[DOH ADMINISTRATIVE ORDER NO. 2007-0027, August 22, 2007]

REVISED RULES AND REGULATIONS GOVERNING THE LICENSURE AND REGULATION OF CLINICAL LABORATORIES IN THE PHILIPPINES

I. Rationale

One of the main thrusts of current health sector reforms under FOURmula One (F1) for Health is regulation. The main objective of regulatory reforms is to ensure access to quality and affordable health products, devices, facilities and services, especially those commonly used by the poor.

Physicians utilize laboratory work-ups in aid of diagnosis and management of patients. Accuracy of laboratory results is important in assuring and improving the quality of patient care. Republic Act No. 4688 s. 1966, "An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring the Registration of the Same with the Department of Health, Providing Penalty for the Violation Thereof, and for Other Purposes", mandated the DOH to look after public welfare by effectively enforcing and updating the current regulations to improve laboratory performance.

Advances in technology necessitate the need to update the minimum standards and technical requirements for clinical laboratories. Current regulatory issuances on this matter may no longer be relevant. One of these is Administrative Order No. 59, s. 2001, entitled: "Rules and Regulations Governing the Establishment, Operation and Maintenance of Clinical Laboratories in the Philippines". Thus, this Order revises such issuance in order to ensure the quality of services of clinical laboratories nationwide.

II. Objective

This Order is promulgated to prescribe a revised minimum standard for clinical laboratories. This shall also ensure accuracy and precision of laboratory examinations in order to safeguard public health and safety.

III. Scope and Coverage

This Administrative Order shall apply to all individuals, agencies, partnerships or corporations that operate clinical laboratories in the Philippines performing examination and analysis of samples of tissues, fluids, secretions, excretions, or other materials from the human body that would yield relevant laboratory information, which physicians use for the prevention, diagnosis, and treatment of diseases, and the management and promotion of personal and public health.

Government clinical laboratories, doing microscopy work only for specific DOH

programs such as but not limited to malaria screening, acid fast bacilli microscopy, tests for sexually transmitted infections, and cervical cancer screening using Pap smears, shall be exempted from the provisions of this Order.

IV. Definition of Terms

For purposes of this Order, the following terms and acronyms shall have the following definition:

1. *Applicant* - a natural or juridical person who intends to operate a clinical laboratory

2. *BHFS* - acronym for the Bureau of Health Facilities and Services

3. *CHD* - acronym for the Center for Health Development.

4. *Clinical Laboratory* - a facility where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis and treatment of diseases. These tests include, but are not limited to, the following disciplines: clinical chemistry, hematology, immunohematology, microbiology, immunology, clinical microscopy, histopathology, cytology, toxicology, endocrinology, molecular biology, and cytogenetics. Other functions of the clinical laboratory are to provide consultative advisory services covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. Facilities that are involved in the pre-analytical processes, such as the collection, handling or preparation of specimens, or act as a mailing or distribution center, such as in a laboratory network or system are also considered to be a part of a clinical laboratory. The total testing process includes pre-analytical, analytical and post-analytical procedures.

5. *Critical Values* - panic values originally described by Lundberg as "life-threatening" unless something is done promptly and for which some corrective action could be undertaken.

6. *DOH* - acronym for the Department of Health

7. *EQAP* - acronym for External Quality Assessment Program. It is a program where participating laboratories are given unknown samples for analysis. These samples are to be treated as ordinary human specimens for the usual processing and examination. The quality of performance of the laboratory shall be assessed through the closeness of its results to the pre-determined value or to the reference value generated by the participating laboratories through peer group analysis.

8. *Inspection Tool* - the checklist used by the regulatory officers during inspection visit(s) to evaluate compliance of a clinical laboratory to the minimum standards and technical requirements.

9. *Institution* - a corporate body or establishment organized for an educational, medical, charitable, or similar purpose.

10. *License* - the document issued by the DOH to an individual, agency, partnership or corporation that operates a clinical laboratory upon compliance with the

requirements set forth in this Order.

11. *Licensee* - the individual, agency, partnership or corporation to whom the license is issued and upon whom rests compliance with this Order.

12. *LTO* - acronym for License to Operate. It also refers to the license

13. *Mobile Clinical Laboratory* - a laboratory testing unit that moves from testing site to another testing site, or has a temporary testing location. It shall have a base laboratory.

14. Monitoring Examinations - tests done in series on patients as a guide for treatment or follow-up of their condition.

15. *NRL* - acronym for the National Reference Laboratory. It is a laboratory in a government hospital which had been designated by the DOH to provide special functions and services for specific disease areas. These functions include provision of referral services such as confirmatory testing, surveillance, resolution of conflicting results between or among laboratories; training; research, implementation of EQAS; evaluation of diagnostic kits and reagents. An NRL may or may not be part of a general clinical laboratory.

16. *POL* - acronym for Physician's Office Laboratory. It is an individual doctor's office/clinic wherein laboratory examinations are performed.

17. *POCT* - acronym for Point of Care Testing. It is a diagnostic testing at or near the site or patient care rather than in the clinical laboratory. It includes bedside testing, outpatient and home care.

18. *Routine Tests* - the basic, commonly requested tests in the laboratory, the results of which are not required to be released immediately upon completion. It shall follow the usual procedures and system in the laboratory.

19. *Satellite Testing Site* - any testing site that performs laboratory examinations under the administrative control of a licensed laboratory, but performed outside the physical confines of that laboratory.

20. *STAT Tests* - tests done or urgent cases, the results of which shall be released immediately, within one (1) hour after the procedure. STAT is an abbreviation for sta'tim which means immediately.

V. Classification of Clinical Laboratories

A. Classification by Ownership

1. Government - operated and maintained, partially or wholly, by the national government, a local government unit (provincial, city or municipal), any other political unit or any department, division, board or agency thereof.

2. Private - owned, established and operated by any individual, corporation, association or organization.

B. Classification by Function

1. Clinical Pathology - includes Clinical Chemistry, Hematology, Immunohematology, Microbiology, Immunology, Clinical Microscopy, Endocrinology, Molecular Biology, Cytogenetics, Toxicology and Therapeutic Drug Monitoring and other similar disciplines.

2. Anatomic Pathology - includes Surgical Pathology, Immunohistopathology, Cytology, Autopsy, Forensic Pathology and Molecular Pathology

C. Classification by Institutional Character

1. Institution Based - a laboratory that operates within the premises and as part of an institution, such as but not limited to hospital, medical clinic, school, medical facility for overseas workers and seafarers, birthing home, psychiatric facility, drug rehabilitation center

2. Freestanding - a laboratory that does not form part of any other institution.

D. Classification by Service Capability

1. General Clinical Laboratory -

(a) Primary Category - provides the following minimum service capabilities:

i. Routine Hematology (Complete Blood Count) - includes Hemoglobin Mass Concentration, Erythrocyte Volume Fraction (Hematocrit), Leucocyte Number Concentration (White Blood Cell or WBC Count) and Leucocyte Type Number Fraction (Differential Count)

ii. Qualitative Platelet Determination

iii. Routine Urinalysis

iv. Routine Fecalysis

v. Blood Typing - for Hospital based

(b) Secondary Category - provides the minimum service capabilities of a primary category laboratory plus the following:

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

Cholesterol Concentration

ii. Quantitative Platelet Determination iii. Cross Matching- for hospital based

iv. Gram Staining - for hospital based

v. KOH - for hospital based

(c) Tertiary Category - provides the minimum service capabilities of a secondary category laboratory plus the following:

i. Special Chemistry

ii. Special Hematology, including coagulation procedures

iii. Immunology

iv. Microbiology - culture and sensitivity

- aerobic and anaerobic (for hospital based)
- aerobic and anaerobic (for non-hospital based)

A clinical laboratory, licensed under any of the above category, shall be permitted to offer laboratory services other than the respective stipulated minimum services, *provided that,* they comply with the requirements with respect to staff, equipment, reagents and supplies for such additional services, provided further, that such additional services are listed under its LTO.

(d) Limited Service Capability (for institution-based only) - provides the laboratory tests required for a particular service in institutions such as but not limited to dialysis centers and social hygiene clinics.

2. Special Clinical Laboratory

A laboratory that offers highly specialized laboratory services that are usually not provided by a general clinical laboratory.

VI. Guidelines

A. GENERAL GUIDELINES

1. The LTO shall be issued only to clinical laboratories that comply with the standards and technical requirements formulated by the BHFS.

2. Clinical laboratories that are operated and maintained exclusively for research and teaching purposes shall be exempted from the licensing requirement of this Order but shall be required to register with the BHFS.

3. Special clinical laboratories that are not subject to the provisions of other