National Tuberculosis Reference Laboratory

Management Review 2012

Introduction

This is the report of the management review (MR) of the National Tuberculosis Reference Laboratory (NTRL). This report presents data on the functioning of the NTRL over the quality year 2012 which ran from January 2012 to December 2012. The input for the MR came from several sources as described in the SOP on Management Review.

The MR serves to identify any changes required to meet the needs and requirements of users of the laboratory services. It also describes any action needed to ensure the continuation of the service of the NTRL. We have chosen a format of reporting in which for each topic the objectives, analysis and conclusions, and actions to be taken are specified. The objectives originate from the Quality Year Plan (QYP) and/or from quality management system (QMS) requirements.

In accordance with the SOP on Management Review, this MR report has been prepared by the Laboratory Manager and discussed with all the NTRL staff.

Faz, February 2013

O. Anujuo
Director

National Tuberculosis Reference Laboratory

1. Follow-up of previous management reviews

Objective To follow-up on actions from previous management reviews.

Analysis of execution of actions from previous MR
A MR was conducted and reported in January 2012. The following actions from the MR 2011 were formulated:

1. Management, technical staff and quality officer (QO) should better monitor the completion of action points through regular discussions, both in bilateral meetings and weekly staff meetings. Action points should be on the agenda of weekly staff meetings.
2. The original ISO 15189 QMS implementation plan should be completed as soon as possible. (QYP 2011-1 NTRL will have followed up all required actions from implementation plan by the end of 2011).
3. Director NTRL should approve the SOP on competency testing and QO should file the competence documentation in personnel files before December 2012.
4. An SOP for microscopy tests has to be written before the February 2012.
5. A simple follow-up system of outstanding action points should be made by the QO before the end of June 2012.
6. Follow-up of outstanding action points from the QYP 2011 and include these actions in QYP 2012.

Ad. 1. Regular discussions both in bilateral and staff meetings are being done. Action points are on the agenda of staff meetings. However, monitoring the progress of actions had been initiated but not fully done by the management and QO.
Ad. 2. Specific actions are being done but not all are completed.
Ad. 3. SOP for competency testing was approved, however, it demands to have competence tested for all personnel but in practice it was concluded to test only the staff that was actually carrying out the tests plus the backups. Competence tests are ongoing for personnel that join new sections. Extra back up personnel for given sections need to be anticipated and their competence performed – see quarterly report 2012-4.
Ad. 4. SOP for HAIN tests was written and implemented.
Ad. 5. A file for “Action Plans” that is easily accessible has been put in place to assist in follow-up of outstanding actions. The QO and Laboratory Manager are following up pending action items with all individuals involved. In case two deadlines are missed the responsible person is forwarded to the Director.
Ad. 6. Outstanding actions from the Quality Year Plan 2011 were included in the 2012 Quality Year Plan.

Conclusion
Although progress has been made in implementing all recommendations/actions, a number of actions to be followed up from previous management review are not yet finalized. It is important that these actions are discussed with both staff and management on a regular basis, so that follow-up can be properly monitored and the Laboratory Manager and Director can intervene when necessary.

New actions

- MR2012-01: Monitoring the progress of actions by the management and QO.
- MR2012-02: Complete all the actions described in the QMS implementation plan.
- MR2012-03: Adjust the competence SOP to be realistic to reflect the need of competence for personnel performing the test and the extra back up staff.

2. Action plans coming from the quality year plan 2012

Below is a list of open action plans copied from the QYP 2012 with an explanation of what has been done to complete these.

QYP-2012-1: NTRL will have followed up all required actions from implementation plan at the end of 2012

Analysis/conclusion

See chapter 1: Follow-up of previous management reviews**.**

QYP-2012-2 and QYP2012-4: NTRL will perform at least 6 internal audits in 2012

Analysis/conclusion

Per December 2012 all audits have been performed according to plan and timely reports and action plans have been prepared (see chapter 3: The outcome of internal audits and corrective measures).

QYP-2012-3: At least 3 staff meetings will be organized before the end of 2012 as to inform and involve all staff about the progress and needs of the Quality Management System

Analysis/actions

Monthly quality meetings involving all staff members are in place and have been very helpful in solving action points and informing the personnel on all updates and plans on QMS.

