



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DEC 28 2020

DEPARTMENT ORDER:

No. 2020- 0820

SUBJECT: Institutionalizing and Strengthening the National Reference Laboratories in the Philippines

I. RATIONALE:

National Reference Laboratories (NRLs) were established through **Department Order No. 393-E s. 2000**, otherwise known as the "*Designation of National Reference Laboratories and Transfer of Corresponding Equipment, Instruments, Supplies, Specimens, and Records from the Bureau of Research and Laboratories to the Designated National Reference Laboratories*," to improve the quality of health services and establish an effective public health laboratory network in the country in line with the Service Delivery Network pillar of FOURmula 1 Plus towards the attainment of Universal Health Care goals. The Technical Working Group (TWG) pursuant to Department Order No. 62-F s. 2002 evaluated the NRLs based on the service capability and readiness of the host's hospital. The six (6) hospitals designated as NRLs are the following:

1. East Avenue Medical Center (EAMC)
2. Lung Center of the Philippines (LCP)
3. National Kidney and Transplant Institute (NKTII)
4. Philippine Heart Center (PHC) – *designated through DPO No. 2009-5148*
5. Research Institute for Tropical Medicine (RITM)
6. San Lazaro Hospital (SLH)

Administrative Order No. 0021 s. 2012, otherwise known as the "*National Framework of the National Health Laboratory Network*," provides the framework for the organization of all government and private laboratories at all levels into a functional National Health Laboratory Network (NHLN), in order to define the road map and direction for strengthening and promoting the institutional and operational capabilities of the health laboratories. The NRL is recognized to provide technical leadership in the related field and is considered to be the highest level laboratory amongst various laboratory levels in the Philippines.

This Order aims to strengthen the NRLs to better respond to various needs of the health sector especially during outbreaks and pandemics.

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II. OBJECTIVES:

A. General Objective:

To provide an updated policy and mandate for the existing six (6) designated host hospitals with the NRL, through institutionalization of their operations, and its structural and functional distinction from the host hospital's main/central laboratory.

B. Specific Objectives:

1. To provide an enabling mechanism for the institutionalization and operations of the NRLs, including the budget, manpower complement, and mechanisms for sustainability.
2. To institutionalize and harmonize enabling mechanisms in the operations of the NRL, thereby providing improved services.
3. To strengthen the capacity and capability of NRLs through networking, partnership and collaboration with other international reference laboratories in line with the Universal Health Care for the Filipinos and for the NHLN to be at par with counterpart national reference laboratories in the ASEAN region, and with international standards for laboratory methods and technology and to provide critical inputs as guide to Department of Health (DOH) policies and stakeholder's response activities.

III. SCOPE AND COVERAGE:

This Order shall apply to the six (6) host hospitals with their designated NRLs based on technical expertise as well as other pertinent DOH Offices, and attached agencies as mentioned in this order (Refer to Annex A).

IV. DEFINITION OF TERMS:

- A. **National Reference Laboratories (NRLs)** – the highest level of laboratory in the country performing high complex procedures including confirmatory testing that is not commonly performed by the lower level of laboratory. It is the responsible entity for facilitating National External Quality Assessment Scheme (NEQAS) to ensure compliance of quality standards for regulation and licensing of all laboratories in the Philippines;
- B. **National External Quality Assessment Scheme (NEQAS)** – a quality assurance activity conducted by the NRLs to assess the quality of performance and accuracy of test results of laboratories. It is used as a requirement of laboratories for the renewal of license to operate;
- C. **In-Vitro Diagnostic Medical Device (IVDMD)** – any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donation, derived from the human body, solely or principally for the purpose of providing information on:

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1. physiological or pathological state;
2. congenital abnormality;
3. safety and compatibility of donations, including blood and tissue donations, with potential recipients; or
4. therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its product owner to be used for in vitro diagnostic examination;

V. GENERAL GUIDELINES:

- A. The DOH shall provide standards in ensuring quality laboratory services to guide laboratory testing procedures in all levels of care.
- B. NRLs shall provide improved access to quality, specialized health laboratory services in their respective areas of technical expertise, to cater to the needs of and which is not otherwise available in other tertiary category health laboratory facilities.
- C. NRLs shall be strengthened in order to provide support to the sub-national, regional, public health laboratories, and referral networks of health laboratory facilities based on service mandates.

