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TB Microscopy Network Accreditation

An assessment tool

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TB MICROSCOPY NETWORK ACCREDITATION – AN ASSESSMENT TOOL

This document is the result of a TBCARE I project sponsored by the Unites States Agency for International Development (USAID). The team of experts responsible for its development came from CDC, IUATLD, KNCV, KIT, NTP Pakistan and WHO, besides an independent expert.

The need for an assessment tool for accreditation of TB microscopy networks complementary to that for accreditation of TB reference laboratories was identified through strategic planning by the GLI. An IUATLD working group for Laboratory Accreditation was created and the project was submitted to USAID / TBCARE I for sponsoring. Via a series of workshops and circulation of drafts the expert team developed the standards, their measures and the accompanying questionnaires for assessment. An advanced draft of the tool was pilot tested in Pakistan, allowing its completion. The standards and the final version of the tool were circulated to the Core Group of the GLI and endorsed with minor modifications.

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CONTENTS

PREFACE

Quality assured AFB-microscopy serves as a critical entry point for the diagnosis of TB and monitoring of treatment. Microscopy laboratories must be maintained at the point of care (POC). AFB microscopy requires careful technique, staff motivation, and supervisory oversight to attain the maximum performance possible for a subjective test. Oversight is provided by National TB Programs (NTPs) and National TB Reference Laboratories (NRLs) in the form of external quality assessment (EQA) programs that include some combination of onsite evaluation, random blinded rechecking of a sample of smears, and panel testing. Although there are many international guidelines and technical materials for procedures and EQA, there is little or no external validation to assure that countries are adequately managing the microscopy networks. There is evidence to the contrary that countries do not provide adequate support and monitoring and this may affect case detection, especially in settings with a high prevalence of HIV where the sensitivity of the smear is already diminished. Additionally, country networks may consist of hundreds or thousands of microscopy centers that are separated by geography and political jurisdictions, further challenging TB program implementation. An international scheme is necessary to promote and guide countries to fully implement WHO-recommended support and monitoring of networks and provide systematic review to validate that quality standards are applied to all AFB-microscopy laboratories.

There are several international efforts and recent attention on laboratory accreditation and especially promoting integrated testing. One challenge is that current efforts may address higher level laboratories such as national or regional reference laboratories but will probably not impact on the many small laboratories at the district and health center level. Additionally, formal recognition and support for a AFB- microscopy network could be a successful starting point/ vehicle for extending EQA and supervision to other tests and establishing integrated network management. Establishing an AFB-microscopy network accreditation would at a minimum allow validation of the TB laboratory components where integrated supervision exists and provide a working model that lays the groundwork for integration of disease specific programs.

I. INTRODUCTION

All national TB programs (NTPs) support a network of AFB-microscopy centers that provide diagnosis and treatment monitoring at the point of care (POC). The number of AFB-microscopy centers may range from 5 in Estonia to over 13,000 in India (WHO 2012. Global Tuberculosis Report 2012) requiring multiple levels of responsibility and different approaches to country network management. Collectively there are over 37,000 microscopy centers in the 22 HBCs and an estimated over 50,000 globally.

Significant global guidance and support has been developed to assist countries with maintaining accessibility to the population for AFB- microscopy while achieving a high level of test performance. WHO, The International Union against TB and Lung Disease (IUATLD) and the Global Laboratory Initiative (GLI) have worked through collaboration and consensus to provide peer reviewed tools in the form of technical guides, forms, policy documents and training materials. The overall management of the network requires that each country establishes, implements, and monitors national policies that also address supply management, personnel, training, and technical guidance. One critical element is the EQA program that continually evaluates AFB microscopy performance and quality, preferably through rechecking of slides combined with onsite supervision (APHL 2002. External Quality Assessment for AFB Smear Microscopy).

The challenges to having a well- managed network are many, including resources, political commitment, geographic distances, and local autonomy. There is minimal external validation to measure the extent of implementation and effectiveness of network management. The periodic TB program reviews allow insufficient time for the laboratory network and are handicapped by the subjectivity of the various consultants that perform reviews. To address external validation this guidance document is constructed as a tool to allow both countries and consultants to objectively evaluate performance against a set of standards that represent existing WHO guidance. Additionally, the many global technical tools are located in different documents and have never been compiled as a set of standards with associated performance measures to specifically guide countries on requirements and expectations for managing the country network.

Formal accreditation, whether it applies to laboratories, organizations, or agencies, involves measuring adherence to a set of standards that have been identified as those practices that are necessary to effectively, safely, and successfully conduct a particular business or activity. Standards indicate that a particular activity is in place and follows a documented protocol or process. Since standards are broad statements they require associated information, usually in the form of measures that describe how compliance with a standard is evaluated. This accreditation tool includes a set of standards for managing and supporting a network of AFB-microscopy laboratories recognizing that microscopy remains the primary point of care test (POCT) for TB diagnosis and treatment monitoring. The standards represent the many technical documents, guidelines and training that have been developed by WHO and the aligned Global Laboratory Initiative (GLI) Stop TB Partnership working group, representing multiple organizations supporting global TB control. Electronic links to the technical documents corresponding to each standard are provided in a separate chapter.

Another goal of this tool is to develop the foundation for a network accreditation program based on WHO-approved guidelines and standards. A formal accreditation process and program will provide an incentive for countries to seek external review and validation of their microscopy network management. Countries currently self-report their AFB-microscopy performance and EQA data to WHO, often blocking a critical evaluation of the actual extent and quality of network support. Having an established accreditation tool will allow countries, organizations and consultants to move forward with improvements to network management based on critical assessment against objective measures. Countries are thus encouraged to use the tool for an internal review of their microscopy network. A structured, peer-governed and WHO-aligned accreditation program will then provide external validation and recognition to those countries that meet the performance measures.

In the end the strength of case detection within TB control is largely based on the accessibility, permanency and accuracy of AFB microscopy. Additionally, even as countries focus on new diagnostics, successful implementation and decentralization of testing will always require a functional network. Therefore, the investment in assessing and improving the country network is not only important for today, but will be the key to future capacity building.

Outline of the tool

Chapter II describes the principles on which this tool is based, also introducing stratified random sampling of sites to be visited (detailed in Appendix C).

Chapter III contains the eleven accreditation standards, their measures and rationale.

Chapter IV provides specific electronic links to documents and guidelines for each of the standards.

Chapter V outlines the assessment questionnaires which can be found in Appendices A and B.

Chapter VI describes how countries can use this tool for themselves.

Chapter VII gives an overview of the formal accreditation procedure based on this tool.

II. PRINCIPLES AND CONTENTS OF THE ACCREDITATION TOOL

This accreditation tool is based on the many WHO-approved guidelines that provide technical direction, recommendations and specific forms to document and monitor performance. Most of these tools can be found online on the GLI webpage: http://www.stoptb.org/wg/gli/default.asp. The tool takes the approach of converting voluntary guidance, in the form of recommendations, to requirements that must be met or otherwise addressed by any country seeking to achieve accreditation. Whenever a requirement does not represent an existing guidance this is based on accepted laboratory practices and reasonable expectations combined with peer review and consensus.

One of the principles guiding the structure of this accreditation tool is the need for every country to establish and then implement national policies that address guidance, supervision, training, quality assessment and support for the network. This is similar to the principle that laboratories must have a quality manual that addresses all aspects of practice and then demonstrate that they follow their plan. Absence of a written policy, clearly outlining the network requirements and assigning responsibilities, inevitably results in poor management. Policies must be comprehensive enough to identify responsibilities at different levels, and should include established documentation that allows leadership and external reviewers to monitor policy implementation and effectiveness. The network accreditation tool outlines these policy requirements as a set of standards with each a corresponding measure, defining the minimum allowable in terms of availability as well as contents.

Policies and plans need to be adhered to throughout the country, leading to optimal performance of AFB-microscopy, and this must be measurable through appropriate documentation. Evaluation of performance, quality and support are addressed through validation of policy implementation at each level of the service, from national to peripheral. External review of the plan, documentation, and visits to a random sample of AFB microscopy and EQA centers will provide sufficient information to measure coverage, performance and quality of the network, besides adequacy of support provided. Also this validation part is reflected in the standards and their measures.

A key strategy of this accreditation tool is to identify a stratified random sample of intermediate and peripheral sites. Although a strong reporting system can provide significant validation, a number of on-site visits are required to validate the situation on the ground. With a stratified random sample a reasonable number of intermediate sites and AFB-microscopy laboratories can be visited to provide confirmation that policies are effective in providing training, supervision, supplies, EQA and feedback to peripheral centers. Based on information provided by the country, external expert assessors (and not the NRL or NTP) would conduct the sampling to assure there is appropriate representation and no bias in selecting the sample. The sampling process is intended to be practical; areas with security problems or sites that cannot be visited by car are excluded from sampling.

III. STANDARDS FOR ACCREDITATION OF AN AFB-MICROSCOPY NETWORK

The accreditation tool is composed of eleven standards with each a corresponding measure defining the minimum allowable performance to achieve accreditation. These minimum allowable performances are based on expert opinion and country inputs.

The standards and corresponding measures are:

Standard 1. The TB microscopy network structure, its services to the NTP, its management, future expansion and appropriate use (balanced with that of other available TB laboratory methods), are defined in a strategic plan.

Measure for standard #1 – A national strategic plan for TB laboratory services exists, either on its own or as part of the general NTP or laboratory services strategic plan. It clearly defines the place of microscopy as the first-line diagnostic and treatment monitoring test, except when Xpert MTB/RIF is available and indicated because of high prevalence of MDR-TB or HIV. The plan includes a gradual switch from Ziehl Neelsen (ZN) to LED fluorescence technique (FM) where feasible.

Rationale: National laboratory strategic plans are recognized as a required step to align all of the program, country, donor, and technical assistance into a unified and coordinated set of policies to develop and maintain capacity. Countries must have a strategic plan to document and demonstrate that they are effectively communicating with all the levels managing a network through clear protocols for implementing new diagnostics and systematic improvements.

Standard 2. A national AFB-microscopy manual with standard operating procedures exists, and is accessible in some format at all microscopy laboratories.

Measure for standard #2 - The national Standard Operating Procedures (SOPs) or guidelines are available and followed at all levels. Internal and external quality assurance policies and procedures are covered in this manual or separately, clearly stating the process and responsibilities at various levels of the microscopy network. The operating procedures and policies respect global guidelines with the exception of minor deviations per national preferences.

Rationale: An effective network requires that every microscopy laboratory has accessible and comprehensive information outlining all of the technical procedures and processes necessary to perform their tasks.

Standard 3. There is documented and recent evidence of complete coverage of the population by AFB-microscopy laboratories, organized as a network.