Conclusion

Monthly quality meetings will continue.

QYP-2012-5: Per January 2013 all planned regular activities have verifiably taken place according to plan:

Activity	Responsible	Deadline
Organize and perform the management review 2012	LM	Q1 2013
Development of draft quality year plan 2013	LM	Q1 2013
Authorize the quality year plan of 2013	LM	Q1 2013
Translation of the quality year plan into specific actions and agree with staff on implementation	LM	Q1 2013
Looking after follow up of implementation of action plans	QO	Continuously
Prepare quarterly reports	QO	Quarterly

Analysis/actions

- The management review 2012 was carried out in January 2013, but this report was one month late: the next 3 activities (see table) are dependent on this management review. These 3 activities will be ready by the end of February 2012.
- The follow-up of implementation of the action plans has been difficult because of various reasons including inability to understand the tasks and complicated recording and follow up system. Effort is made to explain all the assigned tasks and a different recording method, which makes the action plans more visible, is now in place. In addition, all pending actions are reviewed in a general meeting that has enhanced accountability. A long list of action plans have been finalized in the last few months.
- The quality officer prepared all quarterly reports.

Conclusion

In 2014 the management review 2013 will need to be written a bit earlier, as there are follow-up actions depending on it.

Action

MR2012-04 In November 2013 the Laboratory Manager will plan 3 days in his agenda in January 2014 to carry out the management review 2013 and write the draft report.

QYP-2012-6: Per January 2013 all planned internal and external quality controls have taken place according to plan and results are discussed. If needed, corrective actions will be taken.
For the internal quality controls see Chapter 5: Quality indicators – Internal Quality Control. For external quality controls see Chapter 7: Results from external quality assessment and other forms of inter-laboratory comparison.

QYP-2012-7 and QYP 2012-8: Per December 2013 all planned new SOPs and policy/management documents are made and authorized. Per December 2013 all SOPs in need of revision are discussed with staff and revised.
See Chapter 5: Quality indicators – Document Control

QYP-2012-9: Every quarter the QO reports to the Director on the follow-up of ongoing activities.
Analysis/Conclusion
The quality officer has consistently generated quarterly reports on the follow-up of ongoing activities. These have been shared with all staff and have been helpful updates and generated many other follow up actions that have helped improve quality. Quarterly reports will continue.

QYP-2012-10: A form for evaluation of suppliers will be implemented as part of the SOP for procurement before 31 December 2012.
See Chapter 10: Evaluation of suppliers.

QYP-2012-11: In the biosafety manual an SOP on how to work in the newly established BSL 3 facility should be implemented before 2013.
See Chapter 5: Quality indicators – Document Control

QYP-2012-12: All staff should be trained on biosafety issues before 2013.
Analysis/Conclusion
All staff members are trained on biosafety, but need annual refresher training. Specific training is provided before use of the containment room.

Action
MR2012-05: Annual refresher biosafety training for all staff as well as biosafety training for new staff will take place in 2013.

QYP-2012-13: Per January 2013 designated staff has followed work specific trainings and these are documented in the personnel archive.
See Chapter 5: Quality indicators - Personnel issues

QYP-2012-14: Per January 2013 a training on quality management for all personnel has been conducted.
Analysis/Conclusion
All personnel at NTRL were trained on quality in November 2012. These trainings have been instrumental in grounding the QMS at the NTRL.

QYP-2012-15: Per 31 December 2012 all staff will have followed a course on (bio)safety.
See Chapter 5: Quality indicators – Personnel Issues

QYP-2012-16: Per 31 December 2012 the SOP on Feedback and Complaints is revised and authorized. This should include a simple and user-friendly form for submitting feedback
See Chapter 4: Feedback, including complaints and other relevant factors.

QYP-2012-17: Per 31 December 2012 a Quality Manual chapter on validation and an SOP will be written.
See Chapter 5: Quality indicators – Document control

QYP-2012-18: Per January 2013 planned actions described in the ISO 15189 implementation plan are followed up.
See Chapter 1: Follow-up of previous management reviews.

3. The outcome of internal audits and corrective measures

Actions from year plan 2012
QYP-2012-2: NTRL will perform at least 6 internal audits in 2012.
QYP-2012-4: Per December 2012 all audits have been performed according plan and timely reports and action plans have been prepared.

