1.1 Legal identity

1.1.1 (line added at last) or the Blood Bank shall have applied for renewal of the licence in time as per existing regulations.

1.2.1 (line added at last).The organization chart of the blood centre shall show linkage with the parent organization as applicable.

1.2.2 (Clause re-written as) Where the 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.

1.3.4 (line added at last). Every blood centre shall determine its own ethical policy in conformance with national and international guidelines.

1.4.2 (Clause re-written as) Quality policy and objectives of the quality management system shall be defined and issued under the authority of the Director/ In-charge of blood centre and documented in a quality manual. This policy shall be a statement or an undertaking by the management of the blood centre/organization 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 centre is part of a larger organization the quality manual will be issued by Director/in-charge of blood centre with the prior consent of higher management.

1.4.3 (Clause re-written as) 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. When the blood centre is part of a larger organization some of the procedures and protocols may be referenced to organizational protocols and procedures.

1.4.4 (Clause re-written as) All personnel shall be trained in the 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.

1.4.7 (line added at last). It is recommended that all large blood centes have designated area specific supervisory staff (Donor area supervisor/Serology Supervisor/Component supervisor/TTI supervisor to assist the technical manager(s).

2.1.1 Location and surroundings

Last two paragraph added

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 centers shall be such as to facilitate easy evacuation in the event of a fire/hazard.

The 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:

h) Sterilization-cum-washing (line added at last) (may be shared in case of hospital based blood centres),

2.3 Biological, Chemical and Radiation Safety

(Clause re-written as) 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.

(Clause re-written as) 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

(Clause re-written as) 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.

3.1 Personnel Requirement

(Clause re-written as) 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.

3.3 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.

(the two paragraph has been converted into clauses)

3.4.3 (the second paragraph reframed as)

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

3.5.3 (Clause re-written as) There shall be a continuing education program for staff at all levels.

3.8 Personnel records

(two bullets has been added as last)

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.

4.2 (Clause re-framed as) 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:

(first bullet deleted)
a) Installation qualification
b) Operational qualification
c) Performance qualification

4.6.3 (Clause re-written as) 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 (Clause re-written as) 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.

4.8 Breakdown of equipment

(Second para re-written) The 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.

5.1.3 (new clause inserted) Blood Centre shall ensure that all supplies and reagents requiring cold chain maintenance are received at the appropriate temperature.

5.2.2 (last line deleted) 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.

6. PROCESS CONTROL

(Paragraph re-written) **Process control** is discipline that deals with architectures, mechanisms and algorithms for maintaining the output of a specific process within a desired range. Blood centres shall have technicial Standard Operating Procedures for each of the activity described under Process Control.

6.1.2 Standard procedure

(Paragraph re-written) 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 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.

(Paragraph re-written) 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.

6.2 Donor Section

6.2.1 Blood donation

6.2.1.1 (Clause re-framed as) Donor recruitment: Retention and Recall

(Paragraph re-written) 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.

(Paragraph re-written) Efforts shall be directed towards encouraging and retaining adequate number of repeat donors. Donors shall be appropriately recognised for their contribution.

(Paragraph re-written) The blood bank/ blood centre shall have a procedure for voluntary donor recall.

6.2.1.2 Pre-donation counselling

(last bullet has been added as last)

f) May provide information for Confidential Unit Exclusion

6.2.1.3 Donor registration, consent and selection

b) Consent

(Paragraph re-written) 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 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.

(Paragraph added) The final authority for any decision to accept or reject the donor rests with the donor center's physician who will select or defer donors based on laid down "Selection/ Deferal Criteria.

d) Donation interval

(paragraphs in bullet format and also re-written)

- 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) (line added at last) 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.

(paragraph rewritten) 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.

c) Equipment and blood bag

(last line deleted) 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.

e) Additive solutions

(paragraph rewritten) 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.

g) Duration of blood collection

(paragraph rewritten) 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

(paragraph rewritten) 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

(paragraph rewritten) 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 centres 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

(last paragraph deleted)

6.2.1.9 Donor notification of abnormal findings, test results and counselling

a) Information of test results

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

b) (Clause re-framed as) Donor Notification (Counselling and referral)

(paragraph rewritten)
Efforts shall be made by 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

(Paragraph added)

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 s print outs shall be verified by medical officer or in his/her absence by the designee.

Note 2 : The 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 discarded shall be maintained.

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

6.2.1.11 Therapeutic plasmapheresis and cytapheresis

(paragraph rewritten) 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

(paragraph rewritten) 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.

