Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

November 19, 2001

ADMINISTRATIVE ORDER
No. 59 s. 2001

SUBJECT: Rules And Regulations Governing The Establishment, Operation And Maintenance Of Clinical Laboratories In The Philippines

Section 1 Title:

This Administrative Order shall be known as the "Rules and Regulations Governing the Establishment, Operation and Maintenance of Clinical Laboratories in the Philippines."

Section 2 Authority:

These rules and regulations are issued to implement R.A. 4688: Clinical Laboratory Law consistent with E.O. 102 s. 1999: Redirecting the Functions and Operations of the Department of Health. The Department of Health (DOH), through the Bureau of Health Facilities and Services (BHFS) in the Health Regulation Cluster, shall exercise the regulatory functions under these rules and regulations.

Section 3 Purpose:

These rules and regulations are promulgated to protect and promote the health of the people by ensuring availability of clinical laboratories that are properly managed with adequate resources, with effective and efficient performance through compliance with quality standards.

Section 4 Scope:

4.1 These regulations shall apply to all entities performing the activities and functions of clinical laboratories which shall include the examination and analysis of any or all samples of human and other related tissues, fluids, secretions, excretions, radioactive, or other materials from the human body for the determination of the existence of pathogenic organisms, pathologic processes or conditions in the person from whom such samples are obtained.

4.2 These regulations do not include government laboratories doing laboratory examinations limited to acid fast bacilli microscopy, malaria screening and cervical cancer screening, provided their services are declared as extension of a licensed government clinical laboratory.

Section 5 Classification of Laboratories:

5.1 Classification by Function

5.1.1 Clinical Pathology - includes Hematology, Clinical Chemistry, Microbiology, Parasitology, Mycology, Clinical Microscopy, Immunology and Serology, Immunohematology, Blood Banking, Laboratory Endocrinology, Toxicology and Therapeutic Drug Monitoring and other similar disciplines.

5.1.2 Anatomic Pathology - includes Surgical Pathology, Immunohispathology, Cytology, Autopsy and Forensic Pathology.

5.2 Classification by Institutional Character

5.2.1 Hospital-based laboratory - a laboratory that operates within a hospital.
5.2.2 Non-hospital-based laboratory - a laboratory that operates on its own.

5.3 Classification by Service Capability

5.3.1 Primary - provides the minimum service capabilities such as:

5.3.1.1 Routine Hematology (Complete Blood Count or CBC) - includes Hemoglobin Mass Concentration, Erythrocyte Volume Fraction (Hematocrit), Leucocytes Number Concentration (White Blood Cell or WBC Count) and Leucocytes Type Number Fraction (Differential Count), Qualitative Platelet Determination.

5.3.1.2 Routine Urinalysis

5.3.1.3 Routine Fecalysis

5.3.1.4 Blood Typing - hospital based

5.3.1.5 Quantitative platelet determination - hospital based

5.3.2 Secondary - provides the minimum service capabilities of a primary category and the following:

5.3.2.1 Routine Clinical Chemistry - includes Blood Glucose Substance Concentration, Blood Urea Nitrogen Concentration, Blood Uric Acid Substance Concentration, Blood Creatinine Concentration, Blood Total Cholesterol Concentration.

5.3.2.2 Cross matching - hospital based.

5.3.3 Tertiary - provides the secondary service capabilities and the following:

5.3.3.1 Special Chemistry
5.3.3.2 Special Hematology
5.3.3.3 Immunology/Serology
5.3.3.4 Microbiology

Section 6 Policies:

6.1 An approved permit to construct and design lay-out of a clinical laboratory shall be secured from the BHFS prior to submission of an application for a Petition to Operate.

6.2 No clinical laboratory shall be constructed unless plans have been approved and construction permit issued by the BHFS.

6.3 A clinical laboratory shall operate with a valid license issued by BHFS/CHD, based on compliance with the minimum licensing requirements (Annex A).

6.4 The clinical laboratory shall be organized and managed to provide effective and efficient laboratory services.

6.5 The clinical laboratory shall provide adequate and appropriate safety practices for its personnel and clientele.

Section 7 Requirements and Procedures for Application of Permit to Construct and License to Operate:

7.1 Application for Permit to Construct: The following are the documents required:

7.1.1 Letter of Application to the Director of BHFS

7.1.2 Four (4) sets of Site Development Plans and Floor Plans approved by an architect and/or engineer.

7.1.3 DTI/SBC Registration (for private clinical laboratory)

7.2 Application for new license: A duly notarized application form "Petition to Establish, Operate and Maintain a Clinical Laboratory" (Annex B), shall be filed by the owner or his duly authorized representative at the BHFS.

