Produits sanguins
Cellules souches
Tissus humains

HÉMA-QUÉBEC

Response to the Observations of the Health Canada Inspection
At Versailles Globule Blood Donor Centre
December 7, 2016

OBSERVATIONS AND RESPONSES

OPERATING PROCEDURES – 95

1) Some operating procedures were not always followed.

The reporting department did not comply with procedure PFN-00384 v.4 "Management of Non-Compliances" in the case of the following alarms that required immediate action:

1. Event report CDS3-M-16-0118 for an alarm triggered on refrigerator EC10860 on July 15, 2016, was initiated, and Quality Assurance was advised only on October 6, 2016.

2. Event report CDS2-M-16-0081 for an alarm triggered on refrigerator EC10860 on July 29, 2016, was initiated, and Quality Assurance was advised only on August 6, 2016.

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

Response to the Observations of the Health Canada Inspection
At Versailles Globule Blood Donor Centre
December 7, 2016

RECORDS – 117

2) Records were not always accurate, complete, legible, indelible and/or readily retrievable.

1. During a check of the cleaning forms for the period of March to November 2016, the following oversights were noted:

   a) Several forms were not signed by the head of Material Resources, contrary to procedure PFN-00264 v.5 “Cleaning, Maintenance and Pest Control of Facilities.”

   b) Some tasks during the weeks of April 3 to 9 and April 10 to 16, 2016, as well as cleaning during the week of June 19 to 25, were not documented.

   Quality improvement report CDS2-M-16-0154 was initiated during the inspection.

2. There was no documentation indicating that daily cleaning of the six blood bag agitators used on May 28, 2016, had been done. ***Corrected during the inspection.***

Response :

1) Clarification of this observation: In the case of a permanent centre, the person responsible for approving the forms is the department head and not the head of Material Resources, as stated in section 6.1.2 of procedure PFN-00264.

   According to report CDS2-M-16-0154, issued during the inspection, oversights were corrected and the report was closed.

   To avoid a recurrence of this type of documentation error, training will be developed for the staff responsible for checking the forms. The purpose of this training, which is intended for department managers and employees, will be to ensure that they understand their responsibility for checking the documents and for the information to be entered on them. The focus will be on applying good documentation practices in keeping with procedure PFN-00386 “Correction Methods and General Practices.”

   In compliance : May 31, 2017

2) ***Corrected during the inspection***.