

2005-02-24
CBS Control #3321
Ref #AUD05-034 HC125
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 Toronto Centre
17-26 January 2005

The following are the actions undertaken by the Toronto 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. At the mobile clinic T0133, Markville Secondary School on January 20, 2005, a donor in the privacy (voting) booth was filling out questions 1 through 13 on the record of donation (RD) when another individual known to the donor went to the booth and started a conversation. After being informed of this incident, the nurse ensured that the donor obtained privacy to complete the RD.**

The clinic site map for Markville Secondary School will be reviewed by 2005-02-28 to see if an alternate location for the privacy (voting) booth can be found. Written communication addressing privacy issues will be provided to all Toronto clinic staff by 2005-03-11.

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

- 2. At clinic T0006, Peterborough fixed site, on January 21, 2005, three occurrences were observed of a nurse not erasing the previous donor's vital parameters displayed on the IVAC 4200 prior to starting the interview of the next donor.**

There are no work instructions in current SOPs requiring that the IVAC 4200 display screen be cleared between donors. However, Collections work instructions 01 057, Check Vital Signs (Whole Blood / Autologous) and SOP 01 062, Check Vital Signs (Apheresis) will be revised to instruct personnel to clear the IVAC 4200 display panel prior to the Donor leaving the screening booth. These instructions will be included in the RD Error Project submission, targeted for issue to Health Canada in May 2005. Further, all Registered Nurses at Toronto Centre will read and sign a memo from the Assistant Collections Manager that indicates that staff are to clear the previous donors Vital Signs immediately after documenting results. The target date for completion is 2005-03-11.

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

3. **The record of donation 0553 1 321677 for clinic T0001, Toronto Permanent Centre, on December 21, 2004, question #5b (If female, in the last 6 months have you been pregnant?) was not answered yet the donor was accepted. QIR 2005-P1-012 was initiated during the inspection.**

Resolved during inspection.

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

4. **For an autologous donor having cancer as indicated on the Physician's Request for Consideration for Autologous Transfusion form, the corresponding deferral code (0900) was not entered into PROGESA at the time of the first autologous donation (May 04, 2004). A Donor/Donation Inquiry was obtained for May 28, 2004 but did not list the deferral code. The deferral code was entered into PROGESA on August 9, 2004. QIR 2005CO-002 was initiated during the inspection.**

Resolved during inspection.

Manufacturing control / Contrôle de la fabrication – C.02.011

5. **In the Blood Product Management department, the bin located directly beside the irradiator was being used for temporary storage of rejected/expired units but was not labelled as such. A QIR was initiated during the Inspection.**

Quality Improvement Report 2005-BP-017 was initiated on 2005-01-20 to capture the incident and corrective action. Although temporary storage of rejected/expired units in labelled bins in this area is an acceptable practice, the bin was immediately removed and a location for the temporary storage of rejected/expired units was labelled in the quarantine fridge. A meeting was held with Toronto Centre lab staff on 2005-01-21 to review the incident and to remind them of the Toronto Centre requirement to store rejected/expired product in this location.

Manufacturing control / Contrôle de la fabrication – C.02.011

6. **During the review of PROGESA Mobile Clinic Daily Log Sheets, the following were noted:**
- a) **There was no evidence to indicate that for PROGESA Mobile Kit TORMOB4, Clinic T0360 (Clinic Date: December 30, 2004) the verification quantity of the 3.5 prelabelled diskettes at clinic shutdown was not completed yet the sheet was signed as being reviewed.**
 - b) **For PROGESA Mobile Kit TORMOB1, Clinic T0091 (Clinic Date: December 3, 2004), the comments section indicated that there was one diskette found in disk drive of laptop #4 at the time of clinic set up yet there was no evidence of follow up.**

a) Quality Improvement Report 2005-QA-057 was initiated on 2005-01-17 to capture the incident. Corrective action will involve retraining staff who perform the review to

follow up when discrepancies, omissions and other errors are noted. Expected date of completion is 2005-03-15.

- b) *Quality Improvement Report 2005-CS-023 was initiated on 2005-01-20 to capture the incident. Corrective action includes training all personnel including Transport, Clinic Operations, and IT on the process when a disk is found in a laptop. Expected date of completion is 2005-03-31.*

Equipment / Equipement – C.02.005

7. **The following were observed at the mobile clinic T0133 Markville Secondary School on January 20, 2005 with regards to the confirmation of the mobile solution being set up properly:**

- a) **The confirmation for the registration booth with laptop #4 was not performed, contrary to Step 5 of SOP 01 701, PROGESA Mobile Solution: Set-up and Shutdown, Version 2 (2003-01-30).**
- b) **The staff were not clear as to who was to perform the confirmation.**
- c) **There was no mechanism in place to demonstrate that the confirmation was performed before use at the clinic.**
- a) *Quality Improvement Report 2005-M0B6-005 was initiated at the time of the observation on 2005-01-20. The verification steps as noted in step 5 of SOP 01 701 were performed and no problems were noted.*
- b) *Presently at Toronto Centre, set up of laptops, printers and scanners for mobile clinics is performed by Logistics staff, as noted in COP:0030-05, Clinic Set-Up and Take-Down Registration/Technician. Confirmation that the barcode scanner and printer are set up as required in step 5 of SOP 01 701, PROGESA Mobile Solution: Set-up and Shutdown, is then performed by Collections staff. However, in light of this observation, an assessment of these practices will be performed. An update in this respect will be provided no later than 2005-04-30.*
- c) *An assessment of the process related to connectivity checks has been initiated. An update in this respect will be provided no later than 2005-04-30.*

