Response to observations stemming from Health Canada inspection
at the Quebec facility
From September 10 to September 14, 2012

OBSERVATIONS AND RESPONSES

EQUIPMENT – C.02.005

1) The audit of the equipment files revealed the following deficiencies:

1) For equipment whose maintenance interval is greater than one month and less than 6 months, TEC-SPE-001v2 "Interval, acceptable range and maintenance due date," section "acceptable range" was not applied, which could have caused maintenance delays. For example, the ultra-rapid freezing bath EC02299 had undergone maintenance on May 8, 2012, and the due date for the next maintenance was September 28 instead of September 15, 2012.

2) Preventive maintenance of the EC02299 bath following maintenance performed on August 29, 2012, was set for 5 months later rather than 4 months. It was observed that TEC-SPE-001v2 did not cover maintenance performed on the 29, 30 or 31 of the month.

An NC SEB-Q-12-0009 was issued during the inspection.

Response:

1) To prevent this situation from occurring again, equipment whose maintenance interval is greater than 1 month and less than 6 months will be identified on staff work lists so that it can be easily distinguished from the other equipment. In addition, a change order has been created (OC-00830) to modify the forms for the equipment in question so that they include a reminder concerning TEC-SPE-001 with regard to the maintenance due date.

In compliance: Work lists : 19-10-2012
Forms : Feb. 2013

2) Because the TEC-SPE-001 specification describes a schedule based on a 28-day calendar in accordance with the current computer system, maintenance performed on the 29, 30 and 31 of the month was not included. A change order (OC-00791) was created to modify the TEC-SPE-001v2 so that it includes the 29, 30 and 31 of the month.

In compliance: November 2012

Response to observations stemming from Health Canada inspection at the Quebec facility From September 10 to September 14, 2012

MANUFACTURING CONTROL – C.02.011

2) The audit of the apheresis records revealed the following deficiencies:

1) The cumulative plasma volume was incorrect for the plasmapheresis donations made on September 7, 2012, by donor 1684149 and on July 14, 2012, by donor 1464438.

2) The cumulative volume of red blood cell loss was incorrect for the multiple product donation made on March 9, 2012, by donor 1063866.

The donor eligibility criteria had, however, been met. An NC SCP-Q-12-0845 was issued during the inspection.

Response:

Following this observation, all the employees involved were met with and informed of the problem. Verification of all the files in which donors are at risk of exceeding the maximum permitted volume and cumulative red blood cell loss (frequent donors) is currently underway.

Since September 25, 2012, various verifications have been put in place:

- The cumulative volume calculation for the previous donation is rechecked before collection.
- After collection, a second person checks the calculation.
- File review is now performed in a more isolated area to minimize distractions.

These measures will be in place until implementation of the Vista program at the Québec City facility on 19-11-2012, which will calculate cumulative volumes automatically.

In compliance: 15-12-2012 (Files verification)

**Response to observations stemming from Health Canada inspection
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EQUIPMENT – C.02.005

3) The audit of equipment records revealed the following deficiencies:

1) The "Perform FIBER CHECK" box for preventive maintenance of the ACL 7000 machine used in the Quality Control Laboratory to dose factor VIII and fibrinogen, performed by the subcontractor on July 27, 2012, had not been checked to certify that this task had been performed. The supplier was contacted during the inspection; there was no impact on the functioning of the device. An NC LCQ-Q-12-0539 was issued during the inspection.

2) The work orders of the external technician who performs oil changes on the compressors in the refrigerator and freezer rooms did not provide a link between the work carried out and the specific compressors in order to ensure that each compressor had undergone maintenance. An NC RMT-Q-12-0009 was issued during the inspection.

3) The EC00750 Sorvall centrifuge used by the Blood Component Preparation department did not appear on the equipment list of form ENR-00422(1) "Verification and maintenance of Sorvall centrifuges" for the month of September 2012. An NC PCS-Q-12-0319 was issued during the inspection.

Response:

1) This preventive maintenance step was completed by the supplier on 17-09-2012, and the device was in compliance. A staff follow-up was performed.

In compliance: 05-10-2012

2) The work orders associated with each piece of equipment will be modified to include the signature of the person who performed the work and the maintenance date, which will make it possible to track the work carried out.

In compliance: 15-10-2012

3) Maintenance documentation for the centrifuges was reviewed for the months of April to September 2012. Maintenance was also performed on the EC00750 centrifuge during the inspection, as described in non-compliance report PCS-Q-12-0319. In addition, a request was made to modify form ENR-00422 so that it includes the EC00750 centrifuge.

In compliance: 25-11-2012

Response to observations stemming from Health Canada inspection
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From September 10 to September 14, 2012

MANUFACTURING CONTROL – C.02.011

4) The audit of form TRA-ENR-034v4 "Conditioning of temperature-controlled bags (20°C to 24°C)" revealed that the conditioning time for bags on March 22, 2012, was 7 hours 18 minutes instead of 12 hours. However, the temperature of the bags is verified before their use. An NC COP-Q-12-0014 was issued during the inspection.

Response:

A verification of form TRA-ENR-034 was performed for the months of January 2012 to September 14, 2012, and no non-compliance was observed with regard to conditioning time.

In compliance: 30-09-2012

**Response to observations stemming from Health Canada inspection
at the Quebec facility
From September 10 to September 14, 2012**

RECORDS – C.02.020

5) The following documentation errors were observed:

1) The audit of the department for the preparation of IT equipment revealed that form ENR-00379 "Verification of technical equipment" for the QUMIN blood drive (mobile unit 2) held on August 27, 2012, was missing. An NC INF-Q-12-0002 was issued during the inspection.

2) The audit of the archives revealed the following deficiencies:

a. The same box of documents was created twice in the archives register with two different numbers and locations. An NC ASQ-Q-12-0024 was issued during the inspection.

b. Out of ten TRA-ENR-039v2 "Transport Slip" forms examined, used during internal transport of archive boxes in the month of August 2012, nine of the forms were missing information (date or hour of reception or transport, quantity, description or state of the merchandise).

3) The audit of the training records for Globule Laurier nurses in the SmartTrain system revealed that the recertification of one employee on the 13 SOPs of the allogenic role and on the QMS (quality management system) was noted as "Expired" since May 2012. In addition, the overall qualification certification FOR-ENR-006.2v3 had not been completed and signed by this employee. However, the recertification questionnaires, completed and signed by the employee and trainer on May 2 and 3, 2012, were found on file. An NC FOR-Q-12-0017 was issued during the inspection.

4) Form SAH-ENR-021v2 "Merchandise management" used by the Reference and Stem Cell Laboratory for receipt of erythrocyte serology reagents had not been completed for quality control activities to be performed on the product anti-Cw received on June 27, 2012. However, quality control had been performed in order to release the product.

CORRECTED DURING THE INSPECTION.

5) The audit of form SEB-ENR-017.1v4 "Verification and calibration of operations thermometers" for infrared thermometer EC08212 dated March 12, 2012, revealed that there was no indication of the identification number for the heating block used and it was indicated as being "N/A."

CORRECTED DURING THE INSPECTION.

Response to observations stemming from Health Canada inspection at the Quebec facility From September 10 to September 14, 2012

6) The audit of forms TRA-ENR-034v4 "Conditioning of temperature-controlled bags (20°C to 24°C)" and TRA-ENR-035v6 "Conditioning of cooling packs (−8°C to −14°C)" used in the preparation of blood drives revealed missing information in 5 forms for the months of May and June 2012 (in 4 forms, the information related to the end of conditioning and, in 1 form, the date and signature of the direct supervisor who verified the forms). An NC COP-Q-12-0014 was issued during the inspection.

Response:

1) Form ENR-00379 "Verification of technical equipment" for the QUMIN blood drive (mobile unit 2) held on 27-08-2012 was found following the audit.

In compliance: 20-09-2012

2) 2a. The record in the register was corrected. All the boxes in the archive rooms were verified against the register and vice-versa to ensure that the physical inventory and register information match.

In compliance: 03-10-2012

2b. A follow-up was conducted with the Warehouse and Quality Assurance staff. The Warehouse staff will ensure that the form is completed by the receiver during box transport. If any information is missing upon receipt at Quality Assurance, the form will be returned.

In compliance: 05-10-2012

3) Considering that 114 files (4 different nurse roles) were audited and only one showed any deficiencies with regard to documentation, i.e., less than 1% error rate, the system is under control and does not require any adjustment. The information regarding the employee's training file was corrected during the inspection.

In compliance: 13-09-2012

4) CORRECTED DURING THE INSPECTION.

5) CORRECTED DURING THE INSPECTION.

6) A verification of forms TRA-ENR-034 and 035 was performed for the months of January through September 14, 2012; one non-compliance was detected with regard to missing information.

The employees in question were met with to identify the problem and individual responsibilities.

A sporadic cross-check will be performed for the months of September and October 2012 to ensure that verification has been performed properly.

In compliance: 01-11-2012