Measure for standard #3 – There is one functional AFB-microscopy laboratory per 50,000 to 150,000 population, depending on population density. Except in the smallest countries, intermediate level laboratories assure an important part of the required training, external quality assessment (EQA) and supplies management for the peripheral level.

Rationale: TB testing must be permanently accessible throughout the country, and this requires meticulous documentation. In all but the smallest countries, with few well accessible laboratories and a strong NRL, the required training, external quality assessment and supply chain management cannot be assured by the NRL on its own.

Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.

Measure for Standard #4 – On average not more than 15 ZN or 100 FM smears have to be read by one staff per day. There is a national plan for AFB-microscopy training and refresher training. All staff involved in AFB-microscopy has been trained at least on-the-job, independent of qualifications.

Rationale: Every country must adopt and support some combination of personnel standards, workload, training, and performance measurement since each of these components must be in place and balanced to assure quality. Reliable AFB-microscopy can eventually be performed by microscopists without a formal license, provided they are trained and supervised for this work.

Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.

Measure for standard #5 - There is documented evidence of coverage by EQA rechecking or panel testing of at least 75% of the AFB-laboratories, with a plan to achieve full coverage. The system, documented on-site observations and results suggest good reliability of the EQA data. Analyses show possible problems with laboratories and first controllers. Results are reported to the controllers, peripheral laboratories, and to the national level and are used for corrective action, including problem-solving during on-site visit by a laboratory professional.

Rationale: AFB microscopy is a subjective test and performance can vary unless the work is continuously and systematically monitored. There is significant international agreement on EQA as the primary tool for assuring optimal performance and this includes some form of supervisory visits for quality management, training, and appreciation. Analysis of screening data resulting from rechecking or panel testing is essential to strengthen the EQA system and for supportive and targeted supervision leading to quality improvement.

Standard 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.

Measure for standard #6 - Standard registers and reports related to AFB-microscopy and its EQA are used. The information collected is analyzed and used for monitoring and evaluation of quality performance. Workload, quality indicators and on-site observations all suggest good quality AFB-microscopy for at least 75% of the labs. Appropriate use of LED fluorescence microscopy and rapid and complete transmission of results demonstrate high efficiency.

Rationale: Recording and reporting, from the laboratory register to EQA forms, have been standardized into formats that inform TB control and provide critical management information. These standard formats must be in use to document network performance and quality.

Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.

Measure for standard #7 - Microscopy network procurement is regular, comprehensive and of appropriate quantity and quality. There are buffer stocks and absence of stock interruptions for essential items at all levels of the microscopy network. There is documented evidence of adequate quality control of staining solutions at the level where they are prepared or procured ready for use.

Rationale: Stock management is critical in assuring that the network of laboratories has all of the necessary supplies, equipment, and commodities to conduct testing. It assures that TB control and patient management are not interrupted with stock outs. This system of interdependent responsibilities and management at each level must be documented in order to be effective. Staining solutions are particularly important and easily overlooked as a major cause of system failure.

Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.

Measure for standard #8 – A policy regarding private AFB-labs is included in the national strategic plan. There is documented evidence of either integration or referrals for at least a few of these labs.

Rationale: NTPs and NRLs cannot ignore the role and contribution of the private sector in TB control. Extending EQA and/or training to private laboratories are examples of effective strategies to meet the government's role of assuring quality. At a minimum there must be a policy documenting how and to what extent the NTP is interacting with private laboratories as part of a national policy on public/private engagement.

Standard 9. A dedicated budget is available for the microscopy network, ensuring continuous and country-wide availability of free, quality assured AFB-microscopy.

Measure for standard #9 – The NTP, MoH or local administrations have a separate and readily accessible budget line to support the AFB-microscopy network. At least part of this budget is allocated by the national or local government.

Rationale: Documentation of financial resources is recognized as a primary component of program effectiveness and this also extends to supporting a national network of laboratories. Regardless of budget structure there must be documentation that dedicated funds are available to support all the needs of the laboratory network. Next to TB drugs, a functional microscopy network is fundamental to TB control and needs only a modest budget; therefore, its running costs should not entirely depend on foreign donors, which is an important component for sustainability.

Standard 10. AFB-microscopy laboratories are safe for the staff and the community.

Measure for standard #10 – At least 75% of AFB laboratories have good natural or assisted ventilation, with plans to provide this to all the laboratories, as well as safe disposal of infectious waste.

Rationale: The NTP must demonstrate its commitment to safety by providing safe work environment, adequate personal protection and care for the laboratory staff. The staff must be trained, evaluated, and demonstrate their commitment to safe practices for themselves, colleagues, and patients. TB work requires dedicated staff who can effectively manage the risk involved with TB diagnosis, treatment, and care; therefore, a shared commitment to safety is a visible and critical requirement between management and staff.

Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional TB diagnostic testing.

Measure for standard #11 – There must be a national policy outlining the criteria (algorithm), responsibilities and process for referring specimens for additional testing, such as GeneXpert MTB/RIF, from peripheral to intermediate and/or national levels. There is traceable documentation that specimens are referred correctly and results are received back in time.

Rationale: New diagnostic methods are already changing the methods and effectiveness of TB control, especially for MDRTB and HIV-associated TB, but they are only as effective as the referral system that makes them accessible to the entire population. This network tool does not focus on the many additional requirements of higher level diagnostics, but addresses only the referral mechanisms that require policies, patient selection, specimen transport and timely feedback throughout the network.

IV. RESOURCE DOCUMENTS

This chapter provides relevant resources and references for each of the eleven standards to be met for TB microscopy network accreditation. These resources are based upon existing consensus documents developed by WHO, IUATLD, CDC, KNCV and other organizations. Most of these resources can also be found on GLI, WHO, IUATLD and CDC websites, following the links provided below.

Additionally, countries may have their own consensus documents to reflect policies, processes, and procedures that are adapted, modified, or generated based upon peculiar environments or regional situations. Although these documents may not meet the requirements for accreditation, they can be used but may have to be improved to meet the specifications. These country-specific documents should then also be included in the assessments.

Standard	**Resources**
1. The TB microscopy network structure, its services to the NTP, its management, future expansion and appropriate use (balanced with that of other available TB laboratory methods), are defined in a strategic plan.	**Roadmap for Laboratory Strengthening** (http://www.stoptb.org/wg/gli/assets/documents/GLI Roadmap First Issue 2010110.pdf) **WHO Policy Framework** (http://www.who.int/tb/laboratory/whopolicyframework_rev_june2011.pdf) **Global Plan to Stop TB 2011-2015** (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf) **Guidance for Development of National Laboratory Strategic Plan.pdf** (http://www.aphl.org/aphlprograms/global/Documents/GH_2010Aug13_GuidanceNLStrategicPlans.pdf) **A Practical Guide to Assessing and Planning Implementation of Public Health Laboratory Service Changes** (http://stacks.cdc.gov/view/cdc/11883) **Strategic Planning for TB Laboratory** (http://www.tbcare1.org/publications/)

2. A national AFB-microscopy manual with standard operating procedures exists, and is accessible in some format at all microscopy laboratories.	**WHO Policy Statement: Same-day Diagnosis of Tuberculosis by Microscopy** (http://whqlibdoc.who.int/publications/2011/9789241501606_eng.pdf) **WHO Policy Statement: Fluorescent Light-emitting diode (LED) Microscopy for Diagnosis of Tuberculosis** (http://whqlibdoc.who.int/publications/2011/9789241501613_eng.pdf) **Policy on Definition of a New Sputum Smear-positive TB Case** (http://www.who.int/entity/tb/laboratory/policy_sputum_smearpositive_tb_case/en/index.html) **Policy on Reduction of Number of Smears for the Diagnosis of Pulmonary TB** (http://www.who.int/tb/laboratory/policy_diagnosis_pulmonary_tb/en/index.html) **Instructional Poster for ZN AFB Microscopy** (http://wwwn.cdc.gov/dls/ila/documents/AFBSmearStaining.pdf) **Acid-Fast Direct Smear Microscopy Training Package** (http://wwwn.cdc.gov/dls/ila/acidfasttraining/) **Standard Operating Procedures** (http://www.tbcare1.org/publications/toolbox/sops/)
3. There is documented and recent evidence of complete coverage of the population by AFB-microscopy laboratories, organized as a network.	**Priorities for Tuberculosis Bacteriology Services in Low-Income Countries** (http://www.theunion.org/index.php/en/resources/technical-publications/item/103-priorities-for-tuberculosis-bacteriology-services-in-low-income-countries) **WHO Laboratory Services in TB Control Part 1** http://whqlibdoc.who.int/hq/1998/WHO_TB_98.258_(part1).pdf **Global Plan to Stop TB 2011-2015** (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf) **Laboratory Assessment Forms** (http://www.tbcare1.org/publications/toolbox/tools/assess/Laboratory_Assessment_Form.pdf)

4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	**WHO Laboratory Services in TB Control Part 1** http://whqlibdoc.who.int/hq/1998/WHO_TB_98.258_(part1).pdf **External Quality Assurance Package** (http://www.tbcare1.org/publications/toolbox/eqa/) **Acid-Fast Direct Smear Microscopy Training Package** (http://wwwn.cdc.gov/dls/ila/acidfasttraining/)
5. External quality assessment targets all laboratories and includes regular supervision visits.	**External Quality Assessment for AFB Smear Microscopy** (http://www.cdc.gov/dls/ila/documents/eqa_afb.pdf) **Global Plan to Stop TB 2011-2015** (http://www.stoptb.org/assets/documents/global/plan/TB_GlobalPlanToStopTB2011-2015.pdf) **External Quality Assurance Package** (http://www.tbcare1.org/publications/toolbox/eqa/)
6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.	**Management Information System** (http://www.tbcare1.org/publications/toolbox/mis/)
7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	**WHO Guidance for Countries on the Specifications for Managing TB Laboratory Equipments and Supplies** (http://whqlibdoc.who.int/publications/2011/9789241503068_eng.pdf) **Logistics Supply Management Tool** (http://www.tbcare1.org/publications/toolbox/lsm/)
8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	**GLI Roadmap Laboratory Strengthening** (http://www.stoptb.org/wg/gli/assets/documents/GLI%20Roadmap%20First%20Issue%202010110.pdf) **National Strategic plan of the NTP**

9. A dedicated budget is available for the microscopy network, ensuring continuous and country-wide availability of free, quality assured AFB-microscopy.	**WHO Planning and Budgeting for TB control Activities** (http://www.who.int/tb/dots/planning_budgeting_tool/download/en/index.html) **WHO TB Budgeting Manual Part 1** (http://www.who.int/tb/dots/planning_budgeting_tool/manual_part1.pdf) **WHO TB Budgeting Manual Part 2** (http://www.who.int/tb/dots/planning_budgeting_tool/manual_part2.pdf) **National Strategic Plan of the NTP**
10. AFB-microscopy laboratories are safe for the staff and the community.	**Ventilated Workstation Manual for AFB Smear Microscopy** (http://www.aphl.org/aphlprograms/global/Documents/GH_2011July_VentilatedWorkstationGuidance.pdf) **TB Laboratory Biosafety Manual** http://www.who.int/iris/bitstream/10665/77949/1/9789241504638_eng.pdf
11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional TB diagnostic testing.	**Strategic Planning for TB Laboratory** (http://www.tbcare1.org/publications/) **Automated Real-time Nucleic Acid Amplification Technology for Rapid and Simultaneous Detection of Tuberculosis and Rifampicin Resistance: Xpert MTB/RIF System, Policy Statement** (http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf) **Rapid Implementation of the Xpert MTB/RIF diagnostic test Technical and Operational 'How-to' Practical considerations** (http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf) **Laboratory Services in Tuberculosis Control Part-II** http://whqlibdoc.who.int/hq/1998/WHO_TB_98.258_(part2).pdf

V. CHECKLISTS

The detailed accreditation checklists are presented in Appendices A and B. They are structured as:

1) Assessment of policies and procedures
2) Validation of the policies and procedures.

