

# **An Assessment of the Leadership and Managerial Capacity of the National Tuberculosis Reference Laboratory to carry out its mandate and responsibilities for the National TB Laboratory Network of the Philippines**

***Manila, Philippines, 23 May- 5 June 2010***

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## **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

## **Abstract**

The purpose of this visit was to assess the NTRL's capacities that are necessary to carry out its mandate, particularly on the leadership and managerial aspects, and identify technical assistance needs in the context of NTP laboratory network development.

## **Recommended Citation**

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## **Key Words**

Laboratory services; Leadership and Management; Tuberculosis (TB), Drug-resistant TB (DR-TB),

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**The Linking Initiatives and Networking for the Control of Tuberculosis (TB LINC Project)** is a five-year cooperative agreement under the United States Agency for International Development (USAID). The project is being implemented by the Philippine Business for Social Progress (PBSP) and is slated to run from October 2006 to September 2011. TB LINC's goal is to achieve USAID's strategic objective no. 3 (SO3) which is "Improved family health sustainably achieved". TB LINC's main partner is the Philippines' DOH, particularly the NTP under the National Center for Disease Prevention and Control (NCDPC). The National TB Reference Laboratory (NTRL), under DOH's Research Institute for Tropical Medicine (RITM), is another key partner particularly in terms of technical collaboration and support to the NTP's laboratory services. Technical support is provided to these key partners, as well as to other public and private agencies and to the local government units in TB LINC's 20 project sites to help the NTP achieve the program targets of at least 70% case detection rate, and cure rate of at least 85% among the smear positive cases detected.

**Management Sciences for Health (MSH)** is a non-profit international organization dedicated to saving lives and improving the health of the world's poorest and most vulnerable people by closing the gap between knowledge and action in public health. Since 1971, MSH has worked with its partners in more than 140 countries to improve health services and has helped many public and private sector organizations to effectively manage people, medicines, money and information. MSH is organized around three major areas of expertise: (1) leadership, governance and management, (2) pharmaceutical and laboratory management and (3) management of effective curative and preventive health services.

**The Strengthening Pharmaceutical Management Systems (SPS) Program** is a 5 year cooperative agreement (2007-2012) awarded to MSH by USAID, focusing globally on four key results areas: (1) Improve governance in the pharmaceutical sector, (2) Strengthen pharmaceutical management systems to support public health services, (3) Contain the emergence and spread of antimicrobial resistance, and (4) Expand access to and improved use of essential medicines and medical supplies. One mandate of the SPS Program is to increase the availability of and improve the management of essential laboratory services and supplies. The SPS Program complements the U.S. Centers for Disease Control and Prevention's (CDC's), the World Health Organization's (WHO's) and other partners' efforts to build laboratory capacity in resource-poor countries by focusing on systems strengthening and improving management and leadership practices in the public and private sectors.



## **ACRONYMS**

AFB	Acid fast bacilli
AO	Administrative order
ARMM	Autonomous Region of Muslim Mindanao
BHS	Barangay health station
CHD	Center for Health Development (DOH regional offices)
CHO	City Health Office
CDR	Case detection rate
DILG	Department of Interior and Local Government
DOH	Department of Health
DOTS	Directly Observed Treatment Short course
DSSM	Direct sputum smear microscopy
DST	Drug susceptibility test
EQA	External quality assessment
GFATM	Global Fund to Fight AIDS, TB, and Malaria
GLC	Green Light Committee
HC	Health center
IDO	Infectious Disease Office (DOH/NCDPC)
JICA	Japan International Cooperation Agency
KOICA	Korean International Cooperation Agency
LCP	Lung Center of the Philippines (DOH)
LGU	Local government unit
MHO	Municipal Health Office
MDRTB	Multi-drug resistant tuberculosis
NCDPC	National Center for Disease Prevention and Control
NCR	National Capital Region (or Metro Manila)
NEC	National Epidemiology Center (DOH)
NGO	Non-government organization
NPS	National TB prevalence survey
NSCB	National Statistics Coordination Board
NTP	National Tuberculosis Control Program (DOH/NCDPC)
NTRL	National TB Reference Laboratory
PBSP	Philippine Business for Social Progress
PHO	Provincial Health Office
PhilCAT	Philippine Coalition Against Tuberculosis
PMDT	Programmatic Management of Drug resistant Tuberculosis
PPMD	Public-private mix DOTS
PTSI	Philippine Tuberculosis Society Incorporated
QAS	Quality assurance system
RHU	Rural health unit
RITM	Research Institute for Tropical Medicine (DOH)
RJPI	Research Institute for Tuberculosis / Japan Anti Tuberculosis Association Philippines Incorporated

RSS	Remote smearing stations
TB	Tuberculosis
TB LINC	Linking Initiatives and Networking to Control Tuberculosis
TDFI	Tropical Disease Foundation Incorporated
USAID	United States Agency for International Development
WHO	World Health Organization

## **Executive Summary**

### **Objective**

To assess the NTRL's capacities that are necessary to carry out its mandate, particularly on the leadership and managerial aspects, and identify technical assistance needs in the context of NTP laboratory network development.

### **Methods**

An assessment was conducted of the NTRL's organizational capacity for management, strategy development and leadership in the following areas:

- Organization, structure, financing, and human resources
- Policies, standards, and guidelines on biosafety and infection control
- Diagnostic services, laboratory methods, and standard operating procedures (SOPs)
- Methods of implementing quality assurance
- Provision of technical support to intermediate level laboratories
- Human resource development, planning, training, and supervision
- Procurement of laboratory equipment and supplies
- System for data collection, analysis, and feedback
- Monitoring and evaluation of laboratory services

Information for the assessment was gathered through literature reviews, stakeholder interviews and site visits. A facilitated 3-day leadership and managerial capacity participatory assessment workshop for a range of NTP and NTRL stakeholders was conducted to identify specific leadership and management gaps and challenges.

### **Recommendations**

#### **1. External Technical Assistance (TA) Focus over the next year**

As the NTRL and NTP are already well supported by several external organizations to develop and improve laboratory technical capacity, we recommend that the TA focus of this USAID-supported initiative over the next year should be on strengthening the management, leadership and organizational capacity at central and intermediate levels. Immediately, attention should be given to the most critical areas affecting the optimal functioning and performance of the NTRL and the TB laboratory services:

- Human resource management
- Financial management
- Leadership and skills development for NTRL and selected regional laboratory staff

SEE RECOMMENDATIONS 2, 3 AND 4 BELOW FOR DETAILS

Focusing on these areas will support and leverage other partners' technical efforts and enable the NTP to realise a well-managed, sustainable, quality-assured national TB laboratory service to support case detection and the management of drug resistant TB.

#### **2. Human Resources**

- a) We recommend that a review of the NTRL human resource needs be conducted to determine the number of positions and their respective functions, required for the NTRL to carry out its mandate for national TB laboratory services in relation to policy development, research, service provision, quality assurance and monitoring, training and capacity building. A human resource plan, including

a revised organizational chart needs to be developed, based on the review and submitted for approval to the RITM director. Justification for new positions and budget will be essential.

- b) We recommend that a training needs assessment be conducted by the NTRL in order to update the TB laboratory training policy that will guide the development of appropriate curricula, training materials, training-of trainers and the refresher training programs in TB microscopy, culture, DST, new technologies, biosafety and infection control, lab management, quality assurance, supervisory practice, data collection and management, and other areas as needed. We suggest that the NTRL requires a full-time training officer to manage and coordinate the various training programs. Short term technical assistance will be needed to mentor the new appointee and to assist with the development and implementation of a national TB lab training plan and budget.

### **3. Financial management and budgeting.**

In order to determine and understand the budgetary needs of the NTRL to carry out its national mandate, we recommend, as an initial step, a detailed costing of the TB laboratory services. This will provide the information for the development and implementation of a financial management tool which will assist with preparation of budgets, decisions on spending and provide an accurate and complete picture of expenditure, revenue and cash flow in relation to specific lab outputs and services.

### **4. Management and leadership capacity building.**

We recommend building the management and leadership skills of laboratory managers. This program, already developed and used by MSH, will focus initially on equipping central and laboratory staff to be better managers capable of achieving improved results in their laboratories. Four 3-day workshops, each building on the other, will be offered to the selected laboratory management teams with inter-workshop assignments. Initially local facilitators will be trained in the methodology and a scale-up plan prepared for implementation within the regions.

### **5. Short and medium term recommendations for the NTRL**

The following represent areas that the NTRL can address immediately either with existing technical assistance or with additional minimal or no external technical assistance:

- a) **Mission and Values:** We recommend that NTRL refine the NTRL Mission statement to be applicable to all TB laboratory services in the Philippines and define organizational and ethical values for the TB lab services. These need to be disseminated widely
- b) **Development of policies, strategies, standards and guidelines:** In order for the NTP to provide high quality diagnostic lab services throughout the Philippines, it will be essential for the NTRL to work closely with the NTP to develop, disseminate and implement TB laboratory policies, strategies, standards and guidelines applicable to TB laboratory services at the central, intermediate and peripheral levels.
- c) **Standard Operating Procedures:** Although there are various lab manuals for training and lab procedures, we recommend that the NTRL develop a set of comprehensive TB laboratory SOPs covering all areas of TB laboratory practice, obtain official approval for the document and then disseminate and implement the SOPs in all TB microscopy and TB culture/DST labs.
- d) **Biosafety:** Although general National Standards for Biosafety exist, practical guidelines applicable to TB microscopy and TB culture/DST labs need to be developed and implemented in line with these standards and in line with the draft WHO Biosafety Manual 2009. We recommend that a Laboratory Biosafety specialist be identified and engaged to assist the NTRL to coordinate the outputs of the different consultants scheduled to come to the Philippines in June 2010 and to assist the NTRL to develop the policy, standards and guideline.

- e) **New Diagnostic Technologies:** We recommend that the NTP and NTRL work together to specify and endorse the use of internationally-recommended new diagnostic technologies that will strengthen the NTP. These may include LED fluorescence microscopy, liquid culture, and molecular diagnostics (e.g. line probe assays and GeneXpert) and others as they become available.

## **6. Recommendations for medium – longer-term technical assistance:**

The following represent areas that require longer term efforts and external assistance for systems development and implementation

- a) **Supervision:** We recommend that NTRL, together with the NTP, develops a strategy and guidelines for supportive supervision of TB microscopy and culture sites and a program for capacity building in supervisory practice. As supervision of microscopy sites is practically managed from the regional level, we recommend the development and implementation for a TOT supervisory skills course for NTP regional coordinators, to enable them to train laboratory supervisors in their respective regions. Technical assistance over one year will be required to assist NTRL to develop the strategy and guidelines and to develop and implement the TOT supervisory skills course. Long term technical assistance will be required for one year.
- b) **Management Information System:** We recommend the adoption and implementation of an electronic, web-based TB laboratory Management information System, initially at the NTRL and Lung Health Centre, with the aim of rolling it out to other TB culture sites at a later stage. This system needs to be linked to software being used by the NTP for patient management and to the National Epidemiology Centre for analysis. Long term technical assistance for 2 years will be required to identify, customize and implement a suitable system.
- c) **Supply management.** We recommend that NTRL and NTP, in collaboration with the Materials Management Division of the DOH, review and where necessary revise and update the procurement system for all TB laboratory commodities in order to track supplies, forecast requirements, reduce gaps and prevent stock-outs. This will include a review and updating of the standards and specifications for all TB laboratory commodities and ensuring that these are listed in the catalogue of the MMD, and are also disseminated to all LGUs and individual labs. Laboratory staff responsible for ordering supplies will need to be trained in the basic principles of supply management and in the proper use of the updated system. We recommend that NTRL continue to prepare and quality-assure the TB culture media and distribute it to all culture laboratories. Long term technical assistance will be required for a minimum of 2 years.



## 1. Background Information

### 1.1 The Philippines - Demographic Information

The Philippines is an archipelago with 7,107 islands that are categorized broadly into three main geographical divisions: Luzon, Visayas, and Mindanao. The country has a geographic area of 300,000 square kilometers. Its capital city is Manila located in the National Capital Region in Luzon. As of 2008, the country is divided into: 17 administrative regions; 81 provinces; 136 cities including the 16 highly urbanized centers and one urban municipality in Metro Manila; 1,495 municipalities; and 42,008 barangays. (See Figure 1: Map of the Philippines)

The population of the Philippines was estimated to be almost 92 million in 2009. The sex ratio is 1:1.01 in 2000, with life expectancy at birth higher among females at 74.34 years, compared to males at 68.81 years (National Statistics Office, 2006). The population distribution according to age groups showed that in 2000, 37% belong to the 0 to 14 age group, 59.2% belonged to the 15 to 64 group, while 3.8% belonged to those who are 65 and older.

The National Statistics Coordination Board (NSCB) reported in 2006 that about 24% of Filipino families were not able to earn enough to meet the daily food and non-food requirements. An estimated 4.7 million families in the country are considered poor. Among the regions, poverty incidence is highest in Autonomous Region of Muslim Mindanao (ARMM) where more than 55% of families are considered poor; NCR has the lowest percentage of poor families at 7.1%.

### 1.2 Tuberculosis in the Philippines

Tuberculosis (TB) is the 6<sup>th</sup> leading cause of morbidity and mortality in the Philippines which is ranked 9<sup>th</sup> among the 22 high-burden countries of the world. In 2007, the Philippines notified a total of 141,000 cases of TB (Global Tuberculosis Control, WHO Report 2009). The 2007 TB prevalence survey showed a smear (+) TB prevalence of 2.0/1000, while culture positive prevalence is 4.7/1000. Relative to the 1997 survey, a decline by 28% and 38% for smear (+) and culture (+) TB prevalence, respectively, was seen in the last survey. The prevalence of smear and culture (+) TB increased with age and is generally higher among males (NPS 2007).

**Table 1: Selected TB Indicators in the Philippines**

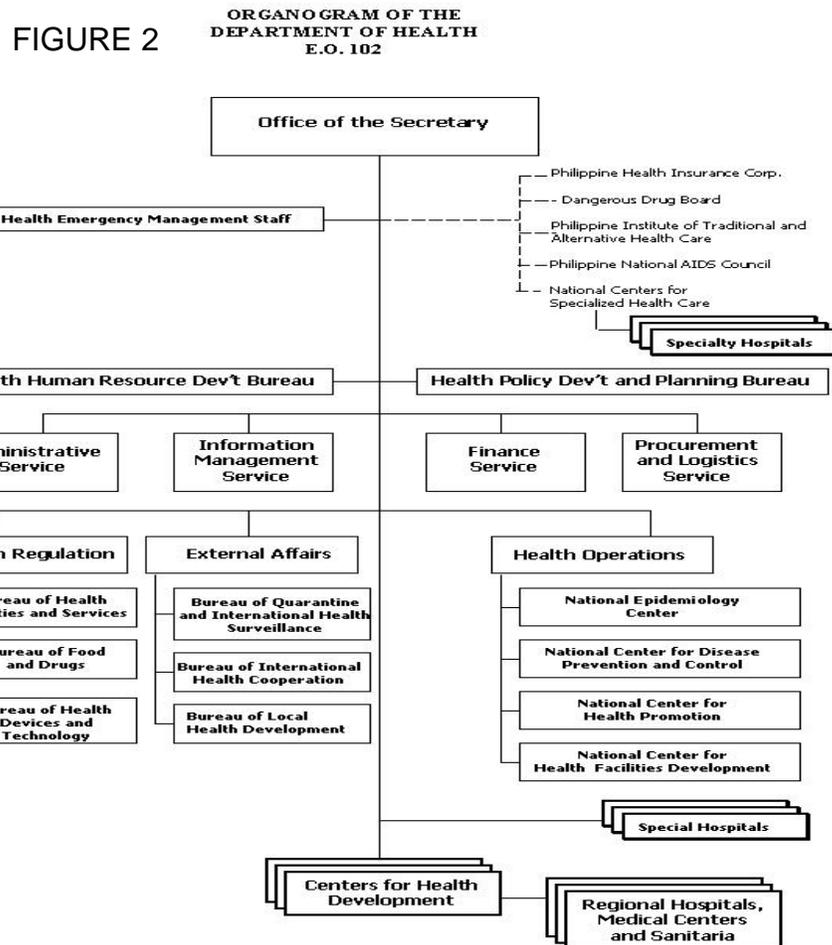
	1981-82	1997	2007
Annual risk of TB infection <sup>1</sup>	2.5%	2.3%	2.1%
Prevalence of TB symptomatics <sup>1</sup>	17%	18.4%	13.5%
Prevalence of radiographic TB <sup>1</sup>		4.2%	6.3%
Smear (+) TB <sup>1</sup>	6.6/100	3.1/100	2.0/1000
Culture (+) TB <sup>1</sup>	8.6/1000	8.1/1000	4.7/1000
Prevalence of multi-drug resistant TB <sup>2</sup>			
• Among new cases			3.8%
• Among re-treatment cases			21%
<sup>1</sup> Source: Philippines National TB Prevalence Surveys (1982, 1997, 2007)			
<sup>2</sup> Source: Philippine National Drug Resistance Survey (2004)			

Figure 1: Map of the Philippines



### 1.3 Health System in the Philippines and provision of TB related health care services

The Philippines health system consists of the public sector, largely financed through a tax-based budgeting system at national and local levels and the private sector (both for-profit and non-profit providers) which is market oriented and charges user-fees at the point of service. The public sector consists of the Department of Health (DOH), Local Government Units (LGUs) and other national government agencies. The DOH is the lead agency in health and provides national policy direction, plans, standards and guidelines. The Policy and Standards Development team for Service Delivery is the National Center for Disease Prevention and Control (NCDPC) which oversees all public health programs including the National Tuberculosis Control Program (NTP). Field operations of the DOH are through the regional health offices (Centers for Health Development [CHD]). (See Figure 2: Organogram of the DOH). The Lung Center of the Philippines (LCP) is the speciality hospital for lung diseases. However, the National Tuberculosis Reference Laboratory (NTRL), which serves as the laboratory arm of the NTP, is under the Laboratories Research Division of the Research Institute for Tropical Medicine (RITM), a research hospital of DOH. Although the NTP provides substantial funding to the NTRL (around 5.4 million pesos for 2010) for managing TB laboratory services, the NTP does not have direct administrative or technical control over the NTRL.



Local Government Units (LGU), administratively under the Department of Interior and Local Governments (DILG), provide direct health services at the primary and secondary levels of care. Under this set-up, provincial and district hospitals are under the provincial government while the municipal government manages the rural health units (RHU) and barangay health stations (BHS) where basic public health services are delivered. However, the DOH is responsible for providing technical support to the LGUs especially in vertical programs such as the National TB control Program (NTP).

#### **1.4 TB Control in the Philippines**

In 1978, the DOH established the National TB Control Program (NTP) under the management of the NCDPC. The NTP undertakes the overall coordination of TB control activities and provides technical assistance, capacity building and training to CHDs, LGUs and other partners. The program manager and central team formulate and evaluate policies, programs and plans for the NTP, while at the CHDs there is an NTP core team of physicians, nurses and laboratory technologists to ensure that the LGUs implement the program based on NTP policies, guidelines and standards. Each province/city also has an NTP core team to manage implementation at the local/peripheral levels. Thus TB control is integrated into the general health services at all levels.

The DOTS strategy was adopted by the NTP in 1996, with 100% DOTS coverage in the public sector attained by the end of 2002. Targets for case detection and treatment success were exceeded at country level in 2007 with 75% case detection rate (CDR), and 88% treatment success rate. However, TB control performance at the local level is variable with many LGUs still unable to reach the targets for case detection and cure rate. Limited access to laboratory services is one of the major factors for the low case detection in many localities, particularly in geographically isolated and remote areas. Treatment outcomes have also been unsatisfactory in many places due to difficulties in case holding particularly in performing directly observed treatment.

The country is now scaling up programmatic management of drug resistant TB (PMDT) beyond Metro Manila, expanding services for TB in children and addressing TB in high risk groups, including the HIV-infected, the urban poor and the prison population. Government commitment to fighting TB is strong as evidenced by increases in funding from domestic sources and through the Global Fund grant which have helped reduce funding gaps. The NTP has several partners and agencies providing technical and financial support. These are shown in Table 3 below.

**TABLE 3: Partners and agencies providing technical and financial support to the NTP:**

NTP Partners and Agencies	Role and Function
Committee of German Doctors	Provides health services, including TB treatment, mostly for the indigent population through their clinics in located in selected parts of the country. They also provide logistical support to a number of non-profit clinics providing TB control services.
Global Fund to Fight Against AIDS, TB, and Malaria (GFATM)	The fund mechanism has been a providing funds for the country since 2002
Japan International Cooperation Agency (JICA)	One of the partner agencies involved in the development and implementation of the revised TB control strategy in the country in the 1990s. The JICA TB control projects were involved in the expansion of DOTS and the development of the QA system for sputum microscopy. They also supported the establishment of the RITM and the NTRL.
Korean International Cooperation Agency (KOICA)	Supports the development of the National MDRTB Referral Center located at the Lung Center of the Philippines compound in Quezon City. It is also providing manpower support to the NTRL.
Philippine Business for Social Progress (PBSP)	An NGO that is currently managing the TB LINC project, and is also the new principal recipient for the GFATM.
Philippine Coalition Against Tuberculosis (PhilCAT)	A coalition of local NGOs involved in TB control in the country. It is currently one of the sub-recipients of GFATM, implementing the public-private mix component of the NTP.
Philippine Tuberculosis Society Incorporated (PTSI)	One of the pioneer NGOs in the country involved in TB control. It provides TB control services through clinics in the country. PTSI is also one of the culture centers in the country, and is the host to one of the MDRTB treatment centers in Metro Manila. It is also a recipient of USAID grant, through the TB LINC project, to strengthen private sector involvement in TB control.
RIT/Japan Anti TB Association, Philippine Chapter (RJPI)	Currently implementing a project supporting the NGOs operating in urban poor settlements in Manila and Quezon City. The project aims to improve the quality and accessibility of TB control services for the urban poor.
Linking Initiatives and Networking to Control Tuberculosis (TB LINC)	A cooperative agreement funded by USAID and managed by PBSP. The project provides technical assistance to the NTP at national and local levels. One of its main areas of assistance is the TB laboratory network.
World Vision Development Foundation (WVDF)	Provides assistance in social and community development; it is implementing a GFATM funded social mobilization initiative for the NTP.
Tropical Disease Foundation Inc. (TDFI)	Up until early 2010, this NGO was involved in the public-private mix DOTS (PPMD) and initiated the development and implementation of the MDRTB treatment program in the country in collaboration with the NTP, WHO.
USAID	The agency is a key partner of the NTP through several initiatives supporting DOTS expansion, public-private collaboration in TB control, and systems strengthening. USAID is assisting the NTP through the TB LINC project in improving the health system, laboratory network strengthening, improving the financial and political environment, and improving utilization of DOTS services.
WHO	WHO provides technical guidance to DOH programs including the NTP, through its Philippine country office and the Western Pacific Regional Office.

### **1.5 TB laboratory services**

The TB laboratory system in the public sector is fully integrated structurally (i.e. in terms of budget, staff and organization) into the NTP. Private laboratories are linked to the NTP through recording/reporting mechanisms, supervision and QA. This network of TB laboratories consists of three levels: central, intermediate and peripheral. The central level refers to the National TB Reference Laboratory (NTRL); the intermediate level refers to the regional TB reference laboratories and provincial TB laboratories including QA centers, while the peripheral refers to the municipal (RHU/HC) microscopy laboratories. Barangay health stations used for smear preparation, generically called as remote smearing stations (RSS), also belong to the peripheral level. Details of the functions of the different levels of laboratories are found in Annex 3: Copy of the DOH-Administrative Order No 2007-0019.

In the *2010-2015 Philippine Plan of Action to Control TB (PhilPACT)*, the number of TB microscopy laboratories is listed as 2,373. However, the accuracy of this number is uncertain. Based on the TB prevalence in the country and the international standard of one microscopy laboratory per 100,000 population, the number of microscopy centres may be considered as adequate. In the provincial and city laboratories (in highly urbanized cities) there are Quality Assurance (QA) centers that perform external quality assessment (based on the LOT QA system and blinded rechecking methodology recommended by WHO) for the microscopy laboratories in the province/city. The QA teams are also responsible for providing technical supervision for quality improvement. The regional NTP coordinators under the DOH Centers for Health Development oversee the provision of laboratory services including quality assurance in their respective areas of jurisdiction.

The laboratory network is undergoing major expansion to support the expansion of the Programmatic Management of Drug resistant Tuberculosis (PMDT). There are currently 9 laboratories at the central and intermediate levels performing TB culture, but there are plans to expand this number to 29 over the next 12-18 months. All TB culture is currently performed using conventional solid media. Diagnostic sensitivity testing (DST), using the proportion method, is currently offered only at the NTRL. This means that positive cultures have to be transported to the NTRL from all culture centres for this purpose. Consequently, it takes between 3 and 3.5 months to receive a TB culture result and from 4 to 5 months to receive a DST result. In an effort to reduce this time, there are plans to phase in Line Probe Assay (LPA) later this year for rapid recognition of MDR-TB, and to introduce a commercial automated liquid culture system in the not too distant future. The overall management of PMDT is also being turned over to the Lung Center of the Philippines (LCP) from the Tropical Disease Foundation Inc. (TDFI), with NTRL taking full responsibility for managing the laboratory component.

The Research Institute of Tuberculosis (RIT) from Japan acts as the supranational reference laboratory for the NTRL. The RIT provides DST proficiency testing and conducts regular annual visits to ensure the technical performance of the NTRL and TB laboratory services.

### **1.6 The role and operation of the National TB Reference Laboratory**

The NTRL is one of several reference laboratories in the RITM. In line with international guidelines and with the Administrative Order 2009-0019 (See Annex 3), the NTRL is responsible for the overall leadership and direction of the TB laboratory services through the development of policies, technical guidelines and standards, consistent with and supporting the NTP policies, and for the overall management, supervision and quality of these services. In addition the NTRL has specific functions related to capacity building, surveillance and operational research.

The NTRL also serves as the country's central TB laboratory to provide specialized technical services to support PMDT. These include TB culture, identification and 1<sup>st</sup> and 2nd line DST. Formerly, this role was shared with the TDFI laboratory, but with the cessation of TDFI's activities, the NTRL has assumed full responsibility for providing these services. Based on previous assessments by experts from WHO-GLC, the NTRL needs to increase its capacities to effectively perform its role as manager of the laboratory network within the short term.

The NTRL has recently developed its own 4-year Strategic Plan 2010-2013. The stated goal in this plan is to develop a quality-assured TB diagnostic laboratory throughout the Philippines. The objectives are:

1. To build a policy environment that will facilitate NTRL's performance of its mandates.
2. To establish an efficient and effective national TB laboratory network
3. To fully implement quality assurance
4. To conduct operation and other researches
5. To develop NTRL's human resource
6. To generate adequate financial resources to support NTRL's operation

The NTRL has 27 medical, scientific, technical and administrative staff. It is planned to add an extra 25 staff to make up for the shortages. Currently, each of the staff members have several different roles and responsibilities to cover for the staff shortages and gaps.

***NTRL budget sources:*** The NTRL has several funding sources to enable it to fulfil its mandate. We were informed that in the current financial year, the budget comes from the RITM for MOOE: 750,000 pesos (2010), and 1 million pesos as part of the DOH Reference laboratories. It also receives a sub-allotment from the NTP; this amounted to 5.4 million pesos in (2010). The NTRL is also expecting to receive a total of 3 million Euros over 5 years from the Global Fund for the laboratory expansion for the PMDT.

### **1.7 Training policies: TB microscopy, culture and DST**

Training on sputum microscopy is provided by the regional medical technologists, who are usually assisted by selected provincial medical technologists. Trainers are required to undergo a Training of Trainers (TOT) conducted by NTRL. Trainings are conducted in regional (DOH), or private laboratories (e.g. PTSI), that have passed NTRL standards.

Criteria for Trainees on TB Culture and DST:

1. Registered medical technologist
2. Current staff of culture center and/or DST center
3. Has undergone training on DSSM

Trainers of TB Culture and DST under NTP are the NTRL staff who have undergone training on TB culture and DST. All training on TB culture and DST are conducted at the NTRL.

## **2. Objective**

**To assess the NTRL’s capacities that are necessary to carry out its mandate, particularly on the leadership and managerial aspects, and identify technical assistance needs in the context of NTP laboratory network development.**

The detailed Scope of Work received from USAID-Philippines on 21 February 2010, is shown in Annex 1.

