

**THE BALOCHISTAN SAFE BLOOD TRANSFUSION  
RULES, 2005**

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*RULES*

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**NOTIFICATION**

[24<sup>th</sup> September, 2005]

No. PC (H) SBT/2005/4691- 4694. In exercise of the powers conferred by section 12 of the Balochistan Safe Blood Transfusion Act, 2004<sup>2</sup> (III of 2004), the Authority with the prior approval of Government of Balochistan is pleased to make the following rules, namely:—

**PRELIMINARY**

1. **Short title and commencement.**— (1) These rules may be called the Balochistan Safe Blood Transfusion Rules, 2005.

(2) They shall come into force at once.

2. **Definitions.**— (a) In these rules, unless there is anything repugnant in the subject of context,—

(b) **“Act”** means the Balochistan Safe Blood Transfusion Act, 2004<sup>2</sup> (III of 2004);

(c) **“Chairman”** means the Chairman of the Authority;

(d) **“Committee”** means Committee appointed under these rules;

(e) **“Existing Blood Bank”** means a Blood Bank existing on the commencement of these rules;

(f) **“Form”** means a form appended to these rules;

(g) **“Government”** means the Government of Balochistan;

(h) **“Meeting”** means a meeting of the Authority;

(i) **“Secretary”** means the secretary of the Authority;

(j) **“Schedule”** means a schedule appended to these rules;

(k) **“Certificate of registration”** means a certificate granted under these rules;

3. **Application for Registration.**— (1) For the purpose of section 8 of the Act, a blood bank shall be registered and granted license in accordance with these rules.

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<sup>1</sup> These rules have been issued by the Health Department, Government of Balochistan, vide its Notification No. PC (H) SBT/2005/4691- 4694, dated 24<sup>th</sup> September, 2005; and published in the Balochistan Gazette (Extraordinary) No. 148, dated 24<sup>th</sup> September, 2005.

<sup>2</sup> Act III of 2004 was passed by the Balochistan Assembly on 4<sup>th</sup> May, 2004; assented to by the Governor of Balochistan on 4<sup>th</sup> May, 2004; and published in the Balochistan Gazette (Extraordinary) No. 34, dated 8<sup>th</sup> May, 2004.

(2) An existing blood bank may continue to function without registration for a period not exceeding 90 days from the commencement of these rules and where an application is made under sub rule (3) below until the application is rejected and where an appeal is preferred against that rejection under the provisions of rules 8, till the decision of that appeal.

(3) Any person intending to establish a new blood bank shall make an application to the Authority in Form-I accompanied by such documents and fee as fixed by the Authority with the approval of the Government. Any existing bank desirous of continuing with the operation may apply for registration within 45 days of Form-1, along with required documents and fee fixed by the Authority with the approval of the Government.

(4) Every blood bank or its branch running under the same name or management at different premises shall be registered and granted license separately.

4. **Procedure for Registration.**— (1) The Authority may on receipt of an application under rule 3, constitute a Committee to make enquiry if the blood bank concerned fulfills and complies with the conditions mentioned in section 10 and in respect of such other matters as may be specified by it.

(2) The Committee shall submit its report to the Authority within a fortnight of the receipt by it of the application under sub-rule (1) or in an extended period duly approved by the Chairman.

(3) The Authority shall after considering the report of the Committee in a meeting and after making such further enquiry as it considers necessary will grant or reject the application.

(4) The Authority shall invariably record reasons for grant or rejecting the application.

5. **License for Registration.**— (1) The Blood Bank of whom the application has been made may be granted a license for registration in Form-II on payment of an amount of non-refundable license fee as may be fixed by the Authority for a period of one year from the date of the registration.

(2) The Authority shall maintain a register in Form-III containing such particulars of the blood bank, which is registered, and granted license for registration.

(3) The license holder shall be responsible for due compliance of the provisions of the Act, rules, the terms and conditions of license and orders or instructions issued from time to time by the Authority.

(4) A license unless canceled earlier shall be valid for one year from the date of its commencement.

(5) The applications for the renewal of registration shall be submitted to the Authority at least one month before expiry of the license.

(6) License of the Blood Bank under complaint or inquiry may not be renewed unless the Authority is satisfied by the report of Inquiry Officer or Committee.

