Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 30–December 9, 2015

OBSERVATIONS AND RESPONSES

PERSONNEL – 98

1- During verification of the training program, discrepancies were found in the mechanism to ensure that all employees concerned are trained on controlled documents prior to the performance of their duties. For example:

1) The following discrepancies were observed in the training files of four nurses and seven assistant technicians working on mobile blood drives (in the Québec City and Montréal regions), at the Laval Globule Blood Donor Centre and at Donor Services (DS):

a) There was no documentation indicating that blood collection nurse no. 64073 had read DIR-00687(0) "Verification of Deferral Codes Applicable to Malaria," which was due to be read by August 10, 2015.

b) There was no documentation indicating that DS technician no. 63117 had taken initial training INI-00157 and INI-00520, due March 15 and August 19, 2015. The training included, among other things, learning eProgesa, handling complaints, conducting information searches in response to donor questions, editing similar names and verifying Code 9030 (donors who have travelled). Event report DEV-PRB-00989 was issued during the inspection.

c) There was no documentation indicating that DS technician no. 63702 had taken recertification training REC-00128 due February 28, 2015. However, it was subsequently shown that this recertification was part of a one-year moratorium and that the employee had mistakenly been omitted from the moratorium by the training team.

d) There was no documentation indicating that blood collection nurse no. 63419 had read SOP-00614(6) "Use and Maintenance of the Beckman/Coulter Ac-T 5 Diff CP Hematology Analyzer" due November 6, 2015, SPE-00620(4) "Reference Guide for the Collection of Products on the TRIMA Accel v6 Device" due November 9, 2015, and SPE-00997(0) "Visual Inspection During Whole Blood Collection" due November 9, 2015.

2) Discrepancies were also observed in periodic training (training on changes made to controlled documents) in November 2015, during which time more than 400 amended documents should have been read. For example: no signatures confirming periodic training were found in the Smart Train database for six of the 11 employees verified and mentioned in point 1). In addition, during the December 3, 2015, inspection of the MPFMV mobile blood drive, prior to the start, one employee was found to not have taken periodic training that went into effect on November 30, 2015. This employee did her periodic training on site during the blood drive. Since this employee had worked on the December 1 mobile blood drive, an event report COL-M-15-1763 was issued during the December 3, 2015 blood drive.

Response to the Observations of the Health Canada Inspection at the Montréal Facility November 30–December 9, 2015

Response:

1)

a)
Indeed, employee #64073 never read directive DIR-00687 from the time of issuing on August 10, 2015 to removal on November 24, 2015. Had the contents of the directive not been followed, a non-compliance report would have been issued by the Donor Services (DS). A verification of non-compliances pertaining to this employee found nothing during this period. We can conclude, therefore, that this lack of training had no impact. Since this directive is no longer in effect and the incident had no impact, no plan of action is necessary.

In compliance

b)
Because we had no documentary proof that the person had been trained, a Donor Services (DS) consultant (trainer) and the DS supervisor (trainer) assessed the employee's competency, filled in and signed the scorecard attesting to the employee's ability to do the work. SmartTrain was updated accordingly on December 3, 2015. The impact analysis contained as part of the event report indicated that the impact was limited to the non-compliance of the training file.

In compliance: December 3, 2015

c)
The file was amended on December 15, 2015 and recertification training REC-00128 was signed in compliance with exemption DEV-PRB-00229 (moratorium) requested in this case.

In compliance: December 15, 2015

d)
Indeed, employee no. 63419 did not take the periodic training dealing with all these documents. The employee worked from November 6 to 11, at which time he went on extended leave. An impact analysis carried out by Quality Assurance confirmed that changes in the documents concerned had no impact on the products. The employee will be trained upon his return.

In compliance: upon the employee's return to work

2)
In order to reduce delays, Supply Services trainers were given access to the training management system to sign the courses and certify that staff complied with training requirements.

In compliance: January 25, 2016

Work is under way to give blood drive staff access to sign their documents directly in the training management system, regardless of their location.

Finally, at the time of the audit, a Kaisen (tool for continuous improvement) was currently being used to find long-term solutions to the problems observed during the inspection. This process will be completed in May 2016 and an implementation plan will be developed.

In compliance: May 31, 2016

Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 30–December 9, 2015

EQUIPMENT – 100

REPEAT OBSERVATION

2- The following discrepancies were observed during verification of forms ENR-01566(4) "Monitoring of Controlled Equipment" for four mobile drives: MLODE, on October 2, 2015, MPICC, on September 21, 2015, MJOPO, on October 1, 2015, and MMLLA, on October 5, 2015:

a) There was no documentation indicating that maintenance or cleaning had been performed on 16 pieces of equipment;

b) Documentation entered on these forms made it impossible to know whether 39 pieces of equipment had been used or not and whether maintenance and/or checks had been performed on these equipments.

These errors were not identified during the weekly review of forms.

Response:

A memo will be sent to blood drive employees stressing the importance of properly filling out form ENR-01566 "Monitoring of Controlled Equipment" when:

- Equipment has been used and cleaning or maintenance has been performed.
- Equipment was not used: enter N/A in the appropriate box.

To ensure follow-up by managers, the memo will also be distributed to mobile blood drive supervisors in Montréal during a coordination meeting.

In compliance: February 29, 2016

Form ENR-01566 will be amended to add a check point by a person in charge to ensure that the form is filled in properly once the blood drive is over.

