NOTICE

Comments are invited on Draft Accreditation standards on Blood Banks/ Blood Centres and Transfusion Services, 3rd edition

Seeking comments/feedback from stakeholders on '**Draft Accreditation standards on Blood Bank/ Blood Centre and Transfusion Services 3rd edition',** (Last date for sending comments is 30th June 2016). The comments may kindly be sent to Dr. Anil Kumar, National Accreditation Board for Hospitals and Healthcare Providers (NABH), Quality Council of India, at email id: anil@nabh.co

ACCREDITATION STANDARDS ON BLOOD BANKS/ BLOOD CENTRES AND TRANSFUSION SERVICES

Third Edition, June 2016

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS

FOREWORD

There is no other fluid, which can totally substitute blood in the human body. Blood contains nutrients along with oxygen in adequate quantities and helps in maintaining a balanced temperature of the body. In many cases transfusion of blood or blood components becomes necessary to save the life of an individual. Therefore we need to have a network of blood banks/ blood centres. The blood stored in blood banks/ blood centres should be pure, safe and free from contamination.The collection and storage of blood/ blood components is done by blood banks/ blood centres attached to hospitals. Voluntary agencies and private sector blood banks/ blood centres also provide this service. The process is controlled through regulation which to great extent is responsible to ensure purity of blood and blood products.

The accreditation programme by NABH strives to maintain the quality and safety of blood and blood products. The accreditation programme assesses the quality and operational systems in place within the facility before accreditation is awarded.

The basis for assessment of blood banks/ blood centres includes compliance with the accreditation standards and guidelines set by National AIDS Control Organisation (NACO).

The independent assessment under accreditation helps the facility to prepare comprehensively for regulatory requirements as well as accreditation standards. It ensures safety as well as quality culture within the facility. Accreditation is granted for collection, processing, testing, distribution and administration of blood and blood components.

The accreditation standards have been prepared by the technical committee constituted by NABH. The standards are a dynamic document and shall be kept up-dated as required.

For information on accreditation programme and related aspects, please contact NABH at **helpdesk@nabh.co**.

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TERMS AND DEFINITIONS

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

Accuracy of measurement: 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: The process, by which blood drawn from a donor, after separating desired plasma or cellular component, is returned simultaneously to the same donor.

Autologous blood: The blood drawn from the patient/ recipient for re-transfusion into him/ her later on.

Biological reference interval: Central 95% interval of the distribution of reference values.

Blood: Includes whole human blood, drawn from a donor and mixed with an anti-coagulant.

Blood bank/ blood centre: A place/ organisation/ unit/ institution or other arrangements made by any such organisation, unit or institution for carrying out all or any of the operations for collection, apheresis, storage, processing and distribution of blood drawn from donors and/ or for preparation, storage and distribution of blood components.

In-Charge or Director of blood bank/ blood centre: Competent person (s) with responsibility for, and authority over, a Blood bank/ Blood centre.

Blood bank/ blood centre Management: Person (s) who manages the activity of a Blood bank/ Blood centre headed by a blood bank/ blood centre director.

Blood component: A drug, prepared, obtained, derived or separated from a unit of blood drawn from a donor.

Blood product: A drug manufactured or obtained from pooled plasma of blood drawn from donors by fractionation.

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: Fulfilment 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 organization) or external (i.e., another organization).

Disaster: An event (internal, local, or national) that can affect the blood supply or the safety of staff, patient/ recipients, 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.

Drug: All medicines for internal or external use of human beings and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings including preparations applied on human body.

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 organization, who have responsibility for the operations of the organization and who have the authority to establish or change the organization’s quality policy. Executive management may be an individual or a group of individuals.

Incident: An unplanned deviation from a facility’s established 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: 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: 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.

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

Plasmapheresis: 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 is 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 cells in the blood. These are called peripheral blood stem cells.

Peripheral Blood 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/ recipient.

Plateletpheresis: 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: It includes the mandatory process and activity done before proceeding with 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, through transformation of inputs into outputs.

Process Control: The efforts to standardize and control processes in order to produce predictable output, and meets standards and minimises variation.

Product: A tangible result of a process or procedure.

Professional donor: A person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient-patient/ recipient 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.

Management system: The organizational structure, responsibilities, policies, processes, procedures, and recourses established by executive management to achieve quality.

Quality Management System: The organisational structure, processes, or procedures necessary to ensure that overall outcome and direction of an organisation's quality programme is met and the quality of the product or service is ensured. This includes strategic planning, allocation of necessary resources, and other systemic activities such as quality planning, implementation and constant evaluation.

Quality Assurance: Activities involving quality planning, control, assessment, reporting and improvements necessary to monitor progress towards changing quality standards and requirements.

Quality indicators: Measurable aspects of process outcomes that provide indication of the condition or direction of performance over a period of time and progress towards stated quality goals or objectives.

Qualification: Demonstration that an entity is capable of fulfilling specified requirements and verification of attributes that must be met or complied with in order that a person or a thing is considered fit for performing a particular function.

Quality control: Testing routinely performed on materials and equipment, product, and services to ensure their proper function.

Quantity: Attribute of a phenomenon, body or substance that may be distinguished qualitatively and determine quantitatively.

Quarantine: To isolate untested/ inconclusive or results pending confirmation including 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 management system requirements.

Replacement donor: A donor who is a family friend or a relative of the patient/ recipient.

Sample: 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 its 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/ recipient blood samples) obtained from a supplier meet specified requirements.

Traceability: Property of the result of a measurement or the volume of a standard whereby 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 necessarily 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: Closeness of agreement between the average values obtained from a large series of results of measurements and a true value.

Uncertainty of measurement: 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 (non-remunerated) blood donor: 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 licence from Regulatory Authorities, as applicable or the blood bank/ blood centre shall have applied for renewal of the licence in time as per existing regulations.

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

1.2 Responsibility

1.2.1 An organization chart (organogram) shall be defined.The organization chart of the blood bank/ blood centre shall show linkage with the parent organization as applicable.

1.2.2 Where the blood bank/ blood centre is a part of a larger organization the director/in charge shall be empowered by the head of the institution to deploy the quality management system.

1.2.3 It is the responsibility of management to operate blood bank/ blood centre and transfusion services, make changes in it whenever required and comply with these standards and applicable laws and regulation.

1.2.4 The responsibilities of 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 blood bank/ blood centre personnel 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 shall need to determine acceptable practice that 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 underpin all the procedures and process carried out in blood bank/ blood centre. Every blood bank/ blood centre shall determine its own ethical policy in conformance with national and international guidelines.

1.4 Quality Management 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 of blood bank/ blood centre and documented in a quality manual. This policy shall be a statement or an undertaking by the management of the blood bank/ blood centre of its desire to provide the desired quality of services/product include scope of services, objective of quality management system with management commitment to comply with the standards and local regulations. When the blood bank/ blood centre is part of a larger organization the quality manual will be issued by Director/in-charge of blood bank/ blood centre with the prior consent of higher management.

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.

1.4.4 All personnel shall be trained in the quality management system with appropriate inhouse training and their knowledge shall be constantly updated when ever changes are made to the quality management system.

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 identify a Quality Manager and deputy.

1.4.7 For supervision and maintenance of technical operations, the management shall identify a Technical Manager and deputy.

1.4.8 Roles and responsibilities of Technical Manager and the Quality Manager (however named) shall be defined, including their responsibility for ensuring compliance with these standards. These personnel shall have responsibilities and authority to oversee compliance with the requirement of the quality management system.

1.4.9 Blood Bank/ Blood Centre shall have defined emergency operation policies and procedures to respond to the effect of internal and external disaster.

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 sewerage, 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 flies. 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 siphoning.

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.

Patient/ recipients, employees and visitors shall be protected from recognized hazards including fire and non-fire hazards within the facility by use of signages and by restricting entry to controlled areas. The design of blood bank/ blood centre shall be such as to facilitate easy evacuation in the event of a fire/hazard.

The blood bank/ blood centre shall have proper signages and restricted area demarcation for safety of staff, donors, patients and others.

2.1.2 Accommodation of blood bank/ blood centre

A blood bank/ blood centre shall have a minimum area for the scope of services as per regulatory requirements. It shall consist of the following:

a) Registration and medical examination with adequate furniture and facilities for registration, waiting and selection of donors,
b) Donor motivation and Counselling area,
c) Blood collection (air-conditioned),
d) Refreshment-cum-restroom (air-conditioned),
e) Laboratory for blood transmissible disease like hepatitis, syphilis, malaria, HIV-antibodies (air-conditioned),
f) Blood component preparation. (This shall be air-conditioned to maintain temperature between 20^0C to 25^0C, with a provision of quarantine area/ equipment,
g) Laboratory for blood group serology (air-conditioned),
h) Sterilization-cum-washing (may be shared in case of hospital based blood bank/ blood centre),

i) Store-cum-record room.

