**Response to observations stemming from Health Canada inspection
at the Montréal facility
from November 13 to November 23, 2012**

OBSERVATIONS AND RESPONSES

EQUIPMENT – C.02.005

1) Cold room L-219, which was put into use in November 2010 to store fractionated products, had not been activated in the SAP-PM database and, as a result, the preventive maintenance had not been done on the air compressors and condensers as provided for in the maintenance program. However, all of the probes had been calibrated on a regular basis, the cold room supervision process was in place and there was no impact on the products. The air condenser maintenance was done on January 25, 2012. On November 21, 2012, the database was updated and the compressor maintenance was done. NC RMT-M-12-0016 was issued during the inspection.

Response:

RESOLVED DURING INSPECTION.

QUALITY CONTROL DEPARTMENT – C.02.015

2) During the verification of the forms ENR-00092 "Accepting reagents used in the blood bank laboratory" the copies of the analytical certificates for the three following reagents were not verified: Liss lot no. 2229121, CorQc lot no. 42962 and CorQc lot no. 40935. NC VLB-M-12-0143 was issued during the inspection.

Response:

RESOLVED DURING INSPECTION.

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EQUIPMENT – C.02.005

3) During the inspection of the following laboratory equipment, the following shortcomings were observed:

1) Virology: cleaning as needed of the internal surfaces of the refrigerated compartments of the two PRISM machines was not included in that equipment's maintenance program. During the inspection, it was noted that the cleaning had not been done.

2) Blood bank: the two following tasks were not checked when the preventive maintenance was done on October 30, 2012, for the PK7300: Densitometer: Bulb and Zero Adjustment. The supplier was contacted during the inspection and there was no impact on the operation of the device. NC VLB-M-12-0144 was issued during the inspection.

Response:

3)1) Maintenance work on the two refrigerated compartments was performed during the quarterly maintenance of January 8, 2012. Form ENR-01071 will be amended to include this maintenance work.

In compliance: 08-04-2013

3)2) RESOLVED DURING INSPECTION.

PERSONNEL – C.02.006

4) For employee no. 63461, the Héma-Québec quality manual re-certification due for August 12, 2012, was not done. However, there was no impact on the work since the employee had been assigned to other duties (receptionist) before August 12, 2012. NC FOR-M-12-0059 was issued during the inspection.

Response:

RESOLVED DURING INSPECTION.

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MANUFACTURING CONTROL – C.02.011

5) For thrombapheresis donor no. 0048277, there was an error in the cumulative calculation of the red blood cell loss for the February 6, 2012, donation as a result of a date error concerning the previous donation. After the date was corrected, the calculation of the red blood cell loss had not been corrected. However, there was no impact on the donor. NC SCP-M-12-1000 was issued during the inspection.

Response:

RESOLVED DURING INSPECTION.

RECORDS – C.02.020

6) For three granulopheresis donors (nos. 0009156, 1355958 and 0048277), the current collective prescription with respect to using Pentaspan 10% was not in the file.

Response:

A memo was distributed to the Globule centre on November 28, 2012, asking staff to staple documents returned to the secretary so as to prevent the loss of any forms.

Moreover, the implementation of a computer system (Vista) at the Globule centre will resolve the problem once and for all since it will ensure traceability of the collective prescription in effect.

In compliance: 18-02-2013

Response to observations stemming from Health Canada inspection at the Montréal facility from November 13 to November 23, 2012

SANITATION – C.02.007

7) During the inspection of the cleaning of the mobile units and the Globule centres, the following shortcomings were observed:

1) The cleaning of the 2 mobile units was only inspected once at the end of the season, which is not enough to ensure that the cleaning had been done as required.

2) With respect to the cleaning of the Laval Globule centre done in February 2012, two reports containing different information were found in the file.

3) The periodic work schedule for May 2012 for the Globule centres was missing one task that is required under the service specification (sweeping the floor in the electric room).

Response:

7)1) It has been established that the cleaning documentation for the mobile units must be verified once a month. The forms will be kept in the cleaning office and transmitted to technical services each month for verification. The Montréal and Québec facilities will each have their own file containing the duly completed forms by their cleaning staff. The forms will be consolidated in a single file for each facility at the end of the year.

In compliance: 21-12-2012

7)2) The two forms for February found during the inspection were appended to the cleaning file with explanations documented on December 4, 2012. A meeting with the supplier took place on November 29, 2012, to explain the problem.

In compliance: 04-12-2012

7)3) The May 2013 periodic work schedule form for Globule centres was amended to reflect the requirements of the approved service specification.

In compliance: 23-11-2012

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

8) During the inspection of the generators, the following shortcomings were observed:

1) Concerning the maintenance and inspection of the 2 generators:

a) The fuel tank of the GEN2 generator was only filled on April 5, 2012;even though the diesel level had reached its minimum level on March 11, 2012, and subsequent weekly inspections indicated a level lower than the minimum limit.

b) Form RMT-ENR-005v1 "Weekly visual verifications of generators" specified the minimum diesel levels required in the tanks, which could be interpreted as being acceptable and indicating that no action was necessary until the level fell below the minimum level, whereas PFN-00267 "Maintenance and verifications of generators" Item 6.2.3, states that the person in charge should be contacted to have the tank filled when the minimum limits are reached.

2) Concerning the maintenance and inspection of the 4 UPS units:

a) The UPS 5 filter was not changed in October 2012, as provided for in the maintenance plan.

b) The work orders for UPS 1 and UPS 5 were not in file for the June 4, 2012, filter changes.

Response:

8)1a) The situation was discussed with the personnel responsible for this during the inspection and negotiations are underway with the fuel suppliers to make sure that the diesel fuel is provided within an acceptable time frame (priority handling). An agreement will be signed with the supplier by May 2013.

In compliance: 31-05-2013

8)1b) Form RMT-ENR-005 will be amended to clarify the actions to be taken when the minimum fuel level is reached.

In compliance: 31-05-2013

8)2) The supplier recommends the filters be changed as needed or every six months; at Héma-Québec, this is done every three months. The filter changing frequency will be revised.

In compliance: 31-05-2013

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8)2a) The UPS 5 filter was changed on November 29, 2012. Since the manufacturer recommends that the filter be changed as needed or every six months and the service report for November 29, 2012, indicates that the filter in place before the change was OK, it can be said that the one-month delay in the quarterly maintenance had no impact on the effectiveness of the filter or on the operation of the UPS.

In compliance: 29-11-2012

8)2b) The UPS 5 and UPS 1 filter changes were planned and performed following the inspection.

In compliance: 29-11-2012

RECORDS – C.02.020

9) During the inspection of the following sectors, the following documentation errors were observed:

1) Bacterial culture: the following forms used in January 2012 were not verified: LAB-ENR-124 "Lot number of culture bottles used daily" LAB-ENR-139 "Maintenance of BactT/Alert incubators" and LAB-ENR-126 "Maintenance of fume hoods" for the two fume hoods. NC VLB-M-12-0146 was issued during the inspection.

2) Training: for employees 61999 and 62793, the training given on April 18, 2012, on the biological and chemical safety manual (Module 0) and the re-certification given on April 11, 2012, concerning Héma-Québec's quality manual, respectively, were not entered in the SmartTrain database, which indicated "INWORK" for both documents. The database was updated on November 15, 2012.

3) Information technology: the request forms for computer incidents encountered during blood drives and reported in the incident management software were not systematically updated after action was taken with respect to the equipment in question.

4) Document control: the following shortcomings were observed with respect to the management of distribution notices:

a) Distribution notice no. 4243 did not contain either the signature of the recipient or the signature verifying the return of the documents.

b) The signature verifying the return of documents was missing for one of the two no. 4218 distribution notices for the same recipient.

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5) Designated donation records: a print-out of the last donation and the complete analyses for donor no. 0441140 were not included in file no. 0014121, as specified in PFN-00285 "Designated Donation Program".

Response:

9)1) RESOLVED DURING INSPECTION.

9)2) RESOLVED DURING INSPECTION.

9)3) The employee was reminded, on November 15, 2012, during the inspection, to follow the incident management process. Moreover, there will be ad hoc verifications of incident requests assigned to this computer technician until June 2013.

In compliance: 01-06-2013

9)4a) and 9)4b) The employee in question has been made aware of the importance of documenting verifications properly (by signing), when returning distribution notices for controlled documents.

In compliance: 20-12-2012

9)5) RESOLVED DURING INSPECTION.