Response to the Observations of the Health Canada Inspection
at Laval Globule Blood Donor Centre
December 8, 2015

OBSERVATION AND RESPONSE

OPERATING PROCEDURES – 95

1- During verification of event report SCP-M-15-0097 regarding the transfer of the blood count control from a refrigerator to another one linked to BAS system, which occurred on December 2, 2015, it was noted that corrective measures were taken on December 2 whereas the initiation of the event and the verbal approval of Quality Assurance (QA) occurred only on December 7, 2015, contrary to SOP-00384(2) "Management of Non-Compliances," which states that QA's approval must be requested before applying the remedy.

Response:

In collaboration with Regulatory Training and Quality Assurance, Training on non-compliance process (SOP-00384) will be developed to meet the needs of the Blood Drive Service. This training will be given by Quality Assurance as stated in the Regulatory Training 2016-103 request form.

In compliance: April 15, 2016

A presentation will be included as part of corrective action CAPA-15-002 "Cycle Time of Non-Compliances." This presentation will focus on the importance of actions and documentation in each section of the event report.

In compliance: April 15, 2016

A report will be issued monthly to measure the cycle time of the following steps of an event:

- Date of detection of the event vs. date of approval of remedies by Quality Assurance.
- Average by service: date of receipt by QA vs. date of closure by QA.

This report will be presented as part of corrective action CAPA-15-002, and quarterly results will be presented to management.

Analysis of this report will enable Quality Assurance to ensure follow-up with services and specialists assigned to review non-compliances and obtain more up-to-date trend analyses. This process will be used until the overhaul of the non-compliance process (project schedule being developed).

In compliance: March 31, 2016 (first report)