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## **BOARD REGULATION No. 3** **Series of 2006**

### **SUBJECT: GUIDELINES FOR THE DRUG PROFICIENCY TESTING (PT) PROGRAM FOR DRUG TESTING LABORATORIES (DTLs)**

Pursuant to the powers vested in the Dangerous Drugs Board under Section 81(b) and (k), Article IX of RA 9165, otherwise known as the Comprehensive Dangerous Drugs Act of 2002, and in consultation and coordination with the Department of Health (DOH), the following Guidelines for the Drug Proficiency Testing (PT) Program for Drug Testing Laboratories are hereby prescribed:

#### **I. Scope:**

All Drug Testing Laboratories (DTLs) shall participate and pass the annual Proficiency Test (PT) as part of their accreditation and re-accreditation/renewal requirements.

#### **II. Reference:**

Section 39, Article III of Republic Act 9165 also known as the "Comprehensive Dangerous Drugs Act of 2002" mandates the Department of Health 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 provided in this article..."

Similarly, Section 6 (16) of the Dangerous Drugs Board Regulation No. 2, series 2003, and the DOH Implementing Rules and Regulations (IRR) governing accreditation of the Drug Testing Laboratories in the Philippines mandate the conduct of a continuing assessment of the proficiency of Screening and Confirmatory laboratories.

#### **III. Rationale:**

The Department of Health (DOH) is responsible for setting and implementing the standards and guidelines of operations, as well as the monitoring, of drug testing laboratories in the country, thus, it is tasked to assure the capacity, competence, integrity, and stability in the conduct of the examination as mandated by RA 9165. The National Reference Laboratory at East Avenue Medical Center (NRL-EAMC) shall formulate, design, implement and evaluate the systems and procedures both administrative and technical as well as work instructions for this program. This will assure the public of quality drug tests and value for money.

#### IV. Definition of Terms:

**Proficiency testing:** refers to the external assessment of a laboratory's performance by the National Reference Laboratory, the PT provider, using samples of known but undisclosed content, in order to assure competence and reliability of test results.

**Laboratory:** refers to a private or government facility that is capable of testing a specimen to determine the presence or absence of dangerous drugs.

**Specimen:** refers to the biological sample that is collected from a person for testing.

**Procedure Manual:** refers to the Manual of Operations for Drug Testing Laboratories published by the National Reference Laboratory which contains the detailed steps to be followed when undertaking a particular task.

#### V. Objectives:

1. To assure competency of Drug Testing Laboratories and their compliance with the standards of conduct for drug tests;
2. To provide assessment for the regulation of Drug Testing Laboratories; and
3. To continually assure the public of Quality Drug Testing Services.

#### VI. General Guidelines:

1. The **Department of Health, thru the National Reference Laboratory for Environmental, Occupational Health, Toxicology and Micro-Nutrient Assay, based at East Avenue Medical Center, East Avenue, Quezon City**, is tasked to conduct a **Proficiency Test (PT)** for screening and confirmatory drug testing laboratories.
2. Specific requirements for Accreditation:
  - 2.1. For Screening Drug Testing Laboratory (STDL)

A Screening Drug Testing Laboratory shall pass the proficiency test conducted by the NRL before the renewal of their accreditation on an annual basis.
  - 2.2. For Confirmatory Drug Testing Laboratory (CTDL)

As part of the CDTL's accreditation, the laboratory shall pass the initial Proficiency Test during the process of initial accreditation application and a maintenance PT for subsequent re-accreditation.
3. All procedures associated with handling and testing of the proficiency-testing sample shall, to the greatest extent possible, be carried out in a manner identical to the routine specimen;

4. The PT cycle shall be conducted preferably in three geographical batches, representing DTLs in Luzon, Visayas and Mindanao. The Philippine Institute of Applied Chemistry (PIPAC) shall assist the NRL during the first nationwide conduct of PT;
5. Procedural steps for the conduct of the Proficiency Test program:
  - 5.1. The NRL shall inform the Bureau of Health Facilities and Services (BHFS) and DTLs regarding the PT schedules.  
**(See Annex A: Letter of Announcement.)**
  - 5.2. The DTL shall submit a Letter of Intent of participation thru DTOMIS.
  - 5.3. The NRL shall prepare the PT samples/unknowns according to the following guidelines:
    - 5.3.1. To prevent analytical bias and ensure confidentiality, the DTL shall be assigned a laboratory code that shall only be known to few, selected laboratory personnel. These assigned lab codes shall vary from every cycle of the PT program.
    - 5.3.2. Urine shall be the specimen test matrix, predetermined to contain normal constituents for urea, creatinine, crystals, pH and specific gravity. In the future, PT specimen test matrix may use other types of sample such as hair or blood.
    - 5.3.3. A predetermined number of PT sample formulations are prepared for every DTL, containing negative metabolite and spiked with Methamphetamine and THC in varying concentration (50% below the cut-off; at the cut-off and 150 % above the cut-off levels). The concentrations of the samples have been quantified using GC-MS, and assayed for homogeneity and intermediate stability.  
Note: The concentration formulation of the drugs /metabolite may vary from different batches and cycles. In the future, other drugs such as morphine, opiates, Methylene-dioxymethamphetamine (MDMA), etc. adulterants or interfering substances may be added to the formulations.
    - 5.3.4. From the twenty (20) formulations, ten (10) PT samples/ unknowns shall be distributed to the DTL based on a protocol for randomization. A computer program for allocation of randomized samples of different concentrations is done with automatic printing and labeling of sample codes into vials.
    - 5.3.5. The PT samples are contained in a polypropylene test vials, packed in dry ice with specific instructions for specimen handling to the DTLs.
  - 5.4. The NRL shall distribute the samples to the DTL within a specified period of time. This shall be accomplished either thru sample pick-up at NRL, East Avenue or thru the use of a contracted delivery courier.
  - 5.5. Upon receipt of the PT samples, the DTL's are instructed to inspect the samples, analyze them and submit the results within 48 hours thru DTOMIS using the acknowledgement form and

result form provided. Hard copies of these forms shall also be mailed to NRL. (See **Annex B: Acknowledgement Form** and **Annex C: Result Form.**)

5.6. The results are statistically evaluated using modified MEQUALAN/Poisson method of analysis of binary responses. Scoring pattern is developed and DTLs are ranked accordingly and inter-laboratory peer performance evaluated.

(See **Annex D: Graphical Representation of PT.**)

5.7. The NRL shall send the Final results and recommendations of the DTL's performance in the Proficiency Test to participating laboratories. A Proficiency Certificate shall be given to the DTL who has passed the proficiency test.

(See **Annex E: Final Result Form.**)

## **VII. Cost of Proficiency Testing:**

Upon submission of a Letter of Intent of participation thru DTOMIS, the DTL shall pay the corresponding PT fee, which covers expenses for sample handling, delivery (courier), sample preparation, documentary forms, Quality Assurance Program, standards, certified reference materials, chemicals and reagents, statistical analysis and other necessary materials needed.

The DOH shall determine the PT cost subject to the approval of the DDB.

## **VIII. Failure to Pass PT Tests:**

A DTL that fails to pass the PT shall be given another test, not earlier than one month after the failed test. Failure to pass the PT shall result in the suspension of its accreditation. Failure to pass the second proficiency test shall result in the revocation of its accreditation.

## **IX. Violations:**

Failure to comply with any provision of the above-mentioned regulation shall be subject to administrative sanctions as well as the penal provisions under Section 32 of RA 9165.

## **X. Separability:**

In the event that any provision of these Guidelines or the application thereof to any person, company, organization or circumstance is held invalid, other provisions of these Guidelines and the application of such, to other persons, companies, organizations or circumstances shall not be affected thereby.

## **XI. Effectivity:**

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

**APPROVED AND ADOPTED** this 6<sup>th</sup> day of June, in the year of Our Lord 2006 in Quezon City.



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

Attested:



**Undersecretary EDGAR C. GALVANTE**  
Secretary of the Board