EXTRAORDINARY

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BALOCHISTAN CLINICAL LABORATORY REGULATORY AUTHORITY

NOTIFICATION

Dated Quetta, the 20th August, 2005

No. Pc(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 rules, namely:-

PRELIMINARY

1. **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 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 professional quality according to its recognized category.

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(c) Authority: means the Balochistan Clinical Laboratory Regulatory Authority.

(d) Clinical Laboratory: means any premises or unit independent or in a clinic or hospital building where practice of Pathology or one or more of its recognized disciplines is carried out. But it does not include 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.

(e) Department: means a specialized unit in an institution, clinic or hospital. which is specially undertaking the practice of the disciplines of Pathology or one of its sub disciplines.

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

(h) Medical Practitioner: means a physician or such other person who is trained and holds qualifications and is recognized 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.

(j) Pathology Practice: means the practice of the disciplines of medical 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, which include,-

(a) Histo Pathology
(b) Clinical Pathology
(c) Haematology
(d) Clinical Haematology
(e) Transfusion medicine
(f) Microbiology and Immunology

(k) Physician: means a medical graduate holding 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 Council.

(f) Government: means Government of Balochistan.

GENERAL PROVISIONS:

(1) Authority may undertake all measures to ensure safety, protection and promotion of human life through a comprehensive and quality clinical laboratory services in the province and sustained development of such services to an internationally accepted standard, by regulating. The cost of these services which is mutually beneficial and affordable for public and providers 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 has been duly licensed and is accredited under the ordinance.

SUPERVISION OF CLINICAL LABORATORIES:

(1) 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.

(3) In case of non availability of pathologist, private hospitals clinics and other setups shall get their investigations done from an accredited laboratory.

(4) A pathologist shall supervise one clinical laboratory at a time.

(5) In remote areas where pathologist is not available in case of emergency or a special situation where question of saving injury to a human life occurs and an accredited 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.

(6) Authority shall check and ensure that non medical person may not operate the clinical laboratories. Only the medical doctors who have been trained and qualified in the relevant field should be allowed to establish and operate the clinical laboratories.

(7) Technologists, technicians and laboratory assistants (duly qualified) will assist pathologists. However in remote areas of province, where pathologists are not available, they shall perform such laboratory tests under the permission of authority till the availability of a pathologist.

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

(9) Those workers/staff who have done their basic qualification (Matric) and are serving in private clinical laboratories without having proper diplomas from a registered/recognized institution, shall only be allowed to work, if a qualified pathologist may certify, regarding his satisfactory knowledge and skills in laboratory work. This exercise shall be allowed only for one 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 technician or
(c) Laboratory Assistant having matriculation and diploma of laboratory assistant.
(d) Laboratory Attendants, responsible for general cleanliness of laboratory premises, washing of glassware and safe disposal of laboratory waste and refuse.
(e) Computer Operator or typist or receptionist to keep the record, typing of reports, delivery of reports etc.

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

6. GENERAL OUT LOOK OF A CLINICAL LABORATORY:

(1) A clinical laboratory should have enough space to accommodate different 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.
(4) A laboratory should have a separate area for sample collection, reception, waiting room, and a very hygienic wash room. Patients and attendants shall not enter in laboratory working area.

7. **EQUIPMENTS/INSTRUMENTS ESSENTIAL FOR A CLINICAL LABORATORY:**

The Clinical Laboratory shall be equipped with the following essential instruments:-

(a) Microscope (s)
(b) Refrigerator (s)
(c) Chemistry Analyzer (s)
(d) Electrolyte Analyzer (optional)
(e) Automated Blood Cell Counter (optional)
(f) Centrifuge Machine (s)
(g) Water Bath (s)
(h) Oven or Incubator (s)
(i) First Aid kit for staff
(j) Emergency kit for blood donors
(k) Syringe destroyer/cutter
(l) Necessary glassware
(m) Balance
(n) Fire extinguisher system
(o) Computer (optional) or typing machine

8. **SAFETY PRECAUTIONS AND MEASURES IN A CLINICAL LABORATORY:**

(1) All laboratory members shall be vaccinated against infectious diseases (i.e Hepatitis-B etc).
(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 waste and refuse according to manual guidelines.
(5) Laboratory staff must be trained, how to use first aid kits, fire extinguisher and other procedures in case of laboratory incidents/accidents.
(6) All the incidents/accidents happened in laboratory shall be entered in a register 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:**

The authority shall regulate the cost of tests. Authority shall prescribe a uniform rate list after going through the rates of provincial and other laboratories of country in such a manner which is mutually beneficial and provider of such

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

10. **UNIFORM REPORTING SYSTEM:**
The Authority shall prescribe a uniform reporting system for professional services performed.