## **3. Methods**

In order to achieve the objective and assess the leadership and managerial capacity of the NTRL in the context of the overall NTP laboratory network of the Philippines, several inter-dependent activities were undertaken, as outlined below. These were designed to facilitate the assessment of the NTRL’s organizational capacity for management, strategy development and leadership in the following areas:

- Organization, structure, financing, and human resources
- Policies, standards, and guidelines on biosafety and infection control
- Diagnostic services, laboratory methods, and standard operating procedures (SOPs)
- Methods of implementing quality assurance
- Provision of technical support to intermediate level laboratories
- Human resource development, planning, training, and supervision
- Procurement of laboratory equipment and supplies
- System for data collection, analysis, and feedback
- Monitoring and evaluation of laboratory services

### **3.1 Information gathering through literature reviews, stakeholder interviews and site visits**

- Literature review of previous assessments, relevant reports and policy documents related to NTRL and laboratory network development. Electronic copies of these documents were provided by USAID and the NTRL.
- Briefing meetings and discussions with USAID, NTP and NTRL and other key stakeholder, including LCP, RITM, WHO, GFATM, PBSP and TB LINC. (See Annex 2)
- Site visits were made to selected regional CHDs and LGUs, TB laboratories and DOTS facilities at different levels of the health systems, including PMDT treatment centres and treatment sites, in Metro Manila and in northern Mindanao (see Annex 2 for itinerary details). The observations were viewed in the context of overall leadership and management capacity at various levels of the health system.

### **3.2 Facilitation of a 3-day leadership and managerial capacity participatory assessment to identify specific leadership and management gaps and challenges.**

#### ***Rationale for the TB laboratory leadership and management participatory assessment***

Traditional laboratory assessments typically rely on external evaluators, intensive data collection and checklists and result in findings and recommendations that often fall short of producing a realistic plan for improvement and do not necessarily foster local ownership or ‘buy-in’. In this 3-day meeting, we set out to harness the knowledge, insights and creativity of a range of NTP and NTRL stakeholders, in order to build a collective perspective of their individual experiences. We employed a structured participatory

process whereby the participants were facilitated to express their individual views on management performance, share these perceptions with each other and reach consensus on the current status of the NTRL leadership, managerial and organizational capacity for the TB laboratory services in the Philippines. They were then able to identify priority areas for TB laboratory capacity strengthening.

Our approach builds on a consistent finding that there are unbreakable linkages between good leadership and management, high-quality services, and organizational sustainability. Good management is the glue that holds all internal parts of the laboratory service together, creates a positive work climate, and supports high-quality services, thus helping to bring the vision of the laboratory service to fruition. Well-managed laboratories that deliver high-quality services are able to satisfy their clients and increase demand. The structure of the laboratory services and financial base allow them to continue their work in a changing environment and to take on new responsibilities.

**Workshop Program and Content:** The workshop program and list of attendees are shown in Annex 4 and Annex 5 respectively

**Assessment focus and methodology:** The assessment focused on critical areas of management: Mission, Values, Strategy, Structure and Systems. These management areas are explained in the text box below.

#### **CRITICAL MANAGEMENT AREAS:**

**Mission.** The Mission of the TB laboratory services is the purpose or reason for the existence of the TB laboratory services. The Mission Statement provides guidance, consistency, and meaning to decisions and activities at all levels. It answers the question: ***Why do we do what we do?***

**Values.** The values of the TB laboratory services are the beliefs and ethical principles that underlie the Mission. They give meaning to the work of the TB laboratories and form the basis for staff commitment. They answer the question: ***What are the core beliefs and principles that we all share and that give direction to our work?***

**Strategy.** The strategies of the NTRL and the TB Laboratory services are the broad approaches used to define the objectives and activities that will fulfil their Mission and Goals. The strategies answer the question: ***How will we get to where we want to go?***

**Structure.** Structure refers to the laboratories, departments, programs, projects, and offices that collectively constitute the TB laboratory services. The functional structure encompasses the formal lines of authority, distribution of responsibilities and ways in which significant decisions are made and people held accountable for carrying out those decisions. Collectively, these answer the question, ***Are we organized in a way that facilitates what we want to do and where we want to go?***

**Systems.** The systems are the interdependent functions that allow the TB laboratories to do their work. This assessment addressed the systems that are the key elements of management: planning, human resource management, monitoring and evaluation, information management (both data collection and use of information), quality assurance, financial management, revenue generation, and supply management. Collectively, these answer the question: ***What helps us to carry out our activities?***

For the purposes of this assessment, each of the management areas was divided into separate measurable components listed in the table below:

**MEASURABLE COMPONENTS ASSESSED DURING THE TB LABORATORY MANAGEMENT ASSESSMENT**

<b>Management areas:</b>	<b>Measurable components:</b>
<b>Mission</b>	<ul style="list-style-type: none"> <li>▪ Existence and knowledge of the Mission of the TB laboratory services</li> </ul>
<b>Values</b>	<ul style="list-style-type: none"> <li>▪ Existence and application of values and ethical principles</li> </ul>
<b>Strategy</b>	<ul style="list-style-type: none"> <li>▪ Links to Mission and Values</li> <li>▪ Links to the National TB Program</li> <li>▪ Links to patients and communities</li> </ul>
<b>Organisation and Structure of the TB Laboratory Services</b>	<ul style="list-style-type: none"> <li>▪ Lines of authority and accountability</li> <li>▪ Communication mechanisms</li> <li>▪ Roles and responsibilities</li> <li>▪ Decision making</li> </ul>
<b>Systems</b>	<ul style="list-style-type: none"> <li>▪ Planning: Existence and implementation of an operational plan</li> <li>▪ Human resource management: Policies and procedures</li> <li>▪ Human resource management: Training</li> <li>▪ Human resource management: Supervision</li> <li>▪ Monitoring and evaluation</li> <li>▪ Information management: Data collection, reporting and use of information</li> <li>▪ Quality: Infrastructure, biosafety and infection control</li> <li>▪ Quality: Existence and use of Standard Operating Procedures</li> <li>▪ Quality assurance: TB microscopy</li> <li>▪ Quality assurance TB culture/DST</li> <li>▪ Supply management: TB microscopy reagents and consumables</li> <li>▪ Supply management: Culture/DST consumables</li> <li>▪ Supply management: Equipment</li> <li>▪ Financial management: Costing of TB laboratory services</li> <li>▪ Financial management: Budgeting and expenditure</li> <li>▪ Financial management: Revenue generation</li> </ul>

**The Assessment Tool:** Annex 6 shows the assessment tool, customised for the TB laboratory services in the Philippines with the assistance of the NTRL Director and his senior staff. The tool is based on the premise that as an organization grows (in this case the NTP’s TB laboratory service), it evolves through a continuum of stages of development. This tool describes the characteristics of the management components at each of four stages of development. Each stage includes and builds on the characteristics of the previous stage. The characteristics of the first stage describe a national TB laboratory service that has done little to develop that component, whilst the fourth stage portrays the characteristics of a national TB laboratory service that is operating extremely effectively with regard to that component. As TB laboratory services pass through these stages at different rates, different management components may be at different stages of development at the same time. This is usually due to a combination of factors, relating to the focus of the NTP, NTRL and laboratory leadership, the comparative strengths of staff, funding availability and various external demands.

**Selection of and evidence for rating each management stage:** During the workshop, each participant rated the stage (1, 2, 3, or 4) for each measurable component and individually recorded

evidence (e.g. a brief description of an event or situation that they had seen, heard or experienced) which supported the rating they selected. In each of three heterogeneous small workshop groups, the participants shared their evidence and taking into account the different perspectives of each person in their group, sought to reach a consensus on the stage of development of each measurable component. The group work was followed by a plenary session, during which each of the three groups presented their evidence and, after discussion, the participants were able to reach an overall consensus. The final consensus results, together with evidence for the current rating of each component, are shown in Annex 6.

***Identification of leadership and management components that need to be addressed as a priority and formulation of recommendations:*** Through small group and plenary discussions, the workshop participants used the assessment results to identify and agree upon priority areas for improving the leadership, management and organization of the TB lab services in the Philippines at central, intermediate and peripheral levels.

Immediately following the workshop, these identified leadership and management areas were discussed in detail with the NTRL leadership team, in the context of (1) observations made during the site visits, (2) the current needs of the NTP and the NTRL, and (3) other scheduled activities and technical assistance being provided to the NTRL and the TB laboratory services. Priority areas that need to be addressed immediately were identified and form the basis of the recommendations in this report on the type of assistance required for improving leadership and management capacity of the NTRL and NTP's TB laboratory services.

## **4. Findings and Discussion**

The information gathered from the literature review, interviews, meetings, site visits and through the participatory assessment was used to identify the strengths, practical challenges and constraints in the delivery of quality-assured, accessible TB laboratory services for initial diagnosis and for identification and monitoring of multi-drug resistant TB. This information was used to identify the achievements as well as the underlying leadership and management challenges and the organizational capacity of the NTRL in the following areas:

### **4.1 Organization, structure, financing, and human resources**

**Organization:** The NTRL is administratively under the authority of the RITM, whose primary mandate is to provide clinical and laboratory research. Historically, RITM has not been involved in providing direct service for or implementation of public health programs. Yet the NTRL's mandate is to support the NTP through development and implementation of TB laboratory policies, plans, procedures and budgets. The NTRL is responsible to the NTP for the overall management of the diagnostic testing for TB, including initial diagnosis by microscopy, and identification of drug resistant TB to support the PMDT program, quality assurance of microscopy and culture services and training of TB laboratory staff. The NTRL research focus represents only a small portion of its activities. Several partnering agencies, as well as consultants for the Green Light Committee and CDC, have noted the difficulties both for the NTRL itself as well as for the NTP, of having the NTRL under the RITM. It is outside the scope of work of this assessment to discuss or recommend structural changes in the DOH to remove the NTRL administratively from RITM to the NTP. In order to discuss this issue, several other factors will need to be considered, including the physical management and maintenance of the NTRL, sharing of the training and research facilities. The current anomaly may be resolved in the short term through a Memorandum of Understanding between the RITM and the NTP including agreements on staffing and funding for the NTRL.

**Structure of the TB laboratory network:** The decentralized structure of the health services into which the TB laboratories are fully integrated, lends itself to assisting the NTP to obtain optimal laboratory support for case detection and for recognition of the drug resistant TB. However, although an administrative order (from 2007) describes overall lines of authority and accountability, this has not been made known or widely distributed to laboratory staff and there is no formally approved organizational document that details lines of responsibility for TB laboratories at the different levels. The current organogram is for the purpose of organizing microscopy EQA centres, but not for TB culture services. This has affected the mechanism for communication and reporting, which works reasonably well for 'upward' reporting to the NTP, but is not sufficient to manage the TB laboratory network. Senior laboratory staff make most of the significant decisions, though they may consult with mid-level staff on various issues.

**Financial management:** As stated earlier in section 1.6 of this report, the NTRL receives funding from several sources to enable it to fulfil its mandate. Normally, the staff of the NTRL and NTP seek input from TB laboratory heads when planning and developing budgets. But, it is not known whether these budgets are adequate or whether there are serious funding gaps. The reason for this situation is because there is no system for collecting laboratory costing data. Consequently, no detailed costing of the TB laboratory services has been conducted and so the annual cost of running the national TB laboratory services is not known. Likewise, it is difficult to track the expenditure and revenue related to specific TB laboratory services and outputs because the accounting system is at the institutional level.

The one exception to this is the Global Fund expenditure on TB laboratories which can be tracked accurately. This situation affects overall planning and provision of services not just for the NTRL but at all levels. For example, we observed in one CHD in northern Mindanao that the annual budget for 2010 was only a fraction of that required for this laboratory to provide TB culture, payment for annual servicing of the biosafety cabinet, conducting training sessions in TB microscopy, and providing quality assurance, monitoring and supervision of microscopy. Although much of the current funding for TB laboratories is from external donors, both the NTP and NTRL have acknowledged the need for a strategy to ensure long-term sustainable funding as evidenced in the PhilPact document, but this strategy has not yet been implemented or operationalized.

**Human Resources:** Although the NTRL has well-qualified, suitably experienced and committed staff, it is acknowledged that these are insufficient in number to carry out its mandate for the national TB laboratories as well as for the specialized service provision in TB culture and 1<sup>st</sup> and 2<sup>nd</sup> line DST. Consequently, many of the staff have been assigned several diverse roles and responsibilities, which mitigates against their efficiency and productivity. As a 'stop-gap' measure, the NTRL is engaging volunteers, sponsored by the Korean government. Although the NTRL plans to hire several more staff the actual number and cadres required have not been systematically determined and therefore it is difficult for the NTRL to justify the additional budget required to increase the number. There may also be difficulties in recruiting sufficient numbers of staff with the needed qualifications and experience.

Human resource policies and procedures exist, but in the health facilities providing TB diagnostic services, there are several variations in the way these are implemented. Consequently, the number of staff required to manage the workload is not known and there are differences in the way laboratory staff are managed, supervised and appraised. During our site visits, we observed that the roles and responsibilities for staff working in TB laboratories are defined by individual institutions or at local level on an 'as needed' basis, but are not regularly reviewed or modified according to needs. The majority of laboratory staff have a job description, but several staff that we met, reported that these are not up to date and do not necessarily reflect their current roles and responsibilities.

#### **4.2 Policies, standards, and guidelines on biosafety and infection control**

Although there are general National Standards for Biosafety developed by the DOH and the Philippines Association for Biosafety, up until now, there have been no practical guidelines to meet the specific biosafety requirements of TB microscopy and TB culture/DST laboratories. Although microscopy laboratories in DOTS facilities have to be certified, we observed several biosafety gaps and inappropriate working practices in these laboratories, particularly at the peripheral level, even though the infrastructural requirements were quite adequate. This was mainly due to poor education and understanding of TB laboratory biosafety and infection control by both clinical and laboratory staff. In higher level laboratories, carrying out TB culture, some of the CHDs had inadequate infrastructure and biosafety features needed for handling TB cultures. Some of the new TB culture sites have commenced work before the necessary renovations and physical improvements have been made to ensure containment of TB organisms.

However, the NTRL and NTP are in the process of remedying this situation. A task force has been convened to develop national biosafety standards and guidelines for TB laboratories. During June 2010, several international consultants were scheduled to visit the Philippines. These included an infection control specialist for the NTP, an engineer to advise on the architectural requirements for new regional culture laboratories, a JICA consultant to advise on the upgrading of the NTRL infrastructure to biosafety level 3 and a specialist to undertake a biosafety risk assessment in the RITM research laboratories. The

challenge for the NTP and the NTRL is how to coordinate the technical recommendations and outputs of each of these consultants and integrate these into the new national biosafety standards and guidelines for TB laboratories. A longer term challenge will be how to manage the dissemination and implementation of the new standards and guidelines throughout the country. This will require careful planning, capacity building of clinical and laboratory staff, possible infrastructural and equipment upgrades, with regular monitoring and evaluation of progress. The NTRL and regional laboratories will require specialised staff to lead and manage the process.

#### **4.3 Diagnostic services, laboratory methods, and standard operating procedures (SOPs)**

From the technical perspective, the TB laboratory services employ valid laboratory methods. Although almost all of the TB smear microscopy is performed using conventional light microscopy, there has been some discussion about introducing the recently-recommended LED fluorescence to increase sensitivity and cut down the time for examining smears. As already mentioned earlier, all TB culture is performed using conventional solid media and the proportion method for DST, which means a lengthy period for getting results to the patient. In terms of managing PMDT, this is no longer acceptable and therefore the NTP and NTRL plan to introduce newer technologies later this year. Planning and technical training for introducing Line Probe Assay has already commenced, while the introduction of *GeneXpert* is being considered. Discussions are underway on the introduction of an automated liquid culture system for TB. All of these will assist the laboratory identification of TB and rapid recognition of drug resistance. Appropriate technical assistance is being provided by the Korean government, the Foundation for Innovative New Diagnostics (FIND), JICA, CDC and others. Previous technical assessments and reports (e.g. from CDC, and GLC consultants) have dealt in detail with technical issues and therefore, our comments are kept to a minimum.

However, the real management challenge, beyond the technical, is one of standardization and ensuring consistent high quality across the country. Although there are some excellent training manuals available which are used in some laboratories as a substitute for SOPs, no formal National TB laboratory Standard Operating Procedures (SOP) manual exists. However, SOP's for some tests and procedures have been developed by and are used in individual TB microscopy & culture/DST laboratories. But these SOPs are not uniformly standardized and have not been formally evaluated or approved. Consequently, staff cannot be held accountable for adhering to these. Whereas the NTRL has the capability to write national TB laboratory SOPs, dissemination and implementation of these SOPs is a lengthy process.

Practical implementation of new technologies (LED microscopy, liquid culture, LOA and other molecular tools) has implications beyond the laboratory and will require the NTP to review and revise diagnostic treatment algorithms in the NTP Manual of Procedures and to train clinical staff on implementation of the revised algorithms. Although we were informed that this has been done for LPA, countrywide dissemination and implementation of these is a major management challenge. In addition, the use of new technologies (e.g. molecular tools) for rapid detection of MDR-TB may also have implications for procurement of 2<sup>nd</sup> line drugs and therefore it will be important to ensure that the software program used for forecasting drug needs is adjusted accordingly.

#### **4.4 Methods of implementing quality assurance**

Internal and decentralized external quality assurance systems for TB microscopy, using internationally recommended methods, are well-established and results recorded and reported to the NTP on a quarterly basis. Although widely implemented, there are gaps in some areas of the country. Even so, the organization of the EQA system is impressive, as there are few low or middle income countries

globally that have satisfactorily managed to implement a countrywide EQA system for microscopy. However, we observed that the results are not used adequately for mentoring staff on performance issues, or to guide problem solving or corrective action. In addition, some performance problems are not always identified by the current EQA system because of the lack of supportive supervision.

Interim guidelines (based on WHO guidelines) for in-country quality monitoring of TB culture and DST are in place and are being used by some staff. Monitoring of culture centres by the NTRL has been done for the last two years. External monitoring of the DST results is done by RIT, the TB supra national reference laboratory in Japan.

#### **4.5 Provision of technical support to intermediate level laboratories**

During our visits to the CHDs, the staff reported that they were well supported technically by the NTRL, through supervisory visits, advice, provision of reagents and culture media and quality assurance of TB cultures. As the number of culture sites increases, this support to the intermediate level laboratories will be very important, but much more time-consuming for the NTRL staff. Dedicated NTRL staff may be required for this purpose.

#### **4.6 Human resource development planning, training, and supervision**

There are some baseline results on human resource development and training needs, and some training plans and refresher programs exist but implementation needs to be improved. However, most of the training is technical. Little, if any, attention has been given to developing the leadership and management skills of laboratory staff with management responsibilities at the central and intermediate levels. As the TB laboratory services develop, it will become increasingly important for these staff to have the capacity to manage resources and to manage people. Although the NTRL staff are not expected to carry out all the capacity building and training, it will be very important for NTRL staff to standardise and coordinate these activities across the country, and to empower regional laboratory staff to take on an enhanced role. Therefore, it would be advisable to have a dedicated staff member at the NTRL to manage capacity building and training.

Checklists for supervision of microscopy services are available and used by EQA supervisors when following up EQA results on site in individual labs. Likewise there are check-lists for supervision of TB culture labs. But, there is no comprehensive tool for supportive supervision of TB laboratories and support supervision is not regularly conducted in all TB microscopy and culture laboratories. EQA is regularly done but is dependent on logistics and human resources. There is no regular financial support for support supervisory visits.

#### **4.7 Procurement of laboratory equipment and supplies**

A supply management system for microscopy supplies is in place at national level for ZN stains, but does not cover all the reagents and consumables needed for sputum smear microscopy. Some consumables, e.g. sputum collection containers, do not conform to international safety recommendations. Orders for supplies are largely dependent on the approved budget rather than the actual needs. Tracking and distribution are the major weaknesses and therefore there is no full coverage of the system. Local purchases are often made. LGAs do their own procurement of laboratory supplies as the need arises.

Procurement of consumables for TB culture and DST is done on "as needed" basis without forecasting or tracking of supplies. TB Culture media are prepared at the NTRL and distributed to the other culture laboratories.

There are some DOH guidelines for management of laboratory equipment, based on WHO Interim Guidelines with listing of items of laboratory equipment. However, policy guidelines and administrative procedures for the selection, procurement, handling and maintenance of TB laboratory equipment are not defined or documented. One of the current management challenges that requires urgent attention to ensure optimal functioning and biosafety in culture laboratories is the servicing and maintenance of biosafety cabinets. It is both difficult and expensive to get an engineer to travel to culture laboratories in the more remote parts of the country such as northern Mindanao. This needs to be addressed urgently in order to sustain a decentralised culture service.

There has been some discussion that the NTRL might be able to take over the responsibility for procurement of TB laboratory supplies and equipment. Currently the NTRL does not have the capacity for this major undertaking, which requires tracking supplies and forecasting requirements in order to reduce gaps and prevent stock-outs. However, a more appropriate role for the NTRL, working in collaboration with the NTP, would be to liaise closely with Management and Materials Division (MMD) of the DOH on the standards and specifications for all TB laboratory commodities and ensure that these specifications are listed in the catalogue of the MMD and are also disseminated to all LGUs and individual labs. It would also be appropriate for the NTRL to provide quality assurance checks on each batch of new reagents.

Rather than take on any additional procurement responsibilities, it would be preferable for the NTRL to continue to prepare and quality-assure the TB culture media for distribution to all culture laboratories.

#### **4.8 System for data collection, analysis, and feedback**

There is a standard paper-based data collection and reporting system in use throughout the country, but feedback is weak and therefore information is not adequately used for decision making. Monitoring of financial data is lacking. The current paper-based system is now too cumbersome for collation, reporting and management of TB culture and drug resistance results. Proper management of PMDT will require the introduction of web-based software. There are various systems already in use in different countries. The challenge for the NTP and the NTRL is to identify a suitable system and to customise and implement it countrywide.

#### **4.9 Monitoring and evaluation of laboratory services**

Monitoring and evaluation is regularly done, e.g. Microscopy EQA results are reported upwards to the NTP. But the indicators and targets for laboratory performance are not adequate, resulting in incomplete information. Therefore it is difficult to use the data for improving laboratory performance or to drive strategies, plans and budgets.

### **CONCLUSIONS**

- The NTRL staff are both technically competent and committed to developing and managing the TB laboratory services. However, in order to improve their abilities to lead, as well as manage for results, they need to strengthen their leadership and management practices and would benefit from leadership and management skills development.
- Considering all of the gathered information, the management systems that require immediate attention in order to leverage the technical inputs and professional efforts of the NTP and NTRL staff and their partners are human resource and financial management. Strengthening of these systems for the TB laboratories is fundamental to leverage and maximise other technical inputs.

## **5. Recommendations**

### **5.1 External Technical Assistance (TA) Focus over the Next Year**

As the NTRL and NTP are already well supported by several external organizations to develop and improve laboratory technical capacity, we recommend that the TA focus of this USAID-supported initiative over the next year should be on strengthening the management, leadership and organizational capacity at central and intermediate levels. Immediately, attention should be given to the most critical areas affecting the optimal functioning and performance of the NTRL and the TB laboratory services:

- Human resource management
- Financial management
- Leadership and skills development for NTRL and selected regional laboratory staff

SEE RECOMMENDATIONS 2, 3 AND 4 BELOW FOR DETAILS

Focusing on these areas will support and leverage other partners' technical efforts and enable the NTP to realise a well-managed, sustainable, quality-assured national TB laboratory service to support case detection and the management of drug resistant TB.

### **5.2 Human Resources**

- a) We recommend that a review of the NTRL human resource needs be conducted to determine the number of positions and their respective functions, required for the NTRL to carry out its mandate for national TB laboratory services in relation to policy development, research, service provision, quality assurance and monitoring, training and capacity building. A human resource plan, including a revised organizational chart needs to be developed, based on the review and submitted for approval to the RITM director. Justification for new positions and budget will be essential.
- b) We recommend that a training needs assessment be conducted by the NTRL in order to update the TB laboratory training policy that will guide the development of appropriate curricula, training materials, training-of trainers and the refresher training programs in TB microscopy, culture, DST, new technologies, biosafety and infection control, lab management, quality assurance, supervisory practice, data collection and management, and other areas as needed. We suggest that the NTRL requires a full-time training officer to manage and coordinate the various training programs. Short term technical assistance will be needed to mentor the new appointee and to assist with the development and implementation of a national TB lab training plan and budget.

### **5.3 Financial Management and Budgeting**

In order to determine and understand the budgetary needs of the NTRL to carry out its national mandate, we recommend, as an initial step, a detailed costing of the TB laboratory services. This will provide the information for the development and implementation of a financial management tool which will assist with preparation of budgets, decisions on spending and provide an accurate and complete picture of expenditure, revenue and cash flow in relation to specific lab outputs and services.

### **5.4 Management and Leadership Capacity Building**

We recommend building the management and leadership skills of laboratory managers. This program, already developed and used by MSH, will focus initially on equipping central and laboratory staff to be better managers capable of achieving improved results in their laboratories. Four 3-day workshops, each building on the other, will be offered to the selected laboratory management teams with inter-

workshop assignments. Initially local facilitators will be trained in the methodology and a scale-up plan prepared for implementation within the regions.

### **5.5 Short and medium term recommendations for the NTRL**

The following represent areas that the NTRL can address immediately either with existing technical assistance or with additional minimal or no external technical assistance:

- a) **Mission and Values:** We recommend that NTRL refine the NTRL Mission statement to be applicable to all TB laboratory services in the Philippines and define organizational and ethical values for the TB lab services. These need to be disseminated widely
- b) **Development of policies, strategies, standards and guidelines:** In order for the NTP to provide high quality diagnostic lab services throughout the Philippines, it will be essential for the NTRL to work closely with the NTP to develop, disseminate and implement TB laboratory policies, strategies, standards and guidelines applicable to TB laboratory services at the central, intermediate and peripheral levels.
- c) **Standard Operating Procedures:** Although there are various lab manuals for training and lab procedures, we recommend that the NTRL develop a set of comprehensive TB laboratory SOPs covering all areas of TB laboratory practice, obtain official approval for the document and then disseminate and implement the SOPs in all TB microscopy and TB culture/DST labs.
- d) **Biosafety:** Although general National Standards for Biosafety exist, practical guidelines applicable to TB microscopy and TB culture/DST labs need to be developed and implemented in line with these standards and in line with the draft WHO Biosafety Manual 2009. We recommend that a Laboratory Biosafety specialist be identified and engaged to assist the NTRL to coordinate the outputs of the different consultants scheduled to come to the Philippines in June 2010 and to assist the NTRL to develop the policy, standards and guideline.
- e) **New Diagnostic Technologies:** We recommend that the NTP and NTRL work together to specify and endorse the use of internationally-recommended new diagnostic technologies that will strengthen the NTP. These may include LED fluorescence microscopy, liquid culture, and molecular diagnostics (e.g. line probe assays and GeneXpert) and others as they become available.

### **5.6 Recommendations for medium – longer-term technical assistance**

The following represent areas that require longer term efforts and external assistance for systems development and implementation

- a) **Supervision:** We recommend that NTRL, together with the NTP, develops a strategy and guidelines for supportive supervision of TB microscopy and culture sites and a program for capacity building in supervisory practice. As supervision of microscopy sites is practically managed from the regional level, we recommend the development and implementation for a TOT supervisory skills course for NTP regional coordinators, to enable them to train laboratory supervisors in their respective regions. Technical assistance over one year will be required to assist NTRL to develop the strategy and guidelines and to develop and implement the TOT supervisory skills course. Long term technical assistance will be required for one year.
- b) **Management Information System:** We recommend the adoption and implementation of an electronic, web-based TB laboratory Management information System, initially at the NTRL and Lung Health Centre, with the aim of rolling it out to other TB culture sites at a later stage. This system needs to be linked to software being used by the NTP for patient management and to the National Epidemiology Centre for analysis. Long term technical assistance for 2 years will be required to identify, customize and implement a suitable system.

- c) **Supply management.** We recommend that NTRL and NTP, in collaboration with the Materials Management Division of the DOH, review and where necessary revise and update the procurement system for all TB laboratory commodities in order to track supplies, forecast requirements, reduce gaps and prevent stock-outs. This will include a review and updating of the standards and specifications for all TB laboratory commodities and ensuring that these are listed in the catalogue of the MMD, and are also disseminated to all LGUs and individual labs. Laboratory staff responsible for ordering supplies will need to be trained in the basic principles of supply management and in the proper use of the updated system. We recommend that NTRL continue to prepare and quality-assure the TB culture media and distribute it to all culture laboratories. Long term technical assistance will be required for a minimum of 2 years.