Analysis/Conclusion
Between January 2012 and December 2012 the NTRL performed all the planned 12 internal audits. A lot of points for improvement were identified and were turned into action items which were discussed with all the staff. Most of the arising action points have been carried out with resultant improvement into quality of the work done. However, the satisfactory and timely follow-up of the actions requires attention. Some actions remain in progress: it appeared that they were not all properly and understandable formulated or seemed difficult to be carried out by the responsible staff.

Action
MR2012-06: Ensure that all action points are properly formulated and are quickly carried out.
MR2012-07: Discuss all action points and their follow up in general meetings. In addition the action points that prove difficult to do should be brought to the attention of the Laboratory Manager and discussed in the management meeting.

4. Feedback, including complaints and other relevant factors

Action from the Quality Year Plan 2012
QYP-2012-16: Per 31 December 2012 the SOP on feedback and complaints is revised and valid. This should include a simple and user-friendly form for submitting feedback
There were a number of complaints and feedbacks from customers. Some were more common than others.

Common complaints:
a) Delayed results
b) Poor performance of microscopy

Infrequent complaints:
a) Inaccurate results on DST
b) Incomplete results

Analysis/actions
Reduction in the delay of results was given a top priority through monitoring of turnaround time (TAT) and reorganizing work flow to improve efficiency. Monitoring TAT helped the NTRL figure out areas for improvement as well as ensuring accountability since the staff knew that every delay will be investigated and responsible people identified. The TAT has greatly improved in all areas with occasional over dues.

Poor performance of microscopy characterized by many false negatives was investigated. The investigations also included members of the NTRL on the microscopy bench working in another laboratory where they compared their techniques. The problem was found to be arising from use of a poor microscope. The microscope was retired. In addition all smear negative results were reviewed before reporting. All these measures greatly improved microscopy performance and are now acceptable according to the proficiency panels, inter laboratory comparison as well as culture comparisons. See for preventive measures QYP2012-11 in Chapter 5: Quality Indicators.

The inaccurate result on DST resulted into misclassifying a susceptible patient as MDR-TB. More samples were requested from the patient and it was later found that there was cross contamination that lead to a false MDR-TB result. Extra caution (such as not over batching, reviewing all the labels before processing) have been undertaken to minimize this. With these measures, no other incident has been reported.

In one instance a patient was issued with rifampicin sensitive results but was not responding to treatment. It was later found that the patient isolate was resistant to all other drugs. The patient is being investigated for a mutation of rifampicin *rpo* gene outside the usual site tested by HAIN. We are also performing the rifampicin resistance test phenotypically.

As a general measure an approved SOP and structured documentation of both complaints and feedback have been implemented. This will enable NTRL passively and actively to receive feedback on performance from customers that will help in continued improvement of the QMS.

5. Quality indicators

Objective:
The overall of objective of this chapter is to show adequate functioning of the quality system through monitoring of relevant indicators. The indicators are divided into internal quality controls, document control and personnel issues. External quality controls are dealt with in Chapter 7: Results from external quality assessment and other forms of inter-laboratory comparison.

Internal quality control

Action from year plan 2012
QYP-2012-6: Per December 2012 all planned internal and external quality controls have taken place according to plan and results are discussed. If needed, corrective actions will be taken.
Analysis/actions
For external quality control, see Chapter 7: Results from external quality assessment and other forms of inter-laboratory comparison.

For internal quality control the following was performed:

ZN/FM: Between January 2012 and January 2013 the NTRL used quality control (QC) slides (negative and positive) when a new batch of slides were to be stained using ZN/FM. However, as noted previously, this procedure did not

help much in ensuring that microscopy results were of acceptable quality as many times this was not satisfactory when compared to culture and clinical expectations. Some of the reasons for the failure of the QC slides to ensure quality microscopy included:

a) The slides were not well blinded. It was sometimes possible to know how a positive and negative slide looked like before staining as we later discovered from the technicians.
b) The positive control used was high grade and was not graded during the reading; therefore it was not adequate to detect minor deviations in the procedure which could impact patients with minimal disease.
c) On some occasions the QC slides were not included.

Action:
MR2012-08: Write and implement an SOP on how to prepare high quality QC slides for ZN/FM and ensure are blinded and are available all the time.

