

# **Standards for Blood Storage Centre (BSC)**

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## **10. ORGANIZATION AND MANAGEMENT**

### **1.1 Legal Identity**

- 1.1.1** The Blood Storage Center (BSC) shall have a valid approval from the State/ Union territory licensing authority under Drug and Cosmetic Rules 1945 (Schedule- K) with further amendments.
- 1.1.2** The Hospital/Organization under which the BSC is functioning shall be legally identifiable.
- 1.1.3** The blood bank with which the BSC is attached shall have valid license of Central Drugs Standard Control Organization (CDSCO) and approved by Drug Controller General (India), Central Licensing approving authority under Drug and Cosmetic Rules 1945 with further amendments.
- 1.1.4** The parent blood bank shall be a government blood bank, Indian Red Cross Society blood bank or Regional Blood Transfusion center. The captive consumption or Whole Human Blood I.P. or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall not be more than 2000 units annually.

### **1.2 Responsibility**

- 1.2.1** The memorandum of understanding (MOU) of BSC with parent blood bank shall define clearly the responsibility of mother blood bank and BSC.
- 1.2.2** The organization chart of BSC (Organogram) shall be defined in reference to the hospital in which it is situated.
- 1.2.3** Responsibility of personnel working in the BSC shall be clearly defined in order to identify conflict of interest.

### **1.3 Ethics**

- 1.3.1** The personnel in BSC shall be bounded by the ethical code of the respective profession and shall not engage in practice restricted by law.
- 1.3.2** The BSC management shall determine acceptable practice that should be appropriate for their own situation.

## **1.4 Management System**

- 1.4.1 The BSC management shall have responsibility for the design, implement, maintain and improvement of the quality management system.
- 1.4.2 Quality policy and objective shall be approved and issued by the In-charge of BSC.
- 1.4.3 A quality manual shall describe the quality management system covering all the aspects of these standards.
- 1.4.4 BSC In-charge shall designate a person with defined responsibilities to oversee the quality management system.

## **2.0 Accommodation and Environment**

- 2.1 Blood storage centre shall be a part of hospital and shall have a minimum area of 10 sqm. The room shall be air-conditioned, well lighted and clean.
- 2.2 Appropriate measure shall be taken to safeguard samples and resources from unauthorized access. (Access to the room should be controlled)
- 2.3 Storage, transportation, use and disposal of dangerous material / biomedical-waste shall be as per the specification by relevant regulations. Special procedure and training for personnel could be necessary to meet these requirements.
- 2.4 BSC shall have adequate back up facility for maintaining electrical supply round the clock.
- 2.5 BSC shall monitor, control and record environmental conditions which may influence the procedure and quality of the test results and blood / blood components.
- 2.6 There shall be appropriate internal communication system for efferent transfer of information.

## **3.0 Personnel**

- 3.1 BSC shall have a process to ensure appointment of an adequate number of individuals qualified by education, training and experience.

### **3.2 Medical officer**

One of the available doctors shall be designated as responsible medical officer for the functioning of the BSC.

### **BSC technician(s)**

Technician either Degree in Medical Laboratory Technology (M.L.T.) or Diploma in Medical Laboratory Technology (D.M.L.T.) shall be designated and responsible for the technical processes of BSC. The number shall be appropriate as per the amount of work load and facility.

**3.3.1** The medical officer and technician shall be trained in operation of blood storage center and their basic procedures like pre transfusion checking i.e. patient identity, blood grouping, cross matching, compatibility, problem in grouping and cross matching, trouble shooting, issue of blood, transfusion reaction and its management, disposal of biomedical-waste material and good laboratory practice.

Personnel performing critical tasks shall be qualified to perform assigned activities on the basis of appropriate education, training and/ or experience.

**3.3.2** All personnel shall also have training specific to quality assurance and quality management for services offered.

**3.3.3** Staff shall be trained to prevent adverse incident and/or contain the effects of, and report adverse incidents.

**3.4** The training shall be recorded and plan for continuous training (in house or in parent blood bank) relevant to their needs shall be defined.

**3.5** The competency of each person to perform assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall occur when necessary.

**3.6** A pre-employment medical examination and regular health check up shall be conducted on all the employees. Occupational health hazards shall be adequately addressed.

**3.7** BSC shall maintain records of the Personal information, relevant educational and professional qualification, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel, and may include:

- a) Certification or license, if required,
- b) Reference from previous employment, if possible,
- c) Job descriptions,
- d) Records of continuing education and achievements,
- e) Provision for untoward incident or accident reports,
- f) Record of identification of signature and initials,
- g) Competency evaluation.

Other records available to authorized person relating to personnel health may include records of exposure to occupational hazards and records of immunization status.

**3.8** All personnel shall maintain confidentiality of information regarding patient/recipient. Health records of staff shall be kept confidential and in a safe place.

#### **4.0 Equipment**

**4.1** The BSC shall be furnished with all the equipment those are required for the provision of its services. A list of equipment is provided at Annexure-A for guidance purpose.

**4.2** Equipment detailed record shall be maintained for all the equipment and these shall include at least the following

- a) Identification of the equipment
- b) Manufacturer's name, type, identification and serial number or other unique identification
- c) Manufacturer's contact person and telephone number
- d) Date of receiving and date of putting into a service
- f) Condition when received (new, used or reconditioned)
- g) Manufacturer's instructions, if available, or reference of their retention
- h) Equipment performance records that confirm the equipment suitability for use
- i) Maintenance carried out and that planned for the future
- j) Damage to or malfunction, modification or repair of the equipment

These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law/regulation.

**4.3** BSC shall establish a programme of regularly monitoring, calibration and preventive maintenance of equipment. Please refer to Annexure-B for calibration frequency.

**4.4** Only authorized personnel shall operate the equipment. Up to date instructions on use and maintenance of equipment shall be readily available to personnel.

#### **4.5 Equipment for storage of Blood and it's components**

**4.5.1** BSC shall have adequate storage facility corresponding to its workload.

**4.5.2** Storage devices shall have design to ensure that the proper temperature is maintained and shall be equipped with alarms.

**4.5.3** There shall be a process to monitor the temperature of refrigerator, freezers, and platelet incubators continuously and to record the temperature at least every 4 hours.

**4.5.4** Policy and procedure of maintaining the temperature of blood and its component in storage in case of breakdown of refrigerator shall be defined.

