

GUIDELINES FOR BLOOD STORAGE CENTRES

Effective Date: 20th Dec. 2001

**CENTRE FOR BIOLOGICS
FOOD AND DRUG ADMINISTRATION
MAHARASHTRA STATE
MUMBAI**

GUIDELINES FOR THE BLOOD STORAGE CENTRES

INTRODUCTION: The Government of India, vide Notification no. G. S. R. 909(E). dated 20th December. 2001 has provided exemption from obtaining licence to store, cross-match and issue Whole Human Blood I. P. and / or its components to the following organizations:

- (1) First Referral Unit,
- (2) Community Health Centre.
- (3) Primary Health Centre,
- (4) Any Hospital.

(The notification is as per annexure "D")

The waiver for the big setup of the Blood Bank with respect to the collection and testing of Whole Human Blood and its Components were given to the above organizations, following the National Blood Policy made by the Government of India, keeping in view the availability of Whole Human Blood and / or its Components to the places where it becomes difficult to get the blood on emergency or to maintain the full fledged Blood Bank.

The whole blood and / or its components shall be procured by the above centres from following categories of blood banks (hereinafter referred to as the mother blood bank) and shall be used for captive consumption only:

- (1) Government Blood Banks.
- (2) Indian Red Cross Society Blood Banks.
- (3) Regional Blood Transfusion Centres.

EXISTING BLOOD BANKS: The blood bank attached to any Hospital, which are already in existence may also get the above waiver, if the total consumption of the said blood bank is not more than 2000 units annually. After getting proper approval from the concerned Licensing Authority, the existing licence has to be surrendered to the concerned Licensing Authority.

INTERSTATE TRANSPORT: Interstate transport of blood and/or its components will be permitted in case of the centres situated in the border area and where the blood bank in the other state is located nearer than the blood bank at Maharashtra.

GENERAL REQUIREMENT:

[A] PREMISES: The organization opting to get the approval as a blood storage centre shall have an area of not less than 10 sq. mt. with independent entry and isolated from all other activities of the organization. The entry to the said area should be restricted to the authorized persons and the area is maintained well lighted, clean and hygienic. The area earmarked for the storage and crossmatching of the Whole Human Blood and / or its Components should be air-conditioned.

[B] EQUIPMENTS:

- (i) Blood storage refrigerator maintaining a temperature of 4°C to 6°C of appropriate capacity fitted with temperature indicator, alarm device and recording thermograph,
- (ii) Platelet agitator with incubator maintaining temperature of 20°C to 24°C (wherever necessary) fitted with temperature indicator, alarm device and recording thermograph.
- (iii) Deep-freezer maintaining a temperature of minus 30°C to minus 40° C (wherever necessary) fitted with temperature indicator, alarm device and recording thermograph.
- (iv) Generator / Uninterrupted power supply facility.
- (v) Other equipments required for grouping and crossmatching as prescribed in schedule F part XII B of the Rules (including plain and EDTA vials).

[C] REAGENTS:

- (i) As prescribed under schedule F Part XII B of the Rules for grouping and cross matching (Antisera in double quantity and each of different brand or if from the same supplier, each supply should be of different lots),
- (ii) Each new lot of reagents should be tested for appearance, titre, avidity and specificity.

[D] PERSONNEL:

- (i) **Medical Officer** - (a) MD (Pathology) or (b) MBBS with atleast one month experience in blood banking
The degree being from a University/Institution recognized by the Central or State Government.
The respective Licensing Authority shall approve the above officer.
- (ii) **Technician** - a) With the qualification and experience as prescribed in schedule F Part XII B of the Rules (amended rules 1999) or
 - b) a technician holding MLT. passed prior to Apr. 1999 and having worked in the blood bank for atleast two years or
 - c) a technician (non MLT) already approved by the Licensing authority of Maharashtra State or
 - d) a technician (MLT / non-MLT) having worked in any Regional Blood Transfusion Centre (as designated by State Blood Transfusion Council, Maharashtra State. Mumbai) for three years.
- (iii) The medical officer and the technician are not required to be full time employee of blood storage centre, however they must be a full time employee of the First' Referral Unit.

