OBSERVATIONS AND REPLIES

MANUFACTURING CONTROL – C.02.011

1. In several error and accident reports for 2006, the 20-day deadline for sending event reports to Quality Assurance, as required by SOP ASQ-INS-021v6 *Management of non-compliances*, was not met and in some cases extended to several months.

Reply:

A committee has been set up to assess the various sources of the problem, and a preliminary report has been drafted.

Starting January 12, 2007, the committee responsible for corrective actions will meet to review the preliminary report and Quality Assurance's reply regarding this report. The proposed actions, as approved by Quality Assurance, will be implemented in the succeeding weeks up to March 31, 2007. The committee will also hold a meeting at least once a month with Quality Assurance to follow up on the actions implemented and results obtained, and make corrections as needed.

In compliance: March 31, 2007

EQUIPMENT – C.02.005

2. In 2006, the documents detailing interventions on the TRIMA apheresis units by the subcontractor Gambro were checked by the Biomedical Equipment Department (SEB) at the request of the user department.

A) However, the documents detailing the following interventions were not checked by the SEB:

- **work orders #5047 and 5048, dated March 6, 2006 for the semi-annual and annual inspection of unit #EC02326;**
- **work order #5059, dated March 20, 2006 for the preventive maintenance on unit #EC02327;**
- **work orders #5042 and 5043, dated February 24, 2006 for the semi-annual and annual inspection of unit #EC02329.**

B) An *Equipment Intervention Request* (SEB-ENR-015) for the TRIMA apheresis unit #EC01524 at the Côte-Vertu GLOBULE Blood Donor Centre, and all of the Equipment Intervention Requests for the TRIMA units at the Place Versailles GLOBULE Blood Donor Centre were not

filled out, checked and signed when the repair was completed and before the units were returned to the department. A non-compliance report was issued during the inspection (SCP-M-06-0250).

A corrective measure, comprising a request to change responsibility for managing and checking equipment preventive maintenance documents for the TRIMA units, was initiated and filled out during the inspection.

Reply:

Corrected during inspection.

MANUFACTURING CONTROL – C.02.011

3. The following were noted during a check of the apheresis procedure files:

A) In donor file #0345063, for the Platelets Pheresis procedure dated:

1) May 4, 2006:
- **a) The Specimen Data Report printout was not initialed, as required when the results are checked;**
- **b) The date was not entered on form SCP-ENR-168v4 *Apheresis Procedure*;**
- **c) The final check section of SCP-ENR-072v13 *Donor file: Apheresis* was not initialed.**

2) February 24, 2006: The TRIMA Unit Data section was not signed.

3) February 3, 2006: There was a calculation error in the cumulative loss of erythrocytes.

B) In donor file #0206283, there was a calculation error in the cumulative loss of erythrocytes for the Platelets Pheresis procedure of October 13, 2006.

C) In donor file #0207083, the granulocytes pheresis procedure dated October 18, 2006 was not signed by the nurse.

Non-compliance reports for these incidents were initiated during the inspection. Retrospective checks of the apheresis files and an action plan to determine a corrective measure for the situation had been initiated during 2006.

Reply:

An action plan was developed and implemented in November 2006 comprising the following elements:

- **systematic check of all donor files;**
- **optimization of review process: Review of all regulatory forms, change in review steps;**
- **monthly communication to personnel of the results of the systematic file check;**

An evaluation report on actions implemented will be completed in September 2007, with actions adjusted as necessary.

In compliance: September 2007

MANUFACTURING CONTROL – C.02.011

4. When labeling units of platelets, the employee had difficulty listing all of the physical parameters to be checked on the units to be labeled, as stipulated in point 6.1 of SOP ETI-INS-001v3 *Labeling of Blood Products*; in particular, the presence of aggregates was not mentioned.

Reply:

All Labeling personnel will be made aware of the importance of checking products, including the possible presence of aggregates in platelet products.

All relevant employees will have been informed by February 2, 2007.

In compliance: February 2, 2007

MANUFACTURING CONTROL – C.02.011

5. Contrary to SOP INF-INS-070v1 *Server Status Verification*, when a result of a server check was non-compliant, non-regulatory documents (LSA tickets) were created instead of filling out form INF-ENR-039 *Information Systems Incident Report*. These LSA tickets did not always indicate the precise status of the request and they were not checked and signed by a supervisor. A non-compliance report was initiated during the inspection (INF-M-06-0057).

Reply:

A one-on-one follow-up with the individuals concerned was conducted on December 7, 2006. These individuals were made aware of the importance of adequately documenting the problems in order to ensure appropriate follow-up. They also reread procedure INF-INS-070 *Server Status Verification*.