#### **4.6 Computer system**

When computers are used for the recording, storage or issuance of blood/component, the BSC shall ensure that:

- a) Computer software is validated as adequate for use in the facility,
- b) Procedures are established and implemented for protecting the integrity of data at all times to prevent unauthorized access for alteration and destruction of data.

#### **4.7 Breakdown of equipment**

Policy and process in case of breakdown of equipment shall be defined. Whenever equipment is found to be defective it shall be taken out of service, clearly labelled and appropriately stored until it is been repaired and shown to be calibrated to meet specified acceptance criteria.

### **5.0 External Services and Supplies**

**5.1** BSC shall define and document its policies and procedures for the selection and use of purchased external services, equipment and consumable supplies that affect the quality of its services.

There shall be procedure and criteria for inspection, acceptance/ rejection and storage of consumable materials.

**5.2** Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedure concerned.

**5.3** All supplies shall be used within given expiry date and stored at proper temperature in a safe and hygienic place in a proper manner.

**5.4** Procedure for inventory management shall be defined.

## **6.0 Process Control**

**6.1** BSC shall have policy and validate process and procedure to ensure the quality of its services. All these shall be carried out under controlled conditions.

## **6.2 Standard procedure**

The BSC shall use procedures including examination procedures, which meet the needs of the users of BSC. National guidelines/ manuals and other regulatory directives shall be followed.

### **a) Written Procedure**

All procedures shall be documented and be available at the workstation for relevant staff.

Documented procedures and necessary instructions shall be available in a language commonly understood by the staff in BSC.

The procedures described, are those performed in the BSC. The procedures can be based on the instructions for use (e.g. package insert) written by the manufacturer.

Any deviation shall be reviewed and documented. Additional information that could be required to perform the procedure shall also be documented. Each new version of kits with major changes in reagents or procedures shall be checked for performance and suitability for intended use. Any procedural changes shall be dated and authorized as for other procedures.

### **b) New Procedures/Changes and Validation**

The new methods and procedures selected for use shall be evaluated to find if they give satisfactory results before being put in practice.

If the BSC intends to change a procedure in such a way that results or their interpretations could be significantly different, the implications shall be explained to the users of the BSC services in writing.

## **6.3 Traceability of blood unit and sample from blood collection to issue blood:**

The BSC centre shall ensure that all blood, components issued as well as patient sample, donor unit and patient/recipient records, are identified and traceable.

## **6.4 Sterility**

The sterility of all components shall be maintained during storage and issuance by the use of aseptic methods.

## Seal & Weld

BSC shall receive blood/ components from parent blood bank where closed system is being used for the preparation of blood components. The seal will not be considered broken if a sterile connecting device is used.

BSC shall receive final components that have integrally connected tubing which are filled with aliquots of the blood/ component. These sealed segments shall be available for subsequent compatibility and assay testing whenever needed without breaking the seal.

If the seal is broken during processing, components stored between  $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$  must be transfused within 24 hours and component stored between  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$  shall be transfused as early as possible and not beyond 6 hours.

Once the frozen components are thawed, these shall be transfused as soon as possible and positively within 6 hours, and within 24 hours if stored at  $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$

## 6.5 Transportation Policy

Policies and procedures for transportation of blood/components from parent blood bank to BSC shall be clearly defined. The personnel responsible for the transportation shall be identified and designated. Whole blood and red cell concentrate shall be transported in a manner that shall maintain a temperature of  $4 - 8^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . Platelet concentrates are transported at  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ . Components stored frozen shall be transported in a manner to maintain them frozen.

When these are issued for transfusion, these shall be thawed at  $37^{\circ}\text{C}$  prior to issue.

The temperature during transport shall be monitored and recorded.

## 6.6 Storage

### a) Refrigerator and freezers for storage

A designated area shall be used for storage to limit deterioration and prevent damage to blood and its component. The access to such areas shall be controlled.

Refrigerator or freezers used for storage of blood, blood components and blood samples shall not be used for any other purpose.

All reagents shall be stored in refrigerators with thermograph or temperature monitor in the specific laboratories.

BSC refrigerator shall have inside temperature of  $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$  and shall have a system to monitor temperature continuously.

Deep freezer shall have inside temperature of  $-30^{\circ}\text{C}$  or below having temperature indicator/recording facility.

Platelet incubator with agitator shall have inside temperature of  $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$  having temperature indicator/recording facility. The equipment shall keep the platelet units in continuous gentle agitation.

All storage equipment with temperature recorder shall be recorded at least every 4 hours. An alarm system and a provision for alternate power supply shall be available.

Adequate alternate storage facility and written display of instructions to maintain the blood and components in the event of failure of power or equipment shall be provided. The alarm of all storage equipment shall signal in an area that has adequate personnel coverage round the clock to ensure immediate corrective action.

## **6.7 Labeling**

Blood shall be issued by the BSC along with the blood cross matching report.

The cross matching report shall have patient/recipient's first name with surname, age, sex, identification/ registration number, ward, bed number, and ABO and Rh(D) type.

The report shall have donor unit identification number, ABO and Rh (D) type and expiry date of the blood/ component.

Interpretation of cross matching report and the name of the person performing the test and issuing the blood shall be recorded.

A label or a tag with patient/recipient's name, hospital name, identification number, blood unit number assigned by the mother blood bank facility and interpretation of the cross matching test, shall also be attached to the blood bag container before it is issued from the BSC.

## **6.8 Compatibility Testing**

### **6.8.1.1 Request for blood and its components**

Request form for whole blood or components accompanied by the recipient's blood samples shall be legible and shall have the following information:

- a) Recipient's name,
- b) Age, Sex, ward and bed number,
- c) Blood group of recipient if done earlier (for error prevention),

- d) Name of the head of treating unit,
- e) Amount of blood/component needed,
- f) Date and time of blood/ component requirement,
- g) Routine/emergency,
- h) Diagnosis,
- i) Reason for transfusion, hemoglobin/platelet count,
- j) History of previous transfusion,
- k) Obstetric history in the case of female patient/recipient,
- l) Name of the hospital/hospital registration number,
- m) Signature of the medical officer,
- n) Name and signature of the phlebotomist collecting patient/recipient's sample.

#### 6.8.1.2 Sample receiving, acceptance and preservation

Blood samples of recipient shall be obtained in two vials i.e. stoppard plain vial/tube and a vial/tube containing anticoagulant, with labels having:

- a) Patient/recipient's full name,
- b) Identification number,
- c) Name of hospital,
- d) Ward/bed number (Optional),
- e) Date and time.

