Canadian Blood Services

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2023-05-25
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Urbee Shome-Pal
Regulatory Compliance & Enforcement Specialist
Biological Product Compliance Program
Regulatory Operations and Enforcement Branch
Health Canada
180 Queen Street West, 10th Floor
Toronto, ON M5V 3L7

Dear Urbee:

Re: Responses to Health Canada Inspection of Registered Activities at Calgary Operations 2023-03-20 to 2023-03-31

The following are the actions undertaken by Canadian Blood Services in response to the observations contained in the Health Canada Exit Notice dated 2023-04-26.

Section 94 - Quality Management System

1. **The system for identifying and investigating errors and accidents was not sufficient. Specifically, the investigation conducted for Deviation # DEV-23-002150, closed on March 16, 2023, where the rad sure label indicator did not have a completely obliterated "NOT" section for product irradiated on March 10, 2023, was not sufficient. The points below were also contrary to 09 230: Deviation/Minor Quality Event Management, Revision 4.1. For example:**
   (i) The implicated product was not immediately quarantined in e-Progesa upon discovery on March 10, 2023. The product was not placed under quarantine until March 11, 2023.
   (ii) Further, there were no notes to indicate that the product had been placed under physical quarantine.
   (iii) The "Containment and Immediate Actions" section of the deviation indicated that the "Component was quarantined awaiting further action." However, there were no other corresponding actions noted, such as, root cause assessment of why the rad sure indicator was not completely obliterated, potential retraining, etc.

   MQE-23-001555 was initiated on 2023-05-04.

   An investigation was conducted and determined that the root cause was the result of a crease in the Rad-sure label. There was no identified impact to other labels, products or the irradiator.

   Staff will be reminded by memo of the requirements to both physically and electronically

quarantine products anytime that product quality, safety and/or efficacy is in question, and to ensure that the full scope of each event and any root cause investigation is documented in the quality event. This will be completed by 2023-06-30.

This event and observation will be discussed at a QA huddle. A memo will be provided and documentation of QA staff understanding of the review requirements will be documented by 2023-06-30.

Section 95 - Operating Procedures

2. Some operating procedures were not always followed. For example:
a) The current Authorized Access list for the Irradiation Room was out of date, contrary to CO-00068: Radiation Safety Manual for Sealed Sources, Revision 1.

MQE-23-001540 was initiated on 2023-05-03.

The most current authorized access list was printed and placed at the security desk.

A memo will be sent to the Distribution Manager and Supervisors by 2023-05-31 reminding them to ensure that Facilities is made aware of staffing changes that would impact the Authorized Access List.

b) Although the 6-month Timer check PM for the [redacted] Irradiator was conducted on April 7, 2022, the records were not entered into RAM, contrary to the relevant sections of 09 350: Management of Equipment by Owners, Revision 7. Therefore, it could not be confirmed whether the PM was actually conducted until the original PM record was located and provided for review on March 23, 2023, during the inspection. Furthermore, the WI did not identify timelines for the equipment owner to submit PM records for upload to RAM.

DEV-23-003645 was initiated on 2023-05-03.

The date of the 6-month timer check referenced in the observation is incorrect. It was confirmed that the 2022-04-07 timer check was completed and uploaded in RAM and closed on 2022-08-04.The 6-month timer check that was noted to be missing was the one conducted on 2022-10-26 which wasn't uploaded at the time of the inspection. The hard copy record of the 6-month timer check confirms that the preventive maintenance was completed and reviewed on 2022-10-26. It was subsequently uploaded into RAM on 2023-05-02.

A communication memo will be sent by 2023-06-30 to remind Production Supervisor/Manager staff of the requirement to review and follow-up on the Events Past Due report, as per WI-00534 (legacy 09350) Management of Equipment by Owners, as well as providing clarification that the timer calibration is to be uploaded into RAM.

In addition, Equipment Services will complete a refresher of the events past due report with the Production Leadership Team by 2023-08-31 to bring a refreshed awareness to the obligations within the work instruction WI-00534 (09-350) Management of Equipment by Owners pertaining to the closure of reports and sending the documentation for upload into RAM as soon as they become available.

c) Some X-Ray irradiation records, specifically for records dated as December 29, 2022; January 29, 2023; and January 31, 2023, were not reviewed as per 02 186: X-Ray Irradiation of Blood Components, Revision 2.

MQE-23-001550 was initiated on 2023-05-04.

The records were reviewed on 2023-05-04. Staff performing review of irradiation records will be reminded through a memo on the requirement to document review on all pages of multi-page records. The review of the memo will be completed 2023-06-30.

Section 100 – Equipment

3. **The validation, calibration, cleaning, or maintenance of critical equipment were not always sufficient. The process followed when equipment is placed out of service and returned to service for critical equipment with maintenance conducted by external service providers, was not consistent. In addition, 09 350 (referenced above) did not provide clear instructions for this. For example: It could not be confirmed when the [redacted] Irradiator was placed back into service after being placed out of service on March 30, 2022.**

WI 09 240 Out of Service In Progress Tags/Labels Application and Removal details the requirements to place an "Out of Service" label when equipment is placed out of service and the removal of the label once the equipment is restored to a validated state. The label must include the reason and the date when the equipment is taken out of operation. Once the equipment is ready to be placed back into service, the "Out of Service label" is removed. The return to service date occurs when the "Out of Service" label is removed.

WI-00534 Management of Equipment by Owners will be revised to include a requirement to enter the date when equipment is returned to service into RAM. This will be completed no later than 2024-03-31.

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,

Christian Choquet

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Quality & Regulatory Affairs
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