

2005-03-17  
CBS Control #3365  
Ref #AUD05-057 HC126  
HC File # C1892-100390

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

Dear Mr. Shelley:

**Re: Responses to the Health Canada Audit of BC & Yukon Centre**  
**14-18 February 2005**

The following are the actions undertaken by the BC & Yukon 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 the review of Record of Donations (RD) the following deficiencies were noted:**
  - a) **for donation number 2-639053 of Walnut Grove clinic dated 2005-01-08, question 1(a), “Are you feeling well today” was marked yes but the collections staff comments stated “1(a) no” with no further explanation. Both recall (10-05-00220) and QIR (10-05-30142) were initiated on 2005-02-15;**
  - b) **for donation number 6-639135 of Walnut Grove clinic dated 2005-01-08, the donor had marked no to question 6(a) “In the past 12 months have you had a tattoo, ear piercing, skin piercing, acupuncture, electrolysis, graft, injury from a needle or come in contact with someone else’s blood?”, but the collection staff comments state “6(a) yes” with no further explanation. QIR 10-05-30144 and Recall 10-05-00224 were initiated on 2005-02-16;**
  - c) **for donation number 6-201177 of Victoria clinic dated 2004-11-11, the donor changed his response to question 1(b), “Do you have a cold, flu, sore throat, fever, infection or allergy problem today?”, from yes to no and dated but did not initial the change. A QIR (10-05-30143) was initiated on 2005-02-16;**
  - d) **donation numbers 3-220839 and 4-220825 at Centre Clinic dated 2005-01-04 had the same initials in the “Spec Labelling Inits” and “Verification Inits” boxes. QIR (10-05-30148 and 10-05-30149) were initiated on 2005-02-17; and**
  - e) **for donation numbers 7-220817 and 1-220876 at Centre Clinic dated 2005-01-04, the donors signed 2004-01-04 in the consent box instead of 2005-01-04. QIR (10-05-30146 and 10-05-30147) were initiated on 2005-02-17.**
  
- a) *Both Recall (10-05-00220) and QIR (10-05-30142), which included review with staff involved, were initiated during the inspection. In addition, a read & sign memo was distributed to all Registered Nurses on 2005-03-14.*

- b) *Both Recall (10-05-00224) and QIR (10-05-30144), which included review with staff involved, were initiated during the inspection. In addition, a read & sign memo was distributed to all Registered Nurses on 2005-03-14.*
- c) *QIR (10-05-30143), which included review with staff involved, was initiated during the inspection. In addition, a read & sign memo was distributed to relevant staff on 2005-03-14.*
- d) *QIRs (10-05-30148 & 10-05-30149), which included review with staff involved, were initiated during the inspection. In addition, a read & sign memo was distributed to relevant staff on 2005-03-14.*
- e) *QIRs (10-05-30146 & 10-05-30147), which included review with staff involved, were initiated during the inspection. In addition, a read & sign memo was distributed to relevant staff on 2005-03-14.*

*An interdivisional working group was struck to implement the Six Sigma recommendations for the Record of Donation with the Reduce RD Errors Project. Phase 1 of the "Reduce RD Errors Project" team has completed a User Acceptance of the proposed changes to the RD and its supporting work instructions for the Phase 1 revisions. CBS is targeting submission of the Phase 1 changes to Health Canada on, or about, 2005-03-29.*

*Following this, the project team will prepare for pilot of the revisions captured in the Phase 1 submission. As well, the team will begin Phase 2, which includes assessment of remaining issues identified during the original data collection. Phase 2 will target omissions on the Health Interview portion of the RD, standardization of documented responses to Health Interview questions and a review of clinic process flow versus flow of documentation requirements on the RD.*

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

- 2. **During the review of donor's plateletpheresis charts, donor number 3331619 signed and completed the annual donor consent form on 2003-08-05 and 2004-08-26 yet this form should have been completed during her donation of 2004-08-12. A QIR (10-05-46010) was initiated on 2005-02-17.**

*QIR (10-05-46010), which included review with staff involved, was initiated during the inspection. In addition, re-training for the Apheresis Registered Nurses on SOP 01 053 "Obtain Informed Consent Plateletpheresis Programme" and SOP 01 061 "Maintain Apheresis Donor File" will be completed by 2005-05-31.*

