# NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS

## STANDARDS FOR BLOOD BANK/ BLOOD CENTRE
AND
## TRANSFUSION SERVICES

**Quality Council of India**

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# Terms and Definitions

For the purpose of this document, the terms and definitions are given as follows

**'Accuracy of measurement'** means closeness of the agreement between the result of a measurement and a true value of the measurand.

**'Agreement'**: A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.

**'Agreement Review'**: Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.

**'Apheresis'** means the process by which blood drawn from a donor, after separating plasma or platelets or leucocytes, is transfused simultaneously into the said donor.

**'Autologous blood'** means the blood drawn from the patient for re-transfusion into him/her later on.

'**Biological reference interval**' means central 95% interval of the distribution of reference values.

**'Blood'** means and includes whole human blood, drawn from a donor and mixed with an anti-coagulant.

**'Blood bank/blood centre'** means a place or organisation or units or institutions or others arrangements made by such organisation, unit or institution for carrying out all or any of the operation for collection, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components.

**'Blood bank/blood centre Director'** means competent person (s) with responsibility for, and authority over, a Blood bank/Blood centre

**'Blood bank/blood centre Management'** means person (s) who manage the activity of a Blood bank/Blood centre headed by a blood bank/blood centre director.

**'Blood component'** means a drug, prepared, obtained, derived or separated from a unit of blood drawn from a donor.

**'Blood product'** means a drug manufactured or obtained from pooled plasma of blood by fractionation, drawn from donors.

**'Closed System'**: A system, the contents of which are not exposed to air or outside elements during preparation and separation of components.

**'Collection Facility'**: A facility that collects blood, components or tissue from a donor.

**'Competence':** Ability of an individual to perform a specific task according to procedure

**'Conformance'**: Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.

**'Corrective Action'**: An activity performed to eliminate the cause of an existing non-conformance, or other undesirable situation in order to prevent recurrence.

**'Customer/Recipient'**: The receiver of a product or service. A customer may be internal (i.e., another department within the same organisation) or external (i.e., another organisation)

**'Disaster'**: An event (internal, local, or national) that can affect the blood supply or the safety of staff, patients, volunteers, and donors.

**'Document (noun)**: Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures, or forms.

**'Document (verb)**: To capture information for use in documents through writing or electronic media.

**'Equipment'**: A durable item, instrument, or device used in a process or procedure.

'**Event**': A generic term used to encompass the terms 'incident', 'error', and accident.

**'Executive Management'**: The highest level personnel within an organisation, including employees and independent contractors, who have responsibility for the operations of the organisation and who have the authority to establish or change the organisation's quality policy. Executive management may be an individual or a group of individuals.

**'Incident'** an unplanned deviation from a facility's establish policy, process or procedure.

**'Label':** An inscription affixed to a unit of blood, component, tissue, derivative, or sample for identification.

**'Labelling'**: Information that is required or selected to accompany a unit of blood, component, tissue, derivative or sample, which may include content, identification, description of processes, storages requirements, expiration date, cautionary statements or indications for use.

**'Laboratory'** Laboratory for the biological, microbiological, immunological, serological, immunohaematological, haematological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, pre-transfusion check and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

**'Leucapheresis'** means the process by which the blood drawn from a donor, after leucocyte concentrate have been separated, is re-transfused simultaneously into the said donor.

**'Maintain'**: To keep in the current state.

**'Material'**: A good or supply item used in the manufacturing process. Materials are a type of input product. Reagents are a type of material.

**'Measurement'** means set of operation having the object of determining a value or a quantity.

**'Non-conformance'**: Failure to meet requirement.

**'Open System'**: A system, the contents of which are exposed to air and out side elements during preparation and separation of components.

**'Organisation'**: An institution, or part thereof, that has its own functions and executive management.

**'Plasmapheresis'** means the process by which the blood drawn from a donor, after plasma has been separated is re-transfused during the same sitting into the said donor

**'Peripheral blood stem cell (PBSC)**': The stem cell are the most immature cell in the bone marrow. Most of the stem cells are found in the bone marrow. There are also a few stem cell in the blood. These are called peripheral blood stem cells.

**'Peripheral stem cell collection**': It is a procedure that uses cell separator machine (Apheresis) and separates and collects one type of white blood cells- called a mononuclear cell-from the blood. Except for a small number of red cells, the machine returns all the blood to the donor/patient.

**'Plateletpheresis'** means the process by which the blood drawn from a donor, after platelet concentrates have been separated, is re-transfused simultaneously into the said donor.

**'Policy':** A documented general principle that guides present and future decisions.

**'Pre-donation procedures'** include the process and activity done mandatory before proceeding for bleeding the donor.

**'Post donation procedures'** all the activities, procedures and instructions carried out after bleeding the donor.

**'Preventive Action'**: an action taken to reduce the potential for non-conformance or other undesirable situations.

**Primary sample**

Specimen
Set of one or more parts initially taken from a system

Note: in some places, the term 'specimen' is used instead of primary sample (or a sub sample of it), which is the sample prepared for sending to, or as received by the blood bank/blood centre or laboratory and which are intended for examination.

**'Procedure'**: A series of tasks usually performed by one person according to instructions.

'**Process':** A set of related tasks and activities that accomplish a work goal.

**'Process Control'**: The efforts to standardize and control processes in order to produce predictable output.

**'Product'**: A tangible result of a process or procedure.

**'Professional donor'** means a person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient-patient and includes a paid donor or a commercial donor.

**'Proficiency Testing'**: The structured evaluation of laboratory methods that assesses the suitability of processes, procedures, equipment, materials, and personnel.

**'Quality'**: Characteristics of a unit of blood, component, tissue, derivative, sample, critical material, or service that bear on its ability to meet requirements, including those defined during agreement review.

**'Quality Control'**: Testing routinely performed on materials and equipment to ensure their proper function.

**'Quality System'**: The organisational structure, responsibilities, policies, processes, procedures, and recourses established by executive management to achieve quality.

**'Quantity'** means attribute of a phenomenon, body or substance that may be distinguished qualitatively and determine quantitatively.

**'Quarantine'**: To isolate nonconforming/ untested blood, components, tissue, derivatives, or materials to prevent their distribution or use.

**'Reference Standards'**: Reference standards define how or within what parameters an activity shall be performed and are more detailed than quality system requirements.

**'Replacement donor'** means a donor who is a family friend or a relative of the patient/ recipient.

**'Sample'** means one or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or it's production.

**'Supplier'**: An activity that provides an input material or service.

**'Supplier Qualification'**: An evaluation method designed to ensure that input materials and services (e.g. material, blood components, tissue and derivatives, patient blood samples) obtained from a supplier meet specified requirements.

**'Traceability'** means property of the result of a measurement or the volume of a standard where by it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

**'Transfusion Service'**: A facility that performs one or more of the following activities: compatibility testing, storage, selection, and issuing of blood and components to intended recipients. Transfusion services do not routinely collect blood or process whole blood into components.

**'True Positive'**: A positive result on both the initial test and the confirmatory test.

**'Trueness of measurement'** means closeness of agreement between the average value obtained from a large series of result of measurements and a true value.

**'Uncertainty of measurement'** means parameter, associated with the result of a measurement that characterised the dispersion of the values that could reasonably be attributed to the measurement.

**'Unit'**: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

**'Validation'**: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specifications and quality attributes.

**'Verification'**: Confirmation by examination and provision of objective evidence that specified requirements has been met.

**'Voluntary Blood Donor'** means a person who voluntarily donates blood after he/she has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor.

# 1. Organisation and Management

## 1.1 Legal identity

1.1.1 The blood bank/blood centre shall have a valid license from Central Drugs Standard Control Organisation (CDSCO) and approved by Drug Controller General (India), central license approving authority under Drug and Cosmetic Rules-1945 with further amendments

1.1.2 The organisation under which the blood bank/blood centre functions shall be legally identifiable.

## 1.2 Responsibility

1.2.1 It is the responsibility of management for compliance with these standards and applicable laws and regulation.

1.2.2 The responsibilities of a personnel working in blood bank/blood centre with an involvement or influence on functioning shall be clearly defined in order to identify conflict of interest.

## 1.3 Ethics in blood bank/blood centre

1.3.1 The professional personnel of a blood bank/ blood centre shall be bound by the ethical code of their respective profession, which have to be observed. Personnel responsible for the management of blood bank/ blood centre should accept that, as with other health professionals, they could have responsibilities over and above the minimum required by law.

1.3.2 A blood bank/ blood centre will need to determine acceptable practice what is appropriate for their own situation and incorporate the detail in their quality manual.

1.3.3 Blood bank/ blood centre shall not engage in practices restricted by law and should uphold the reputation of their profession.

1.3.4 Ethics shall address all the procedures and process carried out in blood bank/ blood centre.

## 1.4 Quality System

1.4.1 The blood bank/blood centre management shall have responsibility for the design, implementation, maintenance and improvement of the quality management system.

1.4.2 Quality policy and objectives of the quality management system shall be defined and issued under the authority of the Director/In-charge and documented in quality manual. This policy shall include scope of services, objective of quality management system with management commitment to compliance with the standards and local regulations.

1.4.3 A quality manual shall describe the quality management system covering all the aspects of standards and the structure of the documentation used in the quality management system. The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation in the quality management system.

1.4.4 All personnel shall be instructed to familiarize themselves with the quality management system with use and application of the quality manual and all referenced documents.

1.4.5 The quality manual shall be kept up to date under the authority of an individual responsible for maintaining quality management system.

1.4.6 For implementation and maintenance of quality management system, the management shall appoint Quality Manager, Technical Manager and deputies. Roles and responsibilities of Technical Manager and the Quality Manager (however named), shall be defined including their responsibility for ensuring compliance with these standard. All these personnel shall have dedicated responsibilities and authority to oversee compliance with the requirement of the quality management system.

### 1.5 Policies, Processes, and Procedures

1.5.1 Quality and operational policies, processes, and procedures shall be developed and implemented to ensure that the requirements of these Standards are satisfied. All such policies, processes, and procedures shall be recorded and followed.

1.5.2 Director/In-charge blood bank/blood centre shall approve all policies, process and procedures.

## 2. Accommodation and Environment

### 2.1 Space Allocation

2.1.1 Location and surroundings:

The blood bank/blood centre shall be located at a place, which shall be away from open sewage, drain, public lavatory or similar unhygienic surroundings.

Building: The building (s), used for operation of a blood bank/blood centre and/or preparation of blood components shall be constructed in such a manner so as to permit the operation of the blood bank/blood centre and preparation of blood components under hygienic conditions and shall avoid entry of insects, rodents and files, It shall be well-lighted, ventilated and screened (mesh) whenever necessary. The walls and floors of the rooms, where collection of blood or preparation of blood components or blood products is carried out shall be smooth, washable and capable of being kept clean. Drains shall be of adequate size and where connected directly to a sewer, shall be equipped with traps to prevent back siphonage.

The blood bank/blood centre shall be designed for the efficiency of its operation, to optimise the comfort of its occupants and to minimize the risk of injury and occupational illness. Patients, employees and visitors shall be protected from recognized hazards.

2.1.2 Accommodation of blood bank/blood centre

A blood bank/blood centre shall have a minimum area of 100 square meters for its operations and an additional area of 50 square meters for preparation of blood components. It shall be consisting of a room each for-

a) Registration and medical examination with adequate furniture and facilities for registration and selection of donors.
b) Blood collection (air-conditioned).

c) Blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degrees centigrade)
d) Laboratory for blood group serology (air-conditioned).
e) Laboratory for blood transmissible disease like hepatitis, syphilis, malaria, HIV-antibodies (air-conditioned)
f) Sterilization-cum-washing.
g) Refreshment-cum-rest-room (air-conditioned).
h) Store-cum-record.

2.1.3 Processing of blood component from whole blood by a blood bank/blood centre

The blood components shall be prepared by blood bank/blood centres as a part of the blood bank services.

Accommodation:

1) Rooms with adequate area and other specifications, for preparing blood component depending on quantum of work load (already defined in point no. 2.1.1 and 2.1.2).

2) Preparation of blood components shall be carried out only under closed system using single, double, triple or quadruple plastic bags except for preparation of red blood cells concentrate, where single bags may be used with transfer bags.

2.1.4 Plasmapheresis Plateletpheresis and Leucapheresis:

An area of 10 square meters shall be provided for apheresis in the blood bank/blood centre.

2.1.5 Blood Donation Camp

For holding a blood donation camp, the following requirements shall be fulfilled/ complied:

Premises

Premises under the blood donation camp shall have sufficient area (permanently constructed or a mobile van) and the location shall be hygienic so as to allow proper operation, maintenance and cleaning.

All information regarding the personnel working, equipment used and facilities available at such a camp shall be well documented and ensuring the following:

a. Continuous and uninterrupted electrical supply for equipment used in the camp
b. Adequate lighting for all the required activities.
c. Hand-washing facilities for staff.
d. Reliable communication system to the central officer of the controller/organiser of the camp.
e. Furniture and equipment arranged within the available space.
f. Refreshment facilities for donors and staff.
g. Facilities for medical examination of the donors.
h. Proper disposal of waste

2.1.6 There shall be effective separation between adjacent blood bank/blood centre sections in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

2.1.7 Access to, and use of areas affecting the quality of the examinations shall be controlled. Appropriate measures shall be taken to safeguard samples and resources from unauthorized access.

