

**Requirements pertaining to accommodation, personnel,
and equipments are mentioned if any other
clarification is needed feel free to contact**

**Dr. Gajendra Gupta
+91-9929607025**

Accommodation and Environment

Space Allocation

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 siphonage.

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

Accommodation of blood bank/blood centre

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

- a) Registration and medical examination with adequate furniture and facilities for registration and selection of donors.
- b) Donor motivation area/Counsellor (optional).
- c) Blood collection (air-conditioned).
- d) Refreshment-cum-rest-room (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 degree Celsius to 25 degrees Celsius), with a provision of quarantine area/equipment.
- g) Laboratory for blood group serology (air-conditioned).
- h) Sterilization-cum-washing.

- i) .
- j) Store-cum-record.

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

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

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

Plasmapheresis Plateletpheresis and Leucapheresis:

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

Blood Donation Camp

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

Premises

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

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

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

PERSONNEL

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.

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 full time Medical Officer possessing following qualification:

Medical Officer

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

OR

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

OR

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

Blood bank/blood centre technician (s)

Technician shall be full time competent staff possessing:

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

OR

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

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

Registered Nurse (s)

Registered with state/central nursing council

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 its components.

OR

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

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

Equipment

Equipment requirement

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

List of Equipment available in the Blood Bank

S.No	Equipment	Authentic make	Remi make	Imported
1	Donor couches	50,000	1,56,000	2,00,000
2	Donor weighing balance	20,000	1,90,000	2,10,000
3	Hemoglobinometer	1,5000	-	-
4	Sphygmomanometer	500	-	-
5	Stethoscope	500	-	-
6	Blood mixer and shaker	2500	-	-
7	Tube stripper	2500	8500	-
8	Di-electric tube sealer	1,10,000	1,60,000	2-3 Lac
9	Needle destroyer	1,000	-	-
10	Oxygen cylinder	3,000	-	-
11	Refrigerated Centrifuges	4,00,000	7,35,000	18-25 Lac
12	Double pan balance	1,000	-	-
13	Plasma Expressor	3,000	33,400	80,000
14	Blood Bank Refrigerator	1,15,000 (300 bags)	1,90,000	2-5 Lac
15	-35 degree C Deep Freezers	1,10,1000 (300 ltrs)	1,39,000	5-6 Lac
16	-80 degree C Deep Freezers	3,00,000	3,50,000	10,00,000
17	Platelet Agitator and Incubator	90,000	1,65,000	-
18	pH Meter	6,000	-	-
19	Cell Counter(optional)	3,00,000	-	3,00,000
20	Coagulometer(optional)	-	-	-
21	Sterile Connecting devices (optional)	-	-	6,00,000
22	Laminar Air-flow bench	50,000	65,000	-
23	Walk-in Cooler (Cold Room)(optional)	-	-	-
24	Leuco-reduction device(when required)	-	-	8,00,000
25	Blood Irradiator(optional)	-	-	25,00,000
26	Cell Separators (Apheresis machine)	-	-	11 to 16 Lac
27	Automated Cell Grouping system(optional)	-	-	25-35 Lac
28	Equipment for Gel technology(optional)	-	-	2,00,000
29	Table top centrifuge	20,000	20,000	1,00,000
30	Serological water bath	25,000	67,000	1,00,000

31	Binocular microscope	20,000	-	-
32	Dry incubator	-	-	-
33	Automatic Cell washer(optional)	-	-	-
34	Digital analytical balance	-	-	20,000
35	Elisa washer	-	-	1,50,000
36	Microplate centrifuge(optional)	-	-	-
37	Elisa reader (Plate reader/ strip reader)	-	-	2,00,000
38	Fully Automated Elisa/ECL system(optional)	-	-	20,00,000
39	VDRL shaker	3,000	6,000	8,000
40	Autoclave	-	15,000	25,000
41	Distilled water	-	-	-
42	Air-conditioner (1/1.5/2 tonnes)	-	-	-
43	Generator (5 KVA/ 30 KVA)	-	-	-
44	Transportation vans(optional)	-	-	-
45	Blood mobile vans(optional)	-	-	-
46	Dry rubber balance material	-	-	-
47	Weighing device for blood bags	-	-	-
48	Emergency medical kit	-	-	-
49	Insulated blood bags containers with provisions for storage between 2 degree centigrade to 10 degree centigrade	-	-	-

