1. **Principle**

To issue and document the issue and final status of blood components and plasma protein products at facilities that do not use a Transfusion Medicine Information System (TMIS) or during computer downtime if required.

1. **Scope and Related Policies**
   1. A record keeping system shall be in place for each issued blood component or blood product, or pooled blood product, which documents 9.1 :

* recipient’s family and given name(s)
* recipient’s unique identification number(s)
* recipient’s ABO (and Rh group for red cells platelets and granulocytes)
* name of blood component or product (including lot number if applicable)
* volume or dose/vials
* manufacturer
* visual inspection
* the blood component unit number(s)
* the blood component ABO (and Rh group for red cells, platelets and granulocytes)
* verification of compatibility (for red cells and granulocytes)
* date and time of issue
* identity of the person issuing the blood component or product
* identity of the person transporting the blood component or product to the recipient’s location (transporter)

The record keeping system shall ensure that a copy of all of the required information relating to the recipient and the transfused blood component or product forms a permanent transfusion record for the patient. The record keeping system shall be designed to make it possible to trace the final disposition of the blood component or blood product. 9.1

* 1. All blood components and blood products shall be inspected for abnormal appearance immediately before issue and the visual inspection must be documented. If an obvious abnormality is detected, the unit shall not be issued and the blood supplier shall be notified regarding the final disposition of the product. Any notification must be documented.9.1
  2. Policies, processes and procedures must be established to ensure continuous and unequivocal identification of the recipient from the sample collection through to transfusion.9.1
  3. A system for validating the identification of the recipient and the blood component or product must be in place in order for blood components/products to be issued.9.1
  4. For shipping blood outside of the hospital refer to procedures IM.006- Shipment of Blood Components/Products using Canadian Blood Services Shipping Containers and IM.007- Shipment of Blood Components/Products Accompanying a Patient.
  5. When a patient is transported out of the facility with blood components or products, the issuing facility should notify the receiving facility. There must be a process in place to ensure traceability of any blood components or blood products is maintained.9.1 The receiving facility shall be responsible for the final disposition documentation of any blood components or products received at their facility.9.1
  6. Blood products may be re-issued if correct storage conditions, as defined by the supplier, have been maintained and documented, and if the container is intact, the component/product visual inspection is acceptable and documented, at least on sealed segment of integral donor testing is attached on red cell components the blood component has not been out of the controlled environment longer than 30 minutes from issue and return.9.2
  7. Under exceptional circumstances it may be necessary to issue blood components before all routine tests performed by the blood supplier are completed. The attending physician shall be notified prior to the issue of any blood component on which testing is incomplete.9.1 A system for documentation of this notification must be in place. The requesting physician must authorize the use of incompletely tested blood components, documenting justification. The label attached to the bag must clearly indicate the tests are not completed. Testing must be completed as soon as possible and the results entered into the appropriate records. The record must show the result(s) of the test(s), date and time recorded, and names of personnel giving and receiving the results. All results must be communicated to the appropriate medical personnel and be documented in the patient’s chart and laboratory record. The recipient’s physician must be notified if any results are unacceptable and this must be documented.
  8. When a technologist is not on duty, only trained hospital personnel may issue blood and blood components from the blood transfusion service.
  9. All blood components and products issued for transfusion are presumed transfused unless returned to the transfusion laboratory.
  10. Some hospital transfusion laboratories do not have 24hr/7 day coverage. See Procedural Notes 8.10 for this type of situation.

1. **Specimens – N/A**
2. **Materials**

**Supplies:** Pick up Request Form (IM.004F1)

Blood Product Issue/Transfusion Record (I/T record)   
(IM.004F2)

Blood, blood components or other related products to   
be issued

1. **Quality Control**
   1. Blood components, products and modifiers must be documented using standardized nomenclature. See IM.001 – Standardized Nomenclature for Blood Components and Plasma Protein Products (example only).
   2. Manipulation of components within the facility (e.g. divided or in lab washed) must be documented.
   3. Each original unit number of blood component contained in a pooled unit must be documented. This must also include the identification of the collecting facility of each blood component contained in the pool.9.2
   4. Units not meeting visual inspection criteria must not be issued for transfusion. See IM.003 – Visual Inspection of Blood Components and Plasma Protein Products.
2. **Procedure**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| * 1. Retrieve the correct number and type of blood component or product from the appropriate storage area using the information supplied by the requestor/transporter.  |  |  | | --- | --- | | *If* | *Then* | | Issuing for home care | See Procedural Notes 8.1. | | Issuing products as ‘stock’ | See Procedural Notes 8.2. | | Unit is shipped to another facility with a patient | See Procedural Notes 8.3. | | Unit is crossmatched at another facility and shipped to your facility with a patient | See Procedural Notes 8.4. | | Unit is to be shipped and transfused at another facility | See Procedural Notes 8.8. | | Unit is issued prior to completion of testing | See Procedural Notes 8.11. | |
| * 1. If issuing a lot number plasma protein product, proceed to Procedural Notes 8.5. |
| * 1. Compare and ensure that the following information received from the transporter and the information on the compatibility label attached to the product match exactly: * Recipient family and given names * Recipient hospital identification number * The component/product type and amount of product is correct as per request   **Note:** Additional information, if available (such as the birthdate, sex and age of the patient), should also be checked. All discrepancies must be resolved prior to issuing the product(s). |
| * 1. Locate the patient and blood product information in the manual record book. If information has not been recorded see Procedural Notes 8.6. |
| * 1. Ensure all information on the compatibility label attached to the blood product is the same as the information in the I/T record form (IM.004F2). |
| * 1. Ensure that the blood type of the unit to be issued and the blood type of the patient on the I/T record form are compatible. |
| * 1. Ensure that the expiry date of the unit to be issued has not passed. |
| * 1. The individual issuing the unit must compare the unit number(s) on the bag(s) and the compatibility label(s). They must be identical. |
| * 1. All discrepancies must be resolved prior to issuing the product(s). |
| * 1. Visually inspect each unit to be issued. See IM.003 - Visual Inspection of Blood Components and Plasma Protein Products.  |  |  | | --- | --- | | *If* | *Then* | | the units meets visual inspection criteria | Document “OK” or add a check mark in the “visual inspection” area on the manual record form | | the component/ product does not meet visual inspection criteria | Document the outcome on the manual record. Do not issue the product. Refer the product to a supervisor or TS Medical Director or designate. See IM.005 – Final Disposition of Blood Components and Plasma Protein Products Not Suitable for Transfusion – Manual Procedure. | | the unit is unsuitable for transfusion | Select another compatible unit for issue, if available, and begin at step 6.1. | |
| * 1. Record the issue date and time on the manual record. |
| * 1. Print or legibly sign your full family name in the “Issuer” area for the appropriate unit(s). See Procedural Notes 8.7 for use of initials. |
| * 1. Print or have the transporter legibly sign his/her full family name in the “Trans” area for the appropriate unit(s). See Procedural Notes 8.7 for use of initials. |
| * 1. The product is now ready for issue and can be released to the transporter after completing the pickup request form. |

1. **Reporting**
   1. Document the final disposition of all units.
      1. If the units are not returned within 24 hours document that the units are presumed transfused.
      2. If a unit(s) is returned from issue, cross out the unit(s) or record as cancelled on the manual record.
         1. When a unit is returned the date and time is recorded on the compatibility voucher and manual record. Return the unit to the appropriate storage area.
         2. Cross out patient information if no units are issued to the patient.
         3. Place a check mark in the “returned” section in the Disposition area of the manual record form and cross off the patient and unit information, initial and date.
         4. If the unit will be re-issued, see Procedural Notes 8.9. Re-write the patient and component or product information on the manual record and return the unit(s) to the fridge.