The first assessment section outlines the required policies and their required contents. The policy should be national in scope to address the various protocols and procedures that pertain to intermediate level and peripheral microscopy laboratories throughout the country. Assessment at the national level includes all eleven standards for AFB network accreditation. If there are some regional differences in policy this should be documented.

The second section, validation of the policies and procedures, is done at the national, intermediate and peripheral (microscopy laboratory) level. For each level the applicable standards with their important elements to assess whether the minimum allowable performance has been reached are included.

In the checklists for both sections, mandatory requirements have been highlighted as Yes/No statements. For accreditation to be granted, none of these mandatory requirements should be lacking.

Assessment of policies and procedures at the national level

At the national level the assessment of policies and procedures includes: 1) a list of the required documentation and 2) assessment of the eleven standards with a checklist.

The country NTP/NRL should be able to retrieve and document all the existing policies at the national level so that these are available for review and assessment by internal assessors, external consultants or as part of a formal accreditation program review.

Validation of policies and procedures at national, intermediate and peripheral levels

For validation at the national, intermediate and peripheral level different checklists will be used to determine that policies are implemented. The validation section follows the general standards, but applies these selectively to the national, intermediate and peripheral levels to take into account the different responsibilities in a tiered laboratory system. This structure recognizes that while policy development is primarily the responsibility of the national level, in the organizational structure of laboratory systems in many countries the responsibilities for e.g. EQA implementation and supervision of the peripheral laboratories require a strong intermediate level. The validation section outlines specific measures, data and documentation that should be provided to validate compliance with country policies. The validation section for the intermediate and peripheral level includes a checklist of documentation on AFB-microscopy performance.

VI. HOW COUNTRIES CAN USE THE ACCREDITATION TOOL

The primary intent is for these standards and accompanying technical resources to serve as immediate guidance for countries to evaluate and strengthen their management of the network of microscopy centers. Meeting the requirements, policies and associated documentation will take time, not only for NTPs still struggling to support network management systems and staff, but also for countries that invested significant time and resources in these structures. Using this tool, countries can and should assess the extent to which they have developed and implemented the appropriate policies for supplies, personnel, equipment and EQA to monitor and assure the best possible test performance. Countries are encouraged to enlist their own internal experts or secure external consultants to begin the process of evaluating the state and extent of their AFB-microscopy network management. Another approach is to request laboratory consultants from other high burden low resource countries, since it will be important to have individuals with expertise in EQA and WHO-approved guidance, methods, and documentation. However, to use this tool properly, these experts should always be thoroughly familiar with the recommended AFB-microscopy technique and strategies for its use, as well as the management of microscopy networks.

The standards and checklists highlight those policies and performance indicators that are considered critical to meeting the standard and therefore are identified as mandatory requirements for network accreditation. While all the policy and performance indicators are important, those identified as mandatory should be considered as priorities when countries are performing an internal review and strengthening their system. This accreditation tool outlines the necessary content and provides links to technical resources that can serve as the basis for policy. Country policy, however, must be customized to the existing system for personnel, laboratory strategies, and supply management. Additionally, countries must adopt their own standards for sampling and performance related to EQA. The first step would be to initiate a process of assessing the current policies and identifying gaps that should be addressed. The second step is to thoughtfully determine the series and sequence of action steps that would be necessary to strengthen the country policy so that it will address the identified gaps.

However, policies are only effective if they have been implemented through training and communication, reinforced by quality supervision, and staff at all levels within the system know their responsibilities and have the resources to carry them out. Merely re-writing policy will not be sufficient since every change in policy must be communicated throughout the system in addition to implementing any necessary changes to assure understanding and compliance with policy. It is important to perform some validation of the existing policy. If there is inconsistent compliance with the existing policy then this will have to be considered in step- by- step efforts to strengthen policy implementation. Although some countries have weak network management due to lack of clear national policy, in other cases there is existing policy but little or no compliance and follow through to enforce policy.

Here below a phased process of systematic review, strengthening and documenting the different policies that are necessary to successfully manage a country wide network is suggested. These phases correspond to four areas of development and evaluation. The first phase of establishing policies, guidance and support for the network is a prerequisite to all other evaluation areas. Once a country's policies have been reviewed, strengthened and implemented it would logically proceed to Phase 2, enforcing adherence to guidelines and high test performance. Phase 3 and 4, i.e. efficient EQA respectively a functional referral system, do not necessarily have to follow in this order. They could also be developed simultaneously with Phase 2.

Phase 1. Policies, guidance and support for the network:

The first phase of self- evaluation should always be a review of all the policies and guidance that outline support for the network since these serve as the protocols and process for managing an interdependent country-wide network of laboratories. Written policies are necessary to clearly identify responsibilities for supplies, personnel, EQA, and performance at every level. The requirement for a national strategic plan for TB laboratory services is a good example of a policy that countries must have to manage their network. Countries are faced with an often overwhelming number of choices for implementing new methods and upgrading practices in response to WHO policies for new diagnostics (e.g. LED microscopy, Xpert MTB/RIF) and evidence-based practices (e.g. 2 AFB smears for diagnosis when an effective EQA system is in place). The national strategic plan should outline the recommended algorithms for diagnosis and monitoring in the context of the local epidemiology of TB (HIV, MDR) and the resources for point of care and referral testing. Additionally, each country must make decisions on the specific methods, protocols and responsibilities at each level, such as for EQA, in the context of existing resources. National strategic plans are extremely important as tools and processes to assure that program priorities and technical support are both country-driven and serve to direct and coordinate the efforts of external donors and consultants that provide support in many high burden countries. There are many existing plans and templates, especially on the GLI website (http://www.stoptb.org/wg/gli/default.asp), that countries can use to develop or strengthen their national policies and strategic plan. Most important is that in the absence of a strategic plan, or other collection of specific country policies, there is no country strategy that outlines both the existing structure and implementation of new diagnostics for improved TB control.

Although the checklist may at first glance seem overwhelming, the policy requirements represent global consensus on effective TB laboratory practice and many require a minimal effort of documentation and communication. The policy checklist starts by listing the policy and procedures documentation that should be present at the national level. As a minimum requirement, those highlighted as mandatory should be present. The second part is meant to guide assessment of these policies and procedures, relating them to each of the standards and its measure. However, implementation aspects of the standard measures are not covered in this first questionnaire, but will be addressed in the complementary validation questionnaires for the different levels.

Phase 2. Adherence to guidelines and technical execution of the tests, including quality:

Policies are critically important, but only if they are implemented and adhered to by all the responsible staff. Once policies have been developed/reviewed their implementation should be validated through specific measures. The checklists for validation of implementation of policies and procedures at the national, intermediate and peripheral levels provide very specific guidance on performance indicators that represent minimal levels of performance. In general they reflect the priority to keep good records and to not only consolidate and review performance measures, but also to demonstrate action in response to any performance problems as defined by policy. Personnel, supplies, and supervision are key examples of network management policies that must be in place to assure trained competent staff and supplies and equipment necessary to support microscopy centres throughout the country. In the absence of monitoring and validating policies and procedures, such as for supply management, there can be stock outs of supplies that potentially shut down the microscopy support for diagnosis and treatment monitoring. Additionally, trained staff and functional equipment are the other key ingredients as the basic structure for supporting the network. Therefore, following the strengthening of policy the recommended second phase is to validate implementation of the policies for supplies, personnel, and equipment as the basic components of the network. The implementation of these national policies can be validated at various levels, following the checklists indicating which documents, reports or other information need to be checked. An essential and final part of this validation exercise will be the appraisal of AFB-microscopy quality, taking into account workload, performance and quality indicators. These may be extracted from reports, but additional on-site evaluation visits will remain indispensable for proper understanding and correct judgment.

Phase 3. Microscopy network EQA conduct:

One of the biggest priorities for support and monitoring of the microscopy network is a functional EQA system and there have been significant efforts to provide technical resources in the form of training materials and guidance over the last decade. In past global reports, WHO has surveyed countries about EQA support and received data indicating rather extensive EQA implementation with high levels of laboratory performance. Country review reports and external consultations, however, have identified gaps in implementation of effective EQA that emphasize the need for systematic internal reviews using these consensus standards and checklists. A functional EQA program requires supervision and assessment at all levels, and this is demonstrated through documentation of performance using the standard records that have been developed and promoted by WHO and GLI. The checklist for validation of the policies provides a detailed list of performance indicators to measure the implementation once countries have established the necessary policies. Although blinded rechecking of a random sample of slides is recommended as the most effective EQA tool if complemented by on-site problem-solving supervision, there is recognition that panel testing might be necessary in the context of prevalence, resources and network characteristics. The checklist recognizes this as a valid option, and it also refrains from imposing rigid guidelines for the conduct of these systems. The many questions are mostly meant to help assessors arriving at correct conclusions regarding the coverage, functionality and optimal use of the system in place. Respect of the national guidelines plus a positive appraisal on these overall points is mandatory for accreditation. EQA coverage does not have to be complete to be accredited. The minimal requirement is only 75% of AFB-laboratories, recognizing that full coverage may take a very long time, but the final aim and plan should be all AFB-laboratories.

