



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

2021-02-24

CBS Control #: CBS6482

HPFB File #: C1892-100390

REF: H-2021-NCC

Inessa Belyavsky
Regional Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada

Dear Ms. Belyavsky:

**Re: Responses to Health Canada Inspection of National Contact Centre
from 2021-01-19 to 2021-01-26**

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2021-02-15.

Section 95 - Operating Procedures

1. **Two Work Instructions were not followed upon the creation of electronic Post Donation Record (ePDI) 20-034338 and upon review of ePDI 20-034428 entries in EtQ and eProgesa for Donor ID 4991886. Specifically:**

a. Contrary to WI 16 009 Rev 1 Appointment Management at the National Contact Centre, Section 2, Step 8 "Disposition the interaction accordingly in Appointment Management Solution", disposition was not performed for ePDI 20-034338. This ePDI was created by the NCC Customer Services Representative (CSR) who contacted Donor ID 4991886 on Dec 14, 2020 and was informed by the donor of a current pregnancy; a corresponding deferral period was applied in eProgesa. Since the interaction disposition step was not performed, a second ePDI 20-034428 was created on Dec 15, 2020 when another CSR contacted the same donor for recruitment. This resulted in multiple active deferrals entered in eProgesa.

b. Contrary to WI 16 018 Rev 1 Execution of Task Delegations in Information Nurse Services, Section 8, Step 4 "Make corrections or additions...and escalating as per applicable Reaction Scheme as appropriate", escalation was not performed by the Information Nurse Services RN who reviewed ePDI 20-034428. This resulted in the nonresolution of active discrepant deferrals reflected in eProgesa. An investigation was initiated as a result of this observation during the inspection as per Quality Event MQE 21-000214 related to staff retraining.

MQE 21-000214 was initiated on 2021-01-19. A duplicate deferral was removed from eProgesa on 2021-01-19. The donor was, and still is, appropriately deferred in the system.

The Customer Service Representatives involved were retrained by 2021-02-17 to ensure the interaction disposition is consistently completed as per work instruction 16 009 Appointment Management.

The Registered Nurse involved was retrained on 2021-02-16 to ensure escalation is consistently performed as per work instruction 16 018 Execution of Task Delegations.

All site staff will be reminded of the importance of following the current processes and will be required to read and sign memo to that effect by 2021-03-31.

2. Section 117 Risk 3 – Record Quality

Some forms were not complete. For example, the “initials” column was not completed by the NCC employee who received the Héma-Québec Form Notification of Donor Deferral to Home Centre for Donor ID 2114181/4728484 on October 22, 2020.

A review of other Notification of Donor Deferral to Home Centre forms from 2020-04-01 to 2020-09-30 was completed on 2021-02-18 and no further documentation errors were found.

The staff member involved was retrained on 2021-02-17 to ensure Form 120007 Notification of Donor Deferral to home Centre is consistently completed as per work instruction 07 713 Management of Donor Deferral Information Received from Héma-Québec.

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
Quality & Regulatory Affairs
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cc: Naima Bendahmane
Supervisor – Biological Product Compliance
Regulatory Operations and Regions Branch