

2017-06-14
CBS Control #: CBS6060
HPFB File #: C1892-100390
REF: H-1718-SAS

Ms. Shelley Smyth
Regulatory Compliance and Enforcement Specialist
Regulatory Operations and Regions Branch
Health Canada
300-391 York Avenue
Winnipeg, Manitoba
R3C 4W1

Dear Ms. Smyth:

**Re: Responses to Health Canada Inspection of Licensed Activities at Saskatchewan Centre
2017-05-15 to 2017-05-19**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2017-05-31.

Section 39 - Donor Suitability Assessment

1. The establishment that collected allogeneic blood did not assess all or part of the donor's suitability before collection.

During the review of donor records in eProgesa from the Prince Albert Mobile Clinic (S0076) that occurred on April 17, 2017 contrary to SOP 01 144 "Screen Donor" v. 3 and MAN 01 200 "Donor Selection Criteria Manual" v. 8 Amendment 9, it was noted there was no record of height and weight for two first time donors who were less than 23 years of age. The specific donation numbers were C05301711362800F and C05301711366200B.

Non-conformance report # 30-17-337240 was initiated on 2017-06-05.

The Clinic Supervisor reviewed the weight and height criteria as per SOP 01 200 Donor Selection Criteria Manual with all clinic staff in Regina on 2017-05-25 and Saskatoon on 2017-06-02.

In addition, individual feedback on the appropriate DSCM criteria will be provided to the staff involved by 2017-06-30.

Section 95 - Operating Procedures

2. Some operating procedures were not always followed.
 - a) Contrary to Canadian Blood Services procedures for donor screening, the eProgesa records from the Prince Albert Mobile Clinic on April 17, 2017 for donation #C053017113592007 had the incorrect date of deferral entered for travel to a Malaria risk country resulting in a deferral date to August 5, 2017 when it should have been July 8, 2017 based on the date of departure of July 8, 2016 that was recorded in the Medical Questionnaire.

Non –conformance report # 30-17-337242 was initiated on 2017-06-05.

The deferral date was corrected in eProgesa on 2017-06-05.

Staff were reminded of the appropriate malaria documentation requirements as per SOP 01 200, Donor Selection Criteria Manual in Regina on 2017-05-25 and Saskatoon on 2017-06-02.

In addition, individual feedback will be provided to the staff involved by 2017-06-30.

b) Two chart recorders, R13651 and R13653, that were observed to be in use on May 16, 2017 as a secondary temperature monitoring system in the main warehouse supply room and the pack storage room, had out of service tags attached to them. It was confirmed that the Preventative Maintenance had been completed on May 10, 2017 and email notification indicating Pass for the work status was sent to the equipment owner the same day. According to SOP 09350 Rev. 3 "Management of Equipment by Owners" the out of service tags should have been removed by the Equipment Owner/Operator after receiving an email notification.

Warehouse staff verified that the chart recorders R13651 and R13653 had passed their Preventative Maintenance on 2017-05-10 and the "Out of Service" tags were removed on 2017-05-16. Warehouse staff will be retrained to SOP 09 350 Management of Equipment by Owner, Rev 3, by 2017-06-30.

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,



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