

**Responses to observations stemming from the Health Canada inspection  
of the Montreal facility  
from October 5-16, 2009**

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**OBSERVATIONS AND RESPONSES**

**MANUFACTURING CONTROL – C.02.011**

- 1. Inspection of the lab forms for the MOLPQ collection of 17/09/2009 revealed two separation weight errors for double apheresis platelet donations #C00030913119300F and #C00030913118500F. Non-compliance report PCS-M-09-1434 was issued and the appropriate corrective measures were implemented during the inspection.**

**Response:**

**Corrected during the inspection**

**MANUFACTURING CONTROL – C.02.011**

- 2. Annual review of regulatory procedures (SOP), as required under SOP CFA-INS-002v1 "Management of controlled documents" was not supported by a defined tracking mechanism.**

**Response:**

In addition to the steps currently implemented in SOP CFA-INS-002, namely sending a list of the documents to be revised and the verification of the CFA-ENR-008 *Annual Revision - SOP and Specification* forms returned by the departments, the following will be added:

- The receipt of the CFA-ENR-008 forms will be documented in the controlled documents database;
- The departments will be informed if the forms are not received in a timely manner;
- If the CFA-ENR-008 form indicates a need for a revision and the CFA-ENR-002 *Change request* is not received on the date indicated, CFA will contact the department to obtain a new date;
- Once the CFA-ENR-002 form is received, the number of the request will be indicated on the CFA-ENR-008 form and it will be filed.

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- 3. The 20-day deadline for submitting non-compliances to the Quality Assurance Department, as required in SOP ASQ-INS-021v7 "Management of non-conformances" was not respected by several departments. However, an improvement was noted since the implementation of a corrective action in 2007 following a similar observation by Health Canada in December 2006.**

**Response:**

Since the implementation of corrective actions AC-06-03 for Operations and AC-06-004 for Hospital Services, 31 out of a total of 50 departments have been withdrawn since they have respected the 20-day deadline (or less) for at least six months as required by SOP ASQ-INS-021. For the 19 remaining departments, the corrective actions remain open.

In order to correct the situation for these departments, the committee dealing with the time cycle problem (calculated as of the time of detection) will focus not only on the detection departments but also on the departments responsible for the non-compliances during their upcoming meetings.

For Operations, several departments are close to attaining the objective (respecting the deadline for at least 6 months) and Quality Assurance plans to close the corrective action during the year.

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**PERSONNEL – C.02.006**

- 4. During an audit of the shipping department employees' training files, the following shortcomings were observed:**
- a) During the monthly training session of 07/04/2009, one employee read the documents LAB-INS-053v3, LAB-INS-058v2 and LAB-SPE-048v2 although they had been in effect since 30/03/2009, without justification. Moreover, the agent responsible for this did not initiate a non-compliance when she noted the situation. Non-compliance form FOR-M-09-075 was issued during the inspection.**
  
  - b) During the April 2009 employee recertification, competency certificate FOR-ENR-006v3 incorrectly indicated version 3 of SOP LGP-INS-024 instead of version 4, which had gone into effect 01/02/2009. Non-compliance form FOR-M-09-074 was issued during the inspection.**

**Response: Corrected during the inspection**

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**MANUFACTURING CONTROL – C.02.011**

5. During the audit of Forms INF-ENR-009v5 "Request for SIPS access", the following shortcomings were noted:
- a) The section entitled "Authorized Access: (Section reserved for IT)" was not completed for three employees on 17/11/2008, 30/03/2009 and 14/04/2009, although the access rights for these employees were authorized. Non-compliance report INF-M-09-0006 was issued during the inspection.
  - b) For the access request dated 29/06/2009, one employee did not sign or date the section concerning the confidentiality of access codes. However, the employees are required to respect the confidentiality of access codes in keeping with the "Access Agreement to the electronic communication network" and the employee in question had signed that document. Non-compliance report INF-M-09-0005 was issued during the inspection.

**Response:**

- a) Individual follow-up with the person responsible for SIPS access, stressing the importance of completing access requests properly, took place during the inspection. A modification request (#2009-0473) was completed and sent to the Compliance and licensing department to modify Form INF-ENR-099. The initials of the system administrator who granted these access rights as well as the date on which the request was completed was added to the form.

**In compliance: April 2010**

- b) A modification request (#2009-0473) was completed and sent to the Compliance and licensing department to modify Form INF-ENR-099. Since all Héma-Québec employees are required to respect the confidentiality of access codes (according to Administrative Directive DTI-001 and the Héma-Québec code of ethics), the section concerning access confidentiality will be removed from the next version of the form.