LJ: Between January 2012 and January 2013, performance of LJ has been monitored using contamination rates and comparison of results from LJ with results from smears. This analysis is performed monthly using baseline samples (samples from patients who are not on treatment). Initially, these parameters were variable (on and off the acceptable ranges). This prompted improvement responses such as demanding strict adherence to SOPs, timely delivery and processing of samples. As a result of these measures, these parameters are now consistently in acceptable range from January 2012 up to now and this has been one of the key improvement areas in the QMS.

DST: When performing DST, strains with known susceptibility (resistant and susceptible to each drug) patterns are always included in every batch tested as an internal control. Between January 2012 to January 2013 the results of all internal controls were according to expectations. There were two constraints in this area:

i) there was a batch of about 200 tests that were contaminated. An analysis performed revealed that this was due to using a batch of media that was not sterile. Measures undertaken included strict observation of SOPs media preparation, media sterility check before use as well as setting small batches of tests at a time. After these measures this incident never recurred.
ii) There was delay in TAT for LJ DST and many overdue reported in this area. This was a result of increased workload as NTRL was conducting a National Drug Survey and the backlog created by the contamination explained in (i) above. The survey has now ended and backlog cleared and the TAT is back to normal. To be prepared for recurrence of such a situation in the future a backup system was established whereby staff is moved from other sections to the DST section (and receives adequate training) to spread workload more evenly.

MGIT and HAIN: Although internal controls were performed with these procedures, they were not monitored. To enable monitoring of these controls in the future the result forms will adapted to include the quality control result.

Negative process controls: These were introduced in the analytical process of samples to improve on the integrity of results. These samples are subjected to microscopy [Fluorescent Microscopy], LJ culture, MGIT and HAIN. The samples are coded and blindly introduced in the lab weekly.

Below are the results:
Between January and June 2012 36 negative samples were blindly introduced in the laboratory. Out of these, 6 (17%) were smear positive (4 actual and 2 high false positive (HFP)). All LJs were negative. Out of the 30 that were inoculated on MGIT 3 (10%) were positive and were proved to have MTB by HAIN. These performances were unacceptable and were likely to be due to incompetence in microscopy reading and cross contamination for MGIT. Measures to improve these areas were undertaken including cross training with another laboratory, observation of work, internal audit, and review of work. The subsequent results are shown in the next section.

Between July and December 2012 42 negative samples were blindly introduced in the lab and handled as indicated above. Out of 42 samples that were analysed, there was one (2%) microscopy with the actual numbers. All LJ and MGIT culture remained negative for MTB for all samples. There was one (2%) LJ contamination. HAIN indicated the positive smear sample as negative, hence confirming it was false positive.

Conclusion
These results show a great improvement in quality in 2012. The plan is to continue with the negative control process.

A Laboratory Information System (LIS) in which all sample data is entered was introduced and this has greatly improved capacity to analyse key performance indicators such as TAT, delays in sample delivery, contamination rates, workload, disparity in results and patient serial samples. This database meets all the requirements for ISO 15189 and is a cornerstone in maintaining the QMS. A new database with advanced functions such as automatic retrieval of results from some equipment, automatic sending of results to health workers, bar code readings, and full indication of an audit trail as well as a bigger storage capacity was acquired from Chase-IT and installed. This database is a pilot system with all personnel to be trained. If all goes well NTRL will shift to this database by end of September 2013.

Conclusion
Monitoring the internal controls for ZN/FM, LJ, DST, negative sample processes and completing the new database evaluation will continue.

Action
MR2012-9: Start monitoring performance of internal controls for HAIN and MGIT.

Document control

Action from year plan 2012

QYP-2012-7: Per December 2012 all planned new SOPs and policy/management documents are developed and authorized.

Analysis/action
All planned (59) new SOPs have been developed and authorized. They were implemented and helped to standardize practice and entrench the QMS. However, there was need to develop 45 SOPs more. Of these 21 have been developed and in the process of approval while 24 SOPs need to be written.

For policy and management documents see QYP-2012-17 below.

Action
MR2012-10: Complete the approval of the 21 SOPs and write the remaining 24 SOPs and implement all of them by December 2012.

