



March 28, 2005

**DEPARTMENT MEMORANDUM**

No. 2005-0058

**TO: ALL UNDERSECRETARIES, ASSISTANT SECRETARIES, DIRECTORS OF BUREAUS, CENTERS FOR HEALTH DEVELOPMENT, SERVICES AND SPECIALTY HOSPITALS, CHIEF OF MEDICAL CENTERS & HOSPITALS, LOCAL GOVERNMENT UNITS & PUBLIC PRIVATE MIX DOTS CENTER.**

**Subject: Implementing Guidelines for Quality Assurance System (QAS) on Direct Sputum Smear Microscopy.**

**I. Purpose:**

This Department Memorandum is issued to all national, regional, provincial / city TB laboratories and all TB sputum smear microscopy centers that offer DOTS strategy of NTP.

**II. Importance of QAS:**

TB laboratory service is a fundamental part of a tuberculosis control program. Yet, it is often not given the needed attention and support under the DOTS strategy.

Laboratory services identify TB cases, the first step in treatment and thus prevention. TB laboratories are also critical for monitoring progress during treatment, reporting cases and TB surveillance. Generally, the inadequate quality of laboratory services and the poorly functioning laboratories result in missed TB cases or wrong diagnosis.

False negative results for sputum smear examination mean infectious cases remain in the community spreading the epidemic, while patients continue to suffer and possibly die. On the other hand, false positive results mean healthy people unnecessarily undergo months of treatment.

In countries with a heavy burden of tuberculosis like the Philippines, quality in the laboratory must be installed. "Quality Assurance (QA) for Sputum Smear Microscopy (SSM) "was published in 2004 and authorized by Secretary of Health to establish

effective QAS in the Philippines. Although the guideline was authorized, the implementation of it faced several problems. Often there is lack of staff or resources. Training is often inadequate and inexperienced staff may miss the bacilli or contaminate the specimen.

Thus to ensure quality of services, QAS must be a vital component in the activities of microscopy centers.

### **III. SCOPE OF QAS:**

#### **a. Implementation for the different levels of laboratory/ health facility:**

All laboratory levels must have a QA program. QA are functions of the National TB Reference Laboratory (NTRL) over the Regional Laboratory, Regional Laboratory over the Provincial QA Center and Provincial QA Center over the Rural Health Units/ City Health Centers. Moreover, External Quality Assessment (EQA) which consist of blinded-rechecking and on-site evaluation of laboratory facility, standards and procedures are main functions of provincial QA center over the microscopy centers located in the RHUs/CHCs and PPMDs. Regional laboratory will do the EQA for DOH retained hospitals in the region while the NTRL will do the EQA for DOH retained hospitals in NCR, CHD 4A& 4B and PTSI, Central Laboratory.

#### **b. Monitoring and Supervision System:**

All NTP activities should be monitored regularly including quality assurance of TB laboratory. Preferably, the program manager and the laboratory manager must go together in monitoring. The NTP national, regional/ provincial coordinator, medical /nurse/ medical technologist coordinator should conduct together monitoring in their respective assignments.

Likewise, the DOH- Representatives who are tasked to monitor the priority programs of the Department of Health should also monitor all TB program activities including QA. The NTP Coordinator will orient them about the program and all its laboratory component. They will be provided with monitoring checklist for identifying issues and concerns to be submitted to the Regional NTP Coordinator for appropriate action.

With regards to collection of slides from the microscopy centers for reading of the controller the following strategies are recommended:

- The Provincial NTP Coordinator (medical /nurse) should collect slides in the different RHUs of their province and submit them to provincial controller for reading and evaluation.
- The Regional NTP Coordinator should collect slides in the DOH regional retained hospitals of their region and submit them for reading of the regional medical technologist.

- The Regional NTP Coordinator should collect slides from DOH retained hospitals in NCR, CHD 4 A & 4 B and submit them to NTRL controller for reading.
- For regions who have no regional laboratory and no regional medical technologists as in the case of ARMM, the NTRL will be in-charge of the monitoring and supervision of the region, retained hospital and partly province who have just established QAS.

#### IV. Definition of Terms:

1. **National Tuberculosis Control Program (NTP)** – It is a DOH priority program to administer TB management based on technically sound evidence and consistent policies and procedures.
2. **Directly Observed Treatment, Short - course (DOTS) Strategy** – . it is the most effective TB control strategy which is recommended internationally. It finds and cures the patient, prevent transmission and drug resistance .
3. **Directly Observed Treatment , SCC (DOTS) or “ Tutok Gamutan”** – it is a strategy developed to ensure treatment compliance by providing constant and motivational supervision to TB patient. DOTS work by having a responsible person , referred to as treatment partner watching the TB patient takes medicines everyday during the whole course of treatment.
4. **Quality Assurance (QA)** – It is a system designed to continuously improve the reliability and efficiency of laboratory services.
5. **Quality Control (QC)** – a systematic internal monitoring of working practices, technical procedures, equipment and materials including quality of stains.
6. **External Quality Assessment (EQA)** – a process to assess laboratory performance. EQA includes on-site- evaluation, panel testing, and blinded re-checking.
7. **Quality Improvement (QI)** – a process by which the components of smear microscopy diagnostic services are analyzed with the aim of looking for ways to permanently remove obstacles to success. Data collection, data analysis and creative problem solving are key components.
8. **On-site evaluation** -observation of work under actual condition in the peripheral laboratories by the reference/ intermediate laboratory.
9. **Blinded slide re-checking** – blinded re-checking or re-reading of routine smears from the peripheral laboratories by a higher level laboratory.

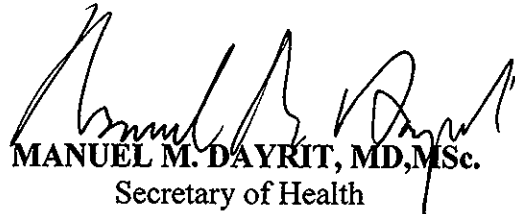
**V. QA Manual of Procedures:**

“Quality Assurance for Sputum Smear Microscopy“ shall provide operating guidelines to all national, regional, provincial /city TB laboratories and all TB sputum smear microscopy centers and shall serve as basis to network the laboratory activities of NTP.

**VI. Effectivity:**

All concerned are hereby encouraged to establish QAS to ensure systematic approach to proper laboratory management.

This order shall take effect immediately.

  
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Secretary of Health