

Guidance

for Establishing a National Health Laboratory System

Graphic Design and Printing done by TIP/AFRO

World Health Organization
Regional Office for Africa
Brazzaville • 2015



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WHO/AFRO Library Cataloguing – in – Publication Data

Guidance for Establishing a National Health Laboratory System

1. Laboratories – organization and administration
 2. Clinical Laboratory Techniques
 3. Diagnosis
 4. National Health Programs
 5. Guideline
- I. World Health Organization. Regional Office for Africa
 - II. Title

ISBN: 978 9 29 023287 2 (NLM classification: QY 39)

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Printed in the Republic of Congo

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ABBREVIATIONS

AFRO	WHO Regional Office for Africa
AIDS	Acquired Immune Deficiency Syndrome
APHL	Association of Public Health Laboratories
BLT	Blood Safety, Laboratories and Technologies
CAREC	Caribbean Epidemiology Centre
CDC	Centers for Disease Control and Prevention
CLSI	Clinical and Laboratory Standards Institute
CLT	Clinical Laboratories and Technologies
EHT	Essential Health technologies
EMRO	WHO Regional Office for the Eastern Mediterranean
EQA	External Quality Assessment
HIV	Human Immunodeficiency Virus
HSS	Health Systems & Services Cluster (WHO/AFRO)
IATA	International Air Transport Association
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations (2005)
IP	<i>Institut Pasteur</i>
IQLS	Integrated Quality Laboratory Services
ISO	International Organization for Standardization
IVE	Immunization, Vaccines and Emergencies Cluster
LAT	Laboratory Assessment Tool
LIMS	Laboratory Information Management System
LMIS	Logistics Management Information System
PAHO	Pan American Health Organization
PIP	Pandemic Influenza Preparedness
PPP	Public Private Partnership
QMS	Quality Management System
SEARO	WHO Regional Office for South-East Asia
SLIPTA	Step-Wise Laboratory Improvement Process Towards Accreditation
SOP	Standard Operating Procedure
TB	Tuberculosis
UN	United Nations
USAID	United States Agency for International Development
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific

FOREWORD

Laboratories are an essential and fundamental part of all health systems and their goal to improve health. Reliable and timely results from laboratory investigations are crucial elements in decision-making in almost all aspects of health services and disease prevention and control programmes. Critical decisions dependent on laboratory results concern health security, national economies and meeting obligations such as the International Health Regulations (IHR) as well as the health and well-being of individuals.

Despite this central role, strengthening nationally coordinated laboratory services has, until recently, received little or inadequate attention in many countries. This has resulted in laboratory services having a very low national priority in respect to financing, planning and service delivery.

Given the growing importance of health laboratories and emphasis on evidence-based medical and public health practices, it is imperative that health laboratories are strengthened to provide critical inputs to making informed decisions.

To bring the laboratory capacity building agenda as a central component of national health system strengthening, Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening was adopted by Member States in the WHO African region during the 58th session of the Regional Committee in September 2008 in Yaoundé, Cameroon.

The WHO AFRO strategic direction priorities for 2010–2015 highlighted the importance laboratory quality services through partnerships and harmonization of technical support to countries in building capacity to respond to diseases of public health importance such as HIV/AIDS, malaria, tuberculosis and other non-infectious diseases. The development of this document is one of the outcomes of these important initiatives.

In order for laboratories to provide high quality test results, the following systems must be in place: human capacity, infrastructure and management of quality systems.

Competent staff who are adequately trained, effective supervision by managerial staff, and recruitment and retention programmes are required to maintain trained laboratory personnel. Formal, pre-service training programmes as well as orientation, performance appraisals and in-service training systems must also be available.

A safe and suitable physical environment with adequate space, power, climate control, water and transport access is a necessity. There should be uninterruptible power supply (UPS) supporting laboratory equipment in case of power surges. Sufficient light, bench space, mains or bore hole water, and distilled water are also required. In place must be high quality, functioning laboratory equipment and a supply chain management system to provide adequate supplies of reagents, consumables and quality control (QC) materials. The laboratory environment should have enough space to perform day-to-day operations safely and efficiently and to store cold chain and non-cold chain supplies.

Effective laboratory quality systems, including well written policies and procedures, a quality control (QC) system, quality improvement (QI), external quality assessment (EQA), and accreditation standards should exist. Standard operating procedures (SOPs) must be understood and implemented to ensure overall test reliability, which includes test accuracy and precision. Laboratory professionals should routinely perform QC testing to guarantee that test methods and equipment perform according to established standards. Laboratory professionals must participate in EQA/proficiency testing (PT) programmes in order to demonstrate that acceptable systems are in place and that specimens are collected and processed appropriately.

