

## CHAPTER XIII

### GUIDELINES FOR OPENING AND LICENSING OF BLOOD BANK

#### 1301. Blood Bank.

Blood Bank: - Blood bank means, a centre within an organisation or an institution for collection, grouping, cross-matching, storage, processing and distribution of Whole Human Blood or Human Blood Products from selected human donors.

#### 1302. Licensing policy and legal framework for Blood Banks:-

An adequate legal framework has been provided in Schedule X B of the Drugs and Cosmetics Act/Rules published in The Gazette of India: Extraordinary (Part II-Sec.3 (i) which stipulates mandatory testing of blood for Blood transmissible Diseases, including HIV. The rules provide for adequate testing procedures, quality control, standard qualifications and experience for blood bank personnel, maintenance of complete and accurate records, etc. The Drugs Controller General (India) is the Central Licence Approving Authority whereas the regulatory control remains under the dual authority of the State and the Central Government. The blood banks under the Act require a manufacturing licence.

#### 1303. Application for grant or renewal of licence

Application for grant or renewal of licence for operation of blood bank shall be made to the Licensing Authority in Form 27-C and shall be accompanied by licence fee of Rs. Six hundred (Rs.600/-) and inspection fee of Rs. Two hundred (RS. 200/-) in the case of renewal of licence.

Provided that if the applicant applies for renewal of licence after its expiry but within six months of such expiry, the fee payable for the renewal of the licence shall be Rs.600/- plus an additional fee at the rate of Rs.200 per month or a part thereof in addition to the inspection fee.

A fee of Rs.100/- shall be paid for a duplicate copy of a licence issued, if the original is defaced, damaged or lost.

The forms required to be filled up for application for grant or renewal of licence, original licence, and renewal of licence is given at the end of this chapter.

#### 1304. Pre-requisite for grant of license for Blood Bank(Rule 122G)

(i) The operation of the Blood Bank or processing of whole human blood for components and /or manufacture of blood products shall be carried out under the active direction and personal supervision of competent technical staff consisting of at least one person who is whole time employee, a Medical Officer who is a Graduate in Medicine of a University recognised by the Central Government having experience in Blood Bank for 6 months during regular service. He shall also have adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood.

(ii) The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processing. The space and equipment required for various operations are given later on in the chapter.

(iii) The applicant shall provide and maintain adequate technical staff.

(iv) The applicant shall provide adequate arrangements for storage of Whole Human Blood, Human Blood components and blood products.

(v) The applicant shall furnish to the licensing authority, if required to do so, data on the stability of Whole Human Blood, its components or blood products which are likely to deteriorate, for fixing the date of expiry which shall be printed on the labels of such products on the basis of the data so furnished.

**1305. Inspection :-** Before a license in Form 28-C is granted, the licensing authority, as the case may be, shall cause the establishment in which Blood Bank is proposed to be operated to be inspected by one or more inspectors, appointed under the Act and/or along with the expert in the concerned field. The Inspector or Inspectors shall examine all portions of the premises and appliances/equipment and inspect the process of manufacture intended to be employed or being employed along with the means to be employed or being employed for operation of Blood Bank together with their testing facilities and also enquire into the professional qualification of the expert staff and other technical staff to be employed.

If within a period of six months from the rejection of application for a license, the applicant informs the licensing authority that the conditions laid down have been satisfied and deposits an inspection fee of RS 50/-, the licensing authority may, if after causing further inspection to be made, is satisfied that the conditions for the grant of a license have been complied with, shall grant a license in Form 28-C.

Any person who is aggrieved by the order passed by the licensing authority or central license approving authority, as the case may be, may within 30 days from the date of receipt of such order, appeal to the State Govt. or Central Govt., as the case may be, after such enquiry into the matter, as it considers necessary and after giving the said person an opportunity for representing his view in the matter may pass such order in relation thereto as it thinks fit.

**1306. Duration of licence:** An original licence in Form 28-C or a renewed licence in Form 26-G, unless suspended or cancelled shall be valid up to the 31st December of the year, following the year in which it is granted or renewed.