VI. SPECIFIC GUIDELINES

- A. To provide an enabling mechanism for the institutionalization and operation of the NRLs:
 1. The NRL shall be recognized as an operational unit with well-defined organizational structure and mandate distinct from the functions and operations of the host hospital's general clinical laboratory.
 2. The NRL operations shall be included as a line item in the National Budget for the DOH.
 3. Upon approval of the requested positions from the Department of Budget and Management, the NRLs shall ensure adequate staffing complement to include the following: management staff, technical staff, and support staff (i.e. data management, administrative, information technology, and biomedical engineering).
 4. The NRL shall be provided with additional operational budget for functions related to national programs of the DOH especially during pandemics and outbreaks.
 5. The NRLs shall retain 100% of its self-generated income and shall incorporate in their Work and Financial Plan (WFP) the contributions to the host hospital to cover for operational expenses which may include but are not limited to utilities (i.e. electricity, water, telephone, internet), supplies, use of other hospital facilities, and other preventive maintenance fees.

B. To strengthen the capacity and capability of NRLs:

1. The NRL shall be capacitated with state-of-the-art equipment, infrastructure and application software suitable for reference laboratory work.
2. The NRL shall work within the efficient and effective Quality Management Systems of its host hospital.
3. The NRL shall be provided with quality supplies, reagents, quality control materials, reference standards and other laboratory supplies for appropriate reference laboratory work; relevant training, continuing education and participation in pertinent avenues for learning and development of NRL staff locally and internationally; appropriate infrastructure, equipment and laboratory facilities; avenues for linkages with networks and partnerships with national and international agencies and reference laboratories.
4. The NRL shall attain certification and accreditation to international quality standards relevant to its operations, to include but not limited to: ISO 9001 (Quality Management System); ISO 15189 (Medical Laboratories – Particular Requirements for Quality Standards and Competence); ISO/IEC 17043 (General Requirements for the Competence of Providers of Proficiency Testing Schemes); ISO/IEC 17025 (General Requirements for the Competence of Testing and Calibration Laboratories).

VII. ROLES AND RESPONSIBILITIES

A. National Reference Laboratories (NRLs):

1. Provide laboratory referral services, e.g., for confirmatory testing, surveillance, outbreak response, and research.
2. Administer the NEQAS to assess the quality of performance and test results of clinical laboratories in collaboration with the Health Facilities and Services Regulatory Bureau.
3. Conduct training to upgrade knowledge and improve the skills of laboratory personnel.
4. Evaluate IVDMD to include reagents in collaboration with the Food and Drug Administration.
5. Provide technical assistance to the DOH, other government agencies, private sector and international partners, as the need arises.
6. Implement surveillance systems to provide critical inputs as guide to DOH policies and stakeholders' response activities.
7. Assess and recommend to the DOH the establishment of subnational reference laboratories, public health laboratories in areas that need special tests not done by a general clinical laboratory.

8. Participate in the Service Delivery Network as the highest level of laboratory services.

B. Health Facility Development Bureau (HFDB):

1. Develops plans, policies, programs, projects and strategies related to health facility development, planning, operation and maintenance of NRLs.
2. Provides technical assistance in the development and strengthening of all NRLs through capability building and advisory services.
3. Acts as the secretariat to the National Health Laboratory Network and its Technical Working Groups.
4. Ensures funds and other resources are provided for the development of NRLs.
5. Consolidate, analyzes, and transmits accomplishment reports of the NRLs to the DOH Management.
6. Supports the achievement of quality and accessible healthcare facilities for better health outcomes as one of the goals of the Universal Health Care.

C. Host Hospitals where NRLs are lodged:

1. Includes NRLs in the Operational Plans of the hospital.
2. Ensures adequate funds are allocated for the continuous operation of the NRLs.
3. Provides administrative support, human resources, and physical infrastructure dedicated to NRLs.

D. Health Facilities and Services Regulatory Bureau (HFSRB):

1. Enforces the effective implementation and participation of laboratories in the NEQAS program of the NRLs.

E. Food and Drug Administration (FDA):

1. Coordinates with the appropriate NRL for the technical evaluation of In-Vitro Diagnostic Medical Devices prior to the issuance of the Certificate of Product Registration, when necessary.

