OBSERVATIONS AND RESPONSES

STAFF—C.02.006

1. The recertification planned for the Erythrocytic Immunology Department ("Sterile Connection" unit) in 2004 was incomplete. The employees had not reread several controlled documents.

Response: The recertification of all of the targeted staff members of the Erythrocytic Immunology Department at the Québec City laboratory will be conducted according to the training grid in effect.

Compliance: April 30, 2005

WHOLE BLOOD—QUALITY CONTROL DEPARTMENT—C.02.015

2. An assistant technician at a mobile clinic shook the purple tubes collected for analysis for several seconds whereas Directive D-CFA-2004-087 and procedure CLI-INS-051v4 state that they must be gently inverted completely 10 times. The supplier insert states that the tubes must be gently inverted at least 10 times and that they must not be shaken vigorously in order to prevent hemolysis.

Response: The employee was met with during the audit to ensure that procedure CLI-INS-051 "*sampling from a bypass pouch"* with respect to directive D-CFA-2004-087 "*Inversion of the new TYCO tubes, purple stoppers"* is respected.

A technical evaluation was conducted on February 9, 2005, and a follow-up with the employee will be performed. The team of supervisors was reminded to inform the affected staff members about the importance of respecting the procedure, take appropriate corrective measures where necessary and inform their managers of their actions.

Compliance: February 28, 2005

WHOLE BLOOD—PRODUCTION CONTROL—C.02.011

3. Following the interruption of thrombapheresis donation 561-4-233375, the label was not crossed out on form SCP-ENR-054 and was not attached to and crossed out on form SCP-ENR-126. A non-conformity report was filled out during the inspection.

Response: Non-conformity report SCP-Q-05-007 was issued during the audit and forms SCP-ENR-054 and SCP-ENR-126 were corrected. There was a meeting with the employee in this regard during the audit and the employee understands the procedures to be followed.

Compliance

WHOLE BLOOD—RAW MATERIALS ANALYSIS—C.02.009

4. During an interview for a plasmapheresis donation, the nurse—contrary to Directive D-CFA-2003-016—omitted to verbally remind the donor to communicate the postdonation information mentioned on card CLI-IND-500 to Héma-Québec.

Response: There was a meeting with the employee following the audit and the employee understands the procedure. In addition, a reminder will be included in the monthly training for the month of February so that Directive D-CFA-2003-016 “Appointment Card (West Nile virus)” is respected.

Compliance: February 28, 2005