EXTRAORDINARY | REGISTERED NO, S-2771

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THE BALOCHISTAN GAZETTE,
PUBLISHED BY AUTHORITY

NO. 83 QUETTA SATURDAY | AUGUST 20, 2005. *
‘BALGCHISTAN CLINICAL LABORATORY REGULATORY

| AUTHORITY
i NOTIFICATION 2) |

Dated Quetta, the 20" August, 2005
No. Pe(H)/BCLRA/2005/3965-67/. In “exercise of “the powers conferred by section 17 of the Balochistan Clinical Laboratories Regulatory Authority Ordinance, 2001 (XLV of 2001), the authority with the prior approval of Government of Balochistan is pleased to make the following tules, namely:-

I. Short title and commencement:

(1) | The rules may be called the Balochistan Clinical Laboratory Regulatory Rules, 2005

(2) They shall come into force at once..

2. Definitions: In these rules, unless the context otherwise. requires, the following terms shall have the meaning hereby respectively assigned to them this is to say,
(a) Accreditation; means the process of,registering, categorizing and, licensing —"
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a Clinical laboratory.

(b) Accredited Clinical Laboratory: means a clinical laboratory licensed to provide clinical laboratory services in the province, guaranteed to provide a certain level of steamer ey genie: to its recognized category.

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Authority: means the “tochisiay Clinical Laporatory icegulatory

Authority.

Clinical Laboratory: meais aay premises or unit independent or in a clinic or hospital building where practice of Pathology or one or moce of its recognized disciplines is carried out. But it does not inciude a unit or premises independent or in a clinic or hospital building where practice of other diagnostic disciplines of medicine like Radiology etc. is carried out.
Department: means a specialized unit in an institution, clinic or fiospital, which is specially undertaking the practice of the disciplines of Pathology or one of its sub disciplines.

License: means a clinical laboratory duly issued a license to operate by the Authority in the province.

Medical Practitioner: means a physician or such other person who is

trained and holds qualifications and is tecognized for the purpose of providing

medicine care to a patient and practice of medical science in Pakistan, by an official body such as the Pakistan Medical & Dental Council or equivalent

provincial body.

(i)

Pathologist: means a qualified physician with necessary post-graduate

qualification recognized by Pakistan Medical and Dental Council to practice the

disciplines of pathology.

. Pathology Practice: means the practicé of the disciplines. of médical

science, which deals with the analysis, and testing of human tissues, excrements, body fluids etc. for the purpose of diagnosis of disease or

medical assessment of a human being, main, inolude, -

(a) Histo Patholopy

(b) — Clinical Pathology

(c) Haematology

(d) Clinical Haematology

(e) Transfusion medicine

(f) Microbiology and Immunology

Physiciari: means a medical graduate holdiig MBBS or equivalent qualification recognized by the Pakistan Medical and Dental Council. But it also include a qualified Dental graduate holding BDS or equivalent qualification recognized by Pakistan Medical and Dental Council. It also include post- -graduate doctors in any discipline recognized for practice of medical science by Pakistan Medical and Dental Souris

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ady ity imay underiake all aicasutes to ensure safety, protection and aoinotion of human life through a comprehensive and quality clinical -sboratery services in ihe province and sustained development of such services to an internaticnally accepted standard, by regulating, The cost of Wiese services which is mutually beneficial and affordable foi public and aoviders of such services.

(2) Every physician, medical practitioner or any person qualified to do so,will ensure that the clinical tests are under-taken by a clinical laboratory Which

nas been duly licensed and is accredited under the ordinance. Y

SUPERVISION OF CLINICAL LABORATORIES:

(i) The Authority shall ensure that all clinical laboratories are being supervised by a pathologist with necessary post-graduate qualification recognized by Pakistan Medical and Dental Council (PMDC Islamabad) to

practice pathology.

(2) The Authority shall also ensure that all independent clinical laboratories or attached with private hospitals, clinics or any other setups, supervised by a clinical pathologist. Pathologists must be present physically in laboratories during routine working hours. _ @ t FF ey 4

_ 3) In case-of non availability of pathologist, :private. hospitals clinics. and

other setups shall get their investigations done . from. an. accredited laboratory.

(4) 4 pathologist shall supervise onc clinical laboratory at atime.

(5) In remote areas where pathologist is not available in case of ‘emergency of a special situation where question of saving injury to a human life occurs and an -aceredited laboratory is not available, clinical: tests .may. be performed by a laboratory not accredited to under take such: test-in a manner. prescribed under the rules. yp Fees ;

son may not operate

o. have been trained
d to establish and

(6) Authority, shal!.check and ensure that non medical per
the clinical laboratories. Only the medical doctors wh
and qualified in the relevant field should be allowe
operate the clinical laboratories.

(7) Techne logists, technicians and laboratory assistants (duly qualified) will

pathologists are jot available, they. shall: perform: such laboratory tests:

under the permission of authority till the availability of a pathologist.

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(8) Laboratory attendants or any other person who has not been qualifies shall not perform laboratory tests independently in any case, anywhere ig the province.

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(9) Those workers/staff who have done their basic qualification (Matric) arg are serving in private clinical laboratories without having proper diploma, from a registered/recognized institution, shall only be allowed to work, if, qualified pathologist may certify, regarding his satisfactory knowledg: and skills in laboratory work. This exercise shall be allowed only for ore year. After that only those laboratory workers shall be allowed to work who will produce their certificates/diplomas from a recognized institution

5. MANPOWER/STAFF IN A CLINICAL LABORATORY:
All clinical laboratory must be equipped with the following staff:-
(a) Pathologist (qualified) FCPS or MRCP or M.Phil or DCP or MCPS in

Pathology
-(b) - B.S.C Technologist having matriculation or intermediate and diploma of . technic‘an or
wants ©. _, Laboratory, meena haying. Fratncaletion: and: einen of laboratory , LAPS UG agsistant. 7 .
(d) Laboratory Attendants, responsible for general éleitiliness of laboratory premises, washing, of ‘Biasswate and ak disposal of spborsteny waste and ““fefuse! ="

(ce) | Computer Operator or typist or receptionist to keep the record, typing of | reports, delivery of reports etc.

: Note:- Number of staff shall be abenedlig to workload of a clinical laboratory.

GENERAL OUT LOOK OF A CLINICAL LABORATORY:

(1). — A clinical laboratory should have enough space to accommodate different oF epee disciplines of pathology for safe and smooth running of laboratory work.
(2) ~ A clinical laboratory should be well lighted; well ventilated and clean.
(3) | Room temperature of a clinical laboratory: must be very comfortable to get | high quality results,
@) _ A laboratory should have a separate area for sample collection, reception, . ; Waiting. room, and a very hygienic wash ri room. ‘Patlents. and attendants;

BELA ie b ‘shall not ‘enter’ in'laboratoh ‘working areal, Yoni sere |

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LAYORATORY: .

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The Clinical Laboratory shall be equipped with fr folloving cssential

instruments:-

(a) Microscope (s)

(b) Refrigerator (s)

(c) Chemistry Analyzer (s)

(d) Electrolyte Analyzer (optional)

(e) Automated Blood Cell Counter (eptional)
(h Centrifuge Machine (s)

(g) Water Bath (s)

(h) Oven er Incubator (s)

(i) First Aid kit for staff

(j) Emergency kit for blood donors

(k) Syringe destroyer/cutter

(1) Necessary glassware

(m) Balance

(n) Fire extinguisher system ,

(o) Computer (optional) or typing machine

SAFETY PRECAUTIONS AND MEASURES IN. A. CLINICAL

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8.
LABORATORY: a
(1) All laboratory members shall be vaccinated azainst infectious diseases (i2
Hepatitis-B ete). ;
(2) All laboratory staff must use disposable gloves and overall while performing

laboratory tests.
(3) Laboratory members shall be informed on periodical basis, the hazards of handling samples working in laboratory and precautions to be taken.
(4) ‘Laboratory staff shall ensure for safe disposal of infectious wasie and refuse according to manual guidelines. . j
(5) Laboratory staff must be trained, how to use first aid’kits, fire extinguisher and other procedures in casé of laboratory incidents/accidents. |
(6) ~All the incidents/accidents happened in laboratory shall be entered in a j registe: mention the nature of incidents and measures taken with name of ; affectees, time and date of incident. A special register shall be maintained for | the purpose. }
(7) All the syringes/lancets must be destroyed before proper.disposal. |
9. UNIFORM COST OF CLINICAL TESTS:
5. Authority shall prescribe a uniform

The authority shall regulate the cost of test
rate list after going through the rates of provincial
country in such a manner which is mutually beneficia

and other taboratories of
| and provider of such

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(1) — The authority may on rece

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services. Authority shall review the rate afler three year according to inflation

rate.