In compliance: December 11, 2006

EQUIPMENT – C.02.005

6. When checking the annual preventive maintenance reports provided by the subcontractor for the generators, the following problems were noted:

a) The report for generator #3 had not been checked, signed and dated by the Head, Material Resources, as described in SOP TEC-INS-012v4 *Maintenance and Inspection of Generators*;

b) The UPS report had been checked by a trainee rather than by the Technical Resources Manager, as described in SOP TEC-INS-017v1 *UPS System, Operation and Maintenance*;

c) In the report for generator #2, the subcontractor had not documented the check code for three items. However, after confirmation with the latter, these three items need only be checked following a power failure;

d) The reports for generator #2 were not sent to Héma-Québec until several months after the subcontractor's visit.

Reply:

a) An event report has been issued (RMT-M-06-0019). The maintenance report for the generator was reviewed and signed by the department manager on December 18, 2006. A memo will be sent to personnel reminding them of the importance of checking reports from subcontractors.

b) Form TEC-ENR-018 UPS *System Weekly Visual Inspection*, indicates that the UPS report can be checked by the department manager or his replacement. The review of SOP TEC-INS-017 *UPS System Operation and Maintenance* will include this point. It is important to stress that the trainee had received the necessary training to check the documentation.

c) and d) These problems had in fact been identified by Material Resources, and a meeting was held on August 21, 2006 between the department manager and the supplier to inform the latter of the problems. The supplier has since amended his work method as indicated in the maintenance report for generator #3 issued late August 2006.

In compliance: February 2007

EQUIPMENT – C.02.005

7. The temperature readings for the Milli-RX 75 water system were regularly out of specifications. The corresponding non-compliance reports were not filled out promptly, but rather collected over a period of about one month. However, the temperatures recorded did not adversely affect performance of the water system.

Reply:

The water temperature has no impact on water quality, but rather on the quantity of water produced. Form TEC-ENR-011 MILLI-RX 75 *Parameter Readings* and SOP TEC-INS-013 *Laboratory Water System Maintenance* are currently under review.

A non-compliance report will be issued as soon as a problem that could affect water quality is detected.

In compliance: March 2007

EQUIPMENT – C.02.005

8. Observation transferred to observation no. 2.

Reply:

Corrected during inspection.

MANUFACTURING CONTROL – C.02.011

9. On July 4, 2006, reissues of several SOPs and directives intended for the blood component preparation department were distributed without a *Notice of change to controlled documents* having been prepared for holder 30.6.

Reply:

This situation is an isolated event. Since the reissue of controlled documents to the Processing department was required following an incident in the department, the technician wanted to return the damaged documents as quickly as possible, and hence did not follow the required steps, i.e., to write "Duplicate" to indicate the copy was a reissue and to formalize its distribution with a *Notice of change to controlled documents*. The personnel was reminded of the importance of following the procedure in order to ensure traceability of all requests for distribution of controlled documents.

In compliance: December 4, 2006

EQUIPMENT – C.02.005

10. In the annual calibration and preventive maintenance file for COBE 2991 cell washer #EC02684, parameter 26 entitled "Upper Travel and Lower Travel Limit Switch Check" was not initialed to confirm it had been checked.

Reply:

The "Upper Travel and Lower Travel Limit Switch" check consists in validating the ability of the detector (upper travel) to limit movement of the pump engine piston. The second detector (lower travel) acts as a back-up to the former. A breakdown of these two detectors would require a major technical intervention to restart the equipment.

The Gambro technician omitted to document this check during the preventive maintenance on April 28, 2006. An event report (SEB-M-06-0025) was issued to document this omission.

The detectors were checked on December 8, 2006 during a visit by the supplier; this check was in compliance. Since the previous preventive maintenance on April 21, 2005 and the check conducted on December 8, 2006 were in compliance, we can confirm that the equipment was in good working order between these two dates.

Compliant

EQUIPMENT – C.02.005

11. During a check of form TEC-ENR-008v11 *Weekly Visual Inspection of Generators*, the following documentation errors were noted:

a) The operating-hour meter and frequency meter readings were not systematically noted with decimals, as required;

b) On two occasions, following a reading omission, there was no mention on the form of the non-compliance reports issued.

Reply:

a) Since different displays are used on the two generators, standardized notation is not possible. The analog frequency meter on GEN-2 does not provide a decimal reading, whereas a decimal reading is possible on GEN-3.

A change request will be submitted for the revision of the form to enable compatibility between the possible readings and those requested. A reminder will be given to the personnel responsible for taking the readings to ensure uniformity in the notation of these measurements and the precision required by the form.

b) A memo will be sent to Material Resources personnel to remind them to document the non-compliance number on the forms.

In compliance: January 2007