- Community Health Centre, Primary Health Centre or Hospital, where the blood storage centres are located.
- (iv) A medical officer will be responsible for all activities of the blood storage centre. He/She will verify if the blood / blood components are procured from the licensed blood bank approved to them, proper labeling on the blood bag and /or its components with all details with respect to all necessary tests i. e. Blood group, HIV, HBsAg, HCV. VDRL. MP and detection of unexpected antibodies. Licence number and status of the donor as voluntary or replacement, date of collection and expiry date.
 - (v) He/She should ensure that proper cold chain is maintained, stored at the requisite temperature and issued after proper cross matching. He/She will supervise the actual destruction of any haemolysed or expired blood and /or its components.
 - (vi) It will be responsibility of the medical officer to maintain the inventory in the blood storage centre and he/she will see that at any time there should not be scarcity of blood and/or its components.
 - (vii) The technician, medical officer and other staff of the blood storage centre shall be free from any infectious and contagious diseases and should be examined for such diseases atleast once a year or during any doubtful circumstances and records thereof shall be maintained by the blood storage centres.
 - (viii) All staff of the blood storage centre shall be immunized for Hepatitis B infection.
 - (ix) The technician and medical officer shall be responsible for the cleanliness and hygiene of the premises of the blood storage centre. A cleaning program should be made by the blood storage centre and should be followed strictly.
 - (x) The storage centre shall ensure that the technicians and the medical officer receive training appropriate to their duties and responsibilities and that they avail the opportunity of updating themselves by attending seminars and workshops.

[E] PROCEDURE OF APPROVAL OF BLOOD STORAGE CENTRE:

- (I) **PLAN APPROVAL:** A layout of the premise to be submitted to the concerned Licensing Authority for approval in triplicate. The plan so received shall be scrutinized by the panel of experts constituted for this purpose by the Licensing Authority. The panel shall be responsible for scrutiny and expeditious disposal of the plans. The panel may also suggest the pre-approval inspection by the Drugs Inspector in certain cases. The layout plan approval committee should hold their meetings once a week for scrutiny of the plans. The layout plan should be taken for scrutiny in the meeting of the committee

in the next week of the submission of the plan, irrespective of the number of plans pending for scrutiny.

After scrutinizing the plan, the committee shall submit it to the Licensing Authority and after approval, one copy of approved plan should be immediately dispatched to the applicant.

(II) **PERSONNEL APPROVAL:** The Technician and medical officer have to submit the proposal to the Licensing Authority for their approval. Alongwith the proposal, the following documents needs to be submitted:

- (a) Appointment letter (mentioning their job responsibilities),
- (b) Job acceptance letter,
- (c) Qualification certificate,
- (d) Experience certificate (if any),
- (e) Previous approval from the Licensing Authority for blood bank (if any),.
- (f) Medical fitness certificate stating absence from ‘any infectious and contagious diseases.

(III) **APPLICATION FOR APPROVAL AS BLOOD STORAGE CENTRE:** The application should be submitted on plain paper duly signed by the authorized person. Following documents need to be attached along with the application:

- a) An agreement between the applicant and the licensed blood bank, from where the applicant will procure blood and/or its components. The contents of the agreement should be as mentioned in annexure “A”.
- b) Licence of the mother blood bank along with the current renewal certificate or any other document to show the validity of the licence of the mother blood bank.
- c) List of products proposed to be stored in the blood storage centre along with the undertaking as prescribed in annexure “B”.
- d) List of equipments needed for storage of whole human blood and/or its components.
- d) Appointment letter, acceptance letter, qualification certificate, experience certificate (if any), approval from the Licensing Authority (if any), medical fitness certificate and relieving certificate from the last organization (if any), of the medical officer and technician,
- e) List of Directors / Trustees / Partners / proprietor along with their residential addresses.

