Produits sanguins
Cellules souches
Tissus humains

HÉMA-QUÉBEC

Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 28 – December 8, 2016

OBSERVATIONS AND RESPONSES

OPERATING PROCEDURES – 96

1- Some operating procedures were not kept up-to-date.

Item 6.4.2 of procedure PFN-00191 v.4 "Leukodepletion Method (PCS)" specified that, in the event of rapid leukodepletion, the blood must be sent to QC for a residual count. However, the procedure did not contain any description for recognizing rapid leukodepletion. In addition, the three employees interviewed could not explain how to recognize rapid leukodepletion.

Response:

The supplier will be consulted to confirm how rapid filtration can be detected. Procedure PFN-00191 will be amended in accordance with the supplier's recommendations. It should be noted that the results of the monthly quality control tests show that the leukocyte reduction procedure is compliant.

In compliance: March 27, 2017

QUALITY MANAGEMENT SYSTEM – 94

2- Obsolete or previous versions of quality documents were not removed and archived.

For example:

1) On May 17, 2016, version 5 of form ENR-00004 "Event Report" was used by the Warehouse Receiving Department instead of version 7, which had been implemented on March 16, 2016. It was determined, however, that no modification had been made between versions 5 and 7 of this form.

2) Version 2 of SPE-00111 "LAB – Acceptable Sample Volume" was found in the NAT laboratory's work specifications binder, while the current version was version 4. Event report DEV-PRB-02104 was issued during the inspection.

3) Version 7 of SPE-00158 was available to the Shipping Department, while the current version was version 8. Report NC EXP-M-16-0139 was initiated during the inspection.

Response:

1) The department saved and reused an outdated digital version of the form instead of using the current version in SmartSolve. The outdated version was deleted, and a reminder was issued to employees about the importance of retrieving forms (controlled documents) from SmartSolve.

In addition, all paper documents available to the Warehouse Receiving Department were checked to ensure that the versions in circulation are current.

In compliance : January 20, 2017

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2) Event report DEV-PRB-02104 confirms that the differences between the outdated version of SPE-00111 found in the laboratory and the current version are minor and had no impact on the NAT laboratory. The outdated version was removed from the laboratory.

In addition, all documents available to the laboratory were thoroughly checked to ensure that only current documents are in circulation.

A reminder was issued to the various product qualification managers about the importance of ensuring that all documents on the distribution list are found during removal.

In compliance : January 30, 2017

3) NC EXP-M-16-0139 was initiated during the inspection, and the outdated document was replaced with the current version. In the event of failure to comply with the quantities required by SPE-00158 “Products Used Monthly for Quality Control,” a non-compliance notice is issued by the Quality Control Department.

In addition, all paper copies available to the Shipping Department were checked to ensure that the versions in circulation are current. An assessment is also under way by the managers to determine the number of paper copies required by the laboratory, as well as the places where these documents must be accessible. Following this assessment, these locations will be clearly identified in the laboratory and the staff will be informed.

In compliance : February 28, 2017

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OPERATING PROCEDURES – 95

3- Some operating procedures were not always followed.

For example:

1) Procedure PFN-00384 v.3 “Management of Non-Compliances” requires that corrective measures associated with the event report be developed. Report SDP3-M-16-0001 was deemed to be incomplete in this respect. No assessment was done to determine whether the problem identified with two PCS2 devices had any impact on the other PCS2 apheresis devices in use.

2) The initial receipt of master batch 136205 (WNV controls) was checked off and released as a subsequent receipt, i.e. without checking or appending the certificate of analysis and reagent manufacturer’s insert, contrary to procedure PFN-00388 v.4 “Inspection and Release of Critical Material.” Event report DEV-PRB-02119 was issued during the inspection.

3) Contrary to procedure PFN-00649 v.3 “Controlled Equipment Management System in SAP-PM,” work orders containing equipment maintenance for Maco-Press EC07911 and scale EC07688 were not found on file. However, this maintenance work was found in the SAP-PM database and had been carried out.

4) The instruments used during the preventive maintenance on BacT/ALERT systems on November 8, 2016, and their series numbers were not entered on the maintenance report, contrary to ENR-02166 v.0 “LAB – Instruction Guide for bioMérieux Preventive Maintenance.” Event report DEV-PRB-02098 was issued during the inspection.

