



CANADIAN BLOOD SERVICES
SOCIÉTÉ CANADIENNE DU SANG

2005-01-25
CBS Control #3191
Ref #AUD05-020 HC122
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 Hamilton Centre
25-29 October 2004

The following is further to Health Canada's letter of 22 December 2004 requesting additional information on the Health Canada's audit of Hamilton Centre.

Observation #2a)

The following deficiencies were noted regarding the handling practices for quarantined components;

- a) There were no documented specified timeframes for the application of the appropriate code(s) in Progesa in order to place components into electronic quarantine.**

CBS response dated 09 December 2004

- a) *Electronic quarantine of components takes effect at the time a Lookback Event is created. Guidelines for the creation of Lookback Events and the resulting electronic quarantine of components in inventory are captured in processes/procedures for the following:*
- *Non-Conformances - control of components whose suitability has been called into question are acted on as part of the immediate actions taken to address the non-conformance, including creation of a Lookback Event OR applying a manual quarantine in PROGESA, to electronically quarantine the components;*
 - *Positive Transmissible Disease (TD) test results – upon entry of positive TD test results, a Lookback Event is automatically created and therefore electronic quarantine is placed on any components in inventory from the donor;*
 - *Recalls (any retrieval not related to TD test results) - due to the variability associated with Recalls (for example, a single donor with one donation versus many donors and/or many donations), the time required to assess the information received and create a Lookback Event varies. Creation of a Lookback Event to place the associated components into electronic quarantine occurs as described in SOP 01 764, Information Received Post Donation.*

Health Canada Follow-up letter dated 22 December 2004

The various processes/procedures identified for the electronic quarantine of components were reviewed at the time of the inspection. However, these processes/procedures do NOT indicate specified time frames for the application of the code(s) to place components into electronic quarantine, especially in circumstances where multiple departments or areas of responsibility exist. In summary, the response provided did not adequately address the observation. Additional information is required.

CBS reiterates that for product retrievals arising from positive Transmissible Disease test results, the creation of a Lookback Event occurs immediately with transfer of results from LDMS to PROGESA. For non-Transmissible Disease related product retrievals (referred to as Recalls), CBS is aware that we do not provide specific timeframes for initiation of Lookback Events. The reason for this is the variable scope associated with Recall events. Once the extent of a Recall is determined it is expected that the Lookback Event would be created without delay. To ensure users understand that Lookback Events associated with Recalls be initiated as soon as is operationally feasible, i.e. once the scope of the Recall is determined, Change Request # 04383 has been initiated to request SOP 08 772, Managing Recalls with PROGESA, be updated to specify this requirement.

Observation #2c)

- c) **There was no mechanism for documenting the physical location (eg. movement of a component from one area to another) of a rejected component or other component that may require temporary quarantine.**

CBS response dated 09 December 2004

- c) *It should be noted that with PROGESA there is no status of temporary quarantine. When a component is placed into quarantine in PROGESA, the quarantine status remains in effect and can only be updated through user intervention in PROGESA to either release or reject the component. It should also be noted that components cannot be distributed to a transfusion facility once an electronic quarantine has been applied to the component, or once the component has been rejected or has expired. With regards to documenting the physical location of these components to track their location, directive D2004-026, Review Status of Rejected/Expired Components, which was implemented on November 22, 2004, requires that sites generate a rejected and expired component report a minimum of once per week. Every component listed on either of these reports must be accounted for.*

Health Canada Follow-up letter dated 22 December 2004

Health Canada is aware that PROGESA does not have the option of a temporary quarantine status for components. There was no designated/restricted area specific for products placed under temporary quarantine or a standardized process that is followed for when this occurs. Further, these situations are not documented, electronically or manually. The response only addressed situations where the components are rejected/expired. In summary, the response provided did not adequately address the observation. Additional information is required.

The quarantine fridge in each Centre is the designated/restricted area for all quarantine products. It should be clarified that the incident observed during the inspection involved a

released unit of RBCs, the Donation Number Label of which could not be scanned during issue to a hospital. The staff member involved handled the situation appropriately by physically placing the unit into the quarantine cage. An electronic quarantine was not applied because the incident was dealt with immediately. A non-conformance report was initiated to document this event.

There is a standardized process to follow in the event that the suitability of a component in released inventory is called into question. Documentation identifying components requiring manual quarantine, which would include a non-conformance, would prompt the steps outlined in SOP 05 717, "Manual Quarantine". This SOP provides instruction on how to place a component into electronic quarantine as well as the physical segregation of the component in temperature controlled storage. This SOP also provides instructions to document the quarantine and segregation of components.

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,



Christian Choquet, Ph.D.
Vice President, Quality Assurance
and Regulatory Affairs