

MHA 207

LEGAL FRAMEWORK FOR HEALTHCARE-I

**By: Dr. Rashika Agarwal
Lecturer**

**MBA Hospital Administration
SOS in Management
Jiwaji University ,Gwalior**



RULES FOR BLOOD BANKS

BLOOD BANKS

- *According to rule 122 – E (A) OF DRUG AND COSMETIC S ACT*

BLOOD BANK means a place or organizational unit or an institute , for carrying out all or any of the operations of collection (from selected donors) of whole human blood or components , their storage , processing , manufacture of components and distribution of whole blood or components.

REQUIREMENTS FOR THE COLLECTION, STORAGE, PROCESSING AND DISTRIBUTION OF WHOLE HUMAN BLOOD AND BLOOD COMPONENTS BY BLOOD BANKS

- For operating a blood bank, it is mandatory that a license is obtained from the licensing authority.
- Under rule 122 G of Drug and cosmetics act, on submission of the application on form 27-C along with a license fees of rs.6000 and an inspection fees of rs.1500 for every inspection thereof or for renewal of license is required.

- *The license is issued for the **period of 5 yrs** if all conditions are fulfilled as per the rules , and subject to conditions stipulated such as:*
 - *Periodic inspection of the blood bank.*
 - *The licensee is required to report to the licensing authority if there is any change in the expert staff responsible for operations or any material change in the premises or plant.*

- *No blood / component / products shall be sold to any person without prescription of a registered medical practitioner.*
- *The licensee is required to maintain an inspection book to enable the inspector to record his impressions and defects noticed.*
- *All biomedical waste should to disposed off or destroyed as per the provision of biomedical waste (management and handling) rules .*

**REQUIRMENTS FOR THE FUNCTIONING
AND OPERATION OF A BLOOD BANK
AND / OR FOR PREPARATION OF BLOOD
COMPONENTS. (RULE 122 G)**

• ***GENERAL REQUIREMENTS:***

- ***Location and surroundings – away from unhygienic surroundings like open sewage , drains etc.***

➤ Hygiene and sanitation – so constructed as to ensure operations under hygienic conditions, like, free from insects, rodents, flies. It should be properly ventilated, well lighted etc.

➤ Health of staff – staff should be free from contagious / infectious disease and should be using clean overalls, foot wear and gloves.

● ACCOMODATION FOR BLOOD BANK :

- *It shall have separate rooms for registration and medical examination.*
- *Blood collection , blood components preparations should be done in air conditioned room .*

● STAFF :

- *Medical officer with minimum qualifications as specified in rule 122 – G*
- *Blood bank technicians- with degree in MLT+6 Months experience OR diploma in MLT + 1 yr experience.*
- *Registered nurse*
- *Technical supervisor.*

● **FACILITIES AND MAINTENANCE:**

- *Thorough examination of individual in privacy to determine their suitability as donors.*
- *Collection of blood from donors with minimum risk of contamination.*
- *Proper arrangement for collection , processing , compatibility testing , storage and distribution of blood and blood components to prevent contamination.*
- *Proper packaging , labeling .*
- *Provision for safe disposal of sample not found suitable for use.*
- *High quality equipments should be used and maintained.*
- *Reagents used shall be of assured quality and stored at a proper temperature.*

- **GOOD MANUFACTURING PRACTICES** : *blood bank shall have documented standard operating procedures (SOPs) for every activity such as collection, processing , testing for diseases , compatibility testing , plasmapheresis , plateletpheresis , etc.*
- **CRITERIA FOR BLOOD DONATION / DONOR SELECTION** :
 - *Good health , mentally and physically.*
 - *Donation not more than once in 3 months.*
 - *Age group 18 – 60 yrs and weight not less than 45 kg.*
 - *Vital parameters should be normal.*
 - *Hemoglobin not less then 12.5*

● **MAINTENANCE OF RECORDS:**

- *Blood donor records.*
- *Master records for blood and its components.*
- *Records of the components supplied.*
- *Register of reagents used.*
- *Record of adverse transfusion reactions and their investigations. Etc.*

● **LABELS :** *label on every bag containing blood should bear following details –*

- *Name of the product.*
- *Name and address of the blood bank.*
- *License number.*
- *Serial number*

- *Date on which the blood is drawn and the date of expiry .*
- *The label on the bags will have following color scheme*
 - blue – ‘o’*
 - yellow – ‘A’*
 - Pink – ‘B’*
 - white – ‘AB’*
- *The Rh group*
- *Total volume of blood etc....*



THANK YOU