When recipient's blood sample is received in the BSC, a qualified member of the staff shall confirm that the information on the label and on the transfusion request form are identical. In case of any discrepancy or doubt, a new sample shall be obtained.

#### 6.8.1.3 Retaining and storing of blood sample

The recipient's blood sample and a segment from each donor unit shall be retained at  $4 \pm 2^{\circ}\text{C}$  for 7 days after each transfusion.

In case of a need for transfusion after 48 hours of earlier transfusion, a fresh sample shall be asked for to perform a cross match.

## 6.8.2 Pre-Transfusion Testing in BSC

### 6.8.2.1 Testing of recipient blood

#### *Determination of ABO group*

ABO grouping shall be determined by testing red cells with anti-A, anti-B, anti-AB sera (anti-AB is optional if monoclonal anti-A and anti-B are used) and testing serum or plasma for expected antibodies with fresh pooled A,B and O cells (pool of 3 for each group) using tube/microplate method/ column agglutination technology (CAT-manual or automated). Either monoclonal/or polyclonal antisera may be used.

#### *Determination of Rh (D) type*

The Rh (D) type shall be determined with anti-D reagents from 2 different sources by tube/ microplate method/ CAT technology. If negative it shall be labelled as Rh-(D) negative.

#### *Test for detection of unexpected antibodies*

Serum of the recipient shall be tested for unexpected antibodies with pooled O Rh(D) positive cells or screening red cell panel at room temperature by saline technique and at 37<sup>o</sup> C by commercially available (use manufacturer's instruction) or in house validated albumin/enzyme as well as indirect antiglobulin test with proper controls (positive, negative). If on screening, antibody(ies) is/ are detected, this/ these should be identified by red cell panel, if possible.

A control system using red blood cells sensitised by IgG anti-D must be used with antiglobulin tests to detect false negatives.

#### *(Crossmatch)*

A sample of donor cells from a segment attached to the bag and recipient serum or plasma shall be cross matched. The method used shall demonstrate ABO incompatibility and clinically significant unexpected complete and/or incomplete antibodies and shall include an antiglobulin test.

If clinically significant antibody(ies) are not detected during the antibody screening test and if there is no record of previous alloantibodies and no history of transfusion or pregnancy within the past three months, then an antiglobulin cross-match is not required. An immediate spin must be performed.

If clinically significant antibody(ies) is/are detected in recipient, blood lacking corresponding antigens on cells shall be cross matched or by trial method the blood, which is compatible, shall be issued. In certain clinical conditions, where autoantibodies are present, the least incompatible unit shall be issued with warning to clinicians.

Minor cross matching using donor serum or plasma and recipient's cells shall not be necessary as tests for complete and incomplete unexpected antibodies in donor sample are mandatory.

#### 6.8.2.2 Repeat Testing of Donor Blood

The BSC performing cross matching shall confirm ABO and Rh (D) group of all blood units using a sample obtained from an attached segment before issue.

#### 6.8.3 Issue of blood and its component

##### 6.8.3.1 Issue of blood

Blood shall be issued by the BSC along with the blood cross matching report. A portion of the integral tube with at least one numbered segment shall remain attached with the blood bag being issued.

The cross matching report shall fulfill clause 6.7

Each unit of blood shall be visually inspected before issue. It shall not be issued if there is any evidence of leakage, hemolysis or suspicion of microbial contamination such as unusual turbidity, or change of colour.

##### 6.8.3.2 Reissue of blood

It is recommended that blood once issued shall not be taken back by the BSC if the cold chain is broken. The unused blood nearing expiry date shall be returned to the mother blood bank

##### 6.8.3.3 Urgent requirement of blood

Blood or blood components shall be issued before completion of routine cross matching tests, in case where delay in providing blood may jeopardize the patient/recipient's life, on receipt of a signed written request of the treating physician stating that the clinical condition of the patient/recipient is sufficiently urgent to require the issuance of blood before completing ABO and Rh(D) tests and compatibility testing. Records of such requests shall be retained for 5 years.

Under such circumstances, recipients whose ABO and Rh(D) type is not known shall receive red cells of group O Rh(D) negative if available, otherwise O Rh(D) positive blood shall be used.

Recipient whose ABO and Rh(D) type has been determined shall receive ABO and Rh(D) specific blood group whole blood or red cells before the tests for compatibility have been completed.

The donor tag or label on the blood container and the cross match report form shall indicate that compatibility testing has not been completed at the time of issue.

However, standard compatibility test shall be completed promptly. If discrepancy in the result is noted, the concerned clinician shall be informed immediately.

#### 6.8.3.4 Selection of blood and components for transfusion

##### *Whole blood, red cell component*

The BSC shall follow a first in first out (FIFO) policy for issuing blood units. Recipient shall receive ABO type specific compatible whole blood or red blood cell components. In the absence of ABO type specific blood, group O packed red cells shall be transfused. Rh(D) negative recipient shall receive Rh(D) negative whole blood or red blood cell components except for reasonable qualifying circumstances when Rh positive may be issued only when Rh antibodies are absent and with due consent of treating physician. Rh(D) positive recipient can receive either Rh(D) positive or negative whole blood or red blood cell components.

If clinically significant unexpected antibodies are detected in recipient, whole blood or red blood cells component, which do not have corresponding antigens and are compatible shall be transfused. On reasonable qualifying circumstance indicated by the clinician, a least incompatible unit shall be issued with instruction to clinician to transfuse under constant observation.

##### *Single donor plasma and fresh frozen plasma*

Single donor plasma or fresh frozen plasma shall be ABO type specific/compatible with recipient's red blood cells. For cryoprecipitate ABO/Rh grouping is not required.

##### *Platelets concentrate*

Platelet concentrates shall be ABO and Rh (D) type specific or compatible with the recipient blood. In case of shortage, platelets concentrate of any ABO/Rh group shall be used provided there is no visual red cell contamination of the platelet concentrate. In case of apheresis platelets, plasma shall be reduced when plasma incompatible concentrate is in use (e.g. use of 'O' group to 'B' group patient/recipient).

6.8.3.5 Policy of choice of alternative blood group in blood/ component shall be defined and clearly displayed. Please refer to Annexure D & E.

#### 6.8.3.6 Massive Transfusion

When an amount of blood equal to or greater than recipient's total blood volume is transfused within 24 hours, a fresh blood sample shall be used after active bleeding is controlled for cross-match at the time of subsequent transfusion of blood. Component therapy shall be actively considered in these cases.

#### 6.8.3.7 Neonates

For ABO grouping of neonates only cell grouping with anti-A, anti-B and anti-AB sera shall be required.

Serum of the mother shall be tested for unexpected antibody(ies).

In the management of haemolytic disease of the newborn it is preferable to use mother's serum for the cross matching. In absence of mother's serum, child's serum shall be used for compatibility testing.

Neonatal recipient shall not be transfused with whole blood/plasma/component containing clinically significant antibodies.

For exchange transfusion or in hypoxic condition, it is recommended that the blood is screened for haemoglobin S, if possible.

Blood preferably within 72 hours of collection, but not exceeding 5 days, shall be used for exchange transfusion.

#### 6.8.4 Records of recipient

- Blood requisition form with full particulars of recipient and identification number.
- Results of ABO and Rh (D) tests and their interpretation.
- Interpretation of compatibility tests.
- Compatibility record.
- Report of adverse reaction and record of their investigation.

Issue Register shall have:

- a) Date and time of issue,
- b) Particulars of patient/recipient and his/her ABO and Rh (D) type,
- c) Identification number and segment number of red cells units issued, ABO and Rh (D) type, blood/component issued,
- d) Signature of persons issuing and receiving components.

#### 6.8.5 Transfusion Related Advices (for clinician)

It shall be the responsibility of BSC to organise regular and documented meeting or other means for educating the users regarding transfusion related advices and other scientific matters.

##### 6.8.5.1 Informed Consent

The patient/recipient shall be informed about his/her need for blood, alternatives available, as well as risks involved in transfusion and non-transfusion. His/ her written consent shall be taken in the language he/she understands best only after providing information. For minors and unconscious patient/recipients the next of kin shall sign the informed consent.

##### 6.8.5.2 Identification of Recipient and Donor Unit

Immediately before transfusion, the doctor/ transfusionist shall verify the identification of the patient/recipient, the blood unit, blood group and cross matching report and associated records.

All identifications attached to the container shall remain attached at least until the transfusion is over.

The blood compatibility report shall be attached in the patient/recipient's file.

Supervision:

Transfusion shall be prescribed and administered under medical direction. The doctor/ transfusionist shall observe the patient/recipient for an appropriate time at the initial stage and during the transfusion to observe any evidence of untoward reaction and to regulate the speed of transfusion.

To ensure good clinical practice (GCP) the user hospital shall formulate a hospital transfusion committee.

##### 6.8.5.3 Administration of Blood and Blood Components

Blood and blood components shall be maintained at the optimum temperature before transfusion.

The transfusion shall be given with sterile, pyrogen-free and disposable transfusion set with filter. The transfusion shall be started immediately on receipt of blood.

Warming of blood to body temperature shall be done in case of rapid transfusion, massive transfusion, exchange transfusion in infants and patient/recipients with cold agglutinins. Warming of blood shall be accomplished using a blood warming device attached to the transfusion set. The warming system shall be equipped with a visible thermometer and ideally with an audible alarm system.

Medication shall never be added to the whole blood or components. Similarly no other intravenous fluid except 0.9% sodium chloride injection I.P. should be administered with blood components.

Red cells shall not be administered with I.V. solution containing calcium, dextrose or lactated ringer's solution.

#### 6.8.5.4 Guidelines for Transfusion Practices

There shall be a written protocol for administration of blood and blood components and the use of infusion device and auxiliary equipment.

Hospital Transfusion Committee of BSC shall define its policies and procedures of transfusion practices.

For appropriate use of blood, guidelines approved by the hospital transfusion committee shall be used.

#### 6.8.5.5 Special Considerations for use of components (Also refer to Annexure F)

##### *Red Cell Transfusion*

Red cell transfusion shall be ABO and Rh (D) compatible.

Transfusion of one unit of red cells shall not take longer than 4 hours and should begin within 30 minutes of taking out of refrigerator.

The viscosity of red cell concentrate can be reduced by the addition of small volume (50 ml) of sterile normal saline through one limb of a Y-infusion set.

##### *Fresh frozen Plasma*

Plasma transfusion shall be ABO compatible. Cross matching tests are usually not performed on plasma products. Products that have been thawed shall be infused without delay to avoid bacterial proliferation. This is thawed at temperature of 37<sup>o</sup> C.

If it is used as a source of labile coagulation factors, it shall be used immediately and in any case within 6 hours after thawing.

If used for a purpose other than labile coagulation factor replacement, it shall be transfused within 24 hours after it is thawed and stored at 1 - 6<sup>o</sup> C.

##### *Cryoprecipitate*

The component shall be thawed at temperature of 37<sup>o</sup> C and shall be used immediately. ABO compatibility is not required.

### *Single donor plasma*

It shall be transfused within 24 hours after it is thawed and stored at 1 - 6 °C.

### *Cryopoor plasma*

The component shall be thawed at temperature of 37 °C and shall be used within 24 hours if stored at 1- 6 °C.

### *Platelets*

Platelets shall be ABO-identical but in absence of availability of ABO compatible platelets, ABO-incompatible platelets can be used, if there is visible red cell contamination in platelet, group specific and cross matched product shall be used.

Platelets shall be administered through a standard filter.

- 6.9** As the most common cause of haemolytic transfusion reaction is a clerical error, a system of preventing such error shall be in place.

The request form shall have the phlebotomist's name and initials.

The blood group of the bag being issued shall be re-confirmed by testing the sample from the donor tubing attached to the bag.

Instructions shall be given to transfusionists to check the identity of patient/recipient on the bag matches the identity of the patient/recipient and ensure correctness of unit number on the bag as well as segment and the cross match report.

## **6.10 Quality Control (Also refer to Annexure C)**

### **6.10.1 ABO and Anti-D Reagents**

A vial of every new batch/ lot shall be checked for its potency (titre) besides specificity and avidity on receipt.

All the antisera and other reagents used for serological work in BSC shall be checked daily for their specificity and avidity, using known positive and negative controls.

All reagents showing turbidity and discoloration suggesting contamination shall be discarded.

Manufacturer's package insert shall specify titre, avidity and all other relevant information.

Methods followed shall be as per manufacturer's instructions.

No reagents after date of expiry shall be used.

At any given time, there shall be two different batches of anti-D reagents available either from two different manufacturers or two different batches from the same manufacturer.

#### 6.10.2 **Reagent Red Blood Cells**

Cells shall be prepared by pooling, daily and shall be free of haemolysis. There shall be a minimum pool of 3 individual cells for each group.

Each batch of reagent cells (A, B and O) for serum grouping prepared shall be tested to confirm specificity.

#### 6.10.3 **Red Cell Panel/ Pooled Cells**

Either commercially available or in house prepared panels or pooled cells shall be in use.

Red cells stored for more than 48 hours at 4 °C, shall be checked for reactivity, of at least one weak reactive antigen by saline and indirect anti-globulin test.

#### 6.10.4 **Anti-Human Globulin Reagent**

One vial from every new batch/lot shall be checked for its specificity and reactivity using (incomplete anti-Rh) IgG coated cells. Commercially available reagents may be used.

Each test shall include positive and negative controls.

Non-sensitised A, B and O cells shall be checked to rule out non-specific reactions.

All negative AHG tests shall be confirmed by addition of IgG coated cells in the test. IgG coated cells shall give positive agglutination.

#### 6.10.5 **Bovine Serum Albumin**

The reagent shall be free of the non-specific agglutinins and shall not react with saline suspension of A, B and O cells.

Reagent shall give positive reaction with Rh (D) positive cells coated with incomplete anti-Rh (D).

#### 6.10.6 **Enzyme Reagents**

Enzymes such as papain, ficin, trypsin or bromelin shall be used for detection of incomplete antibodies.

## **6.11 Proficiency Testing Programme**

The BSC shall participate in External Quality Assurance Scheme (EQAS)/ Proficiency Testing Programme (PT).

It shall monitor the results of these programmes and participate in implementation of corrective action when control criteria are not fulfilled.

Whenever a formal EQAS/ PT programme is not available, the BSC shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated.

They can participate in a suitable inter-laboratory comparison or adopt alternative methods to validate performance.

The BSC shall document, record and as appropriate expeditiously act upon results from this comparison.

Problems and deficiencies identified shall be acted upon and record of action retained.

## **6.12 Bio-medical waste disposal and laboratory safety in BSC**

### **6.12.1 Protection of BSC personnel against laboratory infection**

All laboratory personnel shall be informed of the hazards including transmission of viral infection involved in working in a BSC laboratory.

Incidental exposure to infected samples like bag breakage, splash, needle stick injury shall immediately be reported and recorded with the concerned authorities. Use post exposure prophylaxis as per guidelines of regulatory authority.

Immunization of the BSC staff against hepatitis-B infection should be implemented after appropriate tests.

### **6.12.2 Safety in the laboratory: Following points shall be followed:**

- a) All staff working in laboratories must be adequately trained in the safety aspects of the lab,
- b) Staff must behave in a safe and responsible manner at all times,
- c) Access to the lab must be restricted to authorized personnel only.
- d) Appropriate protective clothing must be worn at all times, this includes aprons and gloves,
- e) Eating, drinking, smoking, applying cosmetic and handling contact lens are prohibited in the lab,
- f) Mouth pipetting prohibited in the lab,
- g) Care must be taken to avoid the formation of aerosols or splashing of materials,

- h) All work surfaces must be decontaminated after any spillage and at the end of each working day,
- i) All contaminated waste or reusable materials must be appropriately decontaminated before disposal or reuse.
- j) In case of needle stick injury, wash the hand with soap and water or anti septic and make out an incident report,
- k) Dispose all sharps in puncture proof containers.

### 6.12.3 Disposal of Blood and Laboratory Material

#### *Method of disposal of Blood Bags*

Shall comply with requirement of Biomedical Wastes Rules of Ministry of Environment and Forest and local Pollution Control Board.

Needles shall be burnt using electric needle destroyers or soaked in hypochlorite solution and discarded in puncture proof container or a non-chlorinated plastic. These shall then be sent for deep burial or incineration

#### *Disinfection of glassware*

All reusable glassware shall be disinfected by treating with hypochlorite and detergent before cleaning. Subsequently glassware must be kept in hot-air oven at 160<sup>o</sup> C for 1 hour.

#### *Spills on the table tops/sinks*

This spill shall be covered with filter papers or plain cloth and soaked with 1% hypochlorite solution for at least 30 minutes and later swabbed.

#### *Hypochlorite/ detergent solution*

0.5 - 1.0 percent solution of hypochlorite is the best general-purpose disinfectant if contact is maintained for at least 30 minutes (except for metallic equipment which could be autoclaved or put in 2% glutaraldehyde).

#### *Disposal by Sterilisation*

Autoclaving for 30 minutes at 121<sup>o</sup> C and 15 p.s.i (68.5 cm Hg) is the method of choice. Validation with use of biological indicator (*Bacillus sterothermophilus*) shall be done at least once a month.

## **7.0 Continuous Improvement**

### **7.1 Identification of deviation and Adverse Events**

BSC shall have policy and procedure to be implemented when any aspect of its test analysis or function does not conform to laid down procedure.

Defined responsible person shall analyze the non-conformity and take corrective action appropriate to medical significance which includes issuing of non-conformity blood component and the event shall be recorded. Procedure to prevent reoccurrence of any non-conformity shall be defined with elimination of root cause.

### **7.2 Complaints**

The BSC shall have policy and procedure for addressing complaints and other feed backs received from clinicians, patients and other parties.

These shall be recorded and maintained.

### **7.3 Corrective action**

Procedure for corrective action shall include root cause analysis

In-charge BSC shall define the corrective action appropriate to the magnitude of the problem which shall be implemented and documented.

### **7.4 Preventive action**

Preventive action is a proactive process for identifying opportunities for improvement, action plan shall be developed to implement these whenever they are identified.

## **8.0 Document Control and Records**

### **8.1 BSC shall define document and maintain procedure to control all documents and information that form part of its quality documentation.**

If the documents are on computer the procedure of maintaining confidentiality, backup of critical data and procedure in case of breakdown shall be defined. The documents which are required to be maintained in BSC refer to Annexure.

### **8.2 Records**

All records relevant to the quality management system shall be uniquely identified and appropriately labeled and stored in such a way that they are easily retrievable. The records shall be retained as per national, regional or local legal requirement. Please refer to Annexure-G.

