BLOOD CENTRES

Applications for grant or renewal of license for operation of Blood Centre or processing of Human blood components shall be made by the Blood Centre run by the Government, Indian Red Cross Society, Hospital, Charitable Trust or Voluntary organization, and Blood Centre run by Charitable Trust or Voluntary organization need to be approved by a State Blood Transfusion Council as per procedure laid down in this regard by the National Blood Transfusion Council.

REQUIREMENTS FOR BLOOD CENTRES

(a) The applicant / licensee shall provide and maintain adequate staff, plant and premises for the proper operation of a Blood Centre for processing whole human blood, its components and/or manufacture of blood products.

(b) The applicant / licensee shall maintain staff, premises and equipments as specified in Rule 122-G. The licensee shall maintain necessary records and registers as specified in Schedule F, Parts XII-B and XII-C.

(c) The licensee shall test in his own laboratory whole human blood, its components and blood products and [maintain records and] registers in respect of such tests as specified in Schedule F, Part XII-B and Part XII-C. The records and registers shall be maintained for a period of five years from the date of manufacture.

(d) The licensee shall maintain/preserve reference [sample and] supply to the Inspector the reference sample of the whole human blood collected by him in adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.

COMPETENT TECHNICAL STAFF

(A) Medical Officer, possessing the qualifications specified in rule 122-G.

Medical Officer : The operation of Blood Centre or processing or both of whole human blood for components shall be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee and who is Medical Officer, and possessing—

(a) Degree in Medicine M.B.B.S. having experience of working in Blood Centre, not less than one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood or preparation of its components or both; or

(b) Degree in Medicine M.B.B.S. with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with six months experience in a licensed Blood Centre; or

(c) Degree in Medicine M.B.B.S. with Diploma in Transfusion Medicine or Diploma inImmunohematology or Blood Transfusion with three months experience in a licensed Blood Centre; or

(d) Doctor of Medicine Pathology or Diplomate of National Board Pathology with three months experience in a licensed Blood Centre; or

(e) Postgraduate degree in Transfusion Medicine - Doctor of Medicine Transfusion Medicine or Diplomate of National Board Transfusion Medicine, Doctor of Medicine Immunohematology and Blood Transfusion,

the degree or diploma being from a University recognized by the Central Government or State Government.

(b) **Blood Centre Technician**(s) ,possessing -

(i) Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood and/or its components in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology (M.L.T.) or Blood Bank Technology with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or

(iii)B.Sc. in Hematology and Transfusion Medicine with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or

(v) Post Graduate Diploma in Medical Laboratory Technology (PGDMLT) / Post Graduate Diploma in Medical Laboratory Science (PGDMLS) with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre.

the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

(c) Registered Nurse(s).

(d) **Technical Supervisor** (where blood components are manufactured), possessing -

(i) Diploma in Medical Laboratory Technology or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood or its components or both in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology or Blood Bank Technology with six month‘s experience in the testing of blood or its components or both in licensed Blood Centre; or

(iii) B.Sc. in Hematology and Transfusion Medicine with six month‘s experience in the testing of blood or its components or both in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month‘s experience in the testing of blood or its components or both in licensed Blood Centre; or

(v) Post Graduate Diploma in Medical Laboratory Technology or Post Graduate Diploma in Medical Laboratory Science with six months experience in the testing of blood or its components or both in licensed Blood Centre; or

(vi) Post Graduate Diploma in Transfusion Technology (PGDTT) approved by the Central Government or State Government with experience of 6 months in testing of blood or its components or both in licensed blood centre.

the degree or diploma being from a University/Institution recognised by the Central Government or State Government.

Note: As regards, the number of whole time competent technical personnel, the blood bank shall comply with the requirements laid down in the Directorate General of Health Services Manual.

Blood Centre organizing blood donation camps shall have following Whole time or part time counseling staff (Counselor or Medical Social Worker) possessing —

(a) Master's degree in social work, sociology, psychology with six months of experience; or
(b) Degree in Science or Health Science with one year of experience; or
(c) Person with 10+2 having three years of experience
in the field of counseling in the Blood centers collecting blood less than 3000 units per annum can share counselor or medical social worker within the institution.