2.1.8 Relevant storage space and condition shall be provided to ensure the continuing integrity of samples, documents, files, manuals, equipment, reagents, blood bank/blood centre supplies, records and results.

2.1.9 Work areas shall be clean and well maintained (good housekeeping), storage and disposal of dangerous material shall be those specified by relevant regulations. Special procedures and training for personnel could be necessary to the end.

2.1.10 Blood bank/blood centre shall have adequate back up facility for maintaining electrical supply round the clock.

## 2.2 Environment Control

The blood bank/blood centre shall have process to minimize and respond to environmentally related risks to the health and safety of employees (including immunization), donors, volunteers, patients and visitors. Suitable environment and equipment shall be available to maintain safe environment.

## 2.3 Biological, Chemical and Radiation Safety

The blood bank/blood centre shall have a process for monitoring adherence to biological, chemical and radiation safety standards and regulation, where applicable.

The blood bank/blood centre shall monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the procedures and quality of the results. Attention should be paid to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature,, sound and vibration levels as appropriate to the technical activities concerned.

## 2.4 Internal Communication System

Communication systems within the blood bank/blood centre shall be those appropriate to the size and complexity of the facility for the efficient transfer of messages.

# 3. PERSONNEL

## 3.1 Personnel Requirement

The blood bank/blood centre shall have a process to ensure the employment of an adequate number of individuals qualified by education, training and/or experience.

## 3.2 Qualification

The operation of blood bank/blood centre and/or processing of whole human blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person who is full time Medical Officer possessing following qualification:

3.2.1 Medical Officer

MD (Pathology)/ MD/DNB (Transfusion Medicine)

OR

Degree in Medicine (M.B.B.S) with Diploma in Clinical Pathology or Transfusion Medicine having adequate knowledge in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/or preparation of its components

OR

Degree in Medicine (M.B.B.S) having experience in blood bank/blood centre for one year during regular services and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood and/ or preparation of its components

3.2.2 Blood bank/blood centre technician (s)

Technician shall be full time competent staff possessing:

Degree in Medical Laboratory Technology (M.L.T.) with six months experience in the testing of blood and/ or its component;

OR

Diploma in Medical Laboratory Technology (M.L.T.) with one-year experience in the testing of blood and/or its component.

(The degree or diploma being from University /Institution recognized by the Central Government or State Government.)

3.2.3 Registered Nurse (s)

Registered with state/central nursing council

3.2.4 Technical Supervisor (where blood components are manufactured) possessing:

Degree in Medical Laboratory Technology (M.L.T.) with six months experience in the testing of blood and/or its components.

OR

Diploma in Medical Laboratory Technology (M.L.T.) one years experience in the testing of blood and/or its components.

(The degree or diploma being from a University/Institute by the Central Government /State Government).

As regards to the number of full time competent personnel the blood bank/blood centre shall comply with the requirements laid down in the Directorate General of Health Services Manual.

### 3.3 Job description/responsibilities

Current job description shall be maintained and shall define appropriate qualifications for each job position.

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

### 3.4 Responsibilities of Director/In-charge, Technical Manager and Quality Manager

3.4.1 The responsibilities of the blood bank/blood centre Director/In-charge shall include professional, scientific, consultative or advisory organisational, administrative and educational matters. These shall be relevant to the services offered by the blood bank/blood centre.

3.4.2 Technical manager shall have overall responsibility for the technical operation and the provision of resources, needed to ensure the required quality of blood bank/blood centre procedures.

3.4.3 Quality Manager with delegated responsibility and authority to oversee compliance with the requirement of the Quality Management system and shall report directly to the level of management at which decision are made on blood bank/blood centre policy and resources.

## 3.5 Training

3.5.1 Personnel shall have training specific to quality assurance and quality management for services offered.

3.5.2 It shall be the responsibility of the management to ensure thorough maintenance of records and other latest techniques used in blood bank/blood centre system that the personnel involved in blood bank/blood centre activities for collection, storage, testing and distribution are adequately trained in the current good manufacturing practices/standards operating procedures for the tasks undertaken by each personnel, and receive initial and continuing training relevant to their needs.

3.5.3 There shall be a continuing education program available to staff at all levels.

3.5.4 Employees shall be trained to prevent adverse incidents and/or contain the effects of adverse incidents.

## 3.6 Competence

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

## 3.7 Personnel health

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

## 3.8 Personnel Records

Blood bank/blood centre management shall maintain records of the 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) Competency evaluation, and
f) Provision for untoward incident or accident reports.

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

## 3.9 Confidentiality of information

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

# 4. Equipment

## 4.1 Equipment requirement

The blood bank/blood centre shall be furnished with all the equipment that is required for the provision of services (including blood collection, component preparation, processing, examination and storage). The blood bank/blood centre shall have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these blood bank/blood centre standards and other specified requirement.

## 4.2 Selection and validation of equipment

Equipment shall show (upon installation and in routine use) to be capable of achieving the performance required and shall comply with specifications relevant to the examinations concerned.

## 4.3 Use of equipment

Authorized personnel only shall operate the equipment. Up-to-date instructions on the use and maintenance of the equipment (including and relevant manuals and direction for use provided by the manufacture of the equipment) shall be readily available to personnel.

Equipment used in the collection, processing, testing, storage and distribution of blood and its components shall be maintained in a clean and proper manner and so placed as to facilitate cleaning and maintenance.

## 4.4 Equipment detail record, unique identification

Records shall be maintained for each item of equipment. These records shall include at least the following:

a) Identification of the equipment.
b) Manufacturers name, type identification and serial number or other unique identification
c) Manufacturers contact person and telephone number.
d) Date of receiving and date of putting into a service.
e) Current location, where appropriate.
f) Condition when received (new, used or reconditioned).
g) Manufacturers 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.

## 4.5 Programme for calibration and maintenance of equipment

4.5.1 Blood bank/blood centre management shall establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It shall also have a documented and recorded programme of preventive maintenance, which, at a minimum, follows the manufacturer's recommendation.

4.5.2 The equipment shall be observed, standardized and calibrated regularly on scheduled basis as described in the standard operating procedure manual and shall operate in the manner for which it was designed so as to ensure compliance with the legal requirement (the equipment) as stated below for blood and its components.

4.5.3 Equipment shall be observed, standardized and calibrated with at least the following frequencies:

| S. No. | Equipment | Performance | Frequency for performance checking | Minimum frequency of calibration (outsource or in house) |
|---|---|---|---|---|
| 1 | Temperature recorder (Display) | Compare against calibrated thermometer | Daily | Once in 6 months |
| 2 | Refrigerator/ Deep freezer for storage of blood / components | Compare against thermometer | Daily | Once in 6 months |
| 3 | Refrigerated blood bag centrifuge | Observe speed temperature and time | Each day of use | Once a year |
| 4 | Hematrocrit centrifuge | Observe speed temperature and time | - | Once a year |
| 5 | General lab centrifuge | Observe speed temperature and time | - | Once a year |
| 6 | Automated blood typing | Observe control of correct result (QC samples) | Each day of use | Once a year |
| 7 | Haemoglobin meter | Standardize against cyanamethemoglobin standard | Each day of use | Once a year |
| 8 | Refractio-meter or Urinometer | Standardized against distilled water | Each day of use | Once a year |
| 9 | Blood container weighing device | Container of known calibrated weight | Each day of use | Once a year |
| 10 | Water bath | Observe temperature | Each day of use | Once a year |
| 11 | Autoclave | Observe temperature and pressure | Each day of use | Once a year |
| 12 | Serologic rotators | Observe control for correct result | Each time of use | Once a year |

| | | | | |
|---|---|---|---|---|
| 13 | Laboratory thermometer | - | - | Once a year |
| 14 | Electronic thermometer | | | Before initial use and once a year |
| 15 | Blood agitator | Observe Weight of the first container of blood filled for correct results | Once in 15 days | Once a year |
| 16 | Platelet shaker cum incubator | Temperature<br>No. of strokes( check in house) | Once a month | Once a year (temperature) |
| 17 | Automated blood cell counter | Known controls | Daily | Once a year |
| 18 | Pipettes | Volume | Once in a month | Once a year |
| 19 | Incubator | Temperature | Once in a month | Once a year |
| 20 | Stop watch | - | - | Once a year |
| 21 | Tachometer | - | - | Once a year |
| 22 | Weight box | - | - | Once a year |

4.5.4 The program for calibration of equipment shall be designed and operated so as to ensure that calibrations are traceable to international system of units (SI). The link to SI units may be achieved by reference to national measurement standards.

## 4.6 Equipment for storage of Blood and component

4.6.1 Blood bank/blood centre shall have adequate storage facility corresponding to its workload.

4.6.2 Storage devices shall have design to ensure that the proper temperature is maintained.

4.6.3 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.

4.6.4 If blood or components are stored in an open storage area, the ambient temperature shall be maintained at 22±2 $^{0}$C.

## 4.7 Computer system

When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination date, the blood bank/blood centre shall ensure that:–

a) Computer software, including that built into equipment is documented and suitably validated as adequate for use in the facility.
b) Procedures are established and implemented for protecting the integrity of data at all times.

c) Computer and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data.
d) Computer programmes and routines are adequately protected to prevent access, alternation and destruction by unauthorized person.

## 4.8 Breakdown of equipment

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 shows to be calibrated to meet specified acceptance criteria.

# 5. External Services: Supplies and Reagents

## 5.1 Policies and procedures for supplier's selection

5.1.1 Blood bank/blood centre management 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. Purchased items shall consistently meet the blood bank/blood centre quality requirements. National, regional or local regulations may require record of purchased items. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of consumable materials.

5.1.2 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.

5.1.3 All supplies and reagents used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place in a proper manner.

5.1.4 All supplies coming in contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product.

5.1.5 Supplies and reagent that do not bear an expiry date shall be stored in a manner that the oldest is used first.

5.1.6 Supplies and reagent shall be used in a manner consistent with instructions provided by the manufacturer.

5.1.7 All final containers and closures of blood and blood components intended for transfusion shall be clean and free of surface solid and other contaminants.

Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling, such examination shall include inspection for breakage of seals, when there is such indication the container shall not be used or, if detected after filling, shall be properly discarded.

## 5.2 Inventory Control

5.2.1 There shall be an inventory control system for supplies. Appropriate quality records of external services, supplies and purchased product shall be established and maintained for period of time as defined in the quality management system.

5.2.2 This system should include the recording of lot number of all relevant reagents, control materials and calibrators, the date of receipt in the blood bank/blood centre and the date the material placed in service. All of these quality records shall be available for blood bank/blood centre management review.

## 5.3 Evaluation of suppliers

The blood bank/blood centre shall evaluate suppliers of critical reagents, supplies and services that affect the quality of examinations and shall maintain records of these evaluations and list of those approved.

# 6. Process control

## 6.1 Policies and Validation of Processes and Procedures

The blood bank/blood centre shall have policies and validated processes and procedures that ensure the quality of the blood, component, issue, derivatives and services. The blood bank/blood centre shall ensure that these policies, processes and procedures are carried out under controlled conditions.

**Process or procedure steps**

For each critical step in collection, processing, compatibility testing and transportation of blood component, issue and derivatives there shall be a mechanism to identify who performed the step and when it was performed.

6.1.1 Traceability of blood unit and sample for blood collection to issue blood

The blood bank/blood centre shall ensure that all blood, components, issue, derivatives and critical materials used in their processing, as well as laboratory sample and donor and patient records, are identified and traceable.

The blood bank/blood centre shall establish a procedure to identify a recipient of a transfusion of blood from a donor who is subsequently found to have been infected with transfusion transmissible infection. In case this happens the blood bank/blood centre shall inform the patient's physician. Appropriate record of such events shall be kept. The unused components from this unit shall be discarded.

6.1.2 Standard Procedure

The blood bank/blood centre shall use examination procedures, including those for selecting/taking sample portions, which meet the needs of the users of blood bank/blood centre services and are appropriate for the examination. National guidelines/ manuals and other regulatory directives shall be followed. In absence of the above, preferred procedures that have been published in established/ authoritative textbooks, peer-reviewed text or journals or in international guidelines shall be used. If in-house procedures are used, these shall be appropriately validated for their intended use and fully documented.

The blood bank/blood centre shall record the result obtained and the procedure used for the validation in case in-house developed methods are used.

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 blood bank/blood centre.

Card files or similar systems that summarize key information are acceptable for use as a quick reference at the workbench, provided that a complete manual is available for reference. The card file or similar systems shall correspond to the complete manual. Any such abridged procedures shall be part of the document control system.

The procedures can be based on the instructions for use (e.g. package insert) written by the manufacturer. The procedures described, are as these are performed in the blood bank/blood centre. Any deviation shall be reviewed and documented. Additional information that could be required to perform the examination shall also be documented. Each new version of examination 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 and found to give satisfactory result before being put in practice. A review of procedures by the blood bank/blood centre director/ in-charge shall be undertaken initially and at defined intervals. Such a review is normally carried out annually. These reviews shall be documented.