7.3 Application for renewal of license: A duly notarized application form "Application for Renewal of License to Establish, Operate and Maintain A Clinical Laboratory" (Annex C), shall be filed by the owner or his duly authorized representative at the respective CHD.

7.3.1 Renewal of License:

Application for renewal of license shall be filed within 90 days before the expiry date of the license described as follows:

Region	Schedule of application for renewal of license
NCR	January to March
1, 2, 3 & CAR	February to April
4, 5 & 6	March to May
7, 8 & 9	April to June
10, 11, 12, CARAGA & ARMM	May to July

7.4 Permit and License Fees:

7.4.1 A non-refundable license fee shall be charged for application for permit to construct, and for license to operate a government and private clinical laboratory.

7.4.2 A non-refundable fee shall be charged for application for renewal of license to operate.

7.4.3 All fees shall be paid to the cashier of the BHFS/CHD.

7.4.4 All fees shall follow the current prescribed schedules of fees of the DOH.

7.5 Penalties:

7.5.1 A penalty of one thousand pesos (₱1,000.00) for late renewal shall be charged in addition to the renewal fee for all categories if the application is filed during the next two (2) months after expiry date.

7.5.2 An application received more than two (2) months after expiry date shall be fined one hundred pesos (₱100.00) for each month thereafter in addition to the ₱1,000.00 penalty.

7.6 Inspection:

7.6.1 Each licensee shall make available to the Director of the BHFS/CHD or his duly authorized representative(s) at any reasonable time, the premises and facilities where the laboratory examinations are being performed for inspection.

7.6.2 Each licensee shall make available to the Director of the BHFS/CHD or his duly authorized representative(s) all pertinent records.

7.6.3 Clinical laboratories shall be inspected every two (2) years or as necessary.

7.7 Monitoring:

7.7.1 All clinical laboratories shall be monitored regularly and records shall be made available to determine compliance with these rules and regulations.

7.7.2 The Director of the BHFS/CHD or his authorized representative(s) shall be allowed to monitor the clinical laboratory at any given time.

7.7.3 All clinical laboratories shall make available to the Director of the BHFS or his duly authorized representative(s) records for monitoring.

7.8 Issuance of License:

The license shall be issued by the Director of the CHD or his authorized representative, if the application is found to be meritorious.

7.9 Terms and Conditions of License:

7.9.1 The license is granted upon compliance with the licensing requirements.

7.9.2 The license is non transferable.

7.9.3 The owner or authorized representative of any clinical laboratory desiring to transfer a licensed clinical laboratory to another location shall inform the CHD in writing at least 15 days before actual transfer.

7.9.4 The laboratory in its new location shall be subject to re—inspection and shall comply with the licensing requirements.

7.9.5 An extension laboratory shall have a separate license.

7.9.6 Any change affecting the substantial conditions of the license to operate a laboratory shall be reported within 15 days in writing by the person(s) concerned, to the BHFS/CHD for notation and approval. Failure to do so will cause the revocation of the license of the clinical laboratory.

7.9.7 The clinical laboratory license must be placed in a conspicuous location/area within the laboratory.

Section 8 Violations:

8.1 The license to operate a clinical laboratory shall be suspended or revoked by the Secretary of Health upon violation of R.A. 4688 or the Rules and Regulations issued in pursuance thereto.

8.2 The following acts committed by the Owner, President, Managers, Board of Trustees/Director, Pathologist or its personnel are considered violations.

8.2.1 Operation of a clinical laboratory without a certified pathologist or without a registered medical technologist.

8.2.2 Change of ownership, location, head of laboratory or personnel without informing the BHFS and/or the CHD.

8.2.3 Refusal to allow inspection of the clinical laboratory by the person(s) authorized by the BHFS during reasonable hours.

8.2.4 Gross negligence.

8.2.5 Any act or omission detrimental to the public.

8.3 The Provincial, City and Municipal Health Officers are authorized to report to the CHD and BHFS the existence of unlicensed clinical laboratories or any private party performing laboratory examinations without prOper license and/or violations to these rules & regulations.