ACCOMODATION FOR A BLOOD CENTRE :

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

(1) Registration and medical examination with adequate furniture and facilities for registration and selection of donors;

(2) blood collection (air-conditioned);

(3) blood component preparation. (This shall be air-conditioned to maintain temperature between 20 degree centigrade to 25 degree centigrade);

(4) laboratory for blood group serology. (air-conditioned)

(5) laboratory for blood transmissible diseases like Hepatitis, Syphilis, Malaria, HIV-antibodies (air-conditioned);

(6) sterilization-cum-washing;

(7) refreshment-cum-rest room (air-conditioned);

(8) store-cum-records;

(9) counseling area with adequate privacy;

(10) Identified Quality Control area with component preparation area may be provided.

GENERAL EQUIPMENTS AND INSTRUMENTS :

1. For blood collection room :
   (i) Donor beds, chairs and tables: These shall be suitably and comfortably cushioned and shall be of appropriate size.
   (ii) Bedside table.
   (iii) Sphygmomanometer and Stethoscope.
   (iv) Recovery beds for donors.
   (v) Refrigerators, for storing separately tested and untested blood, maintaining temperature between 2 to 6 degree centigrade with digital dial thermometer, recording thermograph and alarm device, with provision for continuous power supply.
   (vi) Weighing devices for donor and blood containers.

2. For haemoglobin determination :

   (i) Copper sulphate solution (specific gravity 1.053)
   (ii) Sterile lancet and impregnated alcohol swabs.
   (ii) Capillary tube (1.3x1.4x96 mm or pasteur pipettes)
   (iv) Rubber bulbs for capillary tubings.
   (v) Sahli's haemoglobinometer/ Colorimeteric method.

3. For temperature and pulse determination:
   (i) Clinical thermometers.
   (ii) Watch (fitted with a seconds-hand) and a stop-watch.

4. For blood containers :

   (a) Only disposable PVC blood bags shall be used (closed system) as per the specifications of IP/USP/BP.
   (b) Anti-coagulants: The anti-coagulant solution shall be sterile, pyrogen-free and of the following composition that will ensure satisfactory safety and efficacy of the whole blood and/or for all the separated blood components.
   (i) Citrate Phosphate Dextrose Adenine solution (CPDA) or Citrate

Phosphate Dextrose Adenine- 1 (CPDA-1) ----14 ml. Solution shall be required for 100 ml of blood.

NOTE 1. (i) In case of single/double/triple/quadruple blood collection bags used for blood component preparations, CPDA blood collection bags may be used.
(ii) Acid Citrate Dextrose solution (A.C.D with Formula-A). I.P. -- 15ml. Solution shall be required for 100ml of blood.
(iii) Additive solutions such as SAGM, ADSOL, NUTRICEL may be used for storing, and retaining Red Blood Corpuscles upto 42 days.

NOTE2. The licensee shall ensure that the anti-coagulant solutions are of a licensed manufacturer and the blood bags in which the said solutions are contained have a certificate of analysis of the said manufacturer.

5. Emergency equipments/items .

(i) Oxygen cylinder with mask, gauge and pressure regulator.
(ii) 5 percent Glucose or Normal Saline.
(iii) Disposable sterile syringes and needles of various sizes.
(iv) Disposable sterile I.V. infusion sets.
(v) Ampoules of Adrenaline, Noradrenaline, Mephentin, Betamethasone or Dexamethasone, Metoclorpropamide injections
(vi) Aspirin.

6. Accessories :

(i) Such as blankets, emesis basins, haemostats, set clamps, sponge forceps, gauze, dressing jars, solution jars, waste cans.
(ii) Medium cotton balls, 1.25 cm. adhesive tapes.
(iii) Denatured spirit, Tincture Iodine, green soap or liquid soap.
(iv) Paper napkins or towels.
(v) Autoclave with temperature and pressure indicator.
(vi) Incinerator
(vii) Stand-by generator.