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

## 6.2 Donor laboratory

6.2.1 Blood Donation

6.2.1.1 Donor Recruitment

Blood bank/blood centre shall, as policy, try to collect blood from voluntary, non-remunerated, low risk, safe and healthy donors.

Efforts shall be directed towards encouraging and retaining adequate number of repeat donors. Donors shall be appropriately recognised and felicitated for their contribution.

The blood bank/blood centre shall educate donors prior to collection of blood regarding the risk factors of transfusion transmissible infections.

The blood bank/blood centre shall maintain a voluntary donor directory.

6.2.1.2 Pre-donation counseling

Pre-donation counseling by the counselor / staff with appropriate training shall be made available maintaining privacy and confidentiality. Pre-donation information shall include:

a) Modes of transmission due to risk behaviour and self-exclusion for patient's safety.
b) Information about alternative testing site.
c) Test carried out on donated blood.
d) Confidentiality of test results.
e) Need for honest answers in view of window period.

6.2.1.3 Donor registration, consent and selection

a) Donor registration

A questionnaire shall be prepared in English and local languages which is simple and easy to understand to be answered by the donor.

For donors who are illiterate, assistance shall be given by donor registration staff.

Medical officer with minimum MBBS qualification shall be responsible for reviewing the donor's health conditions and physical examination of the donor.

Demographic details such as name and address of donor, date and time of donor selection and donation shall be registered.

b) Consent

Prior to blood donation, the consent of the donor shall be obtained in writing with donor's signature or thumb impression after the procedure is explained and the donor is informed regarding testing of blood for all mandatory tests for safety of recipients. The donor shall be provided an opportunity to ask questions and refuse consent. After donation, if the donor seeks the status of Transfusion Transmitted Infection (TTI), the same may be provided with prior consent.

c) Criteria for Selection of Donors

The requirements given at annexure B shall be followed in order to ensure that the blood donation will not be detrimental to the donor/recipients.

d) Donation Interval

The interval between two blood donations shall be at least three months.

At least 48 hours must elapse after plasmapheresis or cytapheresis before whole blood is collected from a donor.

Apheresis shall be done only after three months of whole blood collection or in an event when red cells are not returned at the end of pheresis.

Interval between two plateletpheresis shall be 48 hours and not more than twice a week and not to exceed 24 times in a year. The donors shall be tested appropriately to detect a developing cytopenia and decreased serum protein.

For double red cell collection donor shall have haemoglobin 13.5 g/dl and weight >65 Kgs. The interval between the 2 procedures shall be six months.

6.2.1.4 Phlebotomy procedure

a) Blood shall be collected only by a licensed blood bank/blood centre. Blood shall be drawn from the donor by a qualified physician or under his/her supervision by nurse/technician trained in the procedure. A physician shall be present on the premises when the blood is being collected. Blood shall be collected by single venipuncture and flow of blood shall be continuous.

The blood donor area shall be clean, congenial, comfortable and conveniently approachable. As the temperatures vary widely in different seasons, it is mandatory to

have air-conditioned rooms to make the donor comfortable and to minimise chances of contamination.

b) Method of preparation of phlebotomy site

A strict standardised procedure shall be in use to achieve surgical cleanliness for preparing venepuncture site to provide maximum possible assurance of sterile product.

c) Equipment and blood bag

The blood bags for collection of blood shall be sterile, pyrogen-free and disposable, with a closed system of collection as per standards provided by national authority. Multiple interconnected plastic bags shall be used for blood component preparation (closed system). Venting of any container shall be done under laminar airflow bench and such container shall be used within 24 hours. To avoid venting in case of paediatric use, multiple inter-connected closed containers shall be used.

d) Anticoagulant Solutions

The anticoagulant solution shall be sterile and pyrogen-free. One of the following solutions shall be used in the indicated volumes.

Citrate-phosphate-dextrose (CPD) solution:14 ml solution is required for 100 ml of blood.

or

Citrate-phosphate-dextrose-adenine (CPDA-1) solution: 14 ml solution is required for 100 ml of blood.

100 ml SAGM/ADSOL (for 450ml whole blood) and 80 ml (for 350ml whole blood) or any other approved additive solution containing saline adenine and glucose (or with mannitol) is added to packed cells after separation of plasma for storage.

e) Volume

Volume of blood collected shall be proportionate to the volume of anti-coagulant with $\pm$ 10% variation and shall not exceed 10 ml/kg body weight. Units of blood where volume collected is out of the permitted limits shall not be used for transfusion. No attempt shall be made to collect blood from such donor during the same session.

Extracorporeal blood volume shall not exceed 15% of the donor's estimated blood volume.

6.2.1.5 Post donation care

Donor shall be given advice regarding post-phlebotomy care and cautioned as to possible adverse reactions. This shall also be displayed in the blood collection/observation room.

6.2.1.6 Adverse donor reaction management

Necessary drugs and equipment shall be available for treatment of donor reaction, if any. Donor blood collection staff shall be trained in identification and management of donor reactions. like

Syncope (fainting or vasovagal syndrome):

Tetany (twitching or Muscular spasm)

Nausea and vomiting

Hematoma

Convulsions

Cardiac problems

6.2.1.7 Blood Donation camp/drives

*Outdoors blood donation camps*

Blood donation camps shall be organised only by blood bank/blood centres authorised by SBTC (State Blood Transfusion Council) to augment blood stocks. Donor organiser/medical social worker of the blood bank/blood centre shall contact offices, institutions, industries, social and religious organisations, colleges and schools to collect need based volume of blood from targeted group of donors located at a particular venue at regular intervals.

Adequate publicity and Information Education and Communication (IEC) material shall be made available to the organisations.

The number of blood units collected shall commensurate with the actual requirement of blood units rather than by social or emotional pressures.

Authorized person from blood bank/blood centre shall inspect the donation site prior to the day of blood collection to ensure availability of all facilities as prescribed.

The outdoor camps shall be organised in an environment, which is conducive and comfortable. The area shall be cleaned before and after the blood collection.

Blood bank/blood centre shall maintain quality at each step from donor recruitment, selection and collection to the final product. The method of blood collection and management of donor reaction shall be the same as at blood bank/blood centre.

Blood and its components could contain infectious agents and hence these shall be handled with precautions.

*Large Camps*

The large camps organised on a day shall be planned as per criteria laid down by the Drug and Cosmetics Act or any other directive from national/state authority.

Any quality measures, pre-donation counselling and transportation procedures shall not be compromised.

6.2.1.8 Autologous transfusion procedure

The blood bank/blood centre doing autologous transfusion shall have the defined processes and procedures including predeposit, criteria for autologous donation, testing of

units, labelling required, pretransfusion testing, perioperative procedures and post operative procedures.

6.2.1.9 Donor Notification of Abnormal Findings and Test Results and Counselling

a) Information of test results

The medical officer of blood bank/blood centre shall inform the donor about any sero-reactive result of TTI with prior written consent.

b) Counselling and Referral

For ensuring blood safety, the blood bank/blood centres shall provide pre and post donation counselling services.

All blood bank/blood centres shall train their donor organisers/medical officers to undertake counselling in the absence of a donor counsellor.

Donors who are HIV sero-reactive shall be referred to a voluntary counselling and testing centre (VCTC) for post donation confirmation and counselling or may provide with the facilities for the confirmation and counselling at blood bank/blood centre.

For TTI other than HIV, the donor shall be referred for follow up to concerned speciality and management.

6.2.1.10 Records of donor and donor's blood/components

*Following Donor Records shall be maintained:*

- Demographic details of donor.
- Identification number.
- Donor selection record.
  - Medical History.
  - Physical examination.

*Donor deferral records.*

*Donor's blood collection record.*

- Date of collection.
- Batch No. And bag manufacturer's name.
- Segment number on the donor tubing.
- Particulars of donor.
- Identification number.
- Amount of blood collected.
- Time and duration of collection.
- Signature of phlebotomist and medical officer.

*Donor reactions* – State of donation reaction when occurred needs to be mentioned along with the description, management details and action taken for prevention in future.

*Blood components records*

- Identification number.
- Name and volume of component prepared.

- Date, time and mode of preparation.
- Disposition record.

*Record of processing of donor's blood*

- ABO and Rh (D) type.
- Antibody screening and identification.
- Anti-HIV 1 & 2, Anti-HCV, HBsAg, VDRL test and its interpretation.
- Test for absence for malaria parasites.

Documentation of details of grouping shall be done indicating reactionresults, batch number and manufacturer's name of reagents in use, details of reagent red cells in use.

Documentation of all infectious disease tests shall be done including ELISA printouts showing results and interpretation as well as batch number, expiry date and manufacturer's name of the kit in use.

All rapid tests/spot tests shall be interpreted preferably by two competent individuals and recorded.

Quality control records shall be maintained indicating testing of components, reagents and equipment.

Records of apheresis procedures shall be maintained.

Records of all blood discarded shall be maintained.

6.2.1.11Therapeutic Plasmapheresis and Cytapheresis

Therapeutic plasmapheresis / cytapheresis shall be done only at the written request of the patient's physician either preferably in the blood bank/blood centre or in the ward depending on patient's clinical condition.

Records of patient's identification, diagnosis, therapeutic procedures, haemapheresis method, volume of blood removed and returned, time taken, nature and volume of replacement fluids, and adverse reaction if any and medication administered, shall be maintained.

Informed consent of the patient shall be taken in the language he/she understands.

Provision for emergency care shall be available.

Therapeutic Phlebotomy

Therapeutic phlebotomy shall be done only on the request of the patient's physician. The blood bank/blood centre doctor must decide whether to accept the responsibility of the patient. The blood collected in such circumstance shall not be used for transfusion.

6.2.2 Handling of samples and blood units

6.2.2.1 Samples for Laboratory tests

The blood samples in the pilot tubes (plain and with anticoagulant) shall be collected at the time of collection of blood by the same person. They shall be marked before collection to be identified with the unit of blood.

The integral donor tubing of plastic bag shall be filled with anticoagulated blood using appropriate method and sealed in such a manner that it will be available with segment numbers for traceability for subsequent compatibility tests.

6.2.2.2 Identification and Traceability

Each container of blood/blood components/pilot tubes shall be identified by a numeric or alphanumeric number at the time of collection of blood, so that it can be traced back to the donor and also to the recipient. The segment number printed on the integral donor tubing shall be recorded.

a) Blood Unit Identification

A numeric or alphanumeric system shall be used, that will make it possible to trace any unit of blood or component from source to final destination and recheck records applying to the specific unit.

The numeric and alphanumeric identification on label shall be provided by the collecting facility to each unit of blood/its components. This number shall be documented for traceability. Any advanced technology for identification such as barcode system is preferable.

No identification mark of donor should be written on the label. In case of transfer of blood unit to blood storage centre, original label with the same identification shall be retained.

b) Traceability

The blood bank/blood centre shall ensure that all blood, component prepared in their premises, as well as laboratory samples and donor and patient records, are identified and traceable to donor and recipients.

6.2.2.3 Transportation

Immediately after collection, the blood shall be placed at 4-8 ± $2^{o}$ C except if it is used for component preparation which can be stored at $22^{o}$C ± $2^{o}$C until the platelets are separated.

Whole blood, red cell concentrate, shall be transported in a manner that will maintain a temperature of 4-8 ± $2^{o}$ C. Platelet/granulocyte concentrate are stored and transported at $22^{o}$C ± $2^{o}$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 $37^{o}$C prior to issue.

The temperature during transport shall be monitored.

## 6.3 Component Laboratory

6.3.1 Sterility

The sterility of all components shall be maintained during processing by the use of aseptic methods and sterile pyrogen-free disposable bags and solutions.

6.3.2 Seal

Blood bags that allow transfer of component without breakage of the seal (closed system) shall be used. The seal will not be considered broken if a sterile connecting device is used resulting in a closed system.

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

Once the frozen components are thawed, these shall be transfused at the earliest and positively within 6 hours.

At the time of preparation of the final components the integrally connected tubing shall be filled with aliquote of the components and sealed in such a manner that it shall be available for subsequent compatibility and assay testing, if needed.

6.3.3 Preparation of Components

a) Red Blood Cells Components

Red blood cells

Red blood cell concentrate shall be prepared from the whole blood collected in plastic bags, preferably in double or multiple plastic bag system. Plasma is separated from red blood cells following either centrifugation or undisturbed sedimentation at any time before the expiry date of blood. If closed system is in use, the expiry date of red cells shall be the same as whole blood. The hematocrit of packed cells shall be adjusted so that it is not more than 70%.

*Washed Red Cells*

Red blood cells shall be washed with normal saline by automatic cell washer or manually by centrifugation. The cells shall be washed 2–3 times with normal saline by centrifuging at $4^{o}C\pm 2^{o}C$. A laminar bench that is validated from time to time shall be used. Closed system of washing is recommended.

*Leucocyte depleted red blood cells*

Leucocyte depleted red blood cells concentrate shall be prepared by a method known to reduce leucocytes in the final component to less than $5X10^{6}$ when intended to prevent febrile reactions.

*Frozen and deglycerolised red blood cell concentrate.*

Red cells shall be stored frozen continuously at low temperature of $-80^{o}C$ to $-196^{o}C$ in the presence of cryoprotective agent. The red cells shall be washed to remove the cryoprotective agent prior to transfusion.

