Produits sanguins
Cellules souches
Tissus humains

HÉMA-QUÉBEC

Response to the Observation of the Health Canada Inspection
at Dix-30 Globule Blood Donor Centre
December 7, 2016

OBSERVATION AND RESPONSE

OPERATING PROCEDURES – 95

1) Some operating procedures were not always followed.

During verification of the alarm management, the following oversights were noted:

1. Products stored in shipping room 124 were not transferred on May 24, 2016, even though the temperature was above 24 degrees Celsius for a period of 12 hours, contrary to SPE-00341 v.13 "Temperatures and Timelines for Transferring Products to Storage Areas" requiring products to be transferred when the temperature exceeds 24 degrees Celsius for more than 60 minutes (alarm sheet 18313 and 18303). In addition, there was no documentation to explain the lack of transfer, Quality Assurance was not advised and no event report was made.

2. Event report CDS2-M-16-0092 for the two alarms of August 17 and 18, 2016, in room 124, requiring immediate action, was initiated, and Quality Assurance was advised only on August 19, 2016, contrary to procedure PFN-00384 v.4 "Management of Non-Compliances."

Response:

1) Observations N$^{o.}$3 under point 5) and N$^{o.}$8 under point 5), as well as observation N$^{o.}$1 in the inspection reports for the Place Versailles and the Dix30 GLOBULE Blood Donor Centres, identified shortcomings in the documentation of the alarm sheet (ENR-00398), immediate transfer and timeline for notifying Quality Assurance in the event of non-compliance.

Procedure PFN-00265 "Management of the Central Monitoring System" describes the actions to be taken when an alarm goes off and specifies the responsibilities of the various persons involved and the actions to be performed for the various alarm levels. SPE-00244 "Actions to be taken by the initiator during an alarm" contains the actions to be performed by the various persons involved, and alarm file ENR-00398 is the documentation tool. Following analysis of the process in its entirety, the current process is deemed to be complete and functional.

However, the various observations indicate that the persons responsible for the alarm and the area do not fully understand the procedure. Measures to correct this will begin by focusing on training users to ensure that the steps to be followed are well understood and then on standardizing the way the alarm sheet is to be filled out. For the purposes of this training, SPE-00341 "Temperatures and Timelines for Transferring Products to Storage Areas" will be clarified to make it easier to interpret the alarm parameters and the actions to be taken depending on whether an immediate transfer is necessary or not. This updating of the users in the Processing and Shipping Departments in Montréal, as well as in the Place Versailles and Dix30 GLOBULE Blood Donor Centres will ensure that they understand and comply with the alarm management process in accordance with current procedures.

In compliance : June 30, 2017