

2004-10-19  
CBS Control #3130  
Ref #AUD04-353 HC119  
HC File # C1892-100390

Mr. Dennis Shelley  
Operational Manager  
Health Products and Food Branch Inspectorate  
Western Operational Centre  
3155 Willingdon Green  
Burnaby, British Columbia V5G 4P2

Dear Mr. Shelley:

**Re: Responses to the Health Canada Audit of Calgary Centre**  
**13-22 September 2004**

The following are the actions undertaken by the Calgary 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 review of records of donation (RD) the following were noted:**
  - a) **For the Centre Clinic 4 August 2004 donation number 9-522986, the donor's signature and date were missing. NCR 2004CAL2728 was initiated on 13 Sept. 2004 (including product retrieval);**
  - b) **No CuS04 results were recorded for donation number 0-525140 from Medicine Hat Clinic 13 July 2004, yet donor was accepted and proceeded to donate; NCR 2004CAL2730 was initiated on 13 Sept. 2004;**
  - c) **For Medicine Hat Clinic 13 July 2004 donation number 2-525141, there was no response recorded for high risk question #26 (In the last 12 months have you had or been treated for syphilis or gonorrhoea?) NCR 2004CAL2729 (including product retrieval) was initiated on 13 Sept. 2004;**
  - d) **No blood pressure nor pulse results were recorded on the RD from Medicine Hat Clinic 13 July 2004 donation number 6-525303, yet the donor was accepted for donation. NCR 2004CAL2770 was initiated on 15 Sept, 2004;**
  - e) **For Lethbridge Clinic 18 April 2004 donation number 4-353981, the donor was deferred based on a "Yes" response to Question 10(c) (Have you spent a total of 3 months in France since January 1, 1980?), however the RN did not determine if the donor has any blood relatives who have been diagnosed with CJD since the "Yes" box was checked for Question 11 on the RD (Are you aware of a diagnosis of Creutzfeldt-Jakob Disease among any of your blood relatives (parent, child, sibling?). NCR 2004CAL2752 was initiated on 14 Sept. 2004;**
  - f) **For Medicine Hat Clinic 18 August 2004 donation number 8-528015, the donor marked "Yes" for question 8(c) on the RD (Have you ever had heart or blood pressure problems or heart surgery?); yet no notes were taken by the RN and the donor was accepted for donation. NCR 2004CAL2791 was initiated on 17 Sept. 2004.**

*The immediate corrective action involving the initiation of nonconformance reports and product retrievals, as required, is captured in the observation. An interdivisional working group was struck to implement the Six Sigma recommendations for the Record of Donation. SOPs targeted for change, however, are also linked to other important CBS initiatives and as a result, further assessment of the impact of change on these projects is required to ensure that the additional changes do not impact further on errors occurring to the RD. CBS will be filing a licence amendment that will deal with changes to the RD as recommended by the Six Sigma working group. In the interim, the errors were also reviewed at Clinic Operations staff meetings held on 2004-10-18. Staff will be required to read and sign for these minutes by 2004-11-22.*

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

- 2. During the review of donor's plasmapheresis charts it was noted that for two donor's Medical History and Physical Examination records dated 12 Nov. 2003 and 13 Feb 2004, under "Review of Symptoms by Systems" there was no answer (yes or no) beside Haematologic. NCR 2004CAL2774 was initiated on 15 Sept. 2004 and NCR 2004CAL2798 was initiated on 17 Sept. 2004.**

*The immediate corrective action involving the initiation of nonconformance reports is captured in the observation. The Medical Director telephoned the two donors in question on 2004-09-20 to discuss the hematologic section of the physical. No concerns resulted from these discussions. These discussions were documented on the Medical History and Physical Examination Records. This was reviewed again with the physician at the donors' next donations which occurred on 2004-09-21 and 2004-09-22. The Medical Director has also reviewed the errors with the Associate Medical Director.*

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

- 3. The following were noted during the review of RD's:**
- a) For Centre Clinic 4 August 2004 donation number 6-523026, Question 5(b) "If female, in the last 6 months have you been pregnant?", was not answered (note this was a male donor however a yes, no or n/a response is required for this question). NCR 2004CAL2732 was initiated on 13 Sept. 2004;**
  - b) For Lethbridge Clinic 8 April 2004 donation number 5-354009 and 0-353946 the donors dated the wrong year on the RD. NCR 2004CAL2731 and 2004CAL2760 were initiated on 13 Sept. 2004 and 15 Sept. 2004, respectively;**
  - c) For Lethbridge Clinic 8 April 2004 donation number 2-353966 the donor wrote down the date without the year on the RD. NCR 2004CAL2750 was initiated on 14 Sept. 2004;**
  - d) The following 4 RD's from Medicine Hat clinic 13 July 2004 were missing initials for "Verification of Data":**
    - 4-525284; NCR 2004CAL2765 initiated on 15 Sept. 2004**
    - 7-525295; NCR 2004CAL2764 initiated on 15 Sept. 2004**
    - 1-525297; NCR 2004CAL2768 initiated on 15 Sept. 2004**
    - 0-525305; NCR 2004CAL2772 initiated on 15 Sept. 2004**
  - e) For Medicine Hat Clinic 13 July 2004 the following 2 RD's were missing initials for "Data Entry Completed By":**
    - 0-525300; NCR 2004CAL2769 initiated on 15 Sept. 2004**
    - 4-525260; NCR 2004CAL2761 initiated on 15 Sept. 2004**

- f) **No initials were in the required “Unit Labelling Initials” on the RD from Medicine Hat Clinic 13 July 2004 for donation number 9-525272. NCR 2004CAL2763 initiated on 15 Sept. 2004;**
- g) **For Medicine Hat Clinic 18 August 2004 donation number 4-528018, there were no initials recorded under bleed time. NCR 2004CAL2792 was initiated on 17 Sept. 2004.**

*The immediate corrective action involving the initiation of nonconformance reports as required is captured in the observation. An interdivisional working group was struck to implement the Six Sigma recommendations for the Record of Donation. SOPs targeted for change, however, are also linked to other important CBS initiatives and as a result, further assessment of the impact of change on these projects is required to ensure that the additional changes do not impact further on errors occurring to the RD. CBS will be filing a licence amendment that will deal with changes to the RD as recommended by the Six Sigma working group. In the interim, the errors were also reviewed at Clinic Operations staff meetings held on 2004-10-18. Staff will be required to read and sign for these minutes by 2004-11-22.*

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

4. **QS Acceptance label was missing from one of the donation label packages (donation number 724501- 724600) in the locked cabinet in the Released Warehouse. NCR 2004CAL2837 was initiated on 21 Sept. 2004.**

*Resolved during inspection*

#### **Equipment / Equipement – C.02.005**

5. **Repeat Observation: Contrary to CBS response to part 1 of Observation #3 of last year's inspection, the Centre has not provided evidence that a system is in place to determine the need to audit all companies that provide either routine preventive maintenance on laboratory instruments or calibration of test equipment utilized by the Biomed department.**

*COP CQ:0028 “Supplier Quality Audits”, will be revised to indicate that suppliers will be assessed prior to the creation of the audit schedule to determine the need for an audit. The target date for completion is 2004-12-07. In order to provide guidance, and address the observation with a standardized approach, the CBS Head Office Audits Department will initiate a Change Request to rescind SOP QA:323 "Quality Systems Assessments: Suppliers", and replace it with an updated procedure which will include a decision flowchart to identify the requirement to perform audits of suppliers. The plan is to submit this change request to the Change Review Board by 30 November 2004, with an anticipated submission to Health Canada in the first quarter of 2005, dependant upon CBS' project priorities.*

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

6. **Contrary to SOP 04 130 Emergency Release version 3, signature of the requesting physician was not obtained since 28 February 2004, yet the request was reviewed and signed by the department manager. Furthermore, the Quarantined Component Handling form (Form 1000101798) of both platelet units for emergency release was**

**not reviewed by the supervisor. The donation units were not transfused under the emergency release program. NCR 2004CAL2795 was initiated on 17 Sept, 2004.**

*The immediate corrective action involving the initiation of a nonconformance report is captured in the observation. The Quarantine Component Handling form was reviewed by the supervisor on 2004-09-17. The requesting physician will not be asked to provide a signature at this time since the component was not transfused under an emergency release. The Medical Director has attached an explanatory note to the file indicating the reason for not obtaining this signature at this time.*

**Records / Dossiers – C.02.020**

7. **During document review, the following GMP deficiencies were noted:**
- a) **Request for Remote Access to Hema-Quebec Database performed on April 8, 2004, was not reviewed by department supervisor, and**
  - b) **An incident that occurred on 22 July, 2004, was not reviewed and signed off in the equipment binder for the Hamilton Pipettor, serial #2354, control #PIP-C002.**

*Resolved during inspection*

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

