

2018-08-02
CBS Control #: CBS6225
HPFB File #: C1892-100390
REF: H-1819-VAN

Ms. Lesley Beaton
Regional Regulatory Compliance and Enforcement Specialist
Regulatory Operations & Regions Branch
Health Products and Food Branch Inspectorate
#400-4595 Canada Way, 4th Floor
Burnaby, British Columbia
V5G 4P2

Dear Ms. Beaton:

Re: Responses to Health Canada Inspection of Vancouver - Downtown
2018-07-11 to 2018-07-12

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2018-07-18.

1. Section 95 -Operating Procedures

Contrary to Job Aid J800060, Scenarios in Screening (20 18-04-06), while observing a donor screening at Vancouver-Downtown clinic (V0002) on 2018-07-11 the first hemoglobin was out of range but only one repeat hemoglobin test was conducted, recorded and used to accept the donor. J800060 requires a second repeat result to be conducted and found acceptable in order to accept the donor.

Quality Event Report (QER) #10-18-116282 was initiated on 2018-07-12.

Feedback to the staff involved was provided at the time of inspection on the importance of following Job Aid J800060, Scenarios in Screening.

Additionally, Clinic Supervisor completed an assessment on 2018-07-31 that the personnel collect and assess repeat hemoglobin samples as per work instructions.

2. Section 98 – Personnel

There was no Confirmation of Employee Training Record (F800329) available for the Performance Measurement training of a registered nurse on SOP 01 070, Prepare Venepuncture Site v.3, which was implemented at the site on 2018-03-26.

QER # 10-18-131874 was initiated on 2018-07-24.

It was confirmed by the trainer and the staff member that the performance measurement training for SOP 01 070, Prepare Venepuncture Site v.3 was completed on 2018-03-08. A CET with an explanatory note will be generated and signed to that effect.

3. Section 117 – Records

There was a discrepancy on one Docon Maintenance Inspection record (1000106168) dated 2018-01-10 for Docon R000006221 in that the "as left" battery date was recorded as "17 08" whereas the serial number was recorded as 1807-010184, where the first 4 digits represent the battery date. In both situations the battery was within the allowable 2 year lifespan.

QER# 10-18-116283 was initiated on 2018-07-11.

It was confirmed from the battery date that the serial number entered in RAM was incorrect. The RAM entry was updated on 2018-07-31.

Work Plan Templates were implemented on 2018-05-07 to help prevent similar errors as information will be entered directly and only once into RAM.

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
Fax Number: 613-739-2505

cc: Hugo Tremblay
Supervisor – Blood, Tissues, Organs and Xenografts
Regulatory Operations and Regions Branch