	policies, processes and procedures for their Calibration, Maintenance, and Monitoring.			
4.2	**Selection, installation and validation of equipment**			
	Blood Bank has a policy for selection, procurement, and installation of the equipment.			
	Blood bank has a) Installation qualification b) Operational qualification c) Performance qualification			
4.3	**Use of equipment**			
	Equipment is operated by authorized personnel Up-to-date instructions for the use of equipment is available Maintenance plan as per the manufacturer is available			
4.4	**Equipment detail record, unique identification**			
	Records of all equipment aremaintained Equipments have unique identification numbers which are displayed on the equipment			
4.5	**Programme for calibration and maintenance of equipment**			
4.5.1	Blood bank has established and Implemented procedure for regularly monitoring the following Calibration of equipments Function of instruments, Reagents and Analytical system.			
	Documented and recorded programme of preventive maintenance as per the manufacturer's recommendation is followed.			

4.5.2	There is a calibration plan as per the manufacturers instructions and it complies with the legal requirements Records of calibration are maintained			
4.5.3	The calibration of equipment is traceable to international / national measurement standards.			
4.5.4	The blood bank has procedures to investigate and follow up of equipment malfunction, failure or adverse event while working. Equipment is marked in case of being out of order			
4.6	**Equipment for storage of blood and component**			
4.6.1	The blood Bank has detailed procedures for storage of blood and blood components			
	There is adequate storage facility within the blood bank (as per the quantum of work)			
4.6.2	Maintenance and recordingof proper temperature is present.			
4.6.3	There is a documented process to monitor and record the temperature of refrigerator, freezers, and platelet incubators (at least every 8 hours. In case the bloodbank is not monitoring the temperature continuously the recording shall be at least at 4 hourly intervals.			
4.6.4	The temperature of agitator is maintained at 22^0C ± 2^0C and recorded at least at 4 hourly intervals.			
4.7	**Computer system**			
	Computer software is validated Access of computer is restricted to authorized personnel only There is a documented policy and procedure to protect the integrity of data			
4.8	**Breakdown of equipment**			
	There is a documented procedure for repairing and replacement of defective equipment			

	There is appropriate labelling of equipment in case of breakdown Calibration of equipment before put in use is ensured to meet specified acceptance criteria. There is policy and procedure for appropriate alternate storage where the blood/blood components shall be shifted in the event of breakdown of storage equipment.			
5.0	**EXTERNAL SERVICES AND SUPPLIES**			
5.1	The blood bank has policies and procedures for selection of suppliers foruse of purchased external services, equipment and consumables that affect the quality of its services.			
5.1.1	The blood bank has procedures and criteria for inspection, acceptance/ rejection, and storage of consumable materials.			
5.1.2	Purchased equipment and consumable supplies are not used until they have been verified as complying with standard specifications			
5.1.3	Cold chain is maintained for supplies and reagents at the time of receipt (If required)			
5.1.4	Supplies and reagents are stored at proper temperature(as defined by the manufacturer) in a safe and hygienic place in a proper manner.			
5.1.6	Inventory Management system -Supplies and reagents that do not bear an expirydate used in a manner that those received first are used first.			
5.1.7	Supplies and reagent are used in a manner consistent with instructions provided by the manufacturer.			
5.1.8	There is a procedure for examination of blood collecting containersvisually for damage or evidence of contamination prior to use.			
5.2	**Inventory control**			
5.2.1	Availability of procedure for inventory control for			

	Supplies External services Purchase product			
5.2.2	Records of supplies and purchased product is maintained Recording includes : a. lot number of all relevant reagents, control materials and calibrators, b. Date of receipt in the blood bank c. Date the material was placed in service.			
5.3	**Evaluation of suppliers**			
	There is a documented procedure for evaluation of suppliers Records for these evaluation are maintained List of approved suppliers is maintained			
6	**PROCESS CONTROL** **(Depending on scope of the blood bank)**			
6.1	**PROCESS CONTROL** The blood Bank has Policies and validated processes and procedures that ensure quality of blood ,components and services For each critical step mechanism tracking system for performer and time details are available			
6.1.1	There is a procedure for traceability of blood/ component unit and sample from blood collection to issue Identification of a recipient of a transfusion of blood from a donor who is subsequently found to have been infected with transfusion transmitted infection. Record of such events			
	In case in-house procedures are used, the following are done Appropriate validation of procedure Documentation			