## **9.0 Internal audit and Management Review**

### **9.1 Internal Audit:**

Internal audit of all the elements of the system shall be conducted at regular interval at least once a year. It shall be well organized and carried out by the designated qualified personnel. Personnel shall not audit their own activities

The report of internal audit with its corrective action shall be documented and shall be presented in Management Review meeting .

### **9.2 Management Review:**

BSC shall have at least once every twelve months meeting with the higher management when decisions are made. These review meeting shall take into consideration of records of feedback/Complains /non-conformances with corrective and preventive action, internal and external audit reports and reports by supervisor.

The minute of MRM shall be documented.

**List of Equipment for Blood Storage Centre**

1. Air-conditioner (1/1.5/2 ton)
2. Autoclave
3. Automated/ Semi-automated Equipment for Column Agglutination (optional)
4. Binocular Microscope
5. Blood Bank Refrigerator
6. Deep Freezers (-35<sup>0</sup>C)
7. Di-electric tube sealer (Optional)
8. Dry Incubator
9. Generator (5 KVA/ 30 KVA)
10. Insulated blood bags containers with provisions for storage between 2<sup>0</sup>C to 10<sup>0</sup>C
11. Platelet Agitator and Incubator
12. Sterile Connecting Devices (optional)
13. Table Top Centrifuge
14. Transportation Vans (optional)
15. Tube Stripper
16. Water Bath

## Calibration Frequency for Equipments

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsourced or in house)
1	Temperature recorder (Display)	Compare against calibrated thermometer	Daily	Once in 6 months/ year
2	Refrigerator/ Deep freezer for storage of blood / components	Compare against thermometer	Daily	Once in 6 months
3	General lab centrifuge	Observe speed temperature and time	-	Once in 6 months
4	Blood container weighing device	Container of known calibrated weight	Each day of use	Once a year
5	Water bath	Observe temperature	Each day of use	Once a year
6	Autoclave	Observe temperature and pressure	Each day of use	Once a year
7	Laboratory thermometer	-	-	Once a year
8	Platelet shaker cum incubator	Temperature No. of strokes (check in house)	Once a month	Once a year (temperature)
9	Pipettes	Volume	-	Once in 6 months
10	Dry Incubator	Temperature	Once in a month	Once a year
11	Stop watch	-	-	Once a year

### Quality Control

#### Frequency of testing for Reagent and solution

Reagents and solutions	Frequency of testing along with Controls
Anti human serum	Each day of use
Blood grouping serum	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Normal saline (LISS and BPS)	Each day of use
Bovine albumin	Each day of use

#### Quality control of Reagent red blood cells

Parameters	Quality Requirement	Frequency of Control
Appearance	No haemolysis or turbidity in supernatant by visual inspections	Each day
Reactivity and specificity	Clear-cut reactions with selected reagents against declared RBC antigens	Each day

#### Quality control of ABO reagent (anti-A, anti-B, and anti-AB)

Parameters	Quality Requirement	Explanation	Frequency of Control
Appearance	No turbidity, precipitate, particles or gel formation by visual inspection	No precipitate, particles or gel-formation by visual inspection	Each day
Specificity	Positive reaction with red cells having corresponding antigen(s); and no reaction with negative control	Clear-cut reactions with selected reagents against declared RBC antigens	Daily and of each new lot/batch
Avidity	Macroscopic agglutination with 50% red cells suspension in homologous serum/normal saline using the slide test;  <ul style="list-style-type: none"> <li>10 seconds for anti-A, anti-B and anti-AB with A<sub>1</sub> and/or B cells at R.T;</li> </ul>	<ul style="list-style-type: none"> <li>Macroscopic agglutination with specific time according to anti-sera</li> </ul>	Daily and of each new lot/batch

	<ul style="list-style-type: none"> <li>• 20 seconds with A<sub>2</sub> and A<sub>2</sub>B cells.</li> <li>•</li> </ul>		
Reactivity	No immune haemolysis, rouleaux formation or Prozone	<b>Rouleaux formation</b> : Absent  <b>Prozone Phenomenon</b> : Clear-cut reactions with RBC bearing the weakened expression of the corresponding antigen(s), no false reaction	Each new lot/batch.
Potency	Undiluted serum should give +++reactions in saline tube test using a 3% red cells suspensions at R.T.,  titre should be 256 for anti-A, anti-B, and anti-AB with A <sub>1</sub> and/or B cells.	<b>For Titre Refer:</b> Table of Acceptable Titre and Avidity of ABO reagents	Each new lot/batch.

#### Acceptable Titre and Avidity of ABO reagents

Anti-sera	Type of the reagent	Type of red cells (2-3% cells suspension)	Titre	Avidity Time	Intensity
Anti-A	Polyclonal	A <sub>1</sub> A <sub>2</sub> A <sub>2</sub> B O B	1:256 1:128 1:64 - -	10-12 sec 15-18 sec 15-18 sec - -	+++ ++ To +++ ++ - -
	Monoclonal	A <sub>1</sub> A <sub>2</sub> A <sub>2</sub> B O B	1:256 1:128 1:64 - -	3.4 sec 5-6 sec 5-6 sec - -	+++ ++ To +++ ++++ - -
Anti-B	Polyclonal	B A <sub>1</sub> B O A <sub>1</sub>	1:256 1:128 - -	10-12 sec 12-15 sec - -	+++ ++ - -
	Monoclonal	B A <sub>1</sub> B O A <sub>1</sub>	1:256 1:128 - -	3-4 sec 5-6 sec - -	++++ +++ - -

Anti-AB	Polyclonal	A <sub>1</sub>	1:256	10-12 sec	+++
		B	1:256	10-12 sec	+++
		A <sub>2</sub>	1:64	15-18 sec	++ To +++
		O	-	-	-
	Monoclonal	A <sub>1</sub>	1:256	3-4 sec	++++
		B	1:256	3-4 sec	++++
		A <sub>2</sub>	1:128	5-6 sec	+++
		O	-	-	-