5) Products stored in the L011 cold chamber were not transferred on July 8, 2016 (files 19851 and 19852), even though the temperature had exceeded 7 degrees Celsius, contrary to SPE-00341 v.13 “Temperatures and Timelines for Transferring Products to Storage Areas,” which requires immediate transfer when the temperate rises above 7 degrees Celsius. In addition, there was no documentation explaining the lack of transfer, Quality Assurance was not advise and no event report was made. Event report PCS-M-16-1825 was issued during the inspection.

Response:

1) Since the event, verification steps have been added to procedure PFN-00887 [1] “Plasmavie – Plasma Donation for Fractionation,” in effect since 11-27-2016. Sections 6.2 and 6.16 require that the configuration of devices be checked upon return from the Biomedical Equipment Department before being used (including initial use of the device).

   No event report of this type was made. Nevertheless, an impact analysis on other devices and a comprehensive root-cause analysis of the event are under way and will be attached to report SDP3-M-16-0001.

In addition, a meeting will be held with the staff responsible for approving event reports (department managers and Quality Control specialists) to clarify the checkpoints and possible impacts.

In compliance : February 28, 2017

2) The supplier confirmed that master batch 136205 (WNV controls) was received only once by Héma-Québec (initial delivery). In the case of this receipt, the correction of the form and the required verification for an initial delivery were done (certificate of analysis and manufacturer's insert). The impact analysis was appended to event report NC DEV-PRB-02119.

   In addition, the delivery process was reviewed for the entire product qualification laboratory. The various delivery forms were amended to add the mention "Attach a copy of the initial receipt" for subsequent deliveries (forms: ENR-01722, ENR-01724, ENR-01723, ENR-01725, ENR-01726, ENR-01785, ENR-01786, ENR-01788, ENR-01789, ENR-01787, ENR-01791, ENR-01790 and ENR-01727).

   In compliance : February 13, 2017

3) The procedure for filing hard copies of work orders will be revised to ensure that a hard copy proof of work orders is placed in the equipment file. Employees will be notified of the procedure and new practices will be implemented.

   In compliance : May 31, 2017

4) The bioMérieux support technician received confirmation of the series numbers of the multimeter and thermometer used during the preventive maintenance of 11-08-2016. The numbers were matched with the available calibration certificates, and this information was appended to the preventive maintenance record as described in event report DEV-PRB-02098. The employee responsible was made aware of this during the drafting of the event report.

   In addition, there will be a follow-up with the supplier during the bioMérieux technical meeting.

   In compliance : February 14, 2017

5) 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

OPERATING PROCEDURES – 96

4- Some operating procedures were not kept up-to-date.

Procedure PFN-00204 v.5 "Sampling of Platelet Products for Bacterial Culture" failed to mention when in the sampling process the time must be entered (before or after the first or second sample bottle).

Response:

Upon checking with several employees, it was confirmed that the sampling time was entered during the first sampling.

Procedure PFN-00204 will be amended to include the step "enter the sampling time on the workbench sheet" after the first sampling. This clarification will improve the linearity of the process.

In compliance: May 8, 2017

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PERSONNEL – 98

5- The records of staff qualifications, training or evaluation of their competency were not sufficient.

During the review of the training files, the following oversights were noted:

a) There was no documentation indicating that employee 62646 had completed PER-01624 prior to the date of implementation, November 27, 2016.

b) There was no documentation indicating that employees 63286 and 62586 had been trained on procedure PFN-00631 v.8 prior to the date of implementation, November 27, 2016.

Quality improvement report SCH-M-16-0735 was initiated during the inspection.

Response:

Reminders were sent by the Regulatory Training Department and the department manager to employees cited in the observation for points a) and b) prior to implementation of the documents. The impact analysis conducted as part of report SCH-M-16-0735 confirms that amendments to the documents were minor and the missing training had no impact on the safety, traceability or quality of the products. These employees' training files are now compliant.

Meetings were held with the employees to remind them of their responsibility to follow procedure PFN-00559 "Regulatory Training Procedure: Roles and Responsibilities."

In compliance : December 5, 2016

INVESTIGATION AND REPORTING OF ADVERSE RECIPIENT REACTIONS – 113

6- The establishment conducting an investigation into an unexpected or serious adverse reaction did not notify Health Canada within 15 days after it learned of the adverse recipient reaction.

For example:

Adverse reaction reports EPT-PRB-00116 and EPT-PRB-00183 had not been declared to Health Canada.

