



Republic of the Philippines
Office of the President
DANGEROUS DRUGS BOARD

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BOARD REGULATION No. 8
Series of 2007

SUBJECT: AMENDING BOARD REGULATION NO. 2, SERIES OF 2003, ENTITLED “IMPLEMENTING RULES AND REGULATIONS GOVERNING ACCREDITATION OF DRUG TESTING LABORATORIES IN THE PHILIPPINES”

WHEREAS, Section 39 of Republic Act 9165, also known as the “Comprehensive Dangerous Drugs Act of 2002”, mandates the Department of Health (DOH) to “license and accredit drug testing centers in each province and city in order to assure their capacity, competence, integrity and stability to conduct the laboratory examinations and tests”;

WHEREAS, the Dangerous Drugs Board (DDB) promulgated Board Regulation No. 2, Series of 2003, providing for the Implementing Rules and Regulations Governing Accreditation of Drug Testing Laboratories in the Philippines;

WHEREAS, the Drug Testing Operations Management and Information Systems (DTOMIS) was adopted by the DOH and approved by the DDB to gather data on the drug testing laboratories (DTLs) nationwide and monitor and regulate them;

WHEREAS, the DTOMIS was originally designed as an interim information technology solution, utilizing the existing hardware infrastructure of the DOH to address the need for a system to manage drug testing activities for several government agency end-beneficiaries;

WHEREAS, the National Computer Center (NCC) endorsed and released funding for the continuing upgrade of the hardware and software infrastructure development for the DTOMIS;

WHEREAS, there is a need to utilize new technologies recently made available in the Philippines to preserve the integrity and quality of laboratory examinations;

WHEREFORE, be it **RESOLVED**, as it is hereby **RESOLVED**, to amend the Dangerous Drugs Board (DDB) Regulation No. 2, Series of 2003, as hereunder provided:

Section 1. Section 3 (Definition of Terms) of DDB Regulation No. 2, Series of 2003, is hereby amended by inserting the definition of the word “**Board**” between the definition of the phrase “Applications Service Provider” and the definition of the word “Bureau”, as follows:

“**Board** refers to the Dangerous Drugs Board created under Section 77, Article IX of RA 9165.”

Bd. Reg. Amending Bd. Reg. No. 2, s. 2003 entitled “Implementing Rules and Regulations Governing Accreditation of Drug Testing Laboratories in the Philippines” 1

Section 2. Section 6, Sub-Paragraph 5.1 (Information Technology Requirements) of DDB Regulation No. 2, Series of 2003, is hereby amended, such that the provision shall now read as follows:

“5.1 The laboratory shall maintain a set of information technology (IT) equipment whose specification shall conform to the minimum requirement set by the DOH as the need arises and after due consultation with the stakeholders. New IT equipment requirements shall be disseminated through a DOH memorandum circular which shall be posted in the DOH website.”

Section 3. Section 6, Sub-Paragraph 5.2 (Information Technology Requirements) of DDB Regulation No. 2, Series of 2003, is hereby amended, such that the provision shall now read as follows:

“5.2 The laboratory shall have access to and utilize the Integrated Drug Testing Operations Management Information System (IDTOMIS), which is the Application Service Provider (ASP) approved and maintained by the DOH.”

Section 4. Section 6 (Information Technology Requirements) of DDB Regulation No. 2, Series of 2003, is hereby amended by adding Sub-Paragraph 5.3, which reads as follows:

“5.3 Collected subscription fees for the IT Provider shall be used as follows:

“5.3.1 Two-thirds (2/3) or 66.67% of the collected fees shall be used to maintain the IDTOMIS and shoulder confirmatory test requests of screening drug testing laboratories subject to the guidelines approved by the Board and the DOH; and

“5.3.2 One-third (1/3) or 33.33% of the collected fees shall be used to fund drug abuse prevention and control programs, projects and activities of the Board, subject to the guidelines approved by the Board.”

Section 5. Section 6, Paragraph 14 (Urine Specimen Collection: Handling and Disposal) of DDB Regulation No. 2, Series of 2003, is hereby amended, such that the entire paragraph shall now read as follows:

“14. Urine Specimen Collection: Handling and Disposal

“The laboratory shall follow the DOH-prescribed guidelines in the collection, handling and disposal of urine specimens. Universal precaution shall be observed at all times.

“14.1 Clients and analysts shall be required to submit fingerprints for every drug testing transaction following the IDTOMIS Manual as adopted by the Board.

“14.2 Laboratories shall use waterless urinals to prevent dilution and tampering of specimen.

“14.3 Confirmatory laboratories shall comply with the procedures prescribed in the Quality Manual for Confirmatory Drug Testing Laboratories as adopted by the Board.”