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**EQUIPMENT – C.02.005**

**6. During the NAT analysis laboratory:**

**A) With respect to the audit of the files concerning the preventive maintenance done on laboratory equipment by a subcontractor, the following shortcomings were noted, although the subcontractor's work orders were approved by the employee in charge:**

**1- For the annual maintenance performed on 15/05/2009 for the Hamilton ATplus2 EC00181 pipettor, serial no. 2589:**

**a) The serial number of the calibration kit used did not correspond to the document appended to the report. During the inspection, the subcontractor confirmed that it was a transcription error.**

**b) The "Fail" box for the volume verification test had been checked off while the calibration certificate appended to the report indicated that the test results were acceptable.**

**2- For the annual preventive maintenance done on the COBAS Ampliprep in 2009, the box corresponding to the replacement of the parts provided according to the work list (ex: "tubing of wash reservoir and waste container", "cooling unit filter") was marked N/A and no comment was provided in the file. During the inspection, the subcontractor confirmed that the parts had been inspected and were in good condition.**

**Non-compliance report VLB-M-09-0359 was issued during the inspection for these items.**

**B) For the verification of the EC00160 scale in January, June and July 2009, the form LAB-ENR-138.1v1 "Scale verification" with weights of 100g and 500g, had been used instead of form LAB-ENR-138.2v1 "Verification of analytical balances" with a weight of 100mg. A correction was made on the form to indicate the weight actually used, namely 100mg or 0.100g. However, the difference of +/- 1g noted on LAB-ENR-138.1v1 did not allow for the verification of the compliance of the values during the balance verifications, since the acceptable different is +/-0.0002g for a weight of 0.1g. Non-compliance report VLB-M-09-0357 was issued during the inspection.**

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**Response:**

- A) The supplier will be met and will be given written expectations with respect to service reports and related documents. The personnel that revises these documents will be met so as to clarify the verification points in the service reports. A tool will be created to facilitate revision.

**In compliance: January 2010**

- B) Forms LAB-ENR-138.1 for weights of 100g and 500g were withdrawn from the laboratory during the inspection and replaced by form LAB-ENR-138.2. The laboratory personnel will be met to be given a reminder about the importance of using the right form.

**In compliance: November 2009**

**EQUIPMENT – C.02.005**

7. **During the audit of the preventive maintenance reports provided by the subcontractor for the Hamilton EC04376 pipettor at the BDS laboratory, the following shortcomings were observed:**

A) **The photometer (serial no. 1033048) calibration certificate used during the maintenance performed on 22/04/2009 was not in the file. The subcontractor provided the certificate during the inspection.**

B) **In the maintenance report dated 26/11/2008, the box "Hamprint verification" was marked N/A without any justification whereas that verification had been done in the case of other preventive maintenance. During the inspection, the subcontractor confirmed that the lack of this verification had no impact on the operation of the equipment.**

**Non-compliance report VLB-M-09-0358 was issued during the inspection for these two items.**

**Response: Corrected during the inspection**

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**PERSONNEL – C.02.006**

- 8. During the inspection of Access management to server rooms, the training for one employee had not been confirmed by the person responsible for IT training in Form INF-ENR-112v2 "Access to the server room request" before it was sent to the Safety Operation Center (COS). Nevertheless, the employee was given access to the room, contrary to SOP INF-INS-066v2 "Access management to server rooms". Non-compliance report INF-M-09-0007 was issued during the inspection.**

**Response:**

A modification request (#2009-0473) was completed and sent to the Compliance and licensing department to modify Form INF-ENR-112. The forms in effect for Safety Operation Center (COS-030 *Employment notice* and COS-031 *Access card request*) will be used to manage requests for creating or modifying access to the server rooms. Also, SOP INF-INS-066 *Access management to server rooms* will be amended to reflect the use of these forms and to clarify the responsibilities of the stakeholders in the process. The forms should be approved by the manager of the person making the request and the Director of Information Technologies. As well, the individuals who need access to the server room should first be trained with respect to SOP INF-INS-066.

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**EQUIPMENT – C.02.005**

- 9. During the verification of the maintenance done on the water purifiers and distribution systems, the forms corresponding to the activities done have been approved by the employee responsible for this despite certain shortcomings. For example:**
- a) For the calibration of the reference resistivity meter and the remote display of 22/07/2009, indicated on Form RMT-ENR-006.5, the subcontractor's intervention was incomplete and had been done on only one of the two channels, without specifying which one. The work was completed on 26/09/2009, according to non-compliance RMT-M-09-0026.**
  - b) The ionic rejection percentage indicated on Form RMT-ENR-006.1 "Daily verifications of water purifiers and distribution systems for the 25/12/2008" was outside the limits but no comment was indicated on the form.**

**Response:**

The various shortcomings observed during the inspection pertain to good manufacturing practises (GMP). The employee responsible for example a) was met to discuss this matter on 18-09-2009, namely when the error was detected.

Training will be given to the Material Resources employees concerned to ensure that they understand and respect GMPs.

Non-compliance report RMT-M-09-0033 was initiated with respect to the non-compliant reading of the ionic rejection percentage on 25-12-2008. Considering the fact that the measurements taken the days before and after 25-12-2008 were compliant, this non-compliant reading had no impact on the quality of the water produced.

**In compliance: November 2009**

**EQUIPMENT – C.02.005**

- 10. See observation no. 6.**