VIII. REPEALING CLAUSE

Department Order 393-E s.2000 dated November 14, 2000 entitled "Designation of National Reference Laboratories and Transfer of Corresponding Equipment, Instruments, Supplies, Specimens, Records from the Bureau of Research Laboratories to the Designated National Reference Laboratories"; Department Personnel Order 2009-5148 dated December 21, 2009 entitled "Amendment to Department Order 393-E s. 2000

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dated November 14, 2000 Regarding Designation of National Reference Laboratories and Transfer of Corresponding Equipment, Instruments, Supplies, Specimens, Records from the Bureau of Research Laboratories to the Designated National Reference Laboratories” are hereby repealed or rescinded accordingly.

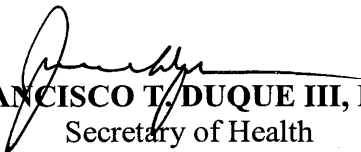
All other provisions of the Department Order 2010-0254 entitled “Guidelines for the Use of Revenues Collected and Earned from the Conduct of Activities by the National Reference Laboratories” and its amendment, Department Order 2010-0254-A, which are not affected by this order shall remain valid and in effect.

IX. SEPARABILITY CLAUSE

If any portion or provision of this Order is held invalid or unconstitutional, the same shall not affect the validity and effectiveness of the provisions hereof.

X. EFFECTIVITY

This Order shall take effect fifteen (15) days after posting in the official gazette or in a newspaper of general circulation.


FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

[ANNEX A]

List of host hospitals with their designated National Reference Laboratories based on technical expertise:

- 1. East Avenue Medical Center:**
 - a. National Reference Laboratory for Environmental & Occupational Health
 - b. National Reference Laboratory for Toxicology
 - c. National Reference Laboratory for Micronutrient Assay
 - d. National Reference Laboratory for Industrial and Chemical Emergencies

- 2. Lung Center of Philippines:**
 - a. National Reference Laboratory for General Clinical Chemistry
 - b. National Reference Laboratory for Anatomic Pathology for Pulmonary and Pleural Diseases

- 3. National Kidney and Transplant Institute:**
 - a. National Reference Laboratory for Hematology
 - b. National Reference Laboratory for Immunohematology
 - c. National Reference Laboratory for Urinalysis
 - d. National Reference Laboratory for Anatomic Pathology for Renal Diseases and other Unassigned Organ Systems
 - e. National Reference Laboratory for Cellular-Based Product Testing
AO No. 2013-0012 "Rules and Regulations Governing Accreditation of Health Facilities Engaging in Human Stem Cell and Cell Based or Cellular Therapies in the Philippines"

- 4. Philippine Heart Center:**
 - a. National Reference Laboratory for Anatomic Pathology for Cardiac Diseases
 - b. National Reference Laboratory for Cardiac Markers

- 5. Research Institute for Tropical Medicine:**
 - a. National Reference Laboratory for Antimicrobial Resistance
 - b. National Tuberculosis Reference Laboratory
 - c. National Reference Laboratory for Transfusion-Transmissible Infections
 - d. National Reference Laboratory for Dengue and Other Arboviruses*
 - e. National Reference Laboratory for Influenza and Other Respiratory Viruses*
 - f. National Reference Laboratory for Emerging and Re-Emerging Bacterial Diseases*
 - g. National Reference Laboratory for Leptospirosis*
 - h. National Reference Laboratory for Special Pathogens*
 - i. National Reference Laboratory for Mosquito Vectors of Human Diseases*
 - j. National Reference Laboratory for Malaria and Other Parasites**
 - k. National Reference Laboratory for Schistosomiasis**
 - l. National Reference Laboratory for Rabies and other Lyssaviruses**
 - m. National Reference Laboratory for Polio and other Enteroviruses
 - n. National Reference Laboratory for Measles and other Exanthems
 - o. National Reference Laboratory for Invasive Bacterial Vaccine Preventable Diseases
 - p. National Reference Laboratory for Rotavirus and other Enteric Viruses***
AO No. 2015-0050 "Designation of RITM as the National Reference Laboratory for Rotavirus and other Enteric Viruses"

- q. National Reference Laboratory for Bacterial Enteric Diseases***
- r. National Reference Laboratory for Mycology

* These NRLs shall support the Emerging and Re-emerging Infectious Disease Control Program

** These NRLs shall support the Neglected Tropical Disease Control Program

*** These NRLs shall support the Food and Waterborne Disease Control Program

6. San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SACCL):

- a. National Reference Laboratory for HIV/AIDS
- b. National Reference Laboratory for Hepatitis B and Hepatitis C
- c. National Reference Laboratory for Syphilis and Other Sexually-Transmitted Infections