6.3.3 Preparation of components

a) Red Blood Cells Components

Red cells concentrate

(paragraph rewritten) 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

(paragraph rewritten) Red blood cells shall be washed with normal saline by automatic cell washer or manually by centrifugation. The cells shall be washed 2-3 times with normal saline by centrifuging at $4^{o}C \pm 2^{o}C$. A laminar bench that is validated 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.

6.4.2 Quarantine and storage

(Paragraph added)

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.

Fresh-frozen plasma and cryoprecipitate

(paragraph rewritten) These components shall be stored at $-30^{o}C$ or below and shall be stored no longer than 12 months.

(paragraph rewritten) Cryo poor plasma shall be stored at $-30^{o}C$ or below.

6.6.4 Test for Transfusion Transmitted Infections

(Last line added) 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

(Last line deleted) All blood units collected shall be tested for HIV1&2 antibodies.

6.6.4.2 Test for Viral Hepatitis

(Last line deleted) A test for hepatitis B (HBsAg) and hepatitis C (anti-HCV).

6.6.4.4 Test for Malaria

(Note at last, deleted)

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.

6.7.2 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

(Paragraph rewritten) 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 Registration number. A numeric and/or alphanumeric system shall be used. Any advanced technology for identification such as barcode system is preferable.

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

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

(Paragraph rewritten and last paragraph deleted)

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

(Two paragraph added at beginning)

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

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

(Last paragraph added) Turn around Time (TAT): TAT of Blood 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

(Paragraph rewritten) After issue the blood bank/ blood centre shall not take back the blood into inventory if the cold chain is broken and the blood 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 unit'/s returned in cases where the cold chain is not broken.

6.7.4.3 Urgent requirement of blood

(Paragraph rewritten) 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.

6.7.4.5 Massive transfusion

(Paragraph rewritten and last paragraph added) 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 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

(Paragraph rewritten) Blood not exceeding 5 days, shall be used for exchange transfusion.

6.7.5 Records of recipient

Issue Register shall have:

c) (paragraph rewritten) 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) (paragraph inserted) Compatibility records.

6.7.6 Transfusion related advices (for clinicians):

(paragraph rewritten) 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.

6.7.6.2 Identification of recipient and donor unit

(paragraph rewritten) 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.

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

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

6.7.6.3 Supervision

(paragraph rewritten) 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.

6.7.6.5 Guidelines for transfusion practices

(Paragraph rewritten)

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

The 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

Irradiation

(Paragraph added) 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.

(Paragraph added)

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.

6.8.2 Immediate complications

(bullet points rewritten)

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.

6.10 Histocompatibility Testing

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

6.11.3 Red cell panel

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

(Last paragraph deleted)

6.11.4 Anti-human globulin reagent

(Paragraph rewritten) 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.

6.13.2 (clause rewritten) Safety in the laboratory: The Blood centre shall have a policy and procedure to ensure laboratory safety which shall include the following:

m) (bullet added at last) Blood centre shall list out chemicals used and have material safety data sheets.

7.1 Policies and procedures when non-conformity is detected

7.1.1 (Paragraph rewritten) 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.

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

7.3 Preventing recurrence of non-conformity

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

8.1.1 The blood bank/ blood centre shall have a policy ~~and procedure~~ 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.

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

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

8.4 Continuous quality improvement

8.4.1 The blood bank/ blood center 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 centres shall enrol under National Haemovigilance Program of India and monitor adverse donor reactions and adverse transfusion reactions as per the directives given.

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.

9.1.6 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.

9.2 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 ~~entry~~ shall be ensured.

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

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.

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 ~~any~~ necessary changes or improvements. The results of the review shall be incorporated into a plan that includes goals, objectives and action plans. A typical period for conducting a management review is once every twelve months.

11.4 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 - B

Requirements for Allogeneic Donor Qualification

Physical Examination

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

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.

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

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. ~~20 seconds with A_2 and A_2B cells.~~	Daily and of each new lot/ batch
Reactivity	No immune haemolysis, rouleaux formation or prozone	Each new lot/ batch.
Potency	Undiluted serum should give +++reactions in saline tube test using a 3% red cells suspensions at R.T., titre should be 256 for anti-A, anti-B, and anti-AB with A_1 and/ or B cells. ~~64 with A_2 and A_2B cells.~~	Each new lot/ 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 ~~by ELISA~~	All units
Anti-HCV	Negative ~~by ELISA~~	All units
Anti-HIV 1/ 2	Negative ~~by ELISA~~	All units
Syphilis	Negative ~~by Screening test~~	All units
Malaria	Negative	All units
Sterility	By culture	Periodically (1% of all units)

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 ~~reporting~~ 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 - 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

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house)
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 first blood filled container for correct results	Once in 15 days	Once a year
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

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house)