HÉMA-QUÉBEC

Blood Products
Stem Cells
Human Tissues

Response to the observation of Health Canada Inspection
at the Quebec City Facility
June 13 to June 16, 2017

OBSERVATIONS AND RESPONSES

OPERATING PROCEDURES – SECTION 95

1) Some operating procedures were not always followed.

   When verifying the events documented on paper, it was observed that the following 5 events had a delay of more than 20 calendar days between detection and receipt by the Quality Assurance department, which is contrary to PFN-00384v4 “Management of non-compliances”.

   ASQ-Q-16-0032: 26/08/2016 to 15/11/2016
   ASQ-Q-16-0043: 10/11/2016 to 04/01/2017
   LCQ-Q-16-0335: 11/10/2016 to 08/02/2017
   LCQ-Q-16-0321: 24/09/2016 to 20/03/2017
   LCQ-Q-16-0302: 06/09/2016 to 17/10/2016

Response: (AEX-1340-EXP)

Given the paper documentation of these event reports, the sole objective of the 20-calendar day period was to limit handling time. Despite this time frame not being respected, these non-compliances were reported and their handling had been pre-approved by Quality Assurance prior to their execution as required by PFN-00384 “Management of non-compliances”. In addition, the register listing the numbers of paper non-compliances (ENR-00009) reported by the departments is sent monthly to Quality Assurance, allowing for follow-up.

A new computerized non-compliance management process will be implemented and used by all departments for the reporting of non-compliant events. Consequently, the 20-day period will no longer be necessary.

In compliance: November 30, 2017

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EQUIPMENT – SECTION 100

2) The validation, calibration, cleaning, or maintenance of critical equipment were not sufficient.

When calibrating the EC05203 calibration chronometer on August 29, 2016 the read-out value of 34 seconds for the time tolerance was not documented in the appropriate section, i.e., the value was documented in the 3- to 30-second section instead of the 31 seconds or more section. Therefore, the appropriate corrective measure was not taken, i.e., the chronometer was calibrated instead of being repaired. The NC DEV-PRB-02745 was initiated during the audit.

Response: (AEX-1341-EXP)

The time tolerance of the calibration chronometer was greater than 4 seconds during calibration on August 29, 2016. The impact analysis of the non-compliance DEV-PRB-02745 demonstrated that none of the equipment calibrated during the at-risk period (August 29, 2016 to October 25, 2016) was non-compliant. Note that this chronometer is calibrated every 2 months. The non-compliance was closed on July 12, 2017.

The root cause analysis has shown that this was an error of inattention. The employees in question were met with to ensure an understanding of the process. A random check of the work orders completed by these employees (51 work orders or ENR-00871 action forms) showed that this was a one-time error.

Following verification of the EC05203 calibration chronometer record, this device was withdrawn because an upward trend was noted in the values read during calibrations.

A follow-up will be conducted with all technicians in the Québec City Biomedical Equipment department regarding the importance of verifying the tolerance deviations, the trends in the values read and the elements to be cross-checked on the work order.

In compliance: September 30, 2017

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INVESTIGATION AND REPORTING – SECTION 108

3) The annual report summarizing all error and accident investigations the establishment conducted in the past 12 months was incomplete.

The accident/error report "PAP-Q-16-0017" was not included in the October 2016 accident/error report (used to create the annual report).

Response: (AEX-1342-EXP)

At the time of the Quality Assurance closing review of the non-compliance PAP-Q-16-0017, the event was considered an accident/error to be reported to Health Canada, and the non-compliance was documented accordingly. The error occurred during the entry of this paper non-compliance in the database by the support staff. The employee in question forgot to check the appropriate box. This database is used to extract accidents and errors to be reported in order to issue the annual report.

For the years 2016 and 2017, a comparative analysis of the database and paper non-compliances identified as accidents/errors will be carried out. An amended report of the targeted years will be issued. In addition, an instruction has been put in place to ensure that any non-compliance classified as an accident/error is transcribed in the database.

In compliance: August 31, 2017

A new IT process for non-compliance management will be implemented whereby Quality Assurance will directly enter accidents/errors to be reported to Health Canada in the system, thus eliminating transcription errors.

In compliance: November 30, 2017

**Response to the observation of Health Canada Inspection
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RECORDS – SECTION 117

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

Section 3 “Verification of time limits during analysis” of form ENR-00467v4 “Release of labile blood product test results” dated June 1st, 2017 had not been documented as being compliant or non-compliant. The NC DEV-PRB-02741 was initiated during the audit.

Response: (AEX-1343-EXP)

The error was documented on the NC DEV-PRB-02741 initiated during the audit. Although the box “Verification of time limits during analysis” was not checked off on form ENR-00467, a verification of the analysis times in question shows that all were respected.

This oversight has no impact on the results issued by the laboratory. All the non-compliances action plans have been completed. In addition, a follow-up was conducted with the staff in question: the error was corrected by the employee when the NC was reported.

In compliance: November 28, 2017