**1307. Cancellation and suspension of licenses –** (1) The licensing authority or central license approving authority may for such licenses granted or renewed by him after giving the licensee an opportunity to show-cause why such an order should not be passed by an order in writing stating the reasons thereof, cancel a license issued under this part or suspend it for such period as he thinks fit, either wholly or in respect of some of the substances to which it relates, if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provision of the Act or Rules thereunder.

(2) A licensee whose license has been suspended or cancelled may, within 3 months of the date of the order under sub-rule (1), prefer an appeal against that order to the State Govt. or Central Govt., which shall decide the same.

**1308. Conditions of license –** A license in Form 28-C shall be subject to the special conditions set out in Schedule F, Part XII-B and Part XII-C, as the case may be, which relate to the substance in respect of which the license is granted to the following general conditions:

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

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

(c) The licensee shall test in his own laboratory whole human blood, its components and blood products and registers in respect of such tests as specified in Schedule F, Part XII-B and 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 an adequate quantity to conduct all the prescribed tests. The licensee shall supply to the Inspector the reference sample for the purpose of testing.

(ii) The licensee shall allow an Inspector appointed under the act to enter, with or without prior notice, any premises where the activities of the Blood Bank are being carried out, for processing of whole human

blood and/or blood products, to inspect the premises and plant and the process of manufacture and the means employed for standardising and testing the substance.

(iii) The licensee shall allow an Inspector appointed under the Act to inspect all registers and records maintained under these rules and to take samples of the manufactured product and shall supply to Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and Rules thereunder have been observed.

(iv) The licensee shall from time to time report to the licensing authority any changes in the expert staff responsible for the operation of a Blood Bank/processing of whole human blood for components and/or manufacture of blood products and any material alterations in the premises or plant used for the purpose which have been made since the date of last inspection made on behalf of the licensing authority before the grant of license.

(v) The licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impression and defects noticed.

**1309. Space, Equipment and Supplies required for a Blood Bank (PART XII-B of schedule F)**

**A. Accommodation for a Blood Bank**

Minimum total area shall be 100 square meters having appropriate lighting and ventilation with washable floors and shall consist of following rooms, namely: -

1. Registration and Medical Examination room with adequate furniture and facilities for registration and selection of donors.
2. Blood Collection Room (This shall be air-conditioned).
3. Room for Laboratory for blood group serology. (This shall be air-conditioned).
4. Room for Laboratory for Transmissible diseases like Hepatitis, Syphilis, Malaria, HIV antibodies etc. (This shall be air-conditioned).
5. Sterilisation and washing room.
6. Refreshment room.
7. Store and Records Room.

Note: The Laboratories of the Blood Bank shall be used exclusively for Blood Bank work.

**B. Equipment:**

**I.** For blood collection room, the following would be needed: -

1. Donor beds or tables: It shall be suitably and comfortably cushioned and shall be of appropriate size.
2. Bed side tables.
3. Sphygmomanometer and Stethoscope.
4. Recovery beds for donors.
5. Refrigerators: Maintaining temperature between 4 to 6 degrees C with recording thermometer and alarm device.
6. Weighing machine.

**II.** Haemoglobin determination:

- (i) Copper sulphate solution (specific gravity 1.053).
- (ii) Sterile lancet.
- (iii) Capillary tubing (1.3 to 1.4 x 65 mm or Pasteur pipettes).
- (iv) Rubber bulbs for capillary tubing.
- (v) Sahli's haemoglobinometer/calorimetric method.

**III.** Temperature and pulse determination:

- (i) Clinical thermometers.
- (ii) Equipment and materials for aseptic cleaning of the thermometer.

(iii) Watch (fitted with a second-hand needle).

