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REQUIRING THE REGISTRATION AND ACCREDITATION OF DANGEROUS DRUGS TESTING LABORATORIES AND PRESCRIBING THE STANDARDS AND CRITERIA FOR SUCH

DDB BOARD REGULATIONS NO. 1, S. 1995, April 27, 1995

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Pursuant to its powers under Sections 36 (a) and 24-A of Republic Act 6425 as amended, and in accordance with the decision in its 308th Meeting on April 27, 1995, the Dangerous Drugs Board hereby prescribes the following rules and regulations:

SECTION 1. Registration and Accreditation - All dangerous drugs testing laboratories, whether government or private, shall be registered and accredited by the Dangerous Drugs Board (DDB) in accordance with the terms and conditions prescribed under the Board Regulation.

SECTION 2. Laboratory Classification - The drug testing laboratories shall be registered and accredited under the following classifications:

A. CLASS A LABORATORIES - are those that are capable of performing with competence, qualitative and quantitative examinations of dangerous drugs in the body fluids.

This class of laboratory must have all the analytical instruments, equipment, glasswares, materials and reagents which are necessary for the qualitative and quantitative examinations of dangerous drugs in the body fluids.

Class A Laboratories shall strictly comply with the following requirements:

- Drug Screening

- Technique - Immunoassay Technique or its equivalent

- Instrument (any of the following):

    b.1 Enzyme Multiplied Immunoassay Technique (EMIT)

    b.2 Fluorescence Polarization Immunoassay (FPIA)

    b.3 Radio Immunoassay (RIA)

    b.4 Agglutination Technique

- Confirmatory

- Technique

    a.1 Spectrophometric Method and

    a.2 Chromatographic Technique

- Instrument/Equipment

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b.1 Ultra-Violet Visible Spectrophotometer (UV)

b.2 Thin Layer Chromatography (TLC) or High Performance Thin-Layer Chromatograph (HPLC)

b.3 Gas Chromatograph Mass Spectrometer (GC-MS)

b.4 High Performance Liquid Chromatograph (HPLC)

b.5 Gas Chromatograph-Mass Spectrometer (GC-MS)

- Quantitative Examination

- Technique

a.1 Chromatographic Technique

- Instrument/Equipment

b.1 Gas Chromatograph (GC)

b.2 High Performance Liquid Chromatograph (HPLC)

b.3 Gas Chromatograph-Mass Spectrometer (GC-MS)

B. CLASS B LABORATORIES - are those that are capable of performing with competence, qualitative and quantitative examinations of dangerous drugs in the body fluids, using sophisticated equipment other than the GC-MS, such as Immunoassay equipment or its equivalent, UV Spectrometer, TLC, or HPTLC, GC and HPLC.

C. CLASS C LABORATORIES - are those which are capable of performing with competence, qualitative examinations of dangerous drugs in the body fluids. The laboratories shall collaborate with a Class A or B laboratory for the confirmation of their findings in body fluids, if necessary. This class of laboratory shall have the necessary instruments, equipment glasswares, reagents and materials for the analysis and identification of dangerous drugs in the body fluids.

Class C laboratories shall observe the following requirements:

- Drug Screening

- Technique

a.1 Immunoassay Technique or its equivalent

- Instrument (any of the following)

b.1 EMIT

b.2 RIA

b.3 FPIA

b.4 Agglutination Test

- Confirmatory Test

- Technique

a.1 Chromatographic Method

- Instrument/Equipment

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b.1 TLC or HPTLC

D. CLASS D LABORATORIES - are those that are capable of performing with competence, preliminary examination of dangerous drugs in the body fluids. Class D laboratories shall collaborate with Class A or Class B laboratories for confirmation of their positive results. This class of laboratory must have any of the following testing equipment to undertake the analysis, such as EMIT, RIA, FPIA, and Agglutination Test.

SECTION 3 - Seized/Referred drugs shall be examined only by the National Bureau of Investigation (NBI), the Philippine National Police Crime Laboratory (PNPCL) and the Dangerous Drugs Board (DDB).

SECTION 4 - Criteria for Accreditation and Registration -

A. Staffing - Class A and B drug testing laboratories shall have a Chemist duly licensed by the Professional Regulation Commission (PRC). However, for Class C and D laboratories, a Medical Technologist or Chemical Engineer duly licensed by the PRC, may be allowed, provided:

- he has undergone an intensive training for at least one (1) month in the analysis and identification of dangerous drugs in the body fluids;

- he has passed the Board's (DDB) Proficiency test.

The owner of the laboratory shall, likewise, secure a no-derogatory National Bureau of Investigation (NBI) Clearance before he is allowed to operate the same.

B. Facilities:

The laboratory shall have an adequate space to allow it to function efficiently, It shall be well ventilated, adequately lighted, clean and have sufficient water supply. Safety devises, as fumehood and exhaust fan shall be installed in Class A and B Laboratories. Class C and D, shall install either fumehood or exhaust fan.

C. Laboratory Results:

An accredited drug testing laboratory shall furnish the Board a duplicate copy of the laboratory examination results.

D. Laboratory Reports:

a. All laboratory reports shall be made in the printed forms especially prepared for the purpose. This is valid for a period of fifteen (15) days from the date of examination.

b. It shall be the duty of the laboratory to undertake all preventive measures which shall forestall the possible falsification of the laboratory report forms or tampering with the results of the laboratory tests.

c. The laboratory report shall be signed by a registered Chemist. However, in Class C and D laboratories, the report shall be signed by a Medical Technologist or Chemical Engineer who meets the qualifications required under Section III-A of this Regulation. The report shall further be approved and signed by the Head of the Laboratory.

E. Sampling of Body Fluids:

The quantity of samples taken shall be sufficient to allow subsequent tests. Extreme care shall be exercised to properly identify and preserve these specimens because these will be used if the affected parties challenge the reliability of the results. However, any challenge can only be made within a period of fifteen (15) days from the date of examination. Thereafter, the remaining samples shall be discarded.

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SECTION 5. Accreditation Procedures -

a. Application for Registration - Application for accreditation shall be filed only by legally identifiable organizations or persons and accomplished in the DDB prescribed application form.

b. Proficiency Testing - The DDB shall conduct proficiency testing among the Technical Staff of the Accredited Laboratories.

c. Non-compliance - Laboratories which fail to comply, to the satisfaction of the Board, with the conditions of accreditation as herein prescribed, shall be closed or their accreditation permanently revoked.

d. Laboratories whose accreditation has been revoked may reapply provided that they comply with the requirement of this Board Regulation.

e. Confidentiality - Laboratory test results, whether screening or confirmatory, and the assessment of proficiency tests shall be confidential in nature. Their contents shall not be revealed to any person other than the parents or guardian of the subject of the test or to the subject himself, if of legal age, and those charged with the prosecution or implementation of any violation of the provisions of R.A. 6425 as amended, otherwise known as the "The Dangerous Drugs Act of 1972".

SECTION 6. Registration Fees - Registration Fees in the following amounts shall be charged annually by the Dangerous Drugs Board for non-government laboratories:

CLASS A - (Yearly amount P 300.00
CLASS B - (Yearly amount P 200.00)
CLASS C - (Yearly amount P 150.00)
CLASS D - (Yearly amount P 100.00)

SECTION 7. Registration and Accreditation - An Accreditation/Technical Committee is hereby created with the following duties and responsibilities:

1. See to it that the drug testing laboratories operate at all times in accordance with the terms and conditions of their registration and accreditation.

2. Provide proper interpretation of the given and specific requirements that shall govern the operations of the laboratory.

3. See to it that the technical demands involved in laboratory work are met.

4. Provide technical notes concerning particular issues in the specialized area of testing.

5. Conduct surprise/periodic inspection of the accredited laboratory to ensure its effectiveness.

6. Perform such other duties as may be assigned to it by the Board.

SECTION 8. Violations - Any violation of these regulations shall subject the officers of the erring laboratories, such as the president, partner, director, manager, officer, stockholder, or employee who violates the provisions of this Board Regulation to administrative and/or criminal sanctions, as warranted in the premises.

SECTION 9. Effectivity - This regulation shall take effect fifteen (15) days after its publication in a newspaper of general circulation once a week after two (2) consecutive weeks.

Adopted: 27 Apr. 1995

(SGD.) MANUEL G. ROXAS, M.D., MPH

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(Undersecretary of Health and Chief of Staff)
Vice-Chairman and Presiding Officer

Attested by:

(SGD.) REY M. SAN PEDRO, M.D.
Officer-In-Charge

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