Procedure SOP-00366 "Follow-up of Controlled Equipment Used in Blood Drive" will be modified to add a check point:

- Once blood drive equipment is returned, ensure that ENR-01566 is filled in properly before filing it.

In compliance: April 4, 2016

Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 30–December 9, 2015

A complete review of the monitoring procedure for controlled blood drive equipment will be performed and an action plan put forward to ensure the traceability and compliance of the equipment used in blood drive as described in the blood regulations.

In compliance: April 30, 2016

OPERATING PROCEDURES – 95

REPEATED OBSERVATION

3- During verification of 7 exemption reports, 3 were found to have been classified as exemptions instead of as non-compliances. These errors were not identified by Quality Assurance.

Response:

All exemptions made in 2015 will be reviewed to ensure that they were properly classified. Where necessary, the classification will be corrected on the non-compliance and in the database.

The concept of exemption will be reviewed by QA specialists (for blood products). During this meeting, all cases of misclassified exemptions made in 2015 will be reviewed.

In compliance: February 26, 2016

OPERATING PROCEDURES – 95

4- During verification of event report RMT-M-15-004 detailing a failure in monitoring the BAS system temperature, which occurred on June 2, 2015, it was noted that corrective measures were taken on June 2 whereas the initiation of the event and the verbal approval of Quality Assurance (QA) occurred only on June 12, 2015, contrary to SOP-00384(2) "Management of Non-Compliances," which states that QA's approval must be requested before applying the remedy. As well, QA only reviewed the closing report on December 4, 2015, during the inspection.

Response:

In collaboration with Regulatory Training and Quality Assurance, Training on non-compliance process (SOP-00384) will be developed to meet the needs of the Infrastructure Service. This training will be given by Quality Assurance as stated in the Regulatory Training 2016-103 request form.

In compliance: April 15, 2016

Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 30–December 9, 2015

A presentation will be included as part of corrective action CAPA-15-002 "Cycle Time of Non-Compliances." This presentation will focus on the importance of actions and documentation in each section of the event report.

In compliance: April 15, 2016

A report will be issued monthly to measure the cycle time of the following steps of an event:

- Date of detection of the event vs. date of approval of remedies by Quality Assurance.
- Average by service: date of receipt by QA vs. date of closure by QA.

This report will be presented as part of corrective action CAPA-15-002, and quarterly results will be presented to management.

Analysis of this report will enable Quality Assurance to ensure follow-up with services and specialists assigned to review non-compliances and obtain more up-to-date trend analyses. This process will be used until the overhaul of the non-compliance process (project schedule being developed).

In compliance: March 31, 2016 (first report)

OPERATING PROCEDURES – 96

5- The procedure for exceptional distribution SOP-00179(2) "Emergency Distribution of Labile Blood Products" does not specify that form ENR-00533 "Request and Release of Products with Incomplete Analyses" and the "Distribution Order" (containing the date and time of distribution) make up the notice of exceptional distribution.

Response:

In order for all the information on the notice of exceptional distribution to be included on form ENR-00533, a section will be added to enter the date and time of distribution of the products by the Shipping Service.

In compliance: June 27, 2016

Response to the Observations of the Health Canada Inspection
at the Montréal Facility
November 30–December 9, 2015

EQUIPMENT – 100

6- The following discrepancies were observed during verification of equipment maintenance:

a) There was no documentation indicating that daily maintenance of thermal sealers EC05501 and EC05498 had been performed on September 5, 2015. Event report PCS-M-15-1786 was issued during the inspection.

b) The work order for monthly maintenance of the central water system for January 2015 was missing. As well, the closing date of this maintenance in the SAP-PM system did not correspond to the date on which the maintenance was performed.

Response:

a) Quality improvement report PCS-M-15-1786 confirms that daily maintenance was performed the next day (September 6, 2015). During the next service meeting, a reminder will be issued to personnel.

b) The work order for monthly maintenance of the central water system for January 2015 was not performed by the SEB technician. As well, the closing date of this maintenance in the SAP-PM system did not correspond to the date on which the work was performed because of an entry error in the system. Since maintenance consists of taking pressure readings, these discrepancies had no impact on the equipment. In the event that the system is no longer compliant, no water would be supplied and users would notify the SEB. Following inspection, maintenance was performed on January 29, 2016.

A change request was initiated to amend the frequency in the maintenance plan for the central water system. Maintenance of the central water system will thus be done weekly instead of monthly and, since there will be only one work order, closing dates of the maintenance in the SAP-PM system will no longer be staggered.

In compliance: a) February 29, 2016
b) May 17, 2016

RECORDS – 117

7- There was no documentation indicating that the review of three bench orders for the "Preparation of Blood Components" for December 2, 2015, had been carried out. Nevertheless, electronic signatures for the review were found in eProgesa. Event report PCS-M-15-1781 was issued during the inspection.

Response:

Following event report PCS-M-15-1781 issued during the inspection, the three bench orders were corrected. A verification (sampling) of the bench orders of January 22, 28, 29, 30 and 31, 2015 was performed. No initials or checkmarks were missing on more than 400 bench orders. During the next

service meeting, staff will be reminded about the importance of complying with the steps set out in SOP-00199 “Verification of Preparatory Documents of Blood Components.”

In addition, a new verification tool for documents used for the preparation of blood components will go into effect in April 2016 (SPE-01043). The purpose of this tool will be to facilitate the verification of the various data on the bench work orders.

In compliance: April 29, 2016