#### Quality Acceptable of Rh Anti sera (Anti-D)

Parameter	Quality requirement	Explanation	Frequency of control
Appearance	No turbidity, precipitation, particles or gel formation by visual inspection	No precipitate, particles or gel-formation by visual inspection	Each day
Specificity	Positive reaction with R <sub>1</sub> r cells or Pooled 'O' Cells minimum 3 donors	Clear-cut reactions with selected reagents against declared RBC antigens	Each day and each new lot/batch. And no reaction with rr cells.
Avidity	Visible agglutination with 40% red cells suspension in homologous serum using the slide test.	<ul style="list-style-type: none"> <li>Macroscopic agglutination with specific time according to anti-sera</li> </ul>	Each day and each new lot/batch
Reactivity	No immune haemolysis, rouleaux formation or prozone phenomenon.	<p><b>Rouleaux formation</b> : Absent</p> <p><b>Prozone Phenomenon</b> : Clear-cut reactions with RBC bearing the weakened expression of the corresponding antigen(s), no false reaction</p>	Each new lot/batch
Potency	Undiluted serum gives +++ reactions in designated test for each serum and a titre 32-64 for anti-D.	<b>For Titre Refer:</b> Table of Acceptable Titre and Avidity of Anti- Rh (D) reagent	Each new lot/batch

### Acceptable Titre and avidity of Anti-D in Anti-Rh (D) Reagent

Type of reagent	Titre+ Immediate spin	Titre+ After 30-45 min incubation	Avidity	Intensity
IgM Monoclonal	1:64-1:128	1:128-1:256	5-10 Sec	+++
Blend of IgM +IgG monoclonal	1:32-1:64	1:128-1:256	10-20 Sec	+++

### Acceptable quality of Anti-globulin reagent:

Parameter	Quality requirement	Explanation	Frequency of control
Appearance	No precipitate, particles or gel formation by visual inspection.	No precipitate, particles or gel-formation by visual inspection	Each day
Reactivity and Specificity	<ul style="list-style-type: none"> <li>• DAT with Sensitized Cells</li> <li>• DAT with Un-sensitized Cells</li> <li>• <b>Potency</b> (Reaction of IgG anti-D with D (RhO) Positive red cells)</li> <li>• No Prozone Phenomenon</li> <li>• No Rouleaux Formation</li> </ul>	<ul style="list-style-type: none"> <li>• Agglutination</li> <li>• No Haemolysis OR No Agglutination</li> <li>• <b>Potency</b> (Titre is positive in more than 1:16 dilution)</li> <li>• <b>Prozone Phenomenon</b> : Clear-cut reactions with RBC bearing the weakened expression of the corresponding antigen(s), no false reaction</li> <li><b>Rouleaux formation</b> : Absent</li> </ul>	Each new lot/ batch.

### Quality Control of 22% Bovine Serum Albumin (BSA)

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual inspection	Each day
Purity	>98% albumin	Certificate provide by Manufacturers
Reactivity	No agglutination of unsensitized red cells; no haemolytic activity; no prozone phenomenon	Each new lot
Potency	IgG anti-D should give a titre of 32-64 with red cells R <sub>1</sub> r or Pooled 'O' Cells minimum 3 donors	Each month

### Quality Control of Normal Saline

Parameter	Quality requirement	Frequency of control
Appearance	No turbidity or particles by visual inspection	Each day
pH	6.0-8.0	Each new batch
Haemolysis	Mixture of 0.1 ml saline and 0.1 ml of 5% red cells suspension centrifuged after 10 min should show no haemolysis	Each new batch

## Choice of Alternate Blood Group for Transfusion

Sl. No.	Patient's Blood Group	First Choice of Blood Group	Second Choice of Blood Group	Third Choice of Blood Group
1.	O Positive	O Positive	O Negative	-
2.	O Negative	O Negative	-	-
3.	A Positive	A Positive	A Negative O Positive O Negative	-
4.	A Negative	A Negative	O Negative	-
5.	B Positive	B Positive	B Negative O Positive O Negative	-
6.	B Negative	B Negative	O Negative	-
7.	AB Positive	AB Positive	AB Negative A Positive, A Negative B Positive, B Negative O Positive, O Negative	-
8.	AB Negative	AB Negative	A Negative B Negative O Negative	-
9.	Oh Bombay	Oh Bombay	-	-
10.	A <sub>2</sub> Containing Anti- A <sub>1</sub>	A <sub>2</sub>	O Red cell	-
11.	A <sub>2</sub> B Containing Anti- A <sub>1</sub>	A <sub>2</sub> B	A <sub>2</sub> or B Red Cells	O Red cell

**Reference:** - Transfusion Medicine Technical Manual by WHO, Edition 2003, Page 106

**Choice of Blood Group  
for  
Exchange Transfusion**

S. No.	Mother	Baby	Group for Exchange Transfusion
1.	O Negative	A,B or O Positive.	O Negative
2.	A Negative	A Positive.	A Negative or O Negative
3.	A Negative	B Positive.	O Negative
4.	A Negative	AB Positive.	A Negative or O Negative
5.	B Negative	B Positive.	B Negative or O Negative
6.	B Negative	A Positive	O Negative
7.	B Negative	AB Positive	B Negative or O Negative
8.	A or B Negative	O Positive.	O Negative
9.	AB Negative	AB Positive.	Any Negative group
10.	AB Negative	A Positive.	A Negative or O Negative
11.	AB Negative	B Positive.	B Negative or O Negative
12.	O Positive	A,B or O Positive.	O Positive.
13.	O Positive	A,B or O Negative	O Negative
14.	A Positive	A Positive	A Positive or O Positive.
15.	A Positive	A Negative	A Negative or O
16.	A Positive	B Positive.	O Positive.
17.	A Positive	B Negative	O Negative
18.	B Positive	B Positive.	B Positive or O Positive
19.	B Positive	B Negative	B Negative or O Negative
20.	B Positive	A Positive	O Positive
21.	B Positive	A Negative	O Negative
22.	A or B Positive	O Positive.	O Positive
23.	A or B Positive	O Negative	O Negative
24.	AB Positive	AB Positive.	Any Positive group
25.	AB Positive	A Positive.	A Positive or O Positive
26.	AB Positive	A Negative	A Negative or O Negative
27.	AB Positive	B Positive	B Positive or O Positive
28.	AB Positive	B Negative	B Negative or O Negative
29.	AB Positive	AB Negative	Any Negative group

