

DOCUMENT- 7

GUIDELINES FOR ISSUANCE OF "NOC" FOR NEW BLOOD BANK, RENEWAL OF LICENSE, CRITERIA'S FOR DESIGNATION BLOOD BANK AS RBTC



सत्यमेव जयते

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भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

राष्ट्रीय एड्स नियंत्रण संगठन

Government of India

Ministry of Health & Family Welfare

National AIDS Control Organisation

D. O. No. S-12016/1/2014-NBTC

Dated : 21st September, 2015

My Dear Secretary,

You would be aware that the Government of India had adopted the National Blood Policy in April 2002, which sought a comprehensive, efficient and a total quality management approach within a nation-wide system, to ensure access to adequate and safe blood supply. The National Blood Transfusion Council (NBTC) has also been set up to oversee and coordinate the functioning of blood transfusion services through the State/UT Blood Transfusion Councils, who are responsible for overall implementation of an organized blood transfusion service through a network of Regional Blood Transfusion Centres and other blood banks.

2. In the past, clarifications has been sought by various States regarding the procedure to be adopted for allowing establishment of new blood banks, renewal thereof, and grant of status of Regional Blood Transfusion Centres etc. The matter was accordingly considered by the NBTC in its meeting on 05.08.2015 and the norms for the above have been approved. These norms are detailed in the enclosure and include

- Norms for setting up of blood banks;
- Norms for grant of no objection certificate for licensing of new blood banks and renewal of license of existing blood banks;
- Norms for grant of status of Regional Blood Transfusion Centre; and
- Norms for grant of permission for conducting voluntary blood donation camps.

3. These have been approved so as to bring clarity and uniformity in the practice and procedure across different States. It may be ensured that the State Blood Transfusion Council in your State adopts and implements the same.

4. Action taken in this regard may be intimated to undersigned within a month of receipt of this communication.

With regards,

Yours sincerely,

(N. S. KANG)

To

Principal Secretary (Health) (By name)
All States as per list

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21/9/15

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NORMS FOR STATE BLOOD TRANSFUSION COUNCIL AS APPROVED BY GOVERNING BODY OF NATIONAL BLOOD TRANSFUSION COUNCIL

A. Norms for set up of New Blood Banks

Every district should have at least one blood bank, but clustering of blood banks in urban/ semi-urban areas should be avoided. New blood banks need to be set up based on geographic location and population demand only.

B. Norms for grant of 'No objection certificate' (NOC) by the SBTC

B1. For New Blood Bank License:

1. A registered voluntary or charitable organizations, which is registered in the, territory of Union of India or Union Territory, as the case may be under any such law which is at the time of enforcement of this rule in force.
2. The aforesaid organization must be atleast two years old and should not be a family society or trust.
3. The objectives mentioned in the Memorandum of Association must include the activities related to health care delivery system or blood transfusion services.
4. The activities undertaken by the organization must showcase social accountability and be reflected in the annual Audited Statement of accounts of the last two year (i.e. before the submission of application).
5. The organization should submit undertaking to ensure annual blood collection - more than 2000 units per year with nearing 100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps.
6. The organization should submit undertaking to appoint Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively.
7. The organization should submit undertaking to establish blood component separation facility of its own or a storage facility for components within a period of two years from receiving license to operate blood bank.
8. The organization should submit undertaking to abide with the guidelines of - SBTC/NBTC issued from time to time, including the guidelines for processing charges for blood and blood components.

Note:

- c. The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- d. The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

B2 For Renewal Blood Bank License:

1. The compliance to point no. 1-4 of norms at B1 (No objection certificate (NOC) for New Blood Bank License) shall be ensured.
2. The organization should submit photocopy of license and application months before the expiry of validity period of license.
3. The organization should submit Annual blood collection report wherein the total blood collection (Jan-Dec) is shown with voluntary contribution to total collection along with number of blood donation camps conducted. (The annual blood collection should be more than 2000 units per year with nearing 100% contribution from Voluntary blood donor, preferably collected from outdoor blood donation camps. The condition may be relaxed for rural, tribal, hilly region, desert, island and Armed Forces)
4. The organization should submit the proof and details of appointment of Medical Social Worker (MSW) and Counselor with the blood bank for arranging Voluntary Blood Donation (VBD) camps and Pre and Post Test counseling respectively along with the training certificates.
5. The organization should submit Annual report indicating blood component separation facility has been established either of its own or a storage facility, wherein the components were sourced from RBTC approved by SBTC.
6. The organization should submit details of processing charges collected by the blood bank after 12th February 2014. The SBTC should verify, if charges collected are subsidized or at par with guidelines issued by NBTC.

Note :

- c) The Organization should submit undertaking on the letter head expressing willingness to abide with aforesaid conditions.
- d) The SBTC should process the application within thirty days from the date of its receipt in the office; failing which NOC shall be deemed granted to the organization.

C. Norms for grant of 'Regional Blood Transfusion Center' (RBTC) status to blood banks.

RBTC is a blood bank approved by the SBTC taking into consideration the regional needs of blood & blood components and the ability of RBTC in terms of premises, personnel and equipment to cater to the same. A center will be designated as RBTC only after SBTC formally networks it with blood bank/ blood storage centers in the region and establishes two way linkages for exchanges of blood and blood components.

1. The blood bank should be licensed and provide round the clock service
2. The blood bank should have minimum collection of 2000 per annum with voluntary contribution nearing to 90%. (The criteria for minimum collection may be relaxed in rural, tribal, hilly region, desert, island and Armed Forces).
3. The Blood bank should have component separation facility. Alternatively, Blood bank should provide undertaking to establish component separation facility within two years' time frame.
4. The blood bank should have adequate facilities to store and transport blood and blood components at required temperature and ambient conditions.

5. The blood bank should have minimum TTI screening by ELISA facility for atleast 80% collected unit and should be practicing tube method for blood grouping and cross matching. (The criteria for minimum testing may be relaxed in -rural, tribal, hilly region, desert, island and Armed Forces).
6. The blood bank should be capable of imparting periodic training to staff attached with Blood Storage Center for blood grouping, cross matching, storage, identifying haemolysis and record keeping.
7. All equipment in the blood bank should be under AMC/CMC and calibrated at the time of applying for RBTC Status and subsequent renewal every year as mandated under Drugs and Cosmetic Act.
8. All records books should be available with the Blood Bank as stipulated in the Drugs and Cosmetics Act 1940 and Rules 1945 there upon.
9. The blood bank should have computer and trained staff to maintain database of donor, blood and products and inventory of demand and supplies made on daily basis.
10. The blood bank must update its stock status of blood availability blood group wise online with NBTC website.

Note:

The RBTC status accorded will be initially for a period of two years only. However, it would be renewed based on the performance and fulfillment of all aforesaid conditions for a further period of five years and at five years interval thereafter.

D. Norms for grant of permission to conduct voluntary blood donation camps:

Drugs and Cosmetics Act, 1940 and rules 1945 thereupon under Schedule F- Part XII B has permitted following types of licensed Blood Banks to collect blood by conducting voluntary blood donations camps.

1. Government Blood Bank.
2. Indian Red Cross Society Blood Bank.
3. Regional Blood Transfusion Centers designated by SBTC.
4. Blood Banks managed by registered voluntary or charitable trust organizations recognized by BTC.

However, to ensure 100% blood collection from voluntary non remunerated blood donors in the country, it was decided to permit hospital based private blood banks also to conduct blood donation camps. The DCGI was requested to examine the same and introduce a suitable amendment to the act.