

**[DOH ADMINISTRATIVE ORDER NO. 2010-0024,
July 19, 2010]**

**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. OBJECTIVES

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 functions 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 those 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 licensing requirements (inputs/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.