

## State Blood Transfusion Council (Maharashtra)

Ravindra Annexe, 5<sup>th</sup> Floor Dinshaw Vaccha Road,

194, Churchgate Reclamation, Mumbai-400 020

Tel-022-22830216, Fax – 022-22854981, E-Mail: [sbtc@mahasbtc.com](mailto:sbtc@mahasbtc.com)



No. SBTC/NOC-BB /2018/931

Date: 28/11/2018

### CIRCULAR

#### **Sub: Criteria / Policy for setting up of new blood bank – Guidelines thereof.**

Read: Circular no.SBTC/NOC-BB/2018/224 dt. 03.03.2018

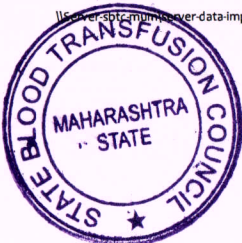
At present there are no definite guidelines / criteria for issue of the No Objection Certificate (NOC) for setting up of new blood bank. Therefore, the issue regarding formulating guidelines / norms / policy was under consideration of the SBTC. A Technical Committee was also constituted to decide the guidelines / norms / policy. On the basis of the recommendations of the Committee the Governing Board of SBTC in its 39<sup>th</sup> meeting held on 03.11.2018 has decided the fix the following guidelines / norms/ policy for issue of the NOC for setting up of new blood bank.

- (1) The geographical area will be classified into following four parts.
  - (i) Metropolitan City (as decided by Govt.)
  - (ii) Urban (district place)
  - (iii) Rural (Taluka place)
  - (iv) Tribal

The Organization / Trust which is intending to set up new blood bank in Metropolitan City should give undertaking to make collection of blood of more than 3000 units through voluntary blood donation camps. The performance will be reviewed by the SBTC after completion of two years.

The Organization / Trust which is intending to set up new blood bank in other geographical areas viz Urban, Rural and Tribal should give undertaking to make collection of blood of more than 2000 units through voluntary blood donation camps. The performance will be reviewed by the SBTC after completion of two years

- (2) Hereinafter irrespective of the area, NOC will be given only to the Organization / Trust who are setting up of new blood bank only with blood component separation facility with a view to maximize judicious use of blood by separating into components; the blood being a precious resource in health delivery system. The preference will also given to the blood banks having apheresis procedure in the proposed blood bank so as to bridge the gap between demand and supply of platelets and safety point of view.
- (3) NOC may be issued for setting up of the new blood bank by the organization / trust at the block headquarter level where there is not a single blood bank even though the base level criteria of population and collection of blood in the district is met.
- (4) While giving NOC to the hospital based blood bank following aspects will be looked into:
  - (i) Whether the need of the hospital can be met by allowing to set up storage centre by making tie up with any stand alone blood bank in the area instead of setting up of new blood bank. The hospital should give detailed justification about this.



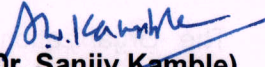
- (ii) Number of beds in the hospital and number of specialty procedures like heart transplant, kidney transplant or other organ transplant and emergencies handled by the hospital.
- (iii) While granting NOC for setting up of new blood bank in the hospital, after satisfying aspects at (i) to (ii) above, the hospital should give undertaking to give blood and blood components to other 3 to 4 hospitals in the vicinity. This will be reviewed by the SBTC after completion of two years.
- (5) While granting NOC for setting up of new stand alone blood bank in Metro, Urban and Rural area, following aspects shall be looked into :
- (i) Geographical Mapping of the blood banks in the area.
- (ii) Number of blood banks in the area and their collection.
- (iii) Number of hospitals in the area, requirement and utilization of blood in the hospitals, need of additional blood supply in the area will be assessed on the basis of specialized procedure and general surgery etc.
- (iv) Number of Thalassemic patients in the area.

2. The Governing Board also approved the revised Form –A i.e. application form for No Objection Certificate for new blood bank license as per Annexure – A.

3. The Form – B i.e. application for NOC for renewal of blood bank license and delegation of powers as notified vide circular no. 224 dt. 03.03.2018 will remain unchanged.

4. The revised guidelines / norms/ policy as stated above shall come into force with immediate effect and the pending cases of NOC shall also be dealt with in accordance with above guidelines / norms/ policy.

5. This circular is available on the sbtc website i.e. [www.mahasbtc.com](http://www.mahasbtc.com) under download link.

  
(Dr. Sanjiv Kamble)  
Director, 26/11/2018  
State Blood Transfusion Council,  
Mumbai

To,

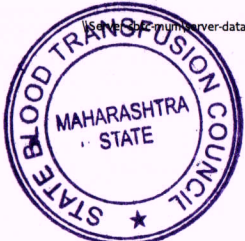
The Dean / Civil Surgeon / Medical Supdt. /B.T.O. of Govt. blood bank

**Copy submitted to:**

1. The Principal Secretary, Public Health Deptt. and President SBTC, Mantralay, Mumbai
2. The Secretary, Medical Education Deptt. and Food and Drugs Administration and Vice President, SBTC, G.T. Mantralay, Mumbai
3. The Commissioner, Food and Drugs Administration, Bandra, Mumbai
4. The Director, Health Services / Medical Education and Research, Mumbai
5. The Jt. Commissioner, (HQ) Food and Drugs Administration, Mumbai
6. The Deputy Director, Drugs Controller (West Zone), Mumbai

**Copy to:**

The Jt. Commissioner, Food and Drugs Administration, Aurangabad / Amravati / Nagpur/ Nashik / Pune / Kolhapur / Thane / Greater Mumbai Division.



## FORM 'A'

### APPLICATION FOR NO OBJECTION CERTIFICATE FOR NEW BLOOD BANK LICENSE

[Accompaniment with circular no. SBTC/NOC-BB/2018/931 dt.28.11.2018]

(DRUGS & COSMETICS ACT 1945 AS AMENDED TIME TO TIME AND NORMS  
ISSUED BY NBTC, NEW DELHI)

TO,  
THE DIRECTOR,  
STATE BLOOD TRANSFUSION COUNCIL,  
MAHARASHTRA STATE,  
RAVINDRA ANNEXE 5<sup>TH</sup> FLOOR,  
DINSHAW VACCHA ROAD,  
194 CHURCHGATE RECLAMATION,  
MUMBAI- 400 020

TEL: 022-22830216

Dear Sir,

We are submitting herewith application for "NO OBJECTION CERTIFICATE" (NOC) for establishing NEW BLOOD BANK before issuing licenses by the FDA. The details are as under:

1. Name of registered voluntary / charitable organization: .....  
with detailed address .....

Contact no.....Email Id:.....

2. Registration nos.:

i) Charitable trust: Registration no.:.....date.....Place of registration.....

ii) Registrar of societies: Registration no.:.....date.....Place of registration.....  
(Copies of the registration certificates should be enclosed)

3. Name of the proposed blood bank :.....

Village/Town/City\_\_\_\_\_Taluka:\_\_\_\_\_Dist:\_\_\_\_\_

4. Population of the village/town/city where new blood bank is proposed to be established:\_\_\_\_\_Lakhs

5. Whether the geographical area falls under

(i) Metropolitan City (as decided by Govt.) (collection criteria 3000 units per annum)

(ii) Urban (district place) (collection criteria 2000 units per annum)

(iii) Rural (Taluka / block headquarter place) (collection criteria 2000 units per annum)

(iv) Tribal (collection criteria 2000 units per annum)



6. Whether the organization is a Public society or trust : YES / NO  
(Attach proof of Public Society or Public Trust)
7. Whether memorandum of association includes the activities related to health care delivery system or blood transfusion services : YES / NO  
(attach copy)
8. Brief details of the activities related to health care delivery system or blood transfusion services during last two years

(Proof towards activities along with audited balance sheet of expenses on the activity should be enclosed)

Sr. no.	Details of the activity	Amount of expenditure as per audited statement of accounts

9. Type of blood bank proposed to be established : Hospital based / Stand alone

**In case of Hospital based blood bank**

10. If hospital based, why need can not be met by setting up of storage centre by making tie up with any standalone blood bank in the area. (please give detailed justification)

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11. If hospital based, no. of beds in the hospital \_\_\_\_\_

12. Details of the specialty procedures proposed to be carried out or carried out in the hospital

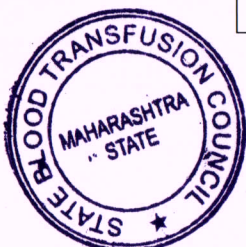
Sr. no	Name of the specialized procedure /diseases for which transfusion of blood is required
1	
2	
3	

(Please attach separate sheet, if required)

13. If the need can not be met by storage centre then hospital should give undertaking to supply blood and blood components from the proposed blood bank to other 3 – 4 hospitals in the area with names of hospitals.

Sr. no	Names of hospital	Consent letter of the hospital
1		
2		
3		

(Please attach separate sheet, if required)



14. **In case of Stand alone blood bank**

(a) Whether geographical mapping has been done? if so attach map indicating the proposed blood bank and distance between the already existing blood banks in the area.

(b) No. of hospitals in the area of the proposed blood bank with details as under

Sr. no	Name of hospital	Existing requirement of blood per annum	Whether consent for tie up with proposed blood bank is attached
1			
2			
3			
4			
5			
6			

(Please attach separate sheet, if required)

(c) No. of Thallasemic patients in the area \_\_\_\_\_

15. Any other point (s) to justify establishing new blood bank:  
(If required attach separate sheet)

.....  
.....  
.....

16. Whether undertaking to ensure blood collection more than 3000 : YES / NO

units per year (for Metro) and more than 2000 (for Rural, Urban and Tribal)  
with nearing 100% contribution from voluntary blood donor  
preferably through out door blood donation camp is enclosed

17. Whether undertaking to appoint Medical Social Worker & counselor with : YES/NO  
the blood bank for arranging voluntary blood donation camps and pre and post  
donation counseling is given :

18. Whether undertaking to establish blood component separation unit alongwith : YES / NO  
blood bank is given (compulsory)

19. Whether apheresis facility will be available or otherwise (preferred) : YES / NO

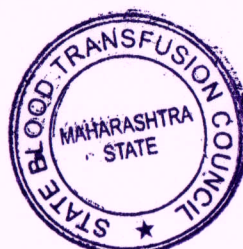
20. Whether undertaking to abide with the directives of SBTC / NBTC : YES / NO  
issued from time to time including the directives for processing  
charges for blood and blood components is enclosed

**NOTE :The undertakings at sr. no. 13, 16 to 18 & 20 should be given separately on the stamp paper of Rs. 100/-**

21. Whether an amount of Rs. 5000/- (Rs. Five Thousand only) towards YES / NO  
processing fees: paid through Internet Banking?

If so, attached copy of the transaction printout.

Bank details of SBTC



Name of Account holder : Director State Blood Transfusion Council  
Bank Account No. : 52091276964  
Bank name : State Bank of India  
Branch Name : P.M. Road Branch, Fort , Mumbai  
IFSC Code : SBIN0060113

## DECLARATION

I hereby declare that all the details submitted are true & correct to the best of knowledge and belief. If any information is found false, incorrect / incomplete, the application is liable to be rejected or cancelled at any stage.

Place :

Name of the applicant:

Date:

Seal / stamp of the organization

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**The following portion to be filled in by the Inspecting Officer i.e. Blood Transfusion Officer of the Govt. blood bank of the Civil Hospital / Govt. Medical College.**

Certified that I have verified all the original documents and data furnished by the Society / Trust mentioned in the application and found correct.

- (1) Details of the blood banks at the proposed place of new blood bank with annual collection is as under:

Sr. no	Name of blood bank	Annual collection
1		
2		
3		

(Please attach separate sheet, if required)

- (2) Recommendations with detailed justification for setting up of new blood bank  
(Please attach separate sheet, if required)

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- (3) If not recommended, reasons thereof  
(Please attach separate sheet, if required)

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Signature of the District BTO  
with name and stamp