III. ON-SITE EVALUATION

A field visit is the best method to obtain a realistic picture of the conditions and practices in the laboratory; therefore, on-site evaluation of peripheral laboratories is an essential component of a meaningful EQA program. Three different types of field visits can be used as part of an ongoing EQA process, depending on the resources available and the performance capability of the laboratory being visited.

- A monthly or quarterly visit to the laboratory by a district supervisor is required as part of the DOTS strategy for TB control.
- When very poor performance has been identified through panel testing or rechecking, an expanded visit by qualified laboratory personnel from a higher level laboratory (the intermediate laboratory or reference laboratory) may be necessary to perform a comprehensive evaluation of all laboratory procedures, implement corrective action, and provide training if needed.
- A routine visit by a laboratory is recommended at least annually. Another option is to form quarterly supervision teams including intermediate lab staff and a district supervisor.

The NTP should use the WHO and IUATLD technical manuals and guidelines as the template to develop laboratory procedures and establish a system to monitor laboratory practices. The national laboratory must provide training to all personnel responsible for on-site evaluation. Non-laboratory personnel will need an adequate understanding of routine laboratory operations, including proper registration procedures, appropriate supplies, laboratory safety, basic microscope operations, and requirements of panel testing or rechecking programs operated by the NTP. Laboratory personnel must be knowledgeable in all operational and technical elements of AFB smear microscopy and have sufficient expertise to observe technicians performing routine tasks. They should also facilitate quality improvement through on the spot problem solving and suggestions for corrective action when needed.

District Supervisor Visits
Monthly or quarterly visits to the health clinics by the district or regional supervisor are required as part of an overall DOTS program. In some countries with very limited resources at the National Reference Laboratory, or countries just beginning to develop an implementation plan for EQA, these visits may be the only type of on-site evaluation possible. On-site evaluation by non-laboratory personnel is generally limited to assuring that NTP requirements for recording and reporting of results are followed, and assessing operational conditions, such as safety, supplies, equipment and total workload unless these supervisors receive special training in laboratory issues. Supervisors should make sure that Standard Operating Procedures are in place, internal QC is performed, and a functional microscope is available. Since the ability to recognize AFB is considered essential for
anyone working in TB control programs where detection and follow-up are largely based on AFB microscopy, some programs have had good experience using well trained district supervisors to read a few recent positive and negative smears as part of the routine quarterly visit. This decision should be made by each RL and NTP based on available resources and existing relationships between district supervisors and peripheral laboratories.

Visits by district supervisors are also useful to collect data on TB laboratory workload, positivity rate for suspects and follow up examinations. These data are often not available to the NTP, but are important for several reasons. Heavy workload (>20 smears per day per technician) may contribute to poor performance. A low workload (<15 smears per week per technician) may not be adequate to maintain proficiency in reading AFB smears. Workload for AFB microscopy may be more difficult to interpret in peripheral laboratories that perform a variety of laboratory tests. Monitoring slide positivity rates is necessary to determine appropriate sample sizes for a blinded rechecking program. Any significant changes in the indicators may indicate performance problems. For example, a change in positivity rate outside the expected range may signal a problem in over-reading or under-reading, especially if a new technician has been hired. Workload data and positivity rates are also useful to calculate necessary laboratory supplies.

Regular visits by the district supervisor also provide an opportunity to collect an appropriate sample of slides to forward to the higher-level laboratory for rechecking.

On-site Evaluation for Corrective Action
Extensive review of laboratory conditions and practices may be necessary when poor performance is identified during the quarterly supervisory visit, or through panel testing or rechecking, and the reasons for the performance problems are not readily apparent or are not corrected through more basic corrective action recommendations. On-site visits by experienced laboratory personnel from a higher-level laboratory provide an opportunity for immediate problem solving, corrective action and on-site retraining.