## 6. Technical Assistance for the next 12 months

The following table represents recommendations for external technical assistance to be provided to the NTRL and NTP over the next 12 months to strengthen the management, leadership and organizational capacity of the NTRL:

ACTIVITY AREA	PERSONNEL REQUIRED	PROPOSED DURATION OF TECHNICAL ASSISTANCE
Human resource needs assessment and development of a human resource plan	Human resource development specialist (Local –if available)	6 months
Training needs assessment and updating of the TB laboratory training policy.	Human resource development specialist (Local –if available)	3 months
Development of a national TB laboratory training plan and budget; Mentoring of NTRL’s training officer	Human resource development specialist (Local –if available)	3 months
Detailed costing of TB laboratory services in relation to expected outputs and services. Identification of suitable financial management tool to assist NTRL and NTP with preparation of TB laboratory budgets and monitoring of expenditure, revenue and cash flow.	Health economist or other suitably qualified financial specialist	6 months
Training of NTRL and NTP staff in budget preparation and monitoring of expenditure.	Health economist or other suitably qualified financial specialist	3 months
Leadership and management development program for selected NTRL and regional laboratory managers	MSH leadership development specialist & MSH laboratory management systems specialist	2 months STTA over 1 year 3 months STTA over 1 year



## **ANNEXES**



**Annex 1**  
**SCOPE OF WORK**  
**21 February 2010**

Linking Initiatives and Networking to Control Tuberculosis  
(TB LINC)

**9/F Ma. Natividad Building**  
**470 T. M. Kalaw cor. Cortada St.**  
**Ermita, Manila**

MEMORANDUM OF APPROVAL  
for  
Scope of Work

Title of STTA/Activity:

**Technical Assistance in Support of**  
**NTP Laboratory Network Strengthening**

The attached Scope of Work has been prepared, reviewed, and edited to a degree sufficient for approval and contracting.

**APPROVED:**

		DOLORES C. CASTILLO, MD, MPH Chief of Party
Date:	Date:	Date: 21 February 2010

## **SCOPE OF WORK**

### **Technical Assistance in Support of NTP Laboratory Network Strengthening**

#### **I. Introduction and background information**

The Linking Initiatives and Networking for the Control of Tuberculosis (TB LINC Project) is a five-year cooperative agreement under the United States Agency for International Development (USAID). The project is being implemented by the Philippine Business for Social Progress (PBSP) and is slated to run from October 2006 to September 2011. TB LINC's goal is to achieve USAID's strategic objective no. 3 (SO3) which is "Improved family health sustainably achieved". TB LINC's main partner is the Philippines' DOH, particularly the NTP under the National Center for Disease Prevention and Control (NCDPC). The National TB Reference Laboratory (NTRL), under DOH's Research Institute for Tropical Medicine (RITM), is another key partner particularly in terms of technical collaboration and support to the NTP's laboratory services. Technical support is provided to these key partners, as well as to other public and private agencies and to the local government units in TB LINC's 20 project sites to help the NTP achieve the program targets of at least 70% case detection rate, and cure rate of at least 85% among the smear positive cases detected.

The Philippines is one of the 22 high-TB burden countries in the world. TB is currently the sixth leading cause of morbidity and mortality in the country and exacts a high toll on the population. In 1997, the DOTS strategy was adopted by the Philippine NTP and was implemented in a number of pilot sites. This was gradually expanded to the rest of the country until DOTS public sector coverage reached 100% by the end of 2002.

DOTS implementation was further expanded through initiatives such as public-private partnerships, hospital DOTS program, workplace TB programs, programmatic management of drug-resistant tuberculosis (PMDT), TB program in children, and strengthened community participation. Much progress has been made in the country's TB control program since DOTS was adopted with improvements in case detection and cure rates. The latest prevalence survey in 2007 showed a reduction in the country's smear (+) TB prevalence from 3.1/1000 in 1997 to 2.0/1000 in 2007. However, the prevalence of multi-drug resistance remains high with rates of 3.8% among new cases, and 20.9% among previously treated patients. The national and global targets for case detection and treatment success have been reached level with a country level CDR of 75% and treatment success rate of 88% in 2007. Program performance at the local level, however, is variable with many localities still unable to reach the targets for case detection and cure.

The Philippines is one of the countries that pioneered the implementation of a GLC-approved program for managing MDRTB (DOTS Plus) through the Tropical Disease Foundation Incorporated (TDFI) with the support of GFATM. The country has recently initiated the integration of the MDRTB treatment program into the NTP, the Programmatic Management of Drug-resistant TB (PMDT), and is currently expanding its coverage in the country. The Lung Center of the Philippines (LCP) is being considered to be the management unit for PMDT, while the National TB Reference Laboratory (NTRL), being the overall manager of the NTP laboratory network, will also manage the PMDT laboratories.

The NTP, through the NTRL, took measures to strengthen its laboratory network by revising its procedures for quality assurance in 2004, and by building the capacity of the intermediate level laboratories for laboratory management. However, the implementation of the quality assurance system needs further improvement. Currently, there are five laboratories in the NTP network that are capable of performing TB culture, while drug susceptibility testing with an acceptable level of proficiency is performed in only two central level laboratories. The use of new technology for rapid TB diagnosis is still limited to one private laboratory. In addition, findings from an external program review in 2008 showed

that NTRL has limited capability to effectively oversee the laboratory network due to organizational and technical weaknesses.

In 2009, the country updated its strategic plan for TB control with the “Philippine Plan of Action to Control TB” (PhilPACT: 2010-2015) to accelerate the country’s efforts to achieve the TB related MDGs and the country’s National Objectives for Health on TB Disease Prevention and Control. It aims to reduce local variations in program performance, scale up and sustain DOTS implementation, ensure quality DOTS services, and reduce out-of-pocket expenses.

The implementation of PhilPACT, along with recent adjustments in GFATM assistance to PMDT, requires an accelerated transfer of PMDT managerial and leadership responsibilities from TDFI to LCP and NTRL (for the laboratory component). Based on previous assessments by experts from WHO-GLC, NTRL needs to increase its capacities to effectively perform its role as manager of the laboratory network within the short term.

## **II. Objective of short-term technical assistance**

The short-term technical consultant will assess the NTRL’s capacities that are necessary to carry out its mandate, particularly on the leadership and managerial aspects, and identify technical assistance needs in the context of NTP laboratory network development.

## **III. Tasks under this consultancy**

Under this Scope of Work, the consultant will perform the following:

1. Refine SOW with TB stakeholders, including NTP, NTRL, Lung Center of the Philippines (LCP), WHO/Philippines, TB LINC and USAID and submit inception report.
2. Desk review of previous assessments by CDC and others conducted on NTRL’s technical capacity.
3. Conduct appropriate information gathering through the review of relevant reports and policy documents related to NTRL and laboratory network development; key informant interviews and/or group discussions with key stakeholders including staff from NTP, LCP, NTRL, RITM, TDFI, USAID, WHO, GFATM, PBSP, TB LINC, selected regional CHDs and LGUs; visit selected TB laboratories and DOTS facilities, including PMDT treatment centers and/or treatment sites.
4. Based on information gathered, assess NTRL’s leadership and managerial capacity in the context of the NTP laboratory network. The assessment will focus on the NTRL’s organizational capacity for management, strategy development and leadership in the following areas:
  - 1.1 Organization, structure, financing, and human resources
  - 1.2 Policies, standards, and guidelines on biosafety and infection control
  - 1.3 Diagnostic services, laboratory methods, and standard operating procedures (SOPs)
  - 1.4 Methods of implementing quality assurance
  - 1.5 Provision of technical support to intermediate level laboratories
  - 1.6 Human resource development planning, training, and supervision
  - 1.7 Procurement of laboratory equipment and supplies
  - 1.7 System for data collection, analysis, and feedback
  - 1.8 Monitoring and evaluation of laboratory services

3. Prepare and submit detailed assessment report. The assessment report will include the following:

- Description of current mandate of NTRL
- Analysis of the level of capacity and functionality of NTRL along the areas previously listed
- Specific recommendations on areas where capacity strengthening is required and how best to improve capacity (including organizational, technical, human resource development, etc.).
- Develop the terms of reference (TORs) for technical assistance as follow through and implementation of the recommendations. The scope and duration of the follow-on TA will be outlined.

**IV. Duration of work and deliverables**

The duration of work is three weeks; the table below describes the estimated level of effort in days:

Activity	LOE (days)
Preparation of inception report	2
Briefing with NTP / NTRL	1
Assessment activities including field visits	15
Report writing	2
Presentation and debriefing	1
<b>TOTAL</b>	<b>21</b>

**V. Minimum qualifications**

- Expertise in the field of TB laboratory services and laboratory management in both developed and developing countries
- Experience in international TB consulting
- Experience in the Philippines not required
- Fluency in the English language

**VI. Period of performance and level of effort**

A Technical Group composed of staff from the DOH/NTP, NTRL, Lung Center of the Philippines, TB LINC, USAID, and WHO will provide technical inputs to the consultant, when needed. TB LINC in coordination with DOH, USAID, and WHO, will provide by administrative and logistical support. All deliverables will be submitted to the Technical Group for initial review and endorsement to the TB LINC Chief of Party for final approval and acceptance.

## ANNEX 2 ITINERARY and PERSONS MET

DATE	PLACES VISITED	PERSONS MET
24 May 2010	Meeting with NTP, Heritage Hotel, Manila	Dr. Jaime Lagahid, Director NCDPC Dr. Rosalind Vianzon, NTP Director Dr. Cindy Am, NTRL Dr. Michael Voniatis WHO Dr. Woojin Lew, WHO
25 May 2010	Meetings at the RITM and NTRL	Dr. Remigio Olveda Dr. Celia Carlos Dr. Socorro Lupisan Dr. Noel Macalalad NTRL staff
26 May 2010	Lung Center of the Philippines	Dr. Dario Defensor Mr Lawrence Laquindanum
	Quezon City Health Department	Dr. Esperanza Arias
	Pag Asa Health Center, Quezon City	Dr. Ferdinand Cavalida Ms. Joy Gatian Magtanong
	PTSI central laboratory	Ms. Francia Gonzales Dr. Elizabeth Cadena
27 May 2010	NTRL - Workshop preparation and customization of the assessment tool	
28 May 2010	Fly to Cagayan de Oro Region 10 TB Reference Laboratory, Cagayan de Oro City	Dr. Evelyn Magsayo Dr. Jocelyn Torrecampo Ms. Teresita Paguidopon Ms. Jenny Alabado
	Carmen Health Center, Cagayan de Oro City	Ms. Yvette Pelaez Ms. Shiela Sabanal
	Opol Rural Health Unit, Misamis Oriental	Mr. Ronald Noel Roldan Dr. Edgel Miranda
31 May – 2 June 2010	3-day TB Laboratory Management Participatory Assessment Workshop, Bay View Hotel, Manila	See Annex 5 – Workshop participants
3 June 2010	USAID Philippines debriefing	Ms. Ann Hirschey Dr. Padma Shetty Ms. Carrie Rasmussen
4 June 2010	DOH debriefing	Dr. Jaime Lagahid (DOH/NCDPC) Dr. Rosalind Vianzon (DOH/NTP) Dr. Allan Fabella (DOH/NTP) Dr. Marl Mantala & Dr. Michael Voniatis (WHO) Dr. Ogtay (WHO/GLC) Ann Hirschey & Carrie Rasmussen (USAID) Dr. Dolores Castillo (TB LINC) Jazmin Gutierrez (PBSP) Dr. Noel Macalalad (NTRL) Dr. Cecilia Ama (NTRL) Cristy Villarico (NTRL) Alma Palparan (NTRL) Basilisa Tan (NTRL)



**ANNEX 3**  
**COPY OF DEPARTMENT OF HEALTH ADMINISTRATIVE ORDER 2007-0019**



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**  
Bldg. No. 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, Manila 1003  
Tel. Nos. (632) 711-95-02, 711-95-03; Telefax No. (632) 743-18-29



April 11, 2007

**ADMINISTRATIVE ORDER**  
No. 2007-0019

**SUBJECT: Guidelines for the Implementation of the Quality Assurance System on Direct Sputum Smear Microscopy (DSSM)**

#### **I. RATIONALE**

Tuberculosis (TB) is one of the deadliest infectious diseases affecting the world today; it is the sixth leading cause of morbidity and mortality in the Philippines (DOH, 2004). The Philippines ranks eighth among the 22 high-TB burden countries in the world, and third in the Western Pacific Region (WHO, 2005). The estimated number of TB cases in the country is over 241,000 (WHO, 2005), and the majority of these cases come from the economically productive age groups. In 2006, the Philippines reached the TB control global targets of 85% treatment success rate, and 70% case detection rate at 90% and 75%, respectively.

The strategy endorsed by the World Health Organization (WHO) to control TB in countries with a high TB burden is called Directly Observed Treatment Short Course (DOTS). A key element of DOTS is the availability of, and access to, quality microscopy services provided through a laboratory network within the National TB Control Program (NTP). Direct sputum smear microscopy (DSSM) is the primary tool for case detection and for follow-up of cases under treatment. The TB laboratory service is an essential, but less supported, part of the National Tuberculosis Control Program (NTP). Poorly functioning laboratories can give rise to erroneous microscopy results and to undetected TB cases that would remain infectious and further fuel the TB epidemic. Hence, the quality of TB laboratory services must be ensured to protect the public from misdiagnosis.

The Quality Assurance System (QAS) for DSSM using blinded rechecking was established under the NTP in 1989 to ensure accuracy and reliability of results. In 1996, the QAS was strengthened with the adoption of DOTS in the Philippines. In 2002, the QAS was modified based on the general methods and guidelines developed in 2001 by experts from the International Union Against Tuberculosis and Lung Disease (IUATLD), World Health Organization (WHO), Japan Anti Tuberculosis Association (JATA), Royal Netherlands

Tuberculosis Foundation (KNCV), Centers for Disease Control and Prevention (CDC), and the Association of Public Health Laboratories (APHL). The modified QAS was pilot tested in Cebu province with the assistance of the Japan International Cooperation Agency (JICA). In 2003, the "Manual of Quality Assurance for Sputum Smear Microscopy" was developed by the NTP through the National Tuberculosis Reference Laboratory (NTRL) of the Department of Health (DOH), with technical support from JICA and WHO, to serve as the guide in implementing the new QAS. The system was officially adopted by the country in 2004 and was then implemented in phases. Capability building for the nationwide implementation of QAS started in 2004 and completed in December 2006. Observations made from monitoring visits and program reviews during the phased implementation of QAS revealed several problems including the (1) variable manner of implementation; (2) constraints related to organization, infrastructure, funds, and human resources; and (3) limited coverage of QAS policies and guidelines.

This administrative order is being issued to (1) clearly define the policies and guidelines on QAS of DSSM including the functions of different organizational levels of the NTP laboratory network based on experiences gained during the initial phase of implementation, and (2) broaden the coverage of QAS to include private TB laboratories.

## **II. POLICY STATEMENTS**

- A. The National Objectives for Health, 2005 - 2010 aims to reduce morbidity and mortality from Tuberculosis in support of the attainment of the MDGs, of which, one of the strategic thrusts is the "Implementation of quality assurance measures in the implementation of DOTS and DOTS PLUS, with emphasis on laboratory diagnosis, to improve TB control program efficiency".
- B. Tuberculosis is one of the diseases included under the Programs Projects and Activities (PPA) *intensified disease prevention and control* under the Health Service Delivery component of the FOURmula One for Health strategy for implementing health reforms. DOH is mandated to ensure that public health services and goods are of good quality including TB laboratory services.
- C. A national Quality Assurance System (QAS) for TB sputum microscopy services must be established in accordance to international standards and practices to ensure that services are of acceptable quality to support the pursuit of the goals of the NTP.
- D. All public and private TB microscopy laboratories in the country shall be covered by the national QAS for TB sputum microscopy; the National Tuberculosis Reference Laboratory (NTRL) shall lead in the development and overall management of the QAS.
- E. Local government units (provincial or chartered city), in collaboration with NTRL and Regional TB Laboratories, shall establish a QA center in their areas of jurisdiction and shall ensure the continuous implementation of QAS in their respective localities. The implementation of QAS shall be according to the operating guidelines contained in the Manual of Quality Assurance for Sputum Smear Microscopy (2003).
- F. DOH offices, particularly the National Center for Disease Prevention and Control, the NTRL, and the Centers for Health Development, shall provide technical and financial support for the sustained implementation of QAS.

- G. Trainings on basic sputum smear microscopy shall be performed only by trainers certified by NTRL, and shall be conducted only in NTRL certified training facilities to ensure that such trainings are in accordance to national and international standards.

### III. OBJECTIVES

- A. To define policies, and broadly describe the implementation of QAS for DSSM;
- B. To define the roles and functions of each level of the TB laboratory network, health facilities including health personnel;
- C. To describe the system for participation of other TB laboratories including the private sector; and
- D. To describe policies governing trainings on QAS.

### IV. SCOPE

This issuance shall cover all agencies/units, whether public, particularly the local government units, private, including non-government organizations, that are supporting and implementing the QAS, performing DSSM, and involved with the implementation of the NTP.

### V. DEFINITION OF TERMS

- A. **Directly observed treatment short course (DOTS)** – refers to the main strategy to control TB and is one of the most cost-effective health strategies. It has five elements namely (1) diagnosis by quality assured bacteriology (including QA DSSM), (2) supply of anti-TB drugs with efficient drug management, (3) supervised intake of short course chemotherapy and patient support, (4) monitoring and evaluation including impact measurement, and (5) political commitment with sustained financing.
- B. **Quality Assurance System (QAS)** – refers to the system designed to continuously improve the proficiency of laboratory services.
- C. **External Quality Assessment (EQA)** – refers to the process of periodic and independent measurement of laboratory performance in collaboration with a competent external laboratory; its components include on-site evaluation to review quality control procedures and on-site re-reading of smears, blinded slide re-checking, and panel testing.
- D. **Quality Control (QC)** – refers to the systematic internal monitoring of working practices, technical procedures, equipment and materials including quality of stains.
- E. **Quality improvement (QI)** – refers to the process by which the various components of the sputum microscopy services are analyzed to find ways to permanently remove obstacles to success. The elements of QI include data collection, data analysis, and problem solving. The process involves continuous monitoring and identification of problems followed by remedial action to prevent a recurrence of the problem. It often relies on effective supervisory visits.

- F. **Laboratory Network** – refers to the different levels of TB laboratories under the NTP and includes the central, intermediate, and peripheral; each level with their respective functions and working in close coordination with each other.
- G. **Central Laboratory** – refers to the National TB Reference Laboratory (NTRL)
- H. **Intermediate Laboratory** – refers to the Regional TB Laboratory and Provincial TB Laboratory or Quality Assurance Centers, located in the level of administrative regions and provinces.
- I. **Peripheral Laboratory** – refers to the microscopy centers or laboratories located in primary care rural health units (RHU), city health centers (CHC), government and private hospitals, and private clinics that provide TB sputum smear microscopy services.

## **VI. THE QUALITY ASSURANCE SYSTEM FOR TB LABORATORIES**

Quality Assurance System (QAS) for TB sputum microscopy is a system designed to continuously improve and maintain the proficiency of the laboratory services. The QAS aims to ensure the reliability of the laboratory services by detecting deficiencies in microscopy work that can be attributed to events within or outside the laboratory. The objectives of QAS are to:

- (1) Ensure the accuracy of sputum microscopy results,
- (2) Identify practices that could be potential sources of error, and
- (3) Ensure that corrective actions are initiated within a reasonably short period of time.

QAS has three components, namely: quality control (QC), external quality assessment (EQA), and quality improvement (QI). The activities of these components are implemented by the NTP's network of laboratories through its three organizational levels, namely: central (NTRL), intermediate (Regional TB laboratories; Provincial/City Quality Assurance centers), and peripheral (microscopy laboratories). The QAS will cover all TB microscopy laboratories in public primary care units (RHU/HC), private clinics and laboratories, government and private hospitals, as well as those in non-government organizations. Ensuring the quality of the microscopy services requires a well functioning QAS that monitors all aspects of laboratory operations. The commitment and support of all stakeholders are required to sustain its implementation.

## **VII. GUIDELINES AND PROCEDURES**

### **A. Establishment of the NTP Laboratory Network**

A country requires a network of TB laboratories to meet the global targets of TB control. International experts recommend that the TB laboratory network in populous countries like the Philippines should have a tri-level organizational structure namely: central, intermediate and peripheral. In general, the central laboratory (NTRL) develops policies and standards and fulfills the overall manager's role; the intermediate level laboratories (regional and provincial TB laboratories) work with the central level in implementing the policies, while the peripheral level (microscopy laboratories) provides the sputum microscopy services.

The functions of each laboratory level are the following:

### **1. Central Laboratory**

The central TB laboratory is the National Tuberculosis Reference Laboratory (NTRL) located at the Research Institute of Tropical Medicine in Alabang, Muntinlupa City. The main functions of the NTRL include the development of policies, technical guidelines and standards that are in consonance with existing NTP policies; exercise overall technical supervision of the TB laboratory services; provide technical advice; research; and surveillance. A number of AFB sputum microscopy examinations, cultures, and drug susceptibility testing (DST) shall be performed at the NTRL to maintain the central staff's skills on training, supervision, and quality assurance. The specific functions of the NTRL are the following:

- Develop, update, and disseminate policies, standards, and guidelines on laboratory procedures for quality assured TB bacteriologic diagnosis;
- Develop a national strategic plan for TB laboratory services in collaboration with the NTP;
- Provide technical advice to the NTP on laboratory matters including requirements of laboratory supplies and equipment;
- Develop technical specifications or standards for TB laboratory equipment and facilities, reagents, consumables, and other laboratory supplies; and monitor compliance to the standards;
- Develop and disseminate guidelines on the care and maintenance of microscopes and other laboratory equipment;
- Monitor, supervise, and evaluate the nationwide implementation of QAS and overall laboratory performance, especially in areas where there are no Regional NTP Medical Technologist Coordinators;
- Provide technical and managerial support to intermediate level laboratories;
- Conduct training on quality assurance and other laboratory support activities (training, supervision, laboratory safety, and equipment maintenance) for intermediate level staff i.e. regional laboratory staff, provincial / city controllers, and NTP coordinators;
- Perform EQA for microscopy examinations done at regional TB laboratories, PTSL Central Laboratory, and specialty hospitals in the National Capital Region;
- In special situations, designate a QA center for TB Laboratories in collaboration with NTP to fill any gaps in QAS; and
- Conduct operational researches related to laboratory services and QAS.

### **2. Intermediate Laboratories**

#### **a. Regional TB Laboratory**

The Regional TB Laboratory covers an administrative region in the country and is administratively under the DOH Centers for Health Development, with technical supervision from the Regional NTP Medical Coordinator. A number of sputum microscopy examinations may be done at the regional TB laboratories to maintain the regional staff's skills in training, supervision, and quality control.

The functions of the Regional TB Laboratory are:

- Prepare a strategic plan for the region's TB laboratory services in collaboration with the Regional NTP Coordinators;

- Assist the central laboratory in the development and dissemination of TB laboratory policies;
- Provide advocacy, and technical, and administrative support for the establishment and operation of QA centers in each province/city;
- Monitor, supervise, and evaluate the implementation of QAS in the region;
- Perform as necessary, EQA on microscopy examinations done at the provincial/city TB laboratories and QA centers;
- Collate and analyze data on EQA and laboratory activities from the provincial and peripheral laboratories;
- Submit quarterly and annual reports on EQA and laboratory activities to NTRL within the prescribed timeline;
- Conduct training on DSSM as endorsed by NTRL; and
- Assess the quality of reagents that were distributed in the field.

**b. Provincial and City TB Laboratory (QA Centers)**

The Provincial or City TB Laboratory under the local government serves as the Quality Assurance (QA) center for the province or chartered city respectively under the technical supervision of the NTP Coordinator. The provincial / city laboratory (QA Center) will cover the TB microscopy laboratories located in their corresponding area. This will include the RHU/CHC; Public-Private Mix DOTS clinics; provincial and district hospitals; private hospitals and clinics; DOH-retained, specialty, and regional hospitals; and the PTSI microscopy laboratories. A number of microscopy examinations may be done at the provincial laboratory to maintain the provincial staff's skills on training, supervision, and quality assurance.

The principal functions of the QA Centers are the following:

- Implement QAS activities including determination of sample size, collection of sample slides (Note: collection of sample slides should **not** be done by the Controller to ensure blindedness), blinded re-checking of slides, provide feedback to microscopists, perform on-site assessment of laboratory activities (supervisory visits), and provide technical or managerial support to the peripheral microscopy laboratories in implementing corrective actions for quality improvement;
- Collate and analyze data on EQA and laboratory activities to identify problematic microscopy centers;
- Submit quarterly and annual reports on EQA and laboratory activities to the Regional TB laboratory within the prescribed timeline; and
- Provide technical advice to LGUs on procurement of laboratory equipment and supplies to ensure that these conform to NTP standards.

**3. Peripheral Laboratory**

The Peripheral Laboratories are TB microscopy laboratories located in rural health units and city health centers (RHU/HC), those in PPMD units, and in public and private hospitals under the supervision of the head of the clinic/unit. The laboratory should have at least one binocular microscope, and at least one NTP trained microscopist covering a population of about 100,000 or less, provided that the daily workload is adequate to maintain the staff's proficiency.

The principal functions include:

- Perform sputum smear microscopy for diagnosis, and for follow up of TB patients on therapy using the Ziehl-Neelsen technique.

- Ensure quality control in the laboratory
- Store sputum slides for EQA
- Receive feedback from QA center and take corrective action as needed
- File EQA results and feedback sheets from the QA center;
- Record and report TB laboratory data

## **B. TRAINING**

### **1. Categories of Staff for Training on Quality Assurance**

The following staff must undergo the standard training on QAS at the NTRL and/or its designated laboratory, e.g. Cebu Tuberculosis Reference Laboratory (CTRL), prior to their involvement in the implementation of QAS.

1. Controllers at QA center
2. Provincial / City NTP Coordinators
3. Regional NTP Coordinators
4. Regional NTP Medical Technologists

Controllers at the QA center and the Regional Medical Technologists should also have been trained in DSSM.

The Provincial / City NTP Team and QA staff must conduct an orientation on the new QAS for the staff of Rural Health Units / Health Centers, PPMD units, and other TB Laboratories. They should also ensure that each health unit or laboratory has a copy of the Manual on Quality Assurance for Sputum Smear Microscopy (DOH, 2004).

## **VIII. QUALITY ASSURANCE (QA) CENTER:**

The provincial or city government, with assistance from the regional TB laboratory and/or NTRL, shall be responsible for the establishment of the QA center and to start and manage its operations. The QA center is under the administrative supervision of the provincial or city government; it is responsible for the effective implementation of QAS in the area. The requirements for a QA center to perform its functions are:

### **A. Location**

There must be at least one QA center per province or city preferably located in sufficient proximity to the Provincial/City NTP office. If the local NTP Coordinators deem that one QA center is insufficient for reasons of workload and/or accessibility to the peripheral microscopy laboratories, another one may be established after consultation with the provincial/city and regional NTP teams, and the NTRL.

### **B. Staffing**

There should be at least one, preferably two, Controller(s) in the QA center. The Controller should be a Registered Medical Technologist who has completed the basic and/or refresher course on sputum microscopy, and QAS training provided by the NTRL or CTRL.

**C. Facilities and Necessary Equipment/ Supplies**

The QA center ideally should have a quiet and comfortable working environment with the necessary laboratory and office equipment and supplies to allow the efficient conduct of its functions. For the specific requirements and physical set-up of a QA Center, refer to the Manual on Quality Assurance for Sputum Smear Microscopy.

**D. Funding and Logistical Support**

The establishment, operation, and maintenance of the QA center is the responsibility of the respective LGUs (province/city). This also includes providing adequate funds for salaries and benefits of staff, equipment, forms, supplies, and funds for field supervisory visits for on-site evaluation and feedback to the peripheral laboratories. Assistance from DOH, international and local partners, may be mobilized to strengthen the QA center. In addition, QA centers may develop and implement financing schemes to sustain the implementation of QAS in accordance to existing laws and policies, and without jeopardizing access to TB laboratory services especially for the poor.

**E. Specific Activities**

The following are the major activities performed by the QA centers; these are described in detail in the Manual for Quality Assurance for Sputum Smear Microscopy

- The specific activities to implement EQA are:
  - a. Determine sample size per microscopy center using the LQAS,
  - b. Collect sample slides from peripheral laboratories on a quarterly basis (in some situations as approved by the Provincial/City NTP Coordinators, peripheral laboratories may bring the slides to the QA center)
  - c. Perform blind re-checking and smear assessment of slides,
  - d. Analyze and interpret results of blind rechecking,
  - e. Perform on-site assessment of laboratory activities using the standard checklist,
  - f. Provide feedback of EQA results to the peripheral laboratories, and
  - g. Monitor compliance to recommendations.
- Consolidate, analyze, and report data on EQA and other TB laboratory activities
- Perform on-the-job training and/or re-training of microscopists in collaboration with the regional TB laboratory and/or NTRL.

**F. Reporting and Feedback Schedule**

Quarterly reports of QA activities must be submitted to the provincial/city health office through the NTP Coordinators, and to the Regional TB Medical Technologist Coordinator. Regional TB laboratories should then send the collated reports with a corresponding analysis to NTRL on a quarterly basis. Timelines will be as follows:

- Feedback from the QA center to the microscopy center should be done within 10 days after detecting a major error.
- Report from Provincial /City TB Laboratories to Regional TB Laboratory: end of the second month following the assessed quarter



## **ANNEX 4 WORKSHOP AGENDA**

### **The TB Laboratory Management Assessment for the Philippines A 3-day participatory assessment workshop for a representative cross section of NTRL and NTP key stakeholders.**

**31 May – 2 June 2010  
0900 – 1700 hours**

**Venue: Bay View Park Hotel, Manila**

**Facilitators: Catherine Mundy  
Gavin Macgregor-Skinner**

#### **Objectives**

To assess the current leadership, management and organizational status of the TB laboratory services in the Philippines in order to identify priority areas for improvement.

#### **Rationale**

Traditional laboratory assessments typically rely on external evaluators, intensive data collection and checklists and result in findings and recommendations that often fall short of producing a realistic plan for improvement and do not necessarily foster local ownership or 'buy-in'. In this 3-day workshop, the knowledge, insights and creativity of the NTP and NTRL stakeholders will be harnessed. Through a structured participatory process the participants will be facilitated to analyze information from their own experience in order to determine the current status of the leadership, managerial and organizational capacity. Through a consensus building process, the participants will identify the priority areas for improving the leadership, management and organization of the country's TB laboratory services.

#### **Expected Outputs**

1. A collective baseline assessment of the current leadership, management and organizational status of the Philippines TB laboratory services.
2. Agreed-upon priority areas for improving the leadership, management and organization of the TB lab services in the Philippines.
3. Recommendations on the type of assistance required for improving leadership and management capacity.

***“Never doubt that a small group of thoughtful, committed citizens  
can change the world. Indeed, it is the only thing that ever has.”***

**- Margaret Mead**

## Day 1 Monday 31 May, 2010

Time	Activities
8.00 – 9.00	Arrivals and registration
<b>INTRODUCTORY SESSION:</b>	
9:00 – 9.30	OPENING SESSION Prayer, Welcome & Opening Remarks
9:30 – 10:00	Introductions and getting to know each other
10:00 – 10:15	<i>Tea break</i>
10:15 - 10:45	Discussion of workshop objectives and agenda, workshop expectations and norms
10:45 – 12:00	The role of National TB Reference Laboratory for TB laboratory services in the Philippines. Review of the Vision, Mission and Values of the NTRL.
12:00 - 1:00	<b>LUNCH</b>
1:00 - 3:00	<ul style="list-style-type: none"> <li>• Introducing the assessment process.</li> <li>• Links between leadership, improved management, work climate, sustainability and organizational results.</li> <li>• What does the assessment contain: Exploring the meaning of the 5 management areas and the management components</li> <li>• Explanation of the assessment tool and the process to be used</li> <li>• The importance of team work</li> </ul>
3:00- 3:15	<i>Tea break</i>
<b>PART 1: Where are we now?</b>	
3.15 – 5:00	<p>Individual and team work on the following management areas: <b>Mission, Values, and Strategy</b></p> <p>a) Completion of the assessment instrument by individual participants</p> <p>b) TEAM WORK: Consensus on Current Status of Management Development with supporting evidence by each of the 3 teams</p>

***“How wonderful it is that nobody need wait a single moment before starting to improve the world”***

- Anne Frank

## Day 2 Tuesday 1 June, 2010

Time	Activities
9:00 – 9:15	Welcome to Day 2, opening prayer and review of today’s agenda and activities
<b>PART 1: Where are we now? (Continued)</b>	
9:15 – 10:00	Individual and team work on the following management areas:  <b>Structure and Systems.</b> <ul style="list-style-type: none"> <li>a) Completion of the assessment instrument by individual participants</li> <li>b) TEAM WORK: Consensus on Current Status of Management Development with supporting evidence by each of the 3 teams</li> </ul>
10:00 – 10:15	<i>Tea Break</i>
10:15 – 12:00	Continuation of team work on the <b>Systems</b>
12:00 – 1:00	<i>LUNCH</i>
1:00 – 5:00	Continuation of team work on the <b>Systems</b>

***“To achieve greatness, start where you are, use what you have, do what you can”***

- Arthur Ashe

### Day 3 Wednesday 2 June, 2010

Time	Activities
9:00 – 9:15	Welcome to Day 3, opening prayer and review of today’s agenda and activities
9:15 – 10:15	PLENARY SESSION: Feedback from teams and discussion to reach full group consensus on current status of management components.
10:15 -10:30	Tea Break
10:30- 12:00	PLENARY SESSION (continued)
12:00 – 1:00	LUNCH
<b>Part 2: Where are we going?</b>	
1:00 – 2:00	TEAM WORK: Selection of 3 priority management components that need to be strengthened
2:00 – 3:30	PLENARY SESSION: <ul style="list-style-type: none"> <li>• Feedback from teams on priority management components that need to be strengthened</li> <li>• Plenary discussion to reach full group consensus on the priorities for strengthening leadership and management over the next 3 years</li> </ul>
3:30 – 3:45	Tea Break
3:45 – 4:15	Workshop evaluation (Participants complete individual evaluation forms)
4:15 – 5:00	Workshop closing and presentation of certificates of participation

***“Martin Luther King did not say, ‘I have a strategic plan’. Instead, he shouted, I have a DREAM’ and he created a crusade”***

- Anonymous

## ANNEX 5 WORKSHOP PARTICIPANTS

NAME	AFFILIATION
1. Arthur Lagos *	USAID-TB LINC Project
2. Noel G. Macalalad *	NTRL
3. Ma. Cecilia Ama *	NTRL
4. Cristino Narciso	NTRL
5. Basilisa A. Tan	NTRL
6. Virgil Belen	NTRL
7. Alma Palparan	NTRL
8. Kristina Pua	NTRL
9. Katherine Burgonio	NTRL
10. Cristina Villarico	NTRL
11. Hector S. Macalalad	NTRL
12. Marienella Galit	NTRL
13. Lydia F. Sombrero	RITM
14. Socorro Lupisan	RITM
15. Allan Fabella	DOH/National TB Control Program
16. Michael Voniatis	WHO Philippine Office
17. Dario Defensor	Lung Center of the Philippines
18. Lawrence Laquindanum	Lung Center of the Philippines
19. Bernard Yumang	Quezon City Health Department
20. Mary Rochelle Paulino	Quezon City Health Department
21. Concepcion F. Ang	UP PGH
22. Eunice Barcena	CHD 5 Regional TB Laboratory
23. Francia Gonzales	PTSI
24. Cleofe S. Arciaga	Muntinlupa City Health Office
25. Aleli P. Molera	Muntinlupa City Health Office
26. Jennifer S. Baluez	Muntinlupa City Health Office
27. Ma. Lourdes Pasion	DOH Center for Health Development Region 3

\* Team leaders of 3 heterogeneous workshop teams



## ANNEX 6

### Assessment Tool<sup>1</sup> and

### Results of the Philippines TB Laboratory Management Participatory Assessment

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Mission</b>						
<b>Existence and Knowledge</b>	No formal mission statement exists for the TB lab services, OR The existing mission is inconsistent with the current purpose of the national TB lab services and the needs of the National TB Program and its clients.	The TB lab mission statement exists, is consistent with the current purpose of the TB lab services and the needs of the NTP. It is sometimes referred to by laboratory staff.	The TB lab mission statement is frequently referred to by laboratory staff and is known by many other staff in the TB Program, DOH and partner organizations.	The TB lab mission statement is widely known and regularly reviewed to ensure that it reflects the current purpose of the TB lab services and the needs of the NTP and its clients throughout the Philippines.	<b>1</b>	<b>Although the NTRL has its own mission statement, there is no specific TB lab services mission statement. It was agreed that the NTRL mission statement could be modified to apply to all TB labs and would then need to be widely disseminated.</b>
<b>Values</b>						
<b>Existence and Application</b>	Organizational values and ethical principles have not been defined for the TB lab Services.	Organizational values and ethical principles have been defined for the TB lab services, are sometimes referred to by senior lab staff and are consistent with the overall values of the TB Program	The values and ethical principles of the TB lab services are frequently referred to by laboratory staff at all levels, across the whole country.	The values and ethical principles of the TB lab services are widely known, and all laboratory staff are held accountable for adhering to them.	<b>1</b>	<b>Although many laboratory staff are practising good values as they work, no core organizational values or ethical principles for the TB lab services have been clearly defined, written down or made known to staff.</b>

<sup>1</sup> Adapted from the *Management and Organizational Sustainability Tool, 2<sup>nd</sup> Edition, 2004*, Management Sciences for Health, Boston, MA, USA. ISBN 0-913723-92-4

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Strategy</b>						
<b>Links to Mission and Values</b>	Strategies are developed for TB diagnostic laboratory services in response to funders' requirements or the preferences of a few decision makers, but without reference to the Mission and Values of the TB lab services	Strategies for TB diagnostic laboratory services are sometimes developed with reference to the Mission and values, but more often in response to other requirements, preferences and mandates	Strategies are almost always developed within the general context of the Mission and Values	The strategies developed for the TB Lab Services are in line with the Mission and the Values, and referred to in all planning exercises affecting TB laboratories.	<b>2</b>	<b>TB lab strategies have been defined in order to support the grant from the Global Fund. The strategic plan of the NTRL is in the process of being revised in order to help to improve TB lab services. It is in line with the NTRL mission statement.</b>
<b>Links to the National TB Program</b>	Strategies for the TB lab services are developed without knowledge of the current or potential demand for TB diagnostic services (across the country) by the TB Program and its clients	Strategies for the TB lab services are developed on the basis of anecdotal knowledge (that is, not based on real data or information) of the demand for TB diagnostic services across the country.	Strategies for the TB lab services are developed on the basis of occasional assessments of the demand for TB diagnostic services, as well as analysis of the TB lab services already provided by other organizations	A mechanism is in place for regularly scanning and dialoguing with the TB Program on current and potential demand for TB diagnostic services and using these findings to develop lab strategies.	<b>3</b>	<b>Strategy development is influenced by occasional lab program assessment results. For example, NTP data such as new/old smear (+)/(-), CDR; NPS; assessment by the TBLINC on accessibility of microscopy centres are used to develop strategies. Sometimes, TB diagnostic services are based on analysis and recommendations by other organization such as WHO, RIT-JATA, USAID-TBLINC</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Links to patients and their communities</b>	Lab strategies are developed without reference to the needs of patients or their communities.	Laboratory strategies are developed based on assumptions about the needs of patients and their communities.	Laboratory strategies are developed based on available information about the needs of patients and their communities.	Laboratory strategies are developed with direct input and feedback from patients and their communities about their needs.	<b>3</b>	<b>NTP and NTRL discuss together on patient and community needs and strategies required to address these. For example, available information on accessibility of microscopy centres, TB in prison, inaccessibility of culture services are used to develop strategies. Data is from surveys such as DRS and NPS is also used for strategy development.</b>
<b>Structure</b>						
<b>Authority and Accountability</b>	There is no formally approved organizational document that defines current lines of authority and accountability at the different levels within the TB Lab Services.	An up-to-date organizational document defines lines of authority and accountability within the TB Lab Services. It is included in the NTP's manual of policies and procedures.	The TB lab services organizational document is sometimes used when issues arise pertaining to lines of authority and accountability.	The TB Lab Services organizational document is regularly updated and consistently used to resolve issues pertaining to lines of authority and accountability.	<b>1</b>	<b>Although an administrative order (from 2007) describes overall lines of authority and accountability, this has not been made known or widely distributed to lab staff. An organogram has been prepared for the purpose of organizing microscopy EQA centres, but not for TB culture services. There is no formally approved document that details lines of responsibility for TB labs at different levels of the health system.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Communication</b>	There are no defined communication mechanisms to share information between the NTP and the TB labs and across the different levels of the TB Lab services.	Communication mechanisms are used only to convey necessary information from senior management to the rest of the lab staff.	Communication mechanisms have been clearly defined and are sometimes used to share information between the NTP and the labs, as well as among staff at different levels of the TB Lab Services.	Clearly defined communication mechanisms are used consistently to share information (i) between the NTP and the different levels of the TB Lab Services, (ii) across the different labs & (iii) among staff at different levels..	<b>2</b>	<b>Lines of communication for official reporting are defined and work well for 'upward' reporting. Day to day communication is through email, texting, cell phone, but is not sufficient to effectively manage the TB lab network. An operationally effective communication mechanism needs to be defined and implemented.</b>
<b>Roles and Responsibilities</b>	Roles and responsibilities of TB lab staff at each level of the health system have not been clearly defined and most staff do not have a written job description. Work is assigned on an 'as needed' basis.	Roles and responsibilities of all TB lab staff are in the process of being defined. Most work is still assigned on an 'as needed' basis.	Roles, responsibilities for all TB lab staff are clearly defined in up-to-date individual job descriptions. These are beginning to be used as the basis for assigning work.	The roles and , responsibilities defined in the job descriptions are consistently used as the basis for assigning work. They are regularly reviewed to ensure that TB lab staff work assignments serve the strategies of the TB Lab Services and the NTP.	<b>2</b>	<b>Roles and responsibilities for staff working in TB labs are defined by individual institutions or at local level on an 'as needed' basis, but are not regularly reviewed or modified according to needs. The majority of lab staff do have a job description, but these are not all up to date and do not necessarily reflect current roles and responsibilities.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Decision Making</b>	The TB lab heads and coordinators make all significant decisions without discussing them with staff	The TB lab heads and coordinators make all significant decisions after listening to the views of selected staff members.	Mid-level lab staff (senior technologists) are encouraged to make and carry out decisions regarding their own work and the work of their lab teams.	All lab staff are expected to make significant decisions regarding their own work and the work of their lab teams and to carry out and be accountable for those decisions.	<b>2</b>	<b>There are some examples of mid-level staff making decisions, but these are often over-ruled by senior staff who make most of the decisions. Consultations are made but final decisions are influenced by positions of authority.</b>
<b>Systems</b>						
<b>Planning: Existence and implementation of an operational plan</b>	Most activities of the TB lab services are unplanned and decided on an 'as needed' basis.	Plans have been developed for some levels/parts of the TB lab services, in line with particular needs or projects or programs, usually to meet funders' requirements, but there is no overall operational plan for the TB lab services	An annual operational TB lab plan has been developed but this is independent of the broad strategies of the TB lab services and the NTP.	The annual operational plan for the TB lab services supports the laboratory strategies and is in line with the strategic and operational plans of the NTP.	<b>2</b>	<b>Annual operational plans for TB labs are nested in the NTPs own operational plan. However, there is no single operational plan for TB labs.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Human Resource Management: Policies and Procedures</b>	There are no policies on job classification, salaries, hiring, firing, promotion, grievances, or work hours for TB lab staff. There are no procedures for performance evaluation, staff development, or maintenance of employee data.	The NTRL/NTP has recognized the need for a formal human resource system and is working with the DOH HR department to clarify human resource policies and procedures, staff positions and job descriptions.	HR policies and procedures are in place and TB lab heads are beginning to use them to hire and retain appropriate numbers and grades of talented and committed lab staff.	HR policies and procedures are widely known and consistently implemented by TB lab heads. Staff performance reviews are carried out regularly.	<b>3</b>	<b>HR policies and procedures exist but there are variations in the way they are implemented.</b>
<b>Human Resource Management: Training</b>	No comprehensive assessment or evaluation of the needs and priorities for training of TB lab staff has been carried out. An orientation program for new TB lab staff and a refresher training plan for existing TB lab staff have not been designed.	A limited assessment of the TB lab staff training needs and priorities has been carried out, but orientation and refresher training plans have not been designed. Some orientation programs for new TB lab staff and some refresher training programs for existing staff have been organized.	A training plan has been defined for new and existing TB lab staff, based on a comprehensive evaluation of the needs and priorities of the TB laboratory services and the NTP. Some orientation and refresher training programs have been organized but the training plan is not fully implemented.	A training plan for all new and existing TB lab staff, based on a comprehensive evaluation of the needs and priorities of the TB lab services and the NTP has been fully defined and implemented. Regular refresher training programs and an orientation program for new TB lab staff have been designed and conducted.	<b>3</b>	<b>There are some baseline results on training needs. Training plans and refresher programs exist but implementation needs to be improved.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Human Resource Management: Supervision</b>	There is no regular supervision of the TB microscopy and culture labs. No adequate system or tool has been developed for this purpose. No budget has been allocated to finance regular supervisory visits.	Some supervisory procedures and check lists have been developed to assist with the supervision of the TB microscopy and culture sites. Some supervisory visits have been made to selected sites.	Supervisory tools and guidelines have been developed and an annual timetable and budget drawn up for regular supervision of TB microscopy and culture sites, but these have not yet been fully implemented.	TB lab heads and designated supervisors consistently use the lab supervisory tools and guidelines during scheduled supervisory visits. Regular financial support is available. Findings and supervision reports are regularly reviewed to identify problems and take corrective action	<b>2</b>	<b>Checklists for supervision of microscopy services are available and used by EQA supervisors when following up EQA results on site in individual labs. Likewise there are check-lists for supervision of TB culture labs. There is no comprehensive tool for supportive supervision of TB labs and support supervision is not regularly conducted in all TB microscopy and culture labs. EQA is regularly done but is dependent on logistics and human resources. There is no regular financial support for support supervisory visits.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Monitoring and Evaluation</b>	The work of the TB lab services (microscopy, culture & DST) is only monitored and their results evaluated by external evaluators when funders demand it.	The TB lab services monitor their own work to determine adherence to planned activities. Results are evaluated by external teams when funders demand it.	The TB lab services regularly monitor their own work to determine progress towards achieving goals and objectives. In collaboration with the NTP, they evaluate results on a quarterly and annual basis and at other times as required.	The TB lab services regularly monitor their own progress, evaluate results in collaboration with the NTP and use the findings to improve TB diagnostic services at all levels and to plan the next phase of work.	<b>2</b>	<b>Monitoring and evaluation is regularly done, e.g. Microscopy EQA results and reported upwards to the NTP, but the indicators and targets for laboratory performance are not adequate, resulting in incomplete information. Therefore it is difficult to use the data for improving laboratory performance or to drive strategies, plans and budgets.</b>
<b>Information Management: Data Collection, Reporting and Use of Information</b>	The national TB Lab services do not have a documented, uniform system for the collection and reporting of data. Data are often inaccurate and reports are rarely submitted on schedule. There is no feedback and report information is not used for decision making.	A standardized laboratory information management system has been introduced for the national TB lab services. This is beginning to improve the accuracy and timeliness of routine service and financial reports. Feedback is sporadic but some information in the reports is used for decision making.	Most TB microscopy & culture labs are using the standardized information management system to produce accurate service and financial data and timely reports. Lab heads are expected to give regular feedback and to use the information in the reports for decision making.	The standardized lab information management system is aligned with the NTP's MIS for diagnosing and managing patients and provides cross-checking to guarantee the accuracy of service and financial data. Prompt feedback is given and there are clear enforced consequences for late reports. Data are widely used for decision making and to improve performance.	<b>2</b>	<b>There is a standard paper-based data collection and reporting system but feedback is weak. Information is not adequately used for decision making. Monitoring of financial data is lacking.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Quality: Infrastructure and Biosafety/Infection control</b>	National standards and guidelines for providing adequate laboratory working space, and a safe, secure and clean working environment have not been defined for (a) microscopy and (b) culture/DST labs.	National safety standards and guidelines, in line with international biosafety recommendations, are in the process of being defined for (a) microscopy and (b) culture/DST labs. Some labs have implemented safe working practices on an informal basis. Some laboratories have adequate physical facilities.	The minimum physical lab requirements for a safe working environment and standard procedures for safe working practices have been defined and implemented in some microscopy and culture/DST labs, but accidents and unsafe occurrences are not systematically recorded. Improvements to the physical facilities of the laboratories are in progress.	All the microscopy and culture/DST lab premises conform to the minimum physical requirements for a safe working environment. All staff regularly conform to the guidelines on safe working practice and systematically record all accidents and unsafe occurrences.	<b>2</b>	<b>Microscopy laboratories in DOTS facilities have to be certified, but several gaps exist in safe working practices. National standards are in the process of being developed. Task Force has been convened to develop national biosafety standards and guidelines for TB.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Quality: Existence and Use of Standard Operating Procedures (SOPs)</b>	TB lab SOPs have not been developed and are not used by the staff working in TB microscopy and in culture/DST labs.	TB lab SOPs for some tests and procedures have been developed, but have not been evaluated or formally approved. They are in use in some of the TB microscopy and culture/DST labs.	Up-to-date TB lab SOPs covering test procedures, safety, preparation of reagents & media, and use & maintenance of equipment have been written and are in the process of being formally evaluated and approved for use in all microscopy and culture/DST labs. Many lab staff use these SOPs.	SOPs containing comprehensive guidelines for all areas of TB laboratory practice have been approved and implemented in all TB microscopy and culture/DST labs. All lab staff consistently use and adhere to these guidelines.	<b>2</b>	<b>SOP's for some tests and procedures have been developed by individual labs and are used in some of the TB microscopy &amp; culture/DST labs. However, these SOPs have not been formally evaluated or approved. Although there are different training manuals available in some labs, no formal national TB lab SOP document exists.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Quality monitoring: TB microscopy</b>	Internal and external quality monitoring systems have not been established for microscopy labs. Quality control is not part of everyday management practice	Internal and external quality monitoring systems for TB microscopy are in the process of being defined and implemented.	Internal and external quality monitoring systems for TB microscopy have been defined and are being implemented by some staff.	Internal and external quality monitoring systems for assessing and improving the quality of TB microscopy have been established, implemented and evaluated. All staff in TB microscopy labs have been orientated in their use and regularly employ the systems.	<b>3</b>	<b>Internal and decentralized external quality assurance systems for TB microscopy are in place and results recorded and reported to the NTP on a quarterly basis. Although widely implemented, there are gaps in some areas of the country. The results are not used adequately for mentoring staff on performance issues or to guide problem solving.</b>
<b>Quality monitoring: TB culture/DST</b>	Internal and external quality monitoring systems have not been established for culture/DST labs. Quality control is not part of everyday management practice	Internal and external quality monitoring systems for TB culture and DST are in the process of being defined and implemented.	Internal and external quality monitoring systems for TB culture/DST have been defined and are being implemented by some staff.	Internal and external quality monitoring systems for assessing and improving the quality of TB culture and DST have been established, implemented and evaluated. All staff in TB culture/DST labs have been orientated in their use and regularly employ the systems.	<b>2</b>	<b>Interim guidelines (based on WHO guidelines) for in-country quality monitoring of TB culture and DST are in place. These are being used by some staff. Monitoring of culture centres by the NTRL has been done for 2 years. External monitoring of the DST results is done by the TB supra national reference lab in Japan.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Supply Management: TB microscopy laboratory reagents and consumables.</b>	There is no system in place to procure, track, or regulate TB microscopy laboratory reagents and consumables. Ordering is done 'as needed'; supplies are simply received and stocked when they arrive and distributed upon demand.	A supply management system for TB microscopy has been designed to accurately forecast, procure, distribute and track all laboratory reagents and consumables in relation to their demand and use. Staff have not yet been trained to use the system and frequent stock outs occur, but are not reported.	TB laboratory staff have been trained to use the TB microscopy laboratory supply management system. The system has been implemented in most laboratories. Stock outs occur infrequently, but are reported to the appropriate authority.	All TB microscopy laboratory staff are familiar with and consistently use the established laboratory supply management system to track supplies, forecast future requirements, reduce gaps and prevent stock-outs. Stock outs rarely occur and are reported promptly to the appropriate authority.	<b>1</b>	<b>A supply management system for microscopy supplies is in place at national level for ZN stains, but does not cover all the reagents and consumables needed for sputum smear microscopy. Orders for supplies are dependent on the approved budget. Tracking and distribution are weaknesses and therefore there is no full coverage of the system. Local purchases are often made. LGAs do their own procurement of lab supplies when the need arises.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Supply Management: TB culture/DST consumables.</b>	There is no system in place to procure, track, or regulate TB culture/DST consumables. Ordering is done 'as needed'; supplies are simply received and stocked when they arrive and distributed upon demand.	A supply management system for TB culture/DST has been designed to accurately forecast, procure, distribute and track all laboratory reagents and consumables in relation to their demand and use. Staff have not yet been trained to use the system and frequent stock outs occur, but are not reported to NTRL.	TB laboratory staff have been trained to use the TB culture/DST laboratory supply management system. The system has been implemented in most laboratories. Stock outs occur infrequently and are reported to NTRL.	All TB culture/DST laboratory staff are familiar with and consistently use the established laboratory supply management system to track supplies, forecast future requirements, reduce gaps and prevent stock-outs. Stock outs rarely occur and are reported promptly to NTRL.	<b>1</b>	<b>Procurement is done on "as needed" basis without forecasting or tracking of supplies. TB Culture media are prepared at the NTRL and distributed to the other culture labs.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Supply Management: Equipment</b>	Policy guidelines and administrative procedures for the selection, procurement, handling and maintenance of TB lab equipment are not defined or documented.	Policy guidelines and administrative procedures have been defined for TB lab equipment management by the NTRL, but are not yet implemented. Decisions regarding equipment are frequently made on an 'as needed' basis.	Laboratory and NTP staff have been oriented in the policy guidelines and administrative procedures for TB lab equipment management. But there is no recording system used for decisions and actions relating to equipment procurement, management and maintenance.	The established policy guidelines and administrative procedures for selecting, procuring, handling and maintaining TB lab equipment are consistently adhered to and a recording system is used for decisions and actions relating to equipment procurement, management and maintenance.	<b>1</b>	<b>There are some DOH guidelines based on WHO Interim Guidelines with listing of laboratory equipments. However, policy guidelines and administrative procedures for the selection, procurement, handling and maintenance of TB lab equipment are not defined or documented.</b>
<b>Financial Management: Costing of TB lab services</b>	No costing of the TB laboratory services has been conducted and the annual cost of running the national TB laboratory services is not known.	A system for collecting TB laboratory cost data and calculating the recurrent and capital costs of the TB labs has been devised and is in the process of being implemented.	The TB laboratory costing system has been implemented to collect the cost data and the TB laboratory heads & senior lab staff have been trained to collect the data.	The TB lab heads work with the NTRL/ NTP/DOH to analyze the cost data and establish the operating costs of the TB labs. This data is regularly used to plan laboratory activities, prepare budgets and make decisions on expenditure.	<b>1</b>	<b>There is no system for collecting lab costing data. Therefore, no costing of the TB lab services has been conducted and the annual cost of running the national TB lab services is not known.</b>

Management Component	Stages of Development and Their Characteristics				Current Stage	Overall Consensus and Evidence
	1	2	3	4		
<b>Financial management: Budgeting and expenditure</b>	NTRL/NTP/DOH staff develop budgets for the TB lab services without input from TB lab heads. The financial system does not accurately track TB laboratory expenditure, revenue and cash flow.	NTRL/NTP/DOH staff develop budgets and usually seek input from TB lab heads. The financial system tracks expenditure, revenue and cash flow by line item (e.g. salaries, equipment, supplies) without links to specific lab outputs or services.	NTRL/NTP/DOH staff develop budgets in conjunction with TB lab heads. The financial system tracks expenditure, revenues and cash flow by line item (e.g. salaries, equipment, supplies) with some links to specific lab outputs and services.	TB lab heads work with financial staff to develop realistic budgets that support the implementation of the TB Laboratory Services annual operational plan. The finance system provides an accurate, complete picture of expenditure, revenue and cash flow in relation to specific lab outputs and services.	<b>2</b>	<b>NTRL/NTP/DOH staff develop budgets and usually seek input from TB lab heads. The accounting system is at the institutional level and can track expenditure and revenue but without links to specific TB lab outputs or services. Expenditure on TB labs using Global Fund monies can be tracked.</b>
<b>Financial management: Revenue generation</b>	The funding for TB laboratory services is not sustainable and does not permit long-term planning.	The NTRL and NTP acknowledge the need for sustainable funding for TB lab services, but have not implemented a strategy for determining the short, mid and long term funding needs.	The NTRL and NTP are working together to implement a sustainable funding strategy to cover the current needs of the TB laboratory services.	The NTRL and NTP are continuously working together to assure sustainable funding to meet the current and future needs of the TB laboratory services	<b>2</b>	<b>The NTRL and NTP acknowledge the need for sustainable funding for TB lab services - evidence lies in the PhilPact document - but not yet implemented or operationalized.</b>