

2004-11-09
CBS Control #3156
Ref #AUD04-391 HC121
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 Ottawa Centre
04-08 October 2004

The following are the actions undertaken by the Ottawa 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 were noted when reviewing the records of donation for the Centre Clinic (K0001, 1575 Carling Avenue) for September 29, 2004:**
 - a) **Donor # 4105517 recorded “N/A” as the response to question 10 b (“If you have been in the United Kingdom since 1980, did you receive a blood transfusion or any medical treatment with a product made from blood?”). While the screening nurse did indicate in the comment section that the answer to 10 b was “no” and to accept the donor, the change to the response was not corrected in the box and the donor did not sign or date that this change should have been made. QIR 55-04-02092 was generated during the inspection.**
 - b) **Donor # 4107639 indicated a “yes” to question 2 a (“In the last 3 days have you taken any medicine or drugs (pills including Aspirin or shots), other than birth control pills and vitamins?”). The screening nurse noted in the comment section that the donor may have taken ASA 2-3 days prior to the donation yet this was not indicated in the ASA box in the Technical Questionnaire section. QIR 55-04-02091 was generated during the inspection.**
 - c) **In four instances (donors # 4123652, # 4136521, # 4121107 and # 4120871) the temperatures recorded were 359, 365, 359 and 362 degrees, all of which were outside the acceptable range. The following QIR’s were generated during the inspection: 55-04-02095, 55-04-02096, 55-04-02090.**

Centre response / Observation #1a)b)c):

The above observations are from a review of the RDs from three clinics totaling 203 Records of Donation. The following actions will be completed:

- *Quality Improvement Reports(QIRs) were initiated for the above incidents at the time of the audit. The completion of the QIRs will include root cause analysis and corrective action. The employees involved with the QIRs will be counseled to prevent any re-occurrence. As per Centre Operating Procedure CQ 002, departments have twenty working days to complete and return the QIRs to Quality Systems. Upon*

receipt by Quality Systems, a review of the corrective action will be performed for acceptability. Recalls were performed where necessary.

- A meeting for Collection employees was held on 2004-10-29 to discuss the audit observations. At the meeting, Quality Systems presented an in-service to review the importance of accuracy and completeness of documentation. All staff will be required to read and sign for the minutes of this presentation by 2004-12-31.

Head Office response / Observation #1 a) b):

An interdivisional working group was struck to implement the Six Sigma recommendations for the Record of Donation with the Reduce RD Errors Project. SOPs targeted for change, however, are also linked to license amendments currently before Health Canada, as well as a multitude of pending license amendments. CBS representatives met with Health Canada Biologics and Genetic Therapies Directorate (BGTD) on 2004-10-20 to discuss the limitations of the current Management of Blood Establishment Submissions Guidelines (MBESG) section 4.3, Submission Updates - Operating Procedures, which states, "Two versions of the same Operating Procedures in two different submissions will not be reviewed at the same time." CBS offered an alternate strategy to allow for review of multiple versions of the same procedure with BGTD. Should the proposed strategy be acceptable to BGTD, CBS will move forward with the above mentioned RD revisions as part of the test case for this strategy.

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

2. **During registration at the Centre Clinic, the clinic assistant asked the donor the questions in the Registration Information box, “Have you ever attended a blood donor clinic in Quebec?” and “Have you ever given blood under a different name?” prior to printing the record of donation which was contrary to the training provided for SOP 01 704, Donor Registration, Version3.**

This observation was isolated to one employee during this clinic. This employee has not been involved in the training of other employees. This issue was addressed with the employee at the time of the audit on 2004-10-05 by the Assistant Manager, Clinic Operations. The employee involved was retrained to SOP 01 704 on 2004-11-02. In addition, this audit observation was presented at a Collections staff meeting held on 2004-10-29.

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

3. **At the October 4, 2004 Centre Clinic, vital signs were repeated after calibration of the IVAC 4200, however, the second readings for the pulse and temperature were not recorded on the record of donation (0555 6 371226). QIR 55-04-01863 was generated at the time of the inspection.**

This issue was addressed with the employee at the time of the audit on 2004-10-05 by the Assistant Manager, Clinic Operations. A meeting for Collections employees was held on 2004-10-29 to discuss the audit observation. At the meeting, Quality Systems presented an in-service to review the importance of accuracy and completeness of documentation. All staff will be required to read and sign for the minutes of this presentation by 2004-12-31.

Premises / Locaux – C.02.004

- 4. At the Centre clinic (1575 Carling Avenue) the outside door leading to the mini depot where critical supplies and product is stored was left open, providing direct access to the clinic.**

A memo was immediately issued to the Transport Drivers detailing the use of this door. As of 2004-10-12 all drivers had read and signed the memo to indicate they understood this deficiency. A cylinder has been installed that will automatically close the door. As well, an audible alarm will be connected to the door by 2005-01-31.

Manufacturing control / Contrôle de la fabrication – C.02.011

- 5. There was no system in place to ensure that active lookback files were monitored when the responsible employee was on leave.**

By 2004-10-15 all open files had been reviewed to ensure the required timelines were met. A process will be implemented by 2005-02-01 to monitor active Lookback files on a monthly basis to ensure timelines are met.