The method of preparation, storage, thawing and washing shall ensure a recovery of at least 80% of original red cells or larger depending on the procedure in use.

Red blood cells shall be ordinarily frozen within 6 days of collection of blood and can be kept frozen upto 10 years.

b) Platelet Concentrate: (Random Donor Platelets)

Platelet concentrate shall be prepared by centrifugation of single unit of whole blood collected with a smooth venipuncture and a continuous flow of blood.

Platelet concentrate shall be separated from whole blood within 6 hours of collection by centrifugation at $22^oC \pm 2^oC$ using either platelet rich plasma (PRP) or buffy coat (BC) method, which is validated.

Platelet shall be suspended in approximately 50 ml of plasma and stored at $22^oC \pm 2^oC$ under agitation. The pH at storage temperature shall not be lower than 6.0 at the end of storage period.

Continuous gentle agitation (60–70 oscillations/per min) using horizontal agitator or a rotator with 5–10 cycles/minute shall be maintained throughout the storage period varying from 3 to 5 days depending on the nature of plastic of the bag in use considering day of blood collection as day zero.

There shall be no grossly visible platelet aggregates during the storage. Swirling phenomenon shall be checked before issue.

The concentrate prepared shall not be contaminated with red cells. The degree of reddish tinge of the concentrate indicates red cell contamination. The units contaminated with red cells shall be used as group specific. If the contamination of RBCs is more than 5 ml the unit shall be issued after cross match.

c) Granulocyte concentrate

Unit of granulocytes prepared by use of cell separator shall have $1X10^{10}$ leucocytes and shall be kept at $22^oC \pm 2^oC$ for a maximum period of 24 hours.

d) Plasma

*Single donor plasma*

Plasma shall be separated from whole blood at any time up to 5 days after the expiry of the whole blood. The plasma separated after 5 days of expiry date will be used only for fractionation.

*Fresh frozen plasma*

Fresh plasma shall be separated from the whole blood not later than 6 hours of collection and frozen solid at $-30^oC$ or lower as early as possible. Prior to infusion the frozen plasma shall be thawed rapidly at $30–37^oC$ in a water bath with shaker. Once thawed it shall be used within 6 hours, when kept at Room/ambient temperature, or within 24 hours when kept at $4^oC \pm 2^oC$

*Cryo poor plasma or Factor VIII deficient Plasma*

This is plasma from which cryoprecipitate has been removed. It shall be stored at –30°C and once thawed shall be used within 6 hours.

e) Single Donor Cryoprecipitate (Cryoprecipitated Anti-hemophilic factor)

For preparation of cryoprecipitate the fresh frozen plasma shall be frozen within 6 hours of collection at –80°C or lower and thawed at 4°C circulating water bath or in 4°C Cold Room Blood bank refrigerator.

Thawed plasma shall be immediately centrifuged and separated from the cold insoluble material under sterile conditions.

The cryoprecipitate (cold insoluble material) shall be frozen within 1 hour and shall be kept at –30°C or lower up to 1 year from the date of donation. Once thawed, it should be used within 6 hours.

f) Donor Apheresis

This procedure shall be carried out only in a blood bank/blood centre licensed for this purpose.

A medical officer trained in apheresis technique shall be responsible for the procedure.

The staff working on the cell separator shall be trained in apheresis procedure and shall work directly under the supervision of the medical officer.

There shall be provision for emergency medical care, in the event of any adverse reaction to the donor.

*Plasmapheresis*

It is a procedure to harvest plasma from the whole blood and returning the cellular component to the donor. Plasma is harvested by automated machine.

In serial plasmapheresis programme with return of the cellular components a minimum interval shall be of 48 hours between two procedures and not more than two procedures in a week shall be allowed.

If a participant of such programme donates a unit of blood or if it is not possible to return red cells, the donor shall not undergo platelet/plasma pheresis for 12 weeks.

Records

Records of donor's periodic examination, laboratory tests, consent of donor/patient, date of last apheresis procedure, certificate of the attending physician, procedure, volume of product separated, drugs used, adverse reaction if any and their treatment shall be maintained.

Volume of plasma

Volume of plasma obtained excluding anticoagulants from a donor weighing at least 55 kg., shall not exceed 500 ml with serum protein within normal limit during one procedure on not more than 1000 ml per month with a maximum of 12 litters/year. Extra corporeal blood volume shall not exceed 15% of donor's estimated blood volume.

*Cytapheresis (*Plateletpheresis, Leukapheresis, Peripheral blood stem cells harvest)

Cytapheresis is the procedure for separation of individual cellular component of blood. It can be achieved by the cell separator machine.

Peripheral blood stem cells are harvested using continuous or intermittent cell separator. Attempt shall be made for harvesting minimum of $2X10^6$ CD34 cells and/or minimum of $2X10^8$ MNCs/Kg of the recipient.

## 6.4 Quarantine and Storage

6.4.1 Refrigeration and freezers for storage

A designated area shall be used for storage to limit deterioration and prevent damage to materials in process and final products. 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 items.

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

Blood bank/blood centre refrigerator/ walk-in-cooler shall have inside temperature of $4^oC \pm 2^oC$ and shall have a system to monitor temperature continuously or at least the temperature shall be recorded every 4 hours . An alarm system and a provision for alternate power supply shall be available.

Deep freezer shall have inside temperature of $–30^oC$ or $–80^oC$ having temperature indicator/recording facility with alarm system and provision for alternate power supply.

Platelet incubator with agitator shall have inside temperature of $22^oC \pm 2^oC$ having temperature indicator/recording facility with alarm system and provision for alternate power supply. The equipment shall keep the platelet units in continuous gentle agitation.

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 in the area of prevention. The alarm of all storage equipment shall signal in an area, that has adequate personnel coverage round the clock to ensure immediate corrective action.

6.4.2 Quarantine

The whole blood or components shall not be issued for transfusion, till the mandatory test are completed and reported as non-reactive. In order to ensure this procedure, the untested blood shall be kept in quarantine storage. The units which test reactive in any test shall be segregated immediately and kept in separate quarantine area till sent for disposal as per BMW rules.

Refrigerator or freezers in which blood and blood components are stored for quarantine shall be appropriately labelled.

*Storage and Expiration (See also Annexure A)*

*Whole blood*

Whole blood shall be stored at $4^oC \pm 2^oC$ in plastic blood bags.

Whole blood collected in anticoagulant citrate-phosphate-dextrose solution (CPD) shall have an expiry date, not exceeding 21 days after phlebotomy. Whole blood collected in anticoagulant citrate-phosphate-dextrose with adenine (CPDA-1) shall have an expiry date not exceeding 35 days after phlebotomy.

Red Blood Cell Components

*Red blood cells*

Red blood cells, which are separated in a closed system shall have the same expiry date as the whole blood from which it is prepared. The time of removal of plasma is not relevant to the expiry date of red cell concentrates. However, if an open system is used, the expiry date shall be 24 hours after separation. Red cell concentrate shall be stored at $4^{o}C \pm 2^{o}C$.

Red cells containing additive solutions shall be stored up to 42 days with day of collection considered as day zero. At midnight (12 'O' clock) the day is completed.

*Frozen red cells*

The expiry date for glycerolized (low or high) frozen red cells is 10 years and shall be stored between $-80^{o}C$ and $-196^{o}C$.

*Washed and deglycerolised red cells*

Washed red blood cells and deglycerolised red blood cells shall be stored at $4^{o}C \pm 2^{o}C$ and shall be transfused as soon as possible and within 24 hours after processing.

*Leucocytes depleted red blood cells*

Leucocytes depleted red blood cells shall be stored at $4^{o}C \pm 2^{o}C$. It shall have the same expiry date as whole blood from which it has been prepared, if closed system is used. In case of open system, the expiry shall be within 24 hours.

Platelet concentrate

The platelet concentrate shall be stored at $22^{o}C \pm 2^{o}C$ with continuous gentle flat bed agitation (60–70 strokes/min) or a rotator (5–10 cycles/min.) maintained throughout the storage period. The expiry date of platelet concentrate prepared in closed system shall be 3 day after the collection of original blood. The expiry date may be extended to 5 days when special plastic bags or anticoagulants are in use.

Granulocyte concentrate

The storage temperature for leucocyte concentrate is $22^{o}C \pm 2^{o}C$. It shall be transfused as soon as possible and not later than 24 hours of phlebotomy.

Plasma

*Single donor plasma*

Single donor plasma separated during shelf life shall be stored for 1 year at $-30^{o}C$, or lower and used as plasma for transfusion.

*Fresh-frozen plasma and cryoprecipitate*

These components shall be stored at –30°C or below and shall be stored no longer than 12 months. If fresh frozen plasma (FFP) remains unused at the end of 1 year at –30°C, it may be labeled as 'Frozen plasma' and shall be used up-to 5 years

Expiry date of any component shall be calculated by considering the day of collection as day zero.

Cryo poor plasma (normal human plasma) shall be stored at –30°C or below and shall be stored no longer than 5 years from the date of collection.

## 6.5 Labelling

A System shall be in place to ensure that final container is labelled only after all mandatory testing is completed as per Indian Pharmacopoeal requirements.

Requirements shall ensure:

a) Traceability of product.
b) Appropriate storage and handling of units.
c) Appropriate selection of units for transfusion.

The label shall be attached firmly to the container and shall be clean and readable. Any hand-written information shall be legible and in permanent and moisture proof ink.

6.5.1 Labelling for whole blood/component

After processing the blood, a final label shall be affixed on the bag with the following information.

a) Name of the product i.e., whole blood or component or intended component.
b) The numeric or alphanumeric identification.
c) The date of collection and expiry.
d) The name and amount of anticoagulant and the approximate volume of blood collected.
e) For platelet concentrate, plasma and for component obtained through apheresis, the approximate volume of the components shall be indicated.
f) Colour Scheme:

   Following colour code is used to differentiate the ABO group label.

   | | |
   |---|---|
   | Blood group O | Blue |
   | Blood group A | Yellow |
   | Blood group B | Pink |
   | Blood group AB | White |

g) Storage temperature,
h) ABO and Rh type.
i) Interpretation of HBsAg/HCV/HIV1 and 2/VDRL/ malaria test/unexpected antibodies
j) Name, address and manufacturing licence number of the collecting facility.

6.5.2 Instructions for transfusion

Following information shall be printed on the label.

a) Do not use if there is any visible evidence of deterioration.

b) Store the product at appropriate temperature (as defined for each of the product) before use. (e.g Keep at $4^{o}C \pm 2^{o}C$)
c) Shake gently before use.
d) Do not add any other medication to the blood/blood component.
e) Check blood group on label and that of the recipient before administration.
f) Use a fresh, clean, sterile and pyrogen-free disposable transfusion set with filter to transfuse blood.
g) Do not dispense without a prescription.

6.5.3 Special requirements for component label

The label shall contain information to identify the facility that carries out any part of the preparation.

a) Rh(D) type is not required to be mentioned for plasma or cryoprecipitate but it is necessary for platelet and granulocyte concentrate especially in case of red cell contamination of the product.
b) Storage temperature shall be indicated.
c) Expiry date/time for use shall be indicated.
d) If the plasma is intended for use of fractionation, suitable documentation and labelling shall be done.
e) Label shall indicate whether the component is prepared by apheresis method.
f) Label shall indicate the addition of any adjuvant or cryoprotective agents used.

## 6.6 Testing of Donated Blood

6.6.1 Determination of ABO group

ABO group shall be determined by testing red cells (forward grouping) with anti-A, anti-B, anti-AB reagents (by tube or microplate method or gel technology by any validated manual or automated methods) and by testing serum for reverse grouping. Serum shall be tested for expected and unexpected antibodies with known type A, B and O pool cells/panel cells, if available. For each group a pool of 3 different cells shall be used. The blood shall not be released until any discrepancy, if found, is resolved.

6.6.2 Determination of Rh(D) type

The Rh(D) type shall be determined with anti-D reagent from two different sources using a validated method. It is preferable to use one IgM and other a blend i.e., IgM+IgG. If blood is typed as D-negative it shall be tested to detect '$D^{u}$'/weak D using IAT method when the test for D or '$D^{u}$' is positive, the label shall read ' Rh(D) positive'. When the test for D and '$D^{u}$' is negative, the label shall read 'Rh(D) negative'.

*Previous Records*

A donor's previous record of ABO and Rh(D) type shall not serve as identification of units of blood subsequently given by the same donor. New determination shall be made for each collection. Discrepancy with previous record shall be investigated and resolved.

6.6.3 Determination of Unexpected Antibodies

Serum or plasma of blood donors shall be tested for unexpected antibody/antibodies) with pooled O Rh (D) positive cells or preferably screening cell panel using albumin/enzyme/indirect AHG test which can identify clinically significant antibody/antibodies.

a) Blood, in which such antibody/antibodies is/are found, shall be used as packed cells only.
b) Any component with cold antibody shall be transfused only with special instructions to warm before transfusion.
c) If warm alloantibody is present only packed cells shall be used for transfusion under observation.
d) In case when warm auto-antibody is present even packed cell shall not be used for transfusion.

