



CANADIAN BLOOD SERVICES  
SOCIÉTÉ CANADIENNE DU SANG

2005-04-29  
CBS Control #3321  
Ref # AUD05-080 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: Follow-up to the Health Canada Audit of Toronto Centre**  
**17-26 January 2005**

The following is further to Health Canada's letter of 15 March 2005 requesting the additional information on the Health Canada's audit of Toronto Centre.

**Observation #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.**

*CBS Response dated 24 February 2005*

*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.*

**Health Canada Follow up letter dated 15 March 2005**

**The CBS response indicated "...Although temporary storage of rejected/expired units in labelled bins in this area is an acceptable practice...". Note that this observation dealt with temporary storage of rejected/expired units in an unlabelled bin.**

*CBS Response*

*This is correct. Temporary storage of rejected/expired components is an acceptable practice, and temporary storage containers must be labelled appropriately as Rejected/Expired Components. Toronto Centre however, has opted not to use temporary storage containers, rather these units are placed in the quarantine fridge in a dedicated location. Should there be a need to employ the use of temporary containers in the future, they will be labelled appropriately as Rejected/Expired Components.*

**Observation #6b**

**During the review of PROGESA Mobile Clinic Daily Log Sheets, the following were noted:**  
**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.**

CBS Response dated 24 February 2005

- 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.*

Health Canada Follow up letter dated 15 March 2005

The CBS response indicated that "...Corrective action includes training...on the process when a disk is found in a laptop...". Please provide details on this process no later than 2005-04-30.

CBS Response

*In the event a disk is found in a laptop, the disk will be forwarded to the IT department where diskettes are retained. Furthermore, a QIR will be initiated to investigate and determine the root cause and corrective actions to prevent future recurrence.*

*In order to address this particular issue, Clinic staff were reminded, during staff meetings, to inform the Clinic Supervisor and initiate a QIR if a diskette is found in a laptop. Transportation Department staff were also informed during a staff meeting to initiate a QIR when a diskette is found in a laptop. As well, the IT staff involved with refreshing of laptops were reminded to initiate a QIR if a diskette is found in a laptop.*

Observation #7b and 7c

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:

- 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.**

CBS Response dated 24 February 2005

- 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.*

Health Canada Follow up letter dated 15 March 2005

We acknowledge that an update will be provided no later than 2005-04-30.

CBS Response

- b) *As of April 11, 2005 all Logistics staff have been trained to perform the mobile solution confirmation. Logistics staff will now confirm 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. It has been communicated to Collections staff that Logistics will now perform the mobile solution confirmation.*

- c) *The process related to connectivity checks as outlined in SOP 01 701 is still under assessment. CBS respectfully requests an extension until May 31, 2005 in order to provide full details of the final assessment and outcome.*

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