2.1.3 Blood bank/ blood centre preparing components shall have area for preparing blood components commensurate with the quantum of work to maintain quality of blood components (as in Clause 2.1.2)

2.1.4 Plasmapheresis, Plateletpheresis and Leucapheresis

A minimum additional air conditioned area as per regulatory requirements 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 with:

Premises:

Premises used for 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 operations, maintenance and cleaning.

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

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

2.1.6 There shall be effective separation between adjacent sections of the blood bank/ blood centre 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 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 including transportation and disposal of dangerous material shall be as per regulatory

requirements. Special procedures and training for personnel is necessary to meet these requirements.

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, patient/ recipients 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 policy and procedure for monitoring adherence to biological, chemical and radiation safety standards and regulations, as 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 shall 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 Systems

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 information.

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 as per applicable regulations.

3.2 Qualification

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

3.2.1 Medical Director/ In-charge/ Medical Officer Blood Bank/ Blood Centre

MD (Transfusion Medicine)/ MD (Immunohaematology and blood transfusion)/ DNB (Immunohaematology and transfusion Medicine)/ MD (Pathology)

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) with experience in blood bank/ blood centre for one year during regular services and also having 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 components.

(The degree or diploma being from an 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 preparation of its components.

OR

Diploma in Medical Laboratory Technology (M.L.T.) with one year experience in the testing of blood and preparation of its components.

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

3.2.5 Counsellor

A person suitably trained in counselling shall be designated by the blood bank/ blood centre as counsellor.

3.3 Job description/ responsibilities

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

3.3.2 Personnel shall perform assigned activities on the basis of appropriate qualification, education, training and/ or experience.

3.4 Responsibilities of Medical Director/ blood bank/ blood centre In-charge/ Medical Officer, Technical Manager and Quality Manager

3.4.1 The responsibilities of the blood bank/ blood centre Medical Director/ In-charge/ Medical Officer shall include professional, scientific, consultative, advisory organizational, administrative and educational matters. These shall be relevant to the services offered by the blood bank/ blood centre. In case of more than one Medical Officer in the blood bank/ blood centre, the responsibility shall be defined by the Medical Director/ In-charge.

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

3.4.3 Quality Manager has the responsibility and authority to oversee compliance with the requirements of the quality management system. The Quality Manager shall report on the performance of quality management system directly to the top management which decides on blood bank/ blood centre policy and resources.

In a blood bank/ blood centre collecting less than 5000 units per year, the same person can be designated as Technical and Quality Manager.

3.5 Training

3.5.1 All personnel shall have training specific to quality assurance and quality management systems .

3.5.2 It shall be the responsibility of the management to ensure that the personnel involved in blood bank/ blood centre activities are adequately trained for the tasks undertaken and receive initial and continual training relevant to their needs.

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

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

3.6 Competence

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

3.7 Personnel health

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

3.8 Personnel records

Blood bank/ blood centre management shall maintain records of the Personal information, relevant educational and professional qualification, training and experience, and competence of all personnel. This information shall be readily available to relevant personnel, and may include:

a) Certification or licence, if required,
b) Reference from previous employment, if possible,
c) Job descriptions,
d) Records of continuing education and achievements,
e) Provision for untoward incident or accident reports,
f) Record of identification of signature and initials,
g) Competency evaluation.
h) Grievance redressal record
i) 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/ recipient. 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 requirements.

4.2 Selection, installation and validation of equipment

Blood Bank/ Blood Centre shall have a policy for selection, procurement, and installation of the equipment. It shall adhere to the following:

a) Installation qualification
b) Operational qualification
c) Performance qualification

4.3 Use of equipment

Only authorized personnel shall operate the equipment. Up-to-date instructions on the use and maintenance of the equipment (including relevant manuals and direction for use provided by the manufacturer 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 suitably placed 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) Manufacturer's name, identification and serial number or other unique identification,
c) Manufacturer's/ service provider's contact person and contact details,
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) Manufacturer's instructions, if available, or reference of their retention,
h) Equipment performance records that confirm the equipment suitability for use,
i) Maintenance carried out and that planned for the future,
j) Damage to or malfunction, modification or repair of the equipment,
k) All the equipment shall have labels identifying the equipment, calibration status and due date of calibration.

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 minimum frequencies defined in Annexure H.

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.

4.5.5 The blood bank/ blood centre shall have a system for investigating and follow up of equipment malfunction, failure or adverse event while working. This shall minimally include assessment of consequences when equipment is found to be out of calibration, such as effect on donor eligibility and quality of blood components.

Steps taken to ensure non-use of equipment, investigation of malfunction or failures, steps taken for the qualification of the equipment, with proper notification to manufacturer where indicated.

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 and record the temperature of refrigerator, freezers, and platelet incubators continuously. The temperature will be recorded at least every 8 hours. In case the Blood bank/ blood centre is not monitoring the temperature continuously the recording shall be at least at 4 hourly intervals.

4.6.4 If platelets are stored in an open storage area on an agitator, the ambient temperature shall be maintained at $22^0C \pm 2^0C$ and recorded at least at 4 hourly intervals.

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 persons
e) An alternative system that ensures continuous operation shall be available in the event that computerised data and computer functions are unavailable. The alternative system shall be tested periodically

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 shown to be calibrated to meet specified acceptance criteria.

The blood bank/ blood centre shall have policy and procedure for appropriate alternate storage where the blood/blood components shall be shifted in the event of breakdown of storage equipment.

5. EXTERNAL SERVICES AND SUPPLIES

5.1 Policies and procedures for selection of supplier

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 consumables that affect the quality of its services. All 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 Blood bank/ blood centre shall ensure that all supplies and reagents requiring cold chain maintenance are received at the appropriate temperature.

5.1.4 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.

5.1.5 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.

5.1.6 Supplies and reagents that do not bear an expiry date shall be used in a manner that those received first are used first.

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

5.1.8 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 shall 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 was placed in service.

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

Process control is discipline that deals with architectures, mechanisms and algorithms for maintaining the output of a specific process within a desired range. blood Bank/ blood centre shall have technicial Standard Operating Procedures for each of the activity described under Process Control.

Note: Some of the following might not be applicable to the scope of all blood banks/ blood centres.

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, components 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 and components issued, there shall be a mechanism to identify who performed the step and when it was performed.

6.1.1 Traceability of blood/ component unit and sample from blood collection to issue

The blood bank/ blood centre shall ensure that all blood and components issued and critical materials used in their processing activities, as well as laboratory sample and donor and patient/ recipient 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 transmitted infection. In case this happens the blood bank/ blood centre shall inform the patient/ recipient'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 validated test procedures which have been documented to give consistently correct results for the performance of tests/procedures done in the blood bank/ blood centre. National guidelines, DGHS manuals, NACO/NBTC manuals and other regulatory directives shall be followed. In absence of the above procedures that have been published in established/ authoritative textbooks, peer-reviewed text or journals or in international guidelines shall be used.

Inhouse Procedures : If in-house procedures are used, these shall be appropriately validated for their intended use and fully documented. Results of validation and the procedure used for validation shall be available for review.

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 those 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 to find if they 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 in such a way 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 Section

6.2.1 Blood donation

6.2.1.1 Donor recruitment: Retention and Recall

Blood bank/ blood centre shall, have a policy and process for recruitment of voluntary, non-remunerated, low risk, safe and healthy donors and their retention and recall.

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

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

The blood bank/ blood centre shall have a procedure for voluntary donor recall.

6.2.1.2 Pre-donation counselling

Pre-donation counselling by the counsellor/ staff with appropriate training shall be made available maintaining privacy and confidentiality. Pre-donation information which includes the following shall be made available to the donor:

a) Modes of transmission due to risk behaviour and self-exclusion for patient/ recipient'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.
f) May provide information for Confidential Unit Exclusion

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

An informed consent shall convey benefits/adverse effects of blood donation along with the information regarding mandatory tests done on donor blood.

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. Written consent to transfer excess blood to another blood bank/ blood centre or excess plasma for fractionation.

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.