Since in Manipur the prevalence of HIV is more you can propose NAT testing also which shall cost you Rs. 1,000/bag and also you have to provide more space for it

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsourced or in house)
1	Temperature recorder (Display)	Compare against calibrated thermometer	Daily	Once in 6 months/ year
2	Refrigerator/ Deep freezer for storage of blood / components	Compare against thermometer	Daily	Once in 6 months
3	Refrigerated blood bag centrifuge	Observe speed temperature and time	Each day of use	Once a year
4	Hematocrit centrifuge	Observe speed temperature and time	-	Once a year
5	General lab centrifuge	Observe speed temperature and time	-	Once a year
6	Automated blood typing	Observe control of correct result (QC samples)	Each day of use	Once a year
7	Haemoglobin meter	Standardize against cyanamethemoglobin standard	Each day of use	Once a year
8	Refractio-meter or Urinometer	Standardized against distilled water	Each day of use	Once a year
9	Blood container weighing device	Container of known calibrated weight	Each day of use	Once a year
10	Water bath	Observe temperature	Each day of use	Once a year
11	Autoclave	Observe temperature and pressure	Each day of use	Once a year
12	Serologic rotators	Observe control for correct result	Each time of use	Once a year
13	Laboratory thermometer	-	-	Once a year
14	Electronic thermometer			Before initial use and once a year
15	Blood agitator	Observe weight of the first blood filled container for correct results	Once in 15 days	Once a year
16	Platelet shaker cum incubator	Temperature No. of strokes (check in house)	Once a month	Once a year (temperature)
17	Automated blood cell counter	Known controls	Daily	Once a year
18	Pipettes	Volume	Once in a month	Once a year

19	Incubator	Temperature	Once in a month	Once a year
20	Stop watch	-	-	Once a year
21	Tachometer	-	-	Once a year
22	Weight box	-	-	Once a year

Labelling

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

Requirements shall ensure:

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

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

Labelling for whole blood/component

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

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

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

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

Instructions for transfusion

Following information shall be printed on the label.

- a) Do not use if there is any visible evidence of deterioration.
- b) Store the product at appropriate temperature (as defined for each of the product) before use. (e.g Keep at 4 °C±2 °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.

Special requirements for component label

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

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

Quality Control

Frequency of testing for Reagent and solution

Reagents and solutions	Frequency of testing along with Controls
Anti human serum	Each day of use
Blood grouping serum	Each day of use
Lectin	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Hepatitis test reagents	Each run
Syphilis serology reagents	Each run
Enzymes	Each run
HIV –1/2 reagent	Each run
Normal saline (LISS and BPS)	Each day of use
Bovine albumin	Each day of use

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

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

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 ₂ B 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 ₂ B cells.	Each new lot/batch.

Acceptable Titre and Avidity of ABO reagents

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

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 R ₁ r cells	Each day and each new lot/batch. And no reaction with rr cells.
Avidity	Visible agglutination with 40% red cells suspension in homologous serum using the slide test.	Each day and each new 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

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

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

Acceptable quality of anti-globulin reagent:

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual 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 containing not more than 0.2 mg/ml antibody activity Agglutination of red cells sensitised with a complement-binding antibody (e.g. anti Le ^a). Agglutination of red cells coated with C3b and C3d, and no/weak agglutination with C4 coated red cells.	Each lot Each day Each day and each new lot/batch. Each new lot/ batch. Each new lot/ batch.