Phase 4. Linkage with other tests and referral system

Standard 11 was established to recognize that the microscopy network structure is a necessary component for effective referral to higher level laboratories that have improved diagnostic methods. Referral policies, criteria, and corresponding mechanisms are absolute requirements to assure that new diagnostic tests, such as GeneXpert MTB/RIF, will be extended to patients at high risk for MDRTB or with HIV-associated TB. Additionally referral is often necessary for other higher level testing such as culture and first and second line DST when MDRTB is detected. In the absence of effective referral of samples from peripheral centers these new diagnostic tests are only available to patients that directly access the intermediate or regional centers supporting these tests. Effective referral policies must include patient selection criteria and algorithms. These referral policies are then validated at the peripheral laboratory checking the referral mechanism and documentation of referred samples. Referral policy compliance will also be validated by measuring the proportion of referred specimens received/expected, the yield (e.g. rifampin resistant treatment failures, and TB-positive HIV-infected) and timely completion of the full cycle until arrival of the results.

In summary these standards and checklists are first and foremost a guide that countries should use to evaluate the extent to which they have implemented the many network management tools developed and promoted through WHO policies, products and GLI technical materials. They serve as a measure of the effectiveness of the current investments in managing the network in addition to identifying gaps. These standards are very specific to TB, but also offer models and specifications to countries working to integrate programmatic disease support to their national laboratory system. The global consensus by WHO, GLI and partners for these specific and mandatory policies and performance indicators is an opportunity to refocus efforts on the critical laboratory tests and network for TB control.

VII. DEVELOPMENT OF AN ACCREDITATION PROGRAM

Development of a formal WHO-aligned accreditation program is necessary to provide objective and consistent assessments to recognize those countries that have invested significant resources and commitment in developing programs to support the AFB-microscopy network. A second justification for a formal external review is the disincentives to appropriately monitor performance at the country level. Local supervisors and laboratory directors are always under pressure to perform and in many cases there is a cultural climate to demonstrate good management through the performance indicators of the laboratory services. Examples are reports that rarely ever indicate errors in rechecking EQA. Errors will always occur and a lack of detected errors indicates a breakdown in the EQA blinded rechecking system. Although the guidance provided in this document can to a large extent be used by countries, an in-depth evaluation for accreditation purpose will require a formal review by external assessors with ample experience and specifically trained in the use of this tool. Exactly the same questionnaires will be used, and the review process will follow the same outline as described in the previous chapter for self-assessment by the country. As a first step, the existence of mandatory policy, guidance and monitoring documents and their content will be checked, using the checklist for the national level. Assessment of the implementation of policies and procedures at the various levels of the network based on the applicable validation questionnaires follows as a second step.

A full assessment will generally require a two-week visit by one or two assessors, with random sampling of sites at the intermediary and peripheral levels of the network. To avoid wasting time and money, on-site assessments would better be performed only if desk review of documentation on policies and procedures suggests that the country is most probably eligible for the validation part of the assessments. This means that the applicant country will first be requested to send all or as many as possible of the documents listed in the first part of the questionnaire on policies and procedures at the national level to an assessor. If the mandatory documents can't be provided, or if their content is not satisfactory, the country will be notified of what is missing or has to be improved before an assessment visit can be planned.

If this desk review shows that the country has at least completed Phase I, the visit will be planned, including random sampling of the sites to be visited. The country will be involved in this process, in as far as stratification and exclusion of some sites is needed for reason of accessibility or safety, as explained in the chapter on sampling. The country will then have to prepare for facilitation of the assessment visit, i.e. announce the visit to the authorities at different levels, arrange for transport and local counterparts to the assessors, and finalise the assessment schedule.

The country's AFB-microscopy network will be fully accredited only if the assessment visit does not find major deficiencies in any of the four technical areas defined above, covering together all minimal requirements to comply with the measures for the eleven standards. Being non-compliant with one of the mandatory requirements indicated in the checklists is a major deficiency. However, if there are only few major deficiencies limited to one area, which could realistically be resolved within one year, the country can be granted provisional accreditation. A re-assessment one year later will then be needed to either confirm full accreditation status, or withdraw the provisional status.

Even if provisional accreditation can not yet be granted, the assessment visit may be useful for the country as it will show in how far each of the network development Phases has been completed, and what are the deficiencies to be addressed. Experience has shown that most often countries are not aware of existing deficiencies or how to address these, and the assessors will give advice also on these very specific technical points. The Phases are aligned with the four technical areas, but not necessarily with their sequence, as explained above. A network passes as at least adequate for an area if it passed on all the mandatory points from the checklist regarding this area. Phase I corresponds with Area 1, i.e. Policies and guidance. To arrive at Phase II, the country needs to pass also on one more area, and for Phase III on two more. Phase IV then means full compliance in all areas, and thus accreditation granted. With Phase III provisional accreditation could be given, if deficiencies in the remaining one area are few and can be removed in a short time. This is for the assessors to decide.

Appendix A. Assessment of policies and procedures at the national level

1. Checklist of documentation on AFB microscopy

Copies of following documentation should be obtained (*for accreditation mandatory documents are highlighted in white on grey background*):

	Document	Provided Y/N	Comment
1	TB Laboratory Strategic Plan (covering several years)		
2	Technical guides on AFB-microscopy including, internal quality control, EQA, and bio-safety		
3	Job descriptions (if not covered in another document)		
4	SOPs or job aids for AFB-microscopy		
5	SOPs for preparation of stains		
6	Diagnostic algorithms showing the place of microscopy besides other techniques (if not part of another document)		
7	Numbers of functional AFB-microscopy laboratories per administrative area (ideally with population data)		
8	Required staff qualifications (if not covered in another document)		
9	Pre-service and in-service training curricula		
10	Current training plan, including training of staff in new techniques (LED)		
11	Database or paper line listing on training performed during last year (if training is administered from national level)		
12	Comprehensive performance data for the last year or four consecutive quarters		
13	Comprehensive EQA data for the last year or four consecutive quarters		
14	Supervision policy (if not covered in another document)		
15	Supervision checklists or other evidence of supervision documented		
16	Supervision reports		

17	Most recent inventory of microscopy supplies and equipment at the national level		
18	Most recent supply and equipment procurement list		
19	Tools used to manage supplies for the microscopy network		
20	Stock cards or ledger		
21	Standard forms for ordering chemicals for stains and AFB-microscopy supplies		
22	Recent supplies distribution list from national to intermediate level		
23	Evidence of quality assurance of staining solutions (prepared nationally, or procured ready-for-use)		
24	AFB-microscopy register		
25	AFB-smear request and report form		
26	EQA forms, rechecking and/or panel testing		
27	AFB-microscopy performance report forms		
28	Current budget for the microscopy network		
29	Policy on referral of specimens for additional testing (e.g Xpert MTB/RIF for treatment failures)		

The column for comments can be used for information such as: included in document…, not applicable at this level, but at level…, other

2. Checklist for assessment of policies and procedures at the national level

For accreditation mandatory policies and procedures are highlighted in white on grey background

Standard 1. The TB microscopy network structure, its services to the NTP, its management, future expansion and appropriate use (balanced with that of other available TB laboratory methods), are defined in a strategic plan.	
A national strategic plan for the TB laboratory services exists	Y/N
- The TB laboratory services are integrated in the NTP strategic plan, or the NRL has its own strategic plan covering the entire TB laboratory network, or the TB laboratory services are included in the strategic plan of the Public Health laboratory services	
- The AFB-microscopy services are in line with the NTP strategic plan and endorsed by the NTP	
- The national strategic plan for the laboratory services clearly defines the place of microscopy as the first-line diagnostic and treatment monitoring test, except when Xpert MTB/RIF is available and indicated because of high prevalence MDR-TB and/or HIV	
- The national strategic plan includes a gradual switch from Ziehl-Neelsen to LED fluorescence microscopy where feasible	
- Responsibilities of the different levels (national, intermediate and peripheral) of the AFB-microscopy network are clearly described	
Standard 2. A national AFB-microscopy manual with standard operating procedures exists, and is accessible in some format at all microscopy laboratories.	
A national AFB-microscopy manual with standard operating procedures exists	Y/N
Operating procedures and policies respect global guidelines on main points	Y/N
SOPs and/or job aids for AFB-microscopy are included in the manual or are in separate documents and in accordance with the national manual	Y/N
Diagnostic algorithms show the place of microscopy besides other techniques	Y/N
Preparation of AFB stains observes international guidelines	Y/N
- Staining solution formulations are adequate with appropriate technique	
- Detailed description of internal quality control procedures (in particular for new staining solutions) is included	
There is a policy for bio-safety, including waste management	
There is a policy for revision/upgrading of laboratory guidelines and SOPs	
Standard 3. There is documented and recent evidence of complete coverage of the population by AFB-microscopy laboratories, organized as a network.	
The national level has up-to-date information on the AFB-microscopy network and its performance	Y/N
There is one functional AFB-microscopy laboratory per 50,000-150,000 population, depending on population density, with exceptions for extremely densely/sparsely populated areas	Y/N
There is a policy for special services for the very remote areas. Specify type of services:	

The intermediate level is the main level for implementation of training, EQA and supply distribution	
Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	
There is a focal person at the national level who oversees the entire AFB-microscopy network	
A national policy of personnel standards/qualifications for each level of the AFB-microscopy network exists	
Job descriptions for all staff of the AFB-microscopy network are available	
In case there are shortages of trained laboratory staff measures are taken to resolve this problem. Elaborate which measures and timeline:	Y/N
There are clear descriptions of the responsibilities of all staff involved in EQA rechecking and supervision	
Non-laboratory supervisors/coordinators are involved in the EQA-rechecking process	
There is a training policy and curriculum for new staff responsible for AFB-microscopy	Y/N
There is a policy for training on new techniques (LED) Elaborate the policy (duration of training, practice-oriented, adequate supervision from an experienced technologist):	Y/N
There is a policy for retraining of laboratory staff on AFB-microscopy. Elaborate the policy (routine frequency, based on performance, practice-oriented, others):	
There is an adequate training curriculum for EQA: - emphasis on the aims - focus on EQA rechecking coordinators, supervisors and controllers - emphasis on practice - emphasis on compilation and analysis of results of rechecking and/or panel testing - emphasis on the importance of feedback	Y/N
There is a policy for retraining on EQA. Elaborate the policy (routine frequency, based on performance, based on responsibilities, others):	
Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.	
The national EQA strategy is correct, i.e. appropriate for local conditions in terms of manpower, slide positivity rates and workload in the peripheral and intermediate level laboratories (e.g, use of rechecking versus panel testing)	Y/N
Number and % of microscopy laboratories currently covered by EQA:	
There is a plan to achieve full coverage of EQA	Y/N
If rechecking is implemented:	