The final authority for any decision to accept or reject the donor rests with the donor centre's physician who will select or defer donors based on laid down Selection/Deferral Criteria.

d) Donation interval

- The interval between two whole blood donations shall be at least three months.
- Apheresis shall be done only after three months of whole blood collection
- Interval between two plateletpheresis donations shall be 48 hours and a donor shall donate not more than twice a week and not more than 24 times in a year.
- The interval between plateletpheresis and whole blood donation shall not be less than 48 hours.
- In the event of red cells not being returned during an apheresis (Plateletpheresis, plasmapheresis, Cytapheresis) procedure the subsequent apheresis procedure will be done only after 3 months and not 48 hours.
- Plateletpheresis donors shall be tested for platelet count before every apheresis procedure and serial Plasmapheresis donors shall undergo Plasma Protein estimation before the procedure.
- For double red cell collection, donor shall have haemoglobin more than 13.5 g/ dl and weight at least 60 Kg in males and 68 Kg in females. The interval between the two procedures shall be six months.

The donors shall be tested appropriately to detect thrombocytopenia and decreased serum protein.

For detailed procedure of apheresis see 6.3.3.f.

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 a 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. In case of second prick, there shall be a procedure to ensure that the occurrence of such events is recorded and reported, and data used for improvement.

The blood donor area shall be clean, congenial, comfortable and conveniently approachable. It is mandatory to have air-conditioned rooms to make the donor comfortable and to minimise chances of donor reaction. The phlebotomy staff shall

be trained to inspect the antecubital skin for evidence of drug abuse or skin infection.

b) Method of preparation of phlebotomy site

A strict standardised procedure shall be in use to achieve surgical cleanliness for preparing venipuncture 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. Multiple interconnected plastic bags (closed system) shall be used for blood component preparation.

d) Anticoagulant solutions

The anticoagulant solution shall be sterile and pyrogen-free. The ratio of anticoagulant solution to blood shall be as follows:

Citrate Phosphate Dextrose (CPD) solution: 14 ml solution for 100 ml of blood

Citrate Phosphate Dextrose Adenine (CPDA-1) solution: 14 ml solution for 100 ml of blood.

e) Additive solutions

100 ml of additive solution for 450 ml whole blood and 80 ml for 350 ml whole blood is added to packed cells after separation of plasma.

f) 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 outside the permitted limits shall not be used for transfusion. No attempt shall be made to collect blood from such a donor during the same session. Extracorporeal blood volume shall not exceed 15% of the donor's estimated blood volume.

The Blood bank/ blood centre shall have a policy for low volume collection.

g) Duration of blood collection

Blood meant for platelet preparation shall be collected with minimal trauma to tissue and units taking longer than 10 minutes for collection shall not be used for such purpose.

6.2.1.5 Post donation care

Donor shall be informed about the possibility of adverse reactions and care to be taken. Advice regarding post-phlebotomy care shall be given to donors and 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. The emergency tray will be periodically checked to remove expired medicines. Donor blood collection staff shall be trained in identification and management of donor reactions. Blood bank/ blood centre shall outline emergency procedures for donor referral and donor transport in case of a serious adverse reaction.

6.2.1.7 Blood donation camp/ drives

Outdoors blood donation camps and in blood mobiles

Blood donation camps shall be organised only by blood bank/ blood centres (RBTCs) authorised by State Blood Transfusion Council (SBTC) to augment blood stocks.

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

The number of blood units collected shall be 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 that is conducive and comfortable for donors. The area shall be cleaned before and after the blood collection.

Blood bank/ blood centre shall maintain quality at each step from donor recruitment, donor selection blood collection to processing of the final product. The method of blood collection and management of donor reaction shall be the same irrespective of where the blood is collected blood bank/ blood centre blood mobile or blood donation drive. Quality measures, pre-donation counselling and transportation procedures shall not be compromised.

6.2.1.8 Procedure for autologous blood collection (predeposit)

The blood bank/ blood centre doing autologous blood collections shall have defined processes and procedures including predeposit criteria for autologous donation, testing of units, labelling required and pretransfusion testing.

6.2.1.9 Donor notification of abnormal findings, test results and counselling

a) Information of test results

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

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

b) Donor Notification (Counselling and referral)

Efforts shall be made by blood bank/ blood centre to recall reactive HIV donors for counselling and re-testing and referral for treatment and /or referral to Integrated testing centres when inhouse facilities for these are not available.

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

Records of donor notification shall be available.

6.2.1.10 Records of donor and donor's blood/ components

Following Donor Records shall be maintained:

- Demographic details
- First time or repeat donor
- Identification number
- Donor selection record
- Medical History
- Physical examination

Donor deferral records

Donors' blood collection record

- Date of collection
- Batch number and bag manufacturer's name
- Segment number on blood bag tubing
- Particulars of donor
- Identification number
- Amount of blood collected
- Time and duration of collection
- Signature of phlebotomist and medical officer

Donor reactions – Details of donor reaction shall be mentioned including management and action taken for its 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
- Test for syphilis
- Test for malaria parasites

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

TTI testing : Documentation of all tests for transfusion transmitted infections shall be done including manufacturer's name ,batch number of the kits and expiry date. Printouts of tests results and its interpretation shall be preserved for record.

Note 1 : All TTI test result print outs shall be verified by medical officer or in his/her absence by the designee.

Note 2 :The blood bank/ blood centre shall also evolve a protocol for safe disposal of reactive units an prevent their inadvertent entry into the inventory.

All rapid tests/ spot tests shall be interpreted 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/ components discarded shall be maintained.

Records of autoclaving of reactive units/untested units shall be maintained.

6.2.1.11 Therapeutic plasmapheresis and cytapheresis

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

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

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

Therapeutic Phlebotomy

Therapeutic phlebotomy shall be done only on the request of the patient's physician/ recipient's physician. The blood bank/ blood centre doctor must decide whether to accept the responsibility of the patient/ recipient. The blood/component so collected shall not be used for transfusion and will be discarded after autoclaving.

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 by stripping the tubing and sealing 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 and/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/or 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 of the donor shall 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, components prepared in their premises, as well as laboratory samples and donor and patient/ recipient records, are identified and traceable to donor and recipients.

6.2.2.3 Transportation

Whole blood shall be transported from the collection site to the component laboratory as soon as possible.

Temperature during transport shall not exceed 10^{o}C in case of whole blood except when platelets are to be prepared from whole blood. Temperature during transport shall be monitored and recorded.

Whole blood and red cell concentrates shall be transported in a manner that shall maintain a temperature of 4^{o}C ± 2^{o}C. Platelet/ granulocyte concentrates 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 with closed system shall be used. The system shall also be considered a closed system if a sterile connecting device or sterile tubing welder is used.

If the seal is broken during processing, components stored between 4^{o}C ± 2^{o}C must be transfused within 24 hours and component stored between 22^{o}C ± 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 as soon as possible and positively within 6 hours.

At the time of preparation of the final components the integrally connected tubing shall be filled with aliquots of the component 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 cells concentrate

Red blood cell concentrate shall be prepared from the whole blood collected in plastic bags, preferably in 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 used, the expiry date of red cells shall be the same as whole blood. (Annexure D Table 13)

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 $4^oC \pm 2^oC$. A laminar bench that is validated at least once a year shall be used. Closed system of washing is recommended. If washing is done in open system, expiry of the component shall be within 24 hours.

Leucoreduced red cells

Leucocyte depleted red blood cells concentrate shall be prepared by a method known to reduce leucocytes in the final component to less than 5×10^6 leucocytes per unit of red cells.

Frozen and deglycerolised red blood cell concentrate

Red cells shall be stored frozen continuously at low temperature as specified by the procedure. 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 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 up to 10 years.

b) Platelets concentrate (random donor platelets)

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

Platelets 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.

Platelets 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 minute) 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. For transfusion platelet units contaminated with red cells shall be group specific.

c) Granulocyte concentrate

Unit of granulocytes prepared by use of cell separator shall have 1 x 10^{10} leucocytes and shall be kept at $22^{o}C \pm 2^{o}C$ 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 shall be used only for fractionation.

Fresh frozen plasma

Fresh plasma shall be separated from the whole blood and frozen solid at $-80^{o}C$ or blast freezer not later than 6 hours of collection. Further storage shall be done at $-30^{\circ}C$ or lower. Prior to infusion the frozen plasma shall be thawed rapidly at 30 – $37^{o}C$ in a water bath with swirling movement of water. Once thawed it shall be used within 6 hours, when kept at room/ ambient temperature, or within 24 hours when kept at $4^{o}C \pm 2^{o}C$.

Cryo poor plasma or Factor VIII deficient Plasma

This is plasma from which cryoprecipitate has been removed. It shall be stored at $-30^{o}C$ or lower and once thawed shall be used within 6 hours.

e) Single donor cryoprecipitate (cryoprecipitated anti-hemophilic factor)

For preparation of cryoprecipitate the plasma shall be separated within 6 hours of collection and frozen hard at $-80^{o}C$ and then can be preserved at -30^{0} C or lower and when needed thawed at $4^{o}C$ in circulating water bath or in $4^{o}C$ 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 $-30^{o}C$ 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 for plasmapheresis

Records of donor's periodic examination, laboratory tests, consent of donor/ patient/ recipient, 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 or not more than 1000 ml per month with a maximum of 12 liters/ year. Extra corporeal blood volume shall not exceed 15% of donor's estimated blood volume.