Section 6. Section 9 (Procedural Guidelines for Accreditation) of DDB Regulation No. 2, Series of 2003, is hereby amended, such that the entire section shall now read as follows:

“Section 9. Procedural Guidelines for Accreditation

“1. The applicant shall submit the following documents before an initial certificate of accreditation shall be issued:

“1.1 DOH Prescribed Application Form - filed either at the Bureau or CHD

“1.2 DTI/SEC Registration (for private laboratory) or Enabling Act (for national government laboratory) or Approved Board Resolution (for local government laboratory)

“1.3 One (1) set of Floor Plan showing specific location of equipment and work areas required, appropriately dimensioned, properly identified and completely labeled, and signed and sealed by an architect or engineer

“1.4 List of Personnel, notarized, including xerox copies of current PRC identification cards and certificates of training

“1.5 List of Equipment with specifications

“1.6 Contract of Lease (if facility is rented)

“1.7 Procedure Manual

“1.8 Chain of Custody Form

“1.9 Facility Tax Identification Number

“2. The following requirements shall be submitted within the first six (6) months of operation after issuance of the initial certificate of accreditation:

“2.1 Documentation of Quality Control Program (for screening laboratory)

“2.2 Certification for Quality Standard System from a DOH-recognized certifying body (for confirmatory laboratory)

“3. The applicant shall observe the following procedures for application for initial certificate of accreditation:

“3.1 The applicant requests for relevant information and prescribed form from the Bureau or CHD under whose jurisdiction the proposed laboratory is located either in person or through mail, e-mail or internet.

“3.2 The applicant accomplishes required documents and submits them to the Bureau or CHD. Upon filing of application, the applicant pays the corresponding fees to the Cashier of the Bureau or CHD either in person, through postal money order or directly to the accredited collecting bank of the DOH.

“3.3 The Bureau or CHD conducts survey on site to determine compliance with standards and technical requirements of accreditation.

“3.4 The Bureau approves or disapproves the issuance of certificate of accreditation.

“3.4.1 If approved, the Bureau registers the laboratory and issues an initial certificate of accreditation to the applicant upon deposit of twenty thousand pesos (P20, 000) cash bond.

“3.4.2 If disapproved, the Bureau sends the findings and recommendations to the applicant for compliance.

“3.5 If the laboratory has not been approved for accreditation, it may submit an appeal to the Secretary of Health or designated authority within fifteen (15) days from the receipt of the official denial of application.

“4. Hospital-based laboratories shall be licensed as part of the hospital through the One-Stop-Shop Licensure for Hospitals and are not required to obtain a separate accreditation.”

Section 7. Section 13 (Renewal Certificate of Accreditation) of DDB Regulation No. 2, Series of 2003, is hereby amended, such that the entire section shall now read as follows:

“Section 13. Renewal Certificate of Accreditation

“1. Application for renewal of accreditation shall be filed ninety (90) days before the expiry date to the Bureau or CHD under whose jurisdiction the laboratory is located.

“2. The applicant shall submit the following documents before a renewal certificate of accreditation shall be issued.

“2.1 Notarized: Application for Renewal of Certificate of Accreditation

“2.2 List of Personnel

“2.3 List of Equipment/Instruments

“2.4 Current Certificate of Accreditation

“2.5 Documentation of Chain of Custody

“2.6 Facility Tax Identification Number

“2.7 Current Certification for Quality Standards Systems-For Confirmatory Laboratory (renewed yearly)

“2.8 Documentation/contract for confirmation of screened positive specimens

“2.9 Currently Proficiency Test Result (renewed yearly)

“3. The applicant shall observe the following procedures for renewal of certificate of accreditation:

“3.1 The applicant requests for relevant information and prescribed form from the Bureau or CHD under whose jurisdiction the proposed laboratory is located either in person or through mail, e-mail or internet.

“3.2 The applicant accomplishes required documents and submits them to the Bureau or CHD. Upon filing of application, the applicant pays the corresponding fees for renewal to the Cashier of the Bureau or CHD either in person, through postal money order or directly to the accredited collecting bank of the DOH.

“3.3 The Bureau or CHD conducts a survey to determine compliance with standards/requirements.

“3.4 The Bureau approves or disapproves the issuance of certification of accreditation.

“3.4.1 If approved, the Bureau renews the certificate of accreditation to the applicant.

“3.4.2 If disapproved, the Bureau sends the findings and recommendations to the applicant for compliance. The applicant requests the Bureau for another survey.

“3.5 If a laboratory has not been approved for renewal, it may submit an appeal to the Secretary of Health or designated authority within fifteen (15) days from the receipt of the official denial of application.”

Section 8. Section 16 (Violations) of DDB Regulation No. 2, Series of 2003, is hereby amended by adding the following sub-paragraphs after Sub-Paragraph 9:

“10. Refusal to perform tests on submitted specimens for screening or confirmation.

“11. Failure to follow the prescribed flow of activities described in the IDTOMIS Manual and Quality Manual for Confirmatory Drug Testing Laboratories as adopted by the Board.”

Section 9. This Regulation shall take effect fifteen (15) days after its publication in two (2) newspapers of general circulation and after its registration with the Office of the National Administrative Register (ONAR), UP Law Center, Quezon City.

ADOPTED and APPROVED this 11th day of December, in the year of Our Lord, 2007 in Quezon City.

Secretary ANSELMO S. AVENIDO, JR.
Chairman, Dangerous Drugs Board

Attested by:

Undersecretary EDGAR C. GALVANTE
Secretary of the Board