- Fluorescence microscopy laboratories are included in the rechecking (if LED FM is used)	
- There is a policy for eventual decentralization towards an autonomous rechecking cycle at intermediate level (except in small countries)	
- Sample size for rechecking is based on LQAS system	
- Responsibilities of all staff involved in rechecking are clearly described	
- Re-staining of sampled slides for rechecking is addressed	
- There is efficient sampling, reporting and feedback of rechecking results involving also non-laboratory NTP supervisors	
- There is a policy for periodical analysis of rechecking results with performance indicators	
- There is adequate analysis of rechecking results allowing identification of problem controllers	
- There is a policy for adequate use of the results, including problem-solving	
If panel testing is implemented:	
- There is a policy for appropriate panel testing with sets of slides, technically covered by SOPs for production and validation of the panels and conduct of this QA	
- The number of slides and composition of the panels is adequate (i.e. emphasis on low positives; stained and unstained slides)	
- A validation procedure of panel smears exists	
- There are criteria for satisfactory performance of panel testing results	
- There is a policy for corrective action in case of unsatisfactory results of panel testing	
Supervision is complementary to either rechecking or panel testing:	Y/N
- The number of intermediate laboratories planned to be covered for supervision by the national level during the previous 2-3 years:	
Standard 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.	
Standard registers and reports for AFB-microscopy, according to WHO/ UNION recommendations, are used	Y/N
Standard forms are used for EQA, manual or electronic	
Information collected on AFB-microscopy is analyzed and used for monitoring and evaluation	
Information collected on EQA is analyzed and used for monitoring and evaluation	
Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	
The NRL is responsible for or involved in estimating the quantities of AFB-microscopy supplies needed for the microscopy network	Y/N

Procurement of AFB-microscopy supplies is exclusively the responsibility of the national level. If not, elaborate:	
The frequency of procurement of AFB-microscopy supplies at the national level is:	
The NRL or Public Health laboratory provides specifications of the type of microscopes, other laboratory equipment and supplies to the procurement department/agency (or can order directly itself) and addresses maintenance	
Specifications provided are respected	
The NRL or Public Health laboratory is involved in follow-up of tenders and approval of the final order based on technical suitability and not only lowest prices	
The policy for procurement and preparation (if not ready-made) of staining solutions at national / intermediate and/or peripheral level is appropriate for the setting	Y/N
There is a policy for replacement of microscopes. Elaborate:	
There is a policy for maintenance of microscopes. Elaborate:	
There is a stock of spare parts kept at national and intermediate level:	
Buffer stocks are kept at the various levels. Elaborate periods:	
There is a policy for regular inventory of supplies at the national level	
Distribution of supplies to the intermediate level(s) is done on a regular basis, and quantities are based on stock situations and requirements	
Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	
There is a policy for collaboration with the private sector in AFB-microscopy	Y/N
There is a policy for collaboration with the private sector in EQA of smear microscopy	
Standard 9. A dedicated budget is available for the microscopy network, ensuring continuous and country-wide availability of free, quality assured AFB-microscopy.	
The NRL is involved in preparation of budgets (for multiple years and annually) for the AFB-microscopy network	Y/N
The AFB-microscopy network has its own budget, either in the NTP budget or in the budget of the Public Health laboratory	
The entire budget for the AFB-microscopy network has to be provided through the national level. If not, what percentage has to be provided through the intermediate level(s) or peripheral level:	
The NRL has control over the budget provided through the national level. If not, elaborate constraints:	

Standard 10. AFB-microscopy laboratories are safe for the staff and the community.	
There is a plan to provide good natural or assisted ventilation or other safety precautions, as internationally recommended, to all AFB-microscopy laboratories	Y/N
There is a plan to implement measures for safe disposal of infectious waste at all AFB-microscopy laboratories	
Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional TB diagnostic testing.	
There is a national policy outlining the criteria (algorithm), responsibilities and process for referring specimens for additional testing, such as Xpert MTB/RIF, from peripheral to intermediate and/or national levels.	Y/N

Appendix B. Validation of implementation of policies and procedures at the national, intermediate and peripheral levels

B1. National level

For accreditation mandatory policies and procedures are highlighted in white on grey background

Annual period of assessment (Note: must include four consecutive quarters): _____

Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	
The number of qualified staff at the NRL for preparation of stains (if not ready-made), and for AFB-microscopy, is sufficient considering the workload.	Y/N
If not, elaborate:	
The number of staff to perform network quality management activities is sufficient (supervision, EQA related activities).	Y/N
If not, elaborate:	
All planned training by the national level, type of training and number of courses, was done during the year assessed	
In case less than planned training was conducted during the year assessed, elaborate which training and the reasons:	
A national database or paper listing on staff training for AFB-microscopy and EQA exists and is regularly updated	
Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.	
There is evidence of a functional EQA system at national level: complete reporting, analysis, validation and feedback.	Y/N
If not, elaborate:	
Actual EQA of the national AFB-microscopy network by rechecking or panel testing during the year assessed covers at least 75% of AFB-microscopy laboratories	Y/N
- Number of microscopy centres actually covered by rechecking or panel testing:	
- Number of covered microscopy centres with rechecking reports for at least 3 out of 4 quarters:	
Number of discordant slides rechecked per second controller during the year assessed:	
Rechecking reports from the intermediate (or peripheral) level are timely and complete (taking into account expanding coverage, if still incomplete)	
- Percentage of complete rechecking reports (with total number of required annual smears rechecked) out of those received during the year assessed:	
- Proportion of laboratories for which performance reports are available:	
There is evidence of critical analysis of rechecking results and feedback to the intermediate level	
- If consistently no errors	
- Identification of problems of first controller	

- Proportion of rechecked laboratories with insufficient sensitivity/specificity calculated and trends analyzed	
If panel testing is implemented:	
- There is evidence of functional panel testing EQA system : complete reporting, analysis, validation and feedback	
- There is evidence of validation of smear panels manufactured at the NRL, resulting in reject of lots of (low) positives that may contain negatives	
- There is evidence of critical analysis of panel testing results and feedback to the intermediate level for corrective action in case of unsatisfactory performance	
No. of realized supervision visits to intermediate laboratories, during the year assessed:	
- At least 75% of laboratories that should have been visited, according to national guidelines, have been visited	Y/N
- Proportion of laboratories visited at least once:	
- Number of supervisions done and not planned. Elaborate reasons:	
- Proportion of supervisions for problem solving / intensive follow-up	
- If frequency and/or coverage was less than 50%, elaborate reason(s):	
- EQA Supervision checklist/ report is available for …. % of all visits:	
There is evidence of corrective actions in case supervision checklists/reports show deficiencies	
- Improvements (or lack thereof) are checked during next visit based on documentation of remedial measures	
- Actions are taken in case of problems	
Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	
Documentation of ordering of laboratory supplies (nationally and/or internationally) during the year assessed on a rational basis is available:	Y/N
- Procurement is done at least annually	
- Procurement is based on good data and planning (national stocks only; supplies expected to arrive; calculated needs plus buffer stocks plus lead time)	
- There has been no interruption of supplies for AFB-microscopy during the last two years	
Documentation of distribution of laboratory supplies is according to the national policy, and on a rational basis:	Y/N
- Stock situations at intermediate level are available and taken into account	
- Numbers of smears done (or patients detected) per intermediate level are taken into account	
National stocks and storage of AFB-microscopy supplies are under sufficient control of NRL (i.e. regular reports of stock positions from Central Medical Stores and/or other national storage facilities)	

- Including items such as spare microscopes and an adequate range of microscope spares	
- Prescribed national buffer stock is present for 90% of essential products	
- Storage conditions of sensitive items are appropriate	
- Stock cards are kept with at least quarterly physical inventory	
- Analysis and monitoring is done, with calculation of months of supply in stock	
There is evidence of maintenance of microscopes	
- Service contract through government or private company	
- Reports on servicing of microscopes and replacement of parts	
- Reports on replacement of microscopes according to national policy	
There is documentation of preparation and quality control of ZN staining solutions, if prepared at the national level, and of distribution of stains	Y/N
- Documentation on assessment of the quality of the stains on negative and positive control smears	
- Documentation on the frequency of distribution of prepared stains to the intermediate (or peripheral) level	
Or , if commercially prepared ZN stains are bought (ready-made), there is documentation on checks of their quality and distribution	Y/N
- Documentation on assessment of the quality of the stains on negative and positive control smears	
- Documentation on the frequency of their distribution to the intermediate (or peripheral) level	
There is documentation on distribution of chemicals for preparation of stains (decentralized preparation)	
Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	
The number and % of private laboratories involved in AFB-microscopy or referrals of TB suspects to NTP facilities is:	
The number of private laboratories included in EQA of smear microscopy is:	
Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional TB diagnostic testing.	
Number of specimens referred, and percent positive and % rifampin resistant during the year assessed:	

B2. Intermediate level

For accreditation mandatory policies and procedures are highlighted in white on grey background

1. Checklist of documentation on AFB-microscopy

Copies of following national technical documents and report formats should be available:

	Document	Available Y/N	Comment
1	National Technical guides on AFB-microscopy, internal quality control, EQA and bio-safety		
2	SOPs or job aides for AFB-microscopy		
3	Job descriptions (if not covered in another document)		
4	Required staff qualifications (if not covered in another document)		
5	SOPs for preparation of stains (if prepared at this level)		
6	Diagnostic algorithms showing the place of microscopy besides other techniques (if not part of another document)		
7	Numbers of functional AFB-microscopy laboratories per administrative area (ideally with population data)		
8	Training curricula		
9	Current training plan		
10	Records on training performed during last year (if administered from national level)		
11	Supervision policy (if not covered in another document)		
12	Supervision checklists or other evidence of supervision documented		
13	Records of internal quality control of stains		
14	Quarterly/annual report form on AFB laboratory performance		
15	Blinded rechecking sampling form		
16	Blinded rechecking discordant form		
17	Quarterly/annual rechecking reporting form (or computer tool)		
18	Computer tool for rechecking and performance (if applicable)		
19	Quarterly/annual aggregated reports on AFB laboratory performance volume		

20	Quarterly/annual aggregated EQA reports, rechecking and/or panel testing		
21	Standard forms for ordering laboratory chemicals for stains (or ready-for-use stains) and AFB-microscopy supplies		
22	Stock cards or ledger		
23	Tool used to manage supplies for the microscopy network		
24	Most recent inventory of microscopy supplies		
25	Most recent procurement list (if procurement is done at this level)		
26	Recent distribution list of laboratory supplies to the AFB-microscopy laboratories		
27	AFB-microscopy register		
28	AFB-smear request and report form		
29	Current budget for the microscopy services (if applicable)		
30	Policy on referral of specimens for reference testing		

The column for comments can be used for information such as: included in document…., not applicable at this level, but at level…, local policy- different from national policy, others

2. Checklist for validation of implementation of policies and procedures at the intermediate level

For accreditation mandatory policies and procedures are highlighted in white on grey background

Annual period of assessment (Note: must include four consecutive quarters): _____