Section 9 Investigation of Charges or Complaints:

The BHFS/CHD or his duly authorized representative(s) shall investigate the complaint and verify if the laboratory concerned or any of its personnel is guilty of the charges.

9.1 If upon investigation, any person is found violating the provisions of R.A. 4688, or any of these rules and regulations, the BHFS/CHD or his duly authorized representative(s) shall suspend, cancel or revoke for a determined period of time the license, as well as the authority of the offending person(s), without prejudice to taking the case to judicial authority for criminal action.

9.2 Any person who operates a clinical laboratory without the proper license from the Department of Health shall upon conviction be subject to imprisonment for not less than 1 month but not more than 1 year or a fine of not less than ₱1,000.00 and not more than ₱5,000.00 or both at the discretion of the court. Provided, however, that if the offender is a firm or corporation, the Managing Head and/or owner/s thereof shall be liable to the penalty imposed herein.

9.3 Any Clinical Laboratory operating without a valid license or whose license has been revoked/cancelled shall be summarily closed upon order issued by the BHFS/CHD or his duly authorized representative. The BHFS/CHD may seek the assistance of the law enforcement agency to enforce the closure of any clinical laboratory.

9.4 The closure order issued by the DOH shall not be rendered ineffective by any restraining order and injunction order issued by any court, tribunal or agency or instrumentalities.

Section 10 Modification and Revocation of License:

10.1 A license maybe revoked, suspended or modified in full or in part for any material false statement by the applicant, or as shown by the record of inspection or for a violation of, or failure to comply any of the terms and conditions and provisions of these rules and regulations.

10.2 No license shall be modified, suspended or revoked unless prior notice has been made and the corresponding investigation conducted except in cases of willful, or repeated violations hereof, or where public health interest or safety requires otherwise.

Section 11 Repealing Clause

These rules and regulations shall supersede all other previous official issuances hereof.

Section 12 Publication of List of Licensed Clinical Laboratories:

A list of licensed clinical laboratories shall be published annually in a newspaper of general circulation.

Section 13 Effectivity:

These rules and regulations shall take effect 15 days after its publication in the Official Gazette, or in a newspaper of general circulation.

(Sgd.) MANUEL M. DAYRIT, M.D., MSc
Secretary of Health

Category	Space in sq. m.
Primary	10
Secondary	20
Tertiary (to include a separate, enclosed and adequately ventilated room for Microbiology)	60

PRIMARY	SECONDARY	TERTIARY

Annex B

Republic of the Philippines
Department of Health
BUREAU OF HEALTH FACILITIES AND SERVICES
Manila

SENTRONG SIGLA
Health ang una!

(IN THE MATTER OF THE PETITION OF

_____)
To Establish, Operate and Maintain a
CLINICAL LABORATORY

PETITION

Now comes the undersigned petitioner and to the Bureau of Health Facilities and Services, respectfully represents:

1. That the petitioner is of legal age, married/single, _____ citizen, and residing at _____
_____

2. That he/she desires to open a CLINICAL LABORATORY at _____
_____Street, Municipality of _____
_____ Province of _____

3. That the CLINICAL LABORATORY shall be known as _____
_____

4. That the CLINICAL LABORATORY shall be managed by Dr. _____
_____citizen, residing at
_____

5. That the owner of the CLINICAL LABORATORY is _____
_____citizen, residing at _____
_____

Wherefore, your petitioner respectfully prays that he be given license to operate said CLINICAL LABORATORY after inspection thereof._____
_____,20___.

Respectfully submitted,

_____
(Print Name and Signature)
Petitioner
Tax Account No._____

SUBSCRIBED AND SWORN to before me this _____day of _____ 20___ at _____ _____. Affiant exhibited to me his Residence Certificate No. _____ issued at _____ on_____,20___.

Doc.No._____
Page No._____
Notarial Reg.No._____
Series of_____
Documentary Stamps P3.00

_____
Notary Public
My Commission expires on Dec. 31, 20_____

PRC Board Registry:

Name of Board	Date of Exam.	Rating	Registry No.

Pathology Specialty Board:

Name of Board	Date Certified	Training Institution Accredited for (AP,CP,AP-CP)
ANATOMIC PATHOLOGY		
CLINICAL PATHOLOGY		
ANATOMIC/CLINICAL PATHO.		

Very truly yours,

_____

(Signature Over Printed Name)

FORM NO. 3

INFORMATION SHEET

IV. SERVICE CAPABILITIES