	of results of validation and procedure used for validation			
6.1.2	Standard procedures National guidelines/manuals/regulatory directives/peer reviewed text/journals/authorized textbooks/international guidelines followed for the standard procedures All procedures are documented and meet the needs of the users Available at the workstation for relevant staff. Documented procedures and necessary instructions are available in a language commonly understood by the staff in blood bank			
6.2	**Donor Section**			
6.2.1	**Blood donation**			
6.2.1.1	There is a documented policy , process and procedure for Donor recruitment Retention and Recall Retaining adequate number of repeat donors. Education of donors prior to collection of blood regarding the risk factors of transfusion transmitted infections.			
6.2.1.2	Pre-donation counseling			

	Pre-donation counselingis done by trained staff which may include Modes of transmission due to risk behaviour and self-exclusion for patient/ recipient's safety Information about alternative testing site Test carried out on donated blood Confidentiality of test results, Need for honest answers in view of window period. Information for Confidential Unit Exclusion			
6.2.1.3	**Donor registration, consent and selection**			
	a) Donor registration			
	A questionnaire in English and local languages is available which is to be filled in by the donor. Assistance is given by donor registration staff.(For donors who are illiterate) Medical officer with minimum MBBS qualification shall be responsible for reviewing the donor's health conditions and physical examination of the donor. Demographic details which include date and time of donor selection and donation are registered.			
	b) Consent			
	There is a documented procedure for taking consent which includes details of Contents of the consent Written consent to transfer excess blood to another blood bank or excess plasma for fractionation			
	c) Criteria for selection/deferral of donors d) Donation interval for			

	Whole blood Interval between two plateletpheresis Interval between plateletpheresis and whole blood donation Double red cell collection			
6.2.1.4	Phlebotomy Procedure			
	There is a documented procedure for phlebotomy including Method of preparation of Phlebotomy site Equipments and blood bag Anticoagulant solutions Additive solutions Volume Duration of blood collection			
6.2.1.5	Post donation care			
	There is a documented procedure for post donation care which includes Advice regarding post-phlebotomy care to donor and the possible adverse reactions Proper display of the same at blood collection/observation room			
6.2.1.6	Adverse donor reaction management			
	For adverse donor reaction ,the blood bank has Availability of necessary drugs and equipment available for treatment of donor reaction, if any. Training in identification and management of various donor reactions Periodically checking of emergency tray to remove expired medicines. Procedure for donor referral and donor transport in case of a serious adverse reaction.			
6.2.1.7	Blood donation camp/ drives			
	There is a procedure for organizing blood donation camp including procedure for Inspection of the camp site prior to the day of blood donation camp			

6.2.1.8	There is a documented procedure for autologous blood collection including Predeposit criteria for Autologous donation Testing of units Labelling required Pre-transfusion testing Perioperative procedure and Post operative procures			
6.2.1.9	Donor notification of abnormal findings, test results and counseling			
	Information of test results			
	There is a procedure for the medical officer of the blood bank to inform the donor about any sero – reactive result of TTI with prior written consent and counseling as per existing regulation			
	Donor Notification (Counseling and referral)			
	The blood bank has a procedure for Pre and Post donation counseling Recallof reactive HIV donors for re-testing. Referral of Sero reactivedonors to the Integrated Counseling and Testing Centre (ICTC) for counseling and confirmation of result Records of donor notification shall be available.			
6.2.1.10	Records of donor and donor's blood/ components			
	The Blood bank has processes and procedures for maintaining Donor records Donor deferral records Donors' blood collection records Donor adverse reaction records Blood component records Record of processing of donor's blood TTI Testing Records of apheresis procedure Records of all blood/ components discarded Records of autoclaving of reactive			