Standard 3. There is documented and recent evidence of complete coverage of the population by AFB-microscopy laboratories, organized as a network.	
The intermediate level has adequate and up-to-date information on the AFB-microscopy network	Y/N
There is at least one functional AFB-microscopy laboratory per 50,000-150,000 population, depending on population density, with exceptions for extremely densely/ sparsely populated areas	
There are special services for very remote areas. Specify type of services:	
The intermediate level is the main level for implementation of training, EQA and distribution of supplies (except in small countries)	
Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	
Job descriptions for all staff are available	
Number and % of intermediate laboratory staff positions that have been filled by qualified* staff (*Qualified=based on experience and/or education per national guidelines)	
At the intermediate level a sufficient number of qualified staff are conducting EQA	Y/N
If there is shortage of staff at the intermediate level, which positions:	
At the AFB-microscopy laboratories (supervised by this intermediate level) all laboratory staff positions have been filled by qualified staff	
If there is shortage of staff at the AFB-microscopy laboratories: - In how many laboratories and % of total laboratories: - Steps that have been taken to resolve this and timeline:	
The intermediate level is responsible for training on AFB-microscopy and EQA	
There is a training policy and curriculum for new staff responsible for AFB-microscopy, including a period of in-service training	
There is a policy for retraining of laboratory staff. Elaborate the policy (frequency, based on performance, others):	
Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.	
Rechecking is decentralized to the intermediate level (except in small countries)	
Number and % of microscopy laboratories (out of total microscopy laboratories) covered by rechecking or panel testing during the year assessed :	
Fluorescence microscopy laboratories (if LED FM is being used) are included in rechecking	

There is a plan to achieve full coverage of EQA	
Rechecking follows national guidelines	Y/N
- The recommended sample size is rechecked for at least 75% of covered laboratories	
- There is evidence of blinding from the collection forms and manually compiled results (different writings)	
- Staff collecting the slide samples, staff compiling and analyzing results, and staff providing feedback is according to national policy	
- There is evidence of remedial action in case of unsatisfactory results	
- The first and second controller are different persons	
- Re-staining of sampled slides for rechecking follows the national policy: - For ZN-stained smear - For auramine-stained smears	
The number of first controller(s) is adequate for the workload and time required for rechecking	Y/N
Sampling of rechecking slides, compiling and analysis of the rechecking results, reporting and feedback involves non-laboratory NTP supervisors/coordinators	
Reporting and analysis of rechecking is regular, complete and combined with performance data	
- At least 75% of complete performance and rechecking reports are available for the year assessed	
- A sufficient number of positive smears are included in the annual sample	
- The electronic workbook is used correctly (if applicable)	
There is evidence of critical analysis of rechecking results and feedback	Y/N
- In case of consistently no errors and/or LFN; interpretation of LFP	
- In case of frequent HFN and HFP results	
- Slides with serious errors are returned to the person who made the error, including first controller(s)	
- Results are discussed in meetings	
There is a schedule for supervision of the peripheral microscopy laboratories	
Collaborating NGO and private laboratories are included in the supervision schedule	
Non-laboratory supervisors are involved in supervision of peripheral microscopy laboratories	
At least 75% of the planned supervision visits were conducted during the year assessed.	Y/N
If less than 75% of planned visits have been conducted, elaborate the reasons:	
Supervision checklist or reports are used	
Supervision checklist/reports are available for …% of the visits conducted during the year assessed	
There is evidence of corrective action and follow-up in case supervision reports show deficiencies	

Standard 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.	
Standard registers and reports for AFB-microscopy are used, according to WHO/ UNION recommendations	Y/N
Information collected on AFB-microscopy is analyzed and used for monitoring and evaluation	
Standard registration and reports for EQA rechecking are used; manual or electronic	
Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	
All supplies and equipment for the microscopy network are obtained from the national level In case all or part of the supplies and equipment are procured by the intermediate level elaborate which supplies and equipment:	
In case all or part of the supplies and equipment are procured by the intermediate level the TB coordinator has control over the procurement:	
- The interval of ordering supplies and equipment	
- The quantities of supplies and equipment ordered	
- The specifications for procurement	
During the year of assessment supplies were ordered from the national level according to the national policy:	
- Orders followed national time lines	
- National supply request forms/tools were used	
During the year of assessment supplies to the AFB-microscopy laboratories were requested and distributed according to the national policy	
- There are records on requests (or at least balance in stock) by the AFB-microscopy laboratories	
- There are records of distribution of supplies to the AFB-microscopy laboratories	
There is documentation on stock management	Y/N
At the time of assessment all essential items are in stock, including spare microscope bulbs and objectives	
At the time of assessment the buffer stock sizes for most items were according to national policy	
Storage conditions of slides, staining solutions and microscopes are adequate	
During the year of assessment there have been no shortages of laboratory supplies	Y/N
In case there have been shortages of laboratories supplies during the last two years: - For which items: - Reasons for shortages: - Actions taken to resolve shortages:	

In case the staining solutions are prepared at the intermediate level: - The frequency of preparation is: - The amounts prepared is determined by: - Essential equipment and mycobacteria-free water is used	
- National guidelines are respected for preparation of stains	Y/N
- National guidelines are respected for quality control of the stains	Y/N
There is recorded evidence of assessment of the quality of staining solutions on control smears	Y/N
- Appropriate control smears (1+ and negatives) are available and used	
- Records on quality control for each staining solution prepared during the year assessed are available	
For each staining solution the name and date of preparation is written on the containers at the intermediate level and on those distributed to the microscopy laboratories	
Auramine staining solution is distributed as concentrated stocks. If otherwise, elaborate:	
The policy for maintenance of microscopes is implemented	
The policy for replacement of microscopes is implemented	
Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	
The number and % (of the total number of private laboratories) collaborating in AFB-microscopy are:	
All private laboratories collaborating in AFB-microscopy are included in EQA of smear microscopy	
Laboratory staff of the private sector are included in training on AFB	
Standard 9. A dedicated budget is available for the microscopy network, ensuring continuous and country-wide availability of free, quality assured AFB-microscopy.	
For its budget for the AFB-microscopy network the intermediate level fully depends on the national level	
In case part of the budget has to be provided through the intermediate level, elaborate the items paid by the intermediate level (supplies, training, supervision, others):	
In case part of the budget has to be provided through the intermediate level, the TB coordinator has full control over the budget. If not, elaborate constraints:	
The budget provided by the intermediate level was adequate during the last two years	Y/N
If not, elaborate:	
Standard 10. AFB-microscopy laboratories are safe for the staff and the community.	
The national plan for bio-safety measures for AFB-microscopy laboratories, including disposal of infectious waste, is available at the intermediate level	
Steps have been taken to implement safety precautions at the intermediate level, including good natural or assisted ventilation	Y/N

- Ventilation at the intermediate laboratory is adequate for the procedures being performed	
- An incinerator or valid alternative is available	
All microscopy laboratories have been instructed on safety precautions, including disposal of infectious waste	
Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional TB diagnostic testing.	
Referred specimens tested reflect compliance with referral policy, e.g. Xpert MTB/RIF for risk groups for HIV-associated TB or drug resistant TB, by all the peripheral laboratories	Y/N
- Number of specimens referred during the year assessed:	
- Percentage positive and % rifampin resistant:	
- Percentage received and tested within one week:	

B3. Peripheral level

For accreditation mandatory policies and procedures are highlighted in white on grey background

1. Checklist of documentation on AFB microscopy

Copies of following national documents and forms should be available:

	Document	Available Y/N	Comment
1	Technical guides on AFB-microscopy, internal quality control , EQA and bio-safety		
2	SOPs or Job Aides		
3	AFB-microscopy register		
4	Sputum request and report form		
5	Quarterly/annual report form on AFB laboratory performance		
6	Standard form for ordering supplies (if existing separately)		
7	Inventory of supplies/stock cards (if required by guidelines)		
8	Policy on referral of specimens for reference testing		
9	Request form for referral of specimens (reflecting eligibility criteria)		

The column for comments can be used for information such as: included in document…., not applicable

2. Checklist for validation of implementation of policies and procedures at the peripheral level

For accreditation mandatory policies and procedures are highlighted in white on grey background

Annual period of assessment (Note: must include four consecutive quarters): _____

Standard 2. A national AFB-microscopy manual with standard operating procedures exists, and is accessible in some format at all microscopy laboratories.	
The national AFB microscopy manual or at minimum SOPs and job aides are available	Y/N
For at least 75% of TB suspect / follow-up examinations, the appropriate number of smears has been tested according to the national policy (last quarter of the period of assessment only)	Y/N
Standard 4. Qualifications and number of staff required for performing AFB-microscopy and its EQA are appropriate and complemented by job descriptions and training curricula with sufficient emphasis on competence.	
The laboratory position(s) for microscopy has/have been filled with qualified staff according to the national policy If not elaborate:	
All staff responsible for AFB-microscopy, including support staff preparing smears, has been trained	Y/N
- The training included substantial time on practical exercises	
- New laboratory staff responsible for AFB-microscopy has been trained within 3 months, either formally or on-the-spot	
Staff responsible for AFB-microscopy has attended refresher training (including introduction of new AFB microscopy techniques). Year since last training:	
There is provision for qualified staff taking over during absence of trained staff assigned to AFB-microscopy	
Standard 5. External quality assessment targets all laboratories and includes regular supervision visits.	
Rechecking of smears is implemented according to national policy (if this is the EQA method)	Y/N
- Slides are identified with Lab. Registration number	
- Slides are stored according to serial number	
- Results are not written on the slides	
- The collection of slides corresponds to the work done since last sample was taken (total number, first and last lab. registration number)	
- Frequency of collection of slides is according to the national policy	
- The person who collects the slides is according to the national policy	
- There is evidence of written and timely feedback on rechecking results	
- The frequency of feedback is according to the national policy	
- Smears with serious errors are returned to the laboratory staff and discussed	
- If excessive serious errors are found the problem is investigated and solved	

Panel testing is implemented accordingly to national policy (if this is the EQA method)	Y/N
- The frequency of testing is according to the national policy	
- The method of testing (taken on-site or unsupervised) is according to the national policy	
- There is evidence of written feedback of the results	
- There is evidence of remedial action in case of serious problems	
Frequency of supervision during the year assessed has been according to the national policy	Y/N
- By laboratory staff	
- By non-laboratory staff	
Non-routine visits by laboratory staff for serious problems during the year assessed have been conducted	
Supervision reports are available at the microscopy laboratory	
There is evidence of follow-up actions in case of identified challenges	
Standard 6. Globally standardized recording and reporting formats for AFB-microscopy and its quality assurance are used at all levels of the network.	
The recording and reporting formats are correctly used	Y/N
- The laboratory register is correctly used	
- The sputum request and report form is correctly used	
- The quarterly/annual reports on sputum tests volume gives the correct data during the last quarter	
- The standard for ordering supplies is correctly used	
There is prompt registration and processing of newly arriving specimen (within 2 days)	
The smear positivity rate among TB suspects during the last quarter (or four quarters in case of small numbers) is:	
The smear positivity rate among follow-up smears from smear-positive cases on treatment during the last year is:	Y/N
The total number of smears examined during the year assessed is:	
The total number of smears examined during the year assessed per full time AFB microscopy staff is:	
Type of available microscope (bright field mono/binocular, classical FM, LED FM):	
The condition of the microscope(s) is good	Y/N
Good quality immersion oil is used (ZN) (no cedar oil nor xylene)	
Small tools for smearing and staining are available	
The quality of staining of the smears is adequate: macroscopically (background ZN) and microscopically (AFB in recently stained smears)	Y/N
The average quality of smears kept for rechecking is adequate	
Standard 7. The NRL manager or laboratory specialist of the NTP ensures excellent control over microscopy network supplies and equipment, including estimates and specifications for procurement, balanced distribution, provision for buffer stocks and stock management at all levels.	

