

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

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

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:

1. Drug Screening

a. Technique - Immunoassay Technique or its equivalent

b. 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

2. Confirmatory

a. Technique

a.1 Spectrophotometric Method and

a.2 Chromatographic Technique

b. Instrument/Equipment

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)

3. Quantitative Examination

a. Technique

a.1 Chromatographic Technique

b. 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:

1. Drug Screening

a. Technique

a.1 Immunoassay Technique or its equivalent

b. Instrument (any of the following)

b.1 EMIT

b.2 RIA

b.3 FPIA

b.4 Agglutination Test