OBSERVATIONS AND ANSWERS

PRODUCTION CONTROL – C.02.012

1. Following the review of recall files, it was noted as documented on form LSC-ENR-002 that there has been a 1 to 3 days delay before the final disposition of the products was done, either in inventory or to be released.

Although the SOP LSC-INS-017 v5 entitled "Recalls of labile products" was indicating at point 6.3.4 to transfer the form LSC-ENR-002 "as soon as possible" to the concerned departments and though the SOP LGP-INS-024 v1 entitled "Inventory of labile products" was indicating at point 6.3 to "move urgently the products from conform area to quarantine area," there was no mechanism present to verify the receipt of the form by the concerned departments.

Answer:

In order to meet the prescribed delays in SOP LCS-INS-017 and LGP-INS-024, a directive (D-CFA-2005-080) was issued describing the control mechanism of a recall.

Compliant: December 7, 2005

ANALYSIS OF RAW MATERIALS – C.02.009

2. On a record of donation (CENVE collection site April 13, 2005, donation # 7 350606), question 5b: "In the past 12 months, have you had a rabies vaccination?" was not answered. A non-conformity report was issued (ASQ-M-05-0108) and the product recall was initiated (RP-M-05-1744).

Former and subsequent donations occurred within a 12-month period around this incident, and the answer "No" was documented each time.

Answer:

A non-conformity report was issued and the product recall was initiated during the inspection. A follow-up was done with the employees.

Compliant

ANALYSIS OF RAW MATERIALS – C.02.009

3. During designated program review of the 2005 files, the selection of a new donor by the personnel (for patient # 1267405, donation # 560 2 403833) on October 17, 2005, was not approved by the medical director.

Answer:

The selection of the new donor was approved by the medical director on December 5, 2005.

Compliant

ANALYSIS OF RAW MATERIALS – C.02.009

4. For plateletpheresis donation (# 560 8 413910) on May 31, 2005, a FSC print was not initialed to assure its verification. A non-conformity report was initiated during the inspection (SCP-M-05-125).

Answer:

A non-conformity report was initiated during the inspection. A monitoring is done to evaluate if this situation is limited. Meanwhile, a follow-up is done with all the employees to sensitize the personnel to this type of error. Three months after this follow-up, a record evaluation will be done to verify the conformity of the files.

Compliant: March 31, 2006

ANALYSIS OF RAW MATERIALS – C.02.009

5. Concerning the training program for the NAT laboratory, the recertification of a technologist for SOP LAB-INS-014 for 2005 was not documented. A non-conformity report was initiated during the inspection.

Moreover, the training grid of this department was erroneously indicating that SOP ASQ-INS-008 was part of the training program.

Answer:

The lab technologist was recertified for SOP LAB-INS-014 on November 3, 2005. After verification, SOP ASQ-INS-008 must be part of the training grid. The technologist was trained on this SOP on November 11, 2005.

Compliant

EQUIPMENT – C.02.005

6. Greasing of the refrigerated centrifuge Mikro 22R (EC00154) from the NAT extraction room was not done on the fifth week of the year 2005 and it was indicated N/A on the form VIR-ENR-084. Even though there was no explanation for this N/A, no non-conformity report was issued.

Answer:

A non-conformity report was documented (TAN-M-05-0332). A follow-up with the personnel will be done.

Compliant: November 25, 2005

PRODUCTION CONTROL – C.02.011

7. Further to the irradiation of 5 platelets, the assistant-technologist had checked the irradiation label of the first unit only, and had documented on the Irradiated Products Log LGP-ENR-001 v11 that all the labels had been verified.

However, another verification of the units irradiated was done on a subsequent process step.

Answer:

First, a reminder on the process was done during a team meeting on October 26, 2005. Moreover, a reminder on SOP LGP-INS-001 Irradiation of blood products will be done with all the employees from the department during the monthly training session of November 2005.

Compliant: December 2005

EQUIPMENT – C.02.005

8. Preventive maintenance documentation relating to 2 COBE 2991 cell washers (EC02683 and EC02684) from the Hospital Service department for spring 2005 was not found. A copy of these documents confirming that the preventive maintenance was done was obtained from the sub-contractor during the inspection.

Answer:

Preventive maintenance documentation for the 2 cell washers was retrieved. These documents were classified in the corresponding files.

Compliant

PRODUCTION CONTROL – C.02.011

9. A red cell concentrate labeled "To be washed" (# 560 8 436186) was found in inventory area L-030. A non-conformity report (LGP-M-05-129) was issued and the red cell concentrate was reforwarded to the Hospital Service department.

Answer:

A reminder to the issuing personnel was done on November 3, 2005 on the process that a red cell concentrate labeled "To be washed" must be forwarded directly to area L-071 at the Hospital Service department.

Compliant