Response:

Specification SPE-01039 "Mandatory Declarations for Blood Components" will be amended to state, within the prescribed timelines, that serious adverse reactions in recipients during the preliminary investigation suggest that the adverse reaction is due to a positive donor.

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A review was conducted of investigations done since the Blood Regulations came into effect, and the two incidents that had been included in the annual report (EPT-PRB-00116 and 00183) were declared to Health Canada.

In compliance March 26, 2017

INVESTIGATION AND REPORTING OF ADVERSE RECIPIENT REACTIONS – 114

7- The establishment did not provide the results of the investigation into an adverse recipient reaction and any required action to the affected establishments.

For example:

Adverse reaction report RP-PRB-5223 was not followed up with the hospital that had notified Héma-Québec, i.e. Section IV Follow-ups of "Adverse reaction/Serious adverse reaction" of form ENR-00513 "Communication to the Blood Bank – Withdrawal of Labile Blood Products," indicating that the findings of the investigation had not been completed or sent to the facility.

Response:

The product withdrawal or transfusion reaction procedure does not clearly specify that a follow-up is required with the client when the findings of Héma-Québec's investigation are similar to those of the client.

To comply with the regulation, SPE-00179 "Actions to be taken for product withdrawal, adverse reaction, serious adverse reaction" will be amended" to specify that Héma-Québec must always notify the client of the findings of the investigation carried out by Héma-Québec.

In compliance : June 11, -2017

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RECORDS – 117

8- Records were not always accurate, complete, legible, indelible and/or readily retrievable.

For example:

1) The number of the heat sealer was not entered on the workbench sheet of November 8, 2016 for T4 packed red blood cells, and this omission was not discovered when the document was checked. Event report PCS-M-16-1801 was issued during the inspection.
Corrected during the inspection.

2) Maco-Press EC07911 was identified as EC07915 on the calibration label. Event report PCS-M-16-1805 was issued during the inspection. ***Corrected during the inspection.***

3) There was no documentation indicating that the daily cleaning of mobile unit N°2 on April 7, 2016, and the daily and weekly cleaning of mobile unit N°2 on April 28, 2016, had been done. Event report DEV-PRB-02100 was issued during the inspection.

4) There was no documentation indicating that the weekly visual inspection of the "Alarm on" indicator light on the control panel of generator N°3 for the week of August 7, 2016 (ENR-00695 "Weekly Visual Inspection of Generators"), and the "Alarm on" indicator light for UPS N°1 for the weeks of July 24 and 31, 2016, all the weeks of August 2016 and the weeks of September 4 and 18, 2016 (ENR-00692 "Weekly Visual Inspection of the SASC"), had been done. This was not discovered during verification of these forms by the Material Resources Department. Event report DEV-PRB-02114 was issued during the inspection.

5) There was no documentation indicating the duration of the alarm on alarm sheet LAB-ENR-007 n°s 19812 and 19816. Quality improvement report EXP-M-16-0134 was initiated. In addition, alarm sheet n° 19825 included an error in the duration of the alarm. It stated 3 hours and 42 minutes, whereas the actual duration of the alarm was 4 hours and 42 minutes. This had not been noted during the verification of the documents. Quality improvement report EXP-M-16-0138 was initiated.

Response :

1) **Corrected during the inspection**
2) **Corrected during the inspection**
3) According to event report DEV-PRB-02100, the oversights were corrected and employees were made aware of them. This event report indicated that there was no impact on the cleanliness of the mobile units, and the report is 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 infrastructure department managers and employees, will be to ensure that they understand their responsibility for checking the contents and information to be entered on the forms. 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

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4) Regarding information oversights for UPS N$^{o.}$1, the column on the form requires that a yes or no be entered regarding verification of the alarm indicator; however, employees interpreted the entry "N/A" as meaning that there had been no alarm. A check of all 2016 forms confirms that all the other forms were properly filled out. The persons responsible (security guard) for entering the information on the form were made aware of the issue through event report DEV-PRB-02114. The report confirmed that there was no impact and has been 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 contents and information to be entered on the forms. 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

5) Quality improvement report EXP-M-16-0138 is closed. Observations N$^{o.}$3 under point 5) and N$^{o.}$8 under point 5), as well as observation N$^{o.}$1 of the inspection reports for the Place Versailles and Dix30 GLOBULE Blood Donor Centres, showed oversights 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 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 sheet 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 the 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 various 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