7. Laboratory equipment:

(i) Refrigerators, for storing diagnostic kits and reagents, maintaining a temperature between 4 to 6 degree ceritigrade (plus/minus 2 degree centigrade) with digital dial thermometer having provision for continuous power supply.
(ii) Compound Microscope with low and high power objectives.
(iii) Centrifuge Table Model

(iv) Water bath: having range between 37 degree centigrade to 56 degree centigrade
(v) Rh viewing box in case of slide technique.
(vi) Incubator with thermostatic control.
(vii) Mechanical shakers for serological tests for Syphilis.
(viii) Hand-lens for observing tests conducted in tubes.
(ix) Serological graduated pipettes of various sizes
(x) Pipettes (Pasteur)
(xi) Glass slides
(xii) Test tubes of various sizes/micrometer plates (U or V type)
(xiii) Precipitating tubes 6mmx50mm of different sizes and glass beakers of different sizes
(xiv) Test tube racks of different specifications.
(xv) Interval timer electric or spring wound. .
(xvi) Equipment and materials for cleaning glass wares adequately.
(xvii) Insulated containers for transporting blood, between 2 degree centigrade to 10 degree centigrade temperatures, to wards and hospitals.
(xviii) Wash bottles
(xix) Filter papers
(xx) Dielectric tube sealer.
(xxi) Plain and EDT A vials
(xxii) Chemical balance (wherever necessary)
(xxiii) ELISA reader with printer, washer and micropipettes.

SPECIAL REAGENTS:

(1) Standard blood grouping sera Anti A, Anti B and Anti D with known controls. Rh typing sera shall be in double quantity and each of different brand or if from the same, supplier each supply shall be of different lot numbers.
(2) Reagents for serological tests for syphilis and positive sera for controls.
(3) Anti Human Globulin Serum (Coomb's serum)
(4) Bovine Albumin 22 percent Enzyme reagents for incomplete antibodies.
(5) ELISA or RPHA test kits for Hepatitis and HIV I & II.
(6) Detergent and other agents for cleaning laboratory glasswares.

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 donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In-charge.

(2) Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II 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 Incharge.

(3) Issue register : It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.

(4) Records of components supplied: quantity supplied; compatibility report, details of recipient and signature of issuing person.

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

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

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

(8) Transfusion adverse reaction records.

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

LABELS:

The labels on every bag containing blood and/or component shall contain the following particulars, namely:

(1) The proper name of the product in a prominent place and in bold letters on the bag.

(2) Name and address of the blood centre

(3) Licence number

(4) Serial number

(5) The date on which the blood is drawn and the date of expiry as prescribed under Schedule P to these rules.

(6) A colored label shall be put on every bag containing blood. The following color scheme for the said labels shall be used for different groups of blood:

Blood Group	Color of the label
O	Blue
A	Yellow
B	Pink
AB	White

(7) The results of the tests for Hepatitis B surface antigen, and Hepatitis C virus antibody, syphilis, freedom from HIV I and HIV II antibodies and malarial parasite.

(8) The Rh group.

(9) Total volume of blood, the preparation of blood, nature and percentage of anti-coagulant.

(10) Keep continuously temperature at 2 degree centigrade to 6 degree centigrade for whole human blood and/or components as contained under III of Part XII B.

(11) Disposable transfusion sets with filter shall be used in administration equipment.

(12) Appropriate compatible cross matched blood without a typical antibody in recipient shall be used.

{13) The contents of the bag shall not be used if there is any visible evidence of deterioration 1ike haemolysis, clotting or discoloration.

(14) The label shall indicate the appropriate donor classification like "Voluntary Donor" or "Replacement Donor" in no less prominence than the proper name.

