



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

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February 3, 2009

DEPARTMENT MEMORANDUM
No. 2009-0086

TO: BUREAU DIRECTORS, CHD DIRECTORS, HEADS OF NRLs, HOSPITAL CHIEFS, HEAD OF CLINICAL LABORATORIES, REGULATORY OFFICERS, NCHFD AND OTHERS CONCERNED OFFICIALS

SUBJECT: IMPLEMENTATION OF EXTERNAL QUALITY ASSESSMENT PROGRAM AS A REGULATORY REQUIREMENT FOR LICENSING OF CLINICAL LABORATORIES

Pursuant to Administrative Order No. 2007-0027 entitled "Revised Rules and Regulations Governing the Licensure and Regulation of Clinical Laboratories in the Philippines," a clinical laboratory is required to have a Quality Assurance Program (QAP). The QAP shall include an Internal and External Quality Control Program. The Internal QAP covers inputs, processes and outputs as well as practice of continuous Quality Improvement Program covering all aspects of laboratory performance. On the other hand for External Quality Assessment Program (EQAP) a clinical laboratory is required to participate in the National External Quality Assessment Scheme (NEQAS) administered by the designated National Reference Laboratories (NRLs) or in other local or international EQAP recognized by the Department of Health. The NEQAS shall be conducted to ensure that laboratory procedures are done in accordance with standards and laboratory results are accurate and within the standard range for quality health care.

As provided in Department Order No. 393-E s. 2000, five institutions were designated as the National Reference laboratories namely:

Research Institute for Tropical Medicine – National Reference Laboratory for Dengue, Influenza, Tuberculosis and other Mycobacteria, Malaria and other parasites, Bacterial enteric diseases, Measles and other Viral exanthems, Mycology, Enteroviruses, Antimicrobial resistance and Emerging Diseases; NRL for confirmatory testing of blood units.

San Lazaro Hospital – National Reference Laboratory for HIV/AIDS, Hepatitis, Syphilis and other Sexually Transmitted Infections (STIs).

East Avenue Medical Center- National Reference Laboratory for Environmental and Occupational Health; Toxicology and Micronutrient Assay

National Kidney and Transplant Institute - National Reference Laboratory for Hematology including Immunohematology, Immunopathology and Anatomic Pathology (consistent with previously issued D.O. 301-I s. 1999)

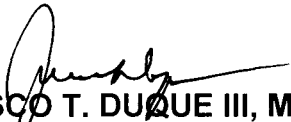
Lung Center of the Philippines- National Reference Laboratory for Biochemistry.

The following specific guidelines shall be enforced to initially implement the NEQAS:

1. A certificate of participation/registration in NEQAS shall be a licensing requirement for the renewal of license to operate a clinical laboratory for 2009 in the following areas:
 - a. Hematology - Primary, Secondary and Tertiary Clinical Laboratories in the National Capital Region (NCR).
 - b. Clinical Chemistry - Tertiary Clinical Laboratories in the National Capital Region (NCR) and Center for Health Development IV-A CALABARZON.
 - c. HIV/AIDS , Hepatitis B & C Proficiency Testing - All HIV Accredited Testing Laboratories and Secondary and Tertiary Clinical Laboratories performing Hepatitis B and C tests.
 - d. Drug and Water Proficiency Testing - All Water and Drug Testing Laboratories.
2. A Certificate of Participation shall be issued by the NRLs to the participating clinical laboratory every time NEQAS is conducted. For the initial implementation of NEQAS, only one (1) certificate is required for the renewal of license to operate.
3. NEQAS/Proficiency Testing for Drug and Water Testing Laboratories requires participation and a satisfactory rating on the survey. For Microbiology, TB and Parasitology, participation in the three component is required and a certificate of participation is issued by the Microbiology Department of RITM. **A certificate of participation in Antimicrobial Resistance Surveillance Program (ARSP) is recognized as NEQAS for Microbiology component** only, and participation in the TB and Parasitology component is still required.
4. The schedule of fees per participation is as follows:

2.1 Hematology	P 2,000.00
2.2 Clinical Chemistry	P 2,000.00
2.3 HIV/AIDS, Hepa B & C	P 2,500.00
2.4 Drug Proficiency Testing	P 1,000.00
2.5 Water Proficiency Testing	P 2,500.00
2.6 Microbiology	P 5,000.00

For strict compliance.


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Secretary of Health