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

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

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

13. **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, a grace period of six months or as may be determined by authority will be allowed for all clinical laboratories to be registered with and obtain a valid licence from the authority, after which no clinical laboratory shall work without licence.
(3) Any person, hospital or clinic intending to establish a laboratory shall make an application to the authority on a prescribed form accompanied with such documents and fee as fixed by authority with the approval of Government.

14. **PROCEEDINGS FOR REGISTRATION /LICENCE:**
(1) The authority may on receipt of an application under rule13, Constitute an accreditation committee to make enquiry if the clinical laboratory fulfills and complies with the terms and conditions mentioned in the Ordinance 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 of application 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 the reasons for rejecting the application.

15. **BRANCHES AND COLLECTION CENTRES:**
Every clinical laboratory or its branch or collection centre under the same name or management at different premises shall be registered and granted licence separately.

16 **LICENCE FOR REGISTRATION:**

(1) The clinical laboratory of whom the application has been accepted will be granted a licence for registration in form prescribed on payment of an amount of Rs.1000/- non-refundable as specified by the authority for a period of one year from the date of the registration.

(2) The authority shall maintain a register containing such particulars of the laboratory which is registered and granted licence for registration.

(3) The Licencee shall be responsible for due compliance of the provisions of Ordinance, rules and the terms and conditions of licence and orders or instructions issued from time to time by the authority.

(4) A licence 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 licence renewal fee of licence shall be Rs.500/- per annum.

(6) Clinical laboratory shall be bound to print or write the licence number on reporting forms.

17. **MONITORING AND INSPECTION:**

(1) The working of the clinical laboratory shall be subject to monitoring by the authority and for the purpose, authority or any person authorized by it, may enter and check the clinical laboratory concerned to satisfy itself if it is functioning satisfactorily in accordance with the provisions of Ordinance and rules.

(2) The licencee shall allow inspection of the clinical laboratory with or without any notice without and any hindrance.

(3) The authorized person after inspection may recommend and inform the Authority about the inadequate discharge of responsibilities by clinical laboratory.

18. **CANCELLATION OR SUSPENSION OF LICENCE:**

(1) Where the authority is satisfied that the licencee is not working properly it may after giving an opportunity to explain and or being heard to the licencee.

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.

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

19. **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.

20. **ANNUAL REPORT:**

The licencee shall furnish to the authority each year a report on annual 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.

21. **MEETINGS OF AUTHORITY:**

(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 three months.

(3) The Secretary under the instructions of Chairman shall convene an ordinary 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 for each meeting.

(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.

(c) Business to be transacted at the meeting including the direction Government, if any.

(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.

(8) Unless, otherwise directed by the chairman no meeting shall be adjourned till the business agenda is disposed-of.

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

22. **QUORUM:**

(1) The quorum of a meeting shall be 3/4th of the total number of members.

(2) If there is no quorum the meeting shall be adjourned to such a date and time

as the presiding member may fix but no quorum shall be necessary for meeting held in lieu of meeting adjourned for want of quorum.

23. **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 by an order in writing otherwise direct.

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.

(3) The minutes shall be submitted to the chairman for approval and signed by 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.

25. **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) Every committee shall be headed by a convener appointed by the chairman.

(4) The convener, if present shall preside at 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 members 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 week for placing it before the authority.

26. **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 HEALTH / CHAIRMAN
BALOCHISTAN CLINICAL LABORATORY AUTHORITY
BALOCHISTAN, QUETTA

APPLICATION FORM FOR THE REGISTRATION AND GRANT OF LICENCE FOR CLINICAL LABORATORY

Nameof the Owner:_____

Father's Name:_____

National Identity Card No:_____

Name of Clinical Laboratory:_____

_____

Independent or attached with a Clinic/Hospital (name):_____

_____

Address:_____

_____ Phone No(s) _____

Staff:

4) Name of Pathologist:_____
   i) Qualification:_____
   ii) PMDC Registration No:_____
5) Technologist/Technician/Laboratory Assistant (give number):_____
6) Laboratory Attendants (give number):_____

Equipments / Instruments:

1) _____
2) _____
3) _____
4) _____
5) _____

Other Facilities, if provided:

_____

_____

_____

_____

Signature.....

Date: .....