6. **Monitoring and Inspection.**— (1) The working of the license shall be subject to monitoring by the Authority and for the purpose the Authority or any person authorized by it may enter and check the blood bank concerned to satisfy itself if it is functioning satisfactorily in accordance with the Act and rules.

2. The license shall allow inspection of the blood bank with or without notice without any hindrance.

3. The Authority or the authorized person after inspection may pass orders about the inadequate discharge of its responsibility by the Blood Bank as given in section 10 of the Act and the orders so passed shall be binding on and complied with by the license.

7. **Cancellation or Suspension of License.**— (1) Where the Authority is satisfied that the license is not functioning properly it may after giving him an opportunity to of being heard to the license suspend or cancel the license:

Provided that where the default is capable of being remedied no order shall be made unless an opportunity is provided to the person concerned to rectify such default within the specified period.

(2) On the cancellation or suspension of the license, the Authority may issue orders in writing.

8. **Appeal.**— Where the Authority rejects an application for registration or suspends or cancels the license, the aggrieved person may, within 30 days from the date of the order of the Authority, prefer an appeal to Government and the order so passed by Government shall be final.

9. **Annual Report.**— The license shall furnish to the Authority each year a report on annual audit and accounts on its activity during the preceding year and such information relating to its activities as may be required by the Authority.

10. **Meetings.**— (1) All business of the Authority shall be disposed in a meeting, which may be held in accordance with the provision herein contained.

(2) Meetings shall be held as often as may be necessary but not less than once in six months.

(3) The Secretary under the instructions of the Chairman shall convene an ordinary meeting on such date and the times as may be fixed by the Chairman.

(4) Meeting shall ordinarily by held in the office of the Authority but the Chairmen may, if he so thinks fit, hold a meeting at any other place.

(5) Ordinarily not less than two days advance notice accompanied by an agenda shall be given for each meeting.

(6) The secretary shall cause the agenda prepared in the following order;

(i) confirmation of minutes of the previous meeting,

(ii) all matters deferred in the previous meetings,

- (iii) business to be transact at the meeting including the direction of the Government, if any
- (iv) reports of the Committee.

(7) The Chairman shall preside over every meeting and in his absence by the member elected by the members present at the meeting from amongst themselves and the person so elected will exercise all the powers of Chairman under these rules during a meeting.

(8) Unless otherwise directed by the Chairman no meeting shall be adjourned till the business agenda is disposed off.

(9) Any person expert or advisor may attend a meeting on invitation but he shall not be entitled to cast a vote.

11. **Quorum.**— (1) The quorum of the meeting shall be one half of the total number of members, fraction being counted as one.

(2) If there is no quorum the meeting shall be adjourned to such date and time as the presiding member may fix but no quorum be necessary for meeting held in lieu of the meeting adjourned for want of quorum.

12. **Decisions.**— (1) All decisions in meeting shall be taken by majority of votes by show of hands.

(2) In the case of equal voting the Chairman shall have a second or casting vote.

(3) Actions on the decision in a meeting shall be taken after confirmation of the relevant minutes, save in the exceptional cases where the Chairman may be an order in writing otherwise direct.

13. **Proceeding of the Meeting.**— (1) The secretary shall record minutes of the proceeding of each meeting.

(2) The minutes shall comprise of only the name of members present at the meeting and the number of items and their brief notes and the decisions taken.

(3) The minutes shall be submitted to the Chairman for approval and signed by the Chairman and thereafter a copy thereof shall be supplied to every member.

(4) A copy of the minutes of the proceedings of each meeting duly confirmed shall be recorded in a minutes book maintained for the purpose by the Secretary.

14. **Committees.**—(1) The Authority may appoint any number of Committees as may appear to it to be necessary for advice on matters referred to and perform such other functions as may be assigned to it by the Authority.

(2) The business of every Committee shall be conducted in such manner as it may decide.

(3) A convener appointed by the Chairman shall be the head of every Committee.

(4) The convener if present shall preside at the meeting of the Committee.

(5) In the absence of the convener, the members of the Committee shall elect one of them to preside and the member so elected shall exercise all powers of the convener under these rules.

(6) The proceedings or report of the Committee shall be submitted to the Chairman within one month for placing it before the Authority.