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	Each batch

	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
--	--	------------

Quality Control of 22% bovine serum albumin (BSA)

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual inspection	Each day
Purity	>98% albumin, as determined by electrophoresis.	Each new lot
Reactivity	No agglutination of unsensitized red cells; no haemolytic activity; no prozone phenomenon	Each new lot
Potency	IgG anti-D should give a titre of 32-64 with red cells R ₁ r	Each month

Quality Control of Normal Saline

Parameter	Quality requirement	Frequency of control
Appearance	No turbidity or particles by visual inspection	Each day
NaCl content	0-154 mol/L (=9g/l)	Each new batch
pH	6.0-8.0	Each new batch
Haemolysis	Mixture of 0.1 ml saline and 0.1 ml of 5% red cells suspension centrifuged after 10 min, no haemolysis	Each new batch

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

The Quality Control of Whole Blood.

Parameter	Quantity Requirement	Frequency of Control
Volume	350/450 ml \pm 10%	1% of all units
Anticoagulants	49/63 ml	All units
PCV (Hct)	30 to 40%	4 units per month
HBsAg	Negative by ELISA	All units
Anti-HCV	Negative by ELISA	All units
Anti-HIV 1/2	Negative by ELISA	All units
Syphilis	Negative by Screening	All units

	test	
Malaria	Negative	All units
Sterility	By culture	Periodically (1% of all units)

The Quality Control of red cell concentrate (Prepared from 350/450 ml Blood)

Note :- Same as for whole blood except.

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

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

Note :- Same as for whole blood except.

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

The Quality Control of Leucocytes-poor red cells

Note :- Same as for whole blood except.

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

The 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	$\geq 3.5 / 4.5 \times 10^{10}$	4 units per month / 1% of all units (whichever is more)

pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	<0.5 ml	4 units per month/ 1% of all units (whichever is more)
WBC contamination	$5.5 \times 10^7 - 5 \times 10^8$	4 units per month/ 1% of all units (whichever is more)

The Quality Control of platelet concentrate prepared from buffy coat

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

Quality of Platelet Concentrate by Apheresis

Parameter	Quality requirement
Volume	>200 ml
Platelets count	$\geq 3.0 - 7.0 \times 10^{11}$
pH	>6.0 (at the end of permissible storage period)
Residual leucocytes	$<5.0 \times 10^6$
Red cells	Traces to 0.5 ml

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	200 units of each factor	4 units per month
Factor VIII	0.7 units/ml	4 units per month
Fibrinogen	200–400 mg	4 units per month

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

Quality Control of Plasma. (Frozen)

Parameter	Quantity requirement
Volume	200–220 ml
Stable coagulation factors	200 units of each factor

Quality Control of Granulocytes

Granulocytes prepared from hemapheresis	
Parameter	Quantity requirement
Granulocytes	1×10^{10}
Other leucocytes	$0.1 \times 0.7 \times 10^9$
Platelets	$2-10 \times 10^{11}$
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	$0.5-1 \times 10^9$

Records

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

1. Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of the donor with other particulars of age, weight, 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. Record of components supplied: Quantity supplied; compatibility report, details of recipient and signature of issuing person.
5. Records of A.C.D/C.P.D-A/SAGM bags giving details of manufacturer batch number date of supply, and results of testing.
6. Register for diagnostic kits and reagents used: Name of the kits/reagents, details of batch number, date of expiry and date of use.
7. patient/recipient
8. Transfusion adverse reaction records.
9. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags.
10. 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.
14. Record of equipment maintenance.
15. Record of document control.
16. Daily group-wise blood stock register (inventory) showing its receipt, issue and balance, units discarded with reason of discarding.
17. Stock register of non-consumable articles.
18. Stock register of consumable articles.

20. Documentation of staff qualifications and training.
21. Documentation of staff competency and proficiency tests.
22. Staff attendance register or any other recording system.
23. Grievance reporting register

Note: The above said records shall be kept for a period of 5 years¹