Cytapheresis (Erythropheresis, 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 (PBSCs) are harvested using a continuous or intermittent cell separator. The recommended minimum dose for PBSC transplant is 2 x 10^6 CD34 cells or 2 x 10^8 mononuclear cells per kg of the recipient. Harvesting these quantities may require more than one sitting.

Plateletpheresis or Single donor Platelets

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.

6.4 Quarantine and Storage

6.4.1 Refrigerators 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 having continuous temperature monitoring with high and low alarm

Blood bank/ blood centre refrigerators/ walk-in-cooler shall have inside temperature of $4^{o}C \pm 2^{o}C$ and shall have a system to monitor temperature continuously and at least the temperature shall be recorded every 8 hours. In case continuous monitoring is not done recording shall be 4 hourly. An alarm system and a provision for alternate power supply shall be available. The performance of alarms for the set temperature of the equipment shall be checked once a week.

Deep freezer shall have inside temperature of –30 to $-40^{o}C$ and –75 to $-80^{o}C$ having temperature indicator/ recording facility with alarm system and provision for alternate power supply.

Platelet incubator with agitator shall have inside temperature of $22^{o}C \pm 2^{o}C$ 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. 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 and storage

The whole blood or components shall be quarantined till the mandatory tests 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 bio medical waste (BMW) rules.

Refrigerators 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 $4^{o}C \pm 2^{o}C$ 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 that are separated in a closed system shall have the same expiry date as the whole blood from which they are 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 $4^{o}C \pm 2^{o}C$.

CPD 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. In case of additive solution bags, if components are not separated for any reason, the shelf life of whole blood is 21 days as the primary bag contains CPD as anticoagulant.

Frozen red cells

The expiry date for glycerolized (low or high) frozen red cells is 10 years and shall be stored as per the procedure adopted.

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.

Irradiated red blood cells

Irradiated red blood cells shall be stored at $4^{o}C \pm 2^{o}C$. The post-irradiation expiration date shall be 28 days or the original expiration date, whichever is earlier.

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 per minute) or a rotator (5-10 cycles/ min.) maintained throughout the storage period. The expiry date of platelet concentrate prepared in closed system shall be 5 days after the collection of original blood. The day of collection is considered as Day Zero. The expiry of platelet concentrate is at midnight (12 'O' clock) of Day 5.

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 shall be stored below –30^{o}C for one year and may be used as plasma for transfusion.

Fresh-frozen plasma and cryoprecipitate

These components shall be stored at –30^{o}C or below and shall be stored no longer than 12 months.

Cryo poor plasma shall be stored at –30^{o}C or below.

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 Pharmacopoeia requirements.

Requirements shall ensure:

a) Traceability of product
b) Appropriate storage and handling of units
c) Appropriate selection of units for transfusion
d) Volume of component should be mentioned on label
e) Indication of whether collected from voluntary or Replacement donor

The label shall be attached firmly to the container and shall be clean and readable. Any handwritten 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 and/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 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(D) type

i) Interpretation of HIV1&2, HBsAg, HCV, syphilis, test for malarial parasites, unexpected antibodies
j) Name, address and manufacturing license 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 products) 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 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
g) Label shall indicate if the product is irradiated or leucodepleted

6.6 Testing of Donated Blood

6.6.1 Determination of ABO group

ABO group shall be determined by cell grouping with anti-A, anti-B, anti-AB reagents (anti-AB is optional if monoclonal of anti-A and anti-B are used) by tube or microplate method or"Column Agglutination Technology" (or by any other validated manual or automated methods) and by serum grouping. Serum/plasma 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 Weak D is positive, the label shall read 'Rh(D) positive'. When the test for D and Weak D testing 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 which shall include indirect anti-human globulin (AHG) and which can identify clinically significant antibody/ antibodies.

a) Blood, with antibody/ antibodies, shall be used as packed cells only
b) Any component with cold antibody shall be transfused only with special instructions to warm the blood before transfusion
c) If warm alloantibody is present, only packed cells shall be used for transfusion under observation
d) If a warm auto-antibody is present, even packed cells shall not be used for transfusion.

6.6.4 Test for Transfusion Transmitted Infections

Blood samples in pilot tubes taken at the time of collection shall be tested for all required mandatory tests. The whole blood or components from any unit that tests positive shall be discarded. Test methods for screening TTI shall be those approved by the Regulatory Authorities.

6.6.4.1 Screening for HIV antibody

All blood units collected shall be tested for HIV1&2 antibodies

6.6.4.2 Test for Viral Hepatitis

All the blood units collected shall be tested for HBV(HbsAg) and HCV (Anti HCV)

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 or ELISA 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 fulfil all regulatory requirements.

6.6.4.5 Nucleic Acid Amplification Testing (NAT)

a) NAT is an optional test for screening of transfusion transmitted infections in blood banks/blood centres.

b) Blood banks/blood centres doing NAT shall define a policy for release of blood bank/ blood centre following completion of ELISA but pending NAT results..

c) In case of testing donor samples by mini pool NAT, every positive pool shall be retested individually and the pool shall be quarantined till the same is complete.

6.7 Compatibility Testing

6.7.1 Request for blood and its components

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

a) Recipient's name,
b) Age, Sex, ward and bed number,
c) Blood group of recipient if done earlier (for error prevention),
d) Name of the head of treating unit,
e) Amount of blood/ component needed,
f) Date and time of blood/ component requirement,
g) Routine/ emergency,
h) Diagnosis,
i) Reason for transfusion, hemoglobin/ platelet count,
j) History of previous transfusion,
k) Obstetric history in the case of female patient/ recipient,
l) Name of the hospital/ hospital registration number,
m) Signature of the medical officer,
n) Name and signature of the phlebotomist collecting patient/ recipient's sample.

6.7.2 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/ recipient's full name
b) Identification number (as applicable) Optional for small nursing homes)
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 that the information on the label and on the transfusion request form is tallying. In case of any discrepancy or doubt, a new sample shall be obtained. Preferably samples shall be identified by unique blood bank/ blood centre registration number. A numeric and/or alphanumeric system shall be used. Any advanced technology for identification such as barcode system is preferable.

Blood bank / blood centre shall have a procedure describing the indications, limitations, and exceptions for the use of hemolyzed and lipemic specimens.

Retaining and storing of blood sample

The recipient's blood sample and a segment from each donor unit shall be retained at 4-6^{o}C $\pm$ 2^{o}C for 7 days after each transfusion.

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

6.7.3 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 (anti-AB is optional if monoclonal anti-A and anti-B are used) and testing serum or plasma for expected antibodies with fresh pooled A, B and O cells (pool of 3 for each group) using tube/ microplate method/"Column Agglutination Technology" (or by any other validated manual or automated methods).

Determination of Rh (D) type

The Rh (D) type shall be determined with anti-D reagents from 2 different sources by tube/ microplate method/ "Column Agglutination Technology" (or by any other validated manual or automated methods). If negative it shall be labelled as Rh-(D) negative.

Test for detection of unexpected antibodies

Serum/ plasma of the recipient should be tested for unexpected antibodies with pooled O Rh(D) positive cells or screening red cell panel to detect clinically significant antibodies. 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.

6.7.3.2 Repeat testing of donor blood

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

Crossmatch

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

If clinically significant antibodies are detected in the recipient, blood lacking corresponding antigens on cells shall be crossmatched and issued or compatible units will be identified by trial method by cross matching multiple units.

Issuing Incompatible Blood: In certain clinical conditions, where autoantibodies are present, the best compatible (least incompatible) unit shall be issued with specific instructions to clinicians.

Minor cross matching using donor serum or plasma and recipient's cells shall not be deemed 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

The blood bank/ blood centre shall have a well defined policy for issue of blood/ blood components both routine and emergency cases.

The blood bank/ blood centre shall have a written procedure outlining who can collect blood/ blood components, how it will be transported and delivered to ward.

Blood/ blood components shall be issued by the blood bank/ blood centre along with compatibility label attached to the blood bag and the compatibility report.

A portion of the integral tube with at least one numbered segment shall remain attached with the blood bag being issued.

The compatibility report shall have patient/ recipient'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.

Method used for compatibility test, interpretation of compatibility test, the name of the person performing the test and issuing the blood/ blood component, date and time of issue of blood/ blood component shall be recorded.

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

Turn around Time (TAT): TAT of Blood/ blood component issues both routine and Emergency shall be monitored and reported to NABH once in 6 months along with other quality indicators. Where IT help is not adequate to audit all transfusions for TAT a representative random sample will be audited every month.

6.7.4.2 Re-issue of blood/ blood component

After issue the blood bank/ blood centre shall not take back the blood/ blood component into inventory if the cold chain is broken and the blood/ blood component is returned to the blood bank/ blood centre after 30 minutes. The blood bank/ blood centre shall have a policy and procedure for acceptance and reissue of blood/ blood component unit'/s returned in cases where the cold chain is not broken.

6.7.4.3 Urgent requirement of blood/ blood component

Blood or blood components shall be issued before completion of routine cross matching tests, in case where delay in providing blood/ blood component may jeopardize the patient/ recipient's life, on receipt of a signed written request of the treating physician stating that the clinical condition of the patient/ recipient is sufficiently urgent to require the issuance of blood/ blood component 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.

Recipients whose ABO and Rh(D) has been determined shall preferably receive ABO specific and Rh(D) compatible Whole Blood/Packed Red Cells, and /or ABO and Rh(D) compatible Packed Red Cells.

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

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

6.7.4.4 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 with instructions to clinician to transfuse under constant observation.

The blood bank/ blood centre shall lay down a policy for issue of blood in autoimmune haemolytic anaemia (AIHA).

Single donor plasma and fresh frozen plasma

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

Platelets concentrate

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

Granulocyte concentrate

Granuloycte concentrate shall be ABO and Rh(D) type specific or compatible with the recipient blood. Granulocyte concentrate shall be irradiated before transfusion.

6.7.4.5 Massive transfusion

In cases of Massive Transfusion (amount of blood equal to or greater than recipient's total blood volume transfused within 24 hours) a fresh blood sample, collected after active bleeding is controlled, is used for crossmatching for issue of blood for subsequent transfusion. Component therapy shall be actively considered in these cases. Every blood bank/ blood centre shall evolve a massive transfusion protocol in consultation with clinicians.

Exchange transfusion of a neonate/infant is also considered a massive transfusion.

6.7.4.6 Neonates

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

Serum of the mother shall be tested for unexpected antibody (ies) or alternatively a DAT (DCT) may be performed on the neonatal sample as part of antibody screening, to detect maternal antibodies coating the neonatal red cells.

In the management of haemolytic disease of the newborn it is preferable to use mother's serum for the crossmatching. 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. Generally red cells with additive solution are avoided for neonatal transfusion.

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

Paediatric blood collection bags are available and are preferable for use.

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

Blood 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/ recipient and his/ her ABO and Rh (D) type
c) Identification number and segment number of red cells units issued, ABO and Rh (D) type, blood/ component issued, quantity in units or ml (in case of paediatric transfusions).
d) Compatibility records.
e) Signature of persons issuing and receiving components

6.7.6 Transfusion related advices (for clinicians):

It shall be the responsibility of blood bank/ blood centre to provide continuing medical education to all clinicians by way of transfusion related advices, hospital transfusion committee meeting and additionally seminars and workshops whenever possible.

6.7.6.1 Informed consent

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

6.7.6.2 Identification of recipient and donor unit

Immediately before transfusion, the transfusionist shall verify the identification of the patient/ recipient using established method. Details on the compatibility label attached to the blood bag shall be preferably compared against details on the patient wrist band. Transfusion shall be withheld if any discrepancy is found.

All identifications (Blood Bag labels) attached to the container shall remain attached at least until the transfusion is over.

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

6.7.6.3 Supervision

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

To ensure Good Clinical Practice (GCP) the user hospital shall formulate a hospital transfusion committee.

6.7.6.4 Administration of blood and blood components

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

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

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

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

Red cells shall not be administered with I.V. solution containing calcium, dextrose or Ringer Lactate solution.

6.7.6.5 Guidelines for transfusion practices

There shall be a written protocol for administration of blood and blood components.

The blood bank/ blood centre shall evolve a protocol for correct patient identification using two independent identifiers.

Training of Staff for Transfusion: Ward staff, Technicians and other hospital staff involved in the transfusion process shall be regularly trained in patient identification and blood administration and their competency assessed.

Protocol for administration of blood shall include the use of infusion devices and auxiliary equipment.

For appropriate use of blood, guidelines approved by the Hospital Transfusion Committee (HTC) 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.

Fresh frozen Plasma

Plasma transfusion shall be ABO compatible. Cross matching tests are usually not performed on plasma. Plasma is thawed at temperature of 30-37^{o}C. Thawed plasma shall be infused without delay to avoid bacterial proliferation. If it is used as a source of labile coagulation factors, it shall be used immediately and in any case within 6 hours after thawing. If used for a purpose other than labile coagulation factor replacement, it shall be transfused within 24 hours after it is thawed and stored at 1-6^{o}C.

Cryoprecipitate

Cryoprecipitate is thawed at 30-37^{o}C for not more than 15 minutes and shall be transfused as early as possible after issue. ABO compatibility is not required.

Single donor plasma

After thawing, single donor plasma shall be transfused immediately. If not, it shall be stored at 1-6^{o}C and used within 24 hours.

Cryopoor plasma

The plasma left after separation of cryoprecipitate shall be immediately frozen and used within five years of collection. The component shall be thawed at temperature of 30-37^{o}C and shall be used within 24 hours if stored at 1-6^{o}C.

Platelets and leucocytes

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

Platelets and leucocytes shall be administered through a standard filter. Microaggregate filters shall not be used for these components.

Platelets and leucocytes shall be infused at the rate of 1-2 ml/ minute or as tolerated by the patient/ recipient.

Irradiation

Irradiation shall be done in the following cases:

- Granulocyte concentrates shall be irradiated before transfusion
- Cellular components shall be irradiated in order to reduce the risk of post-transfusion graft versus host disease (GVHD) when a patient/ recipient is identified as being at risk for GVHD. e.g. for all immunosuppressed patient/ recipients including bone marrow transplant (BMT) patient/ recipients
- When blood from a blood relative is used
- In case of intrauterine transfusion

The minimum dose delivered to the centre of the blood or platelet bag shall be 25 Gy $\pm$ 2 and to any other part of the bag, 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/ recipient provided there is compliance with required storage condition and protocols of issue.

The expiry date, in case of red cell concentrates will be 28 days from the date of irradiation or collection date whichever is earlier. In case of neonates, the component shall be transfused within 24 hours of irradiation.

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

Leukoreduced Components

A leukoreduced component (PRBC/SDP) has less than 5 million WBCs per bag. The same may be prepared by use of inline leukoreduction, use of off line leukoreduction filters, or by use of apheresis equipments.

Storage shall depend on whether a closed or open system is in use. The verification of leucocyte reduction shall be done on 1% of components prepared of which 75% should contain less than 5×10^6 leukocytes in the blood bag (PRBC/SDP). Leukoreduced Platelet concentrates (RDP) shall have less than 8.3×10^5 per 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 crosscheck the Blood group, unit number as well as segment number on the bag with the compatibility report and also ensure that the identity of intended recipient matches that on compatibility report.

Bar coding should be introduced and used where ever feasible.

6.8.2 Immediate complications

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

a) Checks for clerical errors.
b) Examination of post-transfusion sample along with the blood bag that caused the reaction.
c) Testing of patient' sample in accordance with National haemovigilance Program of India(NHvPI) Guidelines.
d) Classification of the reaction as mandated by NHvPI

e) 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/ recipient or the blood unit,

f) A post transfusion properly labelled blood sample, (avoiding haemolysis) shall be obtained from the patient/ recipient from different site and sent to transfusion services along with blood container and attached transfusion set,

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

h) A direct antiglobulin test shall be done on the post transfusion specimen.

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/ recipient 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/ recipient and donor blood from the bag

c) Visual examination of post transfusion urine shall be carried out for haemolysis

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/ recipient shall be tested for bacteria by smear and culture

If investigations are suggestive of a haemolytic reaction or bacterial contamination, patient/ recipient'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/ recipient's medical file.

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

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/ recipient 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 shall not delay proper clinical management of the patient/ recipient.

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 investigation 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/ recipient records.

Records shall be legible and any corrections would be made by only authorized person who shall initial them 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 Annexure E.

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, DP, 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.

Centres having facility of histocompatibility testing shall have the defined processes, procedures and equipment for HLA typing reagents, HLA typing, compatibility testing, sample identification, HLA antibody detection, lymphocytotoxicity cross match, pretransfusion transplant and records. Such centres shall participate in an EQAS program.

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.

No reagents after date of expiry should be used.

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

6.11.2 Reagent red blood cells

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

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

6.11.3 Red cell panel

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

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 or by running IgG coated cells as controls 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

Enzymes such as papain, ficin, 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 & 2 test

Use of enzyme linked immuno sorbent 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, and shall be interpreted with Levy-Jennings Chart (L-J Chart) and as per Westgard Rules.

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

6.11.8 Test for syphilis

VDRL or TPHA or RPR or ELISA method can be used. Test shall be performed as per manufacturer's instructions. Positive and negative controls (kit control and or 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.
Add QC criteria for Hb estimation for different methods like Hemoglobinometer, Copper Sulphate, Sahlis etc.

6.12 Proficiency Testing Programme

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

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

Whenever a formal EQAS/ PT programme is not available, the 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. Eye wash facility shall be available.

Immunization of the blood bank/ blood centre staff against hepatitis-B infection should be implemented after appropriate tests like Anti-HBs titre.

6.13.2 Safety in the laboratory: The blood bank/ blood centre shall have a policy and procedure to ensure laboratory safety which shall include the following:

a) All staff working in laboratories shall be adequately trained in the safety aspects of the lab,
b) Staff shall behave in a safe and responsible manner at all times,
c) Access to the lab shall be restricted to authorized personnel only,
d) Appropriate protective clothing shall be worn at all times, this includes aprons and gloves,
e) Eating, drinking, smoking, applying cosmetic and handling contact lens shall prohibited in the lab,
f) Mouth pipetting shall be prohibited in the lab,
g) Care shall be taken to avoid the formation of aerosols or splashing of materials,
h) All work surfaces shall be decontaminated after any spillage and at the end of each working day,
i) All contaminated waste or reusable materials shall be appropriately decontaminated before disposal or reuse,
j) In case of needle stick injury wash the exposed site thoroughly with soap and running water,
k) Document an incident in a report,
l) Dispose all sharps in puncture proof containers.
m) Blood bank/ blood centre shall list out chemicals used and have material safety data sheets.

6.13.3 Disposal of Blood and Laboratory Material

Method of disposal of Blood Bags

Should comply with requirements of Biomedical Wastes Rules of Ministry of Environment and Forests and local Pollution Control Board.

Disinfection of glassware

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

Spills on the table tops/ sinks

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

Hypochlorite/ detergent solution

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

Disposal by Sterilisation

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

7. IDENTIFICATION OF DEVIATIONS AND ADVERSE EVENTS

7.1 Policies and procedures when non-conformity 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 procedures.

7.1.2 The procedure to analyse the nonconformity and the corrective action to be taken with resumption of the work shall be laid down. This procedure shall be carried out under the guidance of a suitably defined person.

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

7.2 Procedures for release of non-conforming blood component

7.2.1 In case non conformity in collection and preparation of blood/ component is detected, the blood bank/ blood centre shall have a policy and procedure for identification, quarantine, retrieval and recall of non-conforming blood/ components with detailed root cause analysis.

Blood/ components that are detected after issue as not conforming to specify requirement, shall be evaluated to determine the effect of non-conformity on the quality of the product/ effect on recipient.

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

7.2.3 The event shall be recorded.

7.3 Preventing recurrence of non-conformity

If after root cause analysis it is determined that non conformity could recur or it creates a doubt about its compliance with laid down policies and procedures, then the blood bank/ blood centre shall have a procedure to identify, document and eliminate the non conformance.

8. PERFORMANCE IMPROVEMENT

8.1 Addressing complaints

8.1.1 The blood bank/ blood centre shall have a policy for addressing complaints, or other feedback received from donors, clinicians, blood camp organizers or other individuals/ organizations. Blood bank/Blood centre shall develop a mechanism for capturing feedback from donors, patients and Clinicians on a periodic basis. 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. Complaints may be verbal or written.

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 be 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 otherwise, concerning the quality management system. An action plan shall be developed, implemented and monitored to reduce the likelihood of occurrence of such non-conformities.

8.3.2 Procedures for preventive action shall be implemented and followed up for its effectiveness.

8.4 Continuous quality improvement

8.4.1 The blood bank/ blood centre shall have a process to identify, collect and evaluate quality indicator data which shall be from collection to transfusion on regular basis to evaluate and monitor continuous quality improvement. The blood bank/blood centre shall evaluate data on Quality indicators continuously.

8.4.2 Enrolment in National Haemovigilance Program of India: Blood banks/ blood centres shall enrol under National Haemovigilance Program of India and monitor adverse donor reactions and adverse transfusion reactions as per the directives given.

9. DOCUMENT CONTROL

9.1 Procedure for document 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 shall be maintained.

9.1.4 Only currently authorized versions of appropriate documents shall be 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 shall be promptly removed from all points of use, or otherwise assured against inadvertent use.

9.1.7 Retained or archived superseded documents a shall be 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 shall be defined. Amendments are clearly marked, initialled and dated, and a revised document shall be formally re-issued as soon as practicable.

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

9.2 Documents required

For all the documents required please refer to Annexure E.

A copy of all 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, as soft copy or

hard copy. National, regional and local regulations concerning document retention shall 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 (wherever necessary) should be available even when documentation is electronically maintained.

The alternate system shall support maintenance of continuous operations.

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

Personnel must be trained.

Validation of system, integrity and security of data shall be ensured.

The records required by Drugs and Cosmetics Act 1940, 25th Edition 2016 shall additionally be maintained as hard copies.

10. RECORDS

10.1 Record identification

All records shall be uniquely identified and appropriately labelled.

The blood bank/ blood centre shall have policies and procedures to ensure that records are identified, compiled, indexed, reviewed, retained and disposed in accordance with record retention policies.

10.2 Quality and technical records

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

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

The blood bank/ blood centre shall have a procedure to trace any unit of blood/ component from its source to its final issue/ disposition by review of records.

10.3 Records retaining period

The blood bank/ blood centre shall have a policy that defines the length of time various records are to be retained.

National, regional and local regulation must be followed.

For maintaining and retention of records see Annexure E.

11. INTERNAL AUDIT & MANAGEMENT REVIEW

11.1 Policy for internal audit and management review

Internal audit and management review 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 and trained personnel. Personnel shall not audit their own activities. The procedures for internal audits shall be defined and documented and include the type 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 agreed time frame.

All elements of quality management system including managerial and technical shall normally be subject to internal audit once every twelve months.

11.3 Procedure for 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/ recipient care and to introduce 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, feedback, complaints, and 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 review(s) shall be recorded, and the decisions taken implemented. Blood bank/ blood centre management shall ensure that actions arising out of reviews are discharged within an appropriate and agreed time frame.

Annexure - A

Requirements for Storage, Transportation and Expiration

Item No.	Component	Storage	Transport	Expiration	Additional Criteria
Whole Blood components					
1	Whole Blood	$4^0C \pm 2^0C$	Cooling towards $4\text{-}8^0C \pm 2^0C$	ACD/ CPD/ CP2D: 21 days CPDA-1:- 35 days	
2	Whole Blood Irradiated	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	Original expiration or 28 days from date of irradiation, whichever is earlier	
Red Blood Cell Components					
3	Red Blood Cells	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	ACD/ CPD/ CP2D: 21 days CPDA-1: 35 days Additive solution: 42 days Open system: 24 hours	
4	Deglycerolized RBCs	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	Open system: 24 hours closed system:14 days	
5	Frozen RBCs 40% Glycerol	$\leq$-65 C if 40% Glycerol	Maintain frozen state	10 years (A Policy shall be defined by the individual blood bank/ blood centre, if rare frozen units are to be retained beyond this time)	For freezing red cells a cryoprotective agent is added to red cells that are less than 6 days old.
6	RBCs Irradiated	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	Original expiration or 28 days from date of irradiation. Whichever is earlier	
7	RBCs Leukocytes Reduced	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	ACD/ CPD/ CP2D:21 days CPDA-1: 35 days Additive solution: 42 days Open system: 24 hours	
8	Rejuvenated RBCs	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	CPD/ CPDA- 1: 24 hours AS-1 : freeze after rejuvenation	Follow manufacturer's written instructions
9	Deglycerolised Rejuvenated RBCs	$4^0C \pm 2^0C$	$4\text{-}8^0C \pm 2^0C$	24 hours	Follow manufacturer's written instructions

Item No.	Component	Storage	Transport	Expiration	Additional Criteria
10	Frozen Rejuvenated RBCs	≤-65^{0}C	Maintain frozen state	10 year AS-1:3 year (A Policy shall be defined by the individual blood bank/ blood centre, if rare frozen units are to be retained beyond this time)	Follow manufacturer's written instructions
11	Washed RBCs	4^{0}C ± 2^{0}C	4-8^{0}C ± 2^{0}C	24 hours	
12	Apheresis RBCs	4^{0}C ± 2^{0}C	4-8^{0}C ± 2^{0}C	CPDA-1 35 days Additive solution: 42 days Open system: 24 hours	
13	Apheresis RBCs Leukocytes Reduced	4^{0}C ± 2^{0}C	4-8^{0}C ± 2^{0}C	CPDA-1 35 days Additive solution: 42 days Open system 24 hours	
Platelet Components					
14	Platelets	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	24 hours to 5 days, depending on collection system	
15	Platelets Irradiated	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	No change from original expiration date	
16	Platelets Leukocytes Reduced	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	Open system: 4 hours Closed system: No change in expiration	
17	Apheresis Platelets	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	24 hours to 5 days, depending on collection system	
18	Apheresis Platelets Leukocytes reduced	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	No change from original expiration date	
19	Apheresis Platelets Irradiated	22^{0}C ± 2^{0}C with continuous gentle agitation	22^{0}C ± 2^{0}C	Open system: within 4 hours of opening the system Closed system: 5 Days	

Item No.	Component	Storage	Transport	Expiration	Additional Criteria
Granulocyte Components					
20	Apheresis Granulocytes	$22^0C \pm 2^0C$	$22^0C \pm 2^0C$	24 hours	Transfuse as soon possible
21	Apheresis Granulocytes Irradiated	$22^0C \pm 2^0C$	$22^0C \pm 2^0C$	No change from original expiration date	Transfuse as soon Possible, maximum within 24 hours.
Plasma Components					
22	Cryoprecipitated AHF	$\leq$-30^0C	Maintain frozen state	12 months from date of donation	Thaw the FFP at 1-6^0C. Place cryoprecipitate in the freezer within 1 hour
23	Thawed Cryoprecipitate AHF	$22^0C \pm 2^0C$	$22^0C \pm 2^0C$	Open system or pooled: 4 hours Single unit: 6 hours	Thaw at 30-37^0C and transfused as soon as possible
24	Fresh Frozen Plasma (FFP)	$\leq$-30^0C or lower	Maintain frozen state	$\leq$-30^0C: 12 months	Placed in freezer within 6 hours of collection in CPD, CP2D, CPDA-1
25	Thawed FFP	$4^0C \pm 2^0C$	4-$8^0C \pm 2^0C$	24 hours	Thaw at 30-37^0C
26	Plasma Cryoprecipitate Reduced	$\leq$-30^0C	Maintain frozen state	5 years from original collection	
27	Thawed Plasma Cryoprecipitate Reduced	$4^0C \pm 2^0C$	4-$8^0C \pm 2^0C$	24 hours	Thaw at 30-37^0C
28	Liquid Plasma	$4^0C \pm 2^0C$	4-$8^0C \pm 2^0C$	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 • 18 to 65 years. acceptable>45 Kg
Whole Blood Volume Collected	• Maximum of 10 ml per kilogram of donor weight, including samples •
Donation Interval	• 3 months after whole blood donation • 6 months after 2-unit red cell collection. • ≥ 48 hours after platelet/ plasma - pheresis (and not more than twice a week), and for platelet pheresis (not more than 24 times a year)
Blood Pressure	• 100-160 mm Hg systolic • 60-100 mm Hg diastolic
Pulse	• 50-100 beats per minute, without pathologic irregularities • <50 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	One 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 months
• Dental surgery under anaesthesia	Defer for 1 month
Heart Disease	
• Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)	Permanently defer
• Restricted activity	Permanently defer
• Cardiac medication (digitalis, nitroglycerine)	Permanently defer
• Hypertensive on medication	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 defer
• 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
• Personnel 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	Permanently defer
• HIV positive person	Permanently defer
• Donors having symptoms of AIDS	Permanently defer

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

Syphilis	
Genital sore or generalized skin rashes	Defer for 12 months after rashes disappear and completion of therapy
Gonorrhea	12 months deferral after completion of therapy

Dengue	6 months
Tuberculosis	Defer for 5 years after successful completion of treatment.
Typhoid	12 months

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	
Gammaglobulin	Prophylactic Hepatitis B
	Rabies as prophylactic

2. Two weeks deferral before donation if symptoms free

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 following medicine it may not be in his/ her own interest to donate blood and may also affect the patient/ recipient 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 Used for acne	Defer for 1 month after the last dose
Finasteride 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 hormones of human origin
Anticoagulants	Sedatives or tranquillisers in high dose
Antithyroid drugs	Vasodilators
Cytotoxic drugs	Etretinate to treat psoriasis.
Digitalis	Drugs for Parkinson's Disease
Dilantin	

Other conditions requiring Permanent deferral

No person shall donate blood and no blood bank/ blood centre 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 of Apheresis Donor Qualification

General Requirements

- All the points for selection of whole blood donors shall be considered.
- Donor should be preferably repeat donor-might have given blood 1-2 times earlier
- Written consent of the donor is taken after explaining the procedure in detail, time taken, and about possible hazards and benefits.
- Venous access is important consideration in apheresis donor and veins should be examined at the time of selection of donor.

Special Requirements

These are as follows for various apheresis procedures:

1. Platelet-pheresis

Age	18-65 Years
Weight	>55 Kgs
Platelet count	>150,000/ µl

- Donors who have taken aspirin-containing medications within 72 hours are deferred.
- Interval between two plateletpheresis procedures should be at least 48 hours.
- A donor should not undergo the procedure more than 2 times in a week and not more than 24 times in a year.

2. Plasmapheresis

a) Occasional plasmapheresis donor

- Donor undergoes plasmapheresis no more than once in 4 weeks.
- Donor selection and monitoring are the same as for whole blood donation.

b) Serial Plasmapheresis donor

i)

- If the donors red cells can not be returned during an apheresis procedure, hemapheresis or whole blood donation should be deferred for 12 weeks.
- Allowable plasma volume shall be determined.
- At least 48 hours should elapse between successive procedures and donor should not, ordinarily, undergo more than two procedures within a 7 day period.

ii) Donor undergoing plasmapheresis more often than once every 4 weeks, serum or plasma must be tested for total protein and serum protein electropheresis, results must be within normal limits.

3. Red cells pheresis

a) For one red cell unit

- Donor selection and monitoring is same as for whole blood.

b) For two red cell unit

- Removal of two red cell units in one setting needs 6 months interval for consecutive procedure.

4. Granulocyte pheresis

- The donor's consent must include specific permission for any drugs or sedimenting agents to be used. eg. hydroxyethyl starch, corticosteroids, growth factors.
- Before administration of corticosteroids, donors should be questioned about any history of symptoms of hypertension, diabetes, and peptic ulcer.

5. Hematopoietic Progenitor Cell Pheresis (Leukapheresis for Monononulcear cell (MNC) collection)

The donor's consent must include specific permission for any drugs and procedure may be continued for 2-4 days. eg. hematopoitic growth factor; colony stimulating factors (G-CSF); Granulocyte Macrophage-Colony stimulating factors (GM-CSF).

Annexure - D

Quality Control

1. Frequency of testing for reagent and solution

Reagents and solutions	Frequency of testing along with Controls
Anti human globulin serum	Each day of use
Blood grouping anti sera	Each day of use
Lectins	Each day of use
Red cells for serum grouping	Each day of use
Reagent red cells for antibody screening	Each day of use
Hepatitis reagents	Each run
Syphilis serology reagents	Each run
Enzymes	Each run
HIV –1/ 2 reagent	Each run
Normal saline (LISS and PBS)	Each day of use
Bovine albumin	Each day of use
MP by ELISA	Each run
Column agglutination cards	Each day of use

NB: All reagents shall be checked for expiry date and used only when within that date.

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	Positive 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	Positive 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; 10 seconds for anti-A, anti-B and anti-AB with A_1 and/ or B cells at R.T.	Daily and of each new lot/ batch
Reactivity	No immune haemolysis, rouleaux formation or prozone	Each new lot/ batch.
Potency	Undiluted serum should give	Each new lot/ batch.

	+++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.	

