ii. GLOSSARY of TERMS

National Tuberculosis Program (NTP) Countrywide, permanent program responsible for activities directed at controlling tuberculosis through integrated efforts with the general health services for implementing the DOTS strategy promoted by WHO and the IUATLD.

DOT Directly Observed Treatment

DOTS The recommended strategy for TB control. This includes (1) government commitment to TB control activities, (2) case detection by sputum smear microscopy, (3) direct observed treatment (DOT) with standardized short-course chemotherapy, (4) a regular, uninterrupted supply of anti-TB drugs, and (5) a standardized recording and reporting system.

AFB Acid-fast bacilli

Peripheral Laboratory Laboratory located at primary health center or district hospital.

Intermediate Laboratory Regional or provincial laboratory existing in a larger hospital or city.

Central Laboratory May exist as part of the central public health laboratory or as an upgraded laboratory in the country's principal tuberculosis institution. Serves as the national reference laboratory for the tuberculosis program.

Reference Laboratory (RL) National reference laboratory or central laboratory. Plays an essential role in the organization and maintenance of the network of laboratories, and, among other things, develops guidelines for standardizing smear microscopy, assuring quality of testing, and overseeing training. Supports External Quality Assessment efforts in collaboration with the NTP.

District Used in this document to describe the administrative level at which the NTP is implemented. May be Region, Zone, Province, Governorate or Oblast.

Ziehl-Neelsen Stain (ZN) Acid-fast staining method using carbolfuchsin that is steam heated on the slides, decolorized, then counterstained with methylene blue. AFB appear red against a blue background.

Quality Assurance (QA) System designed to continuously improve the reliability and efficiency of laboratory services. Includes internal quality control, external quality assessment, and quality improvement.

> **Quality Control (QC)** Also called Internal Quality Assurance, includes all means by which the TB smear microscopy laboratory controls operation, including instrument checks and checking new lots of staining solutions.

External Quality Assessment (EQA) A process which allows participant laboratories to assess their capabilities by comparing their results with those in other laboratories in the network (intermediate and central laboratory) through panel testing and blinded rechecking. EQA also includes on-site evaluation of the laboratory to review quality of performance and should include on-site rereading of smears. EQA is an expansion of the proficiency testing as described by IUATLD.

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 the key components of this process. It involves continued monitoring, identifying defects, followed by remedial action including retraining when needed, to prevent recurrence of problems. QI often relies on effective on-site evaluation visits.

Proficiency Testing Historically, each organization has used this term differently.

(IUATLD) Assessment of laboratory capabilities by comparing results from different laboratories. EQA is an expansion of proficiency testing as defined by IUATLD.

(WHO) Process for sending smears from the reference laboratory to the peripheral sites.

(International Organization for Standardization ISO) Determination of laboratory testing performance by means of interlaboratory test comparisons.

Panel Testing Sending stained and/or unstained smears from the reference laboratory to the peripheral or intermediate laboratory to check proficiency in reading and reporting. Panel testing is equivalent to the WHO definition of proficiency testing. *The term panel testing is used in these guidelines in order to eliminate the confusion over the different definitions of proficiency testing.*

Rechecking Sending smears from the peripheral laboratory to a reference laboratory (intermediate or central laboratory) for rereading. These guidelines recommend that rechecking is always blinded, ensuring that the controller does not know the results from the peripheral laboratory. In other documents, this may also be referred to as rereading.

Controller Term used to describe the supervisory laboratory or technician responsible for rechecking slides.

Statistically valid sampling A method designed to obtain a random, representative subset of all slides which allows for quantitatively accurate conclusions.

Slide positivity rate (SPR) Proportion of positive slides among all those examined (diagnostic and monitoring) within a microscopy laboratory over a defined period of time.

Major error This type of error is considered the most critical since it has the highest potential impact on patient management, and can result in an incorrect diagnosis or

improper management of a patient. Major errors may indicate gross technical deficiencies, and include both High False Positive and High False Negative errors.

High False Positive (HFP) A negative smear that is misread as 1+ to 3+ positive[1]. This is a major error.

High False Negative (HFN) A 1+ to 3+ positive smear that is misread as negative. This is a major error.

Minor error In clinical practice, these errors may have some impact on patient management. However, for the purpose of evaluating laboratory performance, this type of error is considered less serious, because of inherent limitations in consistently detecting a few AFB that may be unequally distributed within a smear. The frequency of minor errors may indicate technical deficiencies.

Quantification Error (QE) Difference of more than one grade in reading a positive slide between examinee and controller. This is a minor error that generally has no impact on case management.

Low False Positive (LFP) Previously called a scanty false positive. A negative smear that is misread as a low (1-9AFB/100fields) positive. This type of minor error occurs occasionally even in laboratories that are performing well.

Low False Negative (LFN) Previously called a scanty false negative. A low (1-9AFB/100fields) positive smear that is misread as negative. This type of minor error occurs occasionally even in laboratories that are performing well.

Low Positive Term used in this document to describe 1-9 acid-fast bacilli per 100 fields, which is the WHO/IUATLD standard for quantitation. These results are reported to the physician as exact number of AFB seen. It is up to the physician and the NTP to decide if this represents a case or not. Previously referred to as a scanty positive.

Feedback Process of communicating results of EQA to the original laboratory, including suggestions for possible causes of errors and remedies.

[1] Based on IUATLD/WHO recommended grading of sputum smear microscopy results