	units/untested units			
6.2.1.11	Therapeutic plasmapheresis and cytapheresis			
	The blood bank has a documented procedure for Therapeutic plasmapheresis/ cytapheresis 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, are maintained. Informed consent of the patient/ recipient are taken in the language he/ she understands.			
	Therapeutic Phlebotomy			
	There is a documented procedure for therapeutic phlebotomy			
6.2.2	Handling of samples and blood units			
	There is a documented procedure for collecting samples for laboratory tests There are procedures and processes for identification and traceability of blood Blood unit identification Recipient records identification and traceability to donor			
6.2.2.3	Transportation			
	There is a documented procedure for transportation of blood and blood component and record of temperature monitoring during transport			
6.3	**Component Laboratory**			
	The blood bank has a documented procedure for preparation of components			
6.4	**Quarantine and Storage**			
	The blood bank has procedure and process for quarantine and storage of blood and blood components			
6.5	**Labeling**			
6.5.1	There is a documented procedure for labeling blood and			

	blood components			
6.5.2	Instructions for transfusion			
	Instructions for transfusion areprinted on the label on the blood bag			
6.5.3	The component label has all required mandatory information The label shall contain information to identify the facility that carries out any part of the			
6.6	**Testing of Donated Blood**			
	There is a documented procedure for testing all the mandatory and other tests of donated blood			
6.7	**Compatibility Testing**			
	There is a documented procedure for Request for blood and its components Sample receiving, acceptance and rejection criteria preservation Blood samples of recipient Retaining and storing segment of each donor Pre-transfusion testing repeat testing of donor blood Issue of blood and its component Re-issue of blood/ blood component after issue from the blood bank issueof blood/ blood component in case of urgent requirement Selection of blood and components for transfusion massive Transfusion Neonates transfusion and exchange transfusion Records of recipient maintained by the blood bank			
	Transfusion related advice (for clinicians):			
	The blood bank has regular interaction to educate the users regarding transfusion related advices and other scientific matters			
6.7.6.1	Informed consent			
	There is a procedure for informed consent which includes informing the patient/ recipient about his/ her need for blood Alternatives available Risks involved in transfusion and non-			

	transfusion. Need for Written consent in language he/ she understands informed consent in case of minors and unconscious patient/recipient			
6.7.6.2	Identification of recipient and donor unit			
	There is a documented procedure for identification of recipient and donor unit			
6.7.6.3	Supervision			
	Transfusion is given under medical supervision. The transfusionist observes 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. user hospital has a hospital transfusion committee.			
6.7.6.4	Administration of blood and blood components			
	A documented procedure for administration of blood and blood components is available			
6.7.6.5	Guidelines for transfusion practices			
	The blood bank has guidelines for transfusion practices including Written protocol for administration of blood and blood components. Procedure 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 Competency assessment after training Approved guidelines by the Hospital Transfusion Committee (HTC) for appropriate use of blood and components			
6.7.6.6	Special considerations for use of components			

	There is documented instruction for use of component which includes ABO and Rh compatibility Temperature of blood and blood component before transfusion Time taken for transfusion Storage of component after issuing blood from blood bank			
6.8	**Transfusion Reaction and Evaluation**			
	There are policies,processes and procedures for error prevention in transfusion There is a procedure for detection , reporting and evaluation of transfusion reaction			
6.9	**Documentation in Transfusion Service**			
	Regular reports are submitted to respective authority as per the requirement of the state. Records of transfusion reaction and its evaluation and reason of transfusion reaction are maintained Transfusion reactions are reported to the hospital transfusion committee.			
6.10	**Histocompatibility Testing**			
	The process and procedure for Histocompatibility testing is available including Terminology of HLA antigens conformance to the nomenclature adopted by the World Health Organisation. Equipment for HLA typing reagents, HLA typing, compatibility testing, sample identification, HLA antibody detection, lymphocytotoxicity cross match, Pretransfusion transplant and records. Participation in an EQAS program.			
6.11	**Quality Control**			
	There is a documented procedure for running quality control of a. Reagent red blood cells b. Red cell panel			

