[ADMINISTRATIVE ORDER NO. 59, S. 2001, NOVEMBER 19, 2001, November 19, 2001]

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/SEC 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 C), 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

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 (P1,000.00) 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 (P100.00) for each month thereafter in addition to the P1,000.00 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 reinspection 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.