(All copies must be certified and attested by the concerned authority)

(IV) **INSPECTION:** After getting the application from the applicant, an inspection of the blood storage centre should be carried out by the concerned Inspector to verify the facilities provided and the SOP’s made by the applicant. The Inspector shall also inspect the mother blood bank(s) to verify whether it has capacity to cater to the requirements of the blood storage centres. He will also inspect the containers used for transport of blood and/or

its components to ensure that proper cold chain is maintained.

The mother blood bank shall maintain a separate register for supply of blood and/or its components to blood storage centres with all necessary details.

The Inspector, satisfied with the requirements of the blood storage centre, as to premises, storage facility, cross matching and issue facility, shall submit a formal report to the Licensing Authority with his/her recommendation.

NOTE: In case the mother blood bank is situated in another State, the help of an Inspector of that State may be taken with prior permission from the Drug Controller of that State.

- (V) **APPROVAL:** Based on the recommendation from an Inspector, approval will be given to the applicant in the format prescribed as annexure “C” by the Licensing Authority for the period of two years from the date of grant of approval.
- The approval for blood storage centre will be given to the applicant for procurement of blood and/or its components from the blood banks with whom the agreement was made. The approval may be given for more than one blood bank, but not more than three blood banks at any time of the validity of the approval. In case of very rare groups like Bombay blood group, the blood storage centres may procure blood and/or its components from any blood bank, wherever the blood of said group is available.
- (VI) **POST APPROVAL INSPECTION:** The blood storage centres shall be periodically inspected to check if the blood and/or its components are procured from the approved blood banks only, properly stored, issued after proper cross matching and conditions of approval are being followed.
- (VII) **DESTRUCTION OF BIOMEDICAL WASTE:** All biomedical waste, including haemolysed or expired blood units shall be treated, disposed off or destroyed as per the provisions of “Bio-Medical Wastes (Management and Handling) Rules 1996”.
- (VIII) **RECORDS:**
- a) **Blood procurement register:** indicating serial number, procurement date, name of the mother blood bank, blood bag number, blood group, date of collection from donor, quantity in ml, expiry date, signature of medical officer.
 - b) **Stock register:** group wise daily stock position of the blood and/or its component.
 - c) **Issue register:** indicating serial number, whole blood/name of components, blood bag number, date and time of issue, blood group, total quantity in ml, name and address of the recipient, group of recipient, unit/ward, details of cross matching, indication for transfusion, signature of

medical officer.

d) **Master register:** indicating blood bag number, whole blood / component (name), date of procurement, quantity, name of the mother blood bank, date of collection of blood, date of expiry, issue number (serial number of issue register), destruction date (if destroyed), signature of the medical officer.

e) **Register for diagnostic reagents:** name of the reagent, batch number, expiry date, name and address of supplier, date of procurement and date of use.

f) **Destruction register:** indicating serial number, blood and / or components, blood bag number, date of destruction, reason for destruction, destroyed by, signature of the medical officer.

g) **Transfusion adverse reaction record** with investigation details.

h) **Cross-match report:** The storage centre must maintain the cross match report along with the protocol of the cross-match done. The blood storage centre must issue the cross match report along with the blood bag.

i) **Standard Operating Procedures (SOPs):** The blood storage centres must maintain the SOPs with respect to the procurement of the blood bags, storage, crass matching and issue of the blood bags, maintenance and calibration of the equipments, testing of the reagents, transfusion adverse reaction, cleaning program of the premises, etc.

The above records shall be maintained by the blood storage centres for five years and should be made available for inspection.

(IX) **FEES FOR GRANT OR RENEWAL OF APPROVAL:** At present no fees will be charged for approval of blood storage centres; but the proposal to charge fees is under consideration.

(X) **SUSPENSION, REVOCATION OF APPROVAL:** The approval of the blood storage centre is liable for suspension or revocation in case of non-compliance of the conditions of the approval and / or provisions of these guidelines.