PROCESSING OF BLOOD COMPONENTS FROM WHOLE BLOOD BY A BLOOD CENTRE

(A) ACCOMMODATION: As specified above

(B) EQUIPMENT :

(i) Air conditioner;
(ii) Laminar air flow bench;
(iii) Suitable refrigerated centrifuge;
(iv) Plasma Expresser or Automated Extractor or Multi Head Tube Sealer;
(v) Clipper and clips and or dielectric sealer;
(vi) Weighing device;
(vii) Dry rubber balancing material;
(viii) Artery forceps, scissors;
(ix) Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply;
(x) Platelet agitator with incubator (wherever necessary)
(xi) Deep Freezer or Snap Freezer maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade.
(xii) Refrigerated Water bath for Plasma Thawing;
(xiii) Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes.
(xiv) Cryobath and any better equipment or technology.

(C) PERSONNEL: The whole time competent technical staff meant for processing of Blood Components (that is Medical Officer, Technical Supervisor, Blood Centre Technician and Registered Nurse) shall be as specified above.

(D) TESTING FACILITIES:

General: Facilities for A,B, AB and O groups and Rh(D) grouping.

Hepatitis: B Surface antigen and Hepatitis C virus antibody, VDRL, HIV I and HIV II antibodies and malarial parasites shall be mandatory for every

blood unit before it is used for the preparation of blood components. The results of such testing shall be indicated on the label

(E) CATEGORIES OF BLOOD COMPONENTS:

(1) **CONCENTRATED HUMAN RED BLOOD CORPUSCLES:** The product shall be known as "Packed Red Blood Cells IP" — that is packed red blood cells remaining after separating plasma from human blood which also include modified packed red blood cells including semi-packed red blood cells, washed red blood cells, leukoreduced red blood cells, irradiated red blood cells and frozen red blood cells. Storage: shall be kept at a temperature maintained between 2 degree centigrade to 6 degree centigrade.

(2) **PLATELETS CONCENTRATES IP -** may be obtained from the whole blood or by plateletpheresis.
Types of Platelets:
(i) Platelet Rich Plasma
(ii) Random Donor Platelet Concentrate
(iii) Pooled Platelets

(3) **GRANULOCYTE CONCERNTRATE IP:** Granulocyte concentrates is prepared either by pooling multiple units of buffy coat or by apheresis. The same shall be stored at 20-24ºC and used within a maximum period of 24 hours.

(4) **FRESH FROZEN PLASMA BP:** Plasma frozen within 6 hours after blood collection and stored at a temperature not warmer than minus 30 degree centigrade, shall be preserved for a period of not more than one year.

(5) **CRYOPRECIPITATE IP:** Concentrate of anti-hemophiliac factor shall be prepared by thawing FFP at 4ºC in a cold room or blood bank refrigerator or 4-10ºC in a cryobath. Minus 80ºC deep freezer should be used for faster freezing of plasma for preparation of cryoprecipitate.

(6) **APHERESIS USING A CELL SEPARATOR:**

General requirements:

(a) Accommodation: An air-conditioned area of 10 square meters shall be provided for apheresis/therapeutic procedures in the blood Centre.

(b) Equipment:

i. Cell separator

ii. Dielectric tube sealer

iii. Other emergency equipments/ items

- Oxygen cylinder with mask, gauge and pressure regulator.
- 5 per cent Glucose or Normal Saline.
- Disposable sterile syringes and needles of various sizes.
- Disposable sterile I.V. infusion sets.
- Ampoules of Adrenaline, Noradrenaline, Mephentin, Betamethasone orDexamethasone, Metoclorpropamide injections.
- Aspirin.

(c) Criteria for selection of donors:

At least 48 hours must elapse between successive apheresis and not more than twice in a week. For haematopoietic stem cells the procedures can be done daily.

Types of Apheresis:

1. Plasmapheresis
2. Plateletpheresis for harvesting Platelet concentrate (Single Donor Platelets)
3. Leucapheresis for harvesting
   - Granulocyte concentrate
   - Lymphocytes
   - Mononuclear cells
4. Erythrocytapheresis- Red cell apheresis including double unit red cell collection
5. Therapeutic Plasmapheresis and Cytapheresis