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	Positive reaction with pooled Rh (D) positive cells/ R1R1 cells. Negative reaction with Rh (D) negative/ rr cells.	Each day and each new lot/ batch.
Avidity	Visible agglutination with 40% red	Each day and each new

	cells suspension in homologous serum using the slide test.	lot/ batch
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	Pooled O cells/ or R_1 R_1 Cells	1:64-1:128	1:128-1:256	5-10 Sec	+++
Blend of IgM +IgG monoclonal	Same as above	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)	Same as above	Same as above	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 No haemolysis or agglutination of unsensitized red cells Agglutination of red cells sensitised with anti-D serum.	Each lot Each day Each day and 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. 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. The 2-stage enzyme titre should at least be equal to the titre obtained with IgG (anti-D) by AHG test	Each batch 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,	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 'O' pooled red cells/ R_1R1 cells	Each month

10. Quality control of normal saline

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

Parameter	Quantity Requirement	Frequency of Control
Volume	350/ 450 ml ± 10%	1% of all units
PCV (HCT)	>30%	1% of all units or at least 4 units per month. (whichever is more)
HBsAg	Negative	All units
Anti-HCV	Negative	All units
Anti-HIV 1/ 2	Negative	All units
Syphilis	Negative	All units
Malaria	Negative	All units
Sterility	By culture	Periodically (1% of all units)

13. Quality control of red cell concentrate (Prepared from 450 ml blood)

Note: Same as for whole blood except

Parameter	Quantity Requirement	Frequency of Control
* Volume	225-350 ml	1% of all units
HCT	65-75%	Periodically (1% of all units)

14a. Quality control of red cell in preservative solution prepared from 450 ml whole blood (ADSOL/ SAGM)

Note: Same as for whole blood except

Parameter	Quantity Requirement	Frequency of Control
Volume	300-400 ml	1% of all units
HCT	55-65%	Periodically (1% of all units)

14b. Quality control of red cell in preservative solution prepared from 350 ml whole blood (ADSOL/ SAGM)

Note: Same as for whole blood except

Parameter	Quantity Requirement	Frequency of Control
Volume	245ml-325 ml	1% of all units
HCT	55-65%	Periodically (1% of all units)

15. Quality control of Leucocytes-poor red cells

Note: Same as for whole blood except

Method of Preparation	Parameter	Quality requirement	Frequency of control
Filtration	Residual White cells post filtration	Units shall have less than 5X 10^6	4 units a month
Apheresis	Residual White cells in bag post procedure.	Unit shall have less than 5 X 10^6 leukocytes.	

16. Quality control of platelet concentrate prepared from 350/ 450 ml of whole blood

Note: Same as for whole blood except

Parameter Quality	Requirements	Frequency of control
Volume	50-70 ml	All units
Platelets count	$\geq$ 3.5/ 4.5 x 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)

17. Quality Control of platelet concentrate prepared from Buffy coat

Parameter	Quality Requirements	Frequency of control
Volume	50-90 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	>6X10^{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	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 ml
Platelets count	$\geq$ 3.0 x 10^{11}
pH	>6.0 (at the end of permissible storage period)
Red cells	Traces to 5 ml

18a Quality of platelet concentrate by Apheresis

Parameter	Quality requirement
Volume	>200 ml
Platelets count	$\geq$ 3.0 x 10^{11}
pH	>6.0 (at the end of permissible storage period)
Red cells	Traces to 5 ml

18b. Quality criteria for labelling Platelet concentrates(RDP) or apheresis platelets (SDP) as leukoreduced/leukodepleted.

Note: Basic Criteria: Same as in 16, 17, 18a. Additional criteria are as follows:

Parameter	Quality requirement
Residual leukocyte count –RDP	< 8.3 $X10^5$
Residual leukocyte count-SDP	< 5 $X10^5$

19. Quality control of Fresh Frozen Plasma (FFP)

Parameter	Quality control	Frequency of control
Volume	200–220 ml	4 units per month/ 1% of all units (whichever is more)
Stable coagulation factors	Check by PT & APTT	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	1% of all units
Factor VIII	80–120 units	1% of all units
Fibrinogen	150–250 mg	1% of all units

21. Quality control of plasma (Frozen)

Parameter	Quantity requirement
Volume	200–220 ml
Stable coagulation factors	Check by PT & APTT

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 alia 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, haemoglobin, blood grouping, blood pressure, medical examination, bag number and patient/ recipient'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, utilisation 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, name of hospital and unit/ ward, details of cross-matching report, indication for transfusion, issued by.

4. Component preparation records

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

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

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

8. Patient/ recipient.

9. Transfusion adverse reaction records.

10. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags.

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

11. Record showing the daily temperature recordings.

12. Record of quality assurance (internal and external).

13. Record of any adverse incident report with form and resolution

14. Record of equipment maintenance.

15. Record of document control.
16. Daily group-wise blood stock register (inventory) showing its receipt, issue and balance.
17. Disposition record: Units discarded, reasons for discarding and procedure of discarding
18. Personnel health records
19. Stock register of non-consumable articles.
20. Stock register of consumable articles.
21. Documentation of staff qualifications and training.
22. Documentation of staff competency and proficiency tests.
23. Staff attendance register or any other recording system.
24. Grievance redressal register
25. Transfusion Committee meeting minutes with Action Taken Report
26. Haemovigilance reporting records

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 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.

i) Procedures of managing adverse reactions in donors and recipients.

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 against mix-ups in 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 for 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 utilise 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/ blood centre's manuals, subject to the approval of State Licensing Authority and Central Licence Approving Authority.

Annexure - G

List of Equipments available in the Blood Bank/ Blood Centre

1. Donor couches
2. Donor weighing balance
3. Hemoglobinometer/ Calorimeter or any other advanced point of care Hb.
4. Clinical thermometer or donor temperature checking device
5. Sphygmomanometer
6. Stethoscope
7. Blood mixer and shaker
8. Tube stripper
9. Di-electric tube sealer
10. Needle destroyer
11. Oxygen cylinder
12. Refrigerated Centrifuges
13. Double pan balance with standard weights
14. Plasma Expressor
15. Blood Bank Refrigerator
16. -35^{0}C Deep Freezers
17. -80^{0}C Deep Freezers
18. Platelet Agitator and Incubator
19. Fixed or variable pipettes
20. pH Meter
21. Cell Counter (optional)
22. Coagulometer (optional)
23. Sterile Connecting Machine with devices (optional)
24. Laminar Air-flow bench
25. Walk-in Cooler (Cold Room) (optional)
26. Leuco-reduction device (when required)
27. Blood Irradiator (optional)
28. Cell Separators (Apheresis machine)
29. Automated Cell Grouping system (optional)
30. Equipment for column Agglutination technology (optional)
31. Table top centrifuge
32. Serological water bath
33. Binocular microscope
34. Dry incubator

35. Room temperature and humidity checking thermometers.
36. Automatic Cell washer (optional)
37. Digital analytical balance
38. Elisa washer
39. Microplate centrifuge (optional)
40. Elisa reader (Plate reader/ strip reader)
41. Fully Automated Elisa system (optional)
42. VDRL shaker
43. Autoclave
44. Distilled water
45. Air-conditioner (1/ 1.5/ 2 tonnes)
46. Generator (5 KVA/ 30 KVA)
47. Transportation vans (optional)
48. Blood mobile vans (optional)
49. Dry rubber balance material
50. Weighing device for blood bags
51. Emergency medical kit
52. Insulated blood bags containers with provisions for storage between 2^0C to 10^0C
53. Plasma thawing water bath (if components are dispensed)
54. Cryo bath
55. Outdoor camp collection couches/ chairs (optional)
56. Emergency resuscitation kit with required drugs.

Annexure - H

Calibration Frequency for Equipments

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/ year
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 in 6 months
4	Hematrocrit centrifuge	Observe speed temperature and time	-	Once a year
5	General lab centrifuge	Observe speed temperature and time	-	Once in 6 months
6	Automated blood typing	Observe control of correct result (QC samples)	Each day of use	Once a year
7	Haemoglobinometer	Standardize against cyanmethemoglobin standard	Each day of use	Once a year
8	Refractiometer	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	-	-	Before initial use and every 6 months
14	Electronic/digital thermometer			Before initial use and every 6 months
15	Blood agitator	Observe weight of the	Once in 15	Once a year

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house)
		first blood filled container for correct results	days	
16	Platelet shaker cum incubator	Temperature Oscillation rate	Each day of use Once a month	Every 6 months
17	Automated blood cell counter	Known controls	Daily	Once a year
18	Pipettes	Volume	Once in a month	Once in 6 months
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

References

1. AABB Standards for Blood Banks and Transfusion Services, 24th Edition
2. AABB Technical Manual 15th Edition, 2005
3. Drugs and Cosmetic Act 1940, 25th Edition 2016
4. ISO 15189: 2003 'Medical Laboratories - Particular requirements for quality and competence'
5. NACO standards: 'Standards for Blood banks and Blood transfusion services
6. Transfusion Medicine Technical Manual: Edited by Dr. R. K. Saran, Second Edition 2003, Directorate General of Health Services.