BLOOD COMPONENTS OR PRODUCTS HELD AS STOCK AT NON-BLOOD BANK SITES

REASONS FOR ISSUE: Include reference to national standards for vaccine storage and transportation – section 4.4. (DCR33968). Update reference to current version of Immunisation Handbook – section 4.4. Include use of 136F213 for holding stock in a new location - Section 5 (DCR32449).

1. INTRODUCTION

NZBS has a responsibility to maintain an audit trail for all blood components and products issued within New Zealand. From time to time Blood Banks receive requests from a Health NZ/Te Whatu Ora hospital, private hospital, private health care practitioner or independent healthcare practitioner for blood components or products to be held as stock by the requestor.

2. SCOPE

This policy outlines the conditions under which such requests will be agreed to.

Requests for blood **products** to be held as stock at a location that does not currently hold stock	Section 5
Requests for **changes** to the types and/or levels of blood products held as stock	Section 6
Requests for blood **components** to be held as stock for emergency transfusion	Section 7
Requests for provision of blood components or products for **transfusion** to an identified recipient at a novel location	Section 8
NZBS responsibilities	Section 9

3. DEFINITIONS

For the purpose of this document,

- **Stock**: blood components or products that are stored outside of Blood Bank and that are not designated and labelled for an identified recipient.
- **Blood Components**: therapeutic components prepared from blood of a small number of blood donors, by NZBS or overseas blood service, using processes such as centrifugation, filtration and freezing. Examples - red cells, platelets, fresh frozen plasma.
- **Blood Products**: medicines manufactured from pools of human blood components, by a pharmaceutical company, using large-scale manufacturing processes. Examples – Biostate, RhD Immunoglobulin.
- **Serum Eye Drops**: although prepared like a blood component, are managed as a blood product in eTraceline and therefore considered a blood product for the purpose of this policy.
- **External**: outside of the Blood Bank (may be within the hospital or off site).

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4. DOCUMENTS

4.1 Documents related to External Product Stock

- 136M033 External Stocks of Blood Products

4.2 Documents related to Emergency Blood Component Stock

- 136M064a Emergency Blood Stock

4.3 Documents related to New Transfusion Locations

- 136D021 Process Diagram of Response to Request for New Transfusion Facility'

4.4 Documents related to storage and transport of blood components and products

- 108I042 Refrigeration Guidelines
- Section 2.1 of the Immunisation Handbook, 2025, version 3 – available at: https://www.tewhatuora.govt.nz/for-health-professionals/clinical-guidance/immunisation-handbook/2-processes-for-safe-immunisation#2-1-pre-vaccination
- Detailed standards are also available in the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd edition). https://www.tewhatuora.govt.nz/health-services-and-programmes/vaccine-information/vaccine-service-delivery/cold-chain-standards-for-vaccines

5. REQUESTS TO HOLD BLOOD PRODUCTS AS STOCK

- **Request**: A copy of 136F213 'Application to Receive and/or Store Blood Components or Blood Products' must be completed for a location to be granted authorisation to hold blood products as stock, regardless of whether this is to be held at a new or existing eTraceline facility.

  Either provide the requestor with a copy of 136F213 to complete, or the Team Leader, TNS and QBP may complete the form if the information is available.

  Completion of 136F213 will ensure the following aspects are considered:

  - The types of blood products to be held as stock.
  - The stock levels for each type of blood product. No more than 6 weeks' stock should be held at any given time.
  - Justification for holding blood products as stock at that location, rather than having blood products being issued from the local Blood Bank for each designated recipient.
  - Confirmation that the requester is legally entitled to possess medicines:
    - Hospitals – all hospitals are legally entitled to possess medicines.
    - Clinics and day stay facilities – must be under the supervision of a registered medical practitioner, registered midwife or registered nurse to be legally entitled to possess medicines.
    - Pharmacies – all pharmacies are legally entitled to possess medicines.
    - Individuals – must be registered medical practitioners or registered midwives to be legally entitled to possess medicines.
  - Transportation of blood components must meet NZBS documented requirements. Relevant documents for each type of blood product are available from NZBS on request.