15. **Safety measures to be adopted by the Blood Banks and Laboratories.**— For the purpose of section 3 of the Act, the blood bank to which the license of registration with the Authority has been issued will nominate a responsible person under intimation to the Authority for performing the following:—

- (i) Demonstrate the bio-safety measures specified in the schedule of the Act to all staff members.
- (ii) Inform and explain all members, on periodical basis, the hazards of blood banking and of working in the laboratory and the necessary precautions to be taken.
- (iii) Give instructions regarding cleaning of different areas and disposal of refuse.
- (iv) Record any accidents or incidents involving possible escape of potentially infective material even if there has been no personal injury in a register maintaining specially for the purpose.
- (v) Be responsible for the safe and documented disposal of infectious waste.

16. **Application Guidelines and Instructions.**— The first edition of August, 1999, of standards and guidelines for Blood Transfusion services and Administrative Instructions issued on or after publication of these rules by the Ministry of Health or Government of Balochistan for the guidance or implication of all, shall be binding as statutory rules, and have been made and published under these rules.

Secretary Health/Chairman  
Balochistan Blood Transfusion Authority  
Balochistan, Quetta

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(See **Forms** on next page)



**FORM-I**  
(See rule 3 (3))

<b>BALUCHISTAN BLOOD TRANSFUSION AUTHORITY</b>		
<b>APPLICATION FOR LICENSE FOR REGISTRATION OF BLOOD BANKS (*)</b>		
<i>(*)under section 8 (i) of the Balochistan Transfusion of Safe Blood Act, 2004 "blood bank" include private, Government or Armed Forced Blood Banks maintained for the purpose of receiving, preserving, storing, analyzing and processing blood and blood products.</i>		
<b>SECTION- I</b>		
<b>NEW APPLICANT</b> <input type="checkbox"/>	<b>RENEWAL</b> <input type="checkbox"/>	
<b>If renewal than please endorse previous license number</b>		
<b>Name of the Facility</b>		
<b>Address /Location</b>		
.....		
.....		
.....		
.....		
Telephone No:	Fax No:	E-Mail:
Types of Facility <i>(please tick one)</i>	a) Part of Laboratory	<input type="checkbox"/>
	b) Part of Hospital Service	<input type="checkbox"/> If so please indicate number of beds.....
	c) Independent Blood Bank	<input type="checkbox"/>
<b>SECTION- II</b>		
Name of supervisor/Director/Incharge		
Qualification <i>(please check certificates/degrees)</i>		
PMDC Registered <i>(please Check/ registration)</i>	No:	
	Last Renewal:	
	Expiry:	
<b>CERTIFICATE BY THE BLOOD INCHARGE(*)</b>		
<i>Under section 8 (i) of the Balochistan Transfusion of Safe Blood Act, 2004 "incharge" means the owner of a blood banks and in case of company or other body corporate: its chief executive or a person declared as such at the time registration.</i>		
I, Dr..... s/o- d/o- w/o		
.....		
do hereby solemnly affirm that I am working as the officially designated supervisor/ or am the owner of Blood Bank..... located at.....		
Name of facility		address of applicant facility
The information provided above is correct. I accept full responsibility for the facility and shall ensure that all instructions issued by the Balochistan Blood Transfusion Authority, regarding blood banking shall be complied with and proper documentation shall be maintained. Further that I have not lent my name or interest in absentia to any other facility intending to apply for registration. I also understand that in event of any lapse in compliance, I shall be liable to penalization under the law.		
Name:		
Designation:		
NIC. No:		
PMDC Regd No:		
Address:		
Tel No:		
Signature		



<b>CERTIFICATE BY THE ADMINISTRATIVE HEAD OF THE HOSPITAL</b>			
<i>I certify that the details provided above are correct</i>			
Name:			
Designation:			
NIC . No.			
PMDC Regd No.			
Address			
Tel No.		Fax No:	E-mail:
Signature			
<b>DETAILS OF TECHNICAL STAFF</b>			
S. No.	Designation	Experience	Qualification/Training
<b>ONLY BLOOD DONOR ORGANIZER/VOLUNTEER WORKER</b>			
Name of Incharge			
Established since (dd/mm/yy)			
Address:			
Telephone:		Fax:	E-Mail
<b>SECTION-III</b>			
<i>Space or designated areas available : (please stick appropriately)</i>			
Registration room/ Desk			
Working space/size of room/rooms			
Product making lab:			
Cross matching lab;			
List of Equipment available:			
i. Please mention about the specification and working status.			
ii. Please use additional sheets, if required so			
Blood Bank refrigerator:			
Blood Bank freezer:			
Refrigerated Centrifuge:			
Platelet agitator:			