	c. Anti-human globulin reagent d. Bovine serum albumin e. Enzyme reagents f. Hepatitis B Surface Antigen, anti-HCV and anti-HIV 1 & 2 test and syphilis g. Normal saline and buffered solutions h. Blood component There is a Quality control plan including Root cause analysis , Corrective and preventive action in case of outliers			
6.12	**Proficiency Testing Programme**			
	The procedure for PPT program includes Participation in External Quality Assurance Scheme (EQAS)/ Proficiency Testing Programme (PT). Corrective action for Non conformance when control criteria are not fulfilled and record keeping			
6.13	**Bio-medical waste disposal and laboratory safety in blood bank/ blood centre**			
	The blood bank has a procedure for Biomedical waste management including biomedical waste segregation, transportation and disposal as per the bio-medical waste management prophylaxis as per guidelines of regulatory authority. Immunization of the blood bank/ blood centre staff against hepatitis-B infection should be implemented after appropriate tests like Anti-HBs titre. policy and procedure for laboratory safety Training of staff for lab safety Procedure for sterilization			
7.0	**IDENTIFICATION OF DEVIATIONS AND ADVERSE EVENTS**			
7.1	There are policies and procedures when any aspect of the test analysis or function does not conform to laid down procedures.			

	There is a Procedure to analyse the nonconformity and take corrective and preventive action Records of detection of Non conformity, root cause analysis, corrective and preventive action taken by the blood bank are maintained			
7.2	There are documented procedures for release of non-conforming blood component Record for release of non-conforming blood component is maintained			
8.0	**PERFORMANCE IMPROVEMENT**			
8.1	**Addressing complaints**			
	Blood bank has a policy for addressing complaints, or other feedback received from donors, clinicians, blood camp organizers or other individuals/ organizations			
	Procedure for capturing feedback from donors, patients and Clinicians is available			
	Record of complaints, investigations and corrective actions taken.are maintained (Complaints may be verbal or written)			
8.2	**Corrective action**			
	Blood Bank has process of investigation to determine root cause of the problem and Procedure for corrective action Documentation of corrective action with root cause analysis is maintained			
8.3	**Preventive action**			
	Procedure for Preventive action, implementation and monitoring to reduce occurrence of non-conformities is available The follow up for its effectiveness is done and records maintained			
8.4	**Continuous quality improvement**			
	The blood bank has a process to identify, collect and evaluate quality indicator data .			
	The blood bank has Enrolled in in National Haemovigilance Program of India: for adverse donor			

	reactions and adverse transfusion reactions			
9.0	**DOCUMENT CONTROL**			
	There is a documented procedure for document control and review of documents Documents are reviewed and approved by authorized personnel prior to issue. Master list of documents is maintained Only currently authorized versions of appropriate documents are available for active use at relevant locations. Documents are periodically reviewed, revised when necessary, and approved by authorized personnel. Invalid or obsolete documents are removed from all points of use			
	Maintenance of documents in computer software Electronic Records)			
	There is a documented procedure for changes to documents maintained in computerized systems including Procedure for backup of all critical data. Alternative method during system break down Procedures for data retrieval Training of personnel Validation of system, integrity and security of data The records availability as per the requirement of Drugs and Cosmetics Act 1940, 25th Edition 2016 (additionally be maintained as hard copies)			
10.0	**RECORDS**			
	There is a documented policy and procedure for Record identification Record Retention Disposal Procedure to trace any unit of blood/ component from its source to its final issue/ disposition by review of records. List of records maintained by the blood bank			
11.0	**INTERNAL AUDIT & MANAGEMENT REVIEW**			

	There is a documented procedure of internal audit which includes Person responsible for plan organizing and carrying out internal audit internal audit Frequency Methodologies and required documentation			
	Internal audit is done within 12 months			
	All elements of quality management system including managerial and technical are covered in internal audit once every twelve months.			
	Appropriate corrective and/ or preventive actions documented and carried out within agreed time frame.			
	Blood bank has Procedure for management review Agenda of management review covers all the required elements as per the standard requirements			
	Record of internal audit and management review			

NOTES: