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**PROGRESS REPORT ON  
IMPLEMENTATION OF QUALITY  
MANAGEMENT SYSTEM (QMS) IN  
TB LABORATORY NETWORK IN  
TAJIKISTAN  
QMS TRAINING IN DUSHANBE  
DECEMBER 4-7, 2012**

February 2013

This report was produced for review by the United States Agency for International Development. It was prepared by the Quality Health Care Project in the Central Asian Republics.

The USAID Quality Health Care Project is a five-year program designed to improve the health of Central Asians by strengthening health care systems and services, particularly in the areas of HIV/AIDS and TB care and prevention. The project assists governments and communities to more effectively meet the needs of vulnerable populations, with the aim of increasing utilization of health services and improving health outcomes. The Quality Health Care Project is part of USAID's third objective of investing in people as part of the US Strategic Framework for Foreign Assistance.

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**Submitted to:** Leslie Perry  
Director, Office of Health and Education  
USAID Central Asia Regional Mission

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## List of abbreviations

|       |  |
|-------|--|
| CDC   | Centers for Disease Control and Prevention               |
| CLSI  | Clinical and Laboratory Standards Institute              |
| DST   | Drug Susceptibility Testing                              |
| EQA   | External Quality Assessment                              |
| GFATM | Global Fund against AIDS; TB and Malaria                 |
| GLI   | Global Laboratory Initiative (WHO)                       |
| IQC   | Internal Quality Control                                 |
| ISO   | International Standard Organization                      |
| KfW   | German Development Bank (Kreditanstalt für Wiederaufbau) |
| MOH   | Ministry of Health                                       |
| NRL   | National Reference Laboratory                            |
| PHC   | Primary Health Care                                      |
| QMS   | Quality Management System                                |
| RCC   | Rolling Continuation Chanel                              |
| RCTB  | Republican TB Center                                     |
| SES   | Sanitary Epidemiological Services                        |
| SNL   | Supranational Laboratory                                 |
| SOP   | Standard Operating Procedures                            |
| SOW   | Scope of Work  |
| UNDP  | United Nation Development Project                        |
| USAID | United States Agency for International Development       |
| WHO   | World Health Organization                                |

## **1. Introduction**

Implementation of the Quality Management System (QMS) is one of the basic requirements for TB control programs that aim to reach the targets defined in the WHO plan for global TB control by 2015. QMS is a system that ensures that the quality of all processes in the laboratory is managed properly. It ensures that all activities performed in a laboratory are planned, done according to planning, checked if they were done correctly and corrective action is undertaken always when they are not done correctly. The USAID Quality Health Care Project is supporting the practical implementation of the system, providing technical assistance in the development of QMS guidelines, technical training, implementation, and monitoring. This report presents the work done on implementation of QMS in Tajikistan and results of the field visit by the Regional laboratory specialist Dr. Marija Joncevska

## **2. Scope of Work (SOW)**

The trip to Dushanbe took place from December 2-9 with the following SOW

- To conduct QMS trainings for National and intermediate level laboratory coordinators
- To discuss with the NTP the selection of pilot site for QMS implementation
- Discuss monitoring plan with partners

## **3. Background information**

TB laboratory network in Tajikistan is functioning as a three level structure. The third, National level is presented by two laboratories: the National Reference Laboratory (NRL) at the Republican TB Hospital, responsible for culture and DST and RCBT laboratory, responsible for coordination of smear microscopy network. Intermediate level network consist of four Oblast laboratories, currently only two of them performing culture examination and two are in the process of renovation and equipping. There are 92 peripheral laboratories, functioning as first level diagnostic labs for smear microscopy, based at PHC facilities or at Rayon TB Dispensaries. Quality assurance of smear microscopy services has been implemented by Project HOPE since 2007 with participation of all 92 laboratories. Results collected form the external quality assessment (EQA) are analyzed annually and reported to the NTP management, where corrective measures for quality improvement are planned. Quality assurance of culture laboratories is not in place and it is planned to be established with the implementation of QMS by the USAID Quality Health Care Project.

The NTP established collaboration with the Supranational laboratory (SNL) Gauting in Germany, which has a major role in quality assurance of DST. Proficiency testing for DST is conducted on annual basis. SNL is also providing technical assistance in reconstruction of laboratories with funding provided by German Development Bank.

Significant support for improvement of laboratory infrastructure was provided by GFATM project, implemented by Project HOPE (Round 3 and RCC for round) and UNDP (Round 6 and 8)

## **4. Laboratory Quality Management**

Quality Management System can be defined as “coordinated activities to direct and control an organization with regard to quality.” This definition is used by the International Organization for Standardization (ISO) and by the Clinical and Laboratory Standards Institute (CLSI)

QMS consists of various elements, including all procedures and processes that are performed in the laboratory and must be carried out correctly in order to assure accuracy and reliability of lab services. It also addresses many elements of personnel management and oversight, encouragement and motivation. In order to have a functional QMS, the structure and management of the laboratory must be organized to ensure that:

- The laboratory organization and infrastructure provide appropriate working conditions.
- The right equipment is installed correctly, works properly and there is a system for maintenance.
- Procedures for selection and purchase are designed to assure that all reagents and supplies are of good quality and that they are used and stored in a manner that preserves integrity and reliability.
- There is an established system of control for laboratory procedures
- Laboratory data management assures accuracy and confidentiality of test results and accessibility to the health care providers.

The primary goal of QMS is continuous quality improvement of the laboratory services, done in a systematic manner and in compliance with a set of standards. Those standards are listed in document issued by the International Standard Organization (ISO): ISO 15189 Medical Laboratories - Requirements for quality and competence. Based on this document, the WHO developed guidelines for laboratory accreditation, including a set of 53 laboratory best practice standards, grouped in 16 sections (*Best practice for developing standards for infectious disease laboratories in Europe, World Health Organization 2010*). The implementation of QMS in TB laboratory services is also supported by the WHO Global Laboratory Initiative (GLI) which prepared a set of checklists for monitoring the implementation of QMS in four phases.

## **5. Implementation of QMS in Tajikistan**

The implementation of QMS is one of the major activities of the USAID Quality Health Care Project. The implementation is planned in stepwise approach starting from QMS assessment in Year 1 of the Project, continuing with development of training materials; QMS guidelines and standard operating procedures for TB laboratories in Project year 2. Training of senior laboratory staff and laboratory managers and start of the implementation are included in Project year 3 work plan, as well as monitoring of implementation and technical assistance to selected QMS Pilot site. Lessons learned from the Pilot site will be used for development of expansion plan for countrywide implementation of QMS in TB laboratory network.

### **5.1 QMS assessment**

Assessment of laboratory practices for quality management was conducted in March 2011. The main findings of the assessment were:

- Poor infrastructure at PHC laboratories which does not provide an appropriate working environment
- Lack of system for transportation of biological samples and delay in reporting laboratory test results
- Insufficient infection control in bacteriological labs
- Laboratory accreditation standards are not fully developed

Those points were taken into account in development of QMS implementation plan and addressed in QMS guidelines.

## **5.2 Development QMS guidelines and standard operating procedures (SOP)**

QMS laboratory guideline is a descriptive document, providing the information on what a quality management system is and how it is integrated in the organization of TB laboratory network. It presents a framework which divides all the aspects of a quality management system into 12 elements defined as a quality system essentials. The first draft of the document was prepared and currently the Quality office in Almaty is translating the document into Russian language. After the translation is completed, it will be shared with NTP partners for harmonization with the national legislation and requirements for infection control set by Sanitary Epidemiological Serviced (SES). SOPs have been developed as well and will be included as an attachment to the guidelines. They are divided in three major groups: technical procedures: infection control procedures and procedures for use and maintenance of laboratory equipment. The work on QMS guidelines and SOPs was coordinated with the NRL and SNL.

### **5.3 Report on QMS training (December 4 -7, 2012)**

The training in laboratory QMS was prepared by Marija Joncevska, MD, PhD, Quality Project Regional laboratory specialist. It was based internationally adopted standards for TB laboratory quality and in line with the WHO recommendations for implementation of QMS.

The training covered all aspects of the laboratory operation, including:

- Infrastructure and laboratory organization
- Laboratory procedures
- Infection control and bio-safety
- Laboratory supply management
- Laboratory equipment and maintenance
- Documentation and referral system
- Laboratory accreditation

#### Overall training goal:

The overall training goal is to prepare laboratory staff for successful implementation of laboratory QMS in TB laboratory network, ensure the quality of services and support the NTP in its efforts for efficient TB and MDR TB control

#### Training objectives:

At the end of the training participants will be able to:

1. Understand the basic principles of laboratory QMS
2. Implement the methodology for Internal Quality Control (IQC) and External Laboratory Assurance (EQA) for laboratory procedures
3. Identify the level of bio-hazard in TB laboratory network in relation to the laboratory diagnostic level
4. Implement all steps in commodity management cycle
5. Understand the basic principles for laboratory staff management
6. Collect and manage the minimum set of laboratory quality data

Expected outcome:

After successful completion of the training it is expected that laboratory managers will be prepared to start the implementation of QMS in the laboratory network in their respective Oblasts and supervise the implementation process.

Training methodology:

The training is based on adult learning principles using the following training methods:

1. Interactive Power Point presentations/ lectures
2. Demonstration of laboratory management tools
3. Individual and group work
4. Discussion sessions
5. Site visit

Trainers and facilitators:

| Name                      | Position                       | Affiliation           | Technical expertise                            |
|---------------------------|--------------------------------|-----------------------|--|
| Marija Joncevska, MD, PhD | Regional laboratory specialist | USAID Quality Project | TB laboratory management and technical polices |
| Dr Tatiana Bobkova        | Laboratory coordinator         | USAID Quality Project | TB laboratory diagnosis and quality assurance  |
| Mohonim Abduloeva         | Head of NRL Tajikistan         | Republican TB Centre  | TB laboratory network coordination             |

Training program

|                     | <b>Time</b>    | <b>Activity</b>  | <b>Training method</b> |
|---------------------|----------------|--|------------------------|
| <b><u>Day 1</u></b> | 9:00 - 9:30    | Opening, introduction  |                        |
|                     | 9:30 -10:00    | Pre-test   | test                   |
|                     | 10:00 - 10:30  | Introduction of the training program: the aim and objectives of the course |                        |
|                     | 10:30 - 11:00  | Quality assurance in TB laboratory services. introduction                  | Presentation 1         |
|                     | 11:00 - 11:30  | Coffee break   |                        |
|                     | 11:30 - 12:00  | Implementation of laboratory QMS   | Presentation 2         |
|                     | 12:00 - 12:30  | Infrastructure and environmental safety in laboratories                    | Presentation 3         |
|                     | 12:30 - 14:00  | Lunch  |                        |
|                     | 14:00 - 14:30  | Equipment management in TB lab   | Presentation 4         |
|                     | 14:30 - 15: 30 | Management of lab supplies   | Presentation 5         |
|                     | 15:30- 16:00   | Coffee break   |                        |
|                     | 16:00 - 16:30  | Working group  | Practical exercise     |
|                     | 16:30 -17:00   | Presentation of working group results                                      |                        |
|                     |                | Questions and answers  |                        |
| <b><u>Day 2</u></b> | 9:00 - 9:45    | Quality control procedures in the microscopy laboratories                  | Presentation 6         |

|              |               |  |                         |
|--------------|---------------|--|-------------------------|
|              | 9:45 - 10:30  | Quality control procedures in the culture laboratories | Presentation 7          |
|              | 10:30 - 11:00 | Coffee break   |                         |
|              | 11:00 - 11:30 | Quality control procedures in the DST laboratories     | Presentation 8          |
|              | 11:30 - 12:00 | Personnel management                                   | Presentation 9          |
|              | 12:00 - 12:30 | External quality assurance                             | Presentation 10         |
|              | 12:30 - 14:00 | Lunch  |                         |
|              | 14:30 - 15:30 | Documents and records, information management          | Presentation 11         |
|              | 15:30 - 16:00 | Coffee - break   |                         |
|              | 16:00 - 17:00 | Discussion   |                         |
|              |               |  |                         |
| <b>Day 3</b> | 9:00 - 10:00  | Accreditation of labs                                  | Presentation 12         |
|              | 10:00 - 10:30 | Coffee - break   |                         |
|              | 10:30-12:00   | Tools of laboratory QMS                                | Practical demonstration |
|              | 12:00-13:30   | Lunch  |                         |
|              | 13:30         | Departure to the laboratory                            |                         |
|              | 14:00-16:00   | Visit to the culture laboratory                        | Practical work          |
|              | 16:00 - 17:00 | Practical work to develop of QMS implementation plan   | Practical work          |
|              |               |  |                         |
| <b>Day 4</b> | 9:00 - 10:00  | Presentation of QMS plan , discussion                  |                         |
|              | 10:00 - 10:30 | Coffee break   |                         |
|              | 10:30 - 11:00 | Post-test  |                         |
|              | 11:30 - 12:30 | Presentation and discussion of training results        |                         |
|              | 12:30 - 14:00 | Lunch  |                         |
|              | 14:00-14:30   | Closing ceremony and handing certificates              |                         |

Course language:

Training course was delivered in Russian language

Duration:

Training is planned for 4 working days, including 12 theoretical presentations and 8 hours of individual and group practical work.

Training venue:

Theoretical part of the training was organized at the Training Centre at Republican TB Centre in Dushanbe. Practical work in QMS assessment and planning was organized in laboratory at Dushanbe City TB Dispensary.

Participants:

The target group for QMS training are laboratory managers, coordinators of National and Oblast reference laboratories.

## List of participants

| No | Name            | Affiliation                      | Position                |
|----|-----------------|----------------------------------|-------------------------|
| 1  | Abduloeva M     | Republican TB Centre             | Laboratory coordinator  |
| 2  | Hafizov U.      | Oblast TB Dispansery Kurgan Tube | Laboratory coordinator  |
| 3  | Kosimisova Z    | Republican TB Centre             | Laboratory specialist   |
| 4  | Mirzoeva S      | Republican TB Centre             | Lab quality coordinator |
| 5  | Dharipov D.     | Oblast TB Dispansery Kuliab      | Laboratory coordinator  |
| 6  | Rizoeva T.      | Oblast TB Dispansery Kuliab      | Lab quality officer     |
| 7  | Ashurmamadova B | Republican TB Centre             | Lab specialist          |
| 8  | Alihinova H     | Oblast TB Dispansery Hudzhand    | Laboratory coordinator  |
| 9  | Gulaezova L     | Oblast TB Dispansery Khorog      | Laboratory coordinator  |
| 10 | Saidaliev K     | Oblast TB Dispansery Kuliab      | Laboratory coordinator  |

### Materials and equipment :

In order to provide effective training course, selected materials and equipment were used to create interactive learning environment:

1. Laptop
2. Projector
3. Printer
4. White board
5. Markers, flip charts
6. Name Tags/ Badges

Individual (per participant):

7. Folders
8. Writing pads
9. Pens
10. Handouts

For practical work:

1. Personal protective equipment (disposable lab coats; masks; gloves)
2. Check lists with instructions

### Logistics:

All logistic arrangements were completed by administrative staff of Quality Project Dushanbe office:

1. Airport pick up for participants and trainers
2. Hotel booking, organization of coffee breaks and lunches
3. Transport to site visits

**Evaluation methodology and training results:**

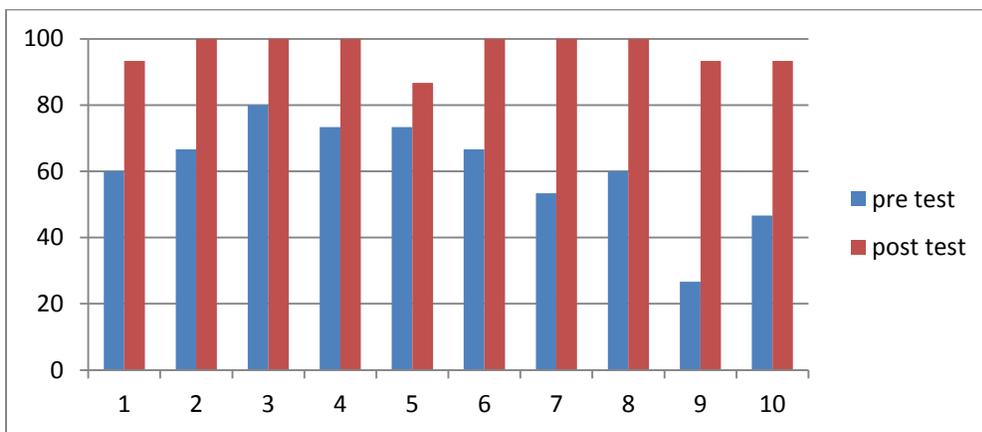
For evaluation of the knowledge gained during the training, a training evaluation tool was developed to determine:

1. Progress in knowledge gained by individual participant
2. Average progress for the group
3. Improvement of knowledge by topic/question

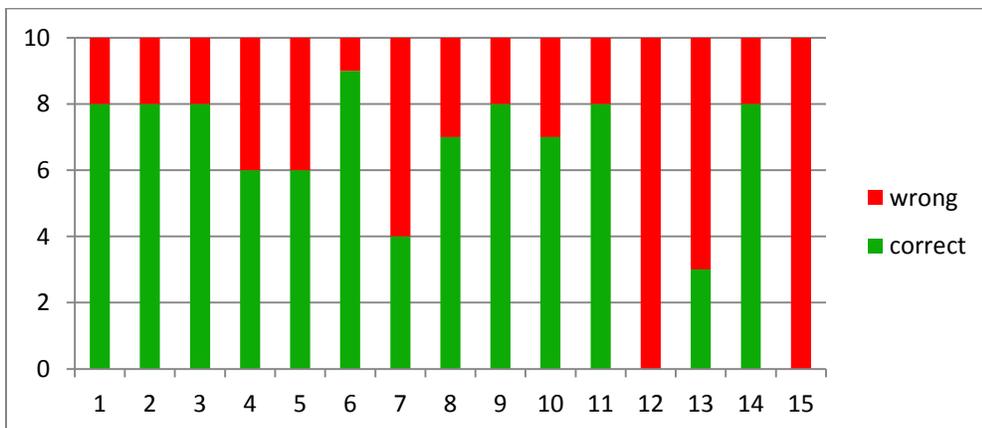
The same tool will be used for follow up on training to monitor improvement in knowledge and skills over time.

Training results were presented and discussed at the end of the training. For the presentation of individual results per participant, a code number was used of each participant, instead of his/her name. The average score per participant in pre-test was 61%, while in post- test it increased to 97% (fig. #1)

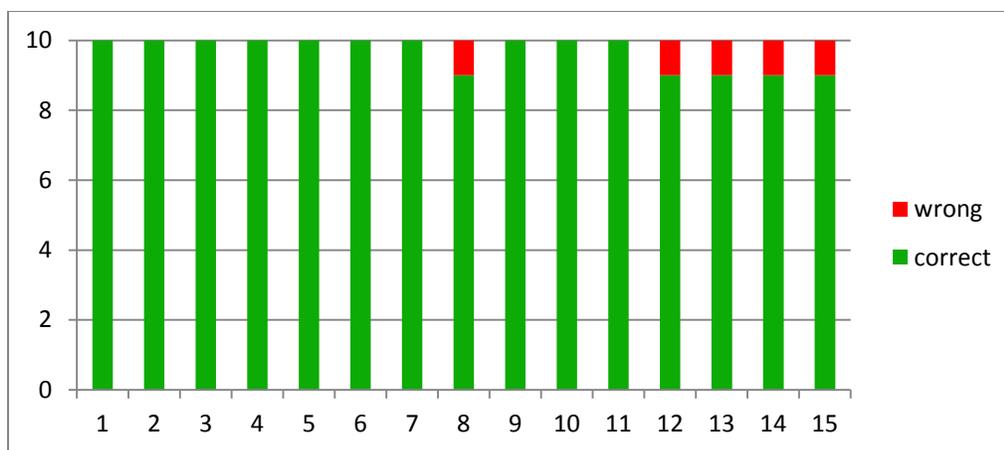
**Fig.# 1. Comparison of pre-test and post-test results per participant**



**Fig. # 2. Correct answers per test question – pre test**



**Fig. # 3. Correct answers per test question – post test**



#### Follow up on training

Results from the evaluation showed that the participants gained significant knowledge in basic principles of QMS and are prepared to start the implementation of QMS in their daily work. The start of the pilot project is foreseen in February in Soght Oblast and Khudjand City and the implementation will be monitored by the NTP Laboratory Coordinator and Quality Project Laboratory specialist. Monitoring team will use QMS checklists based on ISO 15 189 accreditation standards (attachment #3).

#### **5.4 QMS pilot project**

Selection of the Pilot site for implementation of QMS in Tajikistan was based on availability of basic structure of laboratory services, which will allow to demonstrate the advantages of the adopted system. Soght Oblast and the Oblast capital Khudjant were selected because they fulfill the basic requirements:

- Different levels of TB laboratory service
- Basic infrastructure
- SOP (standard operation procedures) documents developed
- System for quality assurance in place

The laboratory network consists of: one intermediate level laboratory, performing smear microscopy; culture examination and implementing the EQA for smear microscopy and a network of 22 laboratories for smear microscopy. Culture laboratory is based at Degmoy Oblast TB Hospital, which is in the process of reconstruction with funds from KfW. This will be an opportunity for Quality Project to contribute in the process of laboratory organization and implementation of required standards for infection control.

#### **5.5 Monitoring and Evaluation (M&E) Plan**

The first visit to the Pilot site will be conducted from February 15 and will provide the baseline information on the QMS elements that are already in place. The information will be analyzed and action plan developed in collaboration with the NRL and SNL. Regular visits for monitoring the progress in QMS implementation will be conducted on quarterly basis and monitoring report submitted to the NTP, in order to present the progress made and identify the gaps and points for improvement. The monitoring team will use the QMS checklists recommended by GII – WHO for evaluation of QMS in specialized TB laboratories.

#### **6. Meetings with partners**

Meeting with Dr. Oktam Bobohadjaev, NTP Manager.

The meeting was held at the RCBT with participation of the Head of NRL Dr Mohonim Abduloeva, Quality Project lab specialists: Marija Joncevska; Tatiana Bobkova and Zamira Baiduloeva. The Quality team presented the plan for QMS implementation and reasons for selection of Pilot Oblast. Dr Bobohadjaev agreed with the proposed activities and offered his personal and his team support in the implementation process. He also pointed out the need for close collaboration between all partners and good coordination of activities for lab strengthening.

Round table on presentation of National Drug Resistance Survey (DRS) results

Project HOPE and CDC from Atlanta jointly conducted nationwide DRS in Tajikistan, in the period 2009 – 2011. The project was managed by Dr Marija Joncevska, Project HOPE Regional Laboratory Adviser and the round table was organized for presentation of results to the MOH; NTP and other national and international partners, involved in implementation of TB control activities. Activities related to organization of this even took place in Dushanbe from December 10 -14, after the SOW related to QMS implementation within the Quality Project (QMS training) was completed.

Meeting with USAID monitoring mission: Dr Erika Vitek and Dr Sevim Ahmedov

The meeting took place at Project HOPE office during the preparatory activities for the Round table on Tajikistan DRS. It was an opportunity to present laboratory activities in implementation of QMS in TB laboratory service in Tajikistan and also discuss the results from the National DRS.

Meeting with USAID CAR team: Kairat Davlatov and Dilorom Kasumova and KNCV team: Mavluda Mahmudova; Valentina Anisimova and Bella Kim)

The meeting was initiated by USAID team to discuss the GeneXpert implementation strategy. The strategy was developed by KNCV, including diagnostic algorithm for GeneXpert testing. The algorithm was discussed in terms of country needs; sustainability and sufficient number of tests required for optimal use of the platform. It was agreed that the KNCV specialist will provide more detailed calculation of number of tests to be done, based on the latest epidemiological data.

## 7. Annexes

Annex # 1.

Trip itinerary December 2 - 9

| Day                                 | Time  | Activity   |
|-------------------------------------|---|--|
| December 2 Sunday                   | 9:45  | Departure from Skopje  |
| December 3<br>Monday                | 6:30  | Arrival Dushanbe   |
|                                     | 6: 30 – 8:30  | Visa procedure at Dushanbe airport   |
|                                     | 8:30  | Pick up from airport   |
|                                     | 14: 00 – 17:00  | Meetings at Quality office:<br>Marian Sheridan, Alisher Mahmudov, Roza Adilbekova,<br>Zamira Baidyloeva, Tatiana Bobbkova, |
| December 4 -7<br>Tuesday- Friday    | 9:00 – 17:00  | Training in QMS  |
| December 8 Friday                   | 9:00 -14:00   | Last training day and closing ceremony   |
|                                     | 15: 00 – 16:00  | Meeting with Dr Bobohadjaev, NTP manager   |
| December 10 – 14<br>Monday - Friday | Participation on Round table on National DRS (Project HOPE) |  |
| December 15,<br>Sunday              | 14:00   | Departure to Bishkek   |

Annex # 2.

List of persons met

| <b>Name</b>             | <b>Title</b>      | <b>Affiliation</b>     |
|-------------------------|-------------------|------------------------|
| 1. Marian Sheridan      | Project Manager   | USAID Quality Project  |
| 2. Roza Adilbekova      | TB Director       | USAID Quality Project  |
| 3. Oktam Bobohadzaev    | Director          | RCBT                   |
| 4. Mohonim Abduloeva    | Head of NRL       | Republican TB Hospital |
| 5. Timur Aptekar        | Project Manager   | Project HOPE GF- RCC   |
| 6. Erika Vitek          | Senior TB Adviser | USAID Ukraine          |
| 7. Sevim Ahmedov        | Senior TB Adviser | USAID Washington DC    |
| 8. Kairat Davletov      | Technical Officer | USAID CAR              |
| 9. Dilarum Kasumova     | Technical Officer | USAID Tajikistan       |
| 10. Mavluda Mahmudova   | Country Director  | KNCV                   |
| 11. Valentina Anisimova | Lab specialist    | KNCV, Netherlands      |
| 12. Bella Kim           | Lab specialist    | KNCV Almaty            |

Annex # 3.

QMS monitoring checklist (Phase I)

### **Checklist questions**

Have the duties, responsibilities, and authority of a quality specialist/officer/manager been assigned to a staff member?

Are technical operations supervised by qualified staff (e.g., a laboratory director)?

Are daily routine work tasks established, assigned (duty roster or workstation assignments) monitored and supervised by qualified professional staff?

Is a trained safety officer designated to implement and monitor the laboratory safety program including training of other staff?

Does the laboratory identify and undertake quality improvement projects?

Is a workplan and budget in place for the laboratory that supports the laboratory's testing operations and maintenance of the quality system?

Are quality checks and internal quality controls for AFB-smear microscopy performed daily by technicians and at random (at least weekly) by the supervisor?

Is the staining method (laboratory manual, wall chart) readily available at the workstation?

Is the staining sink level?

Does the microscopy bench and chair appear to be comfortable for the microscopist?

Is the microscope binocular, electric, and with good optics?

Are all reagent bottles labeled and show preparation and expiry dates?

Is the performance of staining reagents checked with a known positive slide at monthly intervals (or more frequently), and results entered in the register?

Are AFB-positive slides re-read by a second person, if possible?

Are 10% of AFB-negative slides re-read by a second person, if possible?

Are monthly workload statistics collected and analyzed in accord with WHO/IUALTD recommendations?

Are specimens processed within one day of receipt?