Screening lab, Equipment			
Uninterrupted power supply source			
Expressers and sealers			
Centrifuges			
Water both			
Microscope			
Other (please use additional sheets)			
<b>REAGENTS USED</b> (please specify methodology and company)			
Grouping sera			
Haemoglobin reagent			
Albumi/ LISS			
Leishman stain/ Giemsa stain			
Reagents for screening of Hepatitis B			
Reagents for screening of Hepatitis C			
Reagents for screening of HIV			
Reagents for screening of Syphilis			
Reagents for screening of Malaria			
Other (please specify and use additional sheets)			
<b>COMSUMABLES USED</b>			
Blood lancets			
CPDA triple/Double blood bags			
CPDA single blood bags			
Gloves			
Pilot tubes for screening tests			
Glass slides			
Others (please specify and use additional sheets)			
<b>SECTION- IV</b>			
Expected work load/Blood Bags per year (please indicate at least 500 above your load)* Please tick (J) in the appropriate Box below			
100 to 500 donors	501- 1000	1001- 2000	2001- 3000
2001- 4000	4001- 6000	6001- 8000	8001- 10000
No of mobiles or camps intended to be held.			
<b>AFFIRMATION</b>			
<p>1. I/ we do hereby solemnly affirm that the information provided is true and the blood bank is working utilizing the above equipment, reagents and consumables.</p> <p>2. I/ we further commit myself/ourselves of abide by the Balochistan Safe Blood Transfusion Act 2004 and the rules and regulations framed for giving effect to its provisions.</p> <p>3. I/we shall abide by the Authority's instruction issued from time to time and open my / our facility to inspection by the Authority whenever so directed. It is formally requested that my/our facility may accordingly be registered, licensed and /accredited allowing me/us to practice blood banking in the province of Balochistan.</p>			
Signature with Date by the Incharge of Blood Bank.			
Signature with Date by the Head of the Hospital			

**Please do not write below this segment**

Application Performa for Blood Bank's Registration with Balochistan Blood Transfusion Authority

**FOR OFFICE USE ONLY**

Date application received: New Applicant.....	Renewal Case..... ..... Old License No..... ....
Identification Code No.	
Charges received	Rupees:
Charges received for the purpose:	
Charges received by:	
Bank Challan / Bank draft No.	
Inspection Date	
Name(s) of the Inspector(s)	
Date of Inspection Report's submission	
Dated of meeting of Authority to consider the Application No.....	
Decision of the Authority on the Application No.....	

Application Performa for Blood Bank's Registration with Balochistan Blood Transfusion Authority



## FORM-II

(See rule 5(1))

### BALUCHISTAN BLOOD TRANSFUSION AUTHORITY

### LICENSE FOR REGISTRATION OF BLOOD BANKS

According to the powers vested under Section 8 of the Balochistan Safe Blood Transfusion Act, 2004, the Balochistan Blood Transfusion Authority, hereby allows the ..... Blood Bank to conduct the following Blood Banking operations for a period of one (01)year, starting with effect from.....

Receiving	Yes		No	
Preserving	Yes		No	
Storing	Yes		No	
Analyzing	Yes		No	
Processing blood and blood products	Yes		No	

- The license shall function in accordance with the Balochistan Safe Blood Transfusion Act, 2004 and rules framed there under and the instructions issued from time to time by the Authority.
- This registration will expire on .....and the Blood Bank should have to obtain fresh license for the operations.

**Secretary**

Balochistan Blood Transfusion Authority

Dated.....

.....

**FORM-III**  
(See rule 5(2))

**REGISTRATION OF CERTIFICATE OF REGISTRATION**

S. #	Name of the Blood Bank granted certificate of registration	Location and postal address with telephone No. of the Blood Bank	Details of the owner and management of Blood Bank	Remarks
1	2	3	4	5