QYP-2012-8: Per December 2012 all SOPs in need of revision are discussed with staff and revised.

Analysis/action
Of the 25 SOPs in need of revision, 17 have been revised and 8 are in the process of revision. The delay in revision of SOPs was due to lack of tight tracking of the SOPs that are due for revision. An electronic system with automatic reminders was developed, to warn for the SOPs that will soon be due for revision. This has made it possible to plan the revisions ahead of time.

Conclusion
MR2012-11: Complete revision of the 8 SOPs by March 2013.

QYP-2012-11: In the biosafety manual an SOP on how to work in the newly established BSL 3 facility should be implemented before 2013.
Analysis/action.
An SOP on how to work in the BSL3 was written and implemented. However, it was delayed because of the delay in completion of the BSL-3 facility. After commencement of use of the new BSl-3 facility, it was realized that 14 new SOPs needed to be written in the Biosafety manual.

Action
MR2012-12: Write the remaining SOPs in the Biosafety Manual by March 2013.

QYP-2012-17: Per 31 December 2012 a Quality Manual chapter on validation and an SOP will be written.
Analysis/action
Three chapters of the Quality Manual were developed and approved, 7 chapters have been written and are being reviewed by the laboratory manager, the last 4 chapters have been drafted. The chapter and an SOP on validation have been written. Writing of the quality manual has strongly guided the QMS.

Action
MR2012-13: Complete the review of the remaining Quality Manual chapters.

Personnel issues
Action from year plan 2012
QYP-2012-13: Per January 2013 designated staff has followed work specific trainings and these are documented in the personnel archive.
Analysis/action
All personnel at NTRL received work specific training and competence checks were performed and passed. These activities were documented in personnel files. For each work station, two personnel members were trained and competence evaluated. In some instances it was challenging to find a trainer where there was only one person knowledgeable in that section. We resolved for the Director to sign off such a person as trained in the past.

After training and competence checks, all personnel stayed at one station for a year. This allowed us to build two experts in a given area. Now we have begun rotations where at a given time one person leaves the section and the other remains. The person who remains is joined by a new person who they is trained. While the person who leaves becomes the reviewer of that section since they have at least a year experience in that area.

Conclusion
This arrangement has been a corner stone for sustaining quality since it ensures that in each section there is a trainer, reviewer and a backup person. Hence we no longer depend on one person for quality.

QYP-2012-15: Per 31 December 2012 all staff will have followed a course on (bio)safety.
Analysis/conclusion
Several trainings (local and international) took place on biosafety. The Bio-safety Officer, Data manager and DST technologist received international training in biosafety. In addition, all the NTRL staff were trained by international experts in Biosafety. All NTRL staff received training for working in the BL3 facility. These trainings were

documented. All new staff and trainees who join NTRL receive an orientation about biosafety as the original training. All NTRL staff will receive refresher biosafety training annually.

Action
MR2012-14: Continue refresher training in biosafety annually.

Monitoring of turnaround-time

Objectives
To ensure fast release of quality results to customers with an understanding that timely results guide management and improve outcome of patients. The following TAT were set based on analytical protocols, data management and quality control processes:

- ZN/FM diagnosis: results are reported within 2 days after receipt of the sample.
- Culture: LJ results are reported the latest 9 weeks after receipt of the sample (in case of a negative culture) and at the latest t_p+3 days, where t_p is the time for the culture to become positive.
- DST: results are reported within 7 days after a positive culture in case LPA is used.
- EQA: results are reported within 14 days after receipt of the slides.
- LPA: results are reported within 7 days after a positive microscopy/culture
- LJ DST: results are reported within 6 weeks after positive LJ culture.

Analysis/actions
The TAT time is being monitored at three points:

a) By reviewers as they review results. TAT is part of the outcome they review.
b) By the database. An overdue list for Microscopy, culture (LJ and MGIT) and LPA is generated weekly.
c) By customer feedbacks. We have notified, in writing, our customers of our TAT. Some of these have databases that will generate an overdue list and therefore serve as check and balances on our system.

This has greatly improved our performance by each personnel ensuring that they do their work on time. It is also another way of ensuring that all samples that were accessioned are worked on and have a result. The customers are satisfied because they can plan better knowing by when the results will come. Overall this has resulted in improved accountability and fast release of results.

