



**Response to the Observations of the Health Canada Inspections
at the Globule Blood Donor Centre – Place Laurier
June 14, 2017**

OBSERVATION AND RESPONSE

QUALITY MANAGEMENT SYSTEM – SECTION 94

1. Obsolete or previous versions of quality documents were not removed and archived.

Three incorrect versions of the work specification SPE-01036 “Repuncture of phlebotomy area” (Whole blood and apheresis donation) were found in the 10 document binders, i.e., version 4 instead of version 5. These 3 SPEs were replaced by the proper version during the audit.

Response: (AEX-1344-EXP)

A verification confirmed that the differences between the expired versions found at the Globule and the current version of the SPE-01036 are minor and have no impact on staff understanding. The 3 expired versions were removed and replaced by the versions in effect during the inspection. In addition, the document distribution register has been corrected to reflect the number of copies required at the Globule.

A complete verification of all documents available at the Globule will be performed to ensure that only the current documents are in circulation. Also, an assessment is underway by managers to determine the amount of paper copies required for operations.

The distribution notice will be modified so that the actions undertaken, following sending errors or changes in quantity, are clearly indicated on the notice once completed.

In compliance: October 31, 2017