**IV. Blood containers:**

- (a) Disposable plastic packs (closed system) as per the specification of USP.
- (b) Blood collection bottles: 540 ml. with graduated capacity of up to 500 ml graduation mark provided with two rows in opposite direction indicating intervals of 50 ml from 0 to 500 ml.
- (c) Anti-coagulants: Anti-coagulant solution shall be sterile, pyrogen free and of composition that will ensure satisfactory safety and efficacy of the whole human blood and all the separate human blood components.
  - (i) Citrate phosphate dextrose solution (CPD) or citrate phosphate dextrose adenine-I (CPDA-I) 14 ml. Solution shall be required for 100 ml of blood. In case of double/triple blood collection bags used for blood components preparation, CPDA, blood collection bags may be used.
  - (ii) Acid Citrate Dextrose Solution (A.C.D. & Formula-A) IP Grade 15 ml. Solution shall be required for 100 ml. of blood.

Note: The licensee shall ensure that the anti-coagulant solution bottles/packs conform to the standard laid down in IP/USP. Disposable sterile bleeding sets shall only be used.

**V.** Disposable sterile bleeding sets shall only be used.

**VI.** Blood transfusion sets.

Sterile disposable sets with filters and plastic spike shall only be used.

**VI.** Emergency equipment:

- 1. Oxygen cylinder (with gauge and pressure regulator).
- 2. 5 percent glucose or normal saline.
- 3. Disposable sterile syringes and needles of various sizes.
- 4. Disposable sterile I.V infusion set.
- 5. Ampoules of adrenaline, noradrenaline, mephentin, betamethasone or dexamethasone, injection metoclopramide.
- 6. Aspirin and spirit ammonia aromatic.

**VII. Accessories:-**

- 1. Such as: Blankets, emesis basins, haemostats, set clamps, sponge, forceps, mouth gauze, dressing jars, solution jars, waste cans.
- 2. Medium cotton balls, 1.25 cms adhesive tapes.
- 3. Denatured spirit, tincture Iodine green soap or liquid soap and injection of procaine or xylocaine.
- 4. Paper napkins or towels.
- 5. Incinerator
- 6. Standby generator

**C. Refreshment Services:-**

Provision for serving refreshments to the donor after phlebotomy shall be made so that he/she may be kept for observation in the Blood Bank for any untoward reactions.

**D. Laboratory Equipment: -**

- (1) Refrigerator maintaining a temperature of 4 to 6 degrees with Recording Thermometer. The refrigerator shall have temperature recording and alarm device.
- (2) Compound Microscope-with low and high power objectives.
- (3) Centrifuge Table model.
- (4) Water Baths-one for 37 degree C and another for 56 degree C.
- (5) Rh viewing box in case of slide temperature.
- (6) Incubator with thermostatic control.
- (7) Mechanical shakers for serological tests for Syphilis.

- (8) Hand lens for observing tests conducted in tubes,
- (9) Serological graduated pipettes of various sizes.
- (10) Pipettes (Pasteur).
- (11) Glass slides.
- (12) Test tubes of various sizes/microtiter plates (U or V type).
- (13) Precipitating tubes 6 mm x 50-mm glass beakers of different sizes.
- (14) Test tubes racks of different specifications,
- (15) Interval timer electric or spring wound.
- (16) Equipment and materials for cleaning glass wares adequately.
- (17) Shipping containers.
- (18) RPHA/ELISA Test Kits with Reader for Hepatitis.
- (19) Wash bottles; filter papers.
- (20) Ice box for transport of blood units.
- (21) Hot air oven.
- (22) Plain and EDT.A Vials.
- (23) ELISA-Reader, Washer and micropipettes for HIV-antibodies testing (in case HIV-antibodies Testing is done by ELISA Kits).
- (24) Di-electric tube sealer
- (25) Chemical balance( wherever necessary)

#### **E. Reagents:-**

1. Standard blood grouping sera Anti-A and Ant-B and Anti-AB: All in double quantity and each of different brand or if from the same supplier then each supply should be of different lot numbers.
2. Rh typing sera: All in double quantity and each of different brand or if from the same supplier each supply should be of different lot numbers.
3. Reagents for serological tests for syphilis and positive sera for controls.
4. Anti human globulin serum (Coomb's serum).
5. Albumin 20 per cent to 30 per cent for tests/enzymes.
6. 0.9 per cent saline.
7. Culture media and tubes.
8. Wax pencils and tables.
9. RPHA/ELISA kits for hepatitis.
10. Detergents and other agents for cleaning laboratory glass wares.
11. Elisa Kits/rapid diagnostic kits in case the licensee opts for HIV antibodies testing.

