

# National Tuberculosis Reference Laboratory

## Quality Year Plan 2013

### Introduction

The policy of National Tuberculosis Reference Laboratory (NTRL) is aimed at the delivery of quality services. The NTRL aims at implementing a quality management system according to the ISO 15189 standard. In 2011 a plan for implementation was developed together with external consultants. Soon thereafter, we have appointed a quality officer who is coordinating the quality activities. In 2012 major progress was made with implementation of several aspects of the quality management system (QMS), as documented in the Management Review 2012 (MR 2012). For 2013 the main objective will be to continue developing the quality management system, thus to lay down the basis of continuous improvement of the quality of NTRL services. The MR 2012 served as a basis for this Quality Year Plan 2013.

Faz, February 2013



O. Anujoo  
Director

# National Tuberculosis Reference Laboratory

## 1. Implementation of the quality management system

The NLTR follows the implementation plan which was developed in 2011. For 2013 we will continue to give follow up to this plan. In 2013 more attention should be given to writing and making valid SOPs and to timely follow-up of actions. Also the Quality Manual should be finalized before the end of the year.

### Objectives:

1. NTRL will have followed up all required actions from the implementation plan at the end of 2013.
2. NTRL will perform at least 6 internal audits in 2013.
3. At least 3 staff meetings will be organized before the end of 2013 as to inform and involve all staff about the progress and needs of the Quality Management System.

## 2. Regular activities within the quality management system

### 2.1 Internal and external audits

In 2013 all internal audits are performed according to the audit plan. A total of 12 audits are needed for the review of the complete quality management system. An audit plan has to be developed for 2013, comprising of the month in which the audit will be done, the subject of auditing and the auditors.

The quality officer will look after the follow up of the actions resulting from the audits. The management review will report on the follow up of audits in general.

An external audit will be planned for 2013.

### Objectives:

4. Per 31 December 2013 all audits have been performed according to plan and timely reports and action plans have been prepared.

### 2.2 Policy and reporting cycle

The table below gives a planning of the regular activities related to the policy cycle.

Activities related to the policy cycle		
Activity	Responsible	Deadline
Organize and perform the management review 2012	LM	January 2013
Development of draft Quality Year Plan 2013	LM	February 2013
Authorize the Quality Year Plan 2013	LM	February 2013
Translation of the quality year plan into specific actions and agree with staff on implementation	LM	March 2013
Looking after follow up of implementation of action plans	QO	Continuously
Prepare quarterly reports	QO	Quarterly

### Objectives:

5. Per December 2013 all planned regular activities have verifiably taken place according to planning.

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## 2.3 Internal and external quality controls

Internal quality control is a continuous process. The lab manager is responsible for taking corrective actions upon results from internal quality controls. These actions are documented.

The results of external quality control (proficiency testing) are discussed after receipt with the staff and on the basis of these results corrective actions may be taken by the management.

### Objective:

6. Per December 2013 all planned internal and external quality controls have been taken place according planning and results are discussed. If needed corrective actions will be taken.

## 2.4 Other regular activities

- Revision of SOPs where necessary
- Implementation of new SOPs
- Evaluation of suppliers
- Customer satisfaction assessments

The revision of SOPs and Quality Manual chapters happens on the basis of the document control system. The QO will coordinate actions in this respect.

Considering NTRL is in a phase of developing its quality management system, many new SOPs will appear and have to be implemented.

A start has to be made with the documentation of the evaluation of suppliers. This will be part of the procurement SOP, which has to be implemented.

A system for evaluation of suppliers needs to be developed, which should be part of SOPs in which the process of ordering, receipt, identification, labeling, handling and storage of all reagents, reference items and equipment is documented.

Positive and negative feedback from customer needs to be archived and reported in the quarterly reports from the QO, so that it can be evaluated in the management review and actions taken. A form for recording the service provided by suppliers of critical reagents, supplies and services that affect the quality of examinations will be developed.

### Objectives:

7. Per December 2013 all planned new SOPs and policy/management documents are made and valid.
8. Per December 2013 all SOPs in need of revision are discussed with staff and revised.
9. Every quarter the QO reports to the Director on the follow-up of ongoing activities.
10. A form for evaluation of suppliers will be implemented as part of the SOP for procurement before 31 December 2013.

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## 3. Accommodation and environmental conditions

The BSL 3 laboratory has now been built, but awaits full installment of all equipment. It will be expected to be functional at the end of 2013. Despite the availability of this contained laboratory, safety of staff is a legitimate concern considering the work with pathogenic organisms i.e. mycobacteria at NTRL. A number of measures are in place to control infection and essential equipment in this respect is regularly validated by external companies; this is written in the biosafety manual. However working in the BSL 3 laboratory requires a specific procedure. Therefore, an SOP on working in the BSL 3 laboratory should be written and incorporated in the biosafety manual. This should include the description of what to do in case of emergency, infection control, protection measures for personnel, housekeeping and waste disposal.

### Objectives:

11. In the biosafety manual a SOP on how to work in the newly established BSL 3 facility should be implemented March 2013.
12. All staff should be trained on biosafety issues before 31 December 2013

## 4. Competence of staff

On the basis of the requirements of the NTRL as determined by the Director and on the basis of discussions with individual staff an inventory of educational needs will be made. Designated staff will be allowed to follow work related courses as part of the continuous education programme of NTRL.

On the job training on quality management will be organized in consultation with an external training company.

It will be arranged that the rest of the staff will follow a course on (bio)safety. In addition several other activities will take place as part of continuous education, such as attendance of symposia, congresses, etc., provided financial means allow this and upon agreement of the Director.

A fire drill will be organized to practice evacuation procedures.

### Objectives:

13. Per December 2013 designated staff has followed work specific trainings and these are documented in the personnel archive.
14. Per December 2013 on the job trainings by an external training company have been conducted.
15. Per 31 December 2013 all staff will have followed a course on (bio)safety.

## 5. Continuous improvement processes

### 5.1 System of feedback and complaints

The NTRL has not yet built a complete policy and procedures for the resolution of complaints or other feedback received from its customers and/or staff. The SOP, which includes the record keeping of feedback and complaints, and of investigations and corrective actions taken by the laboratory, has to be revised and updated. Thereafter a start can be made with evaluation of feedback, its analysis in the management review, upon which actions can be taken.

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## Objectives:

16. Per 31 December 2013 the SOP on feedback and complaints is revised and authorized. This should include a simple and user-friendly form for submitting feedback.

## **5.2 Validation**

The NTRL uses only validated methods suitable for the intended use, but this is not yet documented. In the quality manual a chapter will be devoted to this topic and an SOP has to be written for validation of methods.

Essential equipment such as laminar flows are validated by external accredited companies (see above). Other equipment is monitored on a daily basis for correct performance.

## Objectives:

17. Per 31 December 2013 a Quality Manual chapter on validation and a SOP will be written.

## **5.3 Implementation of ISO15189 quality management system**

The introduction of the quality management system according to the ISO 15189 standard will continue in 2013 according to the implementation plan which was developed in 2011.

## Objectives:

18. Per December 2013 planned actions described in the ISO 15189 implementation plan are followed up.

## **6. Conclusions**

This is the second Quality Year Plan of the NTRL. The follow up of the actions mentioned herein will be coordinated and reported by the QO. In the management review evaluation of the follow up of this annual plan will take place, so that corrective measures can be taken where appropriate.

The support of all staff and of the QO in particular in implementing the quality management system at NTRL is highly appreciated.