#### **Premises / Locaux – C.02.004**

- 3. **The quarantine cage in Warehouse B was inadequately maintained as per the following conditions:**
  - a) **insufficient storage area to quarantine all incoming critical supplies**
  - b) **poor light conditions further aggravated by having the only light with a burnt out light bulb. The light bulb was replaced; and,**
  - c) **exposure to an electric device box hanging from the ceiling by its wire. The device was removed.**

- a) *Critical supplies will be relocated into the new warehouse area after an air handling unit is installed. Warehouse "B" will be converted into a quarantine storage area. This will provide adequate space for storing quarantined critical supplies. To be completed by 2005-04-30.*
- b) *Resolved During Inspection. The burnt out light bulb in the quarantine area was replaced. As per response to 3a), the new quarantine storage area will provide better lighting.*
- c) *Resolved During Inspection. The indicated device was an unconnected door buzzer which was removed during the inspection.*

#### **Premises / Locaux – C.02.004**

- 4. The Release Warehouse A had bare water pipe running above critical supplies and contained 2 skids of quarantined plateletpheresis sets.**

*Resolved during inspection.*

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

- 5. The following deviations from COP 5003 were noted:**
- a) **The Quarantine Logs (FVO5024) in the centre warehouse binder were not reviewed by department manager/designate during the period of 2003-06-30 through 2005-02-14. A QIR (10-05-42005) was initiated on 2005-02-17;**
  - b) **The Quarantine Log (form FV05024) for centre warehouse dated 2004-09-09 through 2004-09-24 indicated 4 items were still in quarantine although it was verbally stated that these products were released. QS was able to verify through other documentation that all four of these products had been released by QS. A QIR (10-05-40059) initiated on 2005-02-17;**
  - c) **On 2005-02-15 the quarantine log was not included in the request for release package which was submitted to QS. The labels were issued and applied but the release labelled products had to be re-quarantined due to the incomplete quarantine log.**
- a) *Review of all Quarantine Logs (FV05024) referenced in the observations and retraining of relevant staff on COP 5003 "Quarantine of Non-Conforming and Critical Supplies" will be completed by 2005-04-30.*
  - b) *Retraining of relevant staff on COP 5003 "Quarantine of Non-Conforming and Critical Supplies" will be completed by 2005-04-30.*
  - c) *Retraining of relevant staff on COP 5003 "Quarantine of Non-Conforming and Critical Supplies" will be completed by 2005-04-30.*

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

- 6. Contrary to SOP 01 043 which states that the nurse should accept or defer the donor, then ask the donor to read and sign the RD followed by the nurse signing the RD, these two deviations were noted at the centre clinic during donor interviews. On 2005-02-14 during a donor interview for plateletpheresis the donor signed and dated the RD before the nurse accepted the donor. The nurse then checked the accept box immediately prior to signing the RN signature. On 2005-02-15 during a whole blood donor interview at centre clinic the RN accepted and signed the RD before the donor was asked to read the bottom of the form and sign her name.**

*A read and sign memo identifying these issues was distributed to all Registered Nurses on 2005-03-14.*

**Premises / Locaux – C.02.004**

7. **The blinds on donor screening room #2 at centre clinic were broken and thus could not be completely closed and therefore did not adequately provide an area to maintain confidentiality during donor suitability assessment or the confidential unit exclusion process.**

*Resolved during inspection.*

**Premises / Locaux – C.02.004**

8. **There was no reconciliation between the list of current employees on file with Human Resources and the current Facilities ID and Security Access Requisition Forms (FV05032). Furthermore one staff member's Facilities ID and Security Access Request Form was not completed in that the employee's signature and date were missing and no access level was checked. COP 5804 does not clearly indicate who is responsible for ensuring the completion of this form.**

*COP 5804 will be revised to include responsibility for completion of FV05032 Facilities ID and Security Access Requisition Forms. In addition, instructions for distribution of departmental lists, confirmation of employee status and reconciliation will also be included. To be completed by 2005-05-31.*

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

9. **When filling a faxed hospital order, Distribution staff routinely note down the targeted time for completion of an order on the left top corner of the Blood and Blood Product Requisition form (FVO3350); this activity was not described in any of the written SOP or COP.**

*COP 3408, "Receipt and Approval of Requests for Blood Components and Products from Hospitals" will be revised to include a work instruction for the documenting of the targeted completion time for an order on form FV03350, Blood and Blood Product Requisition. To be completed by 2005-04-04.*

**Equipment / Equipement – C.02.005**

10. **There was no active list of Heat Tickets generated by Centre staff in order to track and trend incidents pertaining to Progesa and its accessory equipment occurring at the Centre.**