#### **F. General Supplies: -**

Autoclave with temperature and pressure recording device.

#### **G. Personnel: -**

Every Blood Bank shall have following categories of full time technical staff and their number shall depend upon the quantum of work,

- (1) Doctor- Degree in Medicine of a University recognised by the Central Government having experience in Blood Bank for 6 months during regular services. He shall have adequate knowledge and experience in Blood Group serology. Blood Group Methodology and medical principles involved in procurement of blood.
- (2) Registered nurse.
- (3) Blood Bank technician with MLT qualification or its equivalent having adequate experience in blood grouping and serology work.
- (4) Laboratory Assistant with MLT qualifications or its equivalent.
- (5) Laboratory Attendant.

#### **H. Testing of Whole Human Blood:**

- (1) It shall be the responsibility of the licensee to ensure that the Whole Human Blood supplied conforms to the standards laid down in the current edition of Indian Pharmacopoeia and for all other tests published by the Central Government from time to time.

(2) Every licensee shall get samples of every blood unit tested before use for freedom from HIV-antibodies either from such laboratories specified for the purpose by the Central Government or in his own laboratory. The results of testing shall be recorded on the label of the container also.

**Note: -**

1. Blood samples of donors in pilot tube and the blood samples of the recipient shall be preserved for 72 hours after transfusion.
2. The blood intended for transfusion shall not be frozen at any stage.
3. Blood containers shall not come directly in contact with ice at any stage.

**I. Expiry Date:**

1. The date on which the blood is drawn and the date of expiry which shall be as prescribed under Schedule P to the said Rules.

**J. Records & Labels:**

The permanent records, which the licensee is required to maintain, are: -

- (i) Blood Donor Register – Indicating serial number, date of bleeding, name of donor with particulars, age, weight, haemoglobin, blood pressure, medical examination, signature of Medical Officer bleeding the donor, bottle bag number and patient’s detail for whom donated in case of recipient donation, remarks on donation (voluntary/replacement /professional). Disposal record.
- (ii) Blood Stock Register – Indicating bottle bag number, date of collection, date of expiry, quantity in ml., ABO/Rh Group, results for testing of HIV antibodies, malaria, VDRL, Hepatitis-B surface antigen, irregular antibodies (if any), name of donor with particulars, utilisation issue number, components prepared or discarded, certified by Medical Officer In-charge).

Note: Similar records shall be made for blood components. Group wise stock register shall be maintained.

- (iii) Issue Register – Indicating serial number, date and time of issue, bottle number, ABO/Rh group, total quantity in ml., name of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion. Particulars of product supplied (whole human blood, red cell/platelet concentrates, cryoprecipitates etc), quantity supplied, compatibility report, signature of issuing persons.
- (iv) Register for ACD/CPD/CPD-A – Bottles/packs giving details of firm, batch number, date of supply and results of testing.
- (v) Register for Diagnostic Reagents used.
- (vi) Blood Bank must issue the cross matching report of the blood of the patient along with the blood bottle.
- (vii) Transfusion Adverse Reaction Records.
- (viii) Records of Purchase, use and stock in hand of disposable needles, syringes, plastic bags, sets shall be maintained.

**K. Labels: -**

The label on the blood container shall contain the following particulars namely: -

- (1) The serial number of the bottle.
- (2) The date on which the blood is drawn and the date of expiry as prescribed under Schedule P to the said Rules.
- (3) The ABO groups with the corresponding colour; the following colour scheme for labels shall be used for different groups: -

| Group | Colour of label |
|-------|-----------------|
| O     | Blue            |
| A     | Yellow          |
| B     | Pink            |
| AB    | White           |

- (4) The results of the tests for Hepatitis, Syphilis, freedom from HIV antibodies.
- (5) The Rh group.