Equipment / Equipement – C.02.005

- 6. For the dose mapping results provided by the external service provider as a part of the annual preventative maintenance for the Gamacell 3000 S/N 232, there were no acceptable parameters defined by Canadian Blood Services (CBS) and there was no evidence that the dose mapping results were reviewed for acceptance by CBS.**

Centre response:

Effective immediately, the results from the Dose Mapping will be reviewed and signed off for acceptance by the Lab Manager/designate.

Head Office response:

CBS Purchasing has contacted the supplier, MDS Nordion and communicated the deficiencies identified on the Preventative Maintenance Worksheet. CBS is awaiting a formal response from the supplier.

Premises / Locaux – C.02.004

- 7. The Clinic Site Evaluation Checklist conducted June 22, 2004 for Centre Clinic K0001 (Lincoln Fields) did not clarify whether the criteria for sufficient electrical service was satisfactory or unsatisfactory and the criteria for sufficient electrical outlets was unsatisfactory, yet the clinic site evaluation was accepted by four departments.**

Documentation has been obtained to clarify the site suitability. Deficiencies identified in the site evaluation were corrected by 2004-07-07 prior to the opening of the clinic on 2004-07-12. Site Evaluations will be performed as per SOP 01 010, Evaluate clinic site. Employees performing site evaluations will be re-trained by 2004-12-01 to ensure a re-inspection is performed as required.

Manufacturing control / Contrôle de la fabrication – C.02.011

8. **During the review of Progesa Mobile Clinic Equipment Problem Log Sheets, Progesa mobile kit OTT MOB 3 for clinic date August 17, 2004 was signed off as being reviewed although the problem pertaining to improper shutdown of server was not resolved.**

The problem pertaining to the improper shut-down of the server had been resolved at the time of the incident. This observation addresses incomplete documentation by the employee reporting the problem and by the reviewer. A meeting for Collection employees was held on 2004-10-29 to discuss the audit observation. At the meeting, Quality Systems presented an in-service to review the importance of accuracy and completeness of documentation. All staff will be required to read and sign for the minutes of this presentation by 2004-12-31.

Manufacturing control / Contrôle de la fabrication – C.02.011

9. **The time frames for re-inspections of clinic sites were not clarified. For example, SOP 01 010, Evaluate Clinic Site, Version 5 states that all clinic sites should be re-inspected on a regular basis according to Centre schedule, however, a Centre schedule was not available.**

A schedule will be developed by 2004-12-01 using the time frames of 18-24 months for re-inspection of clinic sites.

Manufacturing control / Contrôle de la fabrication – C.02.011

10. **There was no system in place to ensure that due clinic site evaluations were completed.**

The Centre now has a Supervisor of Donor Services effective 2004-04-29, who will be responsible for ensuring that Site Evaluations are completed by the due date.

Manufacturing control / Contrôle de la fabrication – C.02.011

11. **During the review of Progesa Mobile Clinic Daily Log Sheets, some of the verification quantities at clinic setup (eg. Clinic date August 25, 2004, Progesa mobile kit OTT MOB 3) that showed a discrepancy with the quantity present in the Mobile shipping case did not have a comment for the discrepancy, contrary to SOP 01 701, Progesa Mobile Solution: Set-up and Shutdown, Version 2.**

Due to the unique environment of the Bloodmobile, a portion of the Progesa mobile kit equipment remains on the vehicle and therefore the discrepancy will always exist. An in-service for the Bloodmobile staff will be held prior to 2004-12-31. Details required to accurately document this discrepancy in the comments section of the Progesa Mobile Clinic Daily Log Sheets will be addressed.

Manufacturing control / Contrôle de la fabrication – C.02.011

- 12. There was no security procedure for the Centre.**

A security procedure for the Centre will be implemented by 2004-12-31.

Quality control department / Service du contrôle de la qualité – C.02.015

- 13. During the review of laboratory reports for the Advia 120 in the Quality Control laboratory, 2 of the hematology printouts were not initialed by the technologist performing the test (sample ID: PRE605206-7 and POST605206-7) yet the Quality Control Worksheet for the AS-3 Leukotrap – RC-PL Filter System dated June 15, 2004 was signed off as being reviewed.**

All RBC leukotrap worksheets since March 2004 (date from which the ADVIA 120 has been used to determine Hct) have been reviewed for completeness. No further issues were noted. The identification of the technologist performing the work was not compromised as it was documented on the AS-3 Leukotrap-RC-PL Filter System Worksheet. The haematology printouts noted above have been reviewed and initialed by the technologist who performed the test. SOP 08 229 – Percent Red Blood Cell Recovery Determination for Red Blood Cells, Leukocytes Reduced by Filtration, was implemented on 2004-10-01, which contains instructions on reviewing the documentation for completeness and accuracy of calculations. All Quality Control staff have been trained to this SOP.

Records / Dossiers – C.02.020

- 14. For Centre clinic K0001 (Lincoln Fields), the inspection date in the Event Scheduling System (ESS) which is used to project the next inspection date for clinic site evaluations was entered as 2004-07-22 rather than 2004-06-22.**

This was a clerical error and effective immediately, the input of re-inspection dates into Event Scheduling System will be verified by a second employee.

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