



2017-08-01  
CBS Control #: CBS6075  
HPFB File #: C1892-100390  
REF: H-1718-SUD

Mr. Richard Kirchner  
Regulatory Compliance & Enforcement Specialist  
Regulatory Operations and Regions Branch  
Health Canada  
180 Queen Street West, 10th Floor  
Toronto, ON M5V 3L7

Dear Mr. Kirchner:

**Re: Responses to Health Canada Inspection of Licensed Activities at Sudbury  
2017-06-20 and 2017-06-21**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-07-19.

**Section 95 -Operating Procedures**

1. **Some operating procedures were not always followed. For example:**  
During the review of blood donations from St. Dominique's Hall, Timmins, ON (Y0028) on 19/06/2017, there was no evidence that the height and weight were requested from two first time donors (donor ID 6088985 and donor ID 6088998), who were less than 23 years of age, as this information was not entered into their donor record. This was contrary to SOP 01 144 "Screen Donor" V. 3, effective 2016-07-04.

*All Clinic Services Managers were made aware of this observation during the national management call on 2017-07-24. Further, this will also be discussed with all sites during the national Trainer/Supervisor call, on 2017-08-17 and they will be reminded to follow the approved process for assessments of first time donors under the age of 23.*

**Section 117 - Records**

2. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example:**  
There was insufficient information to link the maintenance of the "remote" Omega temperature chart recorders with the maintenance of the Helmer incubator (R14839) at 944 Barrydowne Road or the Helmer incubator (R15127) at 300 Elm Street. According to CBS staff, the maintenance of the Helmer incubators included the "remote" temperature chart recorders. However, the "remote" Omega temperature chart recorders did not have a RAM label or maintenance label affixed to them that would link them to the incubators. The last maintenance records for these Helmer incubators did not provide the manufacturer's name and serial number for the chart recorder referenced in the report. And, the asset details in the RAM system for R14839 and R15127 did not contain the manufacturer's name and serial number for the "remote" temperature chart recorder.

*Equipment details have been entered into RAM for both chart recorders with a comment linking*

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*their Asset IDs with their respective incubators. Asset ID labels, as well as preventive maintenance labels, will be applied to each of the chart recorders during their next scheduled preventive maintenance by 2017-09-31.*

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