  - Validated Storage that meets Ministry of Health requirements for vaccine storage, as laid out in the Immunisation Handbook. The relevant chapter is available from NZBS on request (refer to 4.4).
  - Approval by NZBS Transfusion Medicine Specialist.

- **Dispensing** systems and competent staff to dispense blood products in compliance with the Medicines Act of 1981 (if relevant for storage location), including:
  - Review of the prescription for acceptability prior to dispensing.
  - Maintenance of all required records of the dispense, including NHI number and other identification of the recipient.
- **Record keeping** systems and practices that assure an audit trail is able to identify the fate of all products, including products received, in storage, dispensed to a patient or discarded. The audit trail must be able to identify any/all patients to whom a given batch number of a product. The information in the audit trail must be returned to NZBS on a regular basis not less often than every 3 months, for entry into eTraceline.
- **Audit** by an NZBS Quality Business Partner of equipment, systems and documentation. Where the requestor holds Cold Chain Accreditation, this may be a paper-based assessment. The initial audit and two-yearly follow-up audits will be at the cost of the requestor and must be passed, with any points of failure corrected by the requestor at the requestor's expense. Once approved, any changes the requestor makes to the system must be approved of and audited by NZBS.

6. REQUESTS FOR CHANGES TO TYPES OR STOCK LEVELS OF BLOOD PRODUCTS

For changes to types of blood products or stock levels, the following are required:

- **Request**: A request must be received by the Blood Bank indicating:
  - The types of blood products to be held as stock, or no longer held as stock.
  - The new stock levels for each type of blood product. No more than 6 weeks' stock should be held at any given time.
  - The reason for the change.
- **Approval by NZBS Transfusion Medicine Specialist**

7. BLOOD COMPONENTS HELD AS EMERGENCY STOCK

For red cell components or plasma components to be held outside of Blood Bank as emergency stock, the following are required:

- **Request**: A request must be received by Blood Bank indicating:
  - The types of blood components to be held as emergency stock.
  - The number of units of each component.
- **Justification** for holding emergency blood stock at that location, rather than at the Blood Bank or alternative existing emergency blood stock locations.
- **Validated Blood Storage Refrigerator** that meets NZBS Refrigeration Guidelines. This document is available from NZBS on request. Evidence of maintenance of the validated state and continuous compliance of the refrigerated storage temperature at all times must be forwarded to the Blood Bank at least weekly.

- **Record keeping**. All record keeping must comply with NZBS systems, including completion of tracking tags and recipient information return forms. The audit trail must be able to identify the fate of each component, including those in storage, transfused to a patient or discarded. Component stock will not be replaced without confirmation of the fate of the previously issued component.
- **Approval by NZBS Transfusion Medicine Specialist**

8. REQUESTS FOR NEW TRANSFUSION FACILITY

For blood components or products to be supplied to a new facility for transfusion at a location where transfusions have not been previously performed, the following are required:

- **Request**: A request must be received by Blood Bank on the appropriate form 136F213 'Application to Receive and/or Store Blood Components or Blood Products'.
- **Authorisation** in accordance with 136D021 **'**Process Diagram of Response to Request for New Transfusion Facility', including **Approval by NZBS Transfusion Medicine Specialist**

9. NZBS RESPONSIBILITIES

NZBS facilitates the provision of blood products and components to meet clinical needs by:

- Providing requestors with guidelines, references and other documents on request
- Providing guidance for selection and validation of storage equipment
- Internal NZBS communication to ensure requests are considered and authorised requests actioned
- Auditing the equipment and systems of the requestor to assure safety of transfusion and accuracy of the audit trail
- Maintaining a record of the authorised stock locations and stock levels
- Recording the issue of each vial / unit of blood product or component to the authorised stock location
- Updating the national transfusion record (eTraceline) with recipient information forwarded to the Blood Bank by the stock holding location
- Ensuring that authorised stock holders are included on the distribution list of relevant NZBS documents (e.g. Refrigeration Guidelines)

NZBS is not responsible for:

- the purchase, maintenance, calibration, or disposal of any equipment related to the storage of blood components or products at sites outside any NZBS blood bank unless explicitly agreed to by NZBS,
- sites supplied by a non-NZBS Blood Bank. These are the responsibility of the issuing Blood Bank.