The frequency of ordering supplies is according to the national policy	
The supplies received during the year assessed were according to the requests. If not, elaborate:	
There is an inventory of supplies/stock cards (if required by national guidelines)	
There have been no stock-outs during the period of assessment	Y/N
There are no expired supplies	
Standard 8. A policy regarding the role of the private sector and its microscopy laboratories within the NTP exists and there is documented evidence of its implementation.	
The laboratory collaborates with the private sector in examination of sputum smears (referral of patients or sputum specimens)	
Standard 10. AFB-microscopy laboratories are safe for the staff and the community.	
The AFB-smear laboratory environment is adequate and safe	Y/N
- There is good natural or mechanical ventilation	
- The sputum collection area is outside or inside with adequate infection control	
- The work surface for smearing is protected, e.g. disposable paper, disinfection	
- There is disinfection or safe disposal of smearing tools	
- Used sputum pots and other waste is correctly disposed of	
Standard 11. A national policy exists for referral of specimens from patients at risk for HIV-associated TB and/or MDR-TB for additional diagnostic testing.	
- There is evidence that specimens are referred (e.g. logbook)	Y/N
- Results of molecular tests on referred specimens arrive within a maximum of 2 weeks	Y/N

Appendix C. Stratified random sampling of sites

Introduction

Assessment of policies and procedures has to be done at the national level. So this level is always included in the sample.

Validation of implementation of policies and procedures is done at the national, intermediate and peripheral (AFB- microscopy laboratory) level.

For selection of intermediate and peripheral sites stratified sampling will be applied. Stratified random sampling or cluster sampling allows for the selection of a limited number of sites thereby reducing the amount of travel required for the network accreditation.

The strategy outlined here uses probability proportionate to size to derive the final set of sites that the assessor(s) will visit. The sampling generates a selection of sites to be visited that is proportionately representative of all the sites of the TB microscopy network.

Selection of the intermediate sites and the AFB-microscopy laboratories has to be done by the assessor(s). For this selection the national level should provide the information, as detailed below, and, in case not all information of the AFB-microscopy network is available at the national level, in collaboration with the intermediate level.

The estimated periods for travel, assessment at the national level, validation at the various levels of the AFB-microscopy network and debriefing at the national level are:

- One day at the national level for assessment and validation
- One day at the national level for debriefing
- One day for travel to each intermediate site
- One day for validation at each intermediate site
- One half to one day for travel to and validation of each AFB-microscopy laboratory

Assessment, validations and debriefing should preferably be done within a period of two weeks by the assessor(s), with local staff support and transport provided by NTP/NRL. To cover all sites within two weeks, in most countries two teams of an assessor with local staff and transport will be required.

While the outlined sampling strategy is the most appropriate to include a representative sample of the network, there may be limitations in selection of a fully representative sample of the intermediate and peripheral levels. These include security issues and non-accessibility of intermediate sites and AFB-microscopy laboratories by car. Intermediate sites facing security problems in any area of the site and those that cannot be reached by car should be excluded from sampling of intermediate sites. AFB-microscopy laboratories that cannot be reached by car should be excluded from sampling of the peripheral sites. In case these limitations occur in the sampling process, these should clearly be reported in the accreditation report, including the names of the intermediate sites and AFB-microscopy laboratories that were excluded from sampling and the reasons for exclusion.

In addition, there may be reasons for diversion from the proposed sampling procedure. These include a very large country, large heterogeneity in accessibility of areas and/or in case the NTP wants to restrict the validation to areas that have already implemented policies and procedures, e.g. EQA or referral of specimens from patients at risk for HIV associated TB and/or MDR-TB. For such situations alternatives for sampling of intermediate sites and AFB-microscopy laboratories are included. This sampling will make the sample non-representative for the entire microscopy network. However, it will provide insight on how the network functions and on major deficiencies and issues that need strengthening or improvement. In such cases the report should clearly describe the sampling decision and process and the reason(s) for this.

Number of intermediate levels and AFB-microscopy laboratories in the sample

The standard methodology will be to select three intermediate levels and two AFB-microscopy laboratories per intermediate level. This is the case if there is only one intermediate level, referred to as district, to which the AFB-microscopy laboratories report. In this situation three districts and six AFB-microscopy laboratories will be sampled.

In case there is more than one intermediate level- the AFB-microscopy laboratories report to the districts, the districts report to regions/provinces and these to the national level- two high intermediate levels (referred to as regions) will be sampled, and in each of these regions two low intermediate levels (referred to as districts). In each of the sampled districts of each region one AFB-microscopy laboratory will be selected. In this case two regions, four districts and four AFB-microscopy laboratories will be sampled.

In case there is no intermediate level and the AFB-microscopy laboratories report directly to the central level, six AFB-microscopy laboratories will be sampled.

Sampling methodology

One intermediate level

Sampling of the districts

For selection of the districts we need to know the number of districts, the district names, and the number of AFB-microscopy laboratories per district. The districts should be listed in alphabetical order. Prepare a table as given below. In this list the district(s) that cannot be visited due to security problems or non-accessibility of the intermediate site by car should not be included.

Number	Name of district	Number of AFB-microscopy laboratories
1	AA	12
2	BB	5
3	CC	6
4	DD	4
5	EE	2
6	FF	15
7	GG	7
Total		51

This is called a sampling frame. The first column of the frame contains a simple numbering scheme beginning with "1" and ending with the final district of the country. The second column contains the names of the districts in alphabetical order. The third column shows how many AFB-microscopy laboratories are located in each district. This is important because the selection of districts will be proportional to the number of the AFB-microscopy laboratories. The chance of a district being selected depends on the number of AFB-microscopy laboratories. Therefore, the sampling technique will select districts using "probability proportionate to size".

The next step is to number the AFB- microscopy laboratories. District AA has 12 AFB-microscopy laboratories and is given the numbers 1-12; district BB has 5 AFB-microscopy laboratories and is given the numbers 13-17, etc, as shown in the table below. At this stage of the sampling, AFB-microscopy laboratories of the listed districts that cannot be reached by car should be excluded. In the example below this is the case for one laboratory in district CC and one laboratory in district FF.

District	Numbers of AFB-microscopy laboratories accessible by car
AA	1-12
BB	13-17
CC	18-22
DD	23-26
EE	27-28
FF	29-42
GG	43-49

Three districts have to be selected. There are 49 AFB-microscopy laboratories in the table above. So our sampling interval is 49 divided by 3, which is 16.

The first district has to be selected randomly by using a random number table (annex 1). Select a starting point on the table by looking away (or closing the eyes) and marking a dot on the table with a pencil. Draw a line down to the left of the column closest to the dot and then a line to the right in the first space between rows (annex 1a). Select the first block of four numbers, either in the row above or below the line in between the two rows, whose last two digits are between 1 and 16. In the example in annex 1a this is number 2. (If, as in this case, the last two digits of the first block of four numbers in the row above, as well as the row below show a number between 1 and 17, select the number in the block above the line). The first sampled district is AA (2 is between 1 and 12), and the second district is the district that includes 2+16= 18 which is district CC. The third district is district FF (18+16=34).

District AA has 12 AFB-microscopy laboratories, district CC has five accessible AFB-microscopy laboratories, and district FF has 14 accessible AFB-microscopy laboratories. In each of these three districts two AFB-microscopy laboratories have to be selected.

Sampling of the AFB-microscopy laboratories

The next step is to prepare the list of AFB-microscopy laboratories per selected district. For this selection the volume of smear examination, rounded off to the nearest 500, during the last year or the last four consecutive quarters, will be used. Thus the chance of an AFB-microscopy laboratory being selected depends on the number of smear examinations.

One way to link the probability of selection of an AFB-microscopy laboratory to the volume of smear examinations is to inflate the sampling frame according to the number of smear examinations in each laboratory. For example, if in a laboratory 4,500 smears have been examined, then this laboratory should be listed 4,500 times in the sampling frame. To make this easier, the number of smear examinations is divided by 100. Now this laboratory should appear 45 times instead of 4,500 times.

Using the inflated sampling frame below random sampling is used to select two laboratories per district. There are 360 elements in the table. Two laboratories have to be selected, thus one in 180. The first laboratory has to be selected randomly by using the random number table, as explained above, selecting a number between 1 and 180. If number 74 is randomly selected, the first sampled laboratory is Bb and the second is Gg (74+180=254).

District AA

Names of AFB-microscopy laboratories in alphabetical order	Number of smear examinations	Number of smear examinations /100	Numbers
Aa	4500	45	1-45
Bb	3000	30	46-75
Cc	2500	25	76-100
Dd	5500	55	101-155
Ee	4500	45	156-200
Ff	3000	30	201-230
Gg	2500	25	231-255
Hh	1500	15	256-270
Ii	1000	10	271-280
Jj	2000	20	281-300
Kk	4000	40	301-340
Ll	2000	20	341-360
Total	36000	360	360

There may be incidental situations that a laboratory cannot be visited, e.g. because the laboratory staff is on sick or other leave during the day of the planned visit or the laboratory is closed for reconstruction. Therefore a back-up laboratory should always be selected. For this selection start again with a fresh AFB-microscopy laboratory sampling frame, excluding already selected sites and select a new random number from the random number table. The table for selection of this laboratory is given below:

Names of AFB-microscopy in alphabetical order	Number of smear examinations	Number of smear examinations /100	Numbers
Aa	4500	45	1-45
Cc	2500	25	46-70
Dd	5500	55	71-125
Ee	4500	45	126-170
Ff	3000	30	171-200
Hh	1500	15	201-215
Ii	1000	10	216-225
Jj	2000	20	226-245
Kk	4000	40	246-285
Ll	2000	20	286-305
Total	30500	305	305

The randomly selected number should be between 1 and 305. If number 250 is selected, the back-up laboratory will be Kk.

The same procedure has to be followed for selection of the AFB-microscopy laboratories and a back-up laboratory of districts CC and FF.