6.6.4 Test for Transfusion Transmitted Infection

Blood samples in pilot tubes taken at the time of collection shall be tested for all required mandatory tests under regulation. The whole blood or components from any unit that test positive shall be discarded.

6.6.4.1 Screening for HIV antibody

All blood units collected shall be tested for HIV 1 and 2 antibodies using ELISA/rapid tests by a validate method. Any alternative technology with similar or higher sensitivity may be used.

6.6.4.2 Test for Viral Hepatitis

A test for hepatitis B (HBsAg) and hepatitis C (anti-HCV) by ELISA/rapid test by a validated method shall be done on each unit of blood. Any technology with similar or higher sensitivity may be used to improve blood safety.

6.6.4.3 Test for syphilis

Each donation of whole blood shall be subjected to serological test for syphilis by VDRL or RPR or TPHA method.

6.6.4.4 Test for Malaria

All blood units shall be tested for malaria parasites using a validated method or sensitive antigen test.

Any other test in addition to above being carried out in a blood bank/blood centre shall use validated methods and fulfill all regulatory requirements.

Note: Test results to be signed by a second trained person before release of results.

## 6.7 Compatibility Testing

6.7.1 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.
l) Name of the hospital/hospital registration number.
m) Signature of the medical officer.
n) Name and signature of the phlebotomist collecting patient's sample.

6.7.2 Sample receiving, acceptance and preservation

Blood samples of recipient shall be obtained (1) in a stoppered plain vial/tube (2) in a vial/tube containing anticoagulant, with labels having:–

a) Patient'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 laboratory, a qualified member of the staff shall confirm, if 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.

*Retaining and storing of blood sample*

The recipient's and donor's blood samples shall be retained for 7 days at $4^{o}C$ to $6^{o}C \pm 2^{o}C$ 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.

6.7.3 Pre-Transfusion Testing

6.7.3.1 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 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/gel technology (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/ gel technology. If negative it shall be labelled as Rh- (D) negative.

*Test for detection of unexpected antibodies*

Serum of the recipient should 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 $37^{o}C$ 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.

6.7.3.2 Repeat Testing of Donor Blood

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

*Cross –Match*

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

If there is no previous record of presence of antibodies and if clinically significant antibodies are not detected during antibody screening test, the antiglobulin crossmatch may not be required.

If clinically significant antibody(ies) is/are detected in recipient, blood lacking corresponding antigens on cells shall be crossmatched 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.

6.7.4 Issue of blood and its component

6.7.4.1 Issue of blood

Blood shall be issued by the blood bank/blood centre 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 have patient's first name with surname, age, sex, identification 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.

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's name, hospital name, identification number, blood unit number assigned by the collecting/ intermediary facility, interpretation of the cross matching test, shall also be attached to the blood bag container before it is released from the blood bank/blood centre.

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.

6.7.4.2 Reissue of blood

It is recommended that blood once issued shall not be taken back by the blood bank/blood centre if the cold chain is broken.

6.7.4.3 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's life, on receipt of a signed written request of the treating physician stating that the clinical condition of the patient is sufficiently urgent to require the release 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, 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 to discontinue the transfusion.

6.7.4.4 Selection of blood and components for transfusion

*Whole blood, red cell component*

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, when the clinician shall be instructed 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. In neonates ABO specific plasma shall be preferred. Cryoprecipitate shall not require ABO/Rh grouping.

*Platelet concentrate*

Platelet concentrate shall be ABO and Rh (D) type specific with the recipient blood as far as possible. In case of shortage random donor platelet of any ABO/Rh group shall be used provided there is no visual red cell contamination of the platelet concentrate. In case of

single donor platelets prepared by apheresis, plasma shall be reduced when plasma incompatible concentrate is in use (e.g. use of 'O' group SDP to B patient).

*Granulocyte concentrate*

Leucocyte concentrate shall be ABO and Rh(D) type specific or compatible with the recipient blood.

6.7.4.5 Massive Transfusion

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

6.7.4.6 Neonates

For ABO grouping 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 donors are screened for haemoglobin S in geographic regions where Hb S is prevalent.

Paediatric blood collection bags are available and are preferable for use. Normal blood collection bags shall not be used for collecting lesser volume after removing proportionate amount of anti-coagulant solution.

Multiple blood bags shall be used to make one aliquot for adult and one for paediatric transfusion.

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

6.7.5 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 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 person issuing and receiving.

6.7.6 Transfusion Related Advices (for clinician)

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

6.7.6.1 Informed Consent

The patient 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 patients the next of kin shall sign the informed consent.

6.7.6.2 Identification of Recipient and Donor Unit

Immediately before transfusion, the doctor/transfusionist shall verify the identification of the patient, 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's file.

6.7.6.3 Supervision

Transfusion shall be prescribed and administered under medical direction. The doctor/ transfusionist shall observe the patient 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.

6.7.6.4 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 patients 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. Blood shall not be warmed above $37^{o}C$.

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 administrated with blood components.

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

6.7.6.5 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.

For appropriate use of blood, guidelines available shall be used.

6.7.6.6 Special Considerations for use of components

*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 shall 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 $37^{o}C$. 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 coagulation factor replacement it shall be transfused within 24 hours after it is thawed and stored at 1–6$^{o}$C.

*Cryoprecipitate*

The component shall be thawed at temperature of 37$^{o}$C and shall be used immediately. ABO compatibility shall not be a must.

*Single donor plasma*

It shall be transfused within 24 hours after it is thawed and stored at 1–6$^{o}$C.

*Cryopoor plasma*

The plasma left after separation of cryoprecipitate shall be immediately frozen and used within one year of collection. The component shall be thawed at temperature of 37$^{o}$C and shall be used immediately.

*Platelets and leucocytes*

Platelet 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 and leucocytes concentrate, group specific and cross matched product shall be used.

Platelets and leucocytes shall be administered through a standard filter. Micro aggregate filters shall not be used for these products.

Platelets and leucocytes shall be infused at 1–2 ml/minute or as tolerated by the patient.

Granulocyte concentrates shall be irradiated before transfusion

***Irradiation***

Cellular components shall be irradiated in order to reduce the risk of post transfusion graft verses host disease (**GVHD)** when a patient is identified as being at risk for **GVHD** e.g.

For all immunosuppressed patients including bone marrow transplant (BMT) patients.

When blood from a first-degree blood relative is used.

In case of intrauterine transfusion.

The minimum dose delivered to the center of the blood bag shall be 25 Gy $\pm$ 2 and any other part, it should be 15 Gy.

Verification of dose delivery system of the irradiator shall be performed and documented annually.

The component irradiated shall be labelled accordingly.

Irradiated components can be issued to immunologically normal patient provided there is compliance with required storage condition and protocols of issue.

The expiry date shall be the original date. However, in case of red cell concentrate it will be 28 days from the date of irradiation or original whichever is earlier. In case of neonate, the component shall be transfused immediately after irradiation.

The irradiation facility may be shared and the user shall be informed about it.

*Leucocyte Depleted Component*

Storage shall depend on whether a closed or open system is in use.

The verification of leucocyte reduction shall be done in 1% of products prepared of which 75% should contain less than $5X10^6$ leukocytes in the blood bag.

## 6.8 Transfusion Reaction and Evaluation

6.8.1 Error Prevention

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 and ensure correctness of unit number on the bag as well as segment and the cross match report.

Bar coding should be introduced and used whenever feasible.

6.8.2 Immediate Complication

If there are symptoms or findings suggestive of a haemolytic transfusion reaction, transfusion shall be discontinued and the following must be done immediately and records maintained.

a) The label on the blood container and all other records shall be checked to detect if there has been an error in identifying the patient or the blood unit.

b) A post transfusion properly labelled blood sample, (avoiding haemolysis) shall be obtained from the patient and sent to transfusion services along with blood container and attached transfusion set.

c) The patient's post-reaction serum or plasma shall be inspected for evidence of haemolysis, comparing with pre-transfusion sample.

d) A direct antiglobulin test shall be done on the post transfusion specimen and on pre reaction sample for comparison.

Based on evaluation of clinical findings, review of accuracy of records and result of laboratory tests, additional tests shall be done such as:–

a) Determination of ABO and Rh(D) type on pre and post reaction blood sample from the patient and from the blood bag.

b) Repeat tests for unexpected antibodies in donor and recipients blood and repeat cross match using pre and post reaction blood samples of the patient and donor blood from the bag.

c) Examination of post transfusion urine shall be carried out for haemoglobin and its metabolites.

d) Determination of bilirubin concentration in serum shall be obtained preferably 5 to 7 hours after the transfusion.

e) Supernatant plasma and remaining blood in the blood container as well as the post reaction sample of the patient shall be tested for smear and culture.

If investigations are suggestive of a haemolytic reaction or bacterial contamination, patient's physician shall be informed immediately.

6.8.3 Delayed Complications

Appropriate test (antibody screening and test for TTI) shall be done to detect the cause of delayed reaction. A record shall be maintained in patient's medical file.

Reported cases of suspected transfusion-transmitted disease shall be evaluated. If confirmed, the involved blood unit must be identified in the report. Attempt shall be made to recall the donor for retesting and counselling. Other recipients who received components from the suspected blood unit shall also be investigated. The remaining components shall be discarded.

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6.8.4 Detection, reporting & evaluation of transfusion reaction

Each blood bank/blood centre shall have a system for detection, reporting and evaluation of suspected adverse reaction to transfusion (hemovigilance). In the event of suspected transfusion reaction, the personnel attending the patient shall notify immediately the responsible physician and transfusion service with necessary documentation and appropriate sample.

All suspected transfusion reactions shall be evaluated promptly. The evaluation should not delay proper clinical management of the patient.

The details of all cases along with the interpretation of evaluation shall be recorded and reported to the hospital transfusion committee.

There shall be a written protocol for the investigations of transfusion reactions.

## 6.9 Documentation in Transfusion Service

Each blood bank/blood centre shall develop a practical record keeping system, which serves its needs.

The record system shall make it possible to trace a unit of blood/component from source (donor and collecting facility) to final destinations.

The system shall ensure confidentiality of donor and patient records.

Records shall be legible and corrections by only authorized person shall be initialled with date.

Date of performance of procedures, tests and interpretation shall be recorded.

All records shall be retained for a minimum of 5 years or according to national or state requirement. For donor retention programme, it is preferable to maintain donor records for a longer term.

Regular reports shall be submitted to respective authority as per the requirement of the state.

*Records for donor and donor's blood/components see clause no. 6.2.1.10*

*Record of recipient see clause no 6.7.5*

*For other record, see clause 10.3*

## 6.10 Histocompatibility Testing

Histocompatibility testing refers to the determination of tissue antigens and their immunologic reactions. Testing includes isolation of cells such as lymphocytes, platelets, granulocytes and other tissue cells, HLA typing for A,B,C,DR and DQ locus antigens, antibody detection cross-matching and mixed lymphocyte culture.

Terminology of HLA antigens shall conform to the nomenclature adopted by the World Health Organisation.

For centers having facility of histocompatibility testing shall have the defined processes ,procedures and equipment, for HLA typing reagents, HLA typing, compatibility testing, sample identification, HLA type, HLA antibody detection, lymphocytotoxicity cross match, pretransfusion transplant and records.s

## 6.11 Quality Control (Also see Annexure D)

6.11.1 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 blood bank/blood centre 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.

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

6.11.2 Reagent Red Blood Cells

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

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

6.11.3 Red Cell Panel

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

The red cells shall be stored frozen, or at $4^{o}$C.

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

6.11.4 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.

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.

6.11.5 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).

6.11.6 Enzyme Reagents

Any enzymes, papain, facin, trypsin or bromelin shall be used for detection of incomplete antibodies.

Using the standard technique employed by individual laboratory, the reagent shall give specific result using incomplete anti-Rh(D) with positive and negative control.

Preparation of working reagent shall be by standard method.

Enzyme shall be aliquoted and stored in frozen state. Only required amount for the day shall be thawed.

The unused enzyme remaining at the end of each day shall be discarded.

6.11.7 Hepatitis B surface Antigen, Anti-HCV And Anti-HIV 1 and 2 Test

Use of enzyme linked immunosorbent assay (ELISA)/ Rapid test is recommended, using kits approved by CDSCO. Any another recent approved technology with same or increased sensitivity may be used.

Test shall be performed as per the instructions of the manufacturer.

Positive and negative control (kit control or in-house) shall be run with every

batch.

Rapid tests approved by CDSCO shall be used for screening in emergency, in rural areas, any centre collecting small volumes or where power and, requirement maintenance is problem.

6.11.8 Test for Syphilis

VDRL or TPHA or RPR, method can be used. Test shall be performed as per manufacturer's instructions. Positive and negative controls (kit control and in-house) must be included with every batch.

6.11.9 Normal Saline and Buffered Solutions

These solutions shall be checked daily for pH between 6.7-7.2. Absence of haemolysis with random A, B and O cells provide useful indications for its suitability.

6.11.10 Blood Component

For quality of blood components, see annexure D.

## 6.12 Proficiency Testing Programme

The blood bank/blood centre shall participate in external quality assurance programme (proficiency programme).

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

Whenever a formal PT programme is not available the blood bank/blood centre 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 blood bank/blood centre 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.

