## **Terms of Reference:**

- (a) Medical Officer, possessing the qualifications specified in condition of rule 122-G.
- 122-G. Form of licence for the operation of a Blood Bank/Processing of Whole Human Blood for components and manufacture of Blood products and the conditions for the grant or renewal of such licence.-
- (i) The operation of the Blood Bank and/or processing of whole human blood for components/manufacture of blood product shall be carried out under the active direction and personal supervision of component technical staff consisting of at least one person who is whole time employee and who is a Medical Officer, and possessing-
- a) Post Graduate degree in Medicine-M.D. (Pathology/Transfusion Medicines); or
- b) Degree in Medicine (M.B.B.S.) with Diploma in Pathology or Transfusion Medicines 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
- c) Degree in Medicine (M.B.B.S.) having experience in Blood Bank for 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 and/or preparation of its components, the degree or diploma being from a university recognized by the Central Government.
- EXPLANATION- For the purposes of this condition, the experience in Blood Bank for one year shall not apply in the case of persons who are approved by the Licensing Authority and/or Central Licence Approving Authority prior to the commencement of the Drugs & Cosmetics (Second Amendment) Rules, 1999.
- (ii) The applicant shall provide adequate space, plant and equipment for any or all the operations of blood collection or blood processing. The space, plant and equipment required for various operations is given in Schedule 'F', Part XII-B and / or XII-C.
- (iii) The applicant shall provide and maintain adequate technical staff as specified in Schedule 'F', Part XII-B and/or XII-C.

- (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.