**Example:**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Product Information** | **Issue Information** | | | | | | **Disposition** | | |
| Source code, Unit # and Check Digit | Date of Issue | Issue  Location | Time | Visual  Inspection | **Print Full Last Name\*** | | Confirmed  Transfused | Presumed  Transfused | Returned |
| Trained Issuer | Transporter |
| ~~555-111112~~ **~~6~~** | ~~Jan 30~~ | ~~ICU~~ | ~~1730~~ | ~~OK~~ | ~~Jones~~ | ~~Avery~~ |  |  | ✓ |
| 555-111112 | Jan 30 | ICU | 1730 | OK | Jones | Avery | Cancelled |  |  |

1. **Procedural Notes**
   1. Issuing coagulation factor concentrates to patients registered in the hemophilia home care program:
      1. Requests for home care patients registered in the Hemophilia or Immunology program should be directed to and administered by the appropriate Dept/Clinic.
      2. Requests for products for specific patients other than Procedural Notes 8.1.1 should be handled and issued according to the laboratory's routine procedure outlined in this document.
   2. It is the facility’s responsibility to obtain the recipient’s name and identify information of products issued originally without recipient information (stock). In this situation, product information should be recorded on the I/T record at the time of issue. Final disposition status must be recorded when recipient information is returned to the facility after transfusion.

If other related products are issued as stock:

* product information is recorded on the I/T record at the time of issue
* obtain the recipient’s name and identifying information of products issued
* after transfusion, record final disposition status and complete patient information on the I/T record form.
  1. When shipping crossmatched units with a patient transferred to another facility:
     1. Complete IM.007F1. Complete all applicable fields on the form. Retain a copy of the form for transfusion service records.
     2. Visually inspect the unit(s). See IM.003 – Visual Inspection of Blood Components and Plasma Protein Products.
     3. Cross off the units from the manual record and (if desired) write, “Shipped to \_\_\_\_” across the disposition area of the manual record. Initial and date the change.
     4. Package as per IM.006 – Shipment of Blood Components Products using Canadian Blood Services Shipping Containers.
     5. Fax or phone the receiving hospital transfusion service to inform them of the transport.
     6. See IM.007- Shipment of Blood Components/Products Accompanying a Patient for further information.
  2. Receiving and documenting units crossmatched at a different facility and shipped with the patient:
     1. Units that are crossmatched at one facility may only be issued at another facility if:
* Units are packaged appropriately. See IM.002 – Receiving Blood Components and Plasma Protein Products
* Units meet visual inspection criteria. See IM.003- Visual Inspection of Blood Components and Plasma Protein Products
* Authorization for issue is given by the most responsible physician/designate for the laboratory
* Patient identification conforms to the facility standards

If authorized to issue, enter the patient and component/product information onto the manual record.

* 1. For plasma protein products, write patient name and identification number and lot number product information on the manual record. See Procedural Notes 8.6 for instructions on what information to enter.
     1. Prepare patient identification label(s) for each vial of product to be issued.
     2. Attach the patient identification label(s) to each vial and compare the patient and product information to the information written in the manual record.
     3. If multiple vials of lot number products are issued, ensure that the correct number of vials is designated beside the lot number (e.g. 6C2002 x2).
     4. Continue to Procedure 6.5.
  2. Blood Product Issue/Transfusion Record: (IM.004F2)

|  |  |
| --- | --- |
| **Column** | **How to Enter** |
| Entry Date | Enter the current date. |
| Patient Name | Family and given names should be transcribed from the request form (not the compatibility label) onto the manual record. Record the middle name if available. |
| Birthdate | Record the date of birth in the correct format YYYY/MM/DD [e.g.1951.01.01 (Jan 1st 1951)]. |
| Unique Identifier | Record the Hospital/Transfusion Medicine unique number |
| ABO/Rh | Record the patient's ABO and Rh from the request form or crossmatch requisition, if applicable. |
| Product Mnemonic | Use standardized product and modifier mnemonics. See IM.001 - Standardized Nomenclature for Blood Components and Plasma Protein Products.  Identify here if this is a divided unit. |
| Modifiers | Record any modifiers associated with the unit, if applicable. See modifier mnemonics in IM.001 - Standardized Nomenclature for Blood Components and Plasma Protein Products as an example. |
| ABO/Rh | Record product ABO and Rh if applicable. |
| Source Code, Unit #,  Check Digit | Record the three-digit source code, the six-digit unit number, and the one digit check digit (e.g. 555 –123456 5).  See Procedural Notes 8.8 for information on documentation of hospital-bled autologous or walk-in donor units. |
| Lot Number and Quantity | Record the lot number and quantity issued of other related products  (e.g. C62002x4). |