## 6.13 Bio-medical Waste Disposal and laboratory safety in blood bank/blood centre

6.13.1 Protection of blood bank/blood centre personnel against laboratory infection

All laboratory personnel shall be informed of the hazards including transmission of viral infection involved in working in a blood bank/blood centre laboratory.

Incidental exposure to infected samples like bag breakage, splash, and 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 blood bank/blood centre staff against hepatitis-B infection should be implemented after appropriate tests.

6.13.2 Safety in the lab: Following points to be followed in the labs

a) Eating, drinking and smoking prohibited in the lab
b) Mouth pipetting prohibited in the lab.
c) Staff must behave in a safe and responsible manner at all times.
d) Appropriate protective clothing must be worn at all times, this includes aprons and gloves.
e) All work surfaces must be decontaminated at the end of each working day and after any spillage
f) Care must be taken to avoid the formation of aerosols or splashing of materials.

g) Access to the lab must be restricted to authorized personnel only.
h) All contaminated waste must or reusable materials must be appropriately decontaminated before disposal or reuse.
i) In case of needle stick injury, squeeze out the blood; wash the hand with soap and water or anti septic and make out an incident report.
j) All staff working in laboratories must be adequately trained in the safety aspects of the lab.

Dispose all sharps in puncture proof containers.

6.13.3 Disposal of Blood and Laboratory Material

*Method of disposal of Blood Bags*

Should 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 or 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 can go to hot-air oven at 160$^{o}$C for 1 hour.

*Spills on the table tops/sinks*

This spill shall be covered with filter papers or plain cloth and soak 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$^{o}$C and 15 p.s.i (68.5 cm Hg) is the method of choice. Validation with use of biological indicator (*Bacillusthermophilus sterothermophilus*) shall be done at least once a month.

# 7. Identification of Deviations and Adverse Events

## 7.1 Polices and procedure when nonconformity is detected

7.1.1 The blood bank/blood centre shall have a defined policy and procedure to be implemented when any aspect of its test analysis or function does not conform to laid down procedure.

7.1.2 The procedure with defined responsibility of person shall be laid down to analyse the nonconformity and the corrective action to be taken with resumption of the work after deviated function.

7.1.3 The corrective action should be appropriate with the medical significance of nonconformity.

## 7.2 Procedures for released non-conforming blood component

7.2.1 The Director/In-charge blood bank/blood centre shall be responsible for release/discard of blood/blood components where nonconformity is detected.

7.2.2 The event shall be recorded.

## 7.3 Preventing recurrence of nonconformity

If it is determined that non-conformity could recur or there is doubt about the compliance with its own policies and procedures, the procedure to identify, document and eliminate the root cause shall be promptly implemented.

# 8. Performance Improvement

## 8.1 Addressing complaints

8.1.1 The blood bank/blood centre shall have a policy and procedure for addressing complaints, or other feed backs received from donors, clinicians, blood camp organizers or other parties. These can be used as improvement tools.

8.1.2 Record of complaints, investigations and corrective actions taken by the blood bank/blood centre shall be maintained.

## 8.2 Corrective action

8.2.1 Root cause analysis

Procedure for corrective action shall include a process of investigation to determine root cause of the problem.

The corrective action shall be appropriate to the magnitude of the problem, and shall commensurate with the risk encountered.

8.2.2 Implementation and monitoring changes resulting from corrective action.

The blood bank/blood centre shall document and implement any changes required after investigation as a corrective action.

Blood bank/blood centre management shall monitor the results of any corrective action taken, in order to ensure that they have been effective in overcoming the identified problems. Whenever the investigation casts doubt on compliance with policies and procedures blood bank/blood centre shall ensure that an additional audit is done for that area.

8.2.3 Documentation of corrective action

All corrective actions taken shall be documented and recorded with root cause analysis and shall be submitted to management review meeting.

## 8.3 Preventive action

8.3.1 Preventive action is a proactive process for identifying opportunities for improvement, whenever they are identified either technical or concerning the quality system, the action plan shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities.

8.3.2 Procedures for preventive action shall include the initiation of such action and ensure that these are effective.

# 9. Document Control

## 9.1 Procedure for control and review of documents

9.1.1 Blood bank/blood centres shall define document and maintain procedures to control all documents and information (from internal and external sources) that form its quality documentation.

Note: In this context, 'document' is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, and documents of external origin such as regulations, standards or examination procedures.

9.1.2 Procedures shall be adopted to ensure that all documents issued to blood bank/blood centre personnel as part of the quality management system are reviewed and approved by authorized personnel prior to issue.

9.1.3 A list, also referred to as a document control log, identifying the current valid revisions and their distribution is maintained.

9.1.4 Only currently authorized versions of appropriate documents are available for active use at relevant locations.

9.1.5 Documents are periodically reviewed, revised when necessary, and approved by authorized personnel.

9.1.6 Invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use.

9.1.7 Retained or archived superseded documents are appropriately identified to prevent their inadvertent use.

9.1.8 If the blood bank/blood centre documentation control system allows for the amendment of documents by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined. Amendments are clearly marked, initialed and dated, and a revised document is formally re-issued as soon as practicable.

9.1.9 Procedures are established to describe how changes to documents maintained in computerized systems are to be made and controlled.

## 9.2 Document required

a) Daily group-wise blood stock register (inventory) showing its receipt, issue and balance, units discarded with reason of discarding.

b) Stock register of non-consumable articles.

c) Stock register of consumable articles.

d) Documentation of staff qualifications and training.

e) Documentation of staff competency and proficiency tests.

f) Staff attendance register or any other recording system.

A copy of each of these controlled documents shall be archived for later reference and the blood bank/blood centre director/ in-charge shall define the retention period. These controlled documents may be maintained on any appropriate medium. National, regional and local regulations concerning document retention should apply.

## 9.3 Maintenance of documents in computer software

**Electronic Records**

There shall be processes and procedures to support the management of computer system.

There shall be a process in place for routine backup of all critical data.

An alternative method to be used during system breakdown must be known. Hard copies should be available even when documentation is electronically maintained.

Maintenance and continuous operations must be ensured.

Procedures shall be in place to ensure that data are retrievable and usable.

Personnel must be trained.

Validation of system and integrity and security of data entry should be ensured.

The records required by Drugs and Cosmetics Act shall also be maintained as hard copies.

# 10. Records

## 10.1 Record identification

All records relevant to the quality management system shall be uniquely identified with appropriately labelled.

The blood bank/blood centre shall have policies, processes and procedures to ensure that records are identified, reviewed, retained and that records are created, stored, and archived in accordance with record retention policies.

## 10.2 Quality and technical records

The blood bank/blood centre shall retain records of original observation, derived date of both quality and technical aspects and sufficient information to establish calibration record and staff record, copy of each test report, calibration certificate kept for defined period.

All records shall be legible and stored such that they are readily retrievable. Records may be stored on any appropriate medium subject to national, regional or local legal requirements. Facilities shall provide a suitable environment to prevent damage, deterioration, loss or unauthorized access.

## 10.3 Records retaining period

For maintaining and retention of records see **annexure E**.

Other records to be maintained:

a) Record showing the daily temperature recordings.
b) Record of quality assurance (internal and external).
c) Record of any adverse incident.
d) Record of equipment maintenance.
e) Record of document control.

# 11. Internal Audit & Management Review

## 11.1 Policy for internal audit and management review

Management review and internal audits of all elements of the system, both managerial and technical, shall be conducted at regular intervals in order to verify that operations continue to comply with the requirements of the quality management system.

## 11.2 Procedure of internal audit

Audits shall be formally, planned, organized, carried out by the quality manager or designated qualified personnel. Personnel shall not audit their own activities. The procedures for internal audits shall be defined and documented and include the types of audit, frequencies, methodologies and required documentation. When deficiencies or opportunities for improvement are noted, the blood bank/blood centre shall undertake appropriate corrective and/or preventive actions, which shall be documented and carried out within an agreed upon time.

The main elements of the quality system should normally be subject to internal audit once every twelve months.

## 11.3 Procedure of Management Review

11.3.1 Blood bank/blood centre management shall review the blood bank/blood centre quality management system and all of its medical services, including examination and advisory activities, to ensure their continuing suitability and effectiveness in support of donor and/or patient care and to introduce any necessary changes or improvements. The results of the review shall be incorporated into a plan that includes goals, objectives and action plans. A typical period for conducting a management review is once every twelve months.

11.3.2 The management review shall take account of but not be limited to the reports from management and supervisory personnel, the outcome of recent internal and external audit, feed back, complaints, non-conformities with corrective and preventive action.

## 11.4 Documentation of Internal Audit and Management Review

The results of internal audits shall be submitted to blood bank/blood centre management for review with proper documentation including follow up corrective action.

Findings and the actions that arise from management reviews shall be recorded, and blood bank/blood centre shall be informed of these findings and the decisions made as a result of the review. Blood bank/blood centre management shall ensure that arising action are discharged within an appropriate and agreed-upon-time.

**Annexure –A**

# Requirements for storage, transportation, and expiration

| Item No. | Component | Storage | Transport | Expiration | Additional Criteria |
|---|---|---|---|---|---|
| | | | | | **Whole Blood components** |
| 1 | Whole Blood | $4^oC \pm 2^oC$ | Cooling towards 4-8 $\pm 2^o$ C. | ACD/CPD/CP2D: 21 days<br>CPDA-1:- 35 days | |
| 2 | Whole Blood Irradiated | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | Original expiration or 28 days from date of irradiation, whichever is earlier | |
| **Red Blood Cell Components** | | | | | |
| 3 | Red Blood Cells | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | ACD/CPD/CP2D: 21 days<br>CPDA-1: 35 days<br>Additive solution: 42 days<br>Open system: 24 hours | |
| 4 | Deglycerolized RBCs | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | Open system: 24 hours<br>closed system:14 days | |
| 5 | Frozen RBCs 40% Glycerol | $\leq$-65 C if 40% Glycerol | Maintain frozen state | 10 years<br>(A Policy shall be defined by the individual blood center, if rare frozen units are to be retained beyond this time) | Open system: Frozen within 6 days of collection with out an additive Frozen prior to red blood cell expiration. If with an additive approved for this purpose Closed system Frozen within 6 days |
| 6 | RBCs Irradiated | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | Original expiration or 28 days from date of irradiation. Whichever is eatlier | |
| 7 | RBCs Leukocytes Reduced | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | ACD/CPD/CP2D:21 days<br>CPDA-1: 35 days<br>Additive solution: 42 days<br>Open system: 24 hours | |
| 8 | Rejuvenated RBCs | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | CPD/CPDA- 1: 24 hours<br>AS-1 : freeze after rejuvenation | Follow manufacturer's written instructions |
| 9 | Deglycerolised Rejuvenated RBCs | $4^oC \pm 2^oC$ | 4-8 $\pm 2^o$ C | 24 hours | Follow manufacturer's written instructions |
| 10 | Frozen Rejuvenated RBCs | $\leq$-65 C | Maintain frozen state | 10 year<br>AS-1:3 year<br>(A Policy shall be defined by the individual blood center , | Follow manufacturer's written instructions |

| | | | | | |
|---|---|---|---|---|---|
| | | | | if rare frozen units are to be retained beyond this time) | |
| 11 | Washed RBCs | $4^oC \pm 2^oC$ | 4-8 $\pm$ $2^o$ C | 24 hours | |
| 12 | Apheresis RBCs | $4^oC \pm 2^oC$ | 4-8 $\pm$ $2^o$ C | CPDA-1: 35 days<br>Additive solution: 42 days<br>Open system: 24 hours | |
| 13 | Apheresis RBCs Leukocytes Reduced | $4^oC \pm 2^oC$ | 4-8 $\pm$ $2^o$ C | CPDA-1: 35 days<br>Additive solution: 42 days<br>Open system : 24 hours | |
| **Platelet Components** | | | | | |
| 14 | Platelets | $22^oC \pm 2^oC$ with continuous gentle agitation | $22^oC \pm 2^oC$ | 24 hours to 5 days, depending on collection system | Maximum time without agitation 24 hours |
| 15 | Platelets Irradiated | $22^oC \pm 2^oC$ with continuous gentle agitation | $22^oC \pm 2^oC$ | No change from original expiration date | Maximum time without agitation 24 hours |
| 16 | Platelets Leukocytes Reduced | $22^oC \pm 2^oC$ with continuous gentle agitation | $22^oC \pm 2^oC$ | Open system: 4 hours<br>Closed system: No change in expiration | Maximum time without agitation 24 hours |
| 17 | Apheresis Platelets | $22^oC \pm 2^oC$ with continuous gentle agitation | $22^oC \pm 2^oC$ | 24 hours to 5 days, depending on collection system | Maximum time without agitation 24 hours |
| 18 | Apheresis Platelets | $22^oC \pm 2^oC$ with | $22^oC \pm 2^oC$ | No change from original expiration | Maximum time without |

| | | | | | |
|---|---|---|---|---|---|
| | Lukocytes reduced | continuous gentle agitation | | date | agitation 24 hours |
| 19 | Apheresis Platelets Irradiated | 22°C ± 2°C with continuous gentle agitation | 22°C ± 2°C | Open system: within 4 hours of opening the system Closed system: 5 Days | Maximum time without agitation 24 hours |
| **Granulocyte Components** | | | | | |
| 20 | Apheresis Granulocytes | 22°C ± 2°C | 22°C ± 2°C | 24 hours | Transfuse as soon possible |
| 21 | Apheresis Granulocytes Irradiated | 22°C ± 2°C | 22°C ± 2°C | No change from original expiration date | Transfuse as soon Possible, maximum within 24 hours. |
| **Plasma Components** | | | | | |
| 22 | Cryoprecipitated AHF | ≤-30 C | Maintain frozen state | 12 months from date of donation | Thaw the FFP at 1-6 °C. Place cryoprecipitate in the freezer within 1 hours |
| 23 | Thawed Cryoprecipitate AHF | 22°C ± 2°C | 22°C ± 2°C | Open system or pooled: 4 hours Single unit: 6 hours | Thaw at 30-37 °C and transfused as soon as possible |
| 24 | Fresh Frozen Plasma (FFP) | ≤-30° C or lower | Maintain frozen state | ≤-30° C: 12 months | Placed in freezer within 6 hours of collection in CPD, CP2D, CPDA-1, |
| 25 | Thawed FFP | 4°C ±2°C | 4-8 ± 2° C | 24 hours | Thawed at 30-37 °C |
| 26 | Plasma Cryoprecipitate Reduced | ≤-30 C | Maintain frozen state | 5 years from original collection | Thaw at 30-37 °C |

| | | | | | |
|---|---|---|---|---|---|
| 27 | Thawed Plasma Cryoprecipitate Reduced | $4^oC \pm 2^oC$ | 4-8 $\pm$ $2^o$ C | 24 hours | Thawed at 30-37 °C |
| 28 | Liquid Plasma | $4^oC \pm 2^oC$ | 4-8 $\pm$ $2^o$ C | 24 days from the date of expiration of whole blood unit | |

**Annexure-B**

# Requirements for Allogeneic Donor Qualification

## Physical Examination

| **Criteria** | |
|---|---|
| Age & Weight | • Conform to applicable state law or<br>• 18 to 60 years<br>• >45 kg |
| Whole Blood Volume Collected | • Maximum of 10 ml per kilogram of donor weight, including samples<br>• Blood collection container shall be cleared for volume collected |
| Donation Interval | • 3 months after whole blood donation<br>• 6 months after 2-unit red cell collection.<br>• ≥ 48 hours after platelet- / plasma - pheresis (and not more than twice a week), and for platelet pheresis ( not more than 24 times a yr) |
| Blood Pressure | • 100-180 mm Hg systolic<br>• 60-100 mm Hg diastolic |
| Pulse | • 60-100 beats per minute, without pathologic irregularities<br>• <60 beats per minute acceptable if an otherwise healthy athlete |
| Temperature | • ≤ 37.5 C if measured orally, or equivalent if measured by another method |
| Haemoglobin/Hematocrit | • ≥ 12.5 g/dl/≥ 38%; |

## Occupation hazard

Air Crews, drivers of long-distance-heavy-duty vehicles and construction workers on high buildings are advised not to give blood within 12 hours of going on duty.

| **Respiratory Infection** | |
|---|---|
| • Cold, flu, cough, sore throat or acute sinusitis | Defer until all symptoms subside and temperature normal |
| • Chronic sinusitis | No deferral unless using antibiotics |
| • Asthmatic attack | 1 week after last attack if chest is clear |
| • Asthmatics on steroids | Defer |

| **Pregnancy and Abortion** | |
|---|---|
| • Pregnancy or recently delivered | Defer for 6 months after delivery |
| • Abortion | Defer 6 months after abortion |
| • Breast feeding | 12 months after delivery |

| **Surgical Procedures** | |
|---|---|
| • Major surgery | 12 months after recovery |
| • Minor surgery | 3 months after recovery |
| • Open heart surgery Including By-pass surgery | Permanently defer |

| | |
|---|---|
| • Cancer surgery | Permanently defer |
| • Localized skin cancer that was removed | 6 months after removal |
| • Tooth extraction or dental manipulation | Defer for 3 days |
| • Dental surgery under anaesthesia | Defer for 1 month |

**Heart Disease**

| | |
|---|---|
| Has any active symptom (Chest Pain, Shortness of breath, health, swelling of feet) | Permanently defer |
| • Restricted activity | Permanently defer |
| • Cardiac medication (digital, nitroglycerine) | Permanently defer |

**Cardio-Vascular Diseases**

| | |
|---|---|
| • Myocardial infarction | Permanently defer |
| • Coronary artery disease | Permanently defer |
| • Angina pectoris | Permanently defer |
| • Rheumatic heart disease with residual damage | Permanently defer |

**Seizures**

| | |
|---|---|
| • Convulsions and Epilepsy | Permanently deferred |
| • Endocrinal Disorders | Permanently defer |

## Infectious Disease

Donors should be free from infectious diseases known to be transmissible by blood, so far as can be determined by usual examination and history.

**Viral Hepatitis**

| | |
|---|---|
| • Has had hepatitis (jaundice other than Hepatitis A, Positive test for Hepatitis B (HBsAg), Hepatitis C (HCV) | Permanently defer |
| • Exposure to hepatitis by tattoos, Acupuncture or body piercing | Defer for 12 months |
| • Worked in renal dialysis | Defer for 12 months |
| • Received transfusion of blood and its components | Defer for 12 months |
| • Close contact with individual suffering with hepatitis | Defer for 12 months |

**Jaundice**

Has ever had jaundice associated with

| | |
|---|---|
| • Newborn | No deferral |
| • Rh disease | No deferral |
| • Gall stone | No deferral |
| • Mononucleosis | No deferral |

**HIV Infection/ AIDS**

| | |
|---|---|
| • High risk group for HIV infection | Defer |
| • HIV positive person | Permanently defer |
| • Donors having symptoms of AIDS | Defer |

**Malaria**

| | |
|---|---|
| History of malaria in endemic area but duly treated and free from any symptoms | Accepted 3 months after treatment |

* Travellers who have been in an area considered endemic for malaria may be accepted as regular donors one year after returning from the endemic area irrespective of the receipt of antimalarial prophylaxis, provided they have been free from unexplained febrile illness.

**Syphilis**

| | |
|---|---|
| Genital sore or generalized skin rashes | Defer for 12 months after rashes disappear and completion of therapy |
| **Tuberculosis** | Defer for 5 years after cessation of symptoms and treatment |

**Fever**

| | |
|---|---|
| Had prolonged or **Rheumatic fever** | Defer till fully recovered and off medication |

**Kidney disease**

| | |
|---|---|
| • Acute infection of kidney (pylonephritis) or acute infection of bladder (cystitis) | Defer for 6 months after cessation |
| • Chronic kidney disease/failure | Permanently defer |

**Digestive system**

| | |
|---|---|
| • Stomach ulcer with symptoms or with recurrent bleeding | Permanently defer |
| • Chronic liver disease/failure | Permanently defer |

## Vaccination and inoculation

**1. Inoculation with toxoid or a killed viral/bacterial vaccine**

| **15 days deferral period** | **No waiting period (if symptoms free)** |
|---|---|
| Typhoid | Paratyphoid |
| Cholera | Influenza |
| Diptheria | Pertusis |
| Tetanus | Polio (salk vaccine, injection) |
| Plague | Rabies as prophylactic |
| Gammaglobulin | Prophylactic Hepatitis B |

**2. No waiting period before donation if symptoms free**

Smallpox (two weeks after scab falls off)
Polio oral (sabine vaccine, oral)
Measles (rubeola)

Mumps
Yellow fever

**3. Four-weeks deferral from time of vaccination**

Anti-tetanus serum
Anti-venom serum
Anti-diphtheria serum
Anti-gas gangrene serum
Rubella (German measles)

**4. Twelve-months deferral from time of vaccination**

Anti-rabies vaccination as a result of animal bite
HBIG (hepatitis B immune globulin)
Immunoglobulins

## Medication

If a donor is taking some medicine it may not be in his/her own interest to donate blood and may also affect the patient who would receive the blood

| | **Medicines** | **Accepted/ Deferred** |
|---|---|---|
| • | Oral contraceptive | Accepted |
| • | Analgesics | Accepted |
| • | Vitamins | Accepted |
| • | Mild sedative and transquillisers | Accepted |
| • | Salicylates (aspirin) taken in last three days | Not accepted if blood be used For preparing platelets |
| • | Isotretinoin (accutane) Used for acne | Defer for 1 month after the last dose |
| • | Finasteride (e.g.Proscar) used to treat benign prostate hyperplasia | Defer for 1 month after the Last dose |
| • | Oral anti-diabetic drugs With no vascular complication | Acceptable |
| • | Diabetics on insulin | Defer while taking the drug |
| • | Antibiotics (oral) | Defer for 3 days and till symptoms free |
| • | Antibiotics (injection) | Defer for 4 days and till symptoms free/after the last injection |
| • | Cortisone | Defer for 7 days after the last dose |
| • | Medicine to treat Hypercholesterolemia | Accepted |

## Donors taking following medicines are permanently rejected:

| | | |
|---|---|---|
| • | Anti-arrhythmics | Immunosuppressive |
| • | Anticonvulsions | Pituitary growth harmones of human origin |

| | | |
|---|---|---|
| • | Anticoagulants | Sedatives or tranquillisers in high dose |
| • | Antithyroid drugs | Vasodilators |
| • | Cytotoxic drugs | Etretinate to treat psoriasis. It is teratogenic. |
| • | Digitalis | Vasodilators |
| • | Dilantin | Drugs for Parkinson's Disease |

## Other conditions requiring Permanent deferral

No person shall donate blood and no blood bank shall draw blood from person, suffering from any of the disease mentioned below, namely-

- Cancer
- Abnormal bleeding tendencies
- Unexplained weight loss
- Polycythemia Vera
- Leprosy
- Schizophrenia
- Severe allergic disorders

**Annexure – C**

# Requirements for Cytapheresis Donor Qualification

## Selection of donor

Donors who undergo cytapheresis no more than once every 4 weeks shall be treated as ordinary blood donors with regards to laboratory studies.

Donors who undergo serial cytapheresis, more than once every 12 weeks, shall be tested as under:

Haemoglobin and/or haematocrit shall be >12 g/dl and or Hct of 36%

Total serum protein shall not be below 6.0 gm/dl. It shall be tested before the 3rd collection if done within week.

Platelet count shall be determined before plateletpheresis and shall not be below 150,000/ul.

Total and differential white cell count shall be normal

Person who have ingested aspirin or similar anti-platelet drugs in the last 72 hours shall not be suitable for plateletpheresis

Donor with personal and family history of bleeding tendency shall not be suitable for plateletpheresis.

Before leukapheresis total white blood cells shall be 4000/ul with normal differential count.

In serial pheresis a minimum interval shall be of 48 hours and not more than two procedures in a week shall be allowed

A participant of such a programme donates a unit of blood or if it has not been possible to reinfuse the red cells during a pheresis donor shall not be accepted for cytapheresis for 12 weeks.

**Annexure-D**

# Quality Control

## 1. 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 |
| Lectin | Each day of use |
| Antibody screening and reverse grouping cells | Each day of use |
| Hepatitis test reagents | Each run |
| Syphilis serology reagents | Each run |
| Enzymes | Each run |
| HIV –I and II reagent | Each run |
| Normal saline (LISS and BPS) | Each day of use |
| Bovine albumin | Each day of use |

N .B: All reagents shall be checked for expiry date before use

## 2. 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 known sera against red blood cells antigens | Each day |

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

| Parameters | Quality Requirement | Frequency of Control |
|---|---|---|
| Appearance | No turbidity, precipitate, particles or gel formation by visual inspection | Each day |
| Specificity | Clear cut reaction with red cells having corresponding antigen(s); and no reaction with negative control | Daily and of each new lot/batch |
| Avidity | Macroscopic agglutination with 50% red cells suspension in homologous serum/normal saline using the slide test;<br>10 seconds for anti-A, anti-B and anti-AB with $A_1$ and/or B cells at R.T ; 20 seconds with $A_2$ and $A_2B$ cells. | |

| | | |
|---|---|---|
| Reactivity | No immune haemolysis, rouleaux formation or Prozone | Each new lot/batch. |
| Potency | Undiluted serum should give +++/C 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 $A_1$ and/or B cells, 64 with $A_2$ and $A_2B$ cells. | Each new lot/batch. |

## 4. 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 | $A_1$ | 1:256 | 10-12 sec | +++ |
| | | $A_2$ | 1:128 | 15-18 sec | ++ To +++ |
| | | $A_2B$ | 1:64 | 15-18 sec | ++ |
| | | O | - | - | - |
| | | B | - | - | - |
| | Monoclonal | $A_1$ | 1:256 | 3.4 sec | +++ |
| | | $A_2$ | 1:128 | 5-6 sec | ++ To +++ |
| | | $A_2B$ | 1:64 | 5-6 sec | ++++ |
| | | O | - | - | - |
| | | B | - | - | - |
| Anti-B | Polyclonal | B | 1:256 | 10-12 sec | +++ |
| | | $A_1B$ | 1:128 | 12-15 sec | ++ |
| | | O | - | - | - |
| | | $A_1$ | - | - | - |
| | Monoclonal | B | 1:256 | 3-4 sec | ++++ |
| | | $A_1B$ | 1:128 | 5-6 sec | +++ |
| | | O | - | - | - |
| | | $A_1$ | - | - | - |
| Anti-AB | Polyclonal | $A_1$ | 1:256 | 10-12 sec | +++ |
| | | B | 1:256 | 10-12 sec | +++ |
| | | $A_2$ | 1:64 | 15-18 sec | ++ To +++ |
| | | O | - | - | - |
| | Monoclonal | $A_1$ | 1:256 | 3-4 sec | ++++ |
| | | B | 1:256 | 3-4 sec | ++++ |
| | | $A_2$ | 1:128 | 5-6 sec | +++ |
| | | O | - | - | - |

