



CANADIAN BLOOD SERVICES  
SOCIÉTÉ CANADIENNE DU SANG

2005-05-09  
CBS Control #3365  
Ref # AUD05-112 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: Follow-up to the Health Canada Audit of BC & Yukon Centre**  
**14 – 18 February 2005**

The following is further to Health Canada's letter of 13 April 2005 requesting the additional information on the Health Canada audit of BC & Yukon Centre.

**Observation #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. QIRs (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. QIRs (10-05-30146 and 10-05-30147) were initiated on 2005-02-17.

**CBS Response dated 17 March 2005**

- 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.

#### **Health Canada Follow up letter dated 13 April 2005**

**Regarding the RD errors in Observation #1, we would like to remind you that the Reduce RD Errors Project will continue to be monitored by Health Canada.**

#### **CBS Response**

Phase 1 of the Reduce RD Errors Project was submitted to the Biologics and Genetic Therapies Directorate on April 11, 2005.

#### **Observation #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.**

#### **CBS Response dated 17 March 2005**

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.

#### **Health Canada Follow up letter dated 13 April 2005**

**For Observation #10, please clarify whether the monthly report of tracking and trending of heat tickets generated by Head Office QA-IT is (a) centre specific, (b) reviewed on a monthly basis by each centre, and (c) containing information pertained to any outstanding heat tickets such that the Centre QA manager can address any local problems for appropriate follow-up in a timely manner.**

CBS Response

HEAT tickets represent all computer problems reported to the IT National Service Desk located at Head Office Ottawa. These problems range from a single user issue (e.g. a forgotten password) to complex multicentre system service disruptions.

- a) The monthly report generated by Head Office QA-IT is divided into two categories, Software and Infrastructure, and not specifically sorted by centre or location. The report does however include specific information regarding the originating centre, the date and time reported, and details of the failure and actions required to correct the problem.
- b) The Coordinators of Donor Records and Business Systems located at each Centre review open HEAT tickets to manage their daily work assignments which include the correction of problems with local equipment such as printers and scanners.
- c) As described, these problems do not necessarily represent non-conformances, therefore the management or review of these tickets by Centre QA staff is not performed. Centre QA would only be involved in the reporting of the impact of a major system outage (non-conformance) to Regulatory Affairs. All decisions on the suitability and prioritization of enhancements and system fixes for PROGESA are made by the business owners at Head Office.

If you require further information please do not hesitate to contact the undersigned. Please refer to the above control number and audit reference number in any correspondence.

Sincerely,



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