

2017-10-24
CBS Control #: CBS6104
HPFB File #: C1892-100390
REF: H-1718-PET

Ms. Anita Mahadeo
Compliance Specialist
Regulatory Operations and Regions Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Ms. Mahadeo:

**Re: Responses to Health Canada Inspection of Licensed Activities at Peterborough Fixed Site
2017-09-13 and 2017-09-14**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-10-06.

Section 117 - Records

1. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**
 - a) **In ePROGESA, the data in the “Summary” section of the Drive Setup Module, for clinics held on June 23, 2017 and May 17, 2017 at clinic T0006, was not accurate. For example:**
 - **For clinic date June 23, 2017, the “# of Donors Presenting” was 44, yet 43 donors had attended based on a manual count of donors listed on the Clinic Attendance List. In addition, the “# of Donations Drawn” was “2”, and the “# of Donations Not Drawn” was “42”, which is not accurate.**
 - **For clinic date May 17, 2017, the “# of Donors Presenting” was 34, yet 27 donors had attended based on a manual count of donors listed on the Clinic Attendance List. In addition, the “# of Donations Drawn” was “-2”, and the “# of Donations Not Drawn” was “36”, which is not accurate.**

The eProgesa menu option to select the Summary Screen in the Drive Setup Module observed during the Health Canada inspection, including the information presented on the screen, is not used by Canadian Blood Services.

This menu option is not referenced in any existing Canadian Blood Services work instruction, nor is this information part of any Canadian Blood Services electronic record. Its use has not been validated as this is not an eProgesa functions used to support our operations. There is also no option in eProgesa to inactivate the Summary Screen.

As eProgesa is a commercial off the shelf (COTS) system rather than a custom-built application

solely for Canadian Blood Services, there are menu items, reports, screens, features, and functionality that are not used by Canadian Blood Services. Canadian Blood Services has only validated functions and configurations used to support its own operations.

Canadian Blood Services does not have any plans to use the eProgesa Summary Screen nor the information presented when this menu option is selected. As such no corrective actions are deemed necessary.

b) For a Digital Thermometer R9012, the Model was not accurately documented in the RAM system. Informer 1 was recorded instead of Informer 2. During the inspection, the electronic record was corrected.

The error was corrected in RAM on 2017-09-13. A memo will be sent by 2017-11-15 to all staff and supervisors involved in RAM data entry and review to ensure accurate information is entered and reviewed in RAM at all times.

c) Section B on the Independent Chart Recorder Maintenance Inspection for R2293 was not fully completed for the maintenance conducted on April 12, 2017. “Replace power backup batteries” and “Check applicable equipment type” fields were not completed in Section B.

This model of chart recorder is actually not equipped with a built-in back up battery. It is plugged into a separate UPS device. The appropriate corrections were made to the maintenance record and were uploaded into RAM on 2017-10-20.

A memo will be sent by 2017-11-15 to all Field Service Representatives/ Supervisors who perform Preventative Maintenance (PM) or review PM records to ensure accurate and complete documentation of the PM form and/ or data entry into RAM.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affairs
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch