[KPL BUREAU ORDER NO. 4, January 15, 1990]

TECHNICAL STANDARDS AND REQUIREMENTS FOR THE REGISTRATION, OPERATION AND MAINTENANCE OF CLINICAL LABORATORIES IN THE PHILIPPINES

SECTION 1. *Title* . — These standards shall be known as "Technical Standards and Requirements for the Registration, Operation and Maintenance of Clinical Laboratories in the Philippines".

SECTION 2. Authority . — These technical standards are issued to implement R.A. 4688 (Clinical Laboratory Law) with its Revised Rules and Regulations (A.O. 49-B, s. 1988) consistent with E.O. 119 (Reorganization Act of the Ministry of Health).

SECTION 3. Purpose . — These standards are promulgated to protect and promote the health of the people by preventing the operation of substandard, improperly managed and inadequately supported clinical laboratories and by improving the quality of performance of clinical laboratory examinations as well as to enable the Bureau of Research and Laboratories, Department of Health to evaluate compliance with such technical standards as requirements for the issuance of a license.

SECTION 4. Scope . — The requirements embodied herein shall apply to primary, secondary and tertiary hospital clinical laboratories and free-standing (non-hospital) clinical laboratories.

SECTION 5. Classification . — Clinical laboratories are classified according to:

1. Function — It may perform any or all of the following:

   1.1. Clinical Pathology includes clinical chemistry, hematology, microbiology, parasitology, mycology, clinical microscopy, immunology and serology, immunohematology and blood banking, radioisotope analysis and laboratory endocrinology and similar discipline.

   1.2. Anatomic Pathology includes surgical pathology, histochemistry, immunopathology, cytology and post-mortem examinations.

   1.3. Forensic Pathology includes all medico-legal examinations.

2. Institutional Character — They may either be a:

   2.1. Hospital laboratory that operates within a hospital, or

   2.2. Free-standing (non-hospital) laboratory that operate on its own or as part of an activity other than a hospital.

3. Service extent and level — They are either (1) primary; (2) secondary; or (3) tertiary category depending on the range of laboratory examinations they perform and the presence of certain manpower, materials and facilities required.

SECTION 6. Service Capabilities . — The minimum services required of each respective category of hospital and free-standing clinical laboratories shall be:

Primary Category

1. Routine Hematology — Complete Blood Count (CBC) which includes:

- Hemoglobin Mass Concentration
- Erythrocyte Volume Fraction (Hematocrit)
- Leucocyte Number Concentration (WBC)
- Leucocyte Type Number Fraction (Differential Count)

2. Routine Urinalysis

3. Routine Fecalysis

4. Gram Staining

Secondary Category

1. Routine Hematology, Urinalysis, Fecalysis and Gram Staining

2. Routine Chemistry

- Blood Glucose Substance Concentration
- Urea Substance Concentration
- Uric Acid Substance Concentration
- Creatinine Substance Concentration
- Cholesterol Substance Concentration
- Total Protein Mass Concentration

Tertiary Category

1. Routine Hematology, Urinalysis, Fecalysis and Gram Staning

2. Routine Chemistry

3. Blood Typing and Cross-matching, donor selection and blood collection for transfusion

4. Special Chemistry

5. Special Hermatology

6. Culture and Sensitivity for Bacteria

SECTION 7. Standards . — The following technical standards and requirements are to be complied with by the following corresponding category of clinical

laboratories:

I
Head

The clinical laboratory shall be managed and supervised by a physician who is licensed and duly registered with the Board of Medicine (PRC), qualified in laboratory medicine and duly authorized by the Undersecretary of Health for Standards and Regulation or his duly authorized representative.

1. Depending on the category, the following shall be the requirements:

Primary Category:

1. *Free standing Clinical Laboratory* shall be managed by a licensed physician, certified by the Philippine Board of Pathology in either Anatomic or Clinical Pathology or both.

2. *Hospital Clinical Laboratory* (in areas where Pathologists are not available) may be managed by a certified pathologist or a physician with training at least three (3) months in laboratory medicine, quality control and laboratory management and authorized by the Bureau of Research and Laboratories.

Secondary Category

1. Hospital and free-standing clinical laboratories shall be managed by a certified pathologist.

2. Hospital clinical laboratory, in areas where there are insufficient pathologists, may be managed by a physician with training of at least three (3) months in laboratory medicine, quality control and laboratory management and authorized by the Bureau of Research and Laboratories.

Tertiary Category

1. Hospital and free-standing clinical laboratories shall be managed by a certified pathologist.

2. A certified pathologist may be authorized to manage or supervise or be an Associate in not more than four (4) clinical laboratories/blood banks.

A physician who is not certified pathologist may be authorized under Sec. 7, 1-2 of A.O. #49-B, s. 1988, to manage/supervise only one (1) hospital laboratory.

II
Personnel

The clinical laboratory shall have adequate staff or qualified and trained personnel with at during hours of laboratory operation, the number of which is dependent on the workload.