Premises / Locaux – C.02.004

8. **The following were noted during the review of Site Evaluation Checklists:**
- a) **For clinic T0133, Markville Secondary School, (Clinic Date: January 20, 2005), it was indicated there was not adequate lighting and 5 lamps were required. However, this was not entered as additional supplies into the Event Scheduling System report which is used to alert staff involved in the set-up of mobile clinics of special instructions.**
- b) **Contrary to COP DS:0007-02, Clinic Site Evaluation Procedure (2003-06-02), some site evaluations were not being reviewed within two whole business days. Examples include site evaluations for the following clinics: T0133, Markville Secondary School (Clinic Date: January 20, 2005); T0006, Peterborough Fixed Site (Clinic Date: February 16, 2004); T0123, Mclean Community Centre (Clinic Date: May 1, 2004) and T0124, MDS Inc. (Clinic Date: June 22, 2004).**

The required lights were present in the booths at the Markville Secondary School clinic on January 20, 2005 thereby ensuring proper illumination for the health assessment process.

As a result of the annual review of the clinic site evaluation process, Change Management form #4243 was issued on 2004-12-07 to modify COP DS:0007-02. This Change Management Form was updated to;

- a) Include the steps involved in entering information into the Event Scheduling System*
- b) Increase the length of time allowed for review of the Clinic Site Evaluation form by each department.*

The expected date of completion for these changes is 2005-05-01.

Manufacturing control / Contrôle de la fabrication – C.02.011

- 9. In the warehouse on Mowat Avenue the most recent cycle count for collection and lab supplies was conducted in September 2004. The Cycle Count Schedule in COP WH:0007-05, Storage of Supplies in the Warehouse (2002-06-28) indicates that cycle counts for collection and lab supplies are to be performed monthly.**

Quality Improvement Report 2005-WK-009 was initiated on 2005-02-08 to investigate the issue noted. The cycle count is an extra step performed to ensure accuracy of the computerized inventory records. As identified during the inspection, cycle counts for supplies such as collection sets and labels had been completed as required. Counts of the supplies specified in the observation were resumed on 2005-01-31 as per the schedule outlined in COP WH:0007-05. A review of this COP and the schedule for cycle counts was performed during the staff meeting held on 2005-02-04.

Manufacturing control / Contrôle de la fabrication – C.02.011

- 10. In the warehouse on Mowat Avenue, some paper records did not appear to be inventory controlled. For example, there was no tracking mechanism for a box of donor files labelled "apheresis inactives UVW 2004-03-05, 32".**

Reorganization of records is currently being performed at the Mowat facility by the Warehouse staff. A listing of records will then be available as an Excel Spreadsheet. The target date for completion is 2005-03-31. Additionally, Change Management form #4489 was initiated on 2005-02-08, to create local procedures for records management. The expected completion date of these procedures is 2005-05-01.

Equipment / Equipement – C.02.005

- 11. In the Blood Product Management department, the Generic Refrigerator Temperature log for the quarantine refrigerator (S/N: 60338) was not completed for the second check on January 19, 2005. A QIR was initiated during the inspection.**

The chart on Refrigerator S/N #60338 was reviewed and the temperature was found to be within acceptable range for the entire charting period (this is a weekly chart). There were no temperature excursions outside of the required operating temperatures. A meeting was held on 2005-01-21 with Blood Product Management staff to remind them of the importance of ensuring that readings are taken as scheduled and the requirement to document missed readings as soon as they are noticed (i.e. at the next scheduled reading). Quality Improvement Report 2005-BP-018 was initiated 2005-01-20, to capture the incident and corrective action.

Equipment / Equipement – C.02.005

- 12. There was no evidence to indicate that the PRISM Retest Server Maintenance and Data Management forms for November 2004 and December 2004 were reviewed and signed by the System Owner. Signed copies were provided during the inspection.**

Resolved during inspection.

Equipment / Equipement – C.02.005

- 13. Some inconsistencies were observed on the Routine Maintenance Inspection sections of the Preventative Maintenance (PM) Program form for the quarterly PM:**
- a) For the Helmer platelet Incubator (S/N: 101789), the Defrost Cycle Timing was checked as "Acceptable" on August 16, 2004 but was checked as N/A on November 15, 2004.**
 - b) For the Kelvinator Freezer (S/N: 614521), the Door Ajar Switch was checked as N/A on August 16, 2004 and was checked as "Acceptable" on November 15, 2004. A QIR was initiated during the inspection.**

A meeting was held on 2005-01-20 with the service provider to investigate the reason for the inconsistencies. The service provider indicated that this was an error. Re-training on the review of service records was provided for all Charge and Senior staff on 2005-01-21. The incident and corrective action was captured in Quality Improvement Report 2005-CP-033, initiated on 2005-01-18.

Manufacturing control / Contrôle de la fabrication – C.02.011

- 14. The Computer Account De-activation Form for a departed employee did not indicate the confirmation of closure of computer network accounts even though the heat ticket 00257349 indicated that the accounts had been removed.**

Quality Improvement Report 2005-AD-026 was initiated on 2005-01-21, in response to this observation. The form was updated and the staff member in the Human Resources department was retrained on SOP 09 625, Computer Account De-activation Process, on 2005-02-08.

If you require any clarification, please do not hesitate to contact the undersigned. Please refer to the above control number in any correspondence.

Sincerely,

Dr. Christian Choquet
Vice President, Quality Assurance
and Regulatory Affairs