Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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blood.ca

2024-01-02
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Wei Zhang
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
2301 Midland Avenue
Toronto, Ontario M1P 4R7

Dear Wei:

Re: Responses to Health Canada Inspection of Licensed Activities at Head Office 2023-10-17 to 2023-10-20

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-12-01.

Section 107 – Investigation and Reporting

1. **The establishment conducting an investigation into a suspected error or accident that happened during an activity it conducted and that was identified after the blood was distributed or transfused did not report to Health Canada as required.**

   Even when all three criteria - 1. error/accident (E/A) occurred during the regulated activity; 2. the blood was distributed to the hospital for transfusion; and 3. there is a reasonable probability that the error or accident could cause a serious adverse reaction had the blood or blood components been transfused, with respect to reportability were met, the establishment did not report some E/As to Health Canada, as required in section 107. Some examples of such E/As are as follows:

   (1) Dev-21-007906: RBC unit was labeled as E- on the end label. Testing at the hospital revealed that the unit tested as E+.

   (2) Dev-21-001389: RBC unit A Pos phenotype as E- neg on label and progesa. Upon phenotyping at the hospital discovered that unit was E Pos (4+).

   Note that these examples are a very limited representation of what was seen during the inspection, as there were also other examples of E/As that could meet potentially the reporting criteria under section 107.

   Even prior to the Health Canada Blood regulations coming into force in 2014 the specific type of errors noted in this observation did not fall into the category of reasonable probability of causing a serious adverse reaction; hence they were reported as part of the regulatory reporting updates as per the blood establishments annex to their licences.

   While phenotype discrepancies may cause fever and hemolysis, there is no reasonable

probability that the reaction would be a serious reaction as defined by the regulations.

As discussed at the BILAT meeting between the Blood Operators and Health Canada on 2023-12-12, a working group will be convened to discuss Health Canada's change in the interpretation of reporting requirements. Canadian Blood Services will continue to report these types of errors as part of our annual reporting.

Section 108 - Investigation and Reporting

2. **The establishment did not prepare an annual report summarizing all error and accident investigations it conducted in the past 12 months. For example, CBS' s E/As Annual Report (at least last four years) only contains EAs discovered after distribution and as per section 108, it must contain all EAs even those discovered before distribution.**

   We will include deviations for products not distributed in our annual report. However, as mentioned at the BILAT meeting between the Blood Operators and Health Canada on 2023-12-12, we continue to question the value of including this information. This is not required of drug manufacturers or medical device manufacturers under the Food and Drugs Regulations or the Medical Devices Regulations and represents undue regulatory burden on the part of Blood Operators. This was raised during stakeholder consultation of the new blood regulations. At that time, we were assured that there would be no additional regulatory reporting requirements with the introduction of the new blood regulations and to this date it had been largely the case. Unfortunately, this change in Health Canada's enforcement discretion will require additional efforts by Canadian Blood Services and Health Canada for little to no benefits to the blood system.

Section 95 - Operating Procedures

3. **Some operating procedures were not always followed. Contrary to Work Instruction Temporary Building Access Control (WI-00661, Rev #2) stated that facilities operation upon being notified of any unreturned access card(s) deactivated access card by 10 am the next business day if access card is not returned, the access card E117 was not returned between August 2-8, 2023, but the access card was not deactivated by facilities operation.**

   MQE-23-004330 was initiated on 2023-12-12.

   F800482 (Legacy # F800086) Temporary Card Audit Log and F800604 (Legacy # F800363) Temporary Access Card Log had not been completed as required by WI-00661 Temporary Building Access Control. The employee card was issued on 2023-08-02, deactivated at 11h00 on 2023-08-03, and not reissued until 2023-08-09. The card was deactivated 1 hour past the allocated time.

   Staff involved were reminded of the importance of following WI-00661 Temporary Building Access Control on 2023-12-20.

Section 96 - Operating Procedures

4. **Some operating procedures were not kept up-to-date. For example,**
   (1) CBS's Work Instructions did not include "unexpected adverse reaction", including

its definition, investigation and reporting requirement under the Blood Regulations.

(2) No documented instructions were developed to address how to submit adverse donor reactions to Health Canada.

The reporting and investigation requirements for unexpected adverse reactions are the same requirements as serious adverse reactions which are described in WIs 00487 Reporting to Regulatory Authorities and 00504 Managing Reports of Adverse Reactions. WI-00487 which includes the definition of serious adverse reactions will be revised to include the definition of unexpected adverse reactions.

In addition, the revision of WI-00487 will include instructions to submit donor adverse reaction reports as per section 109(3) of the Health Canada Guidance document: Blood Regulations.

The revisions will be completed by 2024-06-30.

Section 98 - Personnel

5. **The records of staff qualifications, training or evaluation of their competency were not always sufficient. For example, six employee training records were reviewed, two of them did not complete all required training items prior to corresponding due dates. The two employees took immediately actions to complete the missing items, so the observation was considered resolved during the inspection.**

   With regards to the six employee records reviewed at the time of the audit, it was confirmed during the audit that the employees had not performed the associated tasks in an "untrained" state and consequently, there was no compliance issue. The "due date" listed in the SuccessFactors learning management system is the date on which the change to which the training is associated becomes effective. The "due date" terminology is standard SAP terminology.

   As outlined in work instruction WI-00547, Training Management - Manager, it is anticipated that training might not be completed by this date (i.e., "ensure employees are trained prior to task performance or the implementation of new or revised procedures"). This is in recognition that (1) some employees might be away from the workplace and therefore unable to complete the training prior to its effective date, (2) new employees might be hired after the training effective date, and (3) some employees might not be required to perform the associated tasks for some time following the effective date and for better training retention, it is decided to defer the training until closer to the actual date of performance.

   Section 98 of the Blood Regulations states that "An establishment must have sufficient personnel, who must be qualified by their education, training or experience to perform their respective tasks, to conduct the establishment's activities. This is further described in Health Canada's Guidance document: Blood regulations, as "training must be provided prior to the initiation of job duties or performing the tasks outlined in a new procedure or any revision of an existing procedure." In addition, the documentation requirements outlined are as follows: "training must be documented and include the following: the date(s) on which the training was conducted and/or completed; the mode of training; and identification of the trainer(s) and trainee(s)."

   Documenting the reason training was completed after the effective date provides no control in ensuring that tasks are only performed in a trained state (note: in the event that an

employee performed tasks prior to the completion of training, as per work instruction WI-00547, a quality event and corrective actions are to be initiated). As per section 6 of work instruction WI-00547, managers and/or their delegates are required to regularly monitor training to ensure that task performance does not occur prior to training completion. Additionally, an annual review of training is to be conducted to ensure that tasks are not or have not been performed prior to training completion. Canadian Blood Services believes that this provides sufficient control and meets the requirements of the blood regulations.

Section 117 - Records

6. **Records were not always accurate, complete, legible, indelible and/or readily retrievable. For example,**
   (1) New access cards were activated for new hires BB and TQ, effective date 2023-05-03 and 2023-01-03 respectively, but access card number, recipient signature and date were not documented on the Security Access Form.

   (2) No initial and/or time were documented for access card ID V002 on 2023-06-14, C165 on 2023-05-03, and C160 on 2023-04-01 on the respective Temporary Card Audit Logs.

   Staff involved were reminded of the importance of completing the forms as per WI-00661 Temporary Building Access Control on 2023-12-20.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please reference the above CBS control number in any correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President