to use the mobile laptops in the Winnipeg site (reference E/A #125-04-00001) was made through this consultative process in keeping with the System Recovery Guide. However, CBS will revise SOP 01 795 to specifically reference the use of mobile laptops in the Centre clinic, when required. As this SOP is being updated with the Buffy Coat Project, the revision will be made to this document by the Buffy Coat Project team. In the interim, while the Buffy Coat project is being implemented, we will continue to rely on the provisions of the System Recovery Guide.

Equipment / Equipement – C.02.005

- 6. Chart recorder reading on Platelet Incubator INC 0017 in Component Production was out of range. Temperature range is +20 °C to +24 °C and chart recorder reading was +18 °C. The digital readout on the incubator was 22.0 °C and the report from the Honeywell system, which is the system of record, recorded a temperature of 21.5 °C.**

Quality Improvement Report BIO 04-070 was initiated in response to this observation. The chart recorder was recalibrated on 2004-11-24 and an adjustment was made. Written communication was provided to staff on 2004-11-12 as to how the charts should be changed and to ensure that the temperature is recording correctly following the change.

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