Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2019-10-24
CBS Control #: CBS6310
HPFB File #: C1892-100390
REF: H-1920-BRP-R

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

Dear Ms. Shome-Pal:

Re: Further to the Responses to the Health Canada Inspection of Registered Activities at Brampton Operations from 2019-04-29 to 2019-05-03 and from 2019-05-28 to 2019-05-31

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2019-10-01, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of registered activities at Brampton Operations.

Section 94 - Quality Management System

1. **The document control or records management system was not sufficient. For example: The 2017 and 2018 preventive maintenances were not uploaded into RAM for the Irradiators with equipment ID#s R2471 and R2472. Steps 2.6 and 3.7 of SOP 09 350: Management of Equipment by Owners, Revision 5, were not followed, as the hardcopies of the equipment services were not forwarded to the appropriate department for uploading into RAM.**

   QER# 56-19-140348 was initiated 2019-07-10.

   The reports have been uploaded in RAM for R2471 and R2472 on 2019-07-26.

   Roles and responsibilities for equipment maintenance activities as per SOP 09 350 Management of Equipment by Owners were clarified with Supervisors and their designates.

   Health Canada Follow-up letter dated 2019-10-01:

   Please confirm the mode and date(s) of this communication to Supervisors and their designates.

   Canadian Blood Services Response:

   The communication was done by email on 2019-06-24.

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Section 95 - Operating Procedures

2. **Some operating procedures were not always followed. For example:**
   a) While observing the washing of one unit of red blood cells, it was noted that SOP 02 150: ACP-215 Preparation of Washed Red Cells, Revision 5 was not always followed. Specifically, Step 2.1: "Prepare ACP-215" was done before Step 1.3: "Determine Pre-Wash Weight."
   b) Form 1000105513 (2017-08-17): ACP-215 Saline Washed Red Blood Cells Production Record was not always completed as required. Specifically, for the form completed on 2019-04-02, the DNL Labelling Verification/Confirmation: (Initials) was left blank under section 4, Labelling, contrary to the relevant section of SOP 02 150: ACP-215 Preparation of Washed Red Cells, Revision 5.

   Combined Response for 2a and 2b:

   QER# 56-19-140349 was initiated on 2019-07-10.

   Form 1000105513 ACP-215 Saline Washed Red Blood Cells Production Record has been corrected using a verifiable source.

   The observation will be discussed with staff involved in washing and reviewing the associated ACP-215 Saline Washed Red Blood Cell Production Record. Staff were retrained to the applicable sections of SOP 02 150, Preparation of Washed Red Cells by 2019-08-09.

Health Canada Follow-up letter dated 2019-10-01:

What were the corrections made to Form 1000105513? What was the verifiable source that was used?

Canadian Blood Services Response:

A comment was added to document the QER number. The verifiable source is the end labelling session report in eProgesa.

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

Sincerely,

Christian Choquet

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

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