* 1. If an initial log of all employees in the facility is maintained and updated annually, initials of the individuals issuing or transporting blood components and blood products may be used.
  2. If blood/components are being issued for a specific patient transfusion at another facility. The transfusing facility should be directed to obtain and complete form IM.004F1 – Pick up Request Form Blood Components and Products and fax to issuing TS prior to issue.
  3. Re-issue of returned products

Write all information on the I/T record again if re-issuing any returned product. Blood that has been returned shall not be re-issued unless the following criteria have been met:

* The container closure has not been disturbed
* The red blood cells have not been allowed to warm above 10°C or cool below 1°C or have not been out of a controlled blood storage device for longer than 30 minutes
* The records indicate that the blood to be re-issued has had a visual inspection. See IM.003 - Visual Inspection of Blood Components and Plasma Protein Products
* At least one sealed segment of integral donor tubing has remained attached to the container
* Platelets have not been out of agitation for longer than 24hrs and have passed visual inspection. Adequate in vivo viability can be checked if ‘swirling’ is evident 9.3
  1. For Transfusion Laboratories that do not offer 24/7 coverage, a procedure must be in place for issuing blood after regular laboratory hours, such as:
* Blood/components for only one patient should be issued at a time 9.3
* The laboratory should be locked after regular hours. And the key left in a secure place (e.g. Emergency Department or Nursing office)
* Only trained personnel should pick up blood components or blood products from the transfusion laboratory
* A copy of the patient’s addressographed IM.004F1- Pick up Request Form Blood Components and Products must be left in the laboratory
* Patient information on IM.004F1 must be compared with the product issue voucher/compatibility label. If a discrepancy is noted it must be resolved before any blood/product can be removed from the TS
  1. Emergency release

If the need for blood is urgent and time does not allow for compatibility or infectious disease testing by the supplier; ensure the following:

* Requesting physician authorization / justification is documented
* Where possible, patient informed consent should be obtained
* The tag attached to the component bag clearly indicates that the component testing has not been completed (indicate compatibility or infectious disease as applicable)
* Testing must be completed as soon as possible and results provided to the requesting physician and TS Medical Director (this must be documented)
* If results are communicated by phone this must be documented indicating personnel giving and receiving results, and the date and time received. Any positive results or incompatibility must be reported to the recipient’s physician immediately
* All documentation must remain as part of the recipient’s permanent transfusion record

1. **References**
   1. CSTM Standards for Hospital Transfusion Services Version 3 – February 2011. Canadian Society for Transfusion Medicine, 5.6.1.12, 5.7.5.2, 5.7.5.3, 5.7.5.4, 5.7.3.1, 5.7.6.1, 5.7.7.2,5.7.7.1,5.8.2.1
   2. Blood and Blood Components. CAN/CSA Z902-10 February 2010. 10.10.5, 10.8.4
   3. Roback JD, ed. AABB Technical Manual, 17th ed. Bethesda, MD: American Association of Blood Banks, 2011: 217, 287,298
2. **Revision History**

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| **Revision Date** | **Summary of Revision** |
| August 8, 2014 | * Revised name of manual * Revised title of document * Revised section 1.0, 5.0, 6.0 & 7.0 * Revised and renumbered sections 2.0 & 8.0 * Changed Procedural Notes 8.9 to Procedural Notes 8.8 in section 6.1.5 * Changed Procedural Notes 8.12 to Procedural Notes 8.11 in section 6.1.6 * Changed Procedural Notes 8.8 to Procedural Notes 8.7 in section 6.12 & 6.13 * Updated list of references to include most recent editions |