Regular On-site Evaluation by Trained Laboratory Personnel
Optimally, on-site evaluation should be performed at least once a year by personnel from a higher-level laboratory in order to evaluate the overall operational conditions in the microscopy centers. In many countries where health sector reform has been instituted, these visits should be integrated with evaluation of general health services and laboratory quality assurance activities for HIV, STDs and malaria. The annual (or more frequent, if needed) visit includes a comprehensive assessment of laboratory safety, conditions of equipment, adequacy of supplies as well as the technical components of AFB smear microscopy. Sufficient time must be allotted for the visit to include observation of all the work associated with AFB smear microscopy, including preparing smears, staining and reading of smears. On-site evaluation should also include examining a few stained positive and negative smears to observe the quality of smearing and staining as well as condition of the microscope.
Checklists

Every program will need to develop checklists to assist both laboratory and non-laboratory supervisors during the field visit and to allow for the collection and analysis of standard data for subsequent remedial action. Each country must establish a standard definition of what is acceptable for each checklist item, based on the guidelines established by WHO and IUATLD and the resources available in the area. An important component of using any checklist is to provide sufficient training and standardization so that the checklists are used consistently. Programs may refine the checklists to focus on problems that are frequently identified or most likely to occur, such as preparation of stains.

In addition to being sent to the NTP, results of checklists should always be sent back to the reference laboratory for analysis. A comprehensive list of all operational elements to be observed will help to ensure consistency in laboratory evaluations and provide immediate feedback to the technicians to facilitate rapid corrective action, as well as serve as documentation of the visit and record of current conditions and actions needed. An example of a comprehensive checklist for on-site evaluation is provided in Appendix A. This checklist contains open, non-leading questions and recommended observations along with objective criteria for acceptable practices. By using open, non-leading questions, as well as direct observation of the daily practices, the supervisor can assess how well the technician understands proper procedures, and is not just providing the expected “yes” response. This detailed checklist is provided as a template that may be adapted to meet the specific needs of EQA in each country. The preferred format should include simple, objective “Yes/No” evaluation criteria, yielding data that can easily be entered into a database for long term tracking and comparing performance.

A more simplified checklist, which may be more appropriate for use by well-trained district supervisors, is included in Appendix B. Use of a simple checklist can reduce the time necessary to evaluate a laboratory, especially when supervisors are very familiar with the process. Therefore, a simple checklist requires well established standards of acceptability and extensive training for consistent application and recording of what is observed to be unacceptable.

The on-site visit by both properly trained laboratory or non-laboratory personnel should make sure that:

1. Written standard operating procedures are available.
2. An adequate supply of reagents within expiration dates is available.
3. Proper, well functioning equipment and an adequate supply of consumables are available.
4. Internal QC is performed at the required intervals.
5. Laboratory safety practices are observed.
6. Record keeping is accurate and consistent with requirements of NTP.
7. Results are promptly reported to treatment centers or physicians.
External Quality Assessment

8. A functional microscope is available. At a minimum, district supervisors must be familiar with simple microscope function, and be able to visualize a clear image through the microscope lens.
9. Patient slides are available and properly stored when EQA includes rechecking. Supervisors will collect an appropriate sample to be forwarded to reference laboratory.
10. Staff have received adequate training with refresher courses or corrective action are recommended when appropriate.
11. Workload and proportion of positive smears are evaluated.
12. Suspects recorded as smear positive in the laboratory register are recorded in the TB district register.
13. The findings and need for corrective action or additional resources are reported to the NTP.

On-site evaluation of the technical practices in the laboratory performed by properly trained laboratory staff from a higher-level laboratory includes all of the operational elements listed above, as well as:

1. Evaluating sputum collection procedures.
2. Observing and evaluating procedures for smear preparation, staining, and reading.
3. Assuring that positive and negative control slides are used with all newly made batches of stains as well as with each daily batch of smears.
4. Rechecking several positive and negative smears to evaluate staining, smear thickness, smear size, and results.
5. Reviewing results of panel testing and/or rechecking. Providing suggestions for corrective action or implementing corrective action as needed.

Documentation of any significant problems requires strategies and systems for improvement.