



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

July 19, 2010

ADMINISTRATIVE ORDER  
No. 2010 - 0024

**SUBJECT Requirement of Permit to Construct in the Establishment of Free-standing Screening Drug Testing Laboratories Nationwide**

**I. BACKGROUND AND RATIONALE:**

Pursuant to Republic Act 9165 otherwise known as the "Comprehensive Dangerous Drugs Act of 2002" and its Implementing Rules and Regulations (IRR) and as specified in the Manual of Operations for Drug Testing Laboratories in the Philippines,- the Department of Health (DOH) is mandated to oversee and monitor the integration coordination and supervision of all drug rehabilitation, intervention after-care and follow — up programs, projects and activities as well as the establishment operation maintenance - and management of privately- -owned drug treatment rehabilitation centers and drug testing networks and laboratories throughout the country, in coordination with other government agencies. Moreover, the responsibility of the DOH, through its principal regulatory office, the Bureau of Health Facilities and Services (BHFS) is to accredit drug testing laboratories in order to assure quality, competence and integrity in the conduct of drug testing.

The East Avenue Medical Center (EAMC) is designated by the Secretary of Health as the National Reference Laboratory (NRL) for Environmental and Occupational Health, Toxicology and Micronutrient Assay. The NRL in coordination with the BHFS shall assure the competence, integrity and stability of drug testing centers nationwide.

Furthermore, the BHFS is mandated to formulate and establish the standards for regulation of hospitals, clinics and other health facilities and to enforce standards that shall be the basis of Issuance of license/accreditation of a facility. In accordance with this mandate, the BHFS shall undertake the following tasks : - '

1. Develop policies and guidelines on the establishment operation-and monitoring of drug testing laboratories;
2. Conduct accreditation of all private and government drug testing laboratories
3. Conduct training of DOH regulatory officers, '
4. Conduct research and development on drug testing and other related activities.

In pursuit of the Said mandate, specifically on the accreditation of Drug Testing Laboratories (or

DTL's) nationwide, the BHFS will officially prescribe the requirement of DOH Permit to Construct (or DOH- PTC) for all new applications including transfer of site and change in ownership in the establishment of freestanding Screening Drug Testing Laboratories (SDTL), both government and privately owned, in a countrywide coverage. In addition, the BHFS shall officially require the said application for a DOH PTC and its subsequent approval as a prerequisite prior to the application for accreditation by the freestanding SDTL. Concurrent to this, the BHFS is also authorized to set fees and charges by just and reasonable rates to cover the cost of services rendered and partly to support and to sustain the needed reforms in health regulation.

Lastly, in consonance with the above specific tasks such as conduct of research and development on drug testing and other related activities among others, the BHFS has embarked on the development of prototype plan/s for a freestanding SDTL with the accompanying technical guidelines and specifications.

## II. OBJECTIVE :

As stated in the DOH Manual of Operations for Drug Testing Laboratories in the Philippines, the general objectives include the following

1. Standardize the procedure of drug testing services in the Philippines among all stakeholders;
2. Implement quality assurance program in drug testing laboratories nationwide.

Consistent with the above objectives and in pursuit of the licensing function of the BHFS, the primary objective of this Order is to formally impose the requirement of DOH— Permit To Construct (DOH- -PTC) for all new applications including transfer of site, lapsed accreditation and change in ownership in the establishment of free standing Screening Drug Testing Laboratories (SDTL), government and privately owned, on a nationwide scope. Through this DOH- PTC requirement, the BHFS will be able to screen, review and evaluate new applications for the subject facility with the end goal of permitting only those that will sufficiently comply with the established standards and guidelines together with the other statutory requirements.

As part of its technical assistance, the BHFS shall prescribe prototype plan/s for a freestanding SDTL facility with technical guidelines and specifications for the general information, guidance and compliance of prospective applicants.

Through the above objectives, the BHFS aims to assure the physical acceptability, functional planning and standard design of all approved new applicants of free—standing SDTL including the quality service that they shall eventually render to their clientele.

## III. SCOPE and COVERAGE:

This Order shall be applicable to all government and privately-owned freestanding SDTL's in the Philippines that will apply for New Application with the purpose of establishing, operating and

maintaining a free—standing Screening Drug Testing Laboratory including these freestanding SDTL's with lapsed accreditation and with change of ownership.

#### IV. DEFINITION OF TERMS:

Accreditation: refers to the formal authorization issued by the DOH to an individual, partnership, corporation or association Which has complied- with all licensmg requirements (input/structural standards) and accreditation requirements (process standards and outcome/output/impact standards) as prescribed in the Manual of Operations for Drug Testing Laboratories issued by the DOH. '

Applicant : refers to the owner or president of a freestanding Screening. Drug Testing Laboratory that is applying for the Issuance of a DOH-Permit To Construct and subsequently a Certificate of Accreditation;

BHFS : refers to the Bureau of Health Facilities and services, that shall exercise the regulatory function.

CDA : refers to Cooperative Development Authority. '

CHD : refers to the Centers for Health Development under the Department of Health that are located in the various regions of the country. .

DTI : refers to Department of Tradeand Industry.

DOH : refers to the Department of Health.

DOH Permit-to Construct (or DOH — PTC) : refers to the authority issued by the DOH— BHFS to an Applicant who will establish and operate a freestanding Soreening Drug Testing Laboratory upon compliance with required documents set forth-in this Order'p'rior - to the actual constructiOn of the subject facility.

Freestanding : refers to an adjective that means standing alone, independent, not attached to any health facility regulated by the DOH.

Drug Testing Laboratory : refers to a private or government diagnostic facility that performs a laboratory examination of human biological specimen for identification of dangerous drugs

New application : refers to all initial applications including transfer of site, change of ownership and lapsed accreditation.

Screening Drug Test : refers to the test used to differentiate a non-reactive specimen from one that requires fUrther testing; for drugs or drug metabolites.

SDTL: refers to Screening Drug Testing Laboratory.

SEC: refers to Securities and Exchange Commission.

## V. GUIDELINES:

### A. GENERAL GUIDELINES:

1. A DOH-PTC Shall be required for the construction of all new freeStanding SDTL.
2. All applicants prior to the submiSSION of an Application for Accreditation must first secure an approved DOH-PTC from the BHFS. No accreditation Shall' be issued without the approved DOH —PTC.
3. All freestanding SDTL'S Shall conform with the prescribed requirements for the standardized physical plant set— —up and design Specifications provided in the Prototype Floor Plan/S for freestanding SDTL duly prepared and approved by the BHFS (refer to ANNEXES' "" ,A B" and "C").
4. A non- refundable fee Shall be charged forthe Application for a DOH- PTC for all new applicants of freestanding SDTL either government or private (refer to item VI. Schedule of Fees).
5. A DOH- PTC Shall be considered lapsed and the fee paid shall be forfeited when the work authorized by the permit does not commence within ninety (90) calendar days from date of Issuance or is abandoned during the period specified.

### B. PROCEDURAL GUIDELINES: 1. Required Documents for Application of DOH—PTC:

The following are the required documents to be accomplished and/or submitted before a DOH-PTC can be issued to an Applicant of freestanding SDTL :

- a. "Duly accomplished Application. Form ;
- b. Proof of Ownership:  
DTI registration;  
SEC registration with Articles of Incorporation and By-laws;  
Enabling Act/Board Resolution (for Government)  
Cooperative Development Authority (CDA) registration with Articles of Cooperation and By-laws
- c. Three (3) Sets of Architectural Floor Plans with Location Map (Note: Minimum scale for floor plans Shall be 1: 100 m Showing complete areas, labels and dimensions. All plans shall be signed and sealed by an Architect or Engineer); .

### 2. Procedures for Application for DOH Permit To Construct (DOH-PTC):

- a. The Applicant shall secure a copy of the prescribed Application Form for the DOH-PTC from the BHFS or CHD that has jurisdiction over the proposed freestanding SDTL, or through the DOH

website- ([www.doh.gov.ph](http://www.doh.gov.ph)).

b. The Applicant accomplishes the said form together with the necessary attachments then formally submits to the BHFS. Upon filing of application, the Applicant pays the corresponding fee to the Cashier of the DOH in person, or through postal money order.

c. The BHFS, through the Health Facility Establishment Review Committee (or HFERC) Shall review and evaluate the submitted plans and documents of the subject facility with respect to basic requirements and with the prescribed prototype plan/s and technical guidelines in the planning and design of a freestanding SDTL. Then, the BHFS approves or disapproves the issuance of a DOH—PTC. ' '

d. If disapproved, the BHFS returns the documents, together with their findings and recommendations to the Applicant. The Applicant makes the necessary revisions on the documents. The Applicant submits the revised documents- to the BHFS for another review. The Applicant is entitled to only one revision.

e. If approved, the BHFS issues a DOH—PTC to the Applicant.

#### SCHEDULE OF FEES:

1. A non—refundable fee of one thousand (P1,000.00) . pesos only "or as prescribed by the DOH in its future issuances shall be charged for the Application for a DOH- PTC for freestanding SDTL either government or privately owned.

2. All checks Shall be paid to the order of DOH in person or through postal money order or through online payment, if available, as, the case may be.

#### VII. APPEAL:

The decision of the HFERC may be appealed to the Office of the Director of BHFS within ten (10) days after receipt of the notice of the decision. The decision of the BHFS - Director is final and executory.

#### VIII. REPEALING CLAUSE:

Provisions from previous issuances that are inconsistent or contrary to the provisions of this Order are hereby rescinded and modified accordingly.

#### IX. SEPARABILITY CLAUSE.

In the event that any provision or part Of this Order be declared unauthorized or rendered invalid by any court of law or competent authority, those provisions not affected by such declaration shall remain valid and effective.



## X. EFFECTIVITY

This Order Shall take effeCt fifteen (15) days after its apprOval and publicatiOn in a newspaper of general Circulation.

**ENRIQUE T. ONA, MD, FPCS, FAC**  
Secretary of Health



Republic of the Philippines  
Department of Health  
Bureau of Health Facilities and Services

	<b>LEGEND :</b>  ROOM LABELS / NOTES
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