## 5. Quality Acceptable of Rh anti sera (Anti-D)

| **Parameter** | **Quality requirement** | **Frequency of control** |
|---|---|---|
| Appearance | No turbidity, precipitation, particles or gel formation by visual inspection | Each day |
| Specificity | Clear cut reaction with $R_1r$ cells | Each day and each new lot/batch. And no reaction with rr cells. |
| Avidity | Visible agglutination with 40% red cells suspension in | Each day and each new lot/batch |

| | | |
|---|---|---|
| | homologous serum using the slide test. | |
| Reactivity | No immune haemolysis, rouleaux formation or prozone phenomenon. | Each new lot/batch |
| Potency | Undiluted serum gives +++ reactions in designated test for each serum and a titre 32-64 for anti-D. | Each new lot/batch |

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

| **Type of reagent** | **Type of red cells** | **Titre+ Immediate spin** | **Titre+ After 30-45 min incubation** | **Avidity** | **Intensity** |
|---|---|---|---|---|---|
| IgM Monoclonal | $OR_1r$ or $R_1R_1$ Cells | 1:64-1:128 | 1:128-1:256 | 5-10 Sec | +++ |
| Blend of IgM +IgG monoclonal | $OR_1r$ or $R_1R_1$ Cells | 1:32-1:64 | 1:128-1:256 | 10-20 Sec ‘’ | +++ |
| Blend of IgM monoclonal IgM+Polyclonal (human) IgG. | Same as above | Same as above | Same as above | Same as above | +++ |
| Poly-clonal (Human) anti-Rh- (D) | $OR_1r$ or $R_1R_1$ Cells | - | 1:32-1:64 In Alb/Enz/AHG test | 60 sec | +++ |

## 7. Acceptable quality of anti-globulin reagent:

| **Parameter** | **Quality requirement** | **Frequency of control** |
|---|---|---|
| Appearance | No precipitate, particles or gel formation by visual in inspection. | Each day |
| Reactivity and Specificity | No prozone phenomenon<br>No haemolysis or agglutination of unsensitized red cells<br>Agglutination of red cells sensitised with anti-D serum containing not more than .2 mg/ml antibody activity<br>Agglutination of red cells sensitised with a complement-binding antibody (e.g. anti $Le^a$).<br>Agglutination of red cells coated with C3b and C3d, and no/weak agglutination with C4 coated red cells. | Each lot<br>Each day<br>Each day and each new lot/batch.<br>Each new lot/ batch.<br>Each new lot/ batch. |

## 8. Quality Control of Proteases (Enzymes)

| Parameter | Quality requirements | Frequency of control |
|---|---|---|
| Reactivity | No agglutination or haemolysis using inert AB serum.<br>Agglutination (+++/C) of cells sensitised with a weak IgM (Anti-D). | Each day |
| Potency | An IgG antibody, preferably anti-D standardized to give a titre about 32-64 by the protease technique should show the same titre on repeated testing with different batches.<br>The 2-stage enzyme titre should at least be equal to the titre obtained with IgG (anti-D) by AHG test | Each batch<br><br>Each batch |

## 9. 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, as determined by electrophoresis. | Each new lot |
| 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 $R_1r$ | Each month |

## 10. Quality Control of Normal Saline

| Parameter | Quality requirement | Frequency of control |
|---|---|---|
| Appearance | No turbidity or particles by visual inspection | Each day |
| NaCl content | 0-154 mol/1 (=9g/l) | Each new batch |
| 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, no haemolysis | Each new batch |

## 11. Quality Control of Distilled water

| Parameter | Quality requirement | Frequency of control |
|---|---|---|
| Appearance | Clear, no particles on visual inspections | Each day |
| PH | 6.0-7.0 | Each new batch |

## 12. The Quality Control of Whole Blood.

| Parameter | Quantity Requirement | Frequency of Control |
|---|---|---|
| Volume | 350/450 ml ± 10% | 1% of all units |
| Anticoagulants | 49/63 ml | All units |
| PCV (Hct) | 30 to 40% | 4 units per month |
| HBsAg | Negative by ELISA | All units |
| Anti-HCV | Negative by ELISA | All units |
| Anti-HIV I & II | Negative by ELISA | All units |
| Syphilis | Negative by Screening test | All units |
| Sterility | By culture | Periodically (1% of all units) |

## 13. The Quality Control of red cell concentrate (Prepared from 450 ml Blood)

| Parameter | Quantity Requirement | Frequency of Control |
|---|---|---|
| Volume | 280 ± 40 ml | 1% of all units |
| PCV (Hct) | 70%± 5% | Periodically (1% of all units) |

## 14. The Quality Control of red cell in preservative sol. (ADSOL/SAGM)

| Parameter | Quantity Requirement | Frequency of Control |
|---|---|---|
| Volume | 350 ± 20 ml | 1% of all units |
| PCV (Hct) | 55-65% | Periodically (1% of all units) |

## 15. The Quality Control of Leucocytes-poor red cells

| Method of Preparation | Parameter | Quality requirement | Frequency of control |
|---|---|---|---|
| Leucocytes poor red cell moidified by centrifugation | White cells | <70% leucocytes of original quantity | 4 units a month / 1% of all units (whichever is more) |
| Washed red cells | Plasma removed RBCs loss<br>Leucocytes removed | 99%<br>20%<br>85% | |
| Leucocytes poor | White cells removed | 99% removed | 4 units a month |
| Red cells modified | Red cells remaining by leucocytes filter | 90-95 % | |

## 16. The Quality Control of platelet concentrate prepared from 450 ml of whole blood.

4 units or more to be dded whenever needed

| Parameter Quality | Requirements | Frequency of control |
|---|---|---|
| Volume | 50-70 ml | All units |
| Platelets count | ≥ $5.5 \times 10^{10}$ | 4 units per month/ 1% of all units (whichever is more) |
| pH | >6.0 | 4 units per month/ 1% of |

| | | |
|---|---|---|
| | | all units (whichever is more) |
| RBC contamination | 0.5 ml | 4 units per month/ 1% of all units (whichever is more) |
| WBC contamination | $5.5x10^7$ –$5x10^8$ | 4 units per month/ 1% of all units (whichever is more) |

## 17. The Quality Control of platelet concentrate prepared from buffy coat

| Parameter | Quality Requirements | Frequency of control |
|---|---|---|
| Volume | 70-90 ml | 4 units per month/ 1% of all units (whichever is more) |
| Platelets count | $6\text{-}9X10^{10}$ | 4 units per month/ 1% of all units (whichever is more) |
| pH | >6.0 | 4 units per month/ 1% of all units (whichever is more) |
| WBC contamination | $0>5.5X10^{10}$ | 4 units per month/ 1% of all units (whichever is more) |
| RBC contamination | Traces to 0.5 ml | 4 units per month/ 1% of all units (whichever is more) |

## 18. Quality of Platelet Concentrate by Apheresis

| Parameter | Quality requirement |
|---|---|
| Volume | 200-300 ml |
| Platelets count | $\geq 3.0\text{-}7.0x10^{11}$ |
| pH | >6.0 (at the end of permissible storage period) |
| Residual leucocytes | $<5.0x10^6$ |
| Red cells | Traces to 0.5 ml |

## 19. Quality control of Fresh Frozen Plasma (FFP)

| Parameter | Quality control | Frequency of control |
|---|---|---|
| Volume | 200–220 Plasma | 4 units per month/ 1% of all units (whichever is more) |
| Stable coagulation factors | 200 units of each factor | 4 units per month |
| Factor VIII | 0.7 units/ml | 4 units per month |
| Fibrinogen | 200–400 mg | 4 units per month |

## 20. Quality control of Cryoprecipitate (Factor-VIII)

| Parameter | Quality control | Frequency of control |
|---|---|---|
| Volume | 10–20 ml | Occasionally |
| Factor VIII | 80–120 units | Occasionally |
| Von-Willebrand factor | 40–70 % of the original | Occasionally present. |
| Factor XIII | 20–30% of the original | Occasionally |
| Fibrinogen | 150–250 mg | Occasionally |
| Fibronectin | 55 mg | Occasionally |

## 21. Quality Control of Plasma. (Frozen)

| Parameter | Quantity requirement |
|---|---|
| Volume | 200–220 ml |
| Stable coagulation factors | 200 units of each factor |
| Factor V, VII, fibrinogen | Reduced |

## 22. Quality Control of Granulocytes

| **Granulocytes prepared from hemapheresis** | |
|---|---|
| **Parameter** | **Quantity requirement** |
| Granulocytes | $1X10^{10}$ |
| Other leucocytes | $0.1X\ 0.7X10^{9}$ |
| Platelets | $2\text{-}10X10^{11}$ |
| Red cells | 5–50 ml |
| Plasma | 200–400 ml |
| HES if used | 6–12 % of volume |
| **Granulocytes prepared from single unit of blood** | |
| **Parameter** | **Quantity requirement** |
| Volume | 200–250 ml |
| Granulocytes | $0.5–1x10^{9}$ |

**Annexure-E**

# Records

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

1. Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of the donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In charge.

2. Master records for blood and its components. It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh group, results of testing of HIV1 and HIV2 antibodies, malaria, V.D.R.L, hepatitis B surface antigen [and hepatitis C virus antibody], and irregular antibodies (if any), name and address of the donor with particulars, utilization issue number, components prepared or discarded and signature of the medical officer/in-charge.

3. 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, unit/institution, details of cross-matching report, indication for transfusion.

4. Record of components supplied: Quantity supplied; compatibility report, details of recipient and signature of issuing person.

5. Records of A.C.D/C.P.D-A/SAGM bags giving details of manufacturer batch number date of supply, and results of testing.

6. Register for diagnostic kits and reagents used: Name of the kits/reagents, details of batch number, date of expiry and date of use.

7. Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.

8. Transfusion adverse reaction records.

9. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

10. Record of report sent to State AIDS Control Society.

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

**Annexure-F**

# Good manufacturing practice (GMPs)/standard operating procedures (SOPs)

Written standard operating procedures shall be maintained and shall include all steps to be followed in the collection, processing compatibility testing, storage and sale of distribution of blood and/or preparation of blood component for homologous transfusion, autologous transfusion and further manufacturing purpose. Such procedures shall be available to the personnel for use in the concerned areas. The standard operating procedures shall inter alia include:

1.

a) Criteria used to determine donor suitability.

b) Methods of performing donor qualifying tests and measurements including minimum and maximum values for a test or procedures, when a factor in determining acceptability.

c) Solutions and methods used to prepare the site of phlebotomy so as to give maximum assurance of a sterile container of blood.

d) Method of accurately relating the product (s) to the donor.

e) Blood collection procedure, including in-process precautions taken to measure accurately the quantity of blood drawn from the donor.

f) Method of component preparation including, any time restrictions for specific step in processing.

g) All tests and repeat tests performed on blood and blood components during processing.

h) Pre-transfusion testing, wherever applicable, including precautions to be taken to identify accurately the recipient blood components during processing.

i) Procedures of managing adverse reactions in donor and recipient reactions.

j) Storage temperature and methods of controlling storage temperature for blood and its components and reagents.

k) Length of expiry dates, of any, assigned for all final products.

l) Criteria for determining whether returned blood is suitable for re-issue.

m) Procedures used for relating a unit of blood or blood component from the donor to its final disposal.

n) Quality control procedures for supplies and reagents employed in blood collection, processing and pre-transfusion testing.

o) Schedules and procedures for equipment maintenance and calibration.

p) Labelling procedures to safe guard in mix-ups, receipt, issue, rejected and ready to issue stock

q) Procedures of plasmapheresis, plateletpheresis and leucapheresis if performed, including precautions to be taken to ensure re-infusion of donor's own cells.

r) Procedures for preparing recovered (salvaged) plasma if performed, including details of separation, pooling, labelling, storage and distribution.

s) All records pertinent to the lot or unit maintained pursuant to these regulations shall be reviewed before the release of distribution of a lot or unit of final product. The review or portions of the review may be performed at appropriate periods during or after blood collection, processing, testing and storage. A thorough investigation, including the conclusions and follow-up, of any unexplained discrepancy or the failure of a lot or unit to meet any of its specification shall be made and recorded.

2. A licensee may utilize current standard operating procedures, such as the manuals of the following organisations, so long as such specific procedures are consistent with, and at least as stringent as, the requirements contained in this Part, namely-

a) Directorate General of Health Services Manual;

b) Other organisations or individual blood bank's manuals, subject to the approval of State Licensing Authority and Central License Approving Authority.