ANNEXURE "A"

AGREEMENT BETWEEN THE BLOOD STORAGE CENTRE AND THE MOTHER BLOOD BANK

- 1. Name of the Blood storage centre : _____
- 2. Address : _____

- 3. Phone number : _____
- 4. Expected consumption in a year : _____
- 5. Name of the Mother Blood Bank : _____
- 6. Address : _____

- 7. Phone number : _____
- 8. Licence number and date of grant : _____
- 9. Licence validity : _____
- 10. Annual collection : _____
- 11. Products approved : _____
 - a) _____
 - b) _____
 - c) _____
 - d) _____
 - e) _____
 - f) _____
 - g) _____
 - h) _____

We are ready to give the blood bags and/or components to the above blood storage centre as and when required by them, in a quantity not more than 2000 per year.

Date: _____ (_____)
(Seal) Medical officer/Authorised signatory.

The blood bags and /or components received from the above blood bank will be transported to our blood storage centre maintaining proper cold chain. The units will be stored at requisite temperature and will be issued after proper cross match. The records of each and every unit procured will be maintained along with the protocol of the cross matching of the blood unit.

Date: _____ (_____)
(Seal) Medical officer/Authorised signatory

ANNEXURE "B"

LIST OF BLOOD AND/OR ITS COMPONENTS WITH UNDERTAKING

List of products intended to be stored and cross-matched by _____
at _____

to be procured from 1. _____

2. _____

3. _____

under approval from the Licensing Authority:

1.

2.

3.

4.

5.

6.

7.

UNDERTAKING

1. The above are the only product(s) intended to be stored at present and any deletion or addition will not be carried out without the permission of the Licensing Authority.
2. The above product will only be procured from above mentioned blood bank(s).
3. We will not consume more than 2000 units of blood and/or its components in one year.
4. No blood will be collected from the donors at the blood storage centre under any circumstances.
5. We will follow all the provisions applicable to the blood storage centres, in the Drugs and Cosmetics Act 1940 and Rules 1945 or any amendment published from time to time.

Signature

Designation

Seal

ANNEXURE "C"

CERTIFICATE OF APPROVAL TO BLOOD STORAGE CENTRE FOR STORAGE OF WHOLE HUMAN BLOOD AND/OR* ITS COMPONENTS

No. _____

Date of issue _____

M/s _____ is hereby approved to store the following items on the premises situated at _____ under the supervision of the following staff:

1. Name(s) of the approved medical officer :
2. Name(s) of the items :
3. Name(s) of the qualified blood bank technician :
4. Name and address of the mother blood bank from whom the blood and/or its components would be procured :
5. The approval shall be in force from to

Signature:

Dated:

Designation:
Licensing Authority

*delete whichever is not applicable.

CONDITIONS

1. The captive consumption of whole human blood and/or its components in the above centre shall not be more than 2000 units annually.
2. In the event of any change in the technical staff, it shall be forthwith reported to the Licensing Authority.
3. In the event of any change in the name of the mother blood bank from whom the blood units are procured, the same shall be intimated to the Licensing authority for approval.
4. The centre shall apply for renewal of the approval to the Licensing Authority three months prior to the date of expiry of the approval.
5. The centre shall store samples of donors blood as well as patients sample for a period of seven days after transfusion.
6. No blood shall be collected from the donors at the blood storage centre under any circumstances.
7. The cold chain during transportation shall be maintained.
8. The blood and/or its components shall be stored at requisite temperature,

9. The blood sample shall be properly cross-matched and the records of cross matching along with the protocols shall be maintained.
10. All necessary precautions should be taken while issuing the blood.
11. The SOP's should be followed strictly
12. All records with respect to the procurement of blood and/or its components, storage, cross match, issue of the blood and/or its components. The records of reagents & its tests, kits and other disposable shall be maintained.
13. The medical officer will be responsible for identifying haemolysed blood and ensuring non supply of haemolysed or expired blood and/or its components.
14. All instruments should be calibrated as prescribed in schedule F Part XII B of the subject Act.
15. All provisions of the Drugs and Cosmetics Act 1940 and Rules 1945 applicable to the blood storage centre should be followed.

Annexure 'D'

MINISTRY OF HEALTH AND FAMILY WELFARE (Department of Health) NOTIFICATION

New Delhi, the 20th December, 2001

G. S. R. 909(E) - Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940). in part - II, Section 3, Sub-section (i), of the Gazette of India. Extraordinary, dated the 22nd June, 2001, under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health), number GSR 449(E), dated the 22nd June, 2001, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said Gazette were made available to the public on 23-6-2001.

And whereas objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

2. (1) These rules may be called the Drugs and Cosmetics (10th Amendment) Rules, 2001.
(2) They shall come into force on the date of their publication in the Official Gazette.
3. In the Drugs and Cosmetics Rules, 1945, in Schedule K, after serial number 5A and the entries related thereto, the following shall be inserted namely;

Class of Drugs

5B. Whole Human Blood I. P. and / or its components stored for transfusion by a First Referral Unit, Community Health Centre, Primary Health Centre and a Hospital.

Extent and Conditions of Exemptions.

The provisions of chapter IV of the Act and the rules made thereunder which require obtaining licence for operation of a blood bank or processing Whole Human Blood and / or its components, subject to the following conditions, namely.

- (1) The First Referral Unit. Community Health Centre. Primary Health Centre and / or any Hospital shall be

approved by the State / Union Territory Licensing Authority after satisfying the conditions and facilities through inspection.

- (2) The captive consumption of Whole Human Blood I. P. or its components in the First Referral Unit, Community Health Centre, Primary Health Centre and / or any Hospital shall not be more than 2000 units annually.
- (3) The Whole Human Blood and / or its components shall be procured only from the Government Blood Bank and/or Indian Red Cross Society Blood Bank and/or Regional Blood Transfusion Centre duly licensed.
- (4) The approval shall be valid for a period of two years from the date of issue unless sooner suspended or cancelled and First Referral Unit, Community Health Centre, Primary Health Centre or the Hospital shall apply for renewal to the State Licensing Authority three months prior to the date of expiry of the approval.
- (5) The First Referral Unit, Community Health Centre, Primary Health Centre and/or any Hospital shall have the following technical staff for storage of blood or its components:
 - (a) A trained Medical Officer for proper procurement, storage and cross matching of blood and/or its components. He/She shall also be responsible for identifying haemolysed blood and ensure non-supply of date expired blood or its components.
 - (b) A blood bank Technician with the qualification and experience as specified in Part XII B of Schedule F or an experienced laboratory technician trained in blood grouping and cross matching.

- (6). The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall have an area of 10 sq. meters. It shall be well lighted, clean and preferably air-conditioned. Blood Bank refrigerator of appropriate capacity fitted with alarm device and temperature indicator with regular temperature monitoring shall be provided to store blood units between 2°C to 8°C and if the components are proposed to be stored, specialized equipments as specified in Part XII B of Schedule F shall also be provided.
- (7). The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall maintain records and registers including details of procurements of Whole Human Blood I. P. and/or blood components, as required under Part XII B of Schedule F.
- (8). The First Referral Unit, Community Health Centre, Primary Health Centre and Hospital shall store samples of donors blood as well as patients sera for a period of seven days after transfusion. “

[No. X-1 1014/3/2001-DMS & PFA]
Deepak Gupta. Jt. Secy.

Foot Note - The principal rules were published in the Official Gazette vide notification number F. 28-10/45-H (1), dated the 21st December, 1945 and last amended vide G. S. R. 900(E) dated 12-12-2001. The Drugs and Cosmetics Rules, 1945, as amended upto the 1st May, 1979 are contained in the publication of the Ministry of Health and Family Welfare (Department of Health) containing the Drugs and Cosmetics Act, 1940 (PDGHS-61).

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