Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

2019-11-12
CBS Control #: CBS6363
HPFB File #: C1892-100390
REF: H-1920-CAL-L

Ms. Sandra Jarvis
Compliance Specialist
Regulatory Operations and Regions Branch
Biological Products Compliance Program
730, 9700 Jasper Ave. NW
Edmonton, Alberta
T5J 4C3

Dear Ms. Jarvis:

Re: Responses to Health Canada Inspection of Licensed Activities at Calgary Operations 2019-09-16 to 2019-09-27

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-10-10.

Section 100 – Equipment

1. **At the time of the inspection, the 6 month preventive maintenance (PM) for all of the Hettich Roto Silenta centrifuges was found to be 7 days past due according to the date due maintenance label on each centrifuge. According to the Equipment Services Manager, the centrifuge appeared as "closed" on the weekly RAM generated list of equipment coming due for maintenance, and therefore a work request for the PM had not been initiated. In addition, there was a failure to perform other procedures that may have prevented the error or identified it sooner. Specifically, the equipment owner did not regularly monitor the Scheduled Events Due Report and the Scheduled Events Past Due Report, and the equipment operators did not ensure there were current maintenance labels on the centrifuges prior to each use, both of which are requirements set out in WI 09 350 Management of Equipment by Owners, Rev. 5. It is noted that upon identification of the overdue PM, immediate corrective action was taken, including immediate performance of the 6 month PM on all of the Hettich centrifuges. All were found to be operating within the required specifications.**

   QER #20-19-140573 was initiated on 2019-09-18.

   In addition to the preventive maintenance conducted immediately, a search of the RAM database was conducted on all equipment. Other discrepancies were identified and corrected but none had resulted in a missed scheduled preventative maintenance.

   A Corrective Action/Preventive Action has been launched to identify and address root causes of this issue.

   In addition, staff in production and distribution completed refresher training to 09 350 Management of Equipment by Owners on 2019-10-09.

Section 95 - Operating Procedures

2. **Some operating procedures were not always followed:**
   a) Contrary to SOP 04 729 End Labelling, Rev. 37.1, the End Labelling Record dated 2019-05-13 for Calgary and Saskatoon clinics held 2019-05-11 and 2019-05-10, respectively, did not indicate what blood component was labelled.

   This audit observation was discussed with production staff following the audit.

   The End Labelling Record was corrected using a verifiable source.

   Production & Distribution staff will complete refresher training on SOP 04 729, End Labelling by 2019-11-30.

   b) Contrary to Part 4, Section 3, Step 3 of WI 08 029 Management of Hospital Customer Feedback, Rev. 6, written feedback in relation to a complaint regarding a phenotyping discrepancy was not provided to the hospital (HCF CAL 2019-019; QER 2019-1030730).

   QER# 20-19-107558 was initiated on 2019-10-24.

   A formal letter in response to the complaint was sent to the hospital on 2019-09-18.

   Staff will complete refresher training to 08 029, Management of Hospital Customer Feedback by 2019-11-30.

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,

Christian Choquet

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

cc: Shelley Smyth
A/ Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch