HEALTH CANADA INSPECTION OF THE MONTRÉAL FACILITIES NOVEMBER 17–30, 2004

OBSERVATIONS AND RESPONSES

BIOLOGICAL—ANALYSIS OF RAW MATERIALS—C.02.009

1. The answer "yes" in response to question 9b) on Form CLI-ENR-106 v4 (Blood donation file) for Donation No. 0799843 was not documented so as to permit the application of the donor selection criteria for malaria: the nurse documented the place visited by indicating "North Africa" rather than the name of the country, as required by procedure PFN-01-200 v7. A report of non-compliance was completed during the inspection.

Response: The nurses will be surveyed in order to determine if they classify North Africa as a country or not. Action will be taken in keeping with the results obtained.

Compliance: March 2005

BIOLOGICAL—ANALYSIS OF RAW MATERIALS—C.02.009

2. The review and approval by a nurse of the results of the complete blood count that could lead to the prohibition of donors giving platelets by apheresis were not documented in the files of the donors assessed.

Response: Procedure PFN SCP-INS-044 will be amended to ensure and confirm that when a nurse initials the pre-donation blood count form, she certifies the results that could lead to a prohibition have been reviewed and approved.

Compliance: March 2005

BIOLOGICAL—PROCESSING CONTROL—C.02.011

3. The variable granulopheresis indicated on Form SCP-ENR-055 v17 cannot be used to verify the calculation of the "actual" loss of red blood cells for each donation.

Response: A "weight of product" box has been added to the liquid balance section of form SCP-ENR-055 (granulopheresis procedure).

Compliance: March 2005

BIOLOGICAL—PROCESSING CONTROL—C.02.011

4. The corrective measures to be applied by the labelling personnel in order to prevent losses with respect to the traceability of rejected products that are boxed were documented on a memo that was not regulated. This means of communication does not ensure that corrective measures are implemented on a permanent basis or that the personnel is trained in such measures.

Response: The corrective measures implemented to prevent losses with respect to the traceability of rejected products that are boxed during the labelling stage will be incorporated in a directive.

Compliance: February 2005

BIOLOGICAL—PERSONNEL—C.02.006

5. The training form for the store personnel was incomplete and the 2004 recertification for a store clerk had not been completed. However, during the inspection, the training of all store employees was completed and the training form was updated.

Response: Corrected during the inspection.

Compliance: N/A

BIOLOGICAL—EQUIPMENT—C.02.005

6. The technical follow-up with respect to the emergency installation of a new generator (UPS circuit) was not incorporated in a procedure defining the risk analysis to be conducted, the implementation requirements and the validation needs. Directive D-CFA-2004-135 "Assessing Emergency Changes" was implemented during the inspection.

Response: Corrected during the inspection.

Compliance: N/A

BIOLOGICAL—PROCESSING CONTROL—C.02.011

7. There is no work instruction to indicate the response to enter in Field 13 of PROGESA (billing to be kept) when a product is returned (choosing an incorrect response could block the return process in PROGESA). Directive D-CFA-2004-134 on this matter was issued during the inspection.

Response: Corrected during the inspection.

Compliance: N/A

BIOLOGICAL—EQUIPMENT—C.02.005

8. The quarterly preventive maintenance of the EC00085 quick freezer (Section 2, Form SEB-ENR-018) was not done in December 2003 and May 2004.

Response: A reminder will be sent to the employees concerned so as to ensure that the various preventive maintenance actions for this model of equipment are implemented in a timely manner.

A non-compliance (SEB-M-04-021) was initiated in order to document the preventive maintenance omitted.

Compliance: December 31, 2004

BIOLOGICAL—PROCESSING CONTROL—C.02.011

9. Although Form TRA-ENR-024 "Daily Verification of Blood Drive Computer Boxes" was not completed on a systematic basis, the corresponding non-compliances were not issued after the supervisor revised the forms.

Response: Following the observation made during the Health Canada inspection, non-compliances were documented and transmitted to the departments responsible.

Moreover, the equipment supervisor who is responsible for making the final check of this form was given refresher training.

Compliance: December 23, 2004

BIOLOGICAL—EQUIPMENT—C.02.005

10. The semi-annual generator inspection reports do not indicate the identity of the equipment inspected and are not signed by the individual who verifies the results.

Response: A letter will be sent to the supplier indicating that, during the semi-annual inspections of the generators, the identity of the equipment that is inspected must now be indicated on the inspection reports.

Moreover, refresher training was given to the manager of Material Resources with respect to verifying the generator maintenance service reports.

Compliance: December 22, 2004

BIOLOGIQCAL—PROCESSING CONTROL—C.02.011

11. Contrary to PFN INF-INS-070 "Server Status Verification," Form INF-ENR-115, which is to be used to document daily server inspections, was not used.

Response: Following the observation made during the Health Canada inspection, Form INF-ENR-115 has been duly completed by the administrator responsible for the daily inspection of the PROGRESA servers.

A non-compliance (INF-M-04-011) was initiated to document the omission concerning PFN INF-INS-070, namely the failure to use Form INF-ENR-115.

Compliance: N/A