NTRL now has embarked on monitoring the pre-analytical and post-analytical durations. A system has been built to track the time it takes to receive samples at NTRL after collection. We will work on establishing the cut offs. NTRL has also started monitoring the dispatch time after the reports are printed.

Conclusions
Monitoring of turnaround times has been set up and has improved performance. This should continue.

Action
MR2012-15: Set cut off times and monitor pre-analytical and post-analytical processes by June 2013
MR2012-16: NTRL should continue to monitor process controls for those that do not pass prompt investigation and corrective action should be carried out.

6. Competency of staff and adequacy of equipment

Objectives

- At all times all staff are competent in performing their duties at NTRL.
- Equipment and supplies should be in a state that these do not affect the quality of the services.

Competence

Analysis/actions

Competences of staff are being assessed (continuous process). An SOP on competence testing was approved. Competence checklists have been made, used and filed in the personnel files. Assessing of competence using a standardized tool has enabled personnel to standardize and gain confidence in their work.

Conclusion

Competence assessments will continue annually.

Equipment

A lot of new equipment such as -80C freezers (2), Refrigerators (2), Biosafety cabinets (2), Refrigerated centrifuges (2), Computers (4), Camera surveillance system, ventilation system, pass through autoclave and database (Chase-IT) were installed and identified. Whereas most of these have been validated others such as the pass through autoclave and database are yet to be validated. NTRL lacks funds to validate the pass through autoclave as the anticipated budget for renovation was not adequate. The Chase-IT database has been delayed because of the complexity with access to the codes. Many times we rely on technical assistance abroad to rectify problems. Through trouble shooting, NTRL has now begun validating the database. A UPS to support part of the ventilation system in case of loss of power has been purchased but unnecessarily delayed to be delivered by the supplier. After over 4 months, it has finally arrived in the country. NTRL has a comprehensive equipment contract that assists in maintaining and repair of equipment.

Action

MR2012-17: Complete installation and validation of pass through autoclave, UPS for ventilation equipment and Chase-IT database by July 2013.

7. Results from external quality assessment and other forms of inter-laboratory comparison

Action from year plan 2012

QYP-2012-6: Per January 2013 all planned internal and external quality controls have taken place according to plan and results are discussed. If needed, corrective actions will be taken.

For internal control, see Chapter 5: Quality Indicators – Internal Quality Controls

Objectives

To participate in (international) external quality assessments and other forms of inter-laboratory comparisons.

Analysis/actions

Smear Panels: The NTRL has participated in all three WHO surveys of external quality assessment in smear microscopy; the results were all 100% correct.

DST Proficiency: In November 2012 a DST panel was received and tested from the supranational reference laboratory in Antwerp, Belgium. NTRL scored 100% for isoniazid, rifampicin and ethambutol. However there were 4 false susceptible results for streptomycin (80% score). Review of the results and methods pointed out to use of old powder (but not expired) of streptomycin as the likely cause.

Action
MR2012-18: Directly stop using the old batch of streptomycin and monitor if proficiency scores improve.

HAIN Proficiency: NTRL participated in all two rounds of HAIN proficiency by WHO through MRC South Africa. In both panels NTRL scored 100%.

NTRL participated in inter-laboratory comparisons with AccuLaboratory® in both Microscopy and DST from January 2012 to January 2013. Microscopy and DST were done every month. Below is the report:

Microscopy:
Between January 2012 to December 2012, 56 randomly chosen microscopy slides with sample size determined using the LQAS were blindly compared between the two labs. Discrepant results were resolved by consensus between the laboratories. Out of these NTRL had 2 (3.6%) false positive (1 LFP and 1 HFP) and 1 (1.8%) HFN slides. These results were acceptable according to our cut offs.

Between January 2012 to January 2013, 37 randomly selected microscopy slides with sample size determined by LQAS were blindly compared between the two labs. For the month of May and June only Fluorescent microscopy was done hence we did not perform EQA on ZN. There was no error found for this period. These results indicate a further improvement in the QMS for the NTRL

DST:
Between January 2012 and January 2013 NTRL performed 2 inter-lab DST panels. These were selected based on previous patient strains whose DST was known. They were sent to NTRL and AccuLaboratory® blinded and coded the strains. On both occasions, there were discrepant results. It proved difficult to resolve the discrepant results since there was no agreeable mechanism for this. The NTRL has resolved to use panels with known DST for the laboratory internal control and hence the inter-laboratory DST comparisons will cease.