**Reference:** Transfusion Medicine Technical Manual- American Association of Blood Bank Page No 106



Guidelines for use of Blood Components										
Component	Description	Indications	Dosage and Effect	Special considerations	Not Indicated for	Self Life	Storage Conditions	Start Infusion	Complete Infusion	Precautions
Red Cells in Additive Solution (SAGM)	300-350 ml of RBC's in additive solution collected from 450 ml of whole blood	<ul style="list-style-type: none"> <li>Acute and chronic symptomatic anaemia</li> <li>Use with crystalloid or colloid solutions in acute blood loss</li> </ul>	1 Unit RBC ↑ Hct by 3% ↑ Hb by 1 gm% (approx)	Must be ABO & Rh compatible and x-match compatible	<ul style="list-style-type: none"> <li>Deficiency anemias treatable pharmacologically</li> <li>Coagulation factor deficiencies</li> </ul>	42 days	2°C - 6°C	Within 30 mts or removal from refrigerator	Within 4 hrs or less if ambient temperature is high	If transfusion is not required immediately do not get the blood issued from blood bank, just get is cross matched and ready
Packed Red Cell without additive Solution	200-250 ml of RBC's from 450 ml of whole blood	Same as RBC's with additive solution	1 Unit RBC ↑ Hct by 3% ↑ Hb by 1 gm% (approx)	Must be ABO & Rh compatible and x-match compatible	<ul style="list-style-type: none"> <li>Deficiency anemias treatable pharmacologically</li> <li>Coagulation factor deficiencies</li> </ul>	35 days	2°C - 6°C	Within 30 mts of removal from refrigerator	Within 4 hrs or less if ambient temperature is high	If the blood is received and not transfused immediately store at 4°C - 6°C [i.e. shelf of refrigerator]
Fresh Frozen Plasma	200-250 ml Plasma prepared within 6 hrs of whole blood collection preserving all clotting factors including labile factors [like Factor V & VIII]	<ul style="list-style-type: none"> <li>Replacement of multiple coagulation factor deficiency.</li> <li>Liver disease</li> <li>Anticoagulant over dose</li> <li>Disseminated Intravascular Coagulation (DIC)</li> <li>Thrombotic thrombocytopenic purpura.</li> <li>Deletion of coagulation factors in patients receiving large volume transfusion</li> </ul>	10-15 ml/kg ↑ Factor levels By 20-30% ↑ Albumin level	ABO compatible No Rh compatibility or X-match required	<ul style="list-style-type: none"> <li>Conditions responsive to volume replacement</li> </ul>	Frozen-1 Year	-30°C or lower Use preferably within 6 hrs. after thawing at 37°C.	Within 30 mts of thawing and if delayed store at 4°C - 6°C	Within 20 mts.	<p>Do not warm the blood</p> <p>Do not store platelet in refrigerator</p> <p>Do not transfuse with any medicine</p>
Liquid Plasma	175-230 ml Plasma Albumin Approx. 8 gm	<ul style="list-style-type: none"> <li>Multiple coagulation factor deficiency</li> <li>Massive transfusion</li> <li>Liver disease</li> <li>DIC</li> </ul>	10-15 ml/kg ↑ Stable Factor Level by 20-30% ↑ Albumin level	ABO compatible No Rh compatibility or x-match required	<ul style="list-style-type: none"> <li>Conditions responsive to volume replacement</li> </ul>	Frozen -1 Year	-30°C or lower Use preferably within 6 hrs. after thawing at 37°C.	Within 30 mts of thawing	Within 20 mts	Fill the quality control checklist before starting the transfusion.
Platelet	>0.5 x 10 <sup>9</sup>	<ul style="list-style-type: none"> <li>Bleeding from</li> </ul>	4-6 Units	Preferably	<ul style="list-style-type: none"> <li>Plasma</li> </ul>	5 days	20° to 24°C with	Immediately	Within 20 mts.	Watch the

Random Donor (RDP)	platelet from 450 ml of blood in 45-65 ml.	thrombocytopenia <ul style="list-style-type: none"> <li>Functional defect of platelets</li> </ul>	Increase platelet count by 5,000-10,000/ $\mu$ l per unit	group compatible, however not group specific platelets can be given	coagulation factor deficit <ul style="list-style-type: none"> <li>TTP, HUS, ITP except in life saving situations.</li> </ul>	(special bags)	continuous agitation	[ do not store platelet after issuing from blood bank]		patient closely for first 20 mts for transfusion reaction.
Whole Blood	450 ml or 350 ml of whole blood in anticoagulant (CPDA-1)	<ul style="list-style-type: none"> <li>Exchange transfusion</li> <li>Acute blood loss more than 30% of total blood volume</li> </ul>	1 unit whole blood $\uparrow$ Hct 3% $\uparrow$ Hb by 1 gm% (approx)	Must be ABO & Rh compatible and X-match compatible	<ul style="list-style-type: none"> <li>Deficiency anemias treatable pharmacologically</li> <li>Coagulation factor deficiencies</li> </ul>	35 days	2 <sup>o</sup> C - 6 <sup>o</sup> C	Within 30 mts of removal from refrigerator	Within 4 hrs or less if ambient temperature is high	Record the transfusion details in patients record.

**Reference:** WHO Blood Transfusion Safety; "Handbook of The Clinical Use of Blood"

## **Records**

The records, which the Blood Storage Centre is required to maintain, shall include inter alias the following particulars, namely:

1. Master Records / Receiving Records for blood and its components: It shall indicate Blood / Component, bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh group, results of testing of HIV1 and HIV2 antibodies, malaria, test for Syphilis, hepatitis B surface antigen and hepatitis C virus antibody, and irregular antibodies (if any), utilisation issue number, temperature at the time of receiving, discarded and signature of the medical officer/in-charge.
2. Issue Register: It shall indicate serial number, date and time of issue, bag serial number; ABO/Rh group, total quantity in ml., name and address of the recipient, group of recipient, name of hospital and unit/ward, details of cross-matching report, indication for transfusion, and identification of staff issuing the unit.
3. Record of components supplied: Quantity supplied; compatibility report, details of recipient and signature of issuing person.
4. Register for reagents and kits used: Name of the kits/reagents, details of batch number, date of expiry, date of use and records of purchase of reagents and kits.
5. Blood Inventory register
6. Patient/ recipient records
7. Transfusion Adverse Reaction Records.
8. Record showing the daily temperature recordings.
9. Record of quality assurance (internal and external).
10. Record of equipment maintenance.
11. Record of document control.
12. Daily group-wise blood stock register (inventory) showing its receipt, issue and balance, units discarded with reason of discarding.
13. Stock register (consumable and non-consumables used in blood bank)
14. Documentation of staff qualifications, training and competency.
15. Staff attendance register or any other recording system.
16. Grievance reporting register

**Note: The above said records shall be kept at least for a period of 5 years**