*Tracking and trending of HEAT Tickets is performed on a monthly basis by Head Office Quality Assurance (QA-IT) staff. The reports are published to a public folder where they are available to all Centre Quality Assurance Managers. QA-IT reviews the selected HEAT tickets for compliance to the established problem management procedures and identifies areas requiring further investigation to IT. The HEAT system is also used for alerting CBS management of high impact problems which may be reportable to Health Canada through CBS Regulatory Affairs.*

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

11. COP 6113 (Platelet Agitator Maintenance), states "maintenance is to be performed annually on the platelet agitator" yet the preventative maintenance was performed every 6 months. Furthermore the Platelet Agitator Preventative Maintenance Form (FV06026) was completed on 2004-02-27 but the supervisor review did not occur until 2004-08-27, the date of the next scheduled preventative maintenance. A QIR (10-05-28013) was initiated on 2005-02-17.

*The temperature check on this equipment was required every 6 months. The Biomed performed the Preventative Maintenance of the agitators at the same time as performing the temperature check. The Preventative Maintenance will now be performed every 12 months as per COP 6113.*

*Upon further investigation, it is suspected that the Supervisor documented the wrong date on FV06026 Platelet Agitator Preventative Maintenance Form. A read & sign memo addressing this error will be distributed to the Component Production Supervisors by 2005-03-31.*

**Premises / Locaux – C.02.004**

12. The south entrance to the main floor of the building was not pest controlled.

*Resolved during inspection.*

**Records / Dossiers – C.02.020**

13. During document review, the following GMP deficiencies were noted:
- a) The "cleaning" column on the Installation and Priming of Platelet Disposables form (F0V0009) was incomplete for donation number 0-221078 dated 2005-01-20 on the CobeSpectra (ECN#4491);
  - b) during review of training records it was noted that the Monthly Sign Off Sheet, form FV01901 was missing an employee's initials for Memos 471 Platelet Apheresis, 472 Hct Study and 473 Units with Malaria Codes dated 2004-02-19. Another FV01901 form pertaining to training on "Donor Sample Accessioning" had two employees marked "off" and dated 2003-12-02, thus unable to determine if the employees were trained on this document. A QIR (10-05-28012) was initiated on 2005-02-17;
  - c) the IVAC form "Vital Signs Monitor Preventative Maintenance Form" (FV06027), dated 2004-01-06 was left blank with no cross-off and marked "N/A". A RIR (10-05-55002) was initiated on 2005-02-17;
  - d) the signature was missing on the Progesa Mobile Clinic Daily Log Sheet for the "Verify Quantity at Clinic Shutdown" dated 2005-02-07; and
  - e) contrary to COP 2553, Verification of Interim Storage Units, the temperature charts of the REES refrigerator (ECN#3509) at Prince George clinic site for the week of 2004-11-16 was not signed by the manager. Another chart for the week of 2004-03-09 was not signed and dated by the manager.
- a) QIR (10-05-46014), which included review with staff involved, was initiated during the inspection.
  - b) QIR (10-05-28012), which included review with staff involved, was initiated during the inspection. Staff will re-read the documents indicated in the observation by 2005-03-31.

- c) COP 6110, “Centre Equipment Processing for In House Preventative Maintenance/Calibration” was revised and implemented on 2005-02-14. The updated version of COP 6110 addresses the documentation of N/A. A read & sign of this COP has been completed by Biomed staff.
- d) QIR (10-05-44035) was initiated for follow-up with Transport for the error in documentation and, also with DRBS, as this issue was not captured during Supervisory Review. The error will be reviewed with staff involved.
- e) QIRs (10-05-37012 & 10-05-37013), which included review with staff involved, were initiated during the inspection.

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

- 14. The temperature monitoring chart (FV03313) for the walk-in refrigerator (ECN #409) located in the manufacturing laboratory indicated that the refrigerator was out of service yet there was no “Do Not Use” sign posted.**

*Resolved during inspection.*

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

- 15. QS department has not signed off for the acceptance of the responses to the internal audit reports for the Distribution, Logistic, Production and Kelowna Clinic Operation departments. A QIR (10-05-40063) was initiated on 2005-02-18.**

*The requirement for Quality Systems to sign for acceptance of responses on the audit template will be removed. COP 1410 “Quality Systems – Internal Audits” will be revised to include instruction for the acceptance of responses via memo or e-mail. To be completed by 2005-05-31.*

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