Conclusions
NTRL to continue with the EQA programs as scheduled.

Action
MR2012-19: Use DST panels with known results to test for quality of DST in the lab. This should be done once a year as separate from the panel from SRL. At least 20 strains should be used.

8. Any changes in the volume and type of work undertaken

Objectives
Any changes in the volume and type of work undertaken should be managed such that the quality of services is assured.

Analysis/actions

The LPA SOP for first and second line HAIN tests were written and being implemented. Two new staff members were employed for this purpose and are adequately trained by the date of MR.

LJ DST second line and LPA second line were introduced and SOPs were written and implemented.

There was a National Drug Survey that was carried out from December 2011 to February 2012 this increased the work load.

Between 2011 to May 2012 the NTRL was under renovation. Part of the NTRL staff was working at the Saint Jacque Hospital. This took a lot of effort of all of the staff. The consequences of working at two locations are:

- Increased biosafety risk as you have to transport samples
- Difficulty in transportation of all kinds of materials (samples, slides, worksheets, records, …)
- Difficulty in working under different regulations
- Limited working hours at the Saint Jacque Hospital.

However, despite the difficulties, it was a blessing that there was a free alternative NTRL that could be used to sustain all its activities and add more such as the National Drug Survey.

Conclusion
NTRL has a big capacity to carry on its current activities and ability to add on more without compromising quality.

9. Changes which may influence the quality management system

Objectives
To contain the influence of any change on the quality management as much as possible.

Analysis/actions
Through meetings, internal and external audits, expert reviews, quality controls, customer feedback and management demands, a number of changes of the QMS are suggested and undertaken. These are recorded as action items with an implementation frame and personnel responsible for them.

Most of the actions have been appropriately dealt with. However, a few are not done in time due to various reasons such as inability to raise the needed resources and delays in procurement. A number of measures have been put in place to ensure all who need to perform these actions are reminded. All action items are now discussed in a general meeting and if a person misses two deadlines they are referred to management. An electronic tracking system to ensure that management and the individual concerned are reminded in time has been developed and is in place. Efforts to acquire the necessary resources have been made.

Action
MR2012-20: Follow-up of outstanding actions from the Quality Year Plan 2012 and make these actions for 2013 Quality Year Plan.

10. Evaluation of suppliers

Action from year plan 2012

QYP-2012-10: A form for evaluation of suppliers will be implemented as part of the SOP for procurement before 31 December 2012.

Objectives
To evaluate suppliers on the basis of correct service and reliability.

Analysis
A form to evaluate suppliers has been developed and the process to evaluate suppliers has begun.

Conclusion
The evaluation of suppliers experience with the work of the NTRL will provide input to improve the quality.

Action
MR2012-21: Complete the evaluation process and carry out the arising action points in the new annual quality plan.

11. Reports from managerial and supervisory personnel

Objectives
To evaluate performance and progress of NTRL.

Analysis/actions
Throughout the year the following reports were made and reviewed: Quarterly Reports, supervisory visit reports, reviewers reports, smear microscopy EQA annual report and annual managerial personnel reports. The findings and suggestions are discussed in staff meetings and action points generated. This ensures general sharing of knowledge and improvement in weak sections. The annual EQA report is however too late to correct some abnormalities. Reporting EQA results quarterly would be better.

Conclusion
Continue to generate the reports as scheduled. Generate EQA report quarterly (incorporate in the QYP).

12. Status of corrective actions taken and required preventive action.

Objectives
To monitor occurrences that are generated in the corrective and preventive action logs.

Analysis/actions
Corrective action logs are written, reviewed and followed-up. Corrective Action Findings and suggestions are discussed in staff meetings. There was an initial problem trying to write corrective actions as personnel thought they will be used to reprimand them. After many discussions this has improved performance as personnel take time to analyze the cause of the problem and ensure it is corrected. NTRL is working on a system to analyze corrective action in terms of frequencies and causes.

Conclusion
NTRL should develop a simple system to monitor occurrences, possibly the new LIS will be suitable for this task.