UNIFORM REPORTING SYSTEM:

The Authority shall prescribe a uniform reporting system for professional services

performed.

RECORD KEEPING:

(1) Clinical laboratories shall maintain a proper record of test findings so that it could be used to study the prevalence of different discases in different areas of province.

(2) - Clinical laboratory shall not disclose the results of any patient to anybody in any case, until the patient himself allows to disclose the results to his attendants or relatives. mie

(3) Record of accounts shall also be maintained for annual report.

QUALITY CONTROL AND QUALITY ASSURANCE OF CLINICAL TESTS: There shall be,-

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(1) A system of indoor and outdoor quality control shall be established on ‘regular basis. ss

(2) Quality control sera shall regularly be used to evaluate quality of laboratory

- reagents and instruments. °

~.-(3) — Regular service of all equipments/instruments shall: be ensured: on regular

basis to keep such items in good working condition.

- APPLICATION FOR REGISTRATION AND GRANT OF LICENCE:

(1) All applications for grant of a licence shall contain. such information on a

format prescribed by the authority.
(2) | After commencement of these rules,
be determined by authority will be a
clinical laboratory shall work without licence.
(3) | Any person, hospital or clini
an application to the authority
documents and fee as fixed by authority with the approval of Government.

PROCEEDINGS FOR REGISTRATION /LICENCE: .

ipt of an application under rule]3, Constitute an
ke enquiry, if the, ¢linical laboratory, fulfills
“and coinplies with the terms and conditions mentioned in'the Ordinance
and in respect of such other matters as may be specified by it.

the receipt of application or in an extended period duly approved by the

Chairman.

a grace period of six months or as may
llowed for all clinical laboratories to be
registered with and obtain a valid licence from the authority, after which no

¢ intending to establish a laboratory shall make
on a prescribed form accompanied with such

it its report to the authority within a fortnight of

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yort of the conmittee in a

(3) The authority shall afer considering the rey
mecting, and after making such further enquiry as tt considers necessary
will grant or reject the application.
(4). The authority shall invariably record the reasons for rejecting the
application. |
15. BRANCHES AND COLLECTION CENTRES:
ction centre under the same name oF

Every clinical laboratory or its branch or colle
management at different premises shall be repiste

red and granted licence

separately.

16 LICENCE FOR REGISTRATION:

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CANCELLATION OR SUSPENSION OF LICENCE:

ation has been accepted will be
bed on payment of an amount
authority for a period of one

The clinical laboratory of whom the applic
granted a licence for registration:in form prescri
of Rs.1000/- non-refundable as specified by the
year from the date of the registration.

The authority shall maintain a register containing such particulars of the

laboratory which is registered and pranted licence for registration.

The Livencee shall be responsible for duc compliance of the provisions of Ordinance, mules and the terms and conditions of licence and orders or

issued from time to time by the authority.
A licence unless canceled earlier shall be valid for one year from the date of

its commencement. tt th
al of registration ‘shall be submitted to the

The applications for the renew
authority at least one month. before expiry of the licence renewal fee of

licence shall be Rs.500/- per annum.
Clinical laboratory shall be bound to print or write the licence number on

reporting forms.

MONITORING AND INSPECTION: id ,
subject to monitoring by the

f the clinical laboratory. shall be
ity or any person authorized by it, may

concerned to satisfy itself if it is
isions of Ordinance and

The working’o
authority. and-for the purpose, author
enter and check the clinical. laboratory
functioning satisfactorily in accordance with the prov

rules.

The licencee shall allow ‘ins
any notice without and any hindrance.

The authorized person after inspection may re
Authority ‘about the inadequate discharge of responsibilitie

laboratory.

section of the clinical laboratory with or without

commend and inform the
s by clinical

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is not working properly it

Where the authorily is satisfied that the licencee

ard to the licences.

may after giving an opportunity to explain and or being he

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suspend or cancel the licence: provided that where the default is capable of being remedied.-no order shall be made unless an opportunity rectify such default with the specified period.

On the cancellation or suspension of the ficence, the authority may issue orders in writing.

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“APPEAL:

Where the authority rejects an application for registration or suspends or cancels the licence, the aggrieved person may, within 30 days from the date of orders of

the authority, prefer an appeal to Government and the order passed by Government shall be final. ,

ANNUAL REPORT: .
The licencee shall furnish to the authority each year a report on aniual audit and accounts on the activity of the licencee during the proceeding year and such ~ information relating:to its activities as may. be required by the authority.

