



**Canadian  
Blood  
Services**

BLOOD  
PLASMA  
STEM CELLS  
ORGANS  
& TISSUES

1800 Alta Vista Drive  
Ottawa ON  
K1G 4J5  
Canada

2019-09-05  
CBS Control #: CBS6310  
HPFB File #: C1892-100390  
REF: H-1920-BRP

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

Dear Ms. Shome-Pal:

**Re: Responses to Health Canada Inspection of Registered Activities at Brampton Operations  
2019-04-29 to 2019-05-10 and 2019-05-28 to 2019-05-31**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2019-07-03.

*As many of the observations relate to records keeping and good documentation practices, all staff at Brampton will be required to attend an educational session on "Documentation and chain of custody" in addition to the actions described below. This session will focus on the importance and requirements of clear, accurate and complete record keeping*

**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.*

**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**

*sl*

**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.

**c) The 2018 Irradiator Maintenance Log for IRR-0002/R2471, the review date was indicated as 2018-06-26 for verification conducted on 2018-07-26. This is contrary to SOP 25 055: Irradiator Maintenance (All Models), Revision 7, Step 1.9.1, "Review IML ensuring all required tasks have been completed and documented."**

QER# 56-19-140350 was initiated on 2019-07-11.

The log has been reviewed to ensure it is acceptable and no further deficiencies were identified.

The observation was discussed with staff involved on 2019-08-01 and they were reminded of the importance of accurate and complete documentation.

**d) The following deficiencies were noted during the review of Form 1000106172 (2015-03-30): Frozen Red Blood Cell Assessment Worksheet for some autologous donors contrary to the relevant sections of SOP 05 856: Managing and Assessing Frozen Red Blood Cells Prior to Distribution:**

**(i) For Donation Number 3-149715, form completed on 2018-11-16, Section B: Assessment of Donor Deferral History was left blank. This should have been indicated as N/A.**

**(ii) For Donation Number 0-148597, form completed on 2018-11-16, Section F: Labelling and/or Tag application was left blank.**

QER 56-19-140451 was initiated on 2019-07-11.

Technical Specialists were retrained on the applicable steps of SOP 05 856, Managing and Assessing Frozen Red Blood Cells Prior to Distribution on 2019-08-01. In addition, staff completed training to 08 851 Manual of Good Documentation Practices on 2019-08-01.

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: Anita Mahadeo  
A/Supervisor – Blood, Tissues, Organs and Xenografts  
Regulatory Operations and Regions Branch