- (6) Total volume of fluid, the preparation of blood, nature and percentage of anticoagulant.
- (7) Name and address of Blood Bank.
- (8) License number.
- (9) Instruction to keep continuously at 4-degree to 6 degree C.

The label should also include the following inscriptions -

- (10) Disposable Transfusion sets with filter must be used in administration equipment.
- (11) Appropriate compatible cross-matched blood without a typical antibody in recipient should be used.
- (12) **Caution:** The contents should not be used if there is any visible evidence of deterioration like haemolysis, clotting or discoloration.

**Note:** The above requirements of Blood bank are subject to modifications at the discretion of the Licensing Authority or the Central Licence Approving Authority if he is of the opinion that having regard to the extent of manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

Part XII C of schedule F deals with minimum requirements for grant of License to process blood components from whole blood.

(Railway Board's No.96/H (FW)/10/19 and 97/IH/7/1, The Gazette of India: Extraordinary (Part II Sec.3 (1) - Ministry of Health and Family Welfare - Notification)

**FORM 27 C**  
**(Application for grant or renewal of licence)**

Application for grant or renewal of licence for the Operation of Blood bank processing of Whole Human Blood for components and or manufacture of blood products.

1. I/We \_\_\_\_\_ of \_\_\_\_\_ hereby apply for the grant/renewal of licence to operate a Blood Bank, processing of Whole Human Blood for components and/or manufacture of blood products.

Names of the Human Blood Components intended to be processed shall be specified.

2. The name, qualification and experience of expert staff: -

(a) Name(s) of Medical Officer.

(b) Name(s) of Registered nurse.

(c) Name(s) of Blood Bank Technician.

3. The premises and plan are ready for inspection/will be ready for inspection on \_\_\_\_\_.

4. A fee of Rupees \_\_\_\_\_ and an inspection fee of Rupees \_\_\_\_\_ have been credited to the Government under the Head of Account \_\_\_\_\_.

Dated

Signature \_\_\_\_\_

Designation \_\_\_\_\_



**FORM 28-C**  
**(Original Licence)**

Licence to operate a Blood Bank, processing Whole Human Blood for components and/or manufacture of Blood Products.

Number of Licence \_\_\_\_\_ Date of Issue \_\_\_\_\_

1. \_\_\_\_\_ is hereby licensed to operate a Blood Bank to process Whole Human Blood for components and/or manufacture of blood products as the premises situated at the \_\_\_\_\_.

2. Name of the Product(s) \_\_\_\_\_.

3. Name of approved expert staff \_\_\_\_\_

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

4 The licence authorise the distribution and the sale and storage for distribution or for sale by the licensee of Whole Human Blood, Human Blood Components and/or blood product under this Licence subject to the conditions applicable to licence for sale.

5. The licence shall be in force from \_\_\_\_\_ to \_\_\_\_\_.

6. The licence shall be subject to the conditions stated below and to such other conditions as may.

(xi) The licensee shall destroy the stocks of batch unit, which does not comply with Standard tests in such a way that it would not spread any disease/infection by way of proper disinfection method.

**FORM 26 G**  
(Renewal Licence)

Certificate of renewal of licence for the operation of Blood Bank and/or for processing of Whole Human Blood for components and/or Manufacture of Blood Products.

1. Certified that licence N. \_\_\_\_\_ granted on the \_\_\_\_\_ for the operation of Blood Bank, Processing of Whole Blood for components and/or manufacture of blood products at the premises situated at \_\_\_\_\_ has been renewed from \_\_\_\_\_ to \_\_\_\_\_. Name of the Product(s) \_\_\_\_\_.

2. Name of the Technical staff \_\_\_\_\_

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

Designation \_\_\_\_\_

**Source: Notification of Ministry of Health & Family Welfare (Dept. of Health) Dated 22.1.1993.**