. MEETINGS OF AUTHORITY:

- (1) All business of the authority shail be disposed in a meeting which may be
- held in accordance with the provision lierein contained. : ,
-Meetings:shall.be held as often as may, be necessary, but Not less than once
- .. ‘in three months. ~~ . tit teagan! ,
(3) The’ Secretary ‘under. the instructions of Chairman shall convene an j
- \" grdinary!meeting on such date and time fixed by the Chairman.
(4) *- Meetings shall ordinarily: be :held-in the office, of. the authority but ‘the chairman may, if he so thinks fit, hold a meeting at any other place.
(5) Ordinarily not less than 02 days advance notice accompanied by an
_ agenda shall be given foreach'mecting. .
. (6) . The Secretary shall cause the agendas prepared in the following order:-
«.* (a) » Confirmation of minutes of the previous meeting.
'-(b) . All matters deferred in the previous meetings.
“.(e) Business. to.be transacted-at the meeting including the direction
» + Government: ifany.
* (d). - Reports of the committee(s).
(7) | The chairman shall preside over every meeting and in his absence by the

vice-chairman, who will exercise all the powers of chairman under the
. . rules during a meeting. ye .
(8): “Unless, otherwise directed by the chairman no meeting shall be adjourned
till the business agenda is disposed-of. eo
(9) «. “Anny: person expert or advisor may attend a meeting on:invitation but he.
- shall not be entitled to ‘cast a vote.
| M: .
Ay Fe oauia of a meeting shall be 3/4th of the total number of members.

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(2)... Mfthere.is.no quorum the meeting shall be adjourned to such a date and time ais

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),
fix but no quorum shall be necessary for

as the presiding member may
adjourned for.want of quorum.

meeting held in lieu of mecting

23. DECISIONS:
show of

(1) All decisions in meeting shall be taken by majority of votes by
hands.

(2) Inthe case of equal voting the chairman

(3) Actions on the decision in a meeting sh
relevant minutes, save in the exceptional cases W
an ord¢r in writing otherwise direct.

shall have a second or casting vote.
all be taken after confirmation of the
here the chairman may by

24. PROCEEDINGS OF THE MEETING:
(1) = Minutes of the proceedings of each meting shall be drawn by the Secretary.
(2) Minutes shall comprise of only the names of members present at the meeting
and the number of items and their brief notes and the decisions taken.
for approval and ‘signed by

(3) The minutes shall be submitted to the chairman
the chairman or secretary and thereafter a copy shall be supplied to every

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

mmittees as may appear to it to

. 25. COMMITTEES:
perform such other

(1) The. authority may appoint any number of co
be necessary for advice on matters referred to and
functions as may be assigned to it by the authority. mot,

(2) - The business of every committee shall be conducted in such manner as it

may decide.
(3) Every committee s
(4) | The convener, if present s
(5) In the absence of the convener,
of them to preside and the mem

the convener under these rules.
) e committee shall be submitted to the

(6) ‘The proceedings or report of th
chairman within one week for placing it before the authority.

hall be headed by a convener appointed by the chairman.
hall preside at meeting of the committee.

the members of the committee shall elect one

bers so elected shall exercise all powers of

RELATION WITH BALOCHISTAN HOSPITAL -_REGULATORY

AUTHORITY:
(1) In case of conflict with the Balochistan Hospital Regulatory the Chairman

of the Board shall constitute a special committee to resolve such a conflict
within 30 days and its decision shall be final and binding. — .
(2) The authority may review the instructions issued from time to time and the
licencee shall be responsible for due compliance of the instructions, SO

issued.
SECRETARY HEALTE / CHAIRMAN
UTHORITY

BALOCHISTAN CLINICAL LABORATORY A
BALOCHISTAN, QUETTA

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(Ree CORL FORM FOR THE REGISTRATION AND GRANT
esis" S OF LICENCE: FOR CLINICAL ‘LABORATORY

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Nameof the Owner:
Father’s Name: — =
National Identity Card No:
Name of Clinical Laboratory:

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Independent or attached with a Clinic/Hospital (name);_-
nT

. Address:
Phone No(s)

Staff:

°4) Name of Pathologist: ; ee ,
i) Qualification:

ii) PMDC Registration No:
5) -Technologist/Technician/Laboratory Assistant (give number):
6) Laboratory Attendants (give number):

Equipments / Instruments:

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2) 2...
3) —e—— een

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Other Facilities, if provided:

Date: sossensennanagnegnnes eeevncecesee

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