Are smears prepared on clean, unused glass slides?

Before making the smear, is the slide clearly labeled with the laboratory number ?

Is a swab-stick (or loop) used to collect a representative portion of the sample for smearing?

Is there only one smear per slide?

Is the smear approx. 2cm x 1cm and in the center of the slide?

After drying, is fixation done by gentle heating over a flame?

Does the fixed smear have the appearance of a milky white film on the slide?

Is the objective lens wiped clean after use on a positive smear?

Is the identity of the person reading the slides entered into the register?

Are results entered directly into the laboratory register?

Are results scored in accordance with WHO recommendations?

Are all slides properly stored in sequence for re-examination by EQA?

Are quality checks and internal quality controls for inoculating and incubating cultures performed daily by technicians and at random (at least weekly) by the supervisor?

The method of inoculation (laboratory manual, wall chart) is readily available at the workstation

All media and reagents pass their quality checks and are used prior to their expiration dates

Processed specimens are inoculated onto or into media as soon as possible after resuspension

The Biosafety Cabinet (BSC) is functioning properly

Liquid media is inoculated in accord with manufacturer's instructions

Only one specimen tube or slant is open at a time

A fresh pipette is used at every step to avoid transfer of bacilli from one specimen to the other

A pipette is used to inoculate each slant with 3–4 drops (about 0.1–0.15 ml) ensuring that the entire surface of the slant is inoculated

Tubes are initially incubated in a slanted position such that the surface of the solid media is horizontal and facing upwards

Tubes are incubated in a slanted position with screw-caps loose for at least 1 week

After 1 week of incubation, caps are tightened and tubes may be incubated upright

The incubator maintains a temperature of 35°C to 37°C

Tubes are checked daily for the first week and any contaminated tubes discarded

After the first week, tubes may be read once-a-week

Cultures are incubated for 6 weeks (liquid media) or 8 weeks (solid media) before being reported as negative.

Results are scored in accordance with WHO or NTP recommendations

Results are entered directly into the laboratory register

The identity of the person reading the slides is entered into the register

All isolates are properly stored in accord with WHO and NTP recommendations

Waste is properly disposed

Is internal quality control (IQC) performed?,

Is the performance of staining reagents checked with a known positive slide at monthly intervals (or more frequently), and results entered in the register?

Is each new batch of media shown to be able to support the growth of mycobacteria?

Is each new batch of drug-containing media shown to support the growth of drug resistant strains but not of drug susceptible strains

If a device contains an internal control area, is the internal control area determined to be acceptable before interpreting the test area?

If QC is unacceptable, is there a process for repeating the the test?

Are quality checks and internal quality controls for processing samples performed daily by technicians and at random (at least weekly) by the supervisor?

The method of processing (laboratory manual, wall chart) is readily available at the workstation

All media and reagents passed their quality and sterility checks and are used prior to their expiration dates

Specimens are processed promptly after receiving and accessioning them

The Biosafety Cabinet (BSC) is functioning properly

The NaOH-NALC solution is prepared freshly each day

The sample tubes are properly labelled

The sample tubes must be capable of withstanding a force of at least 3000xg

Aliquots of buffer and decontamination solutions are used

Work is done in batches corresponding to one centrifuge load

Only one specimen tube is open at a time

A fresh pipette is used at every step to avoid transfer of bacilli from one specimen to the other

Aerosol production is minimized

The volume of the specimen is checked and two volumes of digestion-decontamination reagent is added and thoroughly mixed

The decontamination-digestion mixtures are incubated at room temperature (20°C to 25°C) for 15 minute.

Buffer is added to fill the tubes and the sample mixed

Aerosol-containment centrifuge buckets are loaded and unloaded in a BSC

A swinging bucket rotor with aerosol-containment buckets is used

A refrigerated centrifuge is used and the chamber is at 8-10 °C during centrifugation

Samples are centrifuged at an RCF of 3000xg for 15–20 minutes

The supernatant is decanted into a flask a tuberculocidal disinfectant

Samples are resuspended in the recommended volume of buffer

Waste is properly disposed