Required information

For sampling the districts and the AFB-microscopy laboratories the information has to be provided by the NTP/NTRL, with support from the intermediate level if required, in two steps:

Step one:

- Names of all the districts
- Names of the districts that cannot be visited, because of security problems and non-accessibility of the intermediate laboratory by car
- Number of AFB-microscopy laboratories in each eligible district

Step two, after the districts have been selected:

- Names of the AFB-microscopy laboratories of the selected districts
- Names of the AFB-microscopy laboratories that are not accessible by car
- Total volume of smear examinations during the last year or last period of four consecutive quarters of the AFB-microscopy laboratories that are accessible by car

Two intermediate levels

Sampling of regions and districts

Selection of the intermediate levels has to be done in two steps. First a sample of two regions has to be taken. Prepare a table with the names of the regions in alphabetical order, the number of districts per region and assign the numbers to each of the districts. Administrative divisions of cities should be counted as districts. Regions that cannot be visited due to security problems should be excluded.

Number	Names of regions in alphabetical order	Number of districts	Number
1	MM	10	1-10
2	NN	8	11-18
3	OO	4	19-22
4	PP	7	23-29
5	QQ	9	30-38
6	RR	5	39-43
7	SS	7	44-50
8	TT	9	50-59
Total		59	59

There are 59 districts in these 8 regions. Two regions have to be selected; thus the sampling interval is 30. Select a number between 1 and 30 from the random number table. If this is number 21, the first selected region is OO and the second region is TT.

Then prepare for each of the selected regions the table for selection of the districts, excluding districts whose intermediate laboratory cannot be reached by car.

Region OO

Names of districts in alphabetical order	Number of AFB-microscopy laboratories	Number
O1	6	1-6
O2	8	7-14
O3	7	15-21
O4	10	22-31
	31	31

Two districts have to be selected. This is one in 16 districts. Select a number between 1 and 16 from the random table. If this is number 11, the first district is O2, and the second is O4.

Repeat this for region TT, also selecting two districts.

Sampling of the AFB-microscopy laboratories

Then prepare for each of the selected district the table with the AFB-microscopy laboratories, the volume of the smear examinations and the numbering of the AFB-microscopy laboratories, as shown above for one intermediate site, while excluding the laboratories that are not accessible by car. Select one AFB-microscopy laboratory from each district. Then select a back-up laboratory for each district.

Required information

For sampling the regions and districts and the AFB-microscopy laboratories the information has to be provided by the NTP/NTRL in three steps:

Step one:

- Names of the regions
- Names of regions that, for security reasons, cannot be visited
- Number of the districts per region

Step two, after the regions have been selected:

- Names of the districts of the selected regions
- Names of districts whose intermediate laboratory is not accessible by car
- Number of AFB-microscopy laboratories of the selected districts

Step three, after the districts have been selected:

- Names of the AFB-microscopy laboratories of the selected districts
- Names of the AFB-microscopy laboratories that cannot be reached by car
- Total volume of smear examinations per AFB-microscopy laboratory during the last years or last consecutive period of four quarters of the AFB-microscopy laboratories that are accessible by car

No intermediate level

Sampling of six AFB-microscopy laboratories should be done from the list of AFB-microscopy laboratories that are accessible by car and the total volume of smear examinations during the last year or last consecutive period of four quarters.

Alternatives for selection of intermediate sites and AFB-microscopy laboratories

There may be reasons to divert from the above outlined sampling strategy. These include:

- The country is very large
- There is large heterogeneity in accessibility of areas
- Validation of implementation of policies and procedures will be restricted to areas that have already implemented certain policies and procedures, e.g. EQA, or referral of specimens from patients at risk for HIV- associated TB and/or MDR/TB

Following sampling strategies are proposed:

Very large country:

- In case of one intermediate level:
    - Include the intermediate site closest to the capital (where the NRL is situated)
    - Randomly select two intermediate sites.
    - Random select two AFB-microscopy laboratories in each intermediate site and one back-up laboratory

- In case of two intermediate levels:
    - Include the intermediate site closest to the capital
    - Randomly select the second region.
    - Random select two districts in each of the two regions
    - Randomly select one AFB-microscopy laboratory in each district and one back-up laboratory

Large heterogeneity in accessibility:

- In case of one intermediate level:
    - Divide the country into easy, moderate and difficult to access districts
    - Randomly select one district in each of these categories
    - Select two AFB-microscopy laboratories in each of these three districts and one back-up laboratory in each district. This may be randomly or the laboratories are also divided into easy, moderate and difficult to access (excluding those not accessible by car) and one laboratory is selected from each category

- In case of two intermediate levels:
    - Divide the country into easy and difficult to access regions
    - Randomly select one region in each of these categories
    - Select two districts in each of these regions. This may be randomly, or the districts are also stratified into easy and difficult to access and one district in each of these categories is randomly selected.
    - Select in each district one AFB-microscopy laboratory randomly and one back-up laboratory

Restriction of validation to areas where policies and procedures have been implemented

Selection of intermediate levels and AFB-microscopy laboratories should be as outlined for the entire network, however, only including the areas where the policies and procedures have been implemented.

Annex 1

	1 2 3 4	5 6 7 8	9 10 11 12	13 14 15 16	17 18 19 20	21 22 23 24	25 26 27 28	29 30 31 32
1	8 0 9 4	2 5 2 5	8 2 4 7	1 3 4 7	7 4 3 3	3 6 2 0	1 8 9 7	2 1 3 4
2	3 5 6 3	2 1 9 6	8 2 1 1	9 0 4 5	2 6 1 8	2 7 5 1	2 6 2 7	1 0 9 5
3	1 3 3 0	6 3 3 1	3 7 5 3	9 6 9 3	8 7 3 8	6 6 1 5	1 5 3 8	8 5 4 3
4	3 5 6 5	0 0 1 6	2 2 4 3	6 4 3 2	4 7 9 6	6 0 9 5	5 2 8 3	1 6 2 0
5	7 8 5 0	5 9 2 5	5 5 8 8	7 3 1 1	2 1 9 2	4 5 4 5	3 5 3 0	5 5 8 9
6	4 4 9 0	5 4 1 7	9 7 2 7	6 1 5 3	5 9 0 1	4 8 7 8	9 9 8 0	9 8 7 7
7	6 5 4 5	9 1 0 4	9 3 1 8	8 8 1 9	7 5 3 7	2 7 8 5	9 3 7 3	2 4 4 5
8	3 6 2 6	5 9 9 5	1 2 1 5	9 7 5 3	9 2 2 3	5 6 5 8	2 9 4 4	2 8 9 9
9	4 8 6 5	4 8 2 0	7 5 5 4	0 6 1 2	9 6 8 3	4 2 5 1	9 1 3 8	1 7 0 9
10	6 4 9 8	7 5 1 9	0 4 7 4	7 8 1 8	6 8 3 2	9 6 8 3	9 8 7 2	4 0 9 0
11	6 7 2 2	9 8 6 9	9 3 6 1	7 8 7 5	4 8 8 3	1 3 1 5	9 6 7 9	8 8 3 4
12	9 7 4 8	5 9 3 2	5 1 1 5	2 7 2 1	0 0 3 3	9 3 0 3	9 7 1 3	4 0 1 2
13	5 6 4 1	1 4 1 7	1 4 1 9	7 4 3 4	8 1 6 5	7 3 6 8	1 2 1 8	5 0 3 9
14	7 4 4 4	9 2 0 0	8 8 4 0	5 8 8 2	4 3 9 8	3 9 0 4	9 1 9 9	9 3 3 6
15	8 2 7 9	3 0 1 9	4 6 7 2	3 7 4 3	3 9 7 9	4 6 8 9	9 0 2 1	6 9 9 0
16	0 1 6 1	7 6 1 7	1 0 2 4	2 3 8 7	2 8 9 1	6 6 7 7	1 5 8 5	2 4 8 2
17	7 3 8 8	9 7 5 9	7 5 5 5	6 6 2 4	9 9 7 7	2 0 0 8	5 5 9 6	9 7 4 0
18	7 8 3 0	4 7 1 4	3 6 9 5	2 9 1 9	1 8 0 4	4 0 4 4	1 0 3 4	2 5 9 7
19	9 8 8 7	4 2 1 6	6 5 2 6	4 5 3 5	8 4 3 0	5 2 7 0	9 6 0 5	0 7 6 8
20	1 2 6 1	2 5 1 6	8 5 6 9	2 3 1 0	3 9 3 9	8 7 0 3	9 8 4 1	0 3 5 3
21	3 9 4 7	4 9 3 7	7 6 3 4	2 5 4 3	6 2 3 9	7 4 5 5	2 0 5 5	7 7 9 5
22	4 5 5 0	8 1 0 3	1 2 5 0	2 3 0 4	1 1 3 8	9 7 8 8	9 1 4 4	4 5 2 6
23	1 3 4 4	9 6 9 7	2 3 8 3	6 9 7 6	6 2 5 1	4 2 0 1	2 0 3 8	6 5 5 2
24	8 9 7 6	5 8 2 3	8 4 8 7	0 4 5 0	3 1 0 6	9 1 6 6	2 7 1 7	7 6 0 1
25	7 7 1 0	9 9 4 3	6 9 7 8	8 2 7 3	9 7 1 4	9 7 0 0	1 5 6 6	2 8 8 9
26	6 9 5 9	6 0 0 8	8 4 4 2	2 2 8 2	1 5 2 4	2 5 1 7	5 8 1 8	0 0 8 1
27	7 9 4 1	2 3 1 2	2 4 3 1	6 7 0 2	9 9 8 4	3 4 6 9	3 0 8 5	4 7 6 2
28	2 2 8 4	0 8 9 6	9 1 0 7	5 6 4 2	7 3 1 9	3 7 8 2	1 0 6 8	9 5 7 4
29	9 5 9 4	7 4 1 6	9 3 6 5	6 0 4 5	1 1 8 3	5 9 1 6	9 5 9 9	1 1 4 3
30	4 6 1 3	8 5 4 9	6 3 6 9	3 2 0 8	5 1 0 9	9 6 8 0	1 1 6 8	6 1 3 3

Annex 1a. Random selection of the first district

Below the last block of above random number table is copied. When moving down from the marked dot and then to the right between the rows, the first number between 1 and 17 is 2, from the combination 3782. 16 in the combination 5916 below the line is also between 1 and 17, however, in such cases the number in the combination above the line is selected.

6959 6008 8442 2282 1524 2517 5818 0081

7941 2312 2431 6702 9984 3469 3085 4762

2284 0896 9107 5642 7319 3782 1068 9574

9594 7416 9365 6